

# **Screening report**

## *Albania*

### **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: 30 January – 2 February 2023

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

**Date of screening meetings:**

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

Bilateral meeting: 9 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: 17-18 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: 3 February 2023

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

**Date of screening meetings:**

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

Bilateral meeting: 19-20 January 2023

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

**Date of screening meetings:**

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

Bilateral meeting: 6-8 March 2023

## **Chapter 9 – Financial services**

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

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

Bilateral meeting: 13-14 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: 16-17 February 2023

# **PREAMBLE**

After the first Intergovernmental Conference on accession negotiations with Albania in July 2022, the Commission immediately launched 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 Albania 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 Albania has requested participation in certain areas before accession. This report provides the Commission's opinion and answer to these requests.

Regional cooperation and good neighbourly relations remain essential elements of the enlargement process.

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. Albania 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 Albania, 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 trade marks, 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.

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<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 standard 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**.

**Albania stated that it accepts the *acquis* in the chapters of Cluster 2. It reserved however the right to request for transitional arrangements in certain limited areas of the *acquis* in this Cluster at a later stage in the negotiations.**

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<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 radioequipment. The “old approach” *acquis* covers all categories of motor vehicles, chemicals (apart from fertilising products), emissions of pollutants from non-road mobile machinery engines, 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 also the EU *acquis* on product safety, crystal glass, footwear, textile labellings, 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

Albania has started to analyse its national legislation in order to align it with Articles 34-36 TFEU. Currently it has largely focused on the harmonised area, but plans to expand this work to the non-harmonised area. Albania intends to adopt a roadmap for this, then expand the scope of its work on this in 2025, though it does not yet have a date foreseen when it intends to introduce **mutual recognition clauses** in line with the EU *acquis*. There are currently Albanian laws in place that lay down that some consumer information on products has to be in Albanian language.

Albania has appointed its General Directorate of Standardisation as the **contact point for technical regulations** for the WTO and indicated that it is likely to be the same with regard to the EU once this is in place. The competent Albanian authorities currently have a sufficient number of trained staff to cover the areas in question, with the exception of bodies dealing with technical notification, where it is not aligned yet and therefore has not established the full necessary capacity.

## **b. Commission assessment**

Albania has not yet aligned its legislation, and relevant internal procedures and processes with the requirements of Articles 34-36 TFEU. While Albania has started to analyse some national legislation in order to align gradually with Articles 34-36 TFEU, and to identify outdated technical and other requirements for products which are not in line with the EU *acquis*. However, thus far it has largely only examined its laws and implementing legislation covering harmonised product sectors. As, by definition, alignment with the relevant EU *acquis* on product sectors in this chapter should ensure alignment with Articles 34-36 TFEU, Albania should expand this planning and assessment process to all potential areas of law, implementing legislation, processes and procedures, instructions or any other measures that would need to be addressed to ensure alignment with Articles 34-36 TFEU, including those of its customs services. Mutual recognition clauses in individual laws and/or implementing legislation should also be foreseen where Albania defines this as necessary. Albania has also started work to identify the contact point for technical regulations. It needs to ensure necessary capacity building of relevant institutions and their role in the system will also have to be defined in this plan.

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

Albania does not yet have a plan for alignment with the requirements of Articles 34-36 TFEU and relevant CJEU case law. It needs to ensure that such a plan covers both the harmonised and the non-harmonised areas, is completed, adopted, and then implemented in full before accession. It should also complete the work it has started to identify the contact point for technical regulations and ensure the necessary capacity in the relevant institutions.

## **II. HORIZONTAL MEASURES**

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

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

The Albanian legal framework for standardisation is designed to be at a high level of alignment with the EU *acquis*. The national standards body is the General Directorate of Standardisation (GDS). GDS is a member of the European Telecommunication Standards Institute (ETSI), an affiliate (non-voting) member of the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC), and an associate member of the International Electrotechnical Commission (IEC). It applied to become a full Member of CEN/CENELEC in July 2021; whose opinion issued later in 2022 signalled two non-conformities and 11 recommendations for GDS to address to work towards full membership by the end of 2024.

By the end of February 2023, GDS had issued 39 116 Albanian standards and related documents, of which it considers 17,503 are identical to CEN standards (45%), 8 162 to CENELEC standards (21%), and 4 815 identical to ETSI standards (12%). It has also adopted 69 national annexes to align to all the Eurocodes. Many EU standards are adopted by “cover page” method (by translating the first page into national language) but they are fully translated in some priority sectors, notably all the adopted Eurocodes, and is translating others based on demand available budget. GDS currently has 13 employees of which 10 are technical staff, it plans to recruit two further staff by the end of 2023, and two or three more during 2024 – it will adopt a new staffing plan in this period. GDS currently participates as an observer in CEN/CENELEC technical committees, and plans to ask to join further ones (the precise list will be chosen very shortly).

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

Albania has reached a **high level of alignment** with the EU *acquis* on standardisation. A standardisation body (GDS) has been established and it is issuing Albanian standards. GDS has applied to become a full member of CEN and CELENEC, and is in the process of addressing non-compliant issues and the recommendations signalled by CEN/CENELEC that it needs to ensure to enable this to happen.

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

### **a. Country presentation**

Albania's regulatory framework for conformity assessment is partly aligned to the EU *acquis*. Most of the areas that are yet to be aligned are those which only apply to EU Members States or the obligations deriving thereof. Albania does not have its own conformity mark. National legislation already allows the use of CE marking for manufacturers to apply the mark to goods placed on the market in Albania in areas where CE markings are required by the EU *acquis*, notably those that come from the EU or other CEFTA parties. Albania thus far has 31 conformity assessment bodies in place, covering lifts, pressure equipment, and electrical equipment. It did not signal any capacity issues in these bodies.

### **b. Commission assessment**

Albania is **partly aligned** to the EU *acquis* on conformity assessment. It does not have its own conformity mark. Albania's national legislation already allows for manufacturers to apply the CE mark to goods placed on the market in Albania in product sectors where the CE mark is foreseen by the EU *acquis*. (Implementation of the EU *acquis* obligations on the CE mark is incumbent on conformity assessment bodies and also on market surveillance. The evaluation of the administrative capacity of market surveillance is covered in that section of the report).

## **II.C. ACCREDITATION**

### **a. Country presentation**

The regulatory framework in this area stipulates that General Directorate of Accreditation (GDA) is the only national accreditation body. GDA evaluates the competence of conformity assessment bodies based on accreditation certificates. GDA estimates that it currently has sufficient capacity to ensure its role. GDA is designed to be consistent with the relevant EU *acquis* and European cooperation for Accreditation (EA) rules. The GDA register currently includes 102 accredited conformity assessment bodies: 48 test laboratories, 1 calibration laboratory, 8 certification bodies of management system, 5 medical laboratories, 12 certification bodies of persons and 28 inspection bodies. GDA is a signatory of the European Cooperation for Accreditation Multilateral Agreement (EA MLA) in the fields of inspections and management systems certification, testing and certification of persons, a full member of the International Laboratory Accreditation Cooperation Mutual Recognition Agreement (ILAC MRA) in the field of inspection and testing. It is also a signatory of International Accreditation Forum Multilateral Agreement (IAF MLA) in the fields of management systems certification and certification of persons.

Albania legislation is **partly aligned** on conformity assessment with the requirements of Regulation 765/2008 and reference provisions of Decision 2008/768, as laid down in corresponding provisions of sectoral legislation.

### **b. Commission assessment**

Albania's legislation on accreditation is **partly aligned** with the EU *acquis*. The Accreditation Body of Albania is established, has a good level of cooperation in the region, and is a member of EU and international accreditation associations. It is a signatory of the European Cooperation for Accreditation Multilateral Agreement (EA MLA). Albania currently has 102 accredited conformity assessment bodies.

