

# **Screening report**

## *North Macedonia*

### **Cluster 2 – Internal Market**

#### **Chapter 1 – Free Movement of Goods**

**Date of screening meetings:**

Explanatory meeting: 15-18 January 2019, update on 10 October 2022

Bilateral meeting: 6-9 February 2023

#### **Chapter 2 – Free movement of workers**

**Date of screening meetings:**

Explanatory meeting: 13 March 2019, update on 13 October 2022

Bilateral meeting: 3 March 2023

#### **Chapter 3 – Right of establishment and freedom to provide services**

**Date of screening meetings:**

Explanatory meeting: 11-12 December 2018, update on 10 October 2022

Bilateral meeting: 23-24 January 2023

#### **Chapter 4 – Free Movement of Capital**

**Date of screening meetings:**

Explanatory meeting: 11 January 2019, update on 7 October 2022

Bilateral meeting: 15 February 2023

#### **Chapter 6 - Company law**

**Date of screening meetings:**

Explanatory meeting: 21 October 2019, update on 12 October 2022

Bilateral meeting: 27 January 2023

#### **Chapter 7 – Intellectual property law**

**Date of screening meetings:**

Explanatory meeting: 7-8 February 2019, update on 12 October 2022

Bilateral meeting: 25-26 January 2023

#### **Chapter 8 – Competition policy**

**Date of screening meetings:**

Explanatory meeting: 4-6 November 2019, update on 13 October 2022

Bilateral meeting: 13-14 March 2023

## **Chapter 9 – Financial services**

### **Date of screening meetings:**

Explanatory meeting: 9-10 April 2019, update on 7 October 2022

Bilateral meeting: 27-28 February 2023

## **Chapter 28 – Consumer and Health Protection**

### **Date of screening meetings:**

Explanatory meeting: 28-29 March 2019, update on 14 October 2022

Bilateral meeting: 1-2 March 2023

# PREAMBLE

After the first Intergovernmental Conference on accession negotiations with North Macedonia in July 2022, the Commission launched immediately the screening process.

The screening is based on the enhanced enlargement methodology, which was adopted in 2020 and organises the negotiating chapters in thematic clusters in order to inject dynamism into the negotiating process and to foster cross-fertilisation of efforts beyond individual chapters. These thematic clusters bring together the chapters / areas according to broader themes and will allow a stronger focus on core sectors. Within each individual cluster, screening is carried out through meetings on a chapter-by-chapter basis. The substance of those clusters and chapters, as set out in Annex II of the Negotiating Framework, mirror the requirements for membership stemming from the Copenhagen criteria.

This report provides an assessment of where North Macedonia stands in terms of alignment and capacity to apply the *acquis* in Cluster 2. The negotiating framework also refers to the possibility of accelerated integration. At the bilateral meetings North Macedonia has requested participation in certain areas before accession. This report provides the Commissions opinion and answer to these requests.

Regional cooperation and good neighbourly relations remain essential elements of the enlargement process. As provided in paragraph 47 of the Negotiating Framework for North Macedonia, the Commission will give special attention to North Macedonia's commitments to good neighbourly relations and regional cooperation.

It is important to continue the dialogue with civil society and other stakeholders, with the aim of ensuring the support of citizens for the EU accession process. North Macedonia is expected to strategically communicate the benefits and obligations of the accession process to its public.

## A) INTRODUCTION

The enhanced enlargement methodology<sup>1</sup>, as reflected in the Negotiating Framework with North Macedonia, puts the negotiating chapters of the EU *acquis* into clusters. The **Internal Market cluster** covers the four freedoms of the European Union (EU) internal market, which allow people, goods, services and capital to move freely across the EU. The internal market, often also known as the single market, provide opportunities for citizens, workers, businesses and consumers, to create jobs and growth across the EU. It is one of the EU's major achievements, and a major asset to help build a strong and fair EU economy. This cluster includes nine chapters of the EU *acquis*:

- Under Chapter 1, the **free movement of goods** ensures that many products can be traded freely across the EU based on common rules and procedures. Where products are governed by national rules, the principle of the free movement of goods prevents these creating unjustified barriers to trade.
- Under Chapter 2, the **freedom of movement of workers** ensure that citizens of one Member State have the right to work in another Member State and must be given the same working and social conditions as other workers.
- Under Chapter 3, the **right of establishment and freedom to provide services**, ensures that EU natural and legal persons have the right to establish themselves in any Member State and to provide cross-border services. For certain regulated professions, there are rules on mutual recognition of qualifications. EU rules on postal services focus on improving the quality of universal service, gradually opening the market to competition, and the establishment of an independent regulator. Under Chapter 4, the **free movement of capital** ensures that, in the EU, capital and investments must be able to move without restriction and there are common rules for cross-border payments. Banks and other economic operators apply certain rules to support the fight against money laundering and terrorist financing.
- Under Chapter 6, EU **company law** ensures that the EU has common rules on the formation, registration and disclosure requirements of a company, with complementary rules for accounting and financial reporting, and statutory audit.
- Under Chapter 7, EU **intellectual property law** ensures that the EU has harmonised rules for the legal protection of intellectual property rights (IPR) and of copyright and related rights. Rules for the legal protection of IPR cover, for instance, patents and trademarks, designs, biotechnological inventions and pharmaceuticals. Rules for the legal protection of copyright and related rights cover, for instance, books, films, computer programmes and broadcasting.
- Under Chapter 8, EU **competition policy** ensures that EU rules protect free competition. They include antitrust rules against restrictive agreements between companies and abuse of dominant position, and also include rules on concentrations between companies which would significantly impede effective competition. EU rules also set out a system of State aid control. Governments are only allowed to grant State aid if restrictive conditions are met, with a view to preventing distortion of competition.
- Under Chapter 9, EU **financial services** rules aim at ensuring fair competition among, and the stability of, financial institutions, namely banking, insurance, supplementary pensions, investment services and securities markets. They include rules on authorisation, operation and supervision of these institutions.

---

<sup>1</sup> COM(2020) 57 final

- Under Chapter 28, **consumer and health protection**, EU rules protect consumers' economic interests and in relation to product safety, dangerous imitations and liability for defective products. The EU also ensures high common standards for tobacco control, blood, tissues, cells and organs, and medicines for human and veterinary use. The EU also ensures high common standards rules for upholding patients' rights in cross-border healthcare and has rules on the prevention of, preparedness for and response to serious cross-border health threats, including communicable diseases.

The chapters under the **Internal Market cluster** should not be seen in isolation, as several have **commonalities and so interact with each other** to be mutually reinforcing. For example, **market surveillance** is a key component of the structure of the **free movement of goods**, ensuring that **safe products are placed on the EU internal market**, but it is also a key component of the structure of **consumer and health protection**, as it helps to ensure that **consumers are protected from unsafe products**.

This **screening report is structured** according to the **respective areas and chapters** of the cluster. Each area/chapter starts with a short overview of the **main content of the EU *acquis* / European standards**. Each thematic area within a chapter then first summarises the **country's presentations and the outcome of the expert discussions** at the bilateral screening meeting, followed by the **Commission's assessment**.<sup>2</sup>

In the last **section**, from its findings the Commission draws **recommendations for the next steps in the accession negotiations process in the present Cluster**.

North Macedonia stated that it accepts the *acquis* in the Internal Market cluster and that it does not expect particular difficulties to implement the *acquis* and European standards of this cluster by accession. It indicated that it reserved the right to ask for transitional arrangements for certain areas in this Cluster.

---

<sup>2</sup> The *EU acquis* considered in this report is as it was at the time of the meetings

## B) CHAPTER 1 - FREE MOVEMENT OF GOODS

The **general principle** of the free movement of goods is that products must be traded freely across the EU based on common rules and procedures. This is laid down by Articles 34, 35 and 36 of the Treaty on the Functioning of the European Union (TFEU). It prevents Member States from adopting and maintaining unjustified restrictions on intra-EU trade but does not preclude prohibitions justified on grounds of public morality, public policy or public security, the protection of health and life of humans, animals or plants, or the protection of industrial and commercial property, as well as other mandatory requirements recognised by the Court of Justice. Where products are governed by national rules, the principle of the free movement of goods prevents these creating unjustified barriers to trade. Measures having equivalent effect to a quantitative restriction are prohibited subject to a limited and restrictive set of exceptions, implying the elimination of technical barriers to trade and the compliance with the principle of mutual recognition. Adequate administrative arrangements are foreseen to be put in place to apply the information exchange procedures, in line with the EU *acquis*.

In many sectors the general principle is complemented by a harmonised regulatory framework. These **horizontal measures** define the quality infrastructure which Member States should put in place to ensure the free movement of goods. These cover standardisation, conformity assessment, accreditation, metrology and market surveillance, as well as product liability.

Harmonised European product legislation is the largest part of the EU *acquis* under this chapter. It is based on two approaches: the “**new and global approach**” imposes general product requirements, while the “**old approach**” imposes precise product specifications. “New and global approach” *acquis* includes *acquis* on low voltage equipment (LVD), electromagnetic compatibility (EMC), toys, fertilising products, machinery, lifts, noise emissions by outdoors equipment, personal protective equipment (PPE), equipment and protective systems intended for use in explosive atmospheres (ATEX), gas appliances, pressure vessels, cableway installations, construction products, recreational craft, eco-design requirements for energy-related products (ErP), and radio equipment. The “old approach” *acquis* covers all categories of motor vehicles, emissions of pollutants from non-road mobile machinery engines, and of chemicals, as well as good laboratory practice, detergents, aerosol dispensers, pre-packaging, and units of measurement.

A series of **procedural measures** also require sufficient administrative capacity in order to be properly applied. These include a notification procedure in the field of technical standards and regulations, and the EU *acquis* on product safety, crystal glass, footwear, textile labelling and mixtures, and the pricing of medicinal products and their implementation. It also covers defence products and defence procurement, firearms/weapons, and the return of cultural objects unlawfully removed from the territory of a Member State.

### I. GENERAL PRINCIPLES

#### a. Country presentation

North Macedonia already undertook an analysis of national legislation in order to align with Articles 34-36 TFEU and CJEU case law several years ago. At that time, it led to the withdrawal of 41 measures that could had an equivalent effect. North Macedonia recognises that a new analysis and screening is necessary in order to align to Art. 34-36, preparation of this started in late 2022 and is foreseen to start in 2023 and be completed by the end of 2025. During this exercise, the country plans to withdraw or amend those acts and measures that have an equivalent effect, as well as noting measures where mutual recognition will be necessary. However, the country currently only plans to add mutual recognition clauses by the time of its accession to the EU.

North Macedonia is currently not aligned to the EU *acquis* on mutual recognition or to Council Regulation (EC) 2679/98 on the functioning of the internal market in relation to the free movement of goods among EU Member States; it plans to align to these by the time of accession.

North Macedonia has appointed the Internal Market Department in its Ministry of Economy as the focal point for alignment to Art. 34-36. The Ministry of Economy will be the contact point for technical regulations after the country's accession to the EU. It already acts as the "reference point" for ensuring compliance with Art. 34-36. North Macedonia acknowledged that the competent authorities do not currently have sufficient resources to ensure the requirements of Art. 34-36, it foresees reinforce of the resources between 2025 and 2027. It foresees to set up a product contact centre and a SOLVIT centre between 2027 and 2030.

#### **b. Commission assessment**

The Commission notes that North Macedonia plans to re-review its legislation, procedures and rules between 2023 and 2025 to ensure that it is aligned with the requirements of Articles 34-36 TFEU. This is necessary as the country's last review on this took place several years ago. However, the country should also foresee to keep this updated plan under review, and ensure that any resulting necessary actions are taken up to date until its eventual accession to the EU.

North Macedonia is **not aligned** to the EU *acquis* on mutual recognition or to Council Regulation (EC) 2679/98 on the functioning of the internal market, and only plans to align to them by the time of accession. North Macedonia nevertheless plans to identify where it will eventually add mutual recognition clauses in its plan to align with the requirements of Articles 34-36 TFEU, which should be adopted after the ongoing exercise of re-reviewing its relevant legislation, procedures and rules.

### **C. SUMMARY OF FINDINGS - GENERAL PRINCIPLES**

North Macedonia **needs to update its a plan for alignment with the requirements of Articles 34-36 TFEU** and relevant ECJ case law, and it has indicated that it intends to do this by the end of 2025. It has **identified the contact point for technical regulations** after accession to the EU. North Macedonia is **not aligned** to the EU *acquis* on mutual recognition or to Council Regulation (EC) 2679/98 on the functioning of the internal market plan.

## **II. HORIZONTAL MEASURES**

### **II.A. STANDARDISATION**

#### **a. Country presentation**

The national legal framework is the Law on Standardisation. The National Standards Body is the National Standardisation Institute (IS). IS has been a full member of the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) since 2012, and participates in the work of relevant EU standardisation bodies. IS is also a full member of the European Telecommunication Standards Institute (ETSI), and of ISO (International Organization for Standardization) and an associate member of International Electro technical Commission (IEC).

As it is a full member of the European organizations (CEN/CENELEC), IS has an obligation to adopt all European standards into the national system and withdraw standards that are in conflict with EU ones. IS encourages and facilitates SMEs access to standards and proactive participation in standards development process. IS has 31 technical committees at the moment, with over 300 national experts and stakeholders.

By the end of 2022, IS had issued 28,328 standards of North Macedonia and related documents (it stated that 24,354 are identical to CEN and CENELEC standards (86%), and 964 identical to ETSI standards (3%). IS's human and financial resources for standardisation are adequate, though several will soon need replacing due to retirement.

#### **b. Commission assessment**

North Macedonia is **fully aligned** with the EU *acquis* on standardisation. A standardisation body has been established and issues national standards in line with EU harmonised standards. It is a full member of CEN and CELENEC and participates in their technical committees. It is also a full member of the European Telecommunication Standards Institute (ETSI), and of ISO (International Organization for Standardization) and an associate member of International Electro technical Commission (IEC).

### **II.B. CONFORMITY ASSESSMENT AND THE CE MARK**

#### **a. Country presentation**

The national legal framework for conformity assessment (CA) is partly aligned to the relevant EU *acquis*. The recently adopted Law 274/2022 on Technical Requirements for Products and Conformity Assessment is the legal base for alignment both in this area and for many product sectors. It lays down the form, content and appearance of the conformity mark. It is the basis for prescribing technical requirements for products and for aligning to the EU *acquis* under the new and global approach. It also aligns the legislation of North Macedonia to several provisions of the EU *acquis* on a common framework for the marketing of products and on setting out the requirements for accreditation and market surveillance relating to the marketing of products.

The national laws on technical requirements and on conformity assessment are designed to be partly aligned with the EU *acquis* on the CE marking. North Macedonia confirmed that it does not have its own conformity assessment marking, it plans to make the use of CE marking mandatory in the relevant product sectors for products placed on the national market via the adoption of national legislation during 2024. The responsible bodies are the Ministry of Economy and the State Market Inspectorate.

#### **b. Commission assessment**

The legislation of North Macedonia is **partly aligned** with the EU *acquis* for conformity assessment. It has 210 accredited conformity assessment bodies. National legislation is partly aligned with the EU *acquis* on the CE marking. North Macedonia does not have its own conformity assessment marking, it plans to make the use of CE marking mandatory in the relevant product sectors for products placed on the national market via the adoption of national legislation during 2024.

### **II.C. ACCREDITATION**

#### **a. Country presentation**

The national legal framework for accreditation is the Law 120/09 on Accreditation and relevant implementing legislation, which is designed to be fully aligned with the relevant EU *acquis*. The National Accreditation Institute (NAI) has 17 employees. As assessed by European Cooperation for Accreditation (EA) it is an independent, permanent, non-profit organisation with its own permanent staff, with sufficient external evaluators are engaged when needed. NAI salaries come from the state budget, other funds come from fees. NAI's register currently includes 210 accredited conformity assessment bodies: 77 test laboratories, 15 calibration laboratories, 11 medical laboratories, 3 certification bodies of management system, 7 certification bodies for products and 97 inspection bodies.

NAI is a member of EA since 2007, and a signatory of the EA multilateral agreement (EA MLA) for testing laboratories, calibration laboratories, inspection bodies, product certification bodies, process and services since 2012, for medical laboratories in 2015 and for management systems since 2018. It is a full member of the International Laboratory Accreditation Cooperation Mutual Recognition Agreement (ILAC MRA) in the field of inspection since 2012 and the International Accreditation Forum (IAF) since 2015. NIA intends to introduce accreditation on data protection on IT security, and anti-bribery and anticorruption standards during 2023/4, it also plans to reinforce its administrative resources.

With regards to NANDO, the national legal basis is its Law on Technical Requirements of Products and Conformity Assessment and relevant implementation which are designed to be fully aligned with Regulations 765/2008 and reference provisions of Decision 768/2008 (EU), as laid down in corresponding provisions of sectoral legislation.

#### **b. Commission assessment**

National legislation is **fully aligned** with the EU *acquis* on accreditation. The accreditation body of North Macedonia is established and is a member of EA, a signatory of EA MLA, a full member of the International Laboratory Accreditation Cooperation Mutual Recognition Agreement (ILAC MRA) and the International Accreditation Forum (IAF). North Macedonia currently has 210 accredited conformity assessment bodies.

### **II.D. LEGAL METROLOGY**

#### **a. Country presentation**

The Law 55/2002 on Metrology is the basis of legal metrology in North Macedonia, and it is designed to be fully aligned with the relevant EU *acquis*. The responsible body is the Ministry of Economy. The Bureau of Metrology (BoM), the national metrology body, is an official member of the European Association of National Metrology Institutes and the General Conference on Weights and Measures (EURAMET) since 2010, and participates in EU metrology programmes. There is a metrology council with 11 members, one authorised body for the verification of measuring instruments, and 10 calibration laboratories. Further reinforcement of the human resources of BoM is underway.

#### **b. Commission assessment**

National legislation is **fully aligned** with the EU *acquis* on legal metrology. It has established a metrology body, the Bureau of Metrology (BoM), that is a full member of EU metrology bodies, and a metrology council has also been established. Reinforcement of the human resources of BoM is underway.

### **II.E. MARKET SURVEILLANCE**

#### **a. Country presentation**

The legal framework of North Macedonia for the safety and compliance of products currently relies on the Law 48/10 and 79/13 on Market Surveillance, the Law 274/2022 on Technical Requirements for Products and Conformity Assessment, Law 302/2020 on General Product Safety, the Law on Construction Products, Law 236/2022 on Consumer Protection, Law 102/2019 on Inspection, and relevant implementing legislation and lists. These are aligned to a high level with the relevant EU *acquis*; full alignment is foreseen by the end of 2024.

The Ministry of Economy is the competent body for market surveillance in North Macedonia. Market Surveillance is ensured by the state market inspectorate (SMI), the State Sanitary and Health Inspectorate, the State Labour Inspectorate, the State Inspectorate for Technical Inspection (SITI), the State Environmental Inspectorate, and other bodies including Customs which are all part of the coordinating body for market surveillance. Market surveillance capacities need to be reinforced. Several private and one state laboratory are used by market surveillance testing. A RAPEX-like IT system is being developed and is foreseen to be in use in 2023. Both reactive and pro-active market surveillance is ensured. In 2022 38 dangerous products were withdrawn from the market. In 2023 over 31 000 market surveillance inspections were conducted by SMI.

#### **b. Commission assessment**

National legislation is **aligned to a high level** with the EU *acquis* on market surveillance. Market surveillance is being implemented, and dangerous products are being withdrawn from the market as a result. Market surveillance resources are not sufficient and need to be reinforced.

### **II.F. NOTIFICATION PROCEDURES**

#### **a. Country presentation**

The national legal base for notification procedures is the Law on Accreditation and relevant implementing legislation, which is **partly aligned** with the EU *acquis*. Full alignment is planned in 2024. The standardisation institute of North Macedonia acts as the notification body and already notifies the European Commission and standardisation bodies on new areas that will be covered by notification. North Macedonia intends that its authorised bodies for conformity assessment will become notified bodies upon its accession to the EU.

#### **b. Commission assessment**

As regards notification the legislation of North Macedonia is **partly aligned** with the EU *acquis*. It already notifies the European Commission about areas that will be covered by notification.

### **II.G. PRODUCT LIABILITY**

#### **a. Country presentation**

The Ministry of Economy is the responsible body for product safety. The national legal base consists of the Law 236/22 on Consumer Protection, Law 18/01 on Obligations, Law 157/10 on Food Safety, Law 55/07 on Cosmetic Product Safety, and Law 302/20 on General Product Safety. These are partly aligned to the EU *acquis* on product liability, deviations include the definition of “product” and “good” in the legal base. The law on consumer protection was adopted in 2022, therefore outreach to stakeholders and institutions on its scope and relevant procedures are foreseen as part of the 2023 national consumer protection programme.

#### **b. Commission assessment**

North Macedonia is **partly aligned** with the EU *acquis* on product liability, deviations include the definition of “product” and “good” in the legal base.

### **II.H. SUMMARY OF FINDINGS – HORIZONTAL MEASURES**

North Macedonia is **fully aligned** with the EU *acquis* on **standardisation, metrology and accreditation**. A standardisation body has been established and is issuing national standards in line with EU harmonised standards. It is a full member of CEN and CELENEC, and participates in their technical committees. North Macedonia's legislation is **aligned to a high level on product safety**, and **partly aligned** with the EU *acquis* on **conformity assessment, accreditation, on market surveillance, on the CE marking, and on notification procedures**. The accreditation body of North Macedonia (NAI) is established, has a good level of cooperation in the region, and is a member of EU and international bodies. Capacity to ensure market surveillance needs to be reinforced.

### III. 'NEW AND GLOBAL APPROACH' PRODUCT LEGISLATION

#### III.A. LOW VOLTAGE EQUIPMENT (LVD)

##### a. Country presentation

North Macedonia is partly aligned with Directive 2014/35/EU via its Law 274/2022 on Technical Requirements for Products and Conformity Assessment and specific implementing legislation. It plans to ensure full alignment by the end of 2024. North Macedonia has producers of such equipment. The competent authority is the Ministry of Economy. Implementation is ensured by SMI, SITI and the State Labour Inspectorate. These have insufficient resources to fully implement this EU *acquis*. North Macedonia has one conformity assessment body in this area.

##### b. Commission assessment

North Macedonia is **partly aligned** with the EU *acquis* on Low Voltage Equipment (LVD). However, it does not have adequate administrative and market surveillance resources in this area.

#### III.B. ELECTROMAGNETIC COMPATIBILITY (EMC)

##### a. Country presentation

The legislation of North Macedonia is partly aligned with Directive 2014/30/EU via its Law 274/2022 on Technical Requirements for Products and Conformity Assessment. Full alignment is foreseen by the end of 2024. North Macedonia has producers of such equipment. The competent authority is the Ministry of Economy. Implementation is ensured by SMI, SITI and the state labour inspectorate. These have

insufficient resources to fully implement this EU *acquis*. North Macedonia has one conformity assessment body in this area.

#### **b. Commission assessment**

North Macedonia is **partly aligned** to the EU *acquis* on Electromagnetic Compatibility (EMC). It does not have adequate administrative and market surveillance resources.

### **III.C. RADIO EQUIPMENT (RED)**

#### **a. Country presentation**

National legislation consists of Law on Electronic Communications 39/14, as well as the Laws on Technical Requirements for Products and Conformity Assessment, and on General Product Safety. These are partly aligned with Directive 2014/53/EU. Full alignment is foreseen by the end of 2024. North Macedonia has no producers of these products. The competent authorities are the Ministries of Economy and of Information Society. Implementation is performed by the Agency for Electronic Communications and SMI.

#### **b. Commission assessment**

North Macedonia is **partly aligned** with the EU *acquis* on Radio Equipment (RED), and it does not have adequate administrative and market surveillance resources.

### **III.D. TOYS**

#### **a. Country presentation**

The legal base of North Macedonia on toys consists of the Laws on Technical Requirements for Products and Conformity Assessment, the Law on Product Safety and the law on General Product Safety, as well as specific implementing legislation. These are partly aligned to the EU *acquis*. Full alignment is foreseen by the end of 2024. The competent authority is the Ministry of Economy, market surveillance is ensured by SMI and the Ministry of Health. Further implementing resources are needed. An average of 5% of toys subject to market surveillance were taken off the market of North Macedonia in each of the last five years following market surveillance, and 11 700 items destroyed. North Macedonia plans to establish further testing laboratories in this area.

#### **b. Commission assessment**

North Macedonia is **partly aligned** with the EU *acquis* on toys. It does not have sufficient implementing resources.

### **III.E. MACHINERY**

#### **a. Country presentation**

North Macedonia stated that its legal base consists of the Laws on Technical Requirements for Products and Conformity Assessment, the Law on Product Safety and the national Machinery Safety Regulations 123/09 and 103/12, it is designed to be fully aligned with Directive 2006/42/EC (which is replaced by Regulation (EU) 2023/1230, which comes into effect in January 2027). The administrative body is the Ministry of Economy, SITI and SMI ensure market surveillance, currently with a total of 15 inspectors covering different sorts of machinery. To date North Macedonia has granted 14 entities authorisation to perform conformity assessment on machinery.

Regarding accelerated integration, North Macedonia requested to join the expert group on machinery.

#### **b. Commission assessment**

The national legislation is **fully aligned** with the EU *acquis* on machinery. North Macedonia has some market surveillance resources in this area.

The Commission evaluates positively the accelerated integration request of North Macedonia to join the expert group on machinery.

### **III.F. OUTDOOR EQUIPMENT NOISE EMISSIONS (OND)**

#### **a. Country presentation**

The legal base is the Law on Protection against Environmental Noise, and relevant implementing legislation which are designed to have a high level of alignment with Directive 2000/14/EC. The Ministry of Environment and Physical Planning is the competent authority. It is also the market surveillance body. As it has only one person doing this at the moment, this requires reinforcement. There are there are several accredited noise laboratories.

#### **b. Commission assessment**

The legislation of North Macedonia has a **high level of alignment** with the EU *acquis* on outdoor equipment noise emissions. However, some aspects were conflated with Directive 2002/49/EC on environmental noise, which is outside the scope of this chapter. It has limited market surveillance resources in this area.

### **III.G. LIFTS**

#### **a. Country presentation**

There are currently over 30 assemblers of lifts in North Macedonia, and some producers of lift components. Relevant national legislation, includes the Laws on Technical Requirements for Products and Conformity Assessment, the Laws on Product Safety, Accreditation, and Standardisation, laws relevant to market surveillance, and specific implementing legislation on lifts. According, to national authorities the legislation of North Macedonia is designed to be **partly aligned** with the EU *acquis* on lifts, full alignment was planned to be ensured by the end of 2024. The competent authority is the Ministry of Economy. SITI and SMI ensure market surveillance. The current level of resources available for market surveillance are not sufficient. North Macedonia has currently 5 conformity assessment bodies in this area.

#### **b. Commission assessment**

The legislation of North Macedonia is **partly aligned** with the EU *acquis* on lifts. It has limited market surveillance resources in this area.

### III.H. PERSONAL PROTECTIVE EQUIPMENT (PPE)

#### a. Country presentation

National legislation, which consists of Laws on Technical Requirements for Products and Conformity Assessment, the Laws on Product Safety, Accreditation, and Standardisation, laws relevant to market surveillance and to occupational health and safety, and specific implementing legislation, is partly aligned with Regulation 2016/45/EU. Full alignment is foreseen by the end of 2024. The competent authority is the Ministry of Economy. Implementation is ensured by SMI, and the state labour inspectorate.

#### b. Commission assessment

The legislation of North Macedonia is **partly aligned** with the EU *acquis* on PPE, and estimates that it has adequate administrative and market surveillance resources in this area.

### III.I. EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES (ATEX)

#### a. Country presentation

Though ATEX is used extensively in North Macedonia, it has no producers of ATEX. National legislation on ATEX is not yet aligned to EU *acquis* on ATEX, this is foreseen in 2024. The competent authorities are the Ministries of Economy and of the Interior. Market surveillance is performed by SMI, SITI, the Ministry of Interior, and the State Labour Inspectorate. Implementing resources are foreseen to be reinforced. North Macedonia has no conformity assessment bodies in this area, but it is considering establishing some.

#### b. Commission assessment

The legislation of North Macedonia is **not aligned** with the current EU *acquis* on ATEX, and it does not have adequate administrative and market surveillance resources in this area.

### III.J. GAS APPLIANCES

#### a. Country presentation

North Macedonia has no manufacturers of gas appliances. National legislation, which consists of Laws on Technical Requirements for Products and Conformity Assessment, the Laws on Product Safety, Accreditation, and Standardisation, and specific implementing legislation, is **partly aligned** with the relevant EU *acquis*; full alignment is foreseen in 2024. The competent authority for gas appliances is the Ministry of Economy. Implementation is the responsibility of SMI. The current level of resources available for this work are insufficient, it is foreseen to ensure this after a functional analysis of such resources.

#### b. Commission assessment

National legislation is **partly aligned** with the EU *acquis* on gas appliances. North Macedonia does not yet have adequate resources in place to ensure the necessary administrative capacity or market surveillance in this area.

### III.K. PRESSURE EQUIPMENT

#### a. Country presentation

North Macedonia has three manufacturers of pressure equipment. Its legislation is not yet aligned with Directive 2014/68/EU, this is foreseen to be ensured by the end of 2024. The competent authority is the Ministry of Economy. Implementation is the responsibility of SMI, STI and customs. North Macedonia has 3 conformity assessment bodies in this area.

#### **b. Commission assessment**

North Macedonia is **not aligned** with the EU *acquis* on pressure equipment. It needs to ensure alignment and the necessary resources to administer and implement this EU *acquis*.

### **III.L. SIMPLE PRESSURE VESSELS**

#### **a. Country presentation**

North Macedonia has three manufacturers of simple pressure vessels. Its legislation is **not aligned** with the EU *acquis*, this is foreseen to be ensured by the end of 2024. The competent authority is the Ministry of Economy. Implementation will be the responsibility of SMI and STI. North Macedonia has three conformity assessment bodies in this area and plans to establish notified bodies on this.

#### **b. Commission assessment**

The legislation of North Macedonia is **not aligned** with the EU *acquis* on pressure equipment. It needs to ensure alignment and the necessary resources to administer and implement this EU *acquis*.

### **III.M. CABLEWAYS**

#### **a. Country presentation**

National legislation, which consists of on Technical Requirements for Products and Conformity Assessment, the Laws on Product Safety, Accreditation, and Standardisation, and specific implementing legislation, is **partly aligned** with Regulation 2016/425/EU on cableways. Full alignment is foreseen by the end of 2024. North Macedonia does not have any producers of cableways. The responsible authority is the Ministry of Economy. Market surveillance will be ensured by SITI and SMI. North Macedonia currently has two conformity assessment bodies in this area.

#### **b. Commission assessment**

National legislation is **partly aligned** with the EU *acquis* on cableways. Market surveillance resources are not yet sufficient in this area.

### **III.N. CONSTRUCTION PRODUCTS**

#### **a. Country presentation**

The construction sector of North Macedonia includes producers of concrete, gypsum, roof tile, insulating material, and bitumen mixtures. National legislation is the Law on Construction Products, which is **partly aligned** with the Construction Products Regulation (EC) No. 305/2011. North Macedonia has its own national standards for some construction products: concrete, bitumen and bitumen alloys, stainless steel for reinforced concrete, and stainless steel for reinforced concrete. All EU construction standards are accepted by North Macedonia, and the national framework is fully aligned to them. The Ministry of Economy is the competent authority, and SMI and Customs ensure market surveillance. North Macedonia has already established a product contact point for construction products and plans resources and the number of notified bodies in this area.

#### **b. Commission assessment**

National legislation is **partly aligned** with the EU *acquis* on construction products. All EU construction standards are accepted by North Macedonia, and the national framework is fully aligned to them.

### **III.O. RECREATIONAL CRAFT**

#### **a. Country presentation**

There are several small manufacturers of North Macedonia for export in North Macedonia, which also has a requirement of registration of such craft. The legal base is not yet aligned to the EU *acquis*. Alignment was planned by the end of 2024. The Ministry of Economy is the responsible authority. Market surveillance is performed by SMI.

#### **b. Commission assessment**

North Macedonia is **not aligned** to the current EU *acquis* on recreational craft. There is a national requirement to register recreational craft.

### **III.P. ECO-DESIGN**

#### **a. Country presentation**

North Macedonia has producers that need to ensure eco-design (and related energy labelling) requirements. National legislation, which consists of the Energy Law (96/18) the Law on Energy Efficiency (32/20, 110/21 and 236/22), is **partly aligned** with Directive 2009/125/EC. North Macedonia stated that the only deviation is with regard to the categories of product that are covered. Full alignment is foreseen by the end of 2024. The competent authority is the Ministry of Economy, and market surveillance is performed by SMI. There are currently insufficient administrative and market surveillance resources in this area. North Macedonia currently has no authorised body for conformity assessment bodies in this area.

#### **b. Commission assessment**

National legislation is **partly aligned** with the EU *acquis* on Eco-design, and it does not yet have sufficient market surveillance resources in place in this area.

### **III.Q. EXPLOSIVES FOR CIVIL USE**

#### **a. Country presentation**

North Macedonia is not aligned with Directive 2014/28/EU on explosives for civil use. **Full alignment** is foreseen during 2024. The competent authority is the Ministry of Environment. Implementation is performed by the Ministries of Interior, Defence, Foreign Affairs, Justice, the Agency for Confiscated Goods, and Customs. Economic operators need to be licenced by the authorities to buy, sell, import and export, and use these products. An electronic system is in place to track the purchase, transfer, import, transit, and export of explosive for civil use.

#### **b. Commission assessment**

National legislation is **not aligned** with the EU *acquis* on explosives for civil use. North Macedonia does not yet have adequate administrative and market surveillance resources in this area.