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

### **a. Country presentation**

Albania's Law on metrology is its legal base for legal metrology. The General Directorate of Metrology (GDM) is the Albanian body responsible for legal metrology. It has its full complement of 104 employees, as foreseen and, is fully operational. It is a full member of the International Organization of Legal Metrology (OIML), European Association of National Metrology Institutes



(EURAMET) and International Measurement Confederation (IMEKO), and an associate member of the European Legal Metrology (WELMEC) and International Bureau of Weights and Measures (BIPM-CGPM).

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

Albania has a **high level of alignment** on legal metrology. It has established a metrology body that is a full member of EU and some international metrology bodies, and an associate member of other international metrology bodies, and has adequate capacity to ensure the necessary tasks.

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

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

Albania's legal framework is its law on marketing and market surveillance of non-food products, which is partly aligned with the current EU *acquis* on market surveillance, though it is aligned with the principles set out in the previous EU *acquis*. Full alignment is foreseen by 2025. The state inspectorate for Market Surveillance (SIMS) is the main competent body for market surveillance in Albania. The Central Inspectorate (CI) coordinates all market surveillance inspectorates and can also ensure disciplinary control on inspectors and the chief inspector. SIMS ensures both pro-active and reactive market surveillance. SIMS currently has 69 staff out of the 80 staff foreseen in its staffing plan. It plans to recruit the remaining staff by the end of 2023, and it also needs to increase its budget and ensure more training across product types, so to enable it to cover sectors not yet covered (chemicals, gas appliances, simple pressure vessels, aerosols, and pyrotechnic articles).

Other inspectorate bodies involved in market surveillance include the state technical and industrial inspectorate (STII), the national agency on medicines and medical devices, the customs authority, the state police, and the state export control authority. In 2022, SIMS carried out 11,153 market surveillance inspections in Albania, resulting in 179 fines, 38 urgent measures, and 58 products being taken off the market. Information on non-compliance is shared with all CEFTA parties. Albania is at a limited level of alignment to the EU *acquis* on product liability. Its legislation notably does not cover agricultural products (which the EU *acquis* covers) – full alignment is foreseen in 2026.

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

Albania is **partly aligned** with the EU *acquis* on market surveillance. Human and financial resources should be significantly reinforced to ensure market surveillance to ensure compliance with EU requirements, and market surveillance competences need to be expanded to cover the sectors that are currently only partly covered, or are not covered at all, which include chemicals, gas appliances, simple pressure vessels, aerosols, and pyrotechnic articles.

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

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

Albania has not yet aligned its legislation on conformity assessment with the requirements of Directive 2015/1535 EU on notification . It plans to do this by the end of 2028. The competent body is General Directorate of Standardisation (GDS). Albania estimates that it has sufficient resources to ensure the implementation of the EU *acquis*, but further training of staff will be necessary.

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

As regards notification Albania's legislation is **partly aligned** with the EU *acquis*. Further staff training on notification is needed.

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

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

National legislation on product liability is partly aligned with the relevant EU *acquis*, as it currently

does not cover some sectors, definitions, and other provisions that are included in the EU *acquis*.

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

Albania is **partly aligned** with the EU *acquis* on product liability. Some sectors are not covered by national legislation, which also has deviations to the *acquis* on some definitions.

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

Albania has a **high level of alignment** with the EU *acquis* on **standardisation and accreditation**. It has applied to become a full member of CEN and CELENEC, and should continue to address non-compliant issues and the recommendations signalled by CEN/CENELEC that it needs to ensure to enable this to happen.

Albania's legislation is **partly aligned** with the EU *acquis* on **conformity assessment**, on **metrology**, on **market surveillance**, and on **product liability**. Human and financial resources for market surveillance should be significantly reinforced, and market surveillance competences expanded to cover the sectors that are currently not covered adequately or at all, including chemicals, gas appliances, simple pressure vessels, aerosols, and pyrotechnic articles.

Albania does not have its own conformity mark. Albania's national legislation already allows the use of the CE mark for manufacturers to apply the mark to goods placed on the market in Albania in product sectors where the CE mark is foreseen by the EU *acquis*.

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

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

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

Albania's Law 10489/2011 on Marketing and Market Surveillance of Non-Food Products and Decision of the Council of Ministers 349 of 2020 have a high level of alignment with Directive 2014/35/EU on low voltage equipment (LVD). Albania foresees full alignment by 2030. Albania has no producers who place products on the market covered by this EU *acquis*. The competent authority is the Ministry of Economy. It has limited resources working on this area. Market surveillance is ensured by the state inspectorate for market surveillance (SIMS). Albania currently has no plans to set up conformity assessment bodies in this area.

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

While Albania has a **high level of alignment** with the EU *acquis* on Low Voltage Equipment (LVD), it does not have adequate administrative and market surveillance resources in this area.

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

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

Albania's national legislation on Electromagnetic Compatibility (EMC) consists of Law 10489/2011 on Marketing and Market Surveillance of Non-Food Products and Decision of the Council of Ministers 552 of 2019. These are partly aligned with the EU *acquis*. Albania foresees full alignment by 2030. Albania has no producers of such equipment. The competent authority is the Ministry of Economy, with limited resources working on this area. Market surveillance is ensured by the state inspectorate for market surveillance (SIMS). Albania currently has no plans to set up conformity assessment bodies in this area.

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

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

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

#### a. Country presentation

Albania does not have any manufacturers in this area. Its national legislation on radio equipment consists of Decision of the Council of Ministers 378 of 2019 and Regulation 48 of 2020. They have a high level of alignment with the EU *acquis*. No date has yet been foreseen for full alignment. The competent authority is the Ministry of Infrastructure and Energy (MEI), with limited resources working on this area. Market surveillance is ensured by SIMS. Albania currently has no plans to set up conformity assessment bodies in this area.

#### b. Commission assessment

Though Albania has a **high level of alignment** to the EU *acquis* on Radio Equipment (RED), it does not have sufficient administrative resources in this area.

### III.D. TOYS

#### a. Country presentation

There are no producers of toys in Albania. The competent authority is Ministry of Finance and Economy (MFE)<sup>3</sup>, implementation and enforcement are ensured by SIMS and customs. Albania's Law 10489/2011 on Marketing and Market Surveillance of Non-Food Products and Decision of the Council of Ministers 262 of 2013 are partly aligned with Directive 2009/48/EC on toys, its legislation deviates from in regard to terminology, notified bodies, languages and aspects relevant to EU Member States. Further alignment is planned by 2030. Toys placed on the Albanian market are inspected by SIMS and customs. Albania signalled its appreciation of being involved in relevant expert and Administrative Cooperation Groups (AdCos) groups on toys, which offered them the opportunity to witness how changes the EU *acquis* take place and offered insight on implementation.

#### b. Commission assessment

Albania is **partly aligned** to the EU *acquis* on toys, with several deviations, including on terminology, notified bodies, languages and aspects relevant to EU Member States, and it does not have adequate market surveillance resources in this area.

The Commission looks positively on Albania's request on accelerated integration in regard to participating expert and AdCo groups on toys.

### III.E. MACHINERY

#### a. Country presentation

Albania's national legislation is **partly aligned** with Directive 2006/42/EC on machinery. Albania has a small number of producers of such equipment. The competent authority is MFE, implementation is ensured by SIMS. Administrative capacity is insufficient. Albania currently has no plans to set up conformity assessment bodies in this area.

#### b. Commission assessment

Albania is **partly aligned** with the EU *acquis* on machinery, and it does not have sufficient administrative resources and market surveillance resources in this area.

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<sup>3</sup> Since January 2024 the functions of the former Ministry of Finance and the Economy have been divided between the Ministries of Finance on the one hand and of Economy, Culture and Innovation, on the other.

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

#### a. Country presentation

The Albanian Law 10489/2011 on Marketing and Market Surveillance of Non-Food Products and Decision of the Council of Ministers 1063 of 2015 are **partly aligned** with Directive 2000/14/EC on noise emission in the environment by equipment for use outdoors, it foresees full alignment by 2030. MFE and the Albanian energy administration are the competent bodies. Market surveillance performed by SIMS and STII. Administrative capacity is limited but considered sufficient for current needs. There are no manufacturers of these products and their components in Albania. Albania currently has no plans to set up conformity assessment bodies in this area.

#### b. Commission assessment

Albania is **partly aligned** with the EU *acquis* on outdoor equipment noise emissions, and has limited administrative resources and market surveillance resources in this area.

### III.G. LIFTS

#### a. Country presentation

There are no producers of lifts or of their components in Albania, though there are companies that import and install them. Albania's legal base on lifts are Law 10489/2011 on Marketing and Market Surveillance of Non-Food Products and Decision of the Council of Ministers 192 of 2018. They are partly aligned with the relevant EU *acquis*. The competent authority is MFE, and market surveillance is ensured by SIMS. The current level of resources available for this work are deemed to be adequate for current needs. Albania has three bodies that it has identified that could act as notified bodies in this area.

#### b. Commission assessment

Albanian legislation is **partly aligned** with the EU *acquis* on lifts, and estimates that it has adequate administrative and market surveillance resources in this area.

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

#### a. Country presentation

There are currently no producers of Personal Protective Equipment (PPE) in Albania. Albanian legislation on PPE consists of Law 10489/2011 on Marketing and Market Surveillance of Non-Food Products and Decision of the Council of Ministers 674 of 2021. They are partly aligned with Regulation (EU) 2016/425 on PPE. The competent authority is the Ministry of Finance and Economy (MFE). Implementation is ensured by SIMS and by customs. Albania stated that it currently has no plans to set up conformity assessment bodies in this area.

#### b. Commission assessment

Albanian legislation 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

Albanian legislation consists of Law 10489/2011 on Marketing and Market Surveillance of Non-Food Products and Decision of the Council of Ministers 1066 of 2015. They are not aligned with the current EU *acquis* on ATEX. Full alignment is currently planned to take place by the end of 2025. The competent authority is the MEI, and market surveillance is performed by STII. The current level of

resources available for this work are very limited. Albania currently has no plans to set up conformity assessment bodies in this area.

**b. Commission assessment**

Albanian legislation 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**

Albania does not have any manufacturers of gas appliances, and its national legislation is not aligned with Regulation 2016/426/EU on gas appliances. The competent authority for gas appliances is MEI and the MFE. Implementation will be the responsibility of the STII and SIMS. The current level of financial and human resources available for this work are not sufficient. Albania plans to ensure alignment by the end of 2024, and ensure the necessary resources during 2024. It does not current plan to set up any conformity assessment bodies in this area.

**b. Commission assessment**

National legislation is not aligned with the EU *acquis* on gas appliances, and Albania 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**

There are no Albanian manufacturers of pressure equipment. Albania's legislation includes the Law 10489/201 on Marketing and Market Surveillance of Non-food Products Law 32/2016 on Work Safety when working with Pressure Equipment, and Decision of the Council of Ministers 410 of 2015 on is not aligned with Directive 2014/68/EU on pressure equipment. The competent authority is MEI, market surveillance is ensured by STII. The current level of financial and human resources available for this work are not sufficient. Albania plans to ensure alignment by the end of 2024, and ensure the necessary resources during 2025. It does not current plan to set up any conformity assessment bodies in this area.

**b. Commission assessment**

Albania is **not aligned** with the EU *acquis* on pressure equipment, and it does not have adequate administrative or market surveillance resources in this area.

**III.L. SIMPLE PRESSURE VESSELS (SPVD)**

**a. Country presentation**

Albania has no manufacturers of simple pressure vessels. Albanian legislation on this includes the Law 10489/201 on Marketing and Market Surveillance of Non-food Products and Decision of the Council of Ministers 730 of 2022 is partly aligned with Directive 2014/29/EU, it is not aligned in regard to notified bodies, some definitions, and obligations relevant to EU Member States. Full alignment is planned by 2030. The competent authority is MFE. Market surveillance is ensured by SIMS.

**b. Commission assessment**

National legislation is **partly aligned** with the EU *acquis* on simple pressure vessels, and Albania does not yet have adequate resources in place to ensure the necessary administrative capacity or market surveillance in this area.

### III.M. CABLEWAYS

#### a. Country presentation

Albania's legislation is not aligned with Regulation (EU) 2016/424 on cableways, full alignment is planned by 2025. There are no Albanian producers of cableways. The competent authority is the ministry of infrastructure and energy (MIE). Market surveillance responsibilities are yet to be finally decided upon; it is expected to be the State Technical and Industrial Inspectorate (STII). Albania stated that it currently has no plans to set up conformity assessment bodies in this area.

#### b. Commission assessment

National legislation is **not aligned** with the EU *acquis* on cableways. Albania needs to decide on which entity will be responsible for market surveillance, so it is therefore not yet possible to evaluate if it has adequate administrative or resources in this area.

### III.N. CONSTRUCTION PRODUCTS

#### a. Country presentation

Albania has producers of construction products, including ceramic products, concrete and concrete products, limestone, asphalt, iron, and steel. Albania's legislation is Law 2004/9290 on Construction Products. It is partly aligned with the Construction Products Regulation (EU) 305/2011. Full alignment is foreseen in 2024. MEI is the competent ministry. Market surveillance is performed by the national inspectorate for territorial inspection. Albania currently has no plans to set up conformity assessment bodies in this area.

#### b. Commission assessment

Albania's legislation is **partly aligned** with the EU *acquis* on construction products. It has not yet established whether it has sufficient resources to ensure market surveillance in this area.

### III.O. RECREATIONAL CRAFT

#### a. Country presentation

Albania has no production capacities in this field, and its national legislation is not aligned to with Directive 2013/53/EU, this is foreseen during 2025. MIE is the responsible authority. Implementation and enforcement will be performed by Albania's general maritime directorate and the Albanian shipping register. Albania currently has no plans to set up conformity assessment bodies in this area.

#### b. Commission assessment

Albania's national legislation is **not aligned** with the EU *acquis* on recreational craft.

### III.P. ECO-DESIGN

#### a. Country presentation

Albania's legislation is not yet aligned to the EU *acquis* in this area. MEI is the responsible body, implementation is ensured by STII and the Agency for Energy Efficiency, but there are no specific capacities to ensure this in this area yet. Alignment is foreseen to start by the end of 2025 (they also intend to align to the related energy labelling *acquis* during 2024).

#### b. Commission assessment

Albania's national legislation is not aligned with the EU *acquis* on Eco-design, and it has not yet allocated any resources to administrating this *acquis* or ensuring the relevant necessary market surveillance.

### III.Q. EXPLOSIVES FOR CIVIL USE

#### a. Country presentation

There is one producer of explosives in Albania. Albania's Law on Marketing and Market Surveillance of Explosives for Civilian Use and its implementing acts are designed to have an advanced level of alignment to Directive 2014/28/EU on explosives for civil use. Further alignment is foreseen during 2024. The Ministries of Defence, of Infrastructure and Energy, and of the Interior are the responsible bodies, implementation and enforcement is ensured by the State Export Control Authority (which is responsible for licensing import/export, transport and production), the State Police (which authorises storage and transfer within the country, the national mining authority (which authorises use of explosives), and Customs (which ensures import controls).