### **III.R. PYROTECHNIC ARTICLES**

#### **a. Country presentation**

North Macedonia is not aligned with Directive 2013/29/EU on the placing on the market of pyrotechnic articles. Full alignment is foreseen during 2024. The competent authority is the Ministry of Environment. Implementation is performed by the Ministries of Interior, Defence, Foreign Affairs, Justice, the Agency for Confiscated Goods, and Customs.

#### **b. Commission assessment**

The legislation of North Macedonia is **not aligned** with the EU *acquis* on pyrotechnic articles. It does not yet have adequate administrative and market surveillance resources in this area.

### **III.S. MEASURING INSTRUMENTS, NON-AUTOMATIC WEIGHING INSTRUMENTS, UNITS OF MEASUREMENT, PRE-PACKAGING, BOTTLES USED AS MEASURING CONTAINERS**

#### **a. Country presentation**

National legislation, which consists of the Law on Metrology and relevant implementing legislation, is designed to be **fully aligned** with the EU *acquis* on units of measurements, on pre-packaging, and on bottles used as measuring containers. National legislation is **partly aligned** with the EU *acquis* on units of measurement, and on non-automatic weighing instruments, full alignment to both is foreseen during 2025.

#### **b. Commission assessment**

The legislation of North Macedonia is **fully aligned** with the EU *acquis* pre-packaged products, and on bottles used as measuring containers on measuring units (MID), and **partly aligned** to the EU *acquis* on non-automatic weighing instruments (NAWI). There are no sufficient administrative resources in place yet, though there seem to be adequate implementing resources.

### **III.T. FERTILISING PRODUCTS**

#### **a. Country presentation**

North Macedonia has several fertiliser producers. The legal base is its Law on Quality and Safety of Fertilisers, Bio-stimulants and Enhancers of Soil Properties, which is designed to be fully aligned with Regulation (EC) No. 2003/2003 on EC fertilisers, replaced by Regulation (EU) 2019/1009 as of 16 July 2022. The competent authority is the Ministry of Agriculture, Forestry and Water Economy. Implementation is ensured by the phytosanitary administration and by the State Inspectorate for Agriculture, the former has insufficient human resources. North Macedonia has conformity assessment bodies in this area.

#### **b. Commission assessment**

The legislation of North Macedonia is **fully aligned** with the old EU rules. Regulation (EU) 2019/1009 and maintains the optional harmonisation, which implies that North Macedonia, like any Member State, may continue to keep divergent national rules on fertilising products. However, North Macedonia needs to ensure that its national legislation will not impede the free movement of compliant EU fertilising products. In addition, North Macedonia has to set out the legal framework for the notification of conformity assessment bodies (designate a notifying authority responsible for this Regulation and set out the procedures for the notification of conformity assessment bodies and monitoring of notified bodies). Implementing capacity is currently insufficient to implement this EU *acquis*.

### **III.U. SUMMARY OF FINDINGS – EU ‘NEW AND GLOBAL APPROACH’ ACQUIS**

North Macedonia has adopted legislation designed to be **fully aligned** with the EU *acquis* on **machinery, units of measurements, pre-packaging, and bottles used as measuring containers**. It has a **high level of alignment** on **noise emissions by outdoors equipment**.

The relevant legislation of North Macedonia is **partly aligned** with the EU *acquis* on **low voltage equipment (LVD), electromagnetic compatibility (EMC), toys, lifts, personal protective equipment (PPE), gas appliances, cableways, radio equipment (RED), units of measurement, and non-automatic weighing instruments**.

The relevant legislation of North Macedonia is **not aligned** with the EU *acquis* on **equipment, protective systems intended for use in potentially explosive atmospheres (ATEX), pressure equipment, recreational craft, and pyrotechnic articles**.

North Macedonia needs to put in place the necessary administrative capacity in all relevant ministries and other bodies that ensure implementation, both to ensure alignment and to ensure the implementation of legislation once it is all fully aligned to the New and Global Approach EU *acquis*.

### **IV. ‘OLD APPROACH’ PRODUCT LEGISLATION**

#### **IV.A. MOTOR VEHICLES / TRACTORS (AGRICULTURAL, FORESTRY) / MOTOR VEHICLES (2/3 WHEELED VEHICLES) / NON-ROAD MOBILE MACHINERY EMISSIONS**

##### **a. Country presentation**

There is one manufacturer of tractors (T1 vehicle category) and one of tractor trailers (R1 category) in North Macedonia, as well as manufacturers of components for motor vehicles (the latter for export only, which ensure conformity assessment in the EU and other recipient countries). North Macedonia has motor-vehicle importers associations for motor vehicles, one for motorbikes and one for cargo vehicles, there is not one for non-road machinery.

National legislation, the Law on Vehicles (140/08 and several amendments), is partly aligned with the EU *acquis* for motor vehicles, tractors (agricultural, forestry) 2-3 wheeled vehicles, emissions by non-road machinery. Full alignment is foreseen in 2024 via the adoption of a new national law on vehicles and relevant implementing legislation.

The competent authority is the Ministry of Economy for these sectors, the implementing bodies are the Ministry of Interior, BoM, and several market surveillance bodies, though there is no specific vehicle market surveillance body. There is one notified body (BoM) for motor vehicles, the accreditation body has enough resources to ensure accreditation in these sectors. North Macedonia believes that it has sufficient resources to implement the EU *acquis* in these sectors.

At the moment, when a vehicle meets the current national requirements, it is homologated for being placed on the market of North Macedonia and the relevant certificate is issued. Only type homologation for new vehicles in categories R1 and T1 are currently implemented in North Macedonia. All EU type approval levels are accepted by North Macedonia, they currently also accept US type approvals for M1 and L category vehicles (this will not be possible after their eventual accession to the EU). Around 32 000 used vehicles of all types are imported each year, most of which are M1 category vehicles. BoM issues single type approvals.

#### **b. Commission assessment**

The relevant legislation of North Macedonia is **partly aligned** with the EU *acquis* on motor vehicles, on tractors (agricultural, forestry), on 2-3 wheeled vehicles, and on emissions by non-road machinery. There is no specific market surveillance body that deals with vehicle.

### **IV.B. CHEMICALS – REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH)**

#### **a. Country presentation**

North Macedonia has several producers of chemicals. The Law 145/2010 on Chemicals and relevant implementing legislation is partly aligned with REACH, full alignment is foreseen by the end of 2026. The competent authority is the Ministry of Health, which is also the implementing body. It follows the list of substances published by the European Chemicals Agency (ECHA), and has created a chemicals registry. Companies have to apply to the authorities for authorisation for the import of high-risk substances. There are currently insufficient resources and additional capacity building on REACH requirements is needed to ensure implementation, further recruitment depends on budget being made available for this.

#### **b. Commission assessment**

National legislation is **partly aligned** with the EU REACH *acquis*. There are insufficient administrative resources and additional capacity building on REACH requirements is needed to ensure implementation.

### **IV.C. CLASSIFICATION, LABELLING AND PACKAGING [OF CHEMICALS] (CLP)**

#### **a. Country presentation**

The national legal base is the Law on Chemicals and implementing legislation, which is partly aligned with Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures. Full alignment is foreseen by the end of 2026. North Macedonia also has a list of new and classified substances, some classifications are aligned with those CLP requirements in place in the EU up to 2012. There are producers of chemical products in North Macedonia. There are insufficient resources for the implementation of CLP, further recruitment depends on budgetary reinforcement.

#### **b. Commission assessment**

National legislation is **partly aligned** with the EU *acquis* on CLP. There are currently insufficient financial and human resources allocated to the implement of CLP.

#### **IV.D. DETERGENTS**

##### **a. Country presentation**

The national legal framework is the Law on Chemicals and implementing legislation, which is partly aligned with Regulation (EC) 648/2004. Deviations concern biodegradability, duties to the EU, and labelling, limits, and restrictions. North Macedonia has producers of detergent products. The competent authority is the Ministry of Health. Implementation is ensured by the Ministry, SMI and customs, which currently have insufficient resources. North Macedonia has not yet any accredited laboratories that could work on detergents.

##### **b. Commission assessment**

National legislation is **partly aligned** with the EU *acquis* on detergents. Implementing capacity is currently insufficient to implement this EU *acquis*.

#### **IV.E. DRUG PRECURSORS**

##### **a. Country presentation**

North Macedonia does not have any producers of substances that can be used in the production of narcotic drugs and psychotropic substances. Its national legislation, which consists of the Law on Chemicals, the Law 37/04 on Precursors and the Law 103/08 on Control of Narcotic Drugs and Psychotropic Substances, is partly aligned to Regulation (EC) 273/2004 on drug precursors. Full alignment is foreseen by the end of 2026. The competent authority is the Ministry of Health. Implementation is ensured by the Ministries of Health and Interior, and by Customs. North Macedonia classifies drug precursors into three categories, and trade in such products under two categories is only allowed by licensed economic operators. Import or export has to be pre-approved, and is tracked by a national IT system. Legal entities are obliged to report to the authorities any suspicion of abuse of manufacturing, marketing, unusual orders, theft or any other illegal activity regarding narcotic drugs and psychotropic substances.

##### **b. Commission assessment**

National legislation is **partly aligned** with the EU *acquis* on drug precursors. Further work is necessary to ensure full alignment with the EU *acquis*, including with regard to the classification of such substances.

#### **IV.F. GOOD LABORATORY PRACTICE (GLP)**

##### **a. Country presentation**

National legislation is not yet aligned with the EU *acquis* on GLP. Full alignment is foreseen by the end of 2027. A GLP compliance monitoring authority has been established, but it currently only covers medicines for human use. North Macedonia acknowledges that it needs to strengthen its administrative capacities in this area. Its current guidelines on GLP currently only regulates pre-clinical trials for medicines for human use. It does not yet have any laboratories to ensure GLP for medicinal products for human and veterinary use or for toxicological and eco-toxicological chemicals or assess the risk of their potential danger to life and human health and the environment of chemicals. North Macedonia requested to join the EU expert group on GLP.

##### **b. Commission assessment**

National legislation is **not aligned** with the EU *acquis* on GLP. North Macedonia needs to strengthen its capacities necessary to administer and implement this EU *acquis*.

## IV.G. AEROSOL DISPENSERS

### a. Country presentation

North Macedonia has no manufacturers of aerosol dispensers. North Macedonia's legislation is not yet aligned with the EU *acquis* in this area, this is foreseen to be ensured by the end of 2024. The competent authority is the Ministry of Economy. Implementation will be the responsibility of SMI, which currently has no inspection capacity in this area at the moment.

### b. Commission assessment

National legislation is **not aligned** with the EU *acquis* on aerosol dispensers. North Macedonia has not yet allocated the necessary resources for market surveillance in this area.

## IV.H SUMMARY OF FINDINGS – EU ‘OLD APPROACH’ ACQUIS

North Macedonia is **partly aligned with the EU *acquis* on motor vehicles, on tractors (agricultural, forestry), on 2-3 wheeled vehicles, and on emissions by non-road machinery.**

North Macedonia is also **partly aligned with REACH, with the EU *acquis* on Classification, Labelling and Packaging of chemicals (CLP), on detergents, and on drug precursors.**

North Macedonia is **not aligned with the EU *acquis* on good laboratory practice (GLP), and on aerosol dispensers.**

North Macedonia should put in place the necessary administrative capacity in all the relevant ministries and in the bodies that ensure implementation, in order to ensure alignment and its administration and to ensure the implementation of legislation in line with the requirements of each of the EU ‘Old Approach’ *acquis*.

## V. PROCEDURAL MEASURES

### V.A. TRANSPARENCY IN RELATION TO PRICING AND REIMBURSEMENT OF MEDICINAL PRODUCTS

#### a. Country presentation

National legislation, which consists of the Law on Medicinal Products and Medical Devices, the Law on Health Insurance, and implementing legislation, is partly aligned to the relevant EU *acquis*, further alignment is foreseen during 2024. The responsible body is the Ministry of Health, which sets maximum prices, and wholesale and retail prices, the health insurance fund, which sets the reference prices and the fund's management board, under the Ministry of Health, that determines the medicines that feature on the positive list. Administrative capacities need reinforcement. The reference process is set in the basis of three criteria, i) the price applied in five reference countries, and ii) medicine prices in reference countries. Maximum prices are set in March every year. The retail price is set on a formula equalling the wholesale price, plus a fixed margin, plus 5% (VAT). The fixed retail margin is between 20 and 28%, or a fixed amount in local currency. Approval has to be given within 20 days, then prices are published on the Ministry of Health's website. Objections can be made within 15 days. The methodology also includes procedures for the pricing of originator, generic, and biosimilar medicines respectively. The positive list has two categories: A (primary health care medicines) and B (hospital care medicines).

#### b. Commission assessment

National legislation is **partly aligned** with the EU *acquis* on the transparency in relation to pricing and reimbursement of medicinal products.

### V.B. CRYSTAL GLASS

#### **a. Country presentation**

North Macedonia does not have any domestic manufacturers of glass products. National legislation which consists of on Technical Requirements for Products and Conformity Assessment, the Laws on Product Safety, Accreditation, and Standardisation, and specific implementing legislation, is designed to be fully aligned with Directive 69/393/EEC. The competent authority is the Ministry of Economy. Implementation is ensured by SMI (no market surveillance of such products has been ensured recently, but it is programmed in the coming period). North Macedonia currently has no plans to establish notified bodies in this area.

#### **b. Commission assessment**

National legislation is **fully aligned** with the EU *acquis* on crystal glass. Market surveillance has not yet been implemented on this *acquis*.

### **V.C. TEXTILE LABELLING**

#### **a. Country presentation**

North Macedonia has domestic manufacturers of textiles. National legislation is not aligned with the EU *acquis* on textile labelling and mixtures, Regulation (EU) No 1007/2011. Alignment is foreseen by the end of 2025. The competent authority is the Ministry of Economy, SMI will ensure market surveillance. Strengthening implementation and market surveillance capacity is necessary. North Macedonia has conformity assessment bodies for such products, it currently has no plans to establish notified bodies in this area.

#### **b. Commission assessment**

National legislation is **not aligned** with the EU *acquis* on textile labelling and mixtures. There are insufficient resources in place to implement this *acquis*.

### **V.D. FOOTWEAR**

#### **a. Country presentation**

North Macedonia has several domestic manufacturers of footwear, representing about 3% of domestic manufacturing industries. National legislation which consists of on Technical Requirements for Products and Conformity Assessment, the Laws on Product Safety, Accreditation, and Standardisation, and specific implementing legislation, is designed to be aligned with the EU *acquis* on footwear, Directive 94/11/EC. The competent authority is the Ministry of Economy, SMI ensures market surveillance. North Macedonia has conformity assessment bodies for such products, it currently has no plans to establish notified bodies in this area.

#### **b. Commission assessment**

National legislation is **fully aligned** the EU *acquis* on footwear.

### **V.E. FIREARMS (ACQUISITION AND POSSESSION OF WEAPONS)**

#### **a. Country presentation**

There are no manufacturers of products in this area in North Macedonia. The Law 7/05 on Weapons is partly aligned with Directive 2021/555(EU). Full alignment was foreseen by the end of 2024, which should notably eliminate one category of weapons that is no longer applicable under the current EU *acquis*. The responsible authority is the Ministry of Interior. There is a National Commission for the Control of Weapons, that cooperates with the relevant national authorities (Ministries of Interior, Defence, Justice, Finance (Customs Administration), Foreign Affairs, and Agency for Sized and Confiscated Property (for the destruction of weapons)).

#### **b. Commission assessment**

National legislation is **partly aligned** with the EU *acquis* on the acquisition and possession of firearms.

### **V.F. DEFENCE PRODUCTS (TRANSFER OF DEFENCE RELATED PRODUCTS)**

There are manufacturers of defence products in North Macedonia, including ammunition. National legislation, which consists of the Law 298/21 on the Development, Production and Trade in Military Goods and implementing legislation, is partly aligned with the EU *acquis*. Deviations notably concern a national requirement making approval of transit of such products obligatory. Full alignment is foreseen by the time of accession to the EU. North Macedonia acknowledges the need to build up implementing and administrative capacity in this area, and to adopt a new IT system. The responsible authority is the Ministry of Economy. It has a specific Commission (expert body) for Consideration of Applications for Permits for Trade in Military Goods.

#### **b. Commission assessment**

National legislation is **partly aligned** with the EU *acquis*. Deviations notably concern a national requirement making approval of transit of such products obligatory. Implementing and administrative capacity is insufficient in this area.

### **V.G. CULTURAL GOODS UNLAWFULLY REMOVED FROM THE TERRITORY OF AN EU MEMBER STATE**

#### **a. Country presentation**

The legislation of North Macedonia, which consists of the Law on Protection of Cultural Heritage, the Customs Law, and the Law on Foreign Trade Operations, and the Law on Protection of Cultural Heritage is **partly aligned** with Directive 2014/60/EU. Further alignment is foreseen during 2024. A national inventory of dispersed cultural heritage will also be prepared during 2023, as will an IT system to track such items. Deviations are in regard to aspects of the EU *acquis* that apply to EU Member States. The responsible authorities are the ministries of foreign affairs, of internal affairs, of culture and of finance (customs administration). Implementation is ensured by the ministry of culture.

#### **b. Commission assessment**

National legislation is **partly aligned** with the EU *acquis* on cultural goods unlawfully removed from the territory of an EU Member State. North Macedonia needs to fully align and to also ensure that it has the necessary capacity to implement this EU *acquis*.

### **V.H. SUMMARY OF FINDINGS – PROCEDURAL MEASURES**

North Macedonia is **fully aligned** with the EU *acquis* on **crystal glass**, and on **footwear**.

North Macedonia is **partly aligned** with the EU *acquis* on **transparency in relation to pricing and reimbursement of medicinal products**, on **firearms**, on **transfers of defence-related products**, and on **cultural goods unlawfully removed from the territory of an EU Member State**.

The relevant legislation of North Macedonia legislation is **not aligned** with the EU *acquis* on **textile labelling**. North Macedonia needs to ensure the necessary administrative and implementing capacity to be able fully implement all the EU *acquis* on procedural measures.

## **VII. ANTI-CORRUPTION MEASURES WITH REGARD TO THE FREE MOVEMENT OF GOODS**

### **a. Country presentation**

The anti-corruption framework in North Macedonia is laid down in its Law on Corruption and Conflict of Interest, and in the National Strategy for the Prevention of Corruption and Conflict of Interest 2021-2025 with an Action Plan for its Implementation. The State Commission for the Prevention of Corruption (SCPC) also has guidelines which include the protection of public interest, compliance with the code of ethics, merit-based recruitment, transparency, and whistle blowers.

The SCPC is looking into inspection services in 2023, and has flagged that there is no interoperability of information systems between the inspectorates, a finding that is relevant to market surveillance. It has also signalled lack of qualified inspectors, and a lack of clear and imprecise competency frameworks leading to both overlaps and gaps in competencies. It found that some risks of corruption in inspection services and recommended remedial measures. It also found that inspection services at local level have very limited capacity, where some staff are unqualified.

### **b. Commission assessment**

North Macedonia has a legal basis for anti-corruption measures, an ongoing strategy and action plans on the prevention of corruption and conflicts of interest, and a State Commission for the Prevention of Corruption (SCPC). The SCPC has issued guidelines on the protection of public interest, compliance with the code of ethics, merit-based recruitment, transparency, and whistle blowers. SCPC has flagged interoperability issues between inspection services, a lack of qualified inspectors, it also found several risks of corruption in inspection services and recommended remedial measures (findings that are relevant to market surveillance).

## **C. SUMMARY OF FINDINGS – ANTI-CORRUPTION MEASURES**

North Macedonia has a legal framework and an ongoing strategy and action plans on anti-corruption measures. The State Commission for the Prevention of Corruption has flagged several issues which need to be addressed that are, inter alia, relevant to market surveillance bodies, and has recommended remedial measures which North Macedonia should implement. These should be addressed.

## C) CHAPTER 2 - FREE MOVEMENT OF WORKERS

As regards the general principles related to access to labour market, the EU *acquis* under this chapter provides that EU citizens of one Member State have the right to work in another EU Member State, to reside there for that purpose with their family members and to be treated in the same way as national workers in relation to working conditions and social and tax advantages.

In addition, the general principles of freedom of movement for workers include provisions related to supplementary pension rights of employed and self-employed persons moving within the Union.

The EURES network (European Employment Services) is aimed at promoting the freedom of movement for workers within the Union, notably by close cooperation between national employment services to exchange information on employment opportunities. At an operational level, relevant databases of job vacancies need to be integrated with the EURES vacancy exchange mechanism, and general information on the labour market and on living and working conditions needs to be exchanged.

The European Labour Authority aims at providing easier access to information and labour mobility services for individuals, employers, and social partners. It also has for objective to strengthen cooperation between national authorities in cross-border enforcement, including through inspections. It also provides mediation in disputes on the application of the EU *acquis* concerning labour mobility and supports cooperation in tackling undeclared work.

The right to free movement for workers is complemented by a system for the coordination of social security systems, i.e. the right for migrant workers and their dependents to acquire, cumulate or transfer social security benefits as well as to obtain payment of these benefits. This is based on EU regulations that do not harmonise but coordinate the social security systems of Member States, requiring administrative cooperation between them. Moreover, in the health care field, medical expenses need to be reimbursed for all necessary treatment of nationals falling ill or having an accident during a temporary stay in another Member State, e.g., as tourists. To this end, a European Health Insurance Card has to be issued to all nationals. The Electronic exchange of social security information (EESSI) is an IT system that helps institutions in charge of tasks related to the social security coordination to exchange information electronically, more rapidly, accurately and securely.

### I. ACCESS TO LABOUR MARKET - GENERAL PRINCIPLES

#### a. Country presentation

The national law on employment and work of foreigners establishes quotas of **permits for foreigners** who want to work in the country, but following a reciprocity agreement with the EU, those do not apply to EU citizens.

The Law on Foreigners allows for a single work and residency permit for a foreigner, with no distinction between EU citizens and other foreigners. The permits allocated to EU citizens represented 12,8% of such cases in 2020 and 10,7% in 2021. A foreigner needs to apply to the Ministry of Interior, which requests the authorisation of a work permit to the Ministry of Labour. For seasonal employment, workers are allowed to work for 6 months, with an exception in the construction sector, where the allowed stay is nine months within a calendar year; The duration of the engagement for posted workers cannot exceed 24 months, with exceptions regulated by the Bilateral Social Security Agreements. The authorisation is submitted to the approval of both the Ministry of Interior and the Employment Agency, and depends on the need for resources and the fulfilment of quotas.

The Law on Labour Relations, which is the general law on labour, prohibits direct and indirect **discrimination** of persons seeking employment or of employees in respect of race, skin colour, gender,

age, health condition (including disability), religious, political, or other convictions, trade union membership, national or social background, family status, property status, sexual orientation, or other personal circumstances. It therefore specifically refers to discrimination on grounds of nationality. This principle of non-discrimination covers for all conditions of employment and work and ensures that foreigners have access to the same social and tax advantages as nationals.

Foreigners do not have access to employment in the **public sector**. However, exemptions for all foreigners exist for public employment in the sector of health, for experts in the field of medicine, dental medicine, or for pharmacists. Regarding this exemption, EU citizens (and citizens of Switzerland, Canada, Japan, Israel, Türkiye, Russia and the USA) only need the agreement of the Ministry of Health, when for other nationalities, the agreement of the Ministry of Interior is also needed. An exemption also exists in the field of higher education which applies for all foreigners.

**Family reunification** is regulated by the Law on Foreigners which states that a foreigner who has been granted permanent, or temporary residence for a period of one year, for the purposes of employment or scientific-research activity, will be recognised the right to family reunification with the members of their nuclear family. The rights of the members of the nuclear family cover temporary residence, right to education, professional development, employment, and self-employment activity.

#### **b. Commission assessment**

North Macedonia needs to ensure that by the time of accession, EU citizens can access its labour market without any restrictions (e.g., work permit) and are entitled to reside in North Macedonia for the purpose of work without visa or residence permit. North Macedonia also needs to ensure that, by the time of accession, the restrictions of access to the public sector will only apply to posts which are directly related to the specific activities involving the exercise of public authority and the responsibility for safeguarding the general interest of the State. Therefore, North Macedonia needs to examine carefully which categories of civil servants could be reserved for nationals from North Macedonia only, taking into account the CJEU case law.

North Macedonia must finalise the harmonisation of its legislation with the EU *acquis* in the field of free movement of workers and specifically exclude EU citizens from the annual quotas of foreign workers. Efforts should also be made on the improvement of the system to inform EU workers about their rights in the country and an institution responsible for supporting EU mobile workers in their rights should be designated.

#### **C. SUMMARY OF FINDINGS - ACCESS TO LABOUR MARKET - GENERAL PRINCIPLES**

The legislation of North Macedonia in this area is **partially aligned** with the EU *acquis*. More adjustments are still needed regarding the access to labour market. It needs to ensure that by the time of accession, EU citizens can access its labour market without any restrictions. It should designate an institution responsible for supporting EU mobile workers. It should also ensure that, by the time of accession, the restrictions of access to the public sector are in line with the CJEU case law.

## **II. SUPPLEMENTARY PENSIONS**

### **a. Country presentation**

The Law on Pension and Disability Insurance and Law on Mandatory Fully Funded Pension Insurance set the legal framework of the mandatory, pay-as-you-go pension system for the statutory scheme. The Law on Voluntary Fully Funded Pension Insurance sets the legal framework for supplementary (occupational funds and funds for individuals) voluntary scheme. Voluntary supplementary pension funds are also in place for people between 15 and 70 years old. If an employee under occupational fund does not work anymore, their account can be kept turned into an individual account. Assets cannot be withdrawn from

voluntary pension funds before the age for retirement, which is 10 years prior to the age for retirement from statutory pension scheme (52 compared to 62 for women and 54 compared to 64 for men). Occupational pension schemes have already been created by around 4 000 employers.

The Ministry of Labour and social policy's Department for Pension and Disability Insurance is responsible for pensions, with the Unit for Currently Funded Pension and Disability Insurance in charge of the first pillar and the Unit for mandatory and voluntary fully funded pension insurance for the second and third pillar. The latter faces an important human capacities issue, with only one person working in the Unit.

#### **b. Commission assessment**

The legislation of North Macedonia is **not aligned** with Directive 98/49/EC or with Directive 2014/50/EU. However, cross-border membership and the equal treatment of incoming and outgoing EU workers in a voluntary pension funds are provided in the national law with an entry into force on the date of accession. Some thorough training on the topic for the teams in charge should also be envisaged.

#### **C. SUMMARY OF FINDINGS -SUPPLEMENTARY PENSIONS**

|   |
|---|
| North Macedonia is <b>not aligned with most of the EU <i>acquis</i> on supplementary pensions</b> , apart from in regard to cross-border membership and the equal treatment of incoming and outgoing EU workers in a voluntary pension funds. |
|---|

### **III. EURES**

#### **a. Country presentation**

The Employment Service Agency provides support, assistance, and services to labour market participants. It is organised through a central office and 30 regional employment centres. It will be the main implementing body for EURES and will act as National Coordination Office. As part of a Twinning project with Germany and Lithuania, training on EURES were carried out for the employees of the Employment Service Agency between 2014 and 2015, but an update would be needed due to employees' turnover since then.

Regarding the IT aspects, North Macedonia has developed an important service with satisfactory capacities. It has also created a web portal to connect employers with job seekers. The electronic system provided by the Employment Service Agency provides a large part of the necessary data and information - national classifications for employers' main activity (NACE), territorial units (NUTS), occupations (ISCO), and level of education (ISCED) - the structure of the data for the advertisements in the database meets the minimum standards for future exchange with EURES. An ESCO mapping would be useful at a later stage. A memorandum of cooperation with several agencies regulates the access and exchange of information, it also envisages authorised access to the system.

North Macedonia has agreements in place for cooperation with other countries and is also part of the World Association for Public Employment Services (WAPES) and the Centre of Public Employment Services of Southeast European Countries (CPESSEC).

National legislation has not established a system for the appointment of EURES members and partners.

North Macedonia plans to start the preparation of a new law on employment and insurance in case of unemployment. It also foresees the analysis of the needs for harmonisation of the national legislation, with the financial support of the EU; the strengthening of the capacities of the Employment Agency. Other plans cover the continuous development and upgrading of the IT system; the upgrading of the database of the Agency with the possibility to download data from private employment agencies, in order for the Agency to be the only point for the exchange of data with EURES.

### **b. Commission assessment**

North Macedonia has a good level of preparation regarding EURES. All main IT elements are in place. The administrative capacity is also satisfactory, though an update of the training performed in 2014-15 through twinning project, should be performed. North Macedonia needs to establish a system for the appointment of EURES members and partners. It should also ensure an access to the system to private employment agencies.

The adoption of amendments to the current national legislation in order to fully comply with EURES standards has a deadline of 2030, while the implementation of those amendments would take place upon accession.

### **C. SUMMARY OF FINDINGS - EURES**

North Macedonia has a **good level of alignment regarding EURES**, both on IT and structural levels. It will have to ensure the adequate connection of private employment agencies.

## **IV. EUROPEAN LABOUR AUTHORITY**

### **a. Country presentation**

The State Labour Inspectorate of North Macedonia is an entity within the Ministry of Labour and Social Policy carrying inspection supervision over the application of labour relations, employment, and protection at work legislation. It comprises of 71 inspectors in the department of labour relations, and 44 inspectors in the department of safety and health at work.

The State Labour Inspectorate has adopted a methodology for risk assessment in the planning of inspections, in order to direct resources where the risk of serious irregularities is the greatest. Inspectors may take both preventive and repressive measures for which an appeal can be filed.

### **b. Commission assessment**

National legislation is currently **not aligned** with the EU's regulation establishing the European Labour Authority. The country however has plans to harmonise in the medium-term, with full implementation of harmonisation upon accession. Mid-term plans also include institutional, procedural, and administrative preparations for the State Labour Inspectorate to be able to respond to the tasks coordinated by the European Labour Authority, including inspections, access to information and tackling undeclared work.

### **C. SUMMARY OF FINDINGS – EUROPEAN LABOUR AUTHORITY**

North Macedonia **is not aligned with the EU's regulation establishing the European Labour Authority**. The country, however, has plans to harmonise in the medium-term, with full implementation of the EU *acquis* upon accession.

## **V. COORDINATION OF SOCIAL SECURITY SYSTEMS**

### **V.A. COORDINATION OF SOCIAL SECURITY SYSTEMS – MAIN REGULATIONS**

#### **a. Country presentation**

The social security system of North Macedonia covers sickness, maternity and paternity, invalidity, old age pensions, accidents and occupational diseases, unemployment benefits. Regarding the personal scope, it applies to workers and self-employed persons, farmers and unemployed persons receiving cash benefits for unemployment. The Law on Health Insurance provides for health care services in case of illness, injury

outside of the workplace, injury at work, occupational disease and cash benefits in case of temporary absence from work, sick leave, benefits in case of pregnancy, childbirth, and maternity, as well as benefits in case of injury at work and occupational disease. It applies to insured persons and their families. The Law on Employment and Insurance in Case of Unemployment provides for cash benefits for unemployed persons due to salary or income loss. It applies for insured persons who are workers with established labour relations.

North Macedonia has currently signed 22 bilateral social security agreements, including with 13 EU Member States, the others having been signed with Türkiye, Switzerland, the then Federal Republic of Yugoslavia (to which Serbia has succeeded, and a bilateral social security agreement was also signed with Montenegro after its independence), Bosnia and Herzegovina, Australia, Montenegro, Canada, Albania, and Kosovo. Those agreements are based on the principle of coordination: equal treatment, applicable legislation, aggregation of insurance periods and exports of benefits. Bilateral agreements on social security cover pension and disability insurance, health insurance, and insurance in case of unemployment. The bilateral agreements with Australia, Canada and Kosovo only cover pension and disability insurance. North Macedonia plans to initiate a procedure for negotiations in order to conclude a bilateral agreement on social security with Ukraine.

The underlying principle of bilateral social security agreements for posted workers is the *lex loci laboris*.

#### **b. Commission assessment**

The experience North Macedonia gathered through its various bilateral social security agreements, allows it to have a good level of preparation regarding the coordination of social security systems. It should carry on signing such agreements. It should develop its human capacities as well as upgrade its IT capacities in order to strengthen the exchange of digital data.

The national legal framework is partially aligned with Regulations 883/2004/EC and 1231/2010/EU. The Law on Pension and Disability Insurance and the Law on Health Insurance lay down in some cases the holding of citizenship of North Macedonia as a condition for access to insurance and will need to be amended.

### **V.B. ELECTRONIC EXCHANGE OF SOCIAL SECURITY INFORMATION (EESI)**

#### **a. Country presentation**

North Macedonia plans to introduce, a single unified registry of insured persons (Social insurance administration project) in the coming two years, via a loan from the World Bank (2025). Within the coming five years it will also make an analysis of the national legislation, administrative capacities, and IT infrastructure, amend the legislation to harmonise it with the EU *acquis*; and define the access points with the EESSI.

#### **b. Commission assessment**

North Macedonia is still at an early stage regarding EESSI and needs to step up its alignment.

### **V.C. EUROPEAN HEALTH INSURANCE CARD**

#### **a. Country presentation**

The European Health Insurance card (EHIC) is used on unilateral basis with 9 EU Member states (Slovenia, Czechia, Germany, Bulgaria, The Netherlands, Belgium, Austria, Slovakia, and Luxembourg, and agreements could soon be reached with Hungary, Romania and Croatia). However, there is no EHIC reader in the healthcare facilities in North Macedonia, therefore, the data cannot be processed electronically.

### **b. Commission assessment**

The alignment with the technical needs of the EHIC is satisfactory, with various bilateral agreements allowing for the use of EHIC by EU citizens within North Macedonia. North Macedonia will nevertheless need to step up its capacity to use the EHIC data electronically in order to be fully ready for the use of EHIC on the date of accession.