#### b. Commission assessment

Albania has a **high level of alignment** to the EU *acquis* on explosives for civil use, and further alignment is foreseen. The bodies responsible for the implementation and enforcement of this *acquis* have been identified and are ensuring their obligations.

### III.R. PYROTECHNIC ARTICLES

#### a. Country presentation

There is one producer of these products in Albania, which also exports, mostly to the EU. Albania has an advanced level of alignment to Directive 2013/29/EU via its Law on Marketing and Market Surveillance of Pyrotechnical Articles and its several implementing acts. Further alignment is in preparation and is foreseen during 2024. The Albania Ministry of Defence, MIE and the Ministry of Interior are the responsible bodies, implementation and enforcement is ensured by Albanian State Export Control Authority (which is responsible for licensing import/export, transport and production), SIMS, and customs (which ensures control during import).

#### b. Commission assessment

Albania has a **high level of alignment** to the EU *acquis* on pyrotechnical articles, and further alignment is foreseen. The bodies responsible for the implementation and enforcement of this *acquis* have been identified and are ensuring their obligations.

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

#### a. Country presentation

Albanian national legislation consists of Law 10489/201 on Marketing and Market Surveillance of Non-food Products, Decision of the Council of Ministers (DCM) 770/2016 on Measuring Instruments, DCM 631/2019 on Non-Automatic Weighing Instruments, on Law 126/2020 on Metrology, DCM 261/2022 and DCM 349/2021. The relevant Albanian legislation is partly aligned with the EU *acquis* on measuring instruments (MID), on non-automatic weighing instruments (NAWI), units of measurement, on pre-packaged products, and on bottles used as measuring containers. Albania has no manufacturers in the latter sector. It plans to ensure full alignment to the EU *acquis* on MID, on pre-packaging and on bottles used as measuring containers by 2028, and to NAWI by 2029. The responsible ministry is the Ministry of Finance and Economy, which does not have sufficient resources. Implementation of legislation on measuring instruments, pre-packed products, and bottles used as measuring instruments is ensured by SIMS. Implementation of other relevant laws is ensured by the General Directorate of Metrology, for which no resource issues were signalled.

#### b. Commission assessment

Albanian legislation is **partially aligned** with the EU *acquis* on measuring instruments (MID), on non-automatic weighing instruments (NAWI), pre-packaged products, and on bottles used as measuring containers. There are not sufficient administrative resources in place yet, though there seem

to be adequate implementing resources.

### III.T. FERTILISING PRODUCTS

#### a. Country presentation

Around 75% of imported fertilisers come from the EU. Albania's Law 17/2020 on Fertilizer products and Order 145/2020 on the Detailed Classification of Fertilizer Products Allowed for Registration are **partly aligned** with the EU *acquis* on fertilising products, notably in regard to some definitions, classifications and labelling, while many other aspects are not aligned, notably with regard to national requirements for registration of such products. The competent authority is the Ministry of Agriculture and Rural Development. Implementation and enforcement are ensured by the National Food Authority, though its staff are not yet all fully trained in the specific aspects of this EU *acquis*, and the National Centre for the Transfer of Agricultural Technologies, which functions inter alia as a testing laboratory. Albania plans to ensure **full alignment** in 2028, but its ability to ensure complete implementation will take longer. The EU *acquis* in question will require setting up of the legal framework for the notification of conformity assessment body, this is planned to be addressed by a legal act that is foreseen adopted during 2024.

#### b. Commission assessment

Albania may maintain national rules on fertilising products which deviate from the EU *acquis*, as long as such rules do not impede the free movement of EU fertilising products. Albania needs to ensure that its national legislation will not impose any requirements or registration obligations for harmonised products. In addition, Albania has to set out the legal framework for the notification of conformity assessment bodies (by designating a notifying authority and laying down the procedures needed for the notification and monitoring of conformity assessment bodies interested in becoming notified bodies). Further work is needed, including training, to ensure the necessary capacity for the implementation and enforcement of this EU *acquis*.

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

Albania has a **high level of legislative alignment** with the EU *acquis* on **electromagnetic compatibility (EMC)**, on **low voltage equipment (LVD)**, on **radio equipment (RED)**, on **explosives for civil use**, and on **pyrotechnical articles**.

Albanian is **partly aligned** with the EU *acquis* on **toys**, on **machinery**, on **outdoor equipment noise emissions (OND)**, on **lifts**, on **personal protective equipment (PPE)**, on **simple pressure vessels (SPVD)**, on **construction products**, on **measuring units (MID)**, on **non-automatic weighing instruments (NAWI)**, on **pyrotechnical articles**, on **pre-packaged products**, and on **bottles used as measuring containers**.

Albanian legislation is **not aligned** with the EU *acquis* on **equipment and protective systems intended for use in potentially explosive atmospheres (ATEX)**, on **eco-design**, on **gas appliances**, on **pressure equipment**, on **cableways**, on **recreational craft**, and on **eco-design**.

Albania needs to put in place the administrative and implementing for the ‘New and Global Approach’ EU *acquis*. This is particularly necessary in order to ensure conformity assessment (where they intend to do so domestically) and to ensure an adequate level of market surveillance, as Albania does not currently have any trained personnel able to ensure market surveillance in several product sectors.



## 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 are no manufacturers of any category of motor vehicles or non-road mobile machinery, or systems or parts thereof, in Albania. All categories of such vehicles are imported, mostly from the EU but also from third countries. The responsible institution is the Ministry of Infrastructure and Energy. Implementation and enforcement are ensured by the general directorate of road transport services and customs (the latter for imports). Current administrative and enforcement capacity is insufficient.

Albania is a contracting party of the UN-ECE 1958 Agreement on the homologation of wheeled vehicles and their parts. Albania has not aligned to any of the current EU *acquis* in this sector, though it did align to EU previous type-approval *acquis*. At the moment Albania accepts the import of used N1 category vehicles that are Euro4 emissions compliant or above, and used M1 & M2 category vehicles that comply with Euro3 emissions or above, none of which can be more than 15 years old. There are no restrictions on other categories. For new vehicles Albania accepts the import of Euro5 or above N1, M1 & M2 category vehicles, again there are no restrictions on other categories. Albania foresees to ensure alignment to all the relevant EU *acquis* during 2024, if it is able to ensure the necessary capacity to do this.

#### b. Commission assessment

Albanian legislation is **not aligned** with the current EU *acquis* on motor vehicles, tractors (agricultural, forestry), motor vehicles (2/3 wheeled vehicles), and non-road mobile machinery emissions. It has also not yet put in place the necessary administrative capacity in all relevant ministries and other responsible bodies, both to ensure alignment and also to ensure the implementation of legislation once it is aligned with the EU *acquis*. In this area Albania will also need to ensure the country-wide availability of fuel of the correct quality when full alignment to the EU *acquis* on motor vehicles, tractors (agricultural, forestry), motor vehicles (2/3 wheeled vehicles), non-road mobile machinery emissions is reached. Albania will also need to examine if changes to roads and to road-side infrastructures are needed to ensure the correct functioning of vehicle systems regulated in line with the EU *acquis* once alignment to EU *acquis* on motor vehicles and 2/3 wheeled motor vehicles is complete, and act to ensure this if this is the case.

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

#### a. Country presentation

Most chemical products on the Albanian market are imported. Albania's Law on Chemicals Management and several pieces of implementing legislation are partly aligned the EU *acquis*, including parts of Titles I, IV, V, VII and VIII and Annexes I, II, VI to XI, XIII, XIV, XVI and XVII of Regulation EC 1907/2006 (REACH). They are not aligned with REACH titles II, III, and VI, or with several aspects specific to EU Member States and the European Chemicals Agency (ECHA). The responsible bodies are the Ministries of Tourism and Environment, of Health and Social Affairs, of Finance and Economy and of Infrastructure and Energy. Implementation and enforcement are shared between the Chemicals' Office, the Inspection and Control Service for the Environment, the State Inspectorate of Market Surveillance, Customs and the Clinical Toxicology Service. Albania needs to reinforce the resources needed to implement the EU *acquis* on chemicals.

#### b. Commission assessment

Albania is **partly aligned** with the REACH EU *acquis*. While the competent responsible bodies and implementing and enforcement bodies have been identified and nominated, their resources are not yet fully adequate to ensure control and implementation of this EU *acquis*.

## IV.D. DETERGENTS

### a. Country presentation

There are 10-15 manufacturers of detergents in Albania. The legislation of Albania is its Law on Detergents and relevant implementing legislation, which is **partly aligned** with Regulation (EC) No 648/2004 on detergents. However, aspects related to derogations, the duties of EU Member States and other clauses relevant to EU membership, animal protection, biodegradability, and some definitions are currently not aligned. **Full alignment** is foreseen by 2025. The MFE & Ministry of Health and Social Protection are the responsible bodies. Implementation is ensured by SIMS, customs, and the State Health Inspectorate. Administrative and implementation resources are both currently insufficient. There are no accredited laboratories in this area, and insufficient funding on this. Some new human resources are foreseen in 2024, further capacity building and recruitment is also foreseen, without a timescale at this time. Market surveillance in this sector only started in 2018. SIMS uses EU Safety Gate/RAPEX (European rapid alert system for dangerous products) market surveillance data to take action on products found non-compliant by EU Member States, including taking them off the market.

### b. Commission assessment

National law is **partly aligned** with the EU *acquis* on detergents. Areas needing further alignment include derogations, animal protection, biodegradability, and definitions, as well as those that can only be implemented should Albania become an EU Member State. There are insufficient resources in regard to both administrative and implementing needs, including market surveillance.

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

### a. Country presentation

Albania has adopted legislation designed to be **highly aligned** to the EU *acquis* on classification, labelling and packaging of chemicals (CLP), apart from those aspects dealing with ECHA and those only applicable to EU Member States. Most chemicals are imported into Albania. A national register of chemicals is yet to be established to have an overview of chemicals and chemical products imported, exported, or placed on the Albanian market. Four ministries are responsible, the Ministries of Tourism and Environment, of Health and Social Affairs, MFE & MIE. Responsibility for implementation and enforcement are shared between the National Office for Chemicals, the Inspection and Control Service for the Environment, SIMS, Customs and the Clinical Toxicology Service. Some of these entities have only limited resources allocated to this area. The Office for Chemicals will be responsible for the chemicals register, publication of the lists, and for proposing removing any chemicals from the market or limiting it due to human/environmental health risks. The Office for Chemicals also operates a helpdesk for this area, and is in charge of informing the public. MFE is competent for licensing chemicals and activities on chemicals classified as hazardous. Market surveillance in this area started between 2019 and 2022, and capacity building is ongoing. Albania has started to establish a helpdesk on chemicals. Albania is aware that the EU plans to revise the CLP, so no date has yet been set for full alignment.

### b. Commission assessment

Albania has a **high level of alignment** to the EU *acquis* on CLP. It has also established which are the relevant administrative bodies, and which bodies are responsible for implementation and enforcement of CLP. While market surveillance in this area has started, further resource and capacity building are ongoing and will need to continue until they are adequate to ensure sufficient levels of market surveillance.

## IV.F. DRUG PRECURSORS

### a. Country presentation

Albania's legal base on drug precursors are its Law on Narcotic Drugs and Psychotropic Substances, and its Law for the Prevention and War Against Trafficking of Narcotic or Psychotropic Substances, and relevant implementing legislation. These have a **low level of alignment** to the EU *acquis*; full alignment is foreseen by 2025. Albania's legal base divides drug precursors into three categories, the first two of which require export and import control, while the third has less strict rules in application. The responsible body is the Ministry of Health and Social Protection. Implementation and enforcement are ensured by the central structure for the investigation of narcotic substances, the national agency for drugs and medical devices, and customs.

### b. Commission assessment

National legislation is **aligned at a low level** with the EU *acquis* on drug precursors. Further work is necessary to ensure full alignment to the EU *acquis*, including with regard to the classification of such substances, and the necessary controls on them. The capacity to administer and implement the EU *acquis* on drug precursors needs to be ensured.

## IV.G. GOOD LABORATORY PRACTICE (GLP)

### a. Country presentation

Albania is **not yet aligned** with the EU *acquis* on GLP. The Ministry of Tourism and Environment is the responsible body. The responsible implementing bodies have not yet been identified, nor has it been evaluated if sufficient resources are in place to ensure this. Full alignment is currently foreseen by the end of 2024, though prior to this Albania foresees an analysis to evaluate the scope and application of this in the country.

### b. Commission assessment

National legislation relevant to good laboratory practice is **not aligned** with Directive 2004/10/EC. While the responsible administrative body has been identified, the responsible implementing body(ies) have not been identified yet, and Albania has not yet evaluated its resource needs to implement this *acquis*.

## IV.H. AEROSOL DISPENSERS

### a. Country presentation

Albanian legislation consists of its Law 10489/201 on Marketing and Market Surveillance of Non-food Products, and DCM 925/2020. These are partly aligned with the EU *acquis* on aerosol dispensers. Full alignment is foreseen by 2030. The competent authority is MFE, which has limited resources in this area –reinforcement is foreseen by 2024. Implementation is ensured by SIMS, which has sufficient human resources but limited financial resources, and customs.

### b. Commission assessment

National legislation is **partly aligned** with the EU *acquis* on aerosol dispensers. Albania does not yet have sufficient administrative resources in the area, and the resources necessary for market surveillance are also not yet adequate.

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

Albania has a **high level of legislative alignment** with the EU *acquis* on **classification, labelling and packaging (CLP)**.

Albanian is **partly aligned** with the EU *acquis* on **REACH**, on **detergents**, and on **aerosol dispensers**.

Albanian has a **low level of legislative alignment** with the EU *acquis* on **drug precursors**.

Albanian legislation is **not aligned** with the EU *acquis* on **motor vehicles**, on **tractors (agricultural, forestry)**, on **2/3 wheeled vehicles**, on **non-road mobile machinery emissions**, and on **good laboratory practice (GLP)**.

Albania needs to ensure the necessary administrative capacity in all relevant ministries and other responsible bodies. It should especially address the current insufficient levels of human and financial resources needed to ensure market surveillance - it currently does not have any trained market surveillance personnel able to ensure this in several product sectors.

Albania will also need to ensure that the adequate provision of the correct quality of fuels will be available when full alignment to the EU *acquis* on motor vehicles, tractors (agricultural, forestry), 2/3 wheeled vehicles, non-road mobile machinery emissions is ensured by the time alignment to this EU *acquis* is complete, Albania should also examine if changes to roads and to road “furniture” are needed to ensure the correct functioning of vehicle systems regulated in line with the EU *acquis*.