## **V.D. SUMMARY OF FINDINGS – COORDINATION OF SOCIAL SECURITY SYSTEMS**

North Macedonia is **partly aligned with the *acquis* regarding coordination of social security systems**. North Macedonia benefits from an important experience of the basic mechanisms involved in social security coordination, including through its various bilateral social security agreement. Further social security agreements need to be signed, specifically with EU Member States. North Macedonia will need to ensure that by the time of accession at the latest, its laws on pension and disability and its law on health insurance will be aligned with the EU *acquis*, including regarding conditions on nationality. It will need to step up its efforts regarding EESSI and concentrate on the capacity to use the EHIC data electronically.

## **VI. ANTI-CORRUPTION MEASURES**

### **a. Country presentation**

In 2019 North Macedonia adopted a national transversal law on prevention of corruption and conflict of interest. It has also put in place a national strategy for prevention of corruption and conflict of interest for the period 2021-2025 with an action plan. The specific framework for prevention of corruption in the specific domain of free movement of workers is still weak. The capacities of the Ministry of Labour and Social Policy need to be reinforced. The Employment Agency has not signed the Integrity Policy, though it planned to do so, and it still needs to nominate a person to implement the Integrity Policy.

### **b. Commission assessment**

North Macedonia needs to strengthen the framework of fight against corruption in the field of free movement of workers. The capacities of the Ministry of Labour and Social policy need to be reinforced. Regarding the Employment Agency, North Macedonia needs to ensure its signature of the integrity policy, reinforce the staff of the Department for Internal Audit and ensure that controls, complete documentation and monitoring are performed.

## **C. SUMMARY OF FINDINGS – ANTI-CORRUPTION MEASURES WITH REGARD TO FREE MOVEMENT OF WORKERS**

North Macedonia is still at an early stage in the fight against corruption in the domain of free movement of workers. The national laws and strategies against corruption still need to be implemented specifically in the domain of free movement of workers, including by putting in place the adequate controls within the institutions involved.

## D) CHAPTER 3 - RIGHT OF ESTABLISHMENT AND FREEDOM TO PROVIDE SERVICES

Member States must ensure that the right of establishment of EU nationals and legal persons in any Member State and the freedom to provide cross-border services as laid down in Articles 49 and 56 of the Treaty on the Functioning of the European Union (TFEU) is not hampered by national legislation, subject to the exceptions set out in the Treaty.

The *acquis* under this chapter is of horizontal nature divided into three areas, the **mutual recognition of professional qualifications, the right of establishment and the freedom to provide services**, and **postal services**, which consist of a sector-specific regulatory framework ensuring the provision of universal postal services and the establishment of an internal postal market.

Directive on the **mutual recognition of professional qualifications** sets the rules concerning the recognition of diplomas and other qualifications between Member States to facilitate access to regulated professions for European citizens who wish to exercise their profession in a Member State other than in the one where they gained their qualifications. The Directive also facilitates temporary and occasional provision of services by professionals (this is covered by Title II of the Directive). For certain regulated professions, a common minimum training curriculum must be followed in order for the qualification to be automatically recognised in an EU Member State (this is covered by Chapter III of Title III of the Directive). In the case of the health sector professions covered by Chapter III of Title III of the Directive, the minimum training requirements are binding on every Member State as conditions for access to the profession also at national level. In addition, there are directives governing the exercise of the profession of lawyers in Member States other than that in which they obtained their qualifications, the activities of commercial agents, as well as the recognition of professional qualifications for activities related to the use, trade and distribution of toxic products. In terms of administrative capacity, a national contact point is needed to receive enquiries related to the recognition of professional qualifications and to ensure administrative cooperation with authorities in other Member States. Administrative cooperation procedures foreseen by the Directive are further facilitated by the Internal Market Information system (IMI). Professionals must also have access to information, documentation and competent authorities pertaining to the recognition of their qualifications through the points of single contact (PSC) as required under Directive 2006/123/EC.

As regards the **right of establishment and the freedom to provide services**, Directive 2006/123/EC (the Services Directive) contains provisions which aim to make it easier for service providers to establish themselves in other Member States as well as to provide temporary cross-border services in Member States other than their State of establishment. The implementation of the Services Directive requires Member States to take a combination of legislative and non-legislative i.e. organisational or practical measures. The Directive is a horizontal instrument which covers a broad range of different services and which is likely to affect a significant number of national laws and regulations. For this reason, and as far as implementing legislation is concerned, a mix of specific and horizontal legislative measures is required, which is likely to include the amendment of existing laws, as well as the adoption of new specific legislation and of a horizontal “framework” implementation law. The provisions of the Directive are - to a large extent - based upon the case law of the European Court of Justice relating to the freedom of establishment and the free movement of services and they complement existing EU instruments, which remain fully applicable. Member States are obliged by the Directive to set up a PSC, where service providers can obtain information electronically and complete administrative procedures required for access to and the exercise of service activities. In addition, as required by the Services Directive, competent authorities need to use the Internal Market Information System (IMI) – an IT tool which facilitates Member States administrative cooperation - for the purpose of exchanging information between themselves in some of the procedures foreseen by the Directive.

The *acquis* for **postal services** includes the Postal Services Directive and the Regulation for cross-border parcel delivery services. Main pieces of legislation include the following three Postal Directives: the first (framework) postal Directive 97/67/EC of the European Parliament and of the Council as amended by the second postal Directive 2002/39/EC of the European Parliament and of the Council and the third postal Directive 2008/6/EC of the European Parliament and of the Council and the Regulation (EU) 2018/644 on cross-border parcel delivery services of the European Parliament and of the Council. The postal *acquis* provides for the establishment of an internal market for postal services gradual and controlled market opening to competition, and promotes a high quality universal postal service for end users. In terms of administrative capacity, the establishment of an independent National Regulatory Authority (NRA) is important for ensuring compliance with the EU legislation on postal services. The Regulation complements the Postal Services Directive as far as cross-border parcel delivery services are concerned. In this respect, the Regulation aims at enhancing regulatory oversight of parcel delivery services, increasing transparency of cross-order parcel tariffs, and provides for the assessment of single-piece cross-border parcel tariffs.

## **I. MUTUAL RECOGNITION OF PROFESSIONAL QUALIFICATIONS**

### **a. Country presentation**

As regards the alignment of legislation with the EU Directive 2005/36/EC and its amendments, North Macedonia noted that its legislative framework consists of the Law on Recognition of Professional Qualifications (Official Gazette no.171/2010), the Law on Health Protection, the Law on Higher Education (Official Gazette no. 82/2018 and Official Gazette no. 178/2021), the Law on Mutual Recognition of Professional Qualifications of the Bachelors in Dental Science (Dentists) and Architects in context of CEFTA Agreement.

The system of equivalence and recognition of qualifications of higher education and/or recognition and equivalence of diplomas acquired in foreign countries has its legal basis on Article 147 of the Law on Primary Education and Article 78 of the Law on Secondary Education. Procedures are fully digitalized.

In 2018 North Macedonia determined GAP analysis for the provisions that refer to minimum training for the professions of the system of automatic recognition and overall compliance with the Law on Higher Education. In 2019 a new draft Law on Mutual Recognition of Professional qualifications was prepared together with the draft Rulebooks and Decisions. In 2020 North Macedonia new draft legislation was prepared. North Macedonia stated that currently it has not fully aligned with Directive 2005/36/EC and its amendments.

The authority in charge is the Ministry of Education and Science, the established but not fully staffed Coordinative Group for recognition of professional qualifications; they provide trainings for the relevant bodies (ministries, faculties, chambers) on the functioning of the process of recognition of professional qualifications through the IPA instruments.

North Macedonia provided a detailed presentation on the health sector professions with minimum training requirements, dentist, nurse responsible for general care, midwife, veterinaries, pharmacist, architects and lawyers and referred to the requirements for foreigners to exercise those professions in North Macedonia.

In addition, further efforts are needed to align with sector-specific legislation on the free movement of lawyers, namely Directive 98/5/EC to facilitate practice of the profession of lawyer on a permanent basis in a Member State other than that in which the qualification was obtained and Council Directive 77/249/EEC to facilitate the effective exercise by lawyers of freedom to provide services. Moreover, alignment with the Proportionality Test Directive (EU) 2018/958 has not taken place yet. Finally, any nationality requirements upon access to a profession that are not in line with the requirements of Article 51 of the Treaty on the Functioning of the European Union, would need to be removed, as part of North

Macedonia's alignment with this *acquis*.

#### **b. Commission assessment**

The current legislative framework in North Macedonia is not yet aligned with the relevant EU *acquis* in this area. North Macedonia still needs to align in particular with EU Directive 2005/36/EC to comply with minimum training requirements. Furthermore, a transparent list of all regulated professions and an electronic register are yet to be put in place. The institutional capacity of the Ministry of Education and Science's section dealing with the mutual recognition of professional qualifications needs to be strengthened.

### **C. SUMMARY OF FINDINGS – MUTUAL RECOGNITION OF PROFESSIONAL QUALIFICATIONS**

North Macedonia's legislation is **not aligned** in this area, in particular with Directive 2005/36/EC. North Macedonia needs to increase the administrative capacity of the sections of the Ministry of Education and Science dealing with the mutual recognition of professional qualifications.

## **II. FREEDOM TO PROVIDE SERVICES**

### **a. Country presentation**

North Macedonia main legal framework in the area consists of the Law no. 98/2019 on Services, Company Law 99/2022, the Law no. 124/2015 on General Administrative Procedures and the Law on real estate cadastre of 2019. In 2020, it adopted a National Action Plan for the implementation of the Services Directive aiming to amend sector specific legislation in order to bring it in line with the *acquis*. As result of the screening of national legislation to check compliance with the Services Directive, North Macedonia drafted a report on its implementation and currently is preparing a new Action Plan under the IPA project "Strengthening the Internal Market in Macedonia" to complete the alignment in this area; adoption is planned. As result, 10 nationality requirements together with several more restrictive requirements will be abolished, so as to bring national legislation in line with the *acquis* in this area. North Macedonia stated that it is **not aligned** align with the **cross-border provision of services** in the areas identified by the current Action Plan and the one that is currently being drafted, which foresees measures for alignment sector-specific legislation with the *acquis* in order to enable EEA services providers to deliver cross-border services.

As regards the **Point of Single Contact**, Law no. 311/2020 on Central Registry and Law no. 215/2021 One Stop Shop. The Central Register operates as the Point of Single Contact, interacting with the tax administration, the employment agency to allow for simultaneous registration in a single step. The new portal of the Central Register has simplified procedures for businesses.

The Ministry of Economy is the coordinator; North Macedonia also counts with a working group for this chapter and for the implementation of the Law on Services consisting of representatives of the relevant authorities (Chambers, different ministries, etc.). North Macedonia stated that it plans to further reinforce its administrative capacity in this area. IPA project on the implementation of the Internal Market in North Macedonia, component 2 will help to complete the screening of national legislation. b. Commission assessment

North Macedonia's legislative framework is **partially aligned** with the EU Services *acquis*. The 2024-2025 action plan to ensure that sectoral laws comply with the EU Services Directive needs to be adopted and start being implemented. The point of single contact ([www.uslugi.gov.mk](http://www.uslugi.gov.mk)) needs to be developed and upgraded to meet the requirements set out in the Services Directive.

## **b. Commission assessment**

North Macedonia's legislative framework is not aligned with the EU *acquis*. Legislative alignment needs to be completed and the screening of legislation (checking relevant legislation compliance with *acquis* requirements in this area) needs to be finalised. Additionally, the Point of Single contact is not fully in line with EU *acquis* requirements.

## **C. SUMMARY OF FINDINGS – RIGHT OF ESTABLISHMENT AND FREEDOM TO PROVIDE SERVICES**

North Macedonia needs to complete the alignment of its legal framework with the Services Directive as well as to complete the screening of its legislation to identify all the possible barriers for services' providers. The point of Single Contact needs to be further developed to meet *acquis* requirements in this area.

## **III. POSTAL SERVICES**

### **a. Country presentation**

The legal framework on postal services consists of the Postal Law and several bylaws. North Macedonia stated that its legislative framework is **aligned** with the first Postal Services Directive 97/67/EC and the second Directive 2002/39/EC, but only **partly aligned** with the third Directive 2008/6/EC. North Macedonia still needs to open its postal market to full competition and abolish the area of reserved services. Pursuant to the latest amendments of the Law on Postal Services, adopted in October 2022, the universal service provider has an exclusive right to provide reserved postal services until 31 December 2023. The Regulation on cross-border parcel delivery services still needs to be transposed into national legislation. The Postal Agency is a legally separate and operationally independent regulatory authority ensuring compliance with the EU postal rules, and the Ministry of Transport and Communications prepares postal legislation and related acts.

North Macedonia plans to abolish the reserved area of the universal postal services and to adopt a new postal law in line with the Postal Services Directive. It is also preparing to align its legislation with the Regulation on cross border parcel delivery services.

North Macedonia requests accelerated integration to the IMI system.

### **b. Commission assessment**

The legislation of North Macedonia is aligned with the First and Second Postal Services Directives and partly with the Third Postal Services Directive, as the designated universal service provider (the Post of North Macedonia) still has the exclusive right to provide reserved postal services until 31 December 2023. The Postal Agency is the independent regulatory authority ensuring compliance with postal law and monitoring quality of service against European standards for universal service provision in North Macedonia. There are currently one universal service provider and 33 other postal operators. In view of the near future postal market opening to full competition, preparations are ongoing to set up systems for accounting separation and net cost calculation of the universal service, in line with the Postal Services Directive. North Macedonia is preparing to align its framework with the Regulation on cross-border parcel delivery services. The Postal Agency and the Ministry of Transport and Communications should ensure they have sufficient administrative capacity to monitor and enforce the new postal market rules.

The Commission considers positively the request by North Macedonia to integrate into the IMI system once it meets the following requirements: compliance with the *acquis* and alignment of the policy rules. The European Commission is ready to assist North Macedonia in meeting the requirements.

### C. SUMMARY OF FINDINGS – POSTAL SERVICES

North Macedonia is **partially aligned** with the EU *acquis* on postal services, including the Third Postal Services Directive and the Regulation on cross-border parcel delivery. As regards administrative capacity, the Postal Agency should ensure it has the necessary resources, including staff, to monitor and enforce the new postal market rules.

## IV. ANTI-CORRUPTION

### a. Country presentation

North Macedonia relevant legislative framework in this area consists of the Law on Prevention of Corruption and Conflict of Interest (Official Gazette no. 12/19), a National Strategy for combatting corruption and the Law on Services of May 2019. It is based on the principle of legality and the State Commission is the main body, which shall act upon its own initiative and/or on complaints. The National Strategy will be amended to incorporate inspection services, trading companies. It requires the authorities to respect the principle of integrity, requires the Parliament to adopt an annual report. Until 2024, North Macedonia will develop a special software, a register of elected and appointed persons, with electronic submission of assets declarations; it will create electronic portals to connect with 20 other institutions. The Law on Prevention of Corruption and Conflict of Interest will be amended to include new mechanisms for improving the Commission's proceedings and to establish new software for transparent publication of data related to spending from elected and appointed persons.

### b. Commission assessment

The Commission notes the measures in the fight against corruption both overall and specifically in some of the areas concerning this chapter and the importance of their correct implementation to stimulate a free right of establishment and freedom to provide services in line with the EU requirements.

### C. SUMMARY OF FINDINGS – ANTI-CORRUPTION MEASURES WITH REGARD TO RIGHT OF ESTABLISHMENT AND FREEDOM TO PROVIDE SERVICES

North Macedonia has put in place relevant measures in a general framework and specifically in the area of the right of establishment and freedom to provide services; their correct implementation is crucial.

## E) CHAPTER 4 - FREE MOVEMENT OF CAPITAL

The EU *acquis* in Chapter 4 aims to ensure that capital and investments must be able to move without restrictions, and that common rules for cross-border payments exist, and that banks and other economic operators must apply certain rules to support the fight against money laundering and terrorist financing.

The EU *acquis* on **free movement of capital** is based on Article 63 of the Treaty on the Functioning of the European Union (TFEU), which prohibits all restrictions on movement of capital between member states and between member states and third countries (incl. direct investments, real estate investments, securities operations, current and deposit account operations, loans, guarantees and personal capital movements such as gifts and inheritance). The TFEU foresees some grounds that could in principle justify restrictions to the free movement of capital, such as for taxation, prudential and public policy reasons, for risks to the stability of the Economic and Monetary Union (EMU), for balance of payments difficulties, for reasons of national security and defence, for financial sanctions and the grandfathering clause of Article 64 TFEU. The case law of the European Court of Justice (ECJ) also accepts restrictions to the free movement of capital imposed for overriding reasons of general interest. On the basis of international agreements, the same principles apply to the free movement of capital with EEA countries. On the front of Bilateral Investment Treaties (BITs), BITs of Member States with third countries have to be authorised by the Commission pursuant to Regulation 1219/2012. Upon accession, the acceding country must formally terminate any BITs with EU Member States as these are incompatible with EU law.

On **payment systems**, the TFEU provisions are further elaborated in two directives and three regulations. The Payment Services Directive 2 (2015/2366/EU) ensures harmonised rules for payment services across the EU, including rules for licensing, transparency of conditions and charges, rights and obligations of users and service providers and security requirements. The E-Money Directive 2 (2009/110/EC) sets out the rules on the supervision of electronic money institutions, bringing the prudential regime for e-money institutions into line with other institutions under the Payment Services Directive. The SEPA Regulation (2012/260/EU), sets out the rules and technical requirements for credit transfers and direct debit transactions in euro within the single euro payments area (SEPA). The Regulation on interchange fees (2015/751/EU), caps the fees charged between banks for card-based transactions to drive down merchants' costs. The Regulation (2021/1230/EU) on cross border payments lays down rules on cross-border payments and on the transparency of currency conversion charges.

The EU *acquis* on **anti-money laundering (AML) provisions** centres around the fourth (2015/849/EU) and fifth (2018/843/EU) Anti-Money Laundering Directives, which enforce rules on the identification of customers and require that information on beneficial ownership be held in a central register, while strengthening the cooperation between Financial Intelligence Units (FIUs). They also introduce a coordinated EU policy to deal with third countries which have inefficient AML regimes, to protect the EU's financial system. Associated delegated regulations address regulatory technical standards for anti-money laundering. This EU *acquis* constitutes an EU framework built around the international Financial Action Task Force (FATF) standards.

### I. FREE MOVEMENT OF CAPITAL

#### a. Country presentation

Free movement of capital in North Macedonia is regulated by a number of core legal acts, including the Law on Foreign Exchange operations, the Law on Banks, Law on Investment Funds, Law on Supervision of Insurance, Law on Property and Other Real Rights, Law on Real Estate Cadaster, Law on State-Owned Agricultural Land, Law on Payment Systems and Payment Services, Law on Customs Administration as well as related implementing by-laws. The Constitution guarantees ownership and other property rights. The state is entitled to deprive or restrict ownership rights only in the case of public interest and in accordance with legislation, including appropriate reimbursement. Foreign investors are guaranteed by the

Constitution the right to freely export invested capital and profit. The responsible bodies in this area include the Ministry of Finance (notably the financial system department), the National Bank of North Macedonia, the Securities and Exchange Commission (SEC), the Central Registry, the Agency for foreign investments and promotion of exports, the State Attorney and the Ministries of Economy and Foreign Affairs.

North Macedonia does impose restrictions on the sale of agricultural land through the Law on the Sale of State Agricultural Land to provide for the sale of state agricultural land to existing domestic farmers to increase average farm sizes and improve productivity. There are also restrictions as regards the acquisition of privately-owned agricultural land by foreigners, including EU nationals.

There are currently no restrictions on current transactions between residents and non-residents including payments for goods and services, short term banking instruments for payment, interest or net income on loans and investments and remittances. Residents and non-residents carrying foreign currency amounts in excess of EUR 10 000 equivalent and domestic currency in excess of MKD 120 000 must report this to competent customs authorities upon entering North Macedonia. Capital transactions, including direct investments, securities operations, investment funds, loans and deposits have been partially liberalised. Credit related transactions (short, medium and long term) are also partially liberalised. Free entry of capital by non-residents to North Macedonia has been liberalised and investments of the country's residents abroad (including debt and equity securities and investments funds) have also been liberalised (but are subject to administrative requirements including registration with SEC). Residents can only transfer capital in the amount of EUR 2 500 and above if they can prove they have relevant payment obligations. North Macedonia maintains a register of direct investments and a register of real estate investments for both non-residents investing in North Macedonia and residents investing abroad. Investors are required to report all related investments within 60 days from conclusion of the legal basis to the registry. The registries are largely for statistical purposes and cannot block transactions. The Law on Foreign Exchange operations contains a safeguard clause allowing the National Bank to introduce special protective measures in case of significant distortions to the balance of payments or destabilization of the financial system. The protective measures must be time limited.

Insurance operations can only be carried out by a licensed insurance company based in North Macedonia and a branch of an insurance company from a member state. Residents in North Macedonia cannot be insured in insurance companies abroad, including in EU Member States. Residents can conclude contracts for insurance abroad through insurance brokers.

North Macedonia currently has 24 Bilateral Investment Treaties (BITs) with third countries, including Russia, and 18 BITs with EU Member States. These treaties include investor-state dispute settlement provisions. A new BIT model is under preparation.

#### **b. Commission assessment**

The legislation is only **partially aligned** with the EU *acquis*. Notably the acquisition of agricultural land must be fully liberalised. North Macedonia does not intend to achieve this in the short term as it has expressed interest in a transition period for the requirement.

North Macedonia will need to fully liberalise capital movements by residents abroad, as well as the restrictions on the possibility of residents to be insured in insurance companies abroad, including in EU Member States. Deposit operations of residents abroad (opening and holding accounts by resident legal entities and individuals abroad) need to also be fully liberalised in the future (by the end of the second stage of the SAA). The law on investment funds will also need to be revised before accession to align with the passporting system of investment funds.

Existing BITs with third countries are also not aligned with EU requirements although North Macedonia is currently in the process of drafting a new model BIT to address these issues. Existing BITs will then need to be amended which may take some time. Moreover, some BITs with third countries have survival clauses

that extend protection to existing investments for a period beyond termination. These clauses may kick in if, following accession and notification under Regulation 1219/2012, incompatibilities with EU law are found and North Macedonia's third-country counterparts are not willing to engage in their renegotiation or consensual termination.

### C. SUMMARY OF FINDINGS – FREE MOVEMENT OF CAPITAL

North Macedonia is **partially aligned** with the EU *acquis* on free movement of capital. North Macedonia should fully liberalise the acquisition of agricultural land also in line with its obligations under the SAA. North Macedonia will need to fully liberalise capital movements by residents abroad, as well as the restrictions on the possibility of residents to be insured in insurance companies abroad, including in EU Member States. North Macedonia should also amend existing BITs with third countries to remove survival clauses prior to accession and to ensure overall consistency with the EU's relevant policy and requirements.

## II. PAYMENT SERVICES

### a. Country presentation

The Law on Payment Services and Payment Systems (which entered into force on 1 January 2023) is the relevant national legislation and the Ministry of Finance, the National Bank and the Central Registry are the bodies responsible. Additional by-laws further align national legislation with the Payment Services Directive 2. The Law on Payment Services and Payment Systems includes, inter alia, provisions regulated by the Payment Services Directive 2, the E-Money Directive 2 and the Interchange Fee Regulation. Key areas for improvement include the provisions of the Cross-Border Payments Regulation 2 and the SEPA Regulation, which have not yet been fully implemented in North Macedonia.

Regarding accelerated integration, North Macedonia expressed the wish to participate in SEPA schemes.

### b. Commission assessment

North Macedonia has made significant progress in recent years in the area of payment systems but its legislation is only partially aligned with some of the relevant *EU acquis*. The Law on Payment Services and Payment Systems includes, inter alia, provisions related to the Payment Services Directive 2, the E-Money Directive 2 and the Interchange Fee Regulation. Furthermore, North Macedonia still needs to align its national legislation with the SEPA Regulation and the Regulation on Cross-Border Payments. It foresees full alignment by the time of its eventual accession to the EU.

Regarding North Macedonia's request to join SEPA, the Commission notes that decisions on the membership of SEPA schemes are not taken by the EU, but by the European Payments Council (EPC). The EPC is responsible for assessing the applicants' readiness for adherence to the SEPA schemes' geographical scope. In line with the New Growth Plan for the Western Balkans, the Commission supports North Macedonia's efforts to comply with the criteria of the EPC, including inter alia, a high degree of alignment with the relevant current EU regulatory framework: e.g. the Payment Services Directive (PSD2), the Transfer of Funds Regulation, the Capital Requirements Directive, and the Anti-Money Laundering Directive.

### C. SUMMARY OF FINDINGS – PAYMENT SERVICES

The legislation of North Macedonia on payment systems is **partially aligned** with some of the relevant *EU acquis*. Full implementation of Payment Services Directive 2, the E-Money Directive 2 and Interchange fee regulation rules need to be ensured. Alignment with the SEPA regulation and the Regulation on Cross Border Payments is still outstanding.

### III. ANTI-MONEY LAUNDERING

#### a. Country presentation

The Law on Prevention of Money Laundering and Financing of Terrorism (AML/CFT) is the relevant national legislation. The relevant institutions include the Financial Intelligence Office (FIO), law enforcement agencies, the Public Prosecutor's Office, supervisory agencies (including the National Bank, The Securities and Exchange Commission (SEC), The Insurance Supervision Agency (ISA) and others) and entities obliged to report by the legislation.

AML legislation is broad in scope and reporting entities include financial institutions, real estate agents, lawyers, notaries, accountants, tax advisors, investment advisors, auctioneers, casinos and any individual or art brokers, where transactions amount to EUR 10 000 or more. Entities covered by the legislation are obligated to carry out risk assessments and regularly update them, introduce programmes for the reduction of identified risk, carry out client due diligence, submit data and documentation to the Financial Intelligence Office, keep records of data and appoint an AML officer or establish an AML department.

North Macedonia introduced major amendments into its Anti-Money Laundering and Terrorism Financing Law in July 2022, considerably enhancing the requirements for application of preventive measures. Important steps have been undertaken towards improving transparency of legal persons and arrangements. The amendments to the AML/CFT legislation also included Virtual Asset Service Providers (VASPs) into the AML/CFT framework, based on which VASPs are subject to regular AML/CFT preventive measures and supervision from April 2023.

North Macedonia also has a National Strategy for Fighting against Money Laundering and financing of terrorism (2021-2024) and a council to monitor the implementation of the strategy. From 2018 to 2022, on average 285 suspicious transaction reports (STRs) were filed per year, leading to 4.6 investigations and 1.6 convictions for money laundering per year.

#### b. Commission assessment

North Macedonia is **partially aligned** with the EU *acquis* in this area. North Macedonia must align with Directive 2019/1153 laying down rules facilitating the use of financial and other information for the prevention, detection, investigation, or prosecution of certain criminal offences. The legal framework on AML/CFT has been recently assessed by the Council of Europe's Committee of Experts on the Evaluation of Anti-Money Laundering Measures and the Financing of Terrorism (MONEYVAL). After an on-site visit by a team of MONEYVAL evaluators from 21 September to 4 October 2022, the Mutual Evaluation Report was adopted at the 65th Plenary meeting of MONEYVAL in May 2023. Based on the report findings, North Macedonia has entered the enhanced follow-up process and will have to report on progress to the MONEYVAL Plenary in two years' time. In this report, North Macedonia has been rated compliant or largely compliant in 28 of 40 FATF recommendations and with a moderate effectiveness in 10 of 11 immediate outcomes. Among the shortcomings identified are a modest number of ML convictions, concerns about the proportionality, dissuasiveness and effectiveness of pecuniary sanctions, the data quality of the beneficial ownership register, lack of sanctions for failures related to basic or beneficial ownership information, technical deficiencies on confiscation, lack of systematic approach to conducting a financial investigation, and a low number of suspicious transaction reports compared to the to the risk, context, and size of the country.

### C. SUMMARY OF FINDINGS – ANTI-MONEY LAUNDERING

North Macedonia is **partially aligned** with the EU *acquis* in this area. North Macedonia should ensure follow up and compliance with all FATF recommendations. North Macedonia must align with Directive 2019/1153 laying down rules facilitating the use of financial and other information for the prevention, detection, investigation, or prosecution of certain criminal offences.

## **IV. FIGHT AGAINST CORRUPTION – FREE MOVEMENT OF CAPITAL**

### **a. Country presentation**

The relevant legislation framework includes the Law on the Prevention of Corruption and Conflict of Interest, the National Strategy for the Prevention of Corruption and Conflict of Interest 2021-2025, the Law on Foreign Exchange Operations, the Law on Payment Operations and the Law on Prevention on Money Laundering And Financing of Terrorism Legislation. The State Commission for the Prevention of Corruption plays a key role and has drafted guidelines for institutional corruption risk assessment, for the implementation of integrity policy and has developed a special software to monitor integrity policies implementation at central and local level institutions.

The country's National Strategy for the Prevention of Corruption and Conflict of Interest contains methods, indicators and deadlines and selects priority problems that generate a high risk of corruption. The strategy covers 13 sectors including law enforcement, judiciary, public enterprises, urbanism and spatial planning and two horizontal areas – public procurement and recruitment. The implementation of the ISO 37001 standard on anti-bribery management systems is part of the annual plan of the SCPC for 2023.

### **b. Commission assessment**

The country's National Strategy for the Prevention of Corruption and Conflict of Interest provides a broad framework for tackling corruption. The SCPC will soon decide on adding new horizontal areas to the strategy (state properties, services and inspection authorities). The implementation of the ISO 37001 standard on anti-bribery management systems is part of the annual plan of the SCPC for 2023. The existence of specific anti-corruption measures in the main bodies dealing with financial services and its enforcement, supported by legal acts, in addition to the overall anti-corruption efforts of North Macedonia, are a positive sign that, if duly implemented, sets the country in the path towards the prevention of corruption in the field of banking and financial services.

## **C. SUMMARY OF FINDINGS – FIGHT AGAINST CORRUPTION**

North Macedonia has a range of specific anti-corruption measures in the main bodies dealing with financial services and its enforcement, setting the country on the path towards the prevention of corruption in the field of banking and financial services. Focusing on implementation is key going forward. North Macedonia should implement all outstanding recommendations of the State Commission for the Prevention of Corruption in this chapter.

## F) CHAPTER 6 - COMPANY LAW

The *acquis* on **company law** forms part of the EU's internal market policy. It aims to enable businesses to be freely established anywhere in the EU and enjoy the free movement of persons, services and capital. There is now an increased focus on safeguarding stakeholder interest and preventing abuse and fraud. Most of the EU rules in this area are about setting minimum common standards.

The area of **company law and corporate governance** covers formation, registration and disclosure requirements of a company; protection of stakeholder interest (shareholders, employees and creditors); takeover bids for public limited companies; branch disclosure requirements; domestic mergers, conversions and divisions; cross-border operations; minimum rules for single-member private limited liability companies; the interconnection of business registers (BRIS), and the use of digital tools and processes. The EU *acquis* also provides for certain European legal forms: the European Economic Interest Grouping, the European Company (*Societas Europaea*), and European Cooperative Society.

As regards **company reporting**, there are rules covering transparency on capital markets; annual financial statements and consolidated financial statements; the application of international accounting standards; corporate transparency; sustainability reporting, and statutory audit.

### I. COMPANY LAW AND CORPORATE GOVERNANCE

The national legislation recognises the following main legal forms of business entities: limited partnership by shares, limited liability company, general partnerships, limited partnerships, and joint stock company. The joint stock company is a public limited liability company, and the limited liability company is a private company. The other company forms refer to private companies with various types of liability.

#### IA DISCLOSURE REQUIREMENTS IN RESPECT OF COMPANIES AND BRANCHES AND THE USE OF DIGITAL TOOLS AND PROCESSES

##### a. Country presentation

**Disclosure requirements** in respect of companies and branches and the use of digital tools and processes is regulated by the Law on Trade Companies and the Law on Central Registry. North Macedonia stated that it is **aligned** with the *acquis* on disclosure requirements for companies and the use of digital tools and processes. The central registry manages 12 registers, amongst them the trade register and the register of annual accounts. Companies are registered in the trade register, identified by a unique national ID. Electronic registration through e-signature is already possible. Legal personality is acquired from the moment of registration in the Central Registry.

The **Central Registry** provides information as required by the EU Company Law Directive, except for information on legal representatives of companies. Basic information is accessible to the public online, free of charge, while an 'at cost' principle is applied for certified copies (paper or electronic). Documents and information are published in real time, taking a maximum of four hours to process once companies provide all the information needed. The electronic archive dates back to 2005.

Financial statements submitted in paper form are converted to machine-readable digital form (xml files). Penalties are applied in case of failure to prepare, to disclose and to submit the financial statements to the Central Registry.

The Tax Authority - based on information from the Central Registry - can delete a company from the registry if it has three consecutive years of economic inactivity; this is subject to verification that the company does not owe any taxes or other liabilities. North Macedonia stated it was **aligned** with the company law directive regarding disclosure on nullity of a company.

Data in the trade register may be relied upon by the company against third parties, only after disclosure on the register, unless the company can prove that the third party had prior knowledge of the information. North Macedonia stated that by 2024 it plans to ensure that up-to-date information is made available explaining the provisions of national law pursuant to which third parties may rely on company information.

Regarding the EU **Business Registers Interconnection System (BRIS)**, North Macedonia stated that it is ready technically to interconnect with BRIS to exchange information on companies, branches, on mergers, conversions and divisions, and on disqualification of directors. However, it explained that ensuring that all company documents are stored as machine readable/structured data is challenging, both in terms of effort and cost for the business registry. North Macedonia informed that it plans to implement the EU ID in 2024.

Regarding accelerated integration, North Macedonia requested to interconnect with the EU **Business Registers Interconnection System (BRIS)** prior to accession, to facilitate (at least) the provision of company information, including financial documents.

#### **b. Commission assessment**

North Macedonia has a **high level of alignment** with EU disclosure requirements in respect of companies and branches and the use of digital tools and processes, already applicable on a national basis. Regarding the information to be disclosed and exchanged in the context of the interconnection of business registers (BRIS) and given that alignment with the provision on structured/machine-readable data will be a costly and complex exercise, North Macedonia is encouraged to pursue its plans to reach out and follow best practices from EU Member states.

Regarding accelerated integration, BRIS is a single-market tool, and currently interconnects only the business registers of EU Member States and EEA countries. A connection to BRIS is more than an IT matter. It requires connected countries to be fully aligned with EU company law, not only regarding the disclosure of company information, but also regarding the rules on mergers, conversions and divisions (and, starting from August 2023, rules on disqualification of directors), which are not fully met yet by North Macedonia. It would also require companies from North Macedonia, and their branches in the EU, to be treated by EU business registers as EU companies and branches, not as third country companies and branches. Furthermore, the development of BRIS requires the connected countries to be part of expert groups that are currently only open to EU Member States and EEA Countries.

### **I.B. FORMATION AND CAPITAL REQUIREMENTS**

#### **a. Country presentation**

The area of **formation and capital requirements** is governed by the Law on Trade Companies. The establishment of any type of company - and any future changes or termination of the company - can be done fully online in the Central Registry, provided the applicant has a digital certificate. The company is responsible for the validity, correctness and accuracy of the disclosed information. North Macedonia explained that notaries do not perform company registrations. However, 'registration agents' (i.e. lawyers or chartered accountants authorised by the central registry), with direct access to the Central Registry, can act as intermediaries in certain cases (e.g. for those without a digital certificate or with insufficient computer literacy).

The minimum initial capital for setting up a public limited liability company is EUR 25 000. When establishing a limited liability company or a joint stock company, the capital contribution can be made in cash only, in kind only, or a combination of both. Contributions in kind should be transferred no later than five years from the entry of the company in the trade register. The evaluation report for contribution in kind is made publicly available only upon request, as it is attached to the instrument of constitution. For

contributions in cash, a compulsory payment of 25% of the nominal value of the capital shall be paid up. In the case of contributions in cash and in kind, the contribution in cash must be paid in full.

Any decision to reduce or increase the capital must be adopted by a majority of at least two thirds of the voting shares represented at the general meeting, unless a higher majority is determined in the instruments of constitution. Where there are several classes of shares, the decision is subject to a separate vote.

As regards reduction of capital, it is considered that all creditors agreed with the decision of the general assembly if no request for settling claims is submitted after 90 days from the publication of the announcement. There are safeguards for creditors whose claims antedate publication of the decision and special rules for those creditors whose claims exceed EUR 10 000. However, there is no provision for creditors to request security of their claim before an appropriate administrative or judicial authority.

On the increase of capital, the law provides that shares shall be offered on a pre-emptive basis to shareholders in proportion to the capital represented by their shares. However, this right may be restricted by decision of the general meeting with a voting majority of at least three quarters, on the basis of a written report by the management body.

The subscribed capital may not be reduced to an amount less than the minimum capital laid down, otherwise the decision on reducing the basic capital is null and void, unless a decision on increasing the basic capital - to at least the minimum amount determined by law - is adopted, together with the decision on reduction of basic capital. If losses of 50% or more of the basic capital are identified, the management board must prepare a report and within 48 hours convene a general meeting to notify stockholders.

The acquisition of own shares by the company is only allowed in exceptional cases, to be paid in full and sold within three years from the day of their acquisition. If the nominal value of own shares does not exceed 10% of the capital, the company may keep the shares for an indefinite period. The law has safeguard measures for the acquisition of personal stocks, and the obligation for the Board of Directors to report accordingly at the next general meeting. There are no provisions in domestic legislation concerning conditions for the financial assistance by a company on acquisition of shares by a third party.

#### **b. Commission assessment**

North Macedonia is **partially aligned** with the *acquis* on formation and Capital requirements and plans to align fully with Directive (EU) 2017/1132 provisions on formation and nullity, capital maintenance and alteration, by December 2023. This includes capital requirements on the prohibition to acquire own shares, the publication of the expert report, serious loss of capital provisions and administrative/judicial measures (adequate safeguards) in case of a capital reduction. In relation to formation, North Macedonia should also further align with Directive (EU) 2019/1151 as regards the use of digital tools and processes in company law, including scrutiny of the object of the company, procedures to verify the appointment of directors and the disqualification of directors.

### **I.C. SINGLE MEMBER PRIVATE LIMITED LIABILITY COMPANIES**

#### **a. Country presentation**

North Macedonia stated it was fully aligned with the EU *acquis* in this area. As there are no specific legislative provisions covering **single-member companies**, the rules for a limited company, or those for a joint stock company, are applicable regarding a joint-stock company with a single shareholder, or a limited liability company founded by one person. Company details must be published in the Central Registry.

#### **b. Commission assessment**

Although the national legislation does not specifically mention the term single-member companies, the Law on Companies has provisions **aligned** with EU rules in this area.

## **I.D. DOMESTIC MERGERS AND DIVISIONS, AND CROSS-BORDER MERGERS, DIVISIONS AND CONVERSIONS**

### **a. Country presentation**

The Law on Trade Companies regulates **domestic mergers and divisions**, which can be done by acquisition or by the formation of a new company. North Macedonia stated the law is **largely aligned** regarding the main procedural steps i.e. drawing up the draft terms of the merger/division and its publication one month before the date fixed for the general meeting, the written report to shareholders drawn up by the management body, examination of the draft terms by an authorised auditor, and approval and adoption of the agreement by the general assembly of all companies involved.

There are no provisions on ex-ante legal scrutiny for domestic mergers and divisions. The law does however have safeguards for shareholders through the courts, for example, the right to damage compensation and examination of the exchange ratio (in case the ratio for conversion of shares is determined to be too low). The court can also order additional payments that cannot exceed 10% of the nominal amount of the given shares and determine the value of shares if the shareholder wants to exercise his/her exit right.

Creditors are entitled to adequate safeguards, including the right to damage compensation determined by the competent court within a period of 5 years from the day of publication of the registration of the operation. Furthermore, creditors whose claims exceed EUR 10 000 shall be promptly notified, individually, in writing.

There are, however, no specific provisions concerning nullity of a merger/division, civil liability regarding the expert report, or the protection of interests of debenture holders and holders of securities (other than shares). Other areas indicated for alignment were the simplification of formalities for mergers and divisions in specific circumstances, such as mergers by acquisition or the regulation of specific types of operations (e.g. mergers and divisions with cash payment exceeding 10 %, mergers without all the transferring companies ceasing to exist, or the specific procedure for division under the supervision of a judicial authority). North Macedonia stated that it plans to align with these areas of Directive (EU) 2017/1132 in 2024.

The Law on Trade Companies also regulates **cross-border mergers**. The rules apply to both public and private limited liability companies. In line with the EU *acquis*, they do not apply to cooperatives or investment fund companies and there is no derogation for companies that are subject to the use of resolution tools. Types of cross-border mergers allowed include acquisition, merger, and universal transfer of assets and liabilities. To date, no company created from a cross-border merger has been registered in North Macedonia.

The main procedural steps are largely aligned with the EU *acquis*. The law also has a specific provision on court examination of the legality of the operation. North Macedonia informed that it has yet to decide whether the pre- and post-merger legal scrutiny will be left with the court or transferred to the notary public.

In line with the EU *acquis*, the company arising from the cross-border merger and entered in the business register cannot be declared as null and void, and there are provisions on shareholders' rights to damage compensation and the possibility to ask for a court examination of exchange ratio.

North Macedonia stated that employee protection rights are regulated in accordance with the Law on Labour Relations which is largely aligned with Directive 2001/86/EC (*dealt with under Chapter 19 - Social Policy and Employment*).

As regards **cross-border divisions and conversions**, and some aspects of cross border mergers introduced by Directive 2019/2121, North Macedonia informed that an expert legal analysis (under the IPA II project 'Strengthening the Internal Market') highlighted the areas for further *acquis* alignment which they plan to do through the new Law on Trade Companies, expected for adoption in 2024.

## **b. Commission assessment**

North Macedonia is **partially aligned** with the EU *acquis* on **domestic mergers and divisions**. **Further alignment** is required, including the areas of legal scrutiny and nullity of a merger/division, civil liability of an expert drafting an evaluation report, simplification of certain formalities in specific circumstances, and the regulation of certain types of mergers and divisions. On **cross-border mergers**, North Macedonia has a **high level of alignment** with Directive (EU) 2017/1132, while **further alignment** is needed with the amending Directive 2019/2121. It is **not yet aligned** with the *acquis* on **cross-border conversions and divisions**. North Macedonia plans to align with Directives (EU) 2017/1132, and (EU) 2019/2121 through the new Law on Trade Companies, planned for adoption in 2024.

## **I.E. EUROPEAN COMPANY (*Societas Europaea*), EUROPEAN ECONOMIC INTEREST GROUPING AND THE STATUTE FOR A EUROPEAN COOPERATIVE SOCIETY**

### **a. Country presentation**

The EU legal forms European Company and European Economic Interest Grouping (EEIG) are provided for under the Law on European Company and the Law on EEIG, respectively. Both laws have delayed application from the time of North Macedonia's accession to the EU. Both these legal forms will also be subject to the relevant provisions of the Law on Trade Companies and the regulations on one-stop-shop.

Concerning a **European Company**, the general provisions of the law state that a company whose head office is outside the EU can participate in establishing a European Company if it maintains a real and permanent link with the economy of North Macedonia; whereas the EU Regulation provides this as an exception. A European Company is required to prepare and publish annual reports in line with national accounting regulations, the Law on Trade Companies and the Audit Law. There is no provision in national law for creditor protection. As regards **EEIG**, one or more natural or legal persons, who wish to facilitate and promote their economic activities, can incorporate such a group. Any profit from operations is treated as the profit of all members. Member rights cannot be in the form of securities. Areas not aligned with the EU *acquis* include the mandatory storage of documents and data in the central registry, and penalties for non-disclosure.

North Macedonia considers it is mainly aligned with Regulations (EEC) 2137/85 and (EC) 2157/2001 and stated that full alignment with both Regulations is planned for December 2025, following publication and enactment of the new Company Law. It stated that the central registry is ready - from the date of accession - to allow the registration of such companies.

Regarding the statute for a **European cooperative society**, North Macedonia informed that the new Law on Cooperatives (in force since May 2023) has partially aligned national legislation with Regulation (EU) No.1435/2003. TA further assessment on alignment and harmonisation with the relevant EU *acquis* will need to be carried out.

### **b. Commission assessment**

North Macedonia has a **high level of alignment** with EU Regulations (EC) 2157/2001 and (EEC) 2137/85 on the legal forms European Company and EEIG. Full alignment is planned for December 2025, following publication and enactment of the new Company Law. Regarding the statute for a European cooperative society, North Macedonia expects to adopt the new Law on Cooperatives by mid-2023 to partially align with Regulation (EU) No.1435/2003. A further assessment on EU *acquis* alignment within domestic legislation will be done at a later stage.

## **I.F. SHAREHOLDERS' RIGHTS AND CORPORATE GOVERNANCE**

### **a. Country presentation**

The legal framework for **shareholders' rights and corporate governance** is the Law on Trade Companies.

North Macedonia has also a Corporate Governance Code (CGC - October 2021) for companies listed on the *Macedonian Stock Exchange* (MSE). North Macedonia stated that alignment with Directive 2007/36/EC (Shareholder Rights Directive – SRD I) has been largely achieved (through the Law and the CGC). However, discrepancies remain regarding conflict of interest of authorised representatives at the shareholders general assembly, and the minimum number of days required to convene an annual shareholder meeting (national Law prescribes 30 days, whereas the EU Directive stipulates 21 days). North Macedonia stated that the Law provides appropriate sanctions for non-compliance.

North Macedonia acknowledged that further alignment is required with amending Directive (EU) 2017/828 on the encouragement of long-term shareholder engagement (SRD II), although there is already **partial alignment** within various national laws. This includes rules on the identification of shareholders, the transmission of information, facilitation of the exercise of shareholder rights, and rules for non-discrimination, proportionality and transparency of costs charged by intermediaries. There are also rules in the CGC on disclosure of the remuneration policy and the remuneration report and allowing shareholders to have an effective say on both. Also, the Law on Trade Companies and the CGC have rules partially aligned with the *acquis* on related party transactions. There are no provisions regulating the participation of institutional investors, asset managers and proxy advisors. Furthermore, there is no alignment with Implementing Regulation (EU) 2018/121.

The country plans to align with SRD II through the new Law on Trade Companies, expected for adoption in 2024. Alignment with Implementing Regulation (EU) 2018/1212 will be achieved through a Rulebook - based on the relevant provisions of this new law - to be enacted by March 2024. North Macedonia explained, however, that there will be delayed application of the law and the rulebook to January 2027, to allow time for making pertinent technical adjustments to the Central Securities Depository and for analysis on implementation.

The Law on Trade Companies, the CGC and the MSE listing rules regulate independent directors and board committees. There is a one tier system with board of directors only, and a 2-tier system with a management and a supervisory board. The number of executive members must always be less than the number of non-executive members, and the code suggests that at least 1/3 of members on the supervisory board are independent. The supervisory authority must have an internal audit service, organised as an independent unit in the company.

The CGC is based on OECD principles. It stipulates that boards should have an audit commission and establish commissions on compensation and remuneration, and selection and nomination. Remuneration of board members should be linked to the long-term interests of the company. Work of the supervisory board should be evaluated annually. On gender balance, North Macedonia has a 2025 goal for at least 30% representation of women on boards.

Application of the CGC is mandatory only for listed companies that meet certain criteria (i.e. not for all listed companies in general) and is optional for non-listed joint stock companies. North Macedonia has yet to legally oblige all listed companies to include a corporate governance statement in their management report (as required under Art. 20 of the EU Accounting Directive) that includes information on the implementation of the mandatory CGC - and any other codes that the company may have voluntarily decided to apply - and all relevant information on corporate governance practices applied over and above the requirements of national law.

North Macedonia considers that the CGC is **largely aligned** with Commission Recommendations 2004/913/EC, 2005/162/EC and 2009/385/EC (on remuneration of directors of listed companies) and 2014/208/EU on the quality of corporate governance reporting ('comply or explain'). North Macedonia informed that it may (in the future) re-evaluate the quality of its CGC and monitor its compliance with OECD principles, stating it would seek financial and technical support through the EU structural reform support programme in this regard.

## **b. Commission assessment**

North Macedonia has a **high degree of alignment** with SRD I, is **partially aligned** with SRD II, but has **no alignment** with Implementing Regulation (EU) 2018/1212. Particular attention is drawn to Art.3. a, b and c of SRD II which are developed further by the Implementing Regulation and will require some technical adaptations as well as the development of some standards for the marketplace. Full alignment in this area is planned through the new Law on Trade Companies and related implementing legislation. Parliamentary adoption is expected in 2024, with delayed application from January 2027 to allow time for technical implementation and analysis.

As North Macedonia stated it will update its corporate governance code, it is advisable to closely follow ongoing revisions to the OECD corporate governance principles. Furthermore, it should bear in mind that recent EU legislation (Directive (EU) 2022/2381) on improving the gender balance among directors of listed companies and related measures) has a 40% gender balance target for members of the under-represented sex on the board of directors.

## **I.G. TAKEOVER BIDS**

### **a. Country presentation**

Takeover bids are regulated by the Law on Takeover of Joint Stock Companies. The authorised authority is the Securities and Exchange Commission (SEC). The general principles of the Law are aligned with the EU *acquis* regarding equitable treatment of all shareholders of the offeree company, provision of full and timely accurate information on the bid, the board must act in the interest of the employees and business operations, prior agreement at the shareholders assembly meeting, sufficient financial resources (monetary or other) before a takeover bid is launched; also actions that may artificially increase or decrease the price of the offeree company's shares are prohibited.

The takeover bid is mandatory once the threshold of 25% or more of the voting securities has been reached. The SEC must be notified and can impose a takeover bid is launched for any violations of the general principles. A successful bidder who acquires an additional 5% of voting shares in the following two years is obliged to launch a takeover bid, and must do so with every successive 5% acquired, up to a threshold of 75%. North Macedonia confirmed that the exceptions on takeover bids – as mentioned in the Law on Takeover of Joint Stock Companies - relate to specific situations that must not in any case contravene the general principles.

North Macedonia stated that it is **aligned** with Directive 2004/25/EC except for article 4 regarding the supervisory authority and applicable law. Full alignment will be ensured prior to EU accession.

### **b. Commission assessment**

North Macedonia has a **high level of alignment** with Directive 2005/25/EC, the outstanding area being regarding Art. 4 on supervisory authority and applicable law.

## **I.H. SUMMARY OF FINDINGS – COMPANY LAW AND CORPORATE GOVERNANCE**

North Macedonia is **aligned** with EU rules on single-member private limited liability companies. It has a **high level of alignment** with the *acquis* on takeover bids and with EU disclosure requirements for companies and branches and the use of digital tools and processes, which are already applicable on a national basis. It will, however, need to align with *acquis* provisions on structured/machine-readable data to be able to interconnect with the EU Business Registers Interconnection System (BRIS) in the future.

**Further alignment is needed** with the *acquis* on formation and capital requirements.

While there is a **high degree of alignment** with the *acquis* on cross-border mergers, **further alignment is needed** with the 2019 amending Directive, as well as with the *acquis* on domestic mergers and divisions. North Macedonia **has yet to align** with the *acquis* on cross-border conversions and divisions.

There is a **high degree of alignment** with the Directive on shareholder rights in listed companies and **partial alignment** with the amending 2017 Directive, but **no alignment** with Implementing Regulation (EU) 2018/1212. Particular attention is drawn to articles of the amending Directive and Implementing Regulation that will require some technical adaptations and the development of standards for the marketplace.

North Macedonia has a **high level of alignment** with the EU legal forms European Company and European Economic Interest Grouping, but **has yet to align** with the statute for a European Cooperative Society, to ensure application of this *acquis* from the date of accession.

## II. COMPANY REPORTING

### II.A. CORPORATE ACCOUNTING

#### a. Country presentation

Corporate accounting is regulated primarily by the Company Law and related implementing legislation. Certain provisions are included in the Law on banks and the Law on securities.

The criteria for categorising micro, small, medium-sized and large enterprises differ from Directive 2013/34/EU as regards the ceilings of balance sheet total and net turnover. North Macedonia stated its intention to align with the relevant *acquis* in this respect.

The Rulebook on Accounting (No.159/09, 164/10) contains the core text and interpretation of International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB), while the amended Rulebook on accounting (No. 107/11) includes IFRS for SMEs. Since August 2022, the Institute of Chartered Accountants is responsible for the translation of these standards, while the Ministry of Finance is responsible for their publication. North Macedonia stated that all companies, regardless of size, must prepare consolidated statements and consolidated annual report according to IFRS, if they have a dominant influence in one or more companies. They are subject to audit by an authorised auditor and, if approved, submitted to the Central Registry together with the annual report for operations.

Financial reporting obligations are based on company size. All companies must submit their annual accounts to the central registry, to include a balance sheet, income statement and explanatory notes. Medium and large companies, as well as listed companies and banks, must also prepare an annual report of operations and report on change in capital, overall profit and cashflow. Medium and large companies must submit their annual accounts electronically. The central registry has a system of misdemeanour procedures for non-publication of approved financial statements.

There are currently no provisions obliging large and medium-sized companies to publish management reports, or for listed companies to include a corporate governance statement in the management report. North Macedonia informed that discussions are ongoing regarding alignment in these areas, as well as with the *acquis* on country-by-country reporting. According to the listing rules of the Macedonian Stock Exchange, all listed companies have the obligation to publish their management reports on the following website: <https://www.seinet.com.mk/default.aspx> .

Responsibility for implementing accounting rules lies with the Ministry of Finance (MoF), the Ministry of Economy, the Public Revenue Office, the Central Registry and the Institute of Accountants and Chartered

Accountants. The MoF unit for accounting, payment operations and audit currently has four employees..

Following recommendations from a gap analysis (conducted under the IPA II project ‘Strengthening the Internal Market’), a new Law on Accounting is being prepared to align further with Directives 2013/34/EU, 2014/95/EU and 2021/2101/EU, as well as with Regulation (EC) 1606/2002. Adoption is planned in 2024.

#### **b. Commission assessment**

North Macedonia is **partially aligned** with accounting Directive 2013/34/EU on the annual financial statements, consolidated financial statements and related reports of certain types of undertakings. Outstanding areas for alignment include the criteria of average balance sheet total and net turnover for defining company size, the requirement for medium and large sized companies to prepare a management report, and for listed companies to include a corporate governance statement in the management report. North Macedonia is preparing a new Law on Accounting to align with the EU accounting Directive.

North Macedonia applies IFRS and IFRS for SMEs but must align with the *acquis* to ensure full consistency of national Laws and standards with the accounting framework for small companies on limited disclosure in financial statements. Small groups should also be exempt from the obligation to prepare consolidated financial statements.

The country will also need to introduce provisions, and ensure implementation, regarding the obligation of companies or groups active in the extractive or logging industries to prepare and publish a report on payments made to governments, on an annual basis (Directive (EU) 2021/2101).

### **II.B CORPORATE SUSTAINABILITY REPORTING**

#### **a. Country presentation**

On **corporate sustainability reporting**, North Macedonia informed that the (above-mentioned) gap analysis also recommended aligning further with Directive 2014/95/EU when drafting the new Law on Accounting. Although it could not confirm what provisions would ultimately be included in the new Law, key outstanding areas indicated were consolidated non-financial statements, the requirement for large companies exceeding 500 employees to provide a non-financial statement in the management report - approved by a statutory auditor - and the notion of collective responsibility for drafting the annual financial statements. This draft Law is expected for adoption in 2024.

#### **b. Commission assessment**

North Macedonia is **partially aligned** with Directive 2014/95/EU and was already planning further *acquis* alignment on non-financial reporting when Directive (EU) 2022/2464 was adopted. As such, it now needs to consider how to achieve alignment with this more recent *acquis* which strengthens the rules on sustainability reporting and extends the scope of companies who have to apply these rules. An opportunity could be through the new Law on accounting.

### **II.C. REPORTING ON CAPITAL MARKETS**

#### **a. Country presentation**

Reporting on capital markets is regulated by the Law on Securities, the Company Law and listing rules of the Macedonian Stock Exchange (MSE). The MoF is responsible for regulating the capital market and prepares laws and implementing legislation in cooperation with the Securities Exchange Commission (SEC). SEC is the competent authority for implementing the Law on securities and supervising the MSE.

North Macedonia stated that the electronic information system for listed companies (SEI-NET) is the officially appointed mechanism that gathers, archives and publishes information in an impartial manner. Issuers are obliged to publish data and information through SEI-NET, which is received simultaneously by SEC. This information is accessible through the MSE website, free of charge.

The listing rules lay down disclosure obligations, with mandatory half-yearly and quarterly reporting. Listed companies must publish consolidated and standalone audited annual financial statements no later than five months from the end of the fiscal year, whereas the EU transparency directive prescribes a maximum of four months.

The Central Securities Depository SEC publishes weekly a list of every natural and legal person who passes thresholds of 5% ownership of any class of securities. The issuer must notify any change in ownership of 5% or more of the total number of voting and issued shares, as well as any shareholders who owned more than 5% of the voting shares and decreased their ownership in the company's capital.

The listing rules contain administrative and sanctioning measures, with a modest range of financial penalties for violations of non-disclosure.

Regulated information is published in the Macedonian language unless a company is on the super listing, in which case both Macedonian and English is obliged. Listed companies may also voluntarily submit information and reports in Macedonian and English.

North Macedonia considers that the current Law on Securities and the listing rules are **significantly aligned** with Directive 2004/109/EC. It informed that a new Law on Prospectus and Transparency is (currently in parliamentary procedure) aims to achieve alignment in this area, in the mid-term. This will include provisions on home/host member state and relations with the European Securities and Markets Authority. North Macedonia stated that it would need technical assistance for drafting implementing legislation stemming from this new law.

#### **b. Commission assessment**

North Macedonia is **partially aligned** with Directive 2004/109/EC, as amended by Directive 2013/50/EU. It should consider Directive 2007/14/EC when aligning further in this area and ensure it is prepared to apply the relevant Commission Delegated Regulations<sup>3</sup> from the time of accession. Remaining areas for alignment include the need to ensure that national provisions remain within the boundaries set by the maximum harmonisation clause of Directive 2004/109/EC, especially regarding the scope, identification and rules for the notification of major holdings, as well as the treatment of financial instruments for these notifications. It also needs to align with the sanctioning provisions and the deadline for issuers to make their annual financial reports public. North Macedonia should assess whether quarterly reporting constitutes a disproportionate financial burden, in particular for the SME issuers concerned.

## **II.D. STATUTORY AUDIT**

### **a. Country presentation**

Statutory audit is regulated by the Audit Law which entered into force in December 2010. North Macedonia stated this Law is **partially aligned** with Directive 2006/43/EC.

North Macedonia stated that it does not have a body with ultimate responsibility for statutory audit oversight, as required by the EU audit directive. Since 2010, the Council for Advancement and Oversight of Audit (CAOARM) acts as an independent regulatory body, funded partially from the state budget, while the Institute for Certified Auditors (ICARM) is responsible for the quality assurance of all audits. Currently CAOARM has four employees. A CAOARM representative may participate with ICARM during a quality control but has no legal decision-making role. ICARM established a Disciplinary Committee responsible for inspections, investigations, and sanctions. Based on an ICARM decision, CAOARM can impose temporary or permanent revocation of the licenses. North Macedonia stated that it is drafting a new audit law whereby CAOARM will be made responsible for the statutory audit of PIEs, while ICARM will continue to perform the auditing and quality control of all other companies. It explained how it will take

---

<sup>3</sup> Commission Delegated Regulations (EU) 2015/761, 2016/1437, and 2019/815

time to build knowledge and expertise - through specific training and continuous education - for effective implementation.

The Audit Law prescribes that audits are performed in accordance with adopted International Auditing Standards (ISA). ICARM is responsible for the translation and updating of ISA standards.

The definition of public-interest entities (PIEs) in the current Audit Law is not aligned with the *acquis* and relates only to joint-stock companies with special notification obligations in accordance with the Securities Law. The Law obliges PIEs to form an audit board. Certified auditors who perform PIE audits must rotate every seven years, and they cannot become a member of the administrative or management board of that PIE for a period of two years from the expiry of the mandate.

North Macedonia stated that it would align with the provisions of Directive 2014/56 and Regulation (EU) 537/2014 through the new Law on Audit, including the areas of broader definition of PIEs and specific requirements for auditing PIEs, independence requirements for auditors, and strengthening the monitoring and oversight system. The MoF benefits from technical support in this regard under the IPA project. Adoption of the new Law is planned for 2024. North Macedonia stated that it also plans to update the code of ethics for chartered accountants and auditors.

#### **b. Commission assessment**

The legislation of North Macedonia is **partially aligned** with Directive 2006/43/EC. Further alignment is needed, also with amending Directive 2014/56/EU and Regulation (EU) No 537/2014. Given that North Macedonia is preparing a new Law on Audit, it should pay particular attention to Art. 32 of the 2014 EU Directive which requires one body to have ultimate oversight responsibility, with specific provisions on delegation. North Macedonia needs to strengthen the human resource and enforcement capacity of the Council for Advancement and Audit Oversight. Other areas for further alignment include the definition of PIEs and the specific requirements applying to the statutory audit of such companies, the independence of auditors, and the system of investigations.

### **II.E. SUMMARY OF FINDINGS - COMPANY REPORTING**

North Macedonia is **partly aligned** with the *acquis* on **accounting** and needs to ensure compliance with the accounting framework for small companies and introduce provisions aligning with the *acquis* on country-by-country reporting. It will **also need to align with** the more recent 2022 Directive on **corporate sustainability reporting**.

While there is **partial alignment** with the *acquis* on **transparency requirements for listed companies**, particular attention is needed to align with the notification and sanctioning regimes, as well as assess whether quarterly reporting constitutes a disproportionate financial burden, in particular for the SME issuers concerned.

**Further alignment is needed** with the *acquis* on **statutory audits** of annual and consolidated accounts, including the 2014 Regulation on specific requirements for the statutory audit of public-interest entities. In particular, North Macedonia needs to strengthen the human resource and enforcement capacity of the Council for advancement and audit oversight, paying attention to article 32 of the 2014 Directive, which requires **one body to have ultimate oversight responsibility**.

### **III. FIGHT AGAINST CORRUPTION**

#### **a. Country presentation**

North Macedonia stated that fighting corruption in trade companies is regulated by the Law on Prevention of Corruption and Conflict of Interest, and the Law on Trade Companies. There is a national strategy and methodology to assess risk factors and a State Commission for the Prevention of Corruption that can adopt decisions to amend the strategy. The 2022 report on implementation of the national strategy is being

prepared. The results of a risk assessment showed a lack of compliance with the regulatory framework on shareholder's rights, as well as weaknesses in the Council for Advancement and Audit Oversight. On the latter, given the lack of qualitative criteria in the appointing procedure, the Council risks political and business influence when drawing conclusions in its work; to date it has not been called upon to give its opinion in any legal cases. The Council also lacks sufficient and adequate human resources. North Macedonia informed that amendments to the Law on Prevention of Corruption and conflict of interest are planned for 2024.

**b. Commission assessment**

North Macedonia is encouraged to advance with plans to amend the Law on Prevention of Corruption and conflict of interest in 2024, including those company law elements it highlighted as needing particular attention.

**C. SUMMARY OF FINDINGS - FIGHT AGAINST CORRUPTION**

North Macedonia is encouraged to address the shortfalls on shareholder rights and public audit oversight when amending its Law on prevention of corruption and conflict of interest.

## G) CHAPTER 7 - INTELLECTUAL PROPERTY LAW

The EU *acquis* on intellectual property law specifies harmonised rules for the legal protection of copyright and related rights, as well as for industrial property rights, and contains provisions for the enforcement of intellectual property rights (IPR). The *acquis* on **copyright and related rights** harmonises the rights of authors, performers, producers, broadcasters and press publishers and sets rules applicable to all types of copyright protected content (e.g. books, music films, software and broadcasting, etc.). It implements into EU law the international obligations arising from the treaties adopted within the framework of the World Intellectual Property Organisation (WIPO). It also takes into account digital and cross-border uses of protected content.

In the field of **industrial property rights**, the *acquis* sets out harmonised rules for the legal protection of trade marks and designs, as well as a partially harmonised regime for patents, containing specific provisions on biotechnological inventions, supplementary protection certificates (SPCs) for medicinal and plant protection products and compulsory licensing. Accession to the European Patent Convention is an important element of the EU-wide system. The *acquis* also sets rules for the protection of trade secrets, and establishes an EU trade mark and a Community design system. The Directive 2004/48/EC on the **enforcement** of intellectual property rights such as copyright and related rights, trade marks, designs or patents requires all Member States to apply effective, dissuasive and proportionate civil remedies and penalties against those engaged in counterfeiting of goods and piracy.

### I. HORIZONTAL ASPECTS

#### a. Country presentation

The Intellectual Property Strategy 2022-2026 ('the IPR Strategy') has yet to be adopted by the government. This Strategy is to become part of the National Strategy for internal market 2023-2044.

North Macedonia is part of 23 IPR-related international agreements, including the World Intellectual Property Organisation (WIPO) and the Convention and the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). It is also a member of the World Trade Organisation (WTO).

Regarding **accelerated integration**, North Macedonia requested to participate as an observer in the Group of Experts on Industrial Property Policy (GIPP).

#### b. Commission assessment

North Macedonia is **partially aligned** with the EU *acquis* in the area of intellectual property law. The fact that the Strategy for Intellectual Property 2022-2026 has yet to be adopted by the government is a negative sign related to the administrative capacity of North Macedonia in the field of IPR.

Regarding the **accelerated integration** requests, the Commission looks favourably upon North Macedonia's participation as an observer in the Group of Experts on Industrial Property Policy (GIPP)..

### C. SUMMARY OF FINDINGS – HORIZONTAL ASPECTS

North Macedonia is **partially aligned with the EU *acquis* in the area of intellectual property law.**

The fact that the Strategy for Intellectual Property 2022-2026 has yet to be adopted by the government is a negative sign related to the administrative capacity of North Macedonia in the field of IPR. However, the country has the basic administrative structures to manage and enforce IPR, though work in these fields remains to be done.

## II. COPYRIGHT AND RELATED RIGHTS

### II.A. HORIZONTAL ASPECTS IN COPYRIGHT AND RELATED RIGHTS

#### a. Country presentation

The **legal framework** is set by the Law on Copyright and Related Rights (Copyright Law), published in 2010 and last amended in 2016. North Macedonia has drafted a new Law amending the Copyright Law, which has not yet been adopted, in order to align with the EU *acquis* on collective rights management, term of protection, orphan works and the implementation of the Marrakesh Treaty. The preparation of another set of amendments to the Copyright Law was ongoing to fully incorporate the Directive (EU) 2019/789 (SatCab II) and Directive (EU) 2019/790 related to the Digital Single Market, as well as the provisions regarding multi-territorial licensing of Directive 2014/26/EU..

North Macedonia is a party to six international agreements on copyright and related rights.<sup>4</sup> It is not a party to the Beijing Treaty on Audiovisual Performances nor to the Marrakesh VIP Treaty.

The main body in the area of copyright and related rights is the Copyright and Related Rights Unit, within the Department for Normative and Administrative Affairs and Copyright and Related Rights of the Ministry of Culture. The decisions of this Unit can be disputed before the Administrative Court. It is conceived to operate with no less than three civil servants; however, it currently operates with one. Its main competences include the participation in study and analytical works for the regulation of the field, drafting regulations (including decisions on licensing Collective Management Organisations (CMOs)) and monitoring their execution, implementing international obligations, and administering CMOs.