#### V. PROCEDURAL MEASURES

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

###### a. Country presentation

Albania uses economic and administrative measures to control public expenditure on medicinal products, to ensure affordability, and widen and increase the list of such products and funding for their reimbursement. This has been done by removing VAT on medicines, indexing prices to neighbouring countries, and regulating the price of generic medicines. Albania’s legal base on this is its Law on Drugs and Pharmaceutical Service and its Law on Compulsory Health Care Insurance, and related implanting legislation, which are **partly aligned** to the relevant EU *acquis*. **Full alignment** is foreseen by 2025. The responsible body is the Ministry of Health and Social Protection. The pricing of medicinal products is controlled by Albania’s drug pricing commission, and are set via an annual process. The procedure foresees that price of a medicinal product should be approved within a delay of 20 days of the application for the setting of the price, approval of the price is done within 60days after filing the declaration. The reference process is set in the basis of three criteria, a) the price applied in five reference countries, the retail price in the country of origin, and the price of imported drugs over the preceding 12 months. The price of generic medicines must not exceed 80% of the original in Albania or in its country of origin if it is not registered in Albania. Albania recognises that the implementation capacity is insufficient.

###### b. Commission assessment

Albania is **partly aligned** with the EU *acquis* on the pricing and reimbursement of medicinal products. Implementation capacity is not sufficient.

## V.B. CRYSTAL GLASS

### a. Country presentation

Albania does not have any domestic manufacturers of glass products. Albania's legislation on crystal glass are its Law 10489/201 on Marketing and Market Surveillance of Non-food Products, and DCM 221/2012. It is **highly aligned** with the EU *acquis* on crystal glass, apart from aspects relevant to EU Member States, **full alignment** is foreseen by the time of Albania's eventual accession to the EU. The competent authority is MFE. Implementation is ensured by SIMS. Albania acknowledges that there are currently insufficient resources to implement this EU *acquis*.

### b. Commission assessment

National legislation is at a **high level of alignment** with the EU *acquis* on crystal glass. There are insufficient resources in place to implement this *acquis*.

## V.C. TEXTILE LABELLING

### a. Country presentation

There are about 10 textile producers of finished textile products, mostly producing linens using imported textile rolls. Albania's national legislation consists of its Law 10489/201 on Marketing and Market Surveillance of Non-food Products, and DCM 222/2012. These are partly aligned with Regulation (EU) 1007/2011. It is not aligned on some new textile fibre names, delegated acts, and minimum requirements regarding the technical file for new fibre names' applications. Further alignment is foreseen by 2029. MFE is the responsible body, implementation is ensured by SIMS and customs. Administrative and implementing capacity and resources are currently insufficient. Further recruitment for market surveillance is foreseen during 2024.

### b. Commission assessment

Albanian legislation is **partly aligned** to the EU *acquis* on textile labelling and mixtures. There are insufficient resources in place to implement this *acquis*.

## V.D. FOOTWEAR

### a. Country presentation

There are five to ten Albanian producers of footwear for export. Albania's national legislation on footwear is aligned at a high level with Directive 94/11/EC, apart from a couple of articles only relevant to EU Member States. MFE is the responsible body, implementation is ensured by SIMS and customs. Administrative and implementing capacity and resources are currently insufficient. Further recruitment for market surveillance is foreseen during 2024.

### b. Commission assessment

National legislation has a **high level of alignment** with the EU *acquis* on footwear. There are insufficient resources in place to implement this *acquis*.

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

### a. Country presentation

There are currently no producers of firearms in Albania. The Albanian legislation on the acquisition and possession of weapons is its Law on Weapons (amended) and related implementing legislation and Border Police procedures, which are partly aligned to the EU *acquis*. The Ministries of Defence and of the Interior are the responsible bodies. The State Export Control is the implementing body for import/export licenses and transit for A & B category weapons, and the Customs Authority controls imports. Partial alignment concerns deactivation, while Albania is not aligned on aspects relevant to EU Member States and category D and some definitions need to be re-evaluated. Further alignment is

foreseen in 2024 on entry-exit and marking procedures, and gender sensitive aspects. Albania estimates that it has sufficient resources to implement this EU *acquis*.

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

The national legislation of Albania is **partly aligned** to the EU *acquis* on firearms (acquisition and possession of weapons). National resources are sufficient to ensure the implementation of this *acquis*.

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

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

There are currently no producers of defence products in Albania. The Albanian legislation on the acquisition and possession of weapons is its Law on state, international transfer of military goods and dual use items and technologies, and related implementing legislation, which are **partly aligned** to the EU *acquis*, notably with regard to Annex I (Military list). The Ministries of Defence and of Interior are the responsible bodies. The State Export Control, State Police and Customs are the implementing bodies. Albania is **not aligned** on aspects relevant to EU Member States, transfer provisions, transfer licenses, export limitations, the exchange of information, and some definitions. Albania estimates that it has sufficient resources to implement this EU *acquis*.

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

National legislation is **partly aligned** with the EU *acquis* on defence products (transfer of defence related products). Areas where alignment needs to be completed include transfer provisions, transfer licenses, export limitations, the exchange of information, and some definitions, as well as aspects that will become applicable should Albania become an EU Member State. Albania estimates that it has sufficient resources to implement this EU *acquis*.

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

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

Albania is **partly aligned** with Directive 2014/60/EU via its Law on Cultural Heritage and Museums and relevant implementing legislation. It is partly or not aligned with regard to aspects that would apply to EU Member States. Further alignment is foreseen 2024-25, full alignment will be ensured by the time of Albania's accession to the EU. A number of cultural goods have already been returned to EU Member States, and some have been returned to Albania by EU Member States. The competent authority is the Ministry of Culture, implementation is ensured by the National Institute for the Registration of Cultural Heritage, whose capacities need to be reinforced. Further work is necessary on the establishment of registers of export, import and trade of cultural goods.

#### **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. While Albania acknowledges that it needs to fully align and to also ensure that it has the necessary registers of import, export, and trade in such items, Albania has already returned cultural goods to some EU Member States.

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

Albania has a **high level of legislative alignment** with the EU *acquis* on **crystal glass**, on **footwear**, and on **cultural goods unlawfully removed from the territory of an EU Member State**.

Albanian is **partly aligned** with the EU *acquis* on **transparency in relation to pricing and reimbursement of medicinal products**, on **textile labelling**, on **firearms**, and on **the transfer of defence related products**.

Albania should also address the insufficient levels of human and financial resources, which is an issue

across all the procedural measures, especially to ensure adequate levels of market surveillance. It should also establish the necessary registers for the export, import and trade of cultural goods.

## **VI. FIGHT AGAINST CORRUPTION – FREE MOVEMENT OF GOODS**

### **a. Country presentation**

There is Albanian law in place on ethical rules in the public administration, and implementing legislation in place on the approval of the rules for the application of the principles of ethics, classification of the external activities and the value of gifts that may be administered during the activity of the public administration servants. Anti-corruption measures are in place in many of the entities that implement the EU *acquis* on the free movement of goods. SIMS publishes its programmes, reports, and work plans on its website, and has its own transparency programme and is subject to national legislation on the prevention of conflict of interests in the exercise of public functions. STII and the customs agency both have similar transparency and conflict of interest measures in place, and SIMS and STII both have a code of ethics. The National Agency of Medicines and Medical devices has a transparency programme, an electronic register of requests and responses, a coordinator on the right of information, a whistle blower unit, and online templates of denunciation for internal or external whistle-blowers, as does the customs authority. The State Export Control Authority has a transparency programme, a register of requests and responses, and a coordinator for the right of information.

### **b. Commission assessment**

Albania has established several anti-corruption measures in the entities responsible for implementing the EU *acquis* on the free movement of goods, notably in regard to transparency and the provision of information. Most implementing entities involved also have measures against conflict of interests in place, and several also have internal whistle blower entities.

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

Albania has a wide range of anti-corruption measures in place the entities responsible for implementing the EU *acquis* on the free movement of goods. It is important that these measures are extended to all institutions active under this chapter.

## C) CHAPTER 2 - FREE MOVEMENT OF WORKERS

As regards the general principles related to access to labour market, the *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 will 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 will help 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 Albanian legislation aims to create equal opportunities for Albanian and EU citizens in its labour market, educational and professional training, as well as employment conditions. The Albanian Constitution provides for an equal treatment between foreign citizens and Albanian citizens, as well as for a principle of equality before the law, and non-discrimination.

Besides the Department for Border and Migration Policies of the Ministry of Interior, the Ministry of Finance and Economy (MFE), as well as the National Agency for Employment and Skills, share competencies regarding the right to work of foreigners

EU citizens are exempt from the annual quotas on the employment of foreigners. In order to work in Albania, EU citizens are required to obtain a **work permit**. In 2022, most work permits (85%) were issued to non-EU citizens (mainly from Türkiye, Bangladesh, and Egypt), but also to Italian citizens. Foreign citizens in the Albanian labour market are mainly employed in the construction, agriculture, forestry, fishing, retail, and hospitality sectors.

EU citizens do not need a **visa** for temporary residence. In addition to a work permit which is provided while taking into account national preference, non-EU foreign citizens are required to apply for **residency permits** to work in Albania; the work permit and the residence permit being gathered in a



'Unique Permit'. EU citizens, and their family members who do not have EU citizenship, are exempt from the obligation to obtain an Employment Approval from the National Agency for Employment and Skills, before being granted a Unique Permit/Residence Permit and are therefore not submitted to the national preference rule. While non-EU citizens receive one year residency permits, EU citizens, as well as US and Kosovar citizens, receive residency permits valid for five years. After five years of residence in Albania, EU citizens receive a permanent residency permit giving them a right to employment without the need to apply for a work permit. Non-EU family members of EU citizens do not benefit of the same advantages as EU citizens.

The Albanian legislation prohibits direct and indirect **discrimination** of people seeking employment on the basis of gender, race, religion, ethnicity, language, political, religious or philosophical beliefs, economic, educational, social or parental status, unless there is a reasonable and objective justification. Protection from discrimination on the ground of nationality is ensured through article 16/1 of the Constitution.

Legally employed foreigners have equal **employment rights** as Albanian citizens. Therefore, EU citizens employed in Albania are taxed with the same taxation regime as Albanian citizens. In case of violation of those principles, the legal system provides for fines and complaint procedures.

EU and Schengen area citizens, as well as their **family members**, enjoy the same rights to employment as Albanian citizens.

Non-Albanian citizens may not have access to certain types of employment in the **public sector**, including the State police, as those are conditional on possessing Albanian citizenship.

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

Albania's legal framework regarding the access to its labour market for EU citizens and their family members is **partly aligned** with the *acquis* on the freedom of movement for workers concerning the right to enter, reside, work and access to employment. Albania, above all, needs to ensure that by the time of accession, EU citizens can access its labour market without any restrictions (e.g.: a work permit) and that they are entitled to reside in Albania for the purpose of work without a visa or residence permit. Albania 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. Albania needs to carefully examine which categories of civil servants could be reserved for Albanian nationals only. EU citizens must also have the right to bring their family members to Albania; the rights allocated to their spouse and children must be the same, be they EU or non-EU nationals.

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

Albania is **partly aligned** with the *acquis* on **the freedom of movement for workers** concerning the right to enter, reside, work and access to employment. 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 guarantee adequate rights for EU citizens family members, be they EU or non-EU nationals. 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**

There are two types of supplementary pensions in Albania: a supplementary state scheme managed by the Social Insurance Institute and a supplementary private scheme. The supplementary state scheme provides supplementary old age, disability and survivor benefit for persons performing constitutional functions and state employees. The voluntary pension fund structure includes personal pension plan

and occupational pension plans. Both employers and employees contribute to the supplementary pension schemes. A draft law on private pension funds, largely aligned with the Directive (EU) 2016/2341 on institutions for occupational retirement provision (IORP II) is currently being discussed in the Parliament.

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

Albania's Law on Voluntary Pension Funds is **partially aligned** with the *acquis* on pensions. Albania will have to put legislation in place that is in line with EU *acquis* on occupational pension schemes.

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

Albania is **partly aligned** to the EU *acquis* on **supplementary pensions**. Albania is in partial compliance with the *acquis* regarding supplementary pensions. It will have to adopt measures in line with the *acquis*, in particular on occupational pension schemes, which are not yet in place.

## **III. EURES**

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

The National Agency of Employment and Skills (NAES) has established an integrated database within the e-Albania government system to enable connection to EURES. The list of European Skills, Competences, Qualifications and Occupations (ESCO) has been mapped with the national list of professions, and the IT system in place enables automated matching. Albania will carry out further technical developments in order to ensure the connection of its system with EURES upon accession. The National coordination office will be established in the public employment service.

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

Albania has a good level of preparation regarding EURES. All main IT elements for EURES network are in place. However, preparations need to continue for the connection of private employment agencies.

The role of the public employment service as National coordination office needs to be put in place and adequate resources be allocated.

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

Albania has a **good level of alignment** with the EU *acquis* on **EURES**. It will have to ensure the adequate connection of private employment agencies to the system and put in place the National coordination office.

## **IV. EUROPEAN LABOUR AUTHORITY**

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

Albania has taken several measures to advance towards compliance with the mandate of the European Labour Authority, including strengthening cooperation between national authorities, easing the access to information requirements regarding labour mobility, and tackling undeclared work and risk assessment.

The country currently has 11 agreements on social security coordination in force with third countries, three more are expected to be approved soon, and four are in negotiations. The country also has two agreements in force with third countries on employment and labour migration. Two memoranda of understanding and cooperation have also been signed regarding inspection of labour market.

The Ministry of Finance and Economy's Directorate of Employment Policies and Skills covers the role of national contact point.

Albania declared that the fight against undeclared work was a priority for the country, making future collaboration with the European Labour Authority a goal. Albania's plans include further cooperation with the countries of the Western Balkans as well as the strengthening of the country's IT system and capacities of State Labour Inspectorate and Social Services (SLISS).

Regarding accelerated integration Albania requested that the seminars on exchange of good practice by the European Labour Authority have adequate funding.

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

Capacity building needs to be planned in order to develop proper collaboration with the European Labour Authority, specifically as regards IT and SLISS human capacities. Fight against undeclared work must be reinforced.

Regarding accelerated integration the Commission will explore funding opportunities for the European Labour Authority seminars on exchange of good practice.

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

Albania is <b>partly aligned</b> with the EU <i>acquis</i> establishing the <b>European Labour Authority</b> . Capacity building will have to be planned, both as regards IT and human capacities.
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## **V. COORDINATION OF SOCIAL SECURITY SYSTEMS**

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

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

Albania's social security system covers all Albanian nationals, Albanian nationals who are abroad, as well as foreign citizens working in Albania. The country is moving towards universal coverage. The system includes cash sickness benefits, cash maternity benefits, cash benefits for accidents at work and occupational diseases, unemployment cash benefits as well as old-age, disability, and survivor pensions. For males, retirement age is of 65 years for the period 2015-2032 and will increase of one month per year until 2056 to reach 67 years old. For females, retirement age will increase by two months per year between 2015 and 2032 to reach 65 years old, and by one month per year between 2032 and 2056 to reach 67 years old.

The institution responsible for the coordination of social security systems in Albania is the Social Insurance Institute (SII), which is composed of 12 regional directorates of social insurance. Seven bilateral agreements in the field of social protection have been signed, out of which five are with EU member states, three more being in the process of finalisation.