The country acknowledged that understaffing and the existence of only one CMO pose significant limitations to the effective implementation of the Copyright Law and expressed its intentions to tackle these problems. The use of associations that collect fees and redistribute them to cover for the lack of CMOs is an issue that needs to be addressed.

The administrative procedures regarding semiconductors belong to the Department of Patents of the State Office for Intellectual Property (SOIP). The Agency for Audio and Audiovisual Media Services, an independent non-profit regulatory body, and its unit for the protection of copyright, is responsible for informing the copyright authority of suspicions of infringement, particularly on cable retransmission.

#### b. Commission assessment

North Macedonia is **partially aligned** with the EU *acquis* on copyright and related rights. The adoption of draft Law amending the Copyright Law which is expected to bring alignment with the EU *acquis* on orphan works, collective rights management, term of protection, and on implementing the Marrakesh Treaty, remains delayed.

In terms of **administrative capacity**, the fact that the Copyright and Related Rights Unit within the Department for Normative and Administrative Affairs and Copyright and Related Rights of the Ministry of Culture is currently operating with only one civil servant significantly limits the implementation of copyright protection, and therefore needs improvement. Considerably improving and maintaining a clear track record with regards to copyright and related rights is also key.

---

<sup>4</sup> North Macedonia is a party to the following international agreements on copyright and related rights: WIPO Copyright Treaty; WIPO Performances and Phonograms Treaty; Berne Convention for the Protection of Literary and Artistic Works; Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations; Brussels Convention relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite; and the Geneva Convention for the Protection of Producers of Phonograms.

## II.B. COPYRIGHT IN THE INFORMATION SOCIETY

### a. Country presentation

North Macedonia indicated that it is **fully aligned** with Directive 2001/29/EC on the Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society (InfoSoc). The Copyright Law provides for a right of reproduction and distribution, as well as the exclusive right of communication to the public and several exceptions including for temporary copies, reproduction by public libraries, educational establishments or museums, satellite broadcasting, among others. The Law also envisages a right to fair compensation for right holders, including for private copying, and the legal protection of technological measures and rights management information.

North Macedonia is **not aligned** with Directive (EU) 2019/790 on Copyright and Related Rights in the Digital Single Market. . North Macedonia declared that the Government has set up a working group to analyse the provisions of the Directive. Further clarification concerning the functioning of mandatory collective management and extended collective licensing, in the context of the amendments applying the Digital Single Market Directive and amending Directives 96/9/EC and 2001/29/EC, is needed.

### b. Commission assessment

The Copyright Law is **partially aligned** with Directive 2001/29/EC. North Macedonia also needs to ensure harmonisation with the Directive's terminology regarding 'exceptions'.

North Macedonia is **not aligned** with Directive (EU) 2019/790 on the Digital Single Market.

## II.C. BROADCASTING VIA SATELLITE AND RETRANSMISSION BY CABLE

### a. Country presentation

North Macedonia stated its **full alignment** with Directive 93/83/EEC on the Coordination of Certain Rules Concerning Copyright and Rights Related to Copyright Applicable to Satellite Broadcasting and Cable Retransmission (SatCab I). The exclusive rights for communication to the public by satellite are managed collectively through the only Collective Management Organisation (CMO) existent in the country, for music and performances. This CMO has concluded agreements for representation in negotiations with the members of the European Broadcasting Union and others, where it collects compensations or remunerations, to be transferred to the represented parties. In this manner, it has achieved a satisfactory level for the criteria regarding collective management. However, North Macedonia was negotiating with similar organisations of the region (e.g. from Serbia) to integrate a cable retransmission system, and was also considering creating an organisation for phonogram and music producers, hence creating a wider system for cable retransmission, until it is able to introduce CMOs.

The Commission for Mediation is responsible for arbitration in case of dispute regarding cable retransmission. Tariffs are set through negotiations. Another set of amendments to the Copyright Law was being prepared to incorporate Directive (EU) 2019/789 laying down rules on the exercise of copyright and related rights applicable to certain online transmissions of broadcasting organisations and retransmissions of television and radio programmes and amending Council Directive 93/83/EEC (SatCab II).

### b. Commission assessment

North Macedonia is **partially aligned** with Directive 93/83/EEC. The country needs to improve particularly the system for the collective management in the case of cable retransmission. It has **not aligned** with Directive (EU) 2019/789 (SatCab II). It is expected to do so in the upcoming amendments to the Copyright Law.

## II.D. COLLECTIVE MANAGEMENT OF COPYRIGHT AND RELATED RIGHTS

### a. Country presentation

North Macedonia informed about its **partial alignment** with the basic principles of Directive 2014/26/EU on collective management of copyright and related rights and multi-territorial licensing of rights in musical works for online use in the internal market (CRM Directive). It is not aligned on multi-territorial licensing of rights, on the definition of independent management entities (IMEs) and ‘online rights in musical works’. Collective rights management may be carried out by a CMO, on the basis of a license issued by the Ministry of Culture. With this license, CMOs cannot manage tariffs until the tariff book is adopted and published. The draft Law amending the Copyright Law, incorporating several CRM provisions, has not been adopted yet..

### b. Commission assessment

North Macedonia is **partially aligned** with Directive 2014/26/EU. North Macedonia has yet to align with the provisions on multi-territorial licensing. It is also **not aligned** with the definition of IMEs. Further alignment is also expected with the adoption of the draft Law amending the Copyright Law, which remains delayed. Furthermore, the country needs to tackle the lack of CMOs (only one CMO existent in the country) and to fully implement a system of collective rights management.

## II.E. DATABASES

### a. Country presentation

North Macedonia stated that it is **fully aligned** with Directive 96/9/EC on the legal protection of databases, providing for copyright and *sui generis* protection, for qualitative and/or quantitative substantial investments. It clarified that the list of exceptions and limitations for *sui generis* protection is more reduced than for databases, as these enjoy the same exceptions and limitations as other copyright works.

### b. Commission assessment

North Macedonia has reached a **high level of alignment** with Directive 96/9/EC.

## II.F. TERM OF PROTECTION

### a. Country presentation

North Macedonia stated that the draft Law amending the Copyright Law would bring **full alignment** with Directive 2011/77/EU amending Directive 2006/116/EC on the Term of Protection of Copyright and Certain Related Rights, notably the provisions on the protection of authors of musical works and of music performers and phonogram producers (up to 70 years of protection if the phonogram is lawfully published for the first time, within the first 50-year period of protection). North Macedonia provides for a term of protection of 50 years for audio-visual performers.

### b. Commission assessment

North Macedonia is **partially aligned** with Directive 2011/77/EU. The adoption of the draft Law amending the Copyright Law, which remains delayed, is expected to bring full alignment, notably by aligning the provisions on the protection of authors of musical works and of music performers and phonogram producers, of up to 70 years.

## **II.G. RESALE RIGHT**

### **a. Country presentation**

North Macedonia stated its **full alignment** with the provisions of Directive 2001/84/EC on the Resale Right for the Benefit of the Author in articles 41 to 45 of the current Copyright Law. These include the right of resale, the definition of original work of art, the establishment of royalties, and the right of information.

### **b. Commission assessment**

North Macedonia has reached a **high level of alignment** with Directive 2011/77/EU on the artist's resale right.

## **II.H. RENTAL AND PUBLIC LENDING RIGHTS**

### **a. Country presentation**

North Macedonia confirmed its **full alignment** with Directive 2006/115/EC Rental Right and Lending Right and on Certain Rights Related to Copyright in the Field of Intellectual Property, namely on the right of reproduction, right of distribution, right of communication to the public (including satellite broadcasting and cable retransmission), and other definitions.

It provides for an equitable remuneration for rightsholders, for any use of their work, as well as for the right to a share of the single equitable remuneration for performers and phonogram producers. Authors have the right to remuneration for lending. The principle of exhaustion of rights does not apply in this area. It also provides for several exceptions and limitations, including for private use and current events. The author's right of remuneration for public lending can be managed collectively.

### **b. Commission assessment**

North Macedonia is **partially aligned** with Directive 2006/115/EC. The country needs to align with the unwaivable right to equitable remuneration and respective collective management.

## **II.I. IMPLEMENTATION OF THE MARRAKESH TREATY INTO EU LAW**

### **a. Country presentation**

North Macedonia is **not aligned** with Directive (EU) 2017/1564 on Certain Permitted Uses of Certain Works and Other Subject Matter Protected by Copyright and Related Rights for the Benefit of Persons Who Are Blind, Visually Impaired or Otherwise Print-Disabled and amending Directive 2001/29/EC, which implements the Marrakesh Treaty. It is expected to achieve full alignment with the adoption of the draft Law amending the Copyright Law, which remains delayed. The country stated that the recommendations from EU experts had been incorporated. North Macedonia has not yet ratified the Treaty. It included the three-steps-test and technological protection measures. The obligations of authorised entities will be applied after the adoption of the draft amending law, through internal acts. North Macedonia has not determined any compensation scheme regarding the permitted uses of works by authorised entities. This will be done after the adoption of the amendments. North Macedonia will focus on Regulation (EU) 2017/1563 on the cross-border exchange between the union and third countries of accessible format copies of certain works and other subject matter protected by copyright and related rights for the benefit of persons who are blind, visually impaired or otherwise print-disabled once the adherence to the Marrakesh Treaty takes place, and on implementing cross-border exchange of accessible format copies.

### **b. Commission assessment**

The country is **not aligned** with Directive (EU) 2017/1564 and Regulation (EU) 2017/1563. It is expected

to align through the draft Law amending the Copyright Law, which remains delayed. North Macedonia is also expected to ratify the Marrakesh Treaty, define obligations for authorised entities, and to align with the definition of ‘beneficiaries’, after the adoption of the draft amending law.

## II.J. ORPHAN WORKS

### a. Country presentation

North Macedonia is **not aligned** with Directive 2012/28/EU on certain permitted uses of orphan works. The draft Law amending the Copyright Law has aligned the relevant provisions with the EU *acquis*, namely on the permitted uses of orphan works (including on making these available in public libraries, educational establishments, museums, and others) for public interest, and on definitions and type of orphan works. Such provisions also deal with diligent search, end of orphan work status, and mutual recognition of this status in EU Member States.

### b. Commission assessment

North Macedonia is **not aligned** with Directive 2012/28/EU. The adoption of the draft Law amending the Copyright Law, which remains delayed, aims at achieving a high level of alignment on orphan works.

## II.K. PORTABILITY

### a. Country presentation

North Macedonia is **not aligned** with Regulation (EU) 2017/1128 on cross-border portability of online content services in the internal market. It plans to align after EU accession.

### b. Commission assessment

North Macedonia is **not aligned** with Regulation (EU) 2017/1128. It needs to start laying out the necessary conditions to align with the Regulation as soon as possible.

## II.L. COMPUTER PROGRAMMES

### a. Country presentation

North Macedonia stated its **full alignment** with Directive 2009/24/EC on the Legal Protection of Computer Programmes, including on de-compilation. A software is protected by copyright as ‘literary works’, within the meaning of the Berne Convention. The principle of exhaustion is currently only applicable in North Macedonia, and will become valid for the EU at the time of accession.

### b. Commission assessment

North Macedonia is **partially aligned** with Directive 2009/24/EC. North Macedonia is advised to include a provision regarding the principle of exhaustion of distribution rights of a copy of the computer program, with the exception of the right to control further rental of the program, as provided by Article 4.2 of the Directive.

## II.M. SEMICONDUCTORS

### a. Country presentation

The country indicated that it is **partially aligned** with Council Directive 87/54/EEC on the legal protection of topographies of semiconductor products, through the Law on Protection of Topographies of Integrated Circuits, and the regulation of form and content of an application for the registration of a legal protection of topographies of semiconductor products. The country expects to achieve full alignment through the

amendments to the Law on Topographies, foreseen until the end of 2025.

#### **b. Commission assessment**

North Macedonia is **highly aligned** with Council Directive 87/54/EEC.

### **II.N. SUMMARY OF FINDINGS – COPYRIGHT AND RELATED RIGHTS**

North Macedonia is **partially aligned with the EU *acquis* on copyright and related rights**. The draft Law amending the Copyright Law which is expected to bring alignment with the EU *acquis* on orphan works, collective rights management, term of protection, and on implementing the Marrakesh Treaty, remains delayed. North Macedonia's **administrative capacity** in this field needs to be significantly strengthened, notably by increasing the number of civil servants of the Copyright and Related Rights Unit. Further improving the track record with regards to copyright and related rights is also key.

North Macedonia has a **high level of alignment** with the EU *acquis* on the **legal protection of databases**, on the **artist's resale right**, and on the **legal protection of topographies of semiconductor products**.

North Macedonia's Copyright Law is **partially aligned** with the EU *acquis* on the **harmonisation of certain aspects of copyright and related rights in the information society**. North Macedonia is also **partially aligned with the EU *acquis* on broadcasting via satellite and cable retransmission (SatCab I)**, as well as with the EU *acquis* on **collective management of copyright and related rights**, on the **term of protection of copyright and certain related rights**, on **rental and public lending rights**, and on the **legal protection of computer programs**.

The country is **not aligned** with the EU *acquis* on **copyright and related rights in the Digital Single Market** nor with the EU *acquis* on **copyright and related rights applicable to certain online transmissions of broadcasting organisations and retransmissions of television and radio programmes (SatCab II)**. It is also **not aligned** with the EU *acquis* on **orphan works** and on **cross-border portability of online content**. Additionally, North Macedonia is **not aligned with the EU *acquis* implementing the Marrakesh Treaty**. The country is expected to align through the adoption of the draft Law amending the Copyright Law, which remains delayed, and to ratify the Marrakesh Treaty.

### **III. INDUSTRIAL PROPERTY RIGHTS**

#### **III.A. HORIZONTAL ASPECTS IN INDUSTRIAL PROPERTY RIGHTS**

##### **a. Country presentation**

The **legal framework** in the field of industrial property (IP) rights is the Law on Industrial Property, published in 2009 and last amended in 2020 (the IP Law). North Macedonia intends to adopt separate laws for individual IP rights by 2025 (namely a Law on Patents, Law on Trade Marks, Law on Industrial Designs, and a Law on Geographical Indications and Designations of Origin). North Macedonia is a party to 15 international agreements on industrial property rights.<sup>5</sup>

The main body in North Macedonia in the area of IP rights is the State Office for Industrial Property. It is

---

<sup>5</sup> North Macedonia is a party to the following 15 international agreements on IP rights: Paris Convention; Madrid Agreement; Protocol to the Madrid Agreement; Nice Agreement; The Hague Agreement; Lisbon Agreement; Vienna Agreement; Singapore Treaty; Patent Cooperation Treaty; Strasbourg Agreement; Singapore Treaty; Locarno Agreement; Patent Cooperation Treaty; Budapest Treaty; and the European Patent Convention (EPC).

divided into a Department for Trade Marks, Industrial Designs, and Geographical Indications (operating with six civil servants), and a Department of Patents (with four examiners). Its competences include promoting IP protection, approving and administering trade marks and designs, managing registers for acquired rights and others, publishing the data regarding filed and granted trade marks and designs, representing North Macedonia in international forums and cooperating with international and national entities, publishing guidelines, among others. As regards trade marks and industrial designs, the decisions of SOIP can be disputed before the Administrative Court. The Department of Patents is responsible, *inter alia*, for granting the patent, for proposing amendments to laws and regulations related to patents, in order to align them with European and international legislation, and promoting IPR-related activities and trainings (with EU support). Concerning the cooperation with EUIPO, North Macedonia is integrating TMview and TMclass, as well as DesignClass and DesignView. The country pledged to make efforts to reinforce its administrative capacity on patents, and to request for new job openings within the Department of Patents.

On the implementation track record, in 2019-2021, North Macedonia recorded 2 465 national and 21 724 international trade mark applications. Out of a total of 24 189 applications, 3 612 decisions were issued. During the same period, it registered 88 national and 719 international applications for designs. Out of a total of 802 applications, 84 decisions were issued. There had been no requests for compulsory licenses thus far, nor a national patent application for a biotechnological invention. On SPCs, there was an overall submission of 42 applications for medicinal products, out of which 39 were granted, one was refused, and two were pending. **b. Commission assessment**

North Macedonia is **partially aligned** with the EU *acquis* on industrial property rights. The adoption of separate laws for individual IP rights by 2025 is expected to bring full alignment in the IP rights field. The concentration of all IPR competences in SOIP is expected to address the current serious coordination and implementation issues. The very low number of decisions issued on trade marks and designs, in comparison with the number of total applications, needs to be considerably improved.

### **III.B. TRADE MARKS**

#### **a. Country presentation**

North Macedonia indicated that it is **fully aligned** with former Directive 2008/95/EC, which was repealed by Directive (EU) 2015/2436 to Approximate the Laws of the Member States Relating to Trade Marks. It intends to fully align with the current Directive (EU) 2015/2436, when it adopts separate laws for individual IP rights, by 2025. The IP Law provides for protection of trade marks with reputation/well-known trade marks. North Macedonia is partially aligned on both absolute and relative grounds for refusal foreseen in its IP Law, though the country did not provide enough information on this topic.

#### **b. Commission assessment**

North Macedonia is **partially aligned** with Directive (EU) 2015/2436. It is expected to fully align with it through the adoption of a new Law on Trade Marks, by 2025. Further alignment with the provisions of the 2015 Directive is needed. North Macedonia will only be able to be part of the EU-wide trade mark system (European Union trade mark) after accession to the EU.

### **III.C. DESIGNS**

#### **a. Country presentation**

North Macedonia informed that it is **fully aligned** with Directive 98/71/EC on the Legal Protection of Designs. It plans to adopt a separate Law on Industrial Designs by 2025. The country does not provide protection for unregistered designs. A registered design right is eligible for protection under the Copyright Law.

#### **b. Commission assessment**

North Macedonia is **highly aligned** with Directive 98/71/EC. The country will only be able to be part of the EU-wide industrial design system after accession to the EU.

### **III.D. PATENTS**

#### **a. Country presentation**

North Macedonia informed about the **alignment** of its legislation with Regulation (EC) 1610/96 Concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products (SPC), and Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, and its **non-alignment** with Regulation (EU) 2019/933 concerning the supplementary protection certificate for medicinal products (SPC waiver). It plans to adopt a new Law on Patents, to align with the SPC waiver, as well as the paediatric extension, and to adopt 'small patents' in certain technological areas, in line with the priority sectors of the IPR Strategy, until the end of 2025. North Macedonia intends to conduct more trainings of legal representatives in 2024.

The amendments to the IP Law prepared by SOIP aim to **further align** with Regulation (EC) 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, by the fourth quarter of 2025. The Ministry of Economy and the Ministry of Health can also issue compulsory licenses.

North Macedonia presented the domestic provisions aligning with Directive 98/44/EC on the legal protection of biotechnological inventions (Biotech Directive), in regard to the IP Law and the Regulation on Patents.

#### **b. Commission assessment**

North Macedonia is **highly aligned** with Regulation (EC) 1610/96 on the supplementary protection certificates for plant protection products, and Regulation (EC) 469/2009 on SPCs for medicinal products. It is **not aligned** with the SPC waiver (Regulation (EU) 2019/933). It is expected to align until the end of 2025, mainly through the projected new Law on Patents. The country is encouraged to improve trainings of examiners, as well as cooperation with international organisations. North Macedonia is also **partially aligned** with Regulation (EC) 816/2006 on compulsory licensing.

North Macedonia is **highly aligned** with Directive 98/44/EC on biotechnological inventions. It is recommended to include the exclusion confirmed in 2019 by the European Patent Organisation (and justified in the 2016 Commission Notice) regarding plants and animals exclusively obtained through essentially biological processes in the new Law on Patents, foreseen in the IPR Strategy 2022-2026 (which has not yet been adopted).

### **III.E. TRADE SECRETS**

#### **a. Country presentation**

North Macedonia informed about its **intention to align** with Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (Trade Secrets) against their unlawful acquisition, use and disclosure through the planned new Law on Trade Secrets. The Law has been prepared by a working group within SOIP and has incorporated the recommendations from the Commission. The country confirmed the alignment with the EU *acquis* of several provisions of the draft law, which has been previously assessed by the Commission.

## b. Commission assessment

The country is **not aligned** with Directive (EU) 2016/943. It is expected to adopt the new Law on trade secrets in light of the comments provided by the Commission on the draft Law. The fact that the proposed timeline has been considerably delayed, in relation to the initial plan, should be noted. Passing the new draft Law will be key for improvements in the area of trade secrets.

## III.F. SUMMARY OF FINDINGS – INDUSTRIAL PROPERTY RIGHTS

North Macedonia is **partially aligned with the EU *acquis* on industrial property rights**. It is expected to reach full alignment with the adoption of separate laws for individual IP rights, by 2025.

As regards **administrative capacity**, the concentration of all IPR competences in SOIP is expected to address the current serious coordination and implementation issues. This would follow from the IP Strategy, which is still pending adoption. It is not certain yet when the concentration of IP competences will take place.

North Macedonia is **highly aligned** with the EU *acquis* on **industrial designs**.

Regarding **patents**, North Macedonia is **highly aligned** with the EU *acquis* on the **SPC for plant protection products**, and on the **SPCs for medicinal products**. It is **not aligned** with the **SPC waiver**. North Macedonia is **partially aligned** with the EU *acquis* on **compulsory licensing of patents**. North Macedonia is **highly aligned** with the EU *acquis* on **biotechnological inventions**.

**North Macedonia is partially aligned with the EU *acquis* on trade marks.**

North Macedonia is **not aligned with the EU *acquis* on trade secrets**. It is expected to do so through the new Law on Trade Secrets, in light of the comments provided by the Commission on the draft law.

## IV. ENFORCEMENT

### a. Country presentation

North Macedonia declared its **full alignment** with Directive 2004/48/EC on the enforcement of intellectual property rights (IPRED), namely through the Copyright Law and the IP Law. Other relevant legislation includes the Criminal Code, the Law on Customs Measures for Enforcement of IPR, and the Law on Litigation Procedure.

The main administrative bodies dealing with IPR are the Copyright and Related Rights Unit, within the Ministry of Culture, and the State Office for Intellectual Property. According to the Strategy, all the IPR-related competences will be transferred and concentrated in the SOIP. The Coordinating Body for Intellectual Property (composed of 11 representatives of the institutions involved in IPR) is in charge of supervising inspections, seizing suspected pirated or counterfeited goods, and for delivering the confiscated goods for action. These are kept by the Agency for Management of Confiscated Property.

The State Market Inspectorate (SMI), integrated in the Ministry of Economy, does not have a special unit for IPR. It is responsible for undertaking inspection supervision on the enforcement of the Law on the SMI, the IP Law, among others. The Ministry of Economy ensures the coordination of Regulations and Directives. The inspections are initiated upon request of the rightholder or *ex-officio*. It can issue decisions, fines, and misdemeanour warrants and requests. North Macedonia acknowledged the limited number of inspectors in the field of IPR and the lack of a functioning electronic database for the exchange of information among IPR-related bodies. It committed to reinforce IPR inspection supervision, to implement the IPR Strategy 2022-2026, and to modernise the IPR institutional framework, as well as the recognition and effective enforcement, as medium-term objectives. The Customs Administration (Service for the Protection of Intellectual Property Rights) is responsible for storing documents on temporarily confiscated goods and communicating with rightholders. It operates with four independent advisers and one head of

service, including *ex-officio*. The Ministry of Agriculture, Forestry and Water Economy is responsible for geographical indications in the area of agricultural food products and wine.

The Criminal Code provides for several IPR crimes, such as on copyright, trade marks and topographies of semiconductors. The Ministry of Interior/Police can prosecute certain crimes *ex-officio*, in cooperation with the competent prosecution authority. However, there are no specialised units for IPR crimes.

North Macedonia informed about the trainings organised by the Academy of Judges and Public Prosecutors for the specialisation of judges. The country committed to strengthen the capacities of the judiciary through further trainings, and the administrative capacities of the institutions dealing with IPR enforcement, as well as their cooperation. It also acknowledged the need of a functioning e-network for the exchange of IPR data between the relevant institutions. However, the limited capacity and lack of training in courts to deal with IPR was highlighted.

Regarding the **enforcement track record**, during 2019-2020, North Macedonia registered, in its basic civil courts, four cases on copyright, six on trade marks and 19 on other industrial property rights; in the criminal courts, two cases on violation of IP rights and unauthorised use of a company and five on trade marks; and in the appellate courts, one case on trade marks, two on IPR, 10 on industrial property rights, six on copyright, two on topographies of semiconductors, and five on violation of IP rights and unauthorised use of a company. Its Higher Administrative Court has issued 26 decisions on trade marks, one on patents, and three on copyright. The Supreme Court has recorded seven cases regarding protection of copyright and industrial property rights, one regarding infringement of copyright, and four regarding infringement of industrial property rights.

North Macedonia also provided statistics on confiscated counterfeit goods by the Customs Administration. In 2020, it carried out 27 actions based on suspected infringements of IPR, having detained 69 520 goods, out of which 14 456 were counterfeited. In 2021, it carried out 26 actions based on suspected infringements, having detained 236 770 goods, out of which 26 886 were counterfeited. In 2022, it carried out 28 actions based on suspected infringements, having detained 191 330 goods, out of which 10 739 were counterfeited. The SMI undertook 18 inspections under the IP Law in 2020, 18 in 2021, and 43 during the first half of 2022.

#### **b. Commission assessment**

North Macedonia is **partially aligned** with the IPRED Directive. Substantial work is needed on the overall enforcement in practice.

North Macedonia is expected to adopt the Strategy for Intellectual Property 2022-2026 as soon as possible. According to the Strategy, all the IPR-related competences will be transferred and concentrated in the SOIP, after governmental approval. This concentration should bring significant improvements on the coordination between the multiple bodies dealing with the enforcement of IPR and to clearly define competences, to avoid overlapping tasks, enhance effectiveness, and speed up the processes of registering intellectual property rights and decisions at court. This reorganisation will also be key for an effective implementation of the Strategy, which should function as a guide to increase EU *acquis* alignment and enforcement of IPR. In terms of copyright and related rights, North Macedonia informed that the civil procedure for the protection of these rights is undertaken by rightholders and respective organisations, before a competent court. The country needs to take into consideration the general principles applicable in the EU, including those stemming from case-law of the Court of Justice of the EU, concerning civil procedures at EU level.

North Macedonia is also expected to make operational its online information platform for law enforcement institutions to exchange data on IPR, in order to enhance efficiency and implementation in practice, and to provide full insight into the institutional handling of IPR infringements. The Coordinating Body for Intellectual Property has yet to address the key challenges regarding IPR. The SMI is expected to reinforce IPR inspection supervision to implement the IPR Strategy, and to modernise the IPR institutional framework and enforcement in the medium-term.

The training of staff, judges, and prosecutors to deal with IPR needs to be enhanced. North Macedonia also needs to make significant improvements on its track record, notably as regards the number of court cases and decisions on IPR.

### C. SUMMARY OF FINDINGS – ENFORCEMENT

North Macedonia is **partially aligned** with the EU *acquis* on **enforcement of intellectual property rights**. Substantial work is needed on overall enforcement in practice.

North Macedonia is expected to adopt the Strategy for Intellectual Property 2022-2026 as soon as possible and to concentrate all the competences related to IPR to the State Office for Intellectual Property.

North Macedonia is also expected to make operational its online information platform for law enforcement institutions to exchange data on IPR and to provide full insight into the institutional handling of IPR infringements. The Coordinating Body for Intellectual Property has yet to address the key challenges regarding IPR. The State Market Inspectorate is expected to reinforce IPR inspection supervision, to implement the IPR Strategy, and to modernise the IPR institutional framework and enforcement in the medium-term.

The training of staff, judges, and prosecutors to deal with IPR needs to be enhanced. North Macedonia also needs to significantly improve its track record, notably as regards the number of court cases and decisions on IPR.

## V. FIGHT AGAINST CORRUPTION - INTELLECTUAL PROPERTY LAW

### a. Country presentation

North Macedonia's legal framework for the fight against corruption in the IPR field is primarily based on the Law on Prevention of Corruption and Conflict of Interest. The main administrative body dealing with anti-corruption is the State Commission for Protection of Corruption, which has adopted a National Strategy that establishes a methodology for assessing corruption risks. North Macedonia amended the Strategy during 2023, to add two new sectors, including industrial property. The State Commission has prepared an integrity policy, guidelines for implementing it, a handbook for integrity officers, and a software to monitor the execution of such measures.

The SOIP has not signed the integrity policy, nor nominated a member or deputy member to execute the integrity system. It has also not undertaken initiatives to strengthen institutional integrity, nor constituted an internal audit department. Additionally, it has not made a corruption risk assessment, in accordance with the Law on Public Internal Financial Control and following a request by the Deputy Prime Minister's Office for Good Governance. In its initial risk assessment, the State Commission noted the insufficient digitalisation of processes (notably the lack of a functioning electronic registration of trade marks and patents), the lack of control of own incomes, the outdated technical resources, and the lack of human resources.

### b. Commission assessment

Further and more specific anti-corruption measures in the area of intellectual property rights are desirable. The SOIP is expected to sign the integrity policy and to nominate a member and deputy member to implement the integrity system, as well as to make a corruption risk assessment. The IP Strategy should include anti-corruption measures. Further digitalisation and increased transparency of the registration procedure of IPR is needed for an effective implementation of anti-corruption measures.

### C. SUMMARY OF FINDINGS – FIGHT AGAINST CORRUPTION

**Further and more specific anti-corruption measures in the area of intellectual property rights are desirable.** The SOIP is expected to sign the integrity policy and to nominate a member and deputy member

to implement the integrity system, as well as to make a corruption risk assessment.

North Macedonia has amended the National Strategy aimed at assessing corruption risks during 2023, to add industrial property. The IP Strategy should include anti-corruption measures. Further digitalisation and increased transparency of the registration procedure of IPR is needed.

## H) CHAPTER 8 - COMPETITION POLICY

The competition *acquis* covers **antitrust, merger control** and **State aid** control policies. It includes rules and procedures to fight anti-competitive behaviour by companies (restrictive agreements between undertakings and abuse of dominant position), and to prevent governments from granting State aid which distorts competition in the internal market. As regards merger control, the Commission has competence to review mergers above certain turnover thresholds while Member States are free to control mergers below these thresholds.

In the field of **antitrust**, national competition authorities must closely co-operate with the Commission in EU competition procedures. Since 1 May 2004, all national competition authorities are also empowered to apply fully Article 101 and 102 TFEU in order to ensure that competition is not distorted or restricted. For this purpose, they should have powers comparable to those of the European Commission. National courts may also apply EU antitrust rules directly so as to protect the individual rights conferred on citizens by the TFEU.

The main EU *acquis* in the field of **merger control** is the EC Merger Regulation and the Implementing Regulation. The Merger Regulation contains the main rules for the assessment of concentrations, whereas the Implementing Regulation concerns procedural issues (notification, deadlines, right to be heard, etc.).

In the field of **State aid**, the decision as to whether or not aid granted by Member States is compatible with the Single Market falls under the exclusive competence of the European Commission under the TFEU.

The term *liberalisation* refers in substance to Article 3 TFEU, which states that the activities of the EU shall include a system ensuring that competition in the internal market is not distorted. For this purpose, there is a specific surveillance system in the case of public undertakings and undertakings to which Member States grant special or exclusive rights.

The EU *acquis* under this chapter is directly linked to obligations of North Macedonia under Article 69 of the Stabilisation and Association Agreement between the EU and North Macedonia (SAA) presently in force.

### I. LEGAL FRAMEWORK FOR COMPETITION POLICY

#### I.A. ANTITRUST

##### a. Country presentation

The **legal framework** is based on Art.55 of the Constitution ensuring freedom of the market and equal legal position of all parties in the market as well as the Law on Protection of Competition (“LPC”). The LPC covers three main pillars: prohibited agreements, decisions and concerted practices; prohibited abuse of dominant position; and control of concentrations.

The Commission for Protection of Competition (“CPC”), established in 2005, is in charge of application of the LPC. The CPC is an independent state authority with legal status. The CPC consists of five members (President and four other members) and is supported by 23 staff (including 12 case handlers). The President and two members of the CPC are professionally engaged in the CPC's work. The CPC is accountable for its work to the Parliament of North Macedonia.

According to North Macedonia, the LPC is fully aligned with Articles 101 and 102 TFEU and other relevant

acts of the EU *acquis* in this area.

As regard rules on restrictive agreements, North Macedonia relies on Art. 7 of the LPC, which prohibits restrictive agreements, while exempting restrictive agreements when they fulfil conditions similar to those laid down in Article 101(3) TFEU. The rules on the detailed conditions for agreements of minor importance (*de minimis*) are claimed to be fully aligned with the Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) TFEU. Undertakings must do self-assessment of their agreements. CPC will enact infringement decision if it determines the existence of restrictive agreement or concerted practice.

As regards the prohibition of abuses of a dominant position, North Macedonia explained that the LPC defines criteria for determining the existence of a dominant position. The presumption is that a company has a dominant position if its market share is more than 40%, unless the company proves otherwise. The LPC prohibits the abuse of a dominant position in line with Article 102 TFEU. A non-exhaustive list of criteria for determining the existence of a dominant position or prohibited abusive behaviour is provided in the LPC. Examples of abusive behaviour include fixing unfair sale or purchase prices and adopting discriminatory practices.

Secondary legislation provides further rules and guidance on how competition rules should be applied. North Macedonia indicated that it has aligned its legal framework with several Commission Regulations, including on the application of Article 101(3) TFEU to categories of technology transfer agreements, categories of specialisation agreements, categories of research and development agreements, categories of vertical agreements and concerted practice in the motor vehicle sector, categories of agreements, decisions and concerted practice in the insurance sector as well as Commission Guidelines on the applicability of Article 101 TFEU to horizontal co-operation agreements, Commission Guidelines for the application of Article 81 (3) TFEU.

North Macedonia has yet to fully align its secondary legislation with the EU *acquis*, including on Commission Regulation (EU) 2022/720 on the application of Article 101(3) TFEU to categories of vertical agreements and concerted practices (Vertical Block Exemption Regulation (“VBER”)), Commission Guidelines on Vertical Restraints (“Vertical Guidelines”) of 2022, and the Communication from the Commission providing guidance on its enforcement priorities in applying 102 TFEU to exclusionary abusive conduct by dominant undertakings.

As regards **procedural rules**, North Macedonia has stated its legislation is partially aligned with the Commission Regulation, relating to the conduct of proceedings pursuant to Articles 101 and 102 TFEU. It is also partially aligned with Commission Notice on the handling of complaints by the Commission under Article 101 and 102 TFEU and partially with Guidelines on the method of setting fines imposed pursuant to Article 23 (2) (a) of Regulation No 1/2003.

North Macedonia has yet to align its secondary legislation with other EU *acquis* concerning procedural rules including the Commission Notice on co-operation between the Commission and the courts of the EU Member States and the Notice on the rules for access to the file in cases pursuant to Articles 81 and 82 of the EC Treaty.

North Macedonia considers that the CPC has procedural rules and investigative powers that are similar to the powers granted to the Commission and EU national competition authorities. The CPC can issue binding request for information and can impose fines if the undertaking fails to submit data within specified deadline, or submits false, incomplete or misleading data. If there is a justified suspicion that an undertaking owns documents or other objects or information that could be relevant to prove the existence an infringement, the CPC can carry out on-site inspections of the undertaking’s premises (dawn raid).

The CPC may impose administrative fines for infringement of the competition rules, which may amount to 10% of the company's total turnover in the previous financial year. Companies engaged in a cartel may be exempted from the payment of fines or benefit from reduced fines if they apply to the CPC for leniency and cooperate fully with the authority's investigation of the cartel.

#### **b. Commission assessment**

As regards **antitrust**, the legislative framework of North Macedonia has a **high level of alignment** with the primary EU *acquis* in this area. The substantive rules laid down in the Law on competition protection are directly based on Articles 101 and 102 TFEU and other relevant acts of the EU *acquis* in this area. Secondary legislation provides further substantive rules and guidance on how competition rules should be applied and is broadly aligned with the EU *acquis*. However, it has **not yet aligned** with some of the relevant EU secondary legislation, including the Commission Vertical Block Exemption Regulation and Vertical Guidelines of 2022.

The **procedural rules** in the area of antitrust are **partially aligned** with the EU *acquis*. In this respect, the relevant rules are partially aligned with the Commission Regulation relating to the conduct of proceedings pursuant to Articles 101 and 102 TFEU and the Commission Notice on the handling of complaints under Article 101 and 102 TFEU. The country still needs to align its secondary legislation with the EU *acquis* including the Commission Notices on the co-operation between the Commission and the courts of the EU Member States.

The Competition Authority of North Macedonia, which is in charge of application of antitrust rules, has similar powers to those of the Commission and the national competition authorities of the Member States. It can adopt implementing legislation, launch investigations, carry out dawn raids, and impose fines and remedies. However full alignment with all relevant provisions of Directive 2019/1 (except the cross-border aspects) remains to be achieved in order to guarantee that the CPC has the proper independence, resources, powers and procedures to ensure effective enforcement.

### **I.B. MERGERS**

#### **a. Country presentation**

North Macedonia considers that its competition legislation is partially in line with Council Regulation (EC) No.139/2004 on the control of concentrations between undertakings (the "Merger Regulation"). In this respect, the Law on Protection of Competition provides the definition of a concentrations and lays down conditions that trigger the obligation to notify a concentration and the criteria for appraisal of the concentration.

North Macedonia stated that it has aligned its framework with several Commission guidelines including on the assessment of horizontal and non-horizontal mergers, the current version of the Commission Notice on the definition of the relevant market for the purposes of Community competition, Commission remedies notice, the Commission Notice on restrictions directly related and necessary to concentrations. However, legislation remains to be aligned with Commission guidelines such as but not limited to the Guidance on the preparation of public versions of Commission Decisions adopted under the Merger Regulation.

As regards **procedural rules**, the Law on Competition Protection is partially aligned with Commission Regulation (EC) No 802/2004 of 7 April 2004 implementing Council Regulation (EC) No. 139/2004 on the control of concentrations between undertakings (the "Implementing Regulation"). The secondary legislation is aligned with the Commission Notice on a simplified procedure for treatment of certain

concentrations. North Macedonia has yet to align its legislation with Point C of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No. 139/2004 on the control of concentrations between undertakings.

The merger control procedures in the LPC provide concentrations must be notified to the CPC if the parties meet specific notification thresholds during the previous financial year. The CPC is obliged within 25 working days of the day of receipt of the complete notification either to clear the merger or initiate an in-depth investigation, in which case the CPC has an additional 90 working days to adopt a final decision. The initial period of 25 working days can be extended up to 35 working days if the participants in the concentration offer commitments to the CPC with a view to rendering the concentration compliant with the provisions of the Law. At any time following the initiation of the procedure, the time limits may be extended by the CPC in agreement with the merging parties. The total duration of each extension may not exceed 20 working days.

North Macedonia considers that the CPC is entrusted with powers similar to those of the Commission and the national competition authorities of the Member States. The CPC can request additional information from the merging parties and from third parties, prohibit or approve the merger, or accept remedies.

#### **b. Commission assessment**

The Commission notes that, when it comes to merger control, EU member states can and do have their own rules that do not have to be fully aligned with EU merger control rules. In this context, the Commission considers, on the basis of the information available, that the Law on Competition Protection and secondary legislation has a **good level of alignment** with the EU *acquis* in this area.

As regards the **substantive rules**, they are directly based on the Merger Regulation and EU soft law such as the guidelines on the assessment of horizontal and non-horizontal mergers, the current version of the Notice on the definition of the relevant market, and the remedies notice. However, the country still needs to align its secondary legislation with various other EU secondary and soft law instruments.

As regards **procedural rules**, these are partially aligned with the EU *acquis*. North Macedonia still needs to align its framework with the amendments introduced to the Implementing Regulation by the Commission Implementing Regulation (EU) No. 1269/2013 of 5 December 2013. The secondary legislation is aligned with the Commission Notice on a simplified procedure for treatment of certain concentrations. North Macedonia has yet to align its secondary legislation with the Point C of Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No. 139/2004 on the control of concentrations between undertakings.

The Competition Authority of North Macedonia is entrusted with powers similar to those of the Commission and the national competition authorities of the Member States.

### **I.C. STATE AID**

#### **a. Country presentation**

The definitions of **State aid**, including allowed State aid and not allowed State aid are laid down in the Law on State Aid Control (LSAC), adopted in 2010. North Macedonia considers that these definitions reflect Art. 107 TFEU.

As regards **procedural rules**, North Macedonia states its legal framework is **partially aligned** with Council Regulation No. 1589/2015 laying down the rules for the application of Art.108 TFEU and certain other EU regulations on State aid procedure, Commission Regulation (EU) 2015/2282 as regards the notification

forms and information sheets and Commission communication on professional secrecy in State aid decisions.

The LSAC provides for an ex-ante control: the State aid grantor is under the obligation to notify State aid to the CPC, which is also in charge of the application of the LSAC. The CPC can approve, with or without conditions or to disapprove the proposed aid. In line with the standstill clause stipulated in the Law on State aid, the notified aid cannot be granted until the decision allowing it is adopted. Finally, the CPC is responsible for ordering the recovery of any unlawful and incompatible aid that was granted, with interests. The CPC can also initiate an ex-officio investigation regarding non-notified aid.

The notification obligation applies to all aid measures, except *de minimis* aid. North Macedonia stated that the rules for granting *de minimis* aid are harmonised with the EC Regulation 1998/2006 on the implementation of Art. 87 and 88 of TEU on *de minimis* aid. North Macedonia still needs to fully align its legislation with Commission Regulations and Notices, including on the calculation of certain time limits, handling of complaints, and identification and protection of confidential information.

North Macedonia noted that the legislation is **partially aligned** with the Commission Regulation declaring certain categories of aid compatible with the internal market in application of Art.107, 108 of the Treaty (the "General Block Exemption Regulation").

North Macedonia states its legal framework is **partially aligned** the EU *acquis* on **horizontal aid** in the areas of research and development and innovation aid, risk capital aid, training aid and employment aid. The country has yet to align its legislation with Communication from the Commission on criteria for the analysis of the compatibility with the internal market of State aid to promote the execution of important projects of common European interest.

As regards State aid rules on services of general economic interest (SGEI), North Macedonia stated that its legal framework is partly aligned with the EU *acquis* in this area, whereby the legislation is harmonised with basic principles of the EU *acquis* on the state aid for the SGEI.

In the area of **regional aid**, the legal framework of North Macedonia is **partially aligned** with the Commission Guidelines on regional State aid. North Macedonia noted that its rules on State aid for rescue and restructuring are partly aligned with the Commission Guidelines on State aid for rescuing and restructuring non-financial undertakings in difficulty of 2014.

North Macedonia has explained that its legal framework remains to be aligned with the Commission Guidelines on State aid for climate, environmental protection and energy as well as Commission guidelines on certain State aid measures in the context of the system for greenhouse gas emission allowance trading post-2021.

As regards **specific aid instruments**, North Macedonia noted that its legal framework remains to be further aligned with the Commission Notice on State aid in the form of guarantees, Communication from the Commission on the revision of the method for setting the reference and discount rates as well as the EU *acquis* concerning short-term export credit insurance.

As regards the application the State aid rules to measures relating to direct business taxation. North Macedonia noted that the country is **partially aligned** with the EU *acquis* in this area. The country is not yet aligned with the Commission Notice on the application of the State aid rules to measures relating to direct business taxation and DG Competition working paper on State aid and tax rulings.

The national legislation is **partially aligned** with the Commission Directive on the transparency of financial relations between Member States and public undertakings as well as on financial transparency within certain undertakings.

In the area of **sectoral aid**, North Macedonia explained that the legislation on production of films and other audio-visual works is **partially in line** with the EU *acquis* this area. The national legislation remains to be aligned with the EU *acquis* (including sectoral guidelines) in the area of financing of the public broadcasters

and granting aid for the deployment of broadband networks.

As regards postal sector, North Macedonia indicated that its legislation **remains to be aligned** with the Notice from the Commission on the application of the competition rules to the postal sector and on the assessment of certain State measures relating to postal services.

As regards aid to coal sector, North Macedonia has not yet adopted a legal act for the closure of coal mines. The country has to align its framework with the Council Decision on State aid to facilitate the closure of uncompetitive coal mines and with the Commission Communication relating to the methodology for analysing State aid linked to stranded costs.

In the area of steel sector, North Macedonia noted that its rules on State aid for rescue and restructuring are partly aligned with the Commission Guidelines on State aid for rescuing and restructuring non-financial undertakings in difficulty of 2014. The national legislation is yet to be aligned with the Communication from the Commission on Rescue and restructuring aid and closure aid for the steel sector.

In the areas of State aid for transport and infrastructure, North Macedonia **has not yet aligned** its framework with the EU *acquis*, including the Commission Guidelines on State aid to airports and airlines and to maritime transport as well Guidelines on State aid for railway undertakings.

#### **b. Commission assessment**

The **definitions** of State aid in the legislation of North Macedonia are broadly in line with Art. 107 TFEU.

The **procedural rules** on State aid control are partially in line with the *acquis*. The enforcement powers of the CPC broadly reflect those enjoyed by the Commission when carrying out the control of State aid granted by Member States. In particular, the legal framework on State aid includes a standstill clause for notified aid, pending the decision of the CPC and provides for the possibility of recovering incompatible State aid. The CPC can also initiate an ex-officio investigation regarding non-notified aid.

Further alignment is necessary with the Council Regulation No. 1589/2015 laying down the rules for the application of article 108 TFEU and Commission Regulations and Notices, including on the calculation of certain time limits, handling of complaints, and identification and protection of confidential information.

North Macedonia has partially aligned its legal framework with the EU *acquis* on **horizontal aid** in the areas of research and development and innovation aid, risk capital aid, training aid and employment aid. The country has not yet aligned its legislation with Communication from the Commission on criteria for the analysis of the compatibility with the internal market of State aid to promote the execution of important projects of common European interest.

The rules on services of general economic interest (SGEI) need to be further aligned with the EU *acquis* in this area.

The legislation in North Macedonia is partially aligned with the Commission Guidelines on regional State aid and on State aid for rescuing and restructuring non-financial undertakings in difficulty of 2014.

The national rules on State aid for environmental protection and energy aid are not in line with the EU *acquis*.

As regards **specific aid instruments**, the national legislation remains to be further aligned with the Commission Notice on State aid in the form of guarantees, Communication from the Commission on the revision of the method for setting the reference and discount rates as well as the EU *acquis* concerning short-term export credit insurance.

The country is not yet aligned with the Commission Notice on the application of the State aid rules to measures relating to direct business taxation and DG Competition working paper on State aid and tax rulings.

In the area of **sectoral aid**, North Macedonia has partially aligned its legal framework with the EU *acquis*

concerning State aid for production of films and other audio-visual works. Further alignment with the EU *acquis* is needed in the areas of financing of the public broadcasters and granting aid for the deployment of broadband networks.

As regards postal sector, North Macedonia has yet to align with the Notice from the Commission on the application of the competition rules to the postal sector and on the assessment of certain State measures relating to postal services.

As regards aid to coal and steel sector, North Macedonia has yet to align its legislation with the respective EU *acquis*.

In the areas of transport and infrastructure, North Macedonia has not yet aligned its framework with the EU *acquis*, including with Commission Guidelines on State aid to airports and airlines and to maritime transport as well as guidelines on State aid for railway undertakings.

## **I.D. LIBERALISATION**

### **a. Country presentation**

North Macedonia indicated that there are no exceptions (based on sectors or types of enterprises) to the application of competition rules. The rules for the protection of competition are applied and valid for public enterprises, enterprises entrusted with the performance of services of general economic interest, which by their nature represent monopolies that collect revenues or have special and exclusive rights or concessions, except in cases where the application of the provisions of the law would prevent the performance of the competences determined by law or for which those entities were established.

State aid rules apply to state-owned undertakings and undertakings with special or exclusive rights. Rules regulating the services of general economic interest are part of the Regulation on conditions and procedure for granting horizontal aid, enacted by the Government in December 2013. According to North Macedonia, the rules on the financing of SGEI are partially aligned with the EU *acquis*.

North Macedonia noted that the Law on Protection of Competition ensures that there is no discrimination between nationals and foreigners regarding the conditions under which goods are produced and marketed.

### **b. Commission assessment**

The Commission notes that the rules on antitrust and State aid are applicable to public enterprises and undertakings that perform activities of public interests, except if, through the application of this law, they are unable to perform the tasks or activities assigned to them by the public authority.

Nonetheless, the current system in place does not fully reflect EU rules. North Macedonia needs to fully align its legislation with the EU *acquis* relating to the aid in the form of compensation for the costs of provision of services of general economic interest, the Directive on transparency of financial relations between Member States and public undertakings as well as on financial transparency within certain undertakings.

## **I.E. SUMMARY OF FINDINGS – LEGAL FRAMEWORK FOR COMPETITION POLICY**

The legal framework on **antitrust** has a **high level of alignment** with the primary EU *acquis*. and on **mergers a good level of alignment** with the EU *acquis*. The substantive rules are based on Article 101 and 102 TFEU, the Merger Regulation and other EU regulations. North Macedonia has yet to complete the alignment of its legislation with the EU *acquis*.

The legal framework on **State aid** is **partially aligned** with the EU rules. The definition of State aid is

broadly in line with Article 107 TFEU. However, the secondary legislation on horizontal aid, sectoral aid and specific aid instruments is either not aligned or only partially aligned with the relevant EU *acquis*. Procedural rules remain to be aligned with the respective EU rules.

As regards **liberalisation**, the Commission notes that the rules on antitrust and State aid are applicable to public enterprises and undertakings that perform activities of public interests, except if, through the application of these rules, they are unable to perform the tasks or activities assigned to them by the public authority. Nonetheless, the system currently in place does not fully reflect EU rules – North Macedonia needs to fully align its legislation with the EU *acquis* relating to Services of General Economic Interest, to transparency of financial relations with public undertakings, as well as to financial transparency within certain undertakings.

## II. INSTITUTIONAL FRAMEWORK AND IMPLEMENTING CAPACITY

### II.A. ANTITRUST AND MERGERS

#### a. Country presentation

The Commission for Protection of Competition (CPC), established in 2005, is an independent public authority that implements antitrust and merger rules. The CPC consists of a President and four members, who are appointed by the Parliament of North Macedonia for a period of five years with the right to reappointment. The CPC is accountable to the parliament, to which it submits an annual report on its activity.

The secretariat of the CPC is headed by the Secretary General. It has 23 employees, organised in five departments. There are 8 case handlers working in the area of antitrust and mergers. Infringement proceedings are conducted before the CPC and sanctions for infringements are imposed by the Commission for misdemeanours. The Commission for misdemeanours is comprised of the President and the two professional members of the CPC.

During 2017-2022, the CPC handled 12 cases concerning restrictive agreements and one case concerning the abuse of a dominant position (29 and 25 cases respectively in the period 2005-2022). In the period 2005-2022, the CPC imposed fines amounting to approx. EUR 6.2 million. In the period 2017-2022, the CPC adopted 399 decisions authorising concentrations. (639 decisions concerning mergers in the period 2005-2022).

#### b. Commission assessment

The CPC, which has been performing its tasks as an independent public authority, is a well-established institution with procedural rules and investigative powers similar to those of the Commission and the national competition authorities of Member States.

Currently, with 23 employees, including 8 case handlers working on antitrust and mergers, the CPC does not have sufficient resources to carry out its tasks. Its administrative capacities should be further strengthened in particular through hiring additional staff and continuous training, including in the use of forensic software for carrying out inspections. The CPC also needs to further build up its enforcement record, in particular by imposing fines. In the fight against cartels, the CPC needs to make additional efforts in the area of competition advocacy. North Macedonia needs to ensure that the recommendations of the CPC on draft legislation that has an impact on competition are properly taken into account.

## **II.B. STATE AID**

### **a. Country presentation**

The CPC is also the decision-making authority that implements State aid rules in the country.

As regards the implementation of State aid rules, the administrative capacity is not sufficient in terms of the number of staff and available training. There are four case handlers working in its State aid department. North Macedonia has plans to hire another four case handlers in the period 2024-2026. The budget constraints also limit the functioning of the CPC.

In 2022, the CPC adopted 27 decisions and 33 opinions. In that period, no negative or conditional decision were adopted.

Decisions of the CPC decisions can be appealed before the Administrative Court.

### **b Commission assessment**

The administrative capacities of the CPC in the area of state aid are insufficient. It is noted that the authorities envisage strengthening the administrative of the State aid department within CPC by 2026. Continuous training needs to be ensured for staff working in this area.

The number of decisions and opinions adopted by the CPC in the area of State aid demonstrates awareness of the relevant rules by a number of State aid grantors. The CPC needs to continue raising awareness among State granting bodies in order to further improve its enforcement record in this area.

## **II.C SUMMARY OF FINDINGS – INSTITUTIONAL FRAMEWORK AND IMPLEMENTING CAPACITY**

North Macedonia has some level of preparation/is moderately prepared in terms of implementation and enforcement capacity.

The Commission for Protection of Competition is responsible for enforcement of antitrust and merger rules in North Macedonia. It is now a well-established and operationally independent institution based on the assessment of the organisational structure with investigative powers similar to those of Commission and the national competition authorities of the Member States. In order to improve its enforcement record, the CPC should strengthen its administrative capacity, notably through increasing the number of staff and ensuring that it gets relevant training.

The CPC needs to further develop an enforcement record in the area of State aid. The prerequisite for that is strengthening the administrative capacities of the institution.

## **III. FIGHT AGAINST CORRUPTION - COMPETITION POLICY**

### **a. Country presentation**

In the fight against corruption, North Macedonia indicated that the Law on Prevention of Corruption and conflict of interest determines the competences of the State Commission for Prevention of Corruption (SCPC), which prepares analyses of the risks of corruption in different sectors and undertakes activities to strengthen personal and institutional integrity. In this respect, the SCPC has prepared Guidelines for institutional corruption risk assessment.

The SCPC has adopted and has been implementing an Integrity Policy, with a view to setting an example for other public institutions to start the process of adopting anti-corruption policies. The Integrity Policy

includes objectives to protect the public interest, to prevent conflicts of interests and ensure purposeful, rational and efficient management of public resources.

The National Strategy for the prevention of Corruption and Conflict of interest 2021-2025 in the economy and business sector identifies an issue of the lack of register of State aid granted to economic operators (owned by domestic and foreign legal entities). The lack of insight into State aid increases the risk of corruption in the process of awarding grants and subsidies. In order to address this issue, the national strategy includes a measure to establish a comprehensive State aid register. The measure is currently being implemented by the authorities.

#### **b. Commission assessment**

North Macedonia has in place a legal framework for fighting and preventing corruption, including in the area of competition policy, where the State Commission for Prevention of Corruption plays a central role.

The National Strategy for the prevention of Corruption and Conflict of interest 2021-2025 has identified as a problem the lack of a register of State aid granted to economic operators.

The CPC has an important role to play in addressing this issue by developing a comprehensive register of State aid within the institution. In this respect, the CPC should have sufficient resources to ensure effective monitoring of State aid.

#### **c. SUMMARY OF FINDINGS – FIGHT AGAINST CORRUPTION**

North Macedonia has in place a legal framework for fighting corruption, including in the area of competition policy, where the State Commission for Prevention of Corruption (SCPC) plays a central role.

The national strategy for the prevention of Corruption and Conflicts of interest 2021-2025 identifies as an issue the lack of a register of State aid, which increases risk of corruption. To address this issue, the strategy envisages developing a comprehensive register of State aid by the CPC. The CPC should have sufficient resources to implement the measure and ensure effective monitoring of State aid.

## I) CHAPTER 9 - FINANCIAL SERVICES

The EU *acquis* on financial services aims to ensure fair competition between and stability of financial institutions, i.e. banking, insurance, supplementary pensions, investment services, and securities markets, and rules on their authorisation, operation, and supervision.

On **banks, investment firms and financial conglomerates**, the EU *acquis* sets out requirements for the authorisation, operation and prudential supervision of credit institutions, and the requirements concerning the calculation of minimum capital of credit institutions and investment firms (IFs). It establishes the substantive framework of covered bonds in the EU, rules for the prudential regulation and supervision of all banks and all IFs, where the largest IFs that remain under the framework for banks (CRR/CRD). The 2021 Banking Package proposal for the review of the framework for banks aims to implement outstanding elements of Basel III standards under CRR/CRD. Credit institutions are required to join an officially recognised deposit guarantee scheme, which must provide for a protection of EUR 100 000 per depositor per credit institution following the determination by administrative or judicial authorities that deposits are unavailable. The EU *acquis* on investor compensation schemes protects investors by providing compensation if an investment firm fails to return the investor's assets. The EU *acquis* establishes uniform recovery and resolution rules and procedures for credit institutions and investment firms, organises the mutual recognition of reorganisation and winding up of credit institutions, and lays down rules relating to supplementary supervision of financial conglomerates and to the taking-up, pursuit of and prudential supervision of the business of electronic money institutions.

On **insurance and occupational pensions (IORPs)**, the EU *acquis* lays down rules on the authorisation, operation and supervision of life and non-life insurance and re-insurance undertakings, for the supplementary supervision of insurance groups, with specific provisions exist in the non-life sector for co-insurance, tourist assistance, credit insurance and legal expense insurance. It also incorporates a prudential regulatory framework for reinsurance activities in the EU aiming at removing barriers to the pursuit of reinsurance business. The EU *acquis* also regulates the distribution of insurance products and insurance-based investment products, as well as motor third-party liability insurance. The EU also sets common standards for occupational pensions, by harmonising governance requirements, and rules on IORPs' own risk assessment, as well as setting new requirements to use a depositary and enhanced powers for supervisors to enhance information transparency for pension savers and to clarify the procedures for carrying out cross-border transfers and activities.

On **financial market infrastructure**, the EU *acquis* is designed to remove barriers in the post-trading area, enhancing market infrastructure resilience and promoting financial stability. It establishes common rules for the institutions responsible for securities settlement and clearing, and regulates and protects designated securities settlement and payment systems. It also improves the transparency of derivatives markets by regulating over-the-counter (OTC) derivatives, central counter-parties and trade repositories.

As concerns **securities markets and investment services**, the EU *acquis* includes a comprehensive regulatory regime covering the authorisation, operation and supervision of investment firms and trading venues. It strengthens capital markets by ensuring public transparency and regulatory reporting requirements, as well as extensive measures aimed at protecting investors. It introduces a harmonised and comprehensive administrative regime for

prohibiting and prosecuting insider dealing and market manipulation, and it improves the governance and controls over the benchmark process.

The EU *acquis* also sets out a **sustainable finance** framework, in order to transition to a low-carbon economy, in line with climate and energy targets. It includes the EU Taxonomy, which establishes a list of environmentally sustainable economic activities.

## **I. BANKS AND FINANCIAL CONGLOMERATES**

### **I.A. COVERED BOND DIRECTIVES**

#### **a. Country Presentation**

Regarding the covered bond directive, North Macedonia has not yet implemented national legislation to align with the requirements of Directive (EU) 2019/2162 on the issue of covered bonds and covered bond public supervision (the Covered Bonds Directive), with the provisions of Directives 2009/65/EC 2014/59/EU which it amends. However, North Macedonia is fully committed to aligning with the Covered Bonds Directive and the Directives it amends by 2026 and it does not envisage any impediments to its implementation.

Secured bonds are currently regulated under both the Law on Securities<sup>6</sup> and the Law on Contractual Collateral<sup>7</sup>. The competent body for the secured bonds market is the Financial System Department at the Ministry of Finance.

The Financial System Department monitors the legislation that enters into force in the European Union pertaining to the operation of the financial system, with the aim of achieving a timely alignment into the domestic legislation. Overall, 20 people work in the Financial System Department..

#### **b. Commission Assessment**

North Macedonia is **not yet aligned** with the EU *acquis* on the issue of covered bonds and covered bond public supervision.

### **I.B. INVESTMENT FIRM REGULATION AND DIRECTIVE**

#### **a. Country Presentation**

Regarding the investment firm regulation and directive, the EU framework on capital adequacy in investment firms is represented by Regulation (EU) 2019/2033 on the prudential requirements of investment firms and by Directive (EU) 2019/2034 on the prudential supervision of investment firms.

National legislation is not aligned with Regulation (EU) 2019/2033 and Directive (EU) 2019/2034. In particular, the threshold for investment firms' classification diverges substantially. A further partial alignment is expected during the first half of 2024. North Macedonia plans, by 2026, to

---

<sup>6</sup> LAW ON SECURITIES (Official Gazette no. 95/05, 25/07, 7/08, 57/10, 135/11, 13/13, 188/13, 43/14, 15/15, 154/15, 192/15, 23/16, 83/18 и 83/18 and Official Gazette no. 31/20 и 288/21)

<sup>7</sup> LAW ON CONTRACTUAL COLLATERAL (Official Gazette no. 5/03, 4/05, 87/07, 51/11, 74/12, 115/14, 98/15, 215/15 and 61/16)

harmonise its regulatory framework with the EU provisions on capital adequacy in investment firms, and it requested technical assistance to do so.

The market consists of 5 brokerage houses and 5 banks authorised by the Securities and Exchange Commission. The competent body is the Financial System Department at the Ministry of Finance.

#### **b. Commission Assessment**

North Macedonia has a **low level of alignment** with the EU *acquis* on the prudential requirements of investment firms.

### **I.C. CAPITAL REQUIREMENTS DIRECTIVE (CRD) AND THE CAPITAL REQUIREMENTS REGULATION (CRR)**

#### **a. Country Presentation**

Regarding the Capital Requirements Directive (CRD) and the Capital Requirements Regulation (CRR), North Macedonia referred to the Implementing Decision (EU) 2021/1753 of 1 October 2021 which concludes that North Macedonia has in place prudential, supervisory and regulatory arrangements which comply with a series of operational, organisational and supervisory standards reflecting the essential elements of the European Union's prudential, supervisory and regulatory arrangements applicable to credit institutions. Overall, the latest reviews of the EU's frameworks for credit institutions (CRR II and CRD V) have been implemented.

In terms of regulatory gaps, the implementation of Basel III final standards remains outstanding. The absence of the Net Stable Funding Ratio liquidity requirement and overall market risk framework is relevant, despite the fact that the country's market risk exposures may be very low, and no bank is currently above the application threshold. North Macedonia is planning to draft and adopt a number of legislative and regulatory acts to increase its alignment (Draft Banking Law). The EU's full set of guidelines, including implementing technical standards (ITS) and regulatory technical standards (RTS), are also currently being reviewed for implementation. As examples of recent initiatives, the Decision on the Methodology for Credit Risk Management and the Decision on Reports and Data Disclosure were adopted in February 2023. Future milestones include the draft of the Banking Law review and the New Capital Adequacy Framework (by 2025) to further align with the CRR/CRD framework, including the reviews to be agreed in the EU for the 2021 Banking Package. The Guidelines on Management of Climate-Related Risks by Banks were adopted by the National Bank during 2023.

The market includes 13 banks, of which 9 banks are foreign-owned, and 2 saving houses with minor participation in the banking operations. The competent body is the Supervision Sector of the National Bank of North Macedonia, which currently has a workforce of 56 employees to conduct both on-site and off-site supervisory work.

#### **b. Commission Assessment**

North Macedonia has a **high level of alignment** with the EU *acquis* on prudential requirements.

## **I.D. DEPOSIT GUARANTEE SCHEMES**

### **a. Country Presentation**

Regarding deposit guarantee schemes, North Macedonia indicates that national legislation is partially harmonised with the EU *acquis* with regard to deposit guarantee schemes, which is represented by Directive 2014/49/EU.

The Deposit Insurance Fund of North Macedonia is a specialised financial institution that guarantees the household deposits up to € 30,000 (in denar equivalent) per depositor in banks, branches of foreign banks and savings banks for which the Governor of the Central Bank passes a decision on fulfilment of the requirements for opening bankruptcy proceedings. The repayment period is 20 days from the day of a bank's failure. The Deposit Insurance Fund employs 14 people and initiatives to strengthen its administrative capacity are currently ongoing.

The Deposit Insurance Fund is working on drafting new legislation, which will – among other aspects – introduce deposit insurance for deposits of legal entities (along with defined exclusions), protection of temporary high balances, transition to risk-based premium contributions, connection to banks and savings banks for the purpose of monitoring the deposit base and readiness for repayment compensation in a shorter period of time.

The Deposit Insurance Fund of North Macedonia has a narrow pay box function. Resolution regime for banks is yet to be implemented in the country, and therefore participation of the Deposit Insurance Fund in resolution financing is not provided for in the law.

North Macedonia informed the Commission that the new legislation aligning the scope of coverage and exclusions with the EU *acquis* will be implemented by the end of 2024, that the implementation of risk-based contributions will be effective by 2026, and that full harmonisation with the EU *acquis*, including an increase of the amount for compensation of deposits up to € 100,000 and decrease of the pay-out period, will be achieved by 2030.

### **b. Commission Assessment**

North Macedonia has a **low level of alignment** with the EU *acquis* on deposit guarantee schemes.

## **I.E. INVESTOR COMPENSATION SCHEMES**

### **a. Country Presentation**

Regarding investor compensation schemes, the legislation of North Macedonia, namely the Law on Securities, is partially aligned with the EU *acquis* with regard to investor compensation schemes (Directive 97/9/EC). Further partial alignment is expected during 2024. The regulatory gap, which is represented by the adoption of Part V-b of the Law on Securities on the Investors Compensation Fund, will enter into force from the date of accession of North Macedonia.

The Investor Compensation Fund shall be established and managed by an operator (a legal entity) authorized by the Securities and Exchange Commission. The Ministry of Finance is the policy making authority which is authorised to propose the “Law on Securities”. The Securities and

Exchange Commission of North Macedonia participates in the preparation of the legal acts and adopts the relevant bylaws in accordance with the provisions of the “Law on Securities”. Furthermore, the Securities and Exchange Commission will be in charge of implementing the provisions of the “Law on Securities” pertaining to the Investors Compensation Fund.

#### **b. Commission Assessment**

National legislation is **partially aligned** with the EU *acquis* on investor compensation schemes.

### **I.F. RECOVERY AND RESOLUTION FRAMEWORK FOR BANKS (BRRD)**

#### **a. Country Presentation**

Regarding recovery and resolution framework for banks (BRRD), the country’s legislation has a low level of alignment with the EU *acquis*. The regulatory framework consists of the “Banking Law” and the Decision on the methodology for developing a recovery plan for systemically important banks.

The existing regulatory gap is being closed with the adoption of the Bank Resolution Law in 2023 and with the adoption of amendments to the Law on the National Bank (expected in 2024), and amendments to the Banking Law, as well as by adopting by-laws implementing the Bank Resolution Law (over the course of 2024 and 2025).

The National Bank of North Macedonia shall be the resolution authority. Its resolution functions will be exercised through the Banking Regulations and Bank Resolution Department, fully separated from the supervision section of the National Bank. While 7 staff are currently employed at the Department, a capacity building project is ongoing in close cooperation with the World Bank and the International Monetary Fund.

#### **b. Commission Assessment**

North Macedonia has a **low level of alignment** with the EU *acquis* on the recovery, resolution framework for credit institutions.

### **I.G. REORGANISATION AND WINDING UP OF CREDIT INSTITUTIONS**

#### **a. Country Presentation**

Regarding the reorganisation and winding up of credit institutions, the legislation of North Macedonia is partially aligned with Directive 2001/24/EC on the reorganisation and winding up of credit institutions. The main legislative framework in North Macedonia regarding liquidation rules consists of (among other provisions) the “Law on the National Bank of the Republic of North Macedonia”, the “Banking Law”, the “Bankruptcy Law” and the “Law on Deposit Insurance Agency”.

The country’s “Law on the National Bank” stated that the National Bank shall be responsible for the supervision, including the imposition of measures and sanctions. Since the adoption of the “Banking Law” in 2007, no banks have been subject to administration proceedings. However, two banking licences were revoked, resulting in the liquidation of one bank and bankruptcy proceedings over another.

The “Banking Law” already contains a section on the powers of the home authorities of branches of EU Member States banks to decide on reorganisation and winding up measures. These provisions will apply from the day of accession. Full alignment with Directive 2001/24/EC will be possible only upon accession to the EU, as its provisions also include requirements for credit institutions with head offices within or outside the European Union, which is not relevant for North Macedonia at this stage.

#### **b. Commission Assessment**

North Macedonia has a **low level of alignment** with the EU *acquis* in this area.

### **I.H. SUPERVISION OF FINANCIAL CONGLOMERATES**

#### **a. Country Presentation**

Regarding the *supervision of financial conglomerates*, the legal and regulatory framework, namely the “Law on Supplementary Supervision of Financial Conglomerate” is currently aligned with the EU *acquis* on supervision of financial conglomerates, namely Directive 2002/87/EC.

However, the law will only be applicable upon accession of North Macedonia to the European Union. This is due to the nature of the matter regulated by Directive 2002/87/EC (the entities that are part of the conglomerate are usually located in different countries within the common market) and due to the structure of the financial system in North Macedonia.

The relevant competent authority in North Macedonia is the one that supervises and licences the entity belonging to the financial conglomerate.

#### **b. Commission Assessment**

National legislation is **partially aligned** with the EU *acquis* on the supervision of financial conglomerates.

### **II. SUMMARY OF FINDINGS – BANKS AND FINANCIAL CONGLOMERATES**

Overall, North Macedonia achieves a **partial level of alignment** with the EU *acquis* on banks and financial conglomerates.

North Macedonia has a **high level of alignment** with the EU *acquis* on prudential requirements.

North Macedonia has a **partial level of alignment** with the EU *acquis* on investor compensation schemes, and on the supervision of financial conglomerates.

North Macedonia has a **low level of alignment** with the EU *acquis* on deposit guarantee schemes and the recovery, resolution framework for credit institutions, and on the prudential requirements of investment firms. North Macedonia is **not yet aligned** with the EU *acquis* on the issue of covered bonds and covered bond public supervision.

The country’s administrative and technical capacities are satisfactory to perform current regulatory and supervisory tasks. However, in view of increasing responsibilities and future obligations deriving from the application of the evolving EU *acquis*, further capacity building in this area is necessary.

## II. INSURANCE AND OCCUPATIONAL PENSIONS

### II.A. SOLVENCY II

#### a. Country Presentation

Regarding *Solvency II* (life, non-life, reinsurance, winding-up) legislation of North Macedonia is not aligned with Solvency II save for some provisions of the second pillar. The legal and regulatory market in North Macedonia achieves full alignment with Solvency I,

The provisions on right of establishment of a branch in the territory of North Macedonia and the freedom to provide services will apply upon accession of the country to the European Union.

Going forward, the Ministry of Finance is currently drafting a new “Insurance Law” with an aim of alignment with the Solvency II Directive. North Macedonia indicated that it intends to approve the law aligning provisions relating to the first and third pillars and the remaining parts of the second pillar by the end of 2024. In terms of administrative capacity, the Insurance Supervision Agency is the independent regulatory body responsible to safeguard the interests of the policyholders and to promote the fair and efficient functioning of the insurance market. Its governing body is represented by the Council of Experts (5 members, 3 executives and 2 non-executives) and it employed 33 people at the end of 2022.

#### b. Commission Assessment

North Macedonia has a **high level of alignment** with the Solvency I regime. North Macedonia is **not yet aligned** with Solvency II regime.

### II.B. SUSTAINABILITY FACTORS, RISKS AND PREFERENCES

#### a. Country Presentation

Regarding *sustainability factors, risks and preferences*, the country’s regulatory framework is partially aligned with Commission Delegated Regulation (EU) 2021/1257 amending delegated Regulations (EU) 2017/2358 and (EU) 2017/2359 as regards the integration of sustainability factors, risks and preferences into the product oversight and governance requirements for insurance undertakings and insurance distributors and into the rules on conduct of business and investment advice for insurance-based investment products.

Further alignment with the provisions of Delegated Regulations (EU) 2021/1257 and 2017/2358 are planned by the end of 2024 through amendments to the “Insurance Supervisions Law”.

In terms of administrative capacity, the Insurance Supervision Agency is the independent regulatory body responsible for supervision of insurance firms and for revoking authorisations to conduct insurance brokerage and agency activities.

#### b. Commission Assessment

National legislation is **partially aligned** with the EU *acquis* on sustainability factors, risks and preferences.

## II.C. MOTOR INSURANCE

### a. Country Presentation

Regarding *motor insurance*, the regulatory framework is partially aligned with Directive 2009/103/EC relating to insurance against civil liability in respect of the use of motor vehicles, and the enforcement of the obligation to insure against such liability (the “Motor Insurance Directive – MID”), and its amending Directive (EU) 2021/2118. The country’s current minimum amount of cover is significantly lower than in the EU and will be gradually increased. North Macedonia must also eliminate any approval or notification system for the definition of premiums to fully comply with the Solvency II regime.

North Macedonia will further align with the EU *acquis* in the field of motor insurance, at the latest, upon accession to the European Union.

In terms of administrative capacity, the Insurance Supervision Agency is the independent regulatory body responsible for supervising the operation of the insurance companies providing motor third party liability insurance.

### b. Commission Assessment

National legislation is **partially aligned** with the EU *acquis* on insurance against civil liability in respect of the use of motor vehicles.

## II.D. INSURANCE DISTRIBUTION

### a. Country Presentation

Regarding *insurance distribution*, the “Insurance Supervision Law” regulates the insurance intermediation activity in North Macedonia. According to North Macedonia, its regulatory framework is harmonised with the EU *acquis* on insurance mediation, namely Directive 2002/92/EC (Insurance Mediation Directive). However, this Directive has been replaced by Directive (EU) 2016/97 on insurance distribution with effect of 1 July 2018. North Macedonia plans to further align its legal and regulatory system with the provisions of Directive (EU) 2016/97, and the Delegated Regulations 2021/1257 and 2017/2358 on insurance distribution through amendments to the “Insurance Supervision Law” by the end of 2024.

In terms of administrative capacity, the Insurance Supervision Agency is the independent regulatory body responsible to safeguard the interests of the policyholders and to promote the fair and efficient functioning of the insurance market. Its governing body is represented by the Council of Experts (5 members, 3 executives and 2 non-executives) and it currently employs 33 people.

### b. Commission Assessment

National legislation is **partially aligned** with the EU *acquis* on insurance distribution.

## II.E. OCCUPATIONAL PENSIONS

### a. Country Presentation

Regarding *occupational pensions*, the country’s regulatory framework is partially aligned with Directive 2016/2341 on the activities and supervision of institutions for occupational retirement provision (the “IORP II”). Additionally, the country’s legislation is not aligned with the EU *acquis*

in the area of cross-border activities.

Full alignment is foreseen at the latest by the time of the country's accession to the European Union.

The Agency for Supervision of Fully Funded Pension Insurance (MAPAS) is the regulatory and supervisory body that protects the interests of pension fund members, builds public awareness and stimulates the development of fully funded pension insurances. MAPAS has currently 29 employees, but North Macedonia is planning to increase and improve its administrative capacity in the future.

#### **b. Commission Assessment**

National legislation is **partially aligned** with the EU *acquis* on the activities and supervision of institutions for occupational retirement provision.

### **II.F. INSURANCE ACCOUNTS**

#### **a. Country Presentation**

Regarding *insurance accounts*, the regulatory framework of North Macedonia achieves a high level of alignment with Council Directive 91/674/EEC on the annual accounts and consolidated accounts of insurance undertakings.

In terms of administrative capacity, the Insurance Supervision Agency is the independent regulatory body responsible to safeguard the interests of the policyholders and to promote the fair and efficient functioning of the insurance market. Its governing body is a Council of Experts (5 members, 3 executives and 2 non-executives) which currently employs 33 people.

#### **b. Commission Assessment**

North Macedonia has a **high level of alignment** on the annual accounts and consolidated accounts of insurance undertakings.

### **II.G. SUMMARY OF FINDINGS – INSURANCE AND OCCUPATIONAL PENSIONS**

Overall, North Macedonia has a **partial level of alignment** with the EU *acquis* in the field of insurance and occupational pensions.

North Macedonia has a **high level of alignment** with the Solvency I regime and with the EU *acquis* on the annual accounts and consolidated accounts of insurance undertakings.

National legislation is **partially aligned** with the EU *acquis* on sustainability factors, risks and preferences, on insurance distribution, on insurance against civil liability in respect of the use of motor vehicles, and the enforcement of the obligation to insure against such liability and on the activities and supervision of institutions for occupational retirement provision.

North Macedonia is **not yet aligned** with Solvency II regime.

The administrative and institutional capacity of North Macedonia will need to be strengthened further to account for the expanding responsibilities that the EU *acquis* entails.

### III. FINANCIAL MARKET INFRASTRUCTURE

#### III.A. SETTLEMENT FINALITY

##### a. Country Presentation

Regarding *settlement finality*, the country’s legal framework is partially aligned with Directive 98/26/EC on settlement finality in payment and securities settlement systems (the “Settlement Finality Directive – SFD”). The “Law on Payment Services and Payment Systems” implements the relevant EU provisions only with regard to settlement finality in payment systems. The Law includes provisions dealing with types of participants in the payments systems, execution of transfer orders and netting in case of bankruptcy, insolvency proceedings and protection of the rights of holders of collateral. The provisions related to securities settlement systems will be implemented through the law that is currently under negotiation and expected to be adopted during 2024.

The National Bank of North Macedonia, and specifically the Payment Systems Department and the IT Department, is the competent authority and it determines the payment systems the settlement finality rules apply to.

##### b. Commission Assessment

National legislation is **partially aligned** with the EU *acquis* on settlement finality in payment and securities settlement systems and on improving securities settlement in the European Union and on central securities depositories.

#### III.B. FINANCIAL COLLATERAL

##### a. Country Presentation

Regarding *financial collateral*, the country’s current regulatory framework is in material aspects not aligned with Directive 2002/47/EC on financial collateral arrangements (the “Financial Collateral Directive”). Law No. 84/08 “On Financial Collateral” governs all cases of financial collateral agreements in North Macedonia. Currently, financial collateral agreements are to be concluded in writing, duly notarised and registered based on the type of collateral, a requirement which contradicts Article 3(1) of Directive 2002/47/EC.

North Macedonia has recently proposed amendments to the law on Financial Collateral (Official Gazette no. 84/08), expected to be adopted in the first half of 2024. The new draft law on financial collateral is currently being drafted in order to ensure full alignment with Directive 2002/47/EC. The law is in inter-institutional consultation and the expected date of adoption is the first half of 2024.

##### b. Commission Assessment

North Macedonia is not yet aligned with the EU *acquis* on financial collateral arrangements. Proposed amendments to the law on financial collateral seem partially compliant assuming the current requirements on notarisation of a financial collateral agreement are removed. Based on the information provided at this time, the Commission is not able to judge whether the new law is aligned with Directive 2002/47/EC in all material aspects.

### III.C. CENTRAL SECURITIES DEPOSITORIES

#### a. Country Presentation

Regarding central securities depositories, the “Law on Securities” – together with the by-laws adopted by the Securities Exchange Commission and other relevant laws – govern the authorisation process and operation of central securities depositories in North Macedonia. The current legislative framework governing securities settlement is partially aligned with Regulation (EU) No 909/2014 (the “Central Securities Depositories Regulation – CSDR”). North Macedonia has to date not aligned with several delegated and implementing acts, notably on settlement discipline due to the relatively small size of its domestic capital market and the limited number of traded securities. Moreover, the current legislation is not aligned with Regulation (EU) 2022/858 on a pilot regime for market infrastructures based on distributed ledger technology.

The “Law on Financial Instruments” and the “Law on Prospectus and Issuers Transparency” will be the key pieces of legislation that regulate capital markets. The laws are expected to be adopted by the end of 2024.

The domestic Central Securities Depository is a joint stock company and works on a for-profit basis. Currently, the Central Securities Depository employs 18 people. North Macedonia is expecting to upgrade the capacity of the Depository in the medium term, in parallel with the approval and entry into force of the new laws on capital markets. Significant investments will be necessary to upgrade the overall system and to draft new by-laws. Over the long-term the objective remains for the domestic CSD to follow the relevant EU legislation.

#### b. Commission Assessment

North Macedonia is **not yet aligned** with the EU *acquis* on Central Counterparties.

### III.D. SECURITIES FINANCING TRANSACTIONS

#### a. Country Presentation

Regarding *securities financing transactions*, the Law on Securities – together with the by-laws adopted by the Securities Exchange Commission and other relevant laws – govern STFs in North Macedonia. National legislation has so far not been aligned with Regulation (EU) 2015/2365 (the Securities Financing Transactions Regulation – SFTR). This is due to the fact that the country has not yet developed a market for derivative instruments and there are no transactions for which the settlement has to be done through a central counterparty. North Macedonia aims to align with Regulation (EU) 2015/2365 by 2028.

#### b. Commission Assessment

North Macedonia is **not yet aligned** with the EU *acquis* on the transparency requirements of securities financing transactions.

### III.E. OTC DERIVATIVES, CENTRAL COUNTERPARTIES AND TRADE REPOSITORIES

#### a. Country Presentation

Regarding *OTC Derivatives, Central Counterparties and Trade Repositories*, the country’s legal and regulatory framework is not aligned with Regulation (EU) No 648/2012 on OTC Derivatives,

Central Counterparties and Trade Repositories (the “European Market Infrastructure Regulation – EMIR”), nor with other relevant Regulations in the EU *acquis*. This is partly explained by the simple structure of the domestic market and securities, as only bonds and shares are traded and there is no developed market for derivatives or a CCP. Alignment with Regulation (EU) No 648/2012 and the relevant delegated and implementing instruments is planned by 2030. Due to the complexity of the legislation, North Macedonia requests technical assistance to support alignment.

The “Law on Securities” and the corresponding Regulations and Guidelines adopted on the basis of this law are implemented by the Capital Market Supervision Department in the Securities and Exchange Commission. The Department employs 7 people. Considering the upcoming work to ensure alignment with the EU *acquis* on clearing and related activities, North Macedonia expects to hire 4 additional people over the next 3 years.

#### **b. Commission Assessment**

North Macedonia is **not yet aligned** with the EU *acquis* on OTC Derivatives and Trade Repositories.

### **III.F. SUMMARY OF FINDINGS – FINANCIAL MARKET INFRASTRUCTURE**

North Macedonia has **a low level of alignment** with the EU *acquis* in the field of financial market infrastructure. Moreover, the country needs to reinforce administrative capacities in this area, both from a qualitative and quantitative viewpoint.

National legislation is **partially aligned** with the EU *acquis* on settlement finality in payment and securities settlement systems and on improving securities settlement in the European Union and on central securities depositories.

North Macedonia is **not yet aligned** with the EU *acquis* on the transparency requirements of securities financing transactions and of reuse, on financial collateral arrangements (proposed amendments to the law on financial collateral seem partially compliant assuming the current requirements on notarisation of a financial collateral agreement are removed). Based on the information provided at this time, the Commission is not able to judge whether the new law is aligned with Directive 2002/47/EC in all material aspects) and on OTC Derivatives, Central Counterparties and Trade Repositories.

North Macedonia must take the necessary steps, including providing adequate trainings and possibly carrying out staff recruitment, to reinforce administrative capacities.

## **IV. SECURITIES MARKETS AND INVESTMENT SERVICES**

### **IV.A. MARKETS IN FINANCIAL INSTRUMENTS**

#### **a. Country Presentation**

Regarding markets in financial instruments, legislation on financial instruments, namely the “Law on Securities” and accompanying legal provisions, is partially aligned with Directive 2014/65/EU, i.e. MiFID II.

North Macedonia intends to achieve full alignment with the EU *acquis* by the first half of 2024 through the adoption on the Law on Financial Instruments, which will repeal and replace the current Law on Securities. North Macedonia expressed it would need technical assistance to draft secondary legislation to the Law on Financial Instruments.

The Securities and Exchange Commission is the competent authority in charge of the implementation of the Law on Securities and will participate in the adoption of the relevant by-laws.

North Macedonia is not aligned with the Markets in Financial Instruments Regulation (MiFIR).

#### **b. Commission Assessment**

National legislation is **partially aligned** with the EU *acquis* on markets in financial instruments.

### **IV.B. MARKET ABUSE**

#### **a. Country Presentation**

Regarding market abuse, national legislation is designed to have a high level of alignment with the EU *acquis* on market abuse.

Full alignment with the EU *acquis* is foreseen first half of 2024 through the adoption on the “Law on Financial Instruments”, which will repeal and replace the current “Law on Securities”,

The Securities and Exchange Commission is the competent authority for the implementation of the “Law on Securities” and adopts relevant by-laws.

#### **b. Commission Assessment**

North Macedonia has a **low level of alignment** with the EU *acquis* on market abuse.

### **IV.C. BENCHMARKS**

#### **a. Country Presentation**

Regarding *benchmarks*, national legislation is not aligned with the EU *acquis* on benchmarks. There are no administrators for the provision of a benchmark and no index providers in North Macedonia. North Macedonia is fully committed to aligning with the Benchmark Regulation. In terms of timeline, North Macedonia expects to achieve full alignment with the *acquis* on benchmarks at the latest by 2030.

The “Law on Securities” and the corresponding Regulations and Guidelines adopted on the basis of this law are implemented by the Capital Market Supervision Department.

#### **b. Commission Assessment**

North Macedonia is **not yet aligned** with the EU *acquis* on benchmarks.

### **IV.D. ALTERNATIVE INVESTMENT FUND MANAGERS**

#### **a. Country Presentation**

Regarding *alternative investment fund managers*, the country’s legislation (i.e. the “Law on Investment Funds”) is not aligned with the EU *acquis* on Alternative Investment Fund Managers.

However, North Macedonia submits that there are no impediments to alignment and that the “Law

on Alternative Investment Funds” is currently being drafted for submission to the government by end 2024. Full alignment with the EU *acquis* is planned in the medium term, and certainly before the time of accession.

The “Law on Investment Funds” and the corresponding Regulations and Guidelines adopted on the basis of this law are implemented by the Capital Market Supervision Department.

#### **b. Commission Assessment**

North Macedonia is **not yet aligned** with the EU *acquis* on alternative investment fund managers.

### **IV.E. PROSPECTUSES**

#### **a. Country Presentation**

Regarding *prospectuses*, the country’s “Law On Securities”, together with the relevant by-laws, are partially aligned with the EU *acquis* on prospectuses. However, North Macedonia submits that there are no impediments to full alignment and that the “Law on Prospectuses and Transparency of Security Issuers” is currently being drafted for adoption first half of 2024. Full alignment with the EU *acquis* is planned in the medium term, and certainly before the time of accession.

The institutional framework relating to prospectuses is composed of the Ministry of Finance, which is the institution authorised to propose the relevant legislation, and of the Securities and Exchange Commission of North Macedonia, which participates in the preparation of the relevant legislation, adopts the implementing bylaws and enforces the legal provisions.

#### **b. Commission Assessment**

National legislation is **partially aligned** with the EU *acquis* on prospectuses.

### **IV.F. UCITS**

#### **a. Country Presentation**

Regarding UCITS, relevant legislation pertaining to the Collective Investment Undertakings’ market is implemented through the Law On Investment Funds, as well as secondary legislation. Legislation is broadly aligned with the EU *acquis* and, in particular, with Directive 2009/65/EC (UCITS). However, rules on remuneration policies and practices laid down in Article 14a UCITS are have no equivalent provisions in domestic legislation. National authorities took note and plan to introduce these obligations through a piece of secondary legislation to be adopted by the Securities Commission.

The institutional framework relating to undertakings for collective investment in transferable securities is composed of the Ministry of Finance, which is the institution authorised to propose the relevant legislation, and of the Securities and Exchange Commission of North Macedonia. The Commission adopts secondary legislation for the implementation of the Law, maintains the register of investment fund management company for open-end and closed-end investment funds and the register for investment funds. The Commission supervises the operations investment fund management company for open-end and closed-end investment funds, investment funds and depository banks.

Regarding *cross-border distribution of UCITS*, national legislation (i.e. the Law on Investment Funds) is not aligned with the EU *acquis* in this area. As regards cross-border distribution of

UCITS, full alignment with the EU *acquis* is planned in the long term, and certainly before the time of accession.

The institutional framework relating to the cross-border distribution of UCITS is composed of the Ministry of Finance, which is the institution authorised to propose the relevant legislation, and of the Securities and Exchange Commission of North Macedonia. The Securities and Exchange Commission participates in the preparation of the legislation and prepares the implementing by-laws. Additionally, the Securities and Exchange Commission supervises the implementation of the Law on the Investment Funds and supervises the investment funds themselves.

#### **b. Commission Assessment**

North Macedonia is **not yet aligned** with the EU *acquis* on the cross-border distribution of UCITS.

### **IV.G. PAYMENT ACCOUNTS**

#### **a. Country Presentation**

Regarding *payment accounts*, the legal and regulatory framework, namely the “Law on Payment Services and Payment Systems” is fully aligned with the requirements of Chapter II of Directive 2014/92/EU on the comparability of fees related to payment accounts, payment account switching and access to payment accounts with basic features (the “Payment Accounts Directive – PAD”). Bylaws adopted by the National Bank of North Macedonia are fully aligned with the relevant Union Delegated Regulations, namely Delegated Regulation 2018/32, Delegated Regulation 2018/33 and Delegated Regulation 2018/34. Yet, some provisions will apply only upon the country’s accession to the EU. As regards the other Chapters of PAD, North Macedonia affirmed that PAD has been adopted in its entirety, however no further details were given. National rules aligned with Chapter IV of PAD is in force from 1 January 2023 and national rules aligned with Chapter III of PAD will apply as of 19 December 2023.

The institutional framework is represented by the National Bank of North Macedonia, namely by its Payment System Department and by its Consumer Protection and Financial Education Department.

#### **b. Commission Assessment**

North Macedonia has a **high level of alignment** with the EU *acquis* on the comparability of fees related to payment accounts, payment account switching and access to payment accounts with basic features.

### **IV.H. MORTGAGE CREDIT**

#### **a. Country Presentation**

Regarding *mortgage credit*, national legislation (Consumer protection law in consumer loan agreements) is not aligned with Directive 2014/17/EU on credit agreements for consumers relating to residential immovable property (the Mortgage Credit Directive – MCD). North Macedonia confirmed that the national legislation does not cover mortgage and housing loans.

By 2025, North Macedonia will prepare a new law to fully align with Directive 2014/17/EU (including the provisions on freedom of establishment and freedom to provide services by credit intermediaries (passporting)). Moreover, by 2024 North Macedonia plans to adopt a new law on

the institution of a financial ombudsman and, , the rulebook on the manner of supervision of financial companies.

The Financial System Department at the Ministry of Finance monitors the legislation adopted by the European Union that is relevant for the operation of the financial system, with the aim of a timely alignment of the country's domestic legislation. While a total of 20 people are employed in the Financial System Department.

The National Bank of North Macedonia supervises the operation of banks, including the approval of housing loans, whereas the Ministry of Finance supervises the operation of financial companies, including the approval of housing loans.

#### **b. Commission Assessment**

North Macedonia is **not yet aligned** with the EU *acquis* on credit agreements for consumers relating to residential immovable property.

### **IV.I. SUMMARY OF FINDINGS – SECURITIES MARKETS AND INVESTMENT SERVICES**

North Macedonia has a **high level of alignment** with the EU *acquis* on the comparability of fees related to payment accounts, payment account switching and access to payment accounts with basic features.

National legislation is **partially aligned** with the EU *acquis* on markets in financial instruments, on prospectuses and on coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS).

North Macedonia has a **low level of alignment** with the EU *acquis* in the field of securities markets and investment services, and market abuse and MiFID II. The capital market is small, not-well developed.

North Macedonia is **not yet aligned** with the EU *acquis* on benchmarks, on alternative investment fund managers, on the cross-border distribution of UCITS and on credit agreements for consumers relating to residential immovable property, and with MIFIR.

Further administrative capacity building is needed to account for increasing responsibilities and future obligations deriving from the implementation of the EU *acquis*. In addition to a possible need for reinforcement in staff numbers, the country's institutions need to make further efforts to build upon the existing professional quality of their employees and continuously increase their technical expertise through targeted trainings.

## **V. SUSTAINABLE FINANCE**

### **a. Country presentation**

Regarding the Taxonomy Regulation, North Macedonia is not aligned with Regulation (EU) 2020/852.

There are no general or specific impediments for North Macedonia to align with respective EU regulation on sustainable finance upon its accession to the EU.

North Macedonia is not aligned with the requirements of Regulation (EU) 2019/2089 as regards

EU Climate Transition Benchmarks, EU Paris-aligned Benchmarks and sustainability-related disclosures for benchmarks.

There are no general or specific impediments for North Macedonia to align with respective EU regulation on sustainable finance upon its accession to the EU. North Macedonia indicated that it would need technical assistance in this area.

#### **b. Commission assessment**

North Macedonia is **not yet aligned** with the EU *acquis* on EU taxonomy, or on EU Climate Transition Benchmarks, EU Paris-aligned Benchmarks and sustainability-related disclosures for benchmarks.

### **C. SUMMARY OF FINDINGS – SUSTAINABLE FINANCE**

North Macedonia is **not aligned** with the EU *acquis* on **sustainable finance**.

## **VI. FIGHT AGAINST CORRUPTION – FINANCIAL SERVICES**

### **a. Country presentation**

The legislation of North Macedonia qualifies corruption as a serious crime, including in its cross-border dimension. North Macedonia has ratified several international conventions against corruption and adopted specific legislation on the prevention of corruption and money laundering, including in the field of financial services.

Relevant primary legislation and strategic documents in North Macedonia include – among other provisions – the Law on Prevention of Corruption and Conflict of Interest, the National Strategy for Prevention of Corruption and Conflict of Interest 2021-2025, as well as the laws that regulate these matters in the domain of financial services.

North Macedonia plans to amend the National Strategy for Prevention of Corruption and Conflict of Interest and to update its national framework to the ISO 37001 standard. Additionally, North Macedonia will implement a special software solution to streamline the enforcement against corruption.

The institutions tasked with the fighting of corruption vis-à-vis financial services are – in their respective domains – the Ministry of Finance, the Insurance Supervision Agency, the National Bank of the Republic of North Macedonia, the Deposit Insurance Fund, the Securities and Exchange Commission and the Agency for supervision of Fully Funded Pension Insurance. While financial services are not among the sectors identified by the State Commission for Prevention of Corruption (“SCPC”) as most prone to corruption, it points out the critical importance of the selection of management of the financial sector regulatory and supervisory bodies.

#### **b. Commission assessment**

The existence of specific anti-corruption measures in the main bodies dealing with financial services and the enforcement of such measures, in addition to the overall anti-corruption efforts of North Macedonia, represent a positive sign that sets the country in the path towards the prevention of corruption in the field of banking and financial services.

Focusing on implementation of relevant domestic legal provisions as well as international conventions should be a priority for North Macedonia going forward.

**C. SUMMARY OF FINDINGS – FIGHT AGAINST CORRUPTION**

North Macedonia has anti-corruption structures and measures in place to prevent corruption, it should use them to the fullest.

## J) CHAPTER 28 - CONSUMER AND HEALTH PROTECTION

The EU *acquis* in the area of **consumer protection** covers legislation that protects consumers' economic interests and rights, and in relation to product safety, dangerous imitations and liability for defective *products*. It also comprises of the Safety Gate , the EU's rapid alert system. EU *acquis* and standards also cover cooperation and enforcement of consumer protection laws, the pricing of products, unfair contract terms and contracts for the sale of goods, price indications, doorstep selling, distance selling, distance marketing of financial services, consumer credit, misleading and comparative advertising, unfair commercial practices, timeshare, package travel, the supply of digital content and digital services, alternative dispute resolution, and actions for the protection of the collective interests of consumers.

The EU *acquis* in the area of **public health** deals with issues related to tobacco control, medicines for human and veterinary use, medical devices, cosmetic products, communicable diseases, blood, tissues, cells and organs, patients' rights in cross-border healthcare, eHealth, and also with mental health, drug abuse prevention, health inequalities, health information, nutrition, antimicrobial resistance, alcohol-related harm reduction, cancer screenings, healthy environments, safety statistics, and rare diseases.

### I. CONSUMER PROTECTION

#### I.A. HORIZONTAL ASPECTS

##### a. Country presentation

Consumer policy in North Macedonia is based on a wide variety of relevant laws and on the national law on consumer protection. The responsible bodies are the Ministries of Economy (MoE), of Justice, of Finance (MoF), and of Transport and Communications, and the National Bank (NB). Relevant regulatory bodies include the Energy and Water Services Regulatory Commission of the Republic of North Macedonia ERC (RKE), the Agency for Electronic Communications AEC (AEK), the Postal Agency PA (AP), and the Insurance Supervision Agency ISA (ASO). Implementation of consumer policy and legislation is ensured by the State Market Inspectorate (SMI), the State Technical Inspectorate (STI), the State Sanitary and Health inspectorate (SSHI); The Food and Veterinary Agency (FVA) is responsible for food safety and veterinary health. Where necessary the courts also have a role to play. North Macedonia has expressed its interest the European Commission to join the *EU consumer protection programme*, under the EU Single Market Programme.

North Macedonia adopted legislation in 2023 designed to be aligned with Regulation 2017/2394 (EU) on *co-operation between national authorities responsible for consumer protection*. MoE is the responsible body. National legislation is also not yet aligned with Directive (EU) 2020/1828 on *representative actions for the protection of the collective interests of consumers*. Alignment is foreseen by the end of 2026. North Macedonia adopts a new consumer protection programme every other year. It recognises that it needs to reinforce its human resources and their capacities in many of the relevant bodies, and also to improve the coordination between these bodies, in order to be able to fully implement the EU *acquis*.

North Macedonia has a National Consumer Protection Council (NCPC), established under the national law on consumer protection, with regard to Commission Decision 2009/705/EC on setting up a European Consumers Consultative Group. North Macedonia requested that that the consumer's organisation of North Macedonia be able to join the EU Consumer Policy Advisory Group, though it acknowledges that currently this is limited to EU Member States. There are several NGOs working on consumer protection at national

and local levels. Chambers of commerce also play a role in consumer protection in North Macedonia, as do local government authorities.

#### **b. Commission assessment**

National legislation is partly aligned with the horizontal EU *acquis* on consumer protection. There are a large number of state bodies involved in consumer protection. North Macedonia needs to reinforce the human resources and their capacities in many of the relevant bodies, and also to improve the coordination between these bodies, in order to be able to fully implement the EU *acquis*. North Macedonia has established a consumer protection council, as foreseen by the relevant EU *acquis*.

### **I.B. PRODUCT SAFETY RELATED ISSUES**

#### **a. Country presentation**

National legislation consists of Law 236/22 on Consumer Protection, Law 18/01 on Obligations, Law 157/10 on Food Safety, Law 55/07 on Cosmetic Product Safety, and Law 302/20 on General Product Safety. This is aligned at a high level with Directive 2001/95/EC on *General Product Safety* (which is replaced by the general Product Safety Regulation (EU) 2023/988 as of 13 December 2023), deviations from the EU *acquis* are relevant to definitions, where the definition in national law covers both “product” and “goods”, rather than only “product”. North Macedonia has a high level of alignment with the *Dangerous Imitations* Directive 87/357/EEC (also replaced by the general Product Safety Regulation (EU) 2023/988 as of 13 December 2023), apart from the aspects pertaining to EU Member States and the Council. MoE is the responsible body, SSHI is the implementing body.

With regard to the EU rapid alert system for dangerous non-food products (Safety Gate) full alignment with the relevant legal requirements is foreseen by the time of accession. The Ministry of Economy (MoE) is the body with overall responsibility for product safety. Implementation is ensured by SMI, which has been identified as the body that, after accession, will inform the European Commission about products that pose a risk. SMI has 148 market inspectors, 6 product safety inspectors, and 99 other employees, while FVA has 361 employees, including 87 veterinary inspectors and 76 food inspectors. SSHI as a total of 41 inspectors. In 2022 SMI took over 30 products off the market, having ensured 519 market surveillance inspections.

#### **b. Commission assessment**

National legislation has a **high level of alignment** with the EU *acquis* on *general product safety*, apart from some definitions, and with the EU *acquis* on dangerous imitations. It is partly aligned with the the EU rapid alert system for dangerous non-food products (Safety Gate). Market surveillance is being implemented, and dangerous products are being withdrawn from the market as a result. Market surveillance resources are not sufficient.

### **I.C. NON-SAFETY RELATED ISSUES**

#### **a. Country presentation**

The legislation of North Macedonia, Law 236/22 on Consumer Protection, has a high level of alignment with Directive 2019/2161/EU on *the better enforcement and modernisation of Union consumer protection rules*.

National legislation, which consists of Law 236/22 on Consumer Protection and Law 62/04 (amended) on Tourism Activity, has a high level of alignment with Directive 2011/83/EU on *consumer rights*. . Deviations concern articles that can only be ensured by EU Member States, and also articles added or amended in the most recent update of this EU *acquis* remain to be aligned to. The MoF is the responsible body,

implementation is ensured by several relevant agencies; North Macedonia recognises that capacity building of these agencies is necessary.

The national Law on Providing Financial Services is designed to be aligned with Directive 2002/65/EC (which will be replaced by Directive 2023/2673 in 2026) on *distance marketing of consumer financial services*. The MoF is the responsible body, implementation is ensured by several relevant agencies; North Macedonia recognises that capacity building of these agencies is necessary.

National legislation, Law 236/22 on Consumer Protection, is designed to have a high level of alignment with Directive 93/13/EEC, as amended, on unfair terms in consumer contracts, apart from aspects that only apply to EU Member States and articles on reporting. MoE is the responsible body, MoE and SMI ensure implementation. North Macedonia requests that it can participate in relevant EU expert groups, it also recognises that market surveillance in this area needs to be reinforced.

Law 236/22 on Consumer Protection of North Macedonia is designed to have a high level of alignment with Directive 98/6/EC on the indication of the prices of products offered to consumers. The main areas of non-alignment concern articles that only apply to EU Member States. MoE is the responsible body, SMI ensures implementation. North Macedonia requests that it can participate in relevant EU expert groups, it also recognises that market surveillance in this area needs to be reinforced.

In regard to Directive 2005/29/EC on unfair business-to-consumer commercial practices, Directive (EU) 2019/771 on the sale of goods, national legislation, Law 236/22 on Consumer Protection, is designed to be aligned to the EU acquis apart from articles relevant to EU Member States. MoE is the responsible body, SMI ensures implementation. North Macedonia requests that it can participate in relevant EU expert groups, it also recognises that market surveillance in this area needs to be reinforced. National legislation, under the Law 236/22 on Consumer Protection and the Law 24/07 (amended) on State Market Inspectorate, is not yet aligned to Directive 2006/114/EC on misleading and comparative advertising. MoE is the responsible body in this area, SMI ensures implementation.

The legislation of North Macedonia, Law 236/22 on Consumer Protection, is **designed to be aligned** with Directive 2019/770/EU on certain aspects concerning contracts for the supply of digital content and digital services and to Directive 2019/771(EU) on contracts for the sale of goods apart from articles relevant to EU Member States. MoE is the responsible body for both of these sectors, SMI ensures implementation. North Macedonia requests that it can participate in relevant EU expert groups, it also recognises that market surveillance in this area needs to be reinforced.

Law 236/22 on Consumer Protection has a **high level of alignment** with Directive 2008/122/EC on timeshare, long-term holiday product, resale and exchange contracts. the main areas of non-alignment concern aspects relevant to EU Member States, and several annexes remain to be aligned to via implementing legislation which are foreseen to be adopted later in 2024. Macedonia requests that it can participate in relevant EU expert groups, however there are none, it also recognises that market surveillance in this area needs to be reinforced. On package travel and linked travel arrangements, North Macedonia has not yet aligned its legislation to Directive (EU) 2015/2302. Alignment is foreseen to be ensured during 2024. MoE is the responsible body for both of these sectors, SMI ensures implementation.

The national legislation of North Macedonia, which consists of Law 51/11 (amended) on Consumer Protection in Consumer Loan Agreements, Law 67/07 (amended) on Banks, Law 158/10 (amended) on Financial Companies, Law 04/02 (amended) on Leasing, and Law 18/01 (amended) on Obligation Relations, is designed to be aligned to Directive 2008/48/EC on credit agreements, which will be repealed by the Consumer Credit Directive 2023/2225 in 2026), via its laws on consumer protection in consumer loan agreements, law on banks, law on financial companies, law on leasing, and law on obligation relations

and relevant implementing legislation. Supervision of banks is ensured by the National Bank, which compiles lists of relevant information, supervision of consumer credit lenders is also ensured by the SMI, while the MoF ensures supervision of financial companies and financial leasing providers. In July 2023, amendments to the Law on Financial Companies entered into force, designed to give greater protection to consumers and enhance the supervisory role of the Ministry of Finance has been strengthened.

Law 90/22 on Payment Services and Payment Systems of North Macedonia has a **high level of alignment** with Directive 2014/92/EC on comparability of fees relating to payment accounts, payment account switching and access to payments accounts and access to payment accounts with basis features. Implementing legislation has been prepared in order to align to Chapter IV, which was adopted in April 2022 and entered into force in January 2023.

North Macedonia has **not yet aligned** its legislation to Directive 2013/11/EU on alternative dispute resolution for consumer disputes, or to Regulation 524/2013(EU) on online dispute resolution for consumer disputes, full alignment to both is foreseen by the end of 2025.

#### **b. Commission assessment**

In the area of non-safety related issues the legislation of North Macedonia is **aligned** with the EU *acquis* on distance marketing of consumer financial services, on unfair business-to-consumer commercial practices, on the sale of goods, on contracts for the supply of digital content and digital services, on contracts for the sale of goods, and on credit agreements.

The legislation of North Macedonia has a **high level of alignment** with the EU *acquis* on the better enforcement and modernisation of EU consumer protection rules, on consumer rights, , on timeshare, long-term holiday product, resale and exchange contracts, on unfair terms in consumer contracts, on the indication of the prices of products offered to consumers, on comparability of fees relating to payment accounts, payment account switching and access to payments accounts and access to payment accounts with basis features.

North Macedonia has **not yet aligned its legislation to the EU *acquis*** on package travel and linked travel arrangements, on alternative dispute resolution for consumer disputes, or on online dispute resolution for consumer disputes.

There are currently insufficient resources allocated to several of these areas, North Macedonia should build up its capacity in those areas.

#### **I.D. SUMMARY OF FINDINGS – CONSUMER PROTECTION**

In the area of non-safety related issues the legislation of North Macedonia is **designed to be aligned** with the EU *acquis* on **distance marketing of consumer financial services**, on **unfair business-to-consumer commercial practices**, on **certain aspects of the sale of goods**, on **certain aspects concerning contracts for the supply of digital content and digital services**, on **contracts for the sale of goods**, and on **credit agreements**.

North Macedonia has a **high level of alignment** with the EU *acquis* on **general product safety**, and on dangerous imitations, and on **the better enforcement and modernisation of Union consumer protection rules**, on **consumer rights**, , on **timeshare, long-term holiday product, resale and exchange contracts**, **unfair terms in consumer contracts**, and on **the indication of the prices of products offered to consumers**, on **comparability of fees relating to payment accounts**, **payment account switching and access to payments accounts** and **access to payment accounts with basis features**.

With regard to *Safety Gate*, it is **partly aligned** with the relevant legal requirements.

North Macedonia has **not yet aligned its legislation** with the EU *acquis* on **co-operation between national authorities responsible for consumer protection**, or on **representative actions for the protection of the collective interests of consumers**. It needs to reinforce its human resources and their capacities in many of the relevant bodies, and also to improve the coordination between these bodies, in order to be able to fully implement the EU *acquis*. The consumer protection system of North Macedonia is partly in line with EU consumer protection strategies and values. North Macedonia has expressed its interest to the European Commission to join the EU consumer protection programme. North Macedonia has a National Consumer Protection Council (NCPC), established under the national law on consumer protection, as foreseen in the relevant EU *acquis*. Macedonia is also **not yet aligned** to the EU *acquis* on **package travel and linked travel arrangements**, on **alternative dispute resolution for consumer disputes**, or on **online dispute resolution for consumer disputes**.

## II. PUBLIC HEALTH

### II.A. HORIZONTAL ASPECTS

#### a. Country presentation

The legal base for healthcare in North Macedonia is set out in the national constitution. The main national legislation on health is the law on healthcare, which establishes the role of the state in regard to healthcare and also the role and rights of health workers. Other relevant legislation in North Macedonia includes the law on health insurance, and several other laws on specific aspects of health.

Health insurance is compulsory for all citizens in North Macedonia. The annual national budget of the health insurance fund was 574 million euros in 2021, i.e. 4.92% of GDP. 87% of this amount was allocated to health services (24.8% for primary healthcare, 29/4% for specialist consultations, and 32.7% for hospital services). National health programmes are adopted by the government every year based on a proposal by the Ministry of Health, the 2023 programmes were allocated 5.8 million euros, funded by the state budget. The national Health 2030 strategy is being implemented, and a reform of primary healthcare is ongoing.

North Macedonia is already an observer to the EU Health Security Committee, and a signatory and user of the EU Joint Procurement agreement for medical countermeasures. The responsible ministry for health is the Ministry of Health.

North Macedonia applied to join the EU4Health Programme 2021-2027 in May 2023.

#### b. Commission assessment

The legal base for healthcare in North Macedonia is enshrined in the constitution, and health insurance is compulsory for all citizens in North Macedonia. The national Health 2030 strategy is being implemented, and a reform of primary health care is foreseen. North Macedonia is already an observer to the EU Health Security Committee, and a signatory and user of the EU Joint Procurement agreement for medical countermeasures. The responsible ministry for health is the Ministry of Health. North Macedonia plans to join the EU4Health Programme 2021-2027, and sent an application in mid-**2023**.

### II.B. EHEALTH

#### a. Country presentation

National legislation is **not aligned** with the EU on eHealth. eHealth in North Macedonia is defined by its

laws on health care, on healthcare records, and on data protection. The responsible body in this area is the Ministry of Health. North Macedonia has a centralised eHealth tool that creates and stores health data and information in the field of the field of health. This system holds real-time data on patients, doctors, and health services, including health records, referrals, prescriptions, screening results, risk factors, allergies and intolerances, reports of adverse effects, telemedicine, dental records, and issuing certificates.

#### **b. Commission assessment**

Although national legislation is **not aligned** with the EU *acquis* on eHealth, North Macedonia has a centralised eHealth tool that creates and stores health data and health information, including real-time data on patients, doctors, health services, health records, referrals, prescriptions, screening results, risk factors, allergies and intolerances, adverse effects, telemedicine, dental records, and certificates.

### **II.C. MEDICAL PRODUCTS FOR HUMAN AND VETERINARY USE**

#### **a. Country presentation**

The relevant legislation of North Macedonia is its Law on Medicines and Medical Devices, and implementing legislation, which is partly aligned to the EU *acquis* on medical products for human use, on orphan medicines, on medicinal products for paediatric use. National legislation is not yet aligned on, advanced therapy products and on falsified medicines. Further alignment to the EU *acquis* is foreseen between 2024 and 2026, and full alignment is foreseen by 2030. The responsible authority is the Ministry of Health, while the legislation on medicinal products for human use is implemented by the national agency of medicines and medical devices, which implements all aspects apart from pricing of medicines, which is the competence of the Ministry of Health. The agency ensures marketing authorisation, approval for placing on the market, clinical trial approval, approval of variations, and reporting of adverse effects via and integrated IT system. The agency does not have sufficient capacity, and relies on external experts for assessing medicines; is not yet a member of the international pharmaceutical convention. All medicinal products for human use are recorded in a national register, which is available to the public on the agency's website. There are two laboratories for the control of the quality of medicines in North Macedonia. Most medicinal products for human use come from the EU, with authorised for placing on the market in the EU have shorter procedures for market authorisation before being placed on the national market. Medicines from non-EU countries undergo longer national procedures and laboratory analyses.

There are eight manufacturers producing medicinal products for human use in North Macedonia, two of which have certifications from EU regulators. All eight have to have a qualified professional pharmaceutical expert that ensures the quality control of the products.

There are no manufacturers of veterinary medical products in North Macedonia. North Macedonia's legal base for medicines for veterinary use is its Law on veterinary medicinal products which is partly aligned to the EU *acquis*. North Macedonia is partly aligned to the EU *acquis* on medicated animal feed. Full alignment to the EU *acquis* is foreseen to be ensured by 2025. All such products are recorded in a national register, which is available on the internet. The competent body is the food and veterinary agency.

#### **b. Commission assessment**

The legislation of North Macedonia is **partly aligned** to the EU *acquis* on medical products for human use, on orphan medicines, and on medicinal products for paediatric use. The implementing body, the national agency of medicines and medical devices, does not yet have adequate resources to implement the EU *acquis*. All medicinal products for human use are recorded in a national register, which is available to the public on the agency's website. National legislation for medicines for veterinary use is partly aligned to the EU *acquis*. All such products are recorded in a national register, which is available on the internet.

## II.D. COSMETIC PRODUCTS

### a. Country presentation

While the majority of cosmetic products are imported, there are eight manufacturers of cosmetic products in North Macedonia. The law on the safety of cosmetic products of North Macedonia, and relevant implementing legislation, is partly aligned with Regulation 1223/2009/EC on cosmetic products. It is foreseen to align to the EU *acquis* by the end of 2024. The Ministry of Health is the responsible body. The Institute for Public Health is responsible for testing and SSHI is responsible for market surveillance in this area of the EU *acquis*. North Macedonia acknowledges that resources necessary for the implementation of the EU *acquis* on cosmetic products needs to be reinforced.

### b. Commission assessment

North Macedonia is partly aligned with the EU *acquis* on cosmetic products. The resources for the implementation of the EU *acquis* on cosmetic products are not yet sufficient to implement the EU *acquis*.

## II.E. MEDICAL DEVICES

### a. Country presentation

There are 13 domestic manufacturers of medical devices in North Macedonia, mostly of specialist custom-made devices. The national legal basis is the Law 106/07 on Medicines and Medical Devices, and relevant implementing legislation. This is not aligned to Regulation 2017/745/EU on medical devices and Regulation 2017/746/EU on in vitro diagnostic medical devices (it was designed to align with previous EU *acquis* in these areas). It is foreseen to align to the current EU *acquis* by the end of 2027. The responsible body is the national agency for Medicines and Medical Devices, which is foreseen to be reorganised in order to establish specific resources to implement the revised law, also by the end of 2027. All medical devices placed on the market are recorded in a national register. There are no authorised bodies for conformity assessment of medical devices in North Macedonia; 90% of medical devices placed on the market have conformity marks issued by EU notified bodies.

### b. Commission assessment

North Macedonia is **not aligned** to the EU *acquis on medical devices or on in vitro diagnostic medical devices*. All medical devices placed on the market in North Macedonia are recorded in a national register. The responsible body is the national agency for medicines and medical devices, which needs to reinforce its resources in order to implement the EU *acquis*.

## II.F. TOBACCO CONTROL

### a. Country presentation

North Macedonia is a tobacco producing country, exporting more tobacco (by value) than it imports. Its national legislation on tobacco includes Law 98/19 (amended) on Tobacco, Tobacco Products and Related Products, Law 36/9 (amended) on Protection from Smoking, Law 184/2013 (amended) on Audio and Audio-visual Media Services, Law 16/2004 (amended) on Trade, and implementing legislation. The Law on Tobacco, Tobacco Products and Related Products is **partly aligned** to the EU *acquis* on tobacco control. Further alignment is foreseen. National legislation is designed to be **fully aligned** with the EU *acquis*, i.e. Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products, Commission Delegated Directive 2014/109/EU establishing the library of picture warnings to be used on tobacco products, Directive 2003/33/EC on the advertising and sponsorship of tobacco products, Council Recommendation 2003/54/EC on the prevention of smoking and on initiatives to improve tobacco control, Council Recommendation 2009/C 296/02 on smoke-free environments, and Directive 2010/13/EU

on the provision of audiovisual media services.

The ministries of economy, of agriculture, forestry and water management, of health, and of finance and customs are the responsible bodies. Implementation is ensured by the SIA, SMI, SSHI, the national administrative inspection, the State Educational Inspectorate, and the Scientific Institute for Tobacco, which assesses the quality of tobacco products. Reinforcement of resources in this area is foreseen. North Macedonia ratified the WHO Framework Convention on Tobacco Control (FCTC) in 2006. While North Macedonia signed the WHO Protocol to Eliminate Illicit Trade in Tobacco Products in 2014, it has not yet ratified it - this is foreseen to be done by the end of 2024.

#### **b. Commission assessment**

The legislation of North Macedonia is **partly aligned** to the EU *acquis* on tobacco control; it is designed to be fully aligned with the EU *acquis* on tobacco products. Tobacco control measures are not yet fully and consistently implemented. North Macedonia ratified the WHO Framework Convention on Tobacco Control (FCTC) in 2006. It signed the WHO Protocol to Eliminate Illicit Trade in Tobacco Products in 2014, but it has not yet ratified it.

### **II.G. BLOOD, TISSUES, CELLS AND ORGANS**

#### **a. Country presentation**

The national legislation is Law 110/2007 (amended) on Safety in Blood Supply of North Macedonia, and relevant implementing legislation. This is **partly aligned** with Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, and the relevant EU implementing legislation. Full alignment is foreseen by 2025-26. The responsible bodies are the Ministry of Health, the Health Insurance Fund, and the Institute for Transfusion Medicine, while the State Sanitary and Health Inspectorate performs inspection control. Blood donation is voluntary and is carried out through blood donation actions organised by the national Red Cross of the Republic assisted by the Institute of Transfusion Medicine, Skopje. Seven private hospitals use this blood and blood components. Blood and blood components are tested according in line with EU recommendations. The Institute for Transfusion Medicine in Skopje also performs immunological testing and compatibility testing for transplantation of organs. The national legal base is Law 37/08 (amended) on Biomedically Assisted Fertilization, and Law 47/11 (amended) on Explanting and Transplanting of Parts of Human Bodies Intended for Treatment, and relevant implementing legislation. These are partly aligned with the Directive 2004/23/EC on standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, and the relevant implementing legislation. Full alignment is foreseen by the end of 2026-27, by when a cell and tissue bank is also foreseen to be established and a regional bone marrow transplantation centre built at the clinic for haematology, which opened in January 2024. The responsible bodies are the Ministry of Health, and the health insurance fund, the Agency for Medicines and Medical Devices, SSHI and eight health institutions authorised to perform such procedures are the responsible bodies. The University Clinic for Haematology is the only institution that performs hematopoietic stem cell transplantation in the country. Immunological testing, and compatibility testing for transplantation of bone marrow are performed by the Institute for Immunobiology and Human Genetics at the Faculty of Medicine in Skopje

Law 47/11 (amended) on Explanting and Transplanting of Parts of Human Bodies Intended for Treatment and associated implementing legislation are partly aligned with the Directive 2004/23/EC of the European Parliament and the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Full alignment is foreseen by the end of 2026/27. Organ donations are free and anonymous. A date for full alignment has not yet been foreseen. The responsible body is the Ministry of Health. The Government

appoints a National Coordinator for Transplantation and his deputy, and a network of hospital transplant coordinators is established in the respective hospitals. Transplantation is performed in eight public health institutions authorised to perform such procedures.

#### **b. Commission assessment**

In the area of blood, tissues and cells, the legislation of North Macedonia is **partly aligned** with the EU *acquis* on blood, on human tissues and cells, and on human organs intended for transplantation. Systems used to test blood and blood components are designed to be implemented according to the relevant EU recommendations. Immunological testing and compatibility testing for transplantation are designed to be ensured in line with EU recommendations. Organ donations are free and anonymous.

### **II.H. COMMUNICABLE DISEASES AND HEALTH SECURITY**

#### **a. Country presentation**

The legal base of North Macedonia in regard to communicable diseases is its Law 145/12 (amended) on Health Care, Law 22/10 (amended) on Public Health, Law 66/04 (amended) on Protection of the Population Against Communicable Diseases, Law 20/09 (amended) on Health Records, Law 71/06 (amended) on Sanitary and Health Inspection, Law 25/34 and 96/00 (amended) on Health Insurance, Law 82/08 (amended) on Protection of Patients' Rights, and Law 68 and 70/04 (amended) on Waste Management, and their relevant implementing legislation. These are **partly aligned** to Regulation (EU) 2022/2371. Full alignment is foreseen by 2030. It is not fully aligned with the European Centre for Disease Prevention and Control (ECDC), but it works and coordinates regularly with ECDC, and respective national coordinators are in place.

The Ministry of Health is the responsible body, and implementation is led by the institute of public health (IPH), supported by several laboratories, and health care institutions. IPH manages the national database, collects the data, and processes it. Further alignment to EU standards is foreseen. The National strategy for control of antimicrobial resistance 2019-2023 has been implemented. North Macedonia ensures reporting on 64 communicable diseases and is in the process of making an electronic surveillance system on communicable diseases operational. Enhanced surveillance for HIV/AIDS, brucellosis, measles and rubella and other communicable diseases are in place. An alert system for early warning and detection of outbreaks has been in place since 2009. [See also information on epidemic intelligence and health emergency, and threat reporting under II.J Health Reporting].

#### **b. Commission assessment**

In the area of communicable diseases, North Macedonia is **partly aligned** to the EU *acquis* on serious cross-border threats to health and on communicable diseases. It is not fully aligned with European centre for Disease Prevention and Control (ECDC), but it works and coordinates regularly with ECDC, and national coordinators are in place. A national strategy for control of antimicrobial resistance 2019-2023 is in place, and further work will be ensured on aligning to the relevant EU standards. North Macedonia ensures reporting on 64 communicable diseases, and ensures enhanced surveillance for HIV/AIDS, brucellosis, measles and rubella and other communicable diseases. An alert system for early warning and detection of outbreaks is in place.

### **II.I. PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE**

#### **a. Country presentation**

North Macedonia is not aligned to the EU *acquis* on patient's rights in cross-border healthcare. Full alignment is foreseen by 2028, relevant capacities will be reinforced by 2030. The Ministry of Health and

the health insurance fund of North Macedonia are the competent bodies. North Macedonia has social security agreements in place that include the use of the European Health Insurance card (EHIC) with Slovenia, Czechia, Germany, Bulgaria, Luxembourg the Netherlands, Belgium, Austria, and Slovakia. It has social care agreements that do not include EHIC use with France, Hungary, Italy, Croatia, Romania, and Poland, similar agreements with Sweden and Denmark do not cover health care. The competent authorities are the Ministry of Health and social welfare, the Ministry of Labour and social policy, and the compulsory healthcare insurance fund.

#### **b. Commission assessment**

National legislation is **not aligned** to the EU *acquis* on patient's rights in cross-border healthcare, though it has relevant agreements in place with several EU Member States.

### **II.J. HEALTH INFORMATION**

#### **a. Country presentation**

North Macedonia has legislation that is **partly aligned** to the EU *acquis* on health information,(i.e. Law 39/2014) for electronic communications (Official Journal No.39/2014) and Regulation 40/2014 for minimum requirements for safety and health at work for employees related to risks from exposure to physical agents-electromagnetic fields. It has systems in place to ensure epidemic intelligence and health emergency and has an operational centre, with a 24/7 on-call system for monitoring communicable diseases and crisis situations. It provides centralised real-time information, which is used for monitoring, reporting and advising on response to outbreaks and crisis situations. North Macedonia plans to officialise a new system for real-time threat reporting and fully implement a national operational centre for crisis in the next 5-7 years.

#### **b. Commission assessment**

National legislation is **partly aligned** to the EU *acquis* on health information. Systems are in place to ensure epidemic intelligence and health emergency and it has an operational centre. This last has a 24/7 on-call system for monitoring communicable diseases and crisis situations.

### **II.K. CANCER SCREENING**

#### **a. Country presentation**

With regard to cancer, North Macedonia currently ensures screening for cervical cancer (every 3 years) and breast cancer (every 2 years) for women in respective specific age groups. For these programmes efforts are made to reach marginal and remote populations via mobile gynaecological units. A programme to ensure the screening of colon cancer is in preparation, and a pilot programme is ongoing for HPV screening. A cancer register is in place. These screening exercises are designed to be aligned to the relevant EU *acquis*. North Macedonia does not have a strategy in place for cancer control at this time, this is foreseen to be in place by the end of 2027, and to be in line with the EU beating cancer plan. The Ministry of Health is the responsible body.

#### **b. Commission assessment**

Council Recommendation of December 2003 on cancer screening is to a large extent implemented in North Macedonia. Efforts to raise awareness of early detection of breast and cervical cancer have continued and screening programmes are being started. However, further efforts are necessary to establish appropriate administrative and technical capacity-building for organisation and implementation of the National Cancer Control Plan.

## **II.L. MENTAL HEALTH**

### **a. Country presentation**

As regards mental health, there are 11 community mental health centres, and mental health departments in several hospitals in North Macedonia. North Macedonia is implementing its mental health strategy and action plan 2018-2025 in cooperation with WHO and the World Bank. A strategy for child and adolescent mental health is in development, as is a suicide prevention programme.

### **b. Commission assessment**

In the area of mental health, North Macedonia is implementing its mental health strategy and action plan 2018-2025 in cooperation with WHO and the World Bank.

## **II.M. HEALTHY ENVIRONMENTS**

### **a. Country presentation**

The legislation of North Macedonia is designed to be aligned with the EU *acquis* on electromagnetic fields. The competent bodies are the agency for electronic communications, the state labour inspectorate, and there are two laboratories able to measure non-ionising radiation emissions. The agency for electronic communications ensures regular measurements of the values of non-ionising radiation originating from public electronic communications networks and has also ensured measurements on other sectors [*see also above, under health information*]

### **b. Commission assessment**

In the area of healthy environments, the legislation of North Macedonia is **designed to be aligned** with the EU *acquis* on electromagnetic fields.

## **II.N. RARE DISEASES**

### **a. Country presentation**

On rare diseases, North Macedonia's legal framework include its Law 145/12 (amended) on Health Care, Law 22/10 (amended) on Public Health, Law 20/09 96/00 (amended) on Health Insurance, Law 82/08 on patients' rights, Law 20/09 (amended) Law 82/08 (amended) on Protection of Patients' Rights, Law 20/09 (amended) on Personal Data, and Law 106/2007 (amended) on medicines and on medical devices. The Ministry of Health is the responsible body. On rare diseases, there is a national expert Commission on rare diseases as an advisory body, and a rare diseases programme which ensures the purchases of medicinal products for 48 rare disease pathologies. A strategy for rare diseases is foreseen to be adopted by the end of 2024, and the budget on this is foreseen to reinforced, as a register of rare disease and increased cooperation with NGOs and patient associations.

### **b. Commission assessment**

North Macedonia does not yet have a strategy in place on rare diseases. There is a national expert commission advisory body on this, and a rare diseases programme which ensures the purchases of medicinal products for 48 rare disease pathologies.

## **II.O. HEALTH INEQUALITIES**

### **a. Country presentation**

As regards health inequalities, the constitution of North Macedonia establishes the right to healthcare for

all. The Law on Healthcare establishes the principle of availability of healthcare, which is achieved by providing adequate healthcare that is geographically, physically and economically accessible to all citizens, while the law on health insurance establishes mandatory health insurance for all. North Macedonia stated that it ensures access to healthcare to people from rural and remote areas, the poorest members of society, prisoners, for persons with disabilities, and there is an annual programme for people living with HIV/AIDS, LGBTIQ healthcare and for the healthcare of Roma. There is a national action plan for the implementation of the national Roma strategy that includes (*inter alia*) improving access to integrated, quality, preventive and curative health services, with a focus on the extension of Roma life expectancy, and reducing the risk of diseases and the mortality rate among Roma. In the short term there is a plan to ensure the employment of Roma health mediators, while medium-term plans include improving the availability of health services for Roma women and children.

#### **b. Commission assessment**

In the area of health inequalities, the constitution of North Macedonia establishes the right to health care for all. The legal base establishes the principle of availability of health care, and mandatory health insurance for all. North Macedonia ensures access to health care, to people from rural areas, the poor, prisoners, and for persons with disabilities. There is an annual programme for people living with HIV/AIDS, LGBTIQ health care and for health care of Roma.

### **II.P. HEALTHY LIFESTYLES - ALCOHOL AND DRUG ABUSE PREVENTION**

#### **a. Country presentation**

In the area of drug abuse prevention, national legislation is **partly aligned** to the EU *acquis*. The ministries of health, labour and social policy, of education and science, the institute of public health, public and private healthcare bodies, and the food and veterinary agency, and the agency for sports and youth, are the responsible bodies, in cooperation with NGOs. There is an issue of increased drug use by younger people. The national youth strategy 2016-2025 includes actions designed to reduce risky behaviour among young people due to the use of drugs and other psychoactive substances.

North Macedonia has a project aimed at educating young people on the consequences of the use of tobacco, alcohol, and drugs. A programme for the treatment of children who use drugs and amendments to the law on the control of narcotic drugs and psychotropic substances are both foreseen to be adopted by the end of 2024. There are also 13 treatment centres for drug users, including some in prisons. In the area of alcohol related harm reduction, national legislation is partly aligned to the EU *acquis*. There is an issue of increased alcohol use by younger people. The national youth strategy 2016-2025 includes actions designed to reduce risky behaviour among young people due to the use of alcohol. There is also a project aimed at educating young people on the consequences of the use of tobacco, alcohol, and drugs. On nutrition, there is an issue of obesity, both in children and adults. Underweight prevalence among children is of low public health significance

#### **b. Commission assessment**

In the area of drug abuse prevention, national legislation is partly aligned to the EU *acquis*. The national youth strategy 2016-2025 includes actions designed to reduce risky behaviour among young people due to the use of drugs and other psychoactive substances. In the area of alcohol related harm reduction, national legislation is partly aligned to the EU *acquis* of different strategies in force.

### **II.Q. SUMMARY OF FINDINGS – PUBLIC HEALTH**

The legal base for healthcare in North Macedonia is enshrined in the constitution, and health insurance is

compulsory for all citizens. North Macedonia is already a signatory and user of the EU Joint Procurement agreement for medical countermeasures. North Macedonia intends to apply to join the EU4Health Programme 2021-2027. North Macedonia has legislation **designed to be aligned** with the relevant EU *acquis* on **electromagnetic fields**, on **the prevention of smoking**, on **smoke-free environments**, and on **the advertising of tobacco products** respectively. A national strategy for **control of antimicrobial resistance 2019-2023** is in place, it is **highly aligned** to the relevant EU *acquis*.

North Macedonia is **partly aligned** to the rest of the EU *acquis* on **tobacco control**. North Macedonia ratified the WHO Framework Convention on Tobacco Control (FCTC) in 2006. It signed the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products in 2014, but it has not yet ratified it. North Macedonia is also **partly aligned** to the EU *acquis* on **medicinal products for human use** (including on **general pharmaceutical legislation**, on **legislation on medicines for rare diseases**, on **medicinal products for paediatric use**, and on **advanced therapy products**) and on **medicines for veterinary use**, on **cosmetic products**, on **blood**, on **human tissues and cells**, and on **human organs intended for transplantation**, on **serious cross-border threats to health** and on **communicable diseases**, on **drug abuse prevention**, and on **alcohol related harm reduction**. It should strengthen the administrative capacity to implement the EU *acquis* in these areas, notably that of pharmaceutical *acquis* for human and veterinary medicines, and strengthen the sustainability of the administration.

North Macedonia is **not aligned** with the EU *acquis* on **eHealth**, on **medical devices** or on **in vitro diagnostic medical devices**, on **the establishment of the European centre for Disease Prevention and Control (ECDC)**, but it works and coordinates regularly with ECDC, and national coordinators are in place. North Macedonia is **not aligned** with the EU *acquis* on **patient's rights in cross-border healthcare**, though it has relevant agreements in place with several EU Member States.

In the area of **mental health**, North Macedonia is implementing its mental health strategy and action plan 2018-2025 in cooperation with WHO and the World Bank, rather than in line with EU guidance. In the area of health inequalities, the constitution and legal bases of North Macedonia establish the right to health care and mandatory health insurance for all. North Macedonia ensures access to health care to people from rural areas, the poor, prisoners, and for persons with disabilities. There is an annual programme for people living with HIV/AIDS, LGBTIQ health care and for health care of Roma.

#### **IV. FIGHT AGAINST CORRUPTION - CONSUMER AND HEALTH PROTECTION**

##### **a. Country presentation**

Anti-corruption measures in this area are stipulated in the Law on prevention of corruption and Conflict of interest of North Macedonia, and also in its laws on healthcare, and on medicines and medicinal products. These notably include articles on the conflict of interests, influence, the obligation to not conceal corruption or conflict of interest, and – specifically with regard to healthcare - an obligation in the exercise of discretionary powers to take decisions conscientiously, based on the principle of legality and fairness. A national strategy against corruption is in place.

The national anti-corruption Commission has identified potential issues in the area of consumer protection in regard to market surveillance and inspection services, and a lack of a transparent complaint system for consumer protection. Specific problems are about the lack of qualified inspectors, and lack of clear and imprecise competency frameworks leading to both overlaps and gaps in competencies. It found that some risks of corruption in inspection services and recommended remedial measures. Inspection services at local level have very limited capacity, sometimes without qualifications.

The national anti-corruption Commission has identified potential issues in the area of healthcare are

specifically related to public procurement for health services, of medicines, and of medical equipment, and of potential subjectivity in the selection of medicines covered by public funds, as well as donations, unethical practices on the marketing of medicines, and issues with treatment abroad. The anti-corruption Commission has recommended actions to address these issues to the responsible institutions, including establishing independent bodies, better accountability measures, revising the system to establish the price of healthcare services, and digitalisation of public procurement. While some of these have been implemented, partly implemented or are being implemented, several have not yet been implemented or are awaiting a response from the competent authority.

#### **b. Commission assessment**

There is a legal basis for anti-corruption measures in North Macedonia, an ongoing strategy and action plans on the prevention of corruption and conflicts of interest, and a State Commission for the Prevention of Corruption (SCPC). SCPC has flagged interoperability issues between inspection services, a lack of qualified inspectors, it also found several risks of corruption in inspection services and recommended remedial measures (findings that are relevant to market surveillance). The SCPC has issued guidelines on the protection of public interest, compliance with the code of ethics, merit-based recruitment, transparency, and whistle blowers. SCPC has identified anti-corruption issues relevant to healthcare related to public procurement for health services, of medicines, and of medical equipment, and of potential subjectivity in the medicines area, as well as donations, unethical practices on the marketing of medicines, and issues with treatment abroad. The anti-corruption Commission has recommended actions to address these issues.

#### **C. SUMMARY OF FINDINGS – FIGHT AGAINST CORRUPTION**

North Macedonia has a legal framework and an ongoing strategy and action plans on anti-corruption measures. The State Commission for the Prevention of Corruption has issued guidelines on the protection of public interest, compliance with the code of ethics, merit-based recruitment, transparency, and whistle blowers. It has flagged several issues which need to be addressed are relevant to both consumer protection and to health sector. The recommendations of the State Commission for the Prevention of Corruption should be implemented.