Currently, Albania has concluded bilateral social security agreements with 11 countries including six EU Member States. Bilateral social security agreements have also been signed with Kosovo, North Macedonia, and Türkiye. These agreements are based on the principle of equal treatment for all employed people, regardless of nationality and insurance in the country of work for all branches of social security (*lex loci laboris*). Agreements signed between Albania and third countries follow the principle of aggregation, meaning that all branches of social security are covered by the agreements.

With regard to the export of benefits, the payment of all benefits may be carried out to the country of residence on the basis of bilateral agreements, to Albanian nationals and foreigners. Some special benefits, notably for war veterans and martyrs, cannot be exported as they are means-tested and based on residency. The fees incurred for transfers abroad are covered by the Albanian government. The amount of benefits is not indexed to the cost of living of the country of residency; it is however indexed when paid in Albania.

### **b. Commission assessment**

The experience Albania gathered through bilateral social security agreements, allows it to have a good level of preparation in the field of the coordination of the social security system. It will nevertheless need to develop its social security system, identify its special non-contributory benefits (SNCB) and carry on signing social security agreements, specifically with Member States. The discrepancy between the retirement age of men and women, will have disappeared by 2032.

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

### **a. Country presentation**

Albania expects to be able to carry on electronic exchange of data (EESI) with foreign institutions when it becomes an EU Member State. However, it was flagged that relevant data from 1994 to 2011 is yet to be digitalised, while data from 2012 onwards has been completed online and is therefore under digital format.

### **b. Commission assessment**

Albania will have to finalise the digitalisation of relevant past social security information data (specifically the pay rolls for the period between 1994 to 2011 in order to be able to participate smoothly in the Electronic Exchange of Social Security Information (EESI).

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

### **a. Country presentation**

Albania has aligned its Albanian Health Card to elements of the European Health Insurance Card (EHIC), health protection is realised on the grounds of bilateral agreements on social security.

### **b. Commission assessment**

Albania already benefits from a national health card, to which it has aligned elements of the EHIC. It will need to finalise its alignment by the date of accession.

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

Albania is **partly aligned** with the EU *acquis* on **the coordination of social security systems**. It benefits from an substantial experience of the basic mechanisms involved in social security coordination. However, sufficient administrative capacity as well as deeper knowledge and further digitalisation needs to be developed to apply the EU *acquis* in this field. Further social security agreements need to be signed, specifically with EU Member States.

## **VI. FIGHT AGAINST CORRUPTION - FREE MOVEMENT OF WORKERS**

### **a. Country presentation**

An ethics code for the Social Insurance Institute is in place. A law on the protection of whistle-blowers has also been adopted.

### **b. Commission assessment**

Albania has put in place specific measures in order to limit corruption in the field of free movement of workers through transparency and digitalisation measures.

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

Albania is moderately prepared regarding anti-corruption measures in the domain of free movement of workers. It has put in place relevant measures, but the general framework will have to be reinforced.



## 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 EU *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. A number of administrative cooperation procedures foreseen by the Directive is 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 2006/123/3C (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 and the Regulation: 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 on cross-border parcel delivery services 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

Albania stated that its legislation is not aligned with Directive 2005/36/EC on the recognition of professional qualifications and its amendments, but that its sectorial legislation is largely aligned with the *acquis* in regard to minimum training conditions. Full alignment is expected by the end of 2025. Albania stated that regulated professions are found in the sectors of health, legal services, agriculture & forestry and fisheries, security and civil protection, civil engineering, energy, maritime aviation, veterinary, intellectual property, customs, crafts, accounting and auditing, education and sports. The relevant legislation in Albania is the Constitution (article 11 on market economy and freedom of economic activity; article 17 on limitation of rights only by law and proportionality principle, article 18, general principle of non-discrimination; article 49 on economic rights; article 16 on protection of foreigners/legal persons) and the regulatory framework.

Albania's Law 10 171/2009 on Regulated Professions establishes the criteria for exercising certain professions in order to protect public interest, public safety and health. The Law defines regulated professions and professional qualifications, their requirements, the principles for exercising professions, the exemptions and duties. The scope of the Law is nationals, foreigners and natural persons seeking to exercise a profession in Albania. The professions included are doctors, dentists, pharmacists, nurses, midwives, physiotherapists, veterinary doctors, architects, engineers, teachers, social workers and psychologists. Exemptions apply to professions related to the judicial authority (judges, magistrates, bailiffs) and other professions whose functions do not need to be regulated (e.g. specialists or street vendors). Other regulated professions are subject to specific legislation (for instance, lawyers, maritime professions, translators).

The Law on Higher Education and scientific Research in Higher Education Institutions and the Law on vocational education and training define the competent authority for the recognition procedure and the requirements. Regulated professions are organised in a total of 43 Professional Orders subject to sectorial legislation and regulating access and exercise to the professions.

Albania plans to fully align with the Directive on the recognition of professional qualifications in 2025; to complete the screening of sectorial legislation in 2025 and to strengthen its administrative capacity in order to be able to implement the *acquis*.

The general criteria for accessing/exercising sectorial professions in Albania are having the relevant qualification, official certification, completion of relevant professional internship/practice, passing the state exam and registration with respective professional body.

As regards the **Proportionality Test Directive (EU) 2018/958**, Albania stated that it plans to align with it by 2025. Albania explained that the Law no.146/2014 on public information and consultation stipulates publication in an electronic register of draft laws, their notification, direct consultation and public meetings with interested parties. The Law regulates a complaint review process. Decree of the Council of Ministers (DCM) 584/03 on the Regulation of the Council of Ministers establishes the obligation to consult every regulatory initiative. According to the Albanian authorities, some Albanian

legislation falls under the proportionality assessment. Albania has established a list of the Orders' membership criteria for foreigners.

As regards the **European Professional Card and the Alert Mechanism**, Albania stated that it would align its legislation with that aspect of Directive 2005/36/EC in 2025.

Albania provided a detailed presentation on the health sector professions with minimum training requirements, the Law no. 10 107/2009 on health for medical doctors, dentists, nurses responsible for general care, midwives, veterinaries, pharmacists, architects and lawyers and referred to the requirements for foreigners to exercise those professions in Albania.

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

Overall, Albania is **partly aligned** to the EU *acquis* on qualifications, in particular with Directive 2005/36/EC on the Recognition of Professional Qualifications and its amendments remains to be ~~transposed~~ **aligned with the *acquis***. Sector-specific legislation in Albania is **partly aligned** with the EU *acquis* – concerning minimum training conditions, but further efforts are needed to complete alignment. 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. Albania expects to fully align with the *acquis* in this area by the end of 2024 and to further increasing its administrative capacity. 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 Albania's alignment with this *acquis*.

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

Albania is **partly aligned** to the EU *acquis* on qualifications. Albania needs to complete the alignment of its legislation in this area, in particular with Directive 2005/36/EC and its amendments and increase its administrative capacity due to the complexity of the *acquis* in this field, which requires preparations well before accession.

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

### **a. Country presentation**

Albania main piece of legislation in the area of services and the right of establishment is the Law no. 66/2016 on Services, which is partly aligned with Directive 2006/123/EC (the Services Directive). Further legislation consists of Law no. 10 081/2009 on licences, authorizations and permits, new Code on Administrative Procedures and Law no.13/2016 on Public Service Delivery. Other relevant legislation is the Constitution (article 11 on market economy and freedom of economic activity, article 17 on limitation of rights only by law and proportionality principle, article 18 on non-discrimination principle, art 49 on economic rights and article 16 on protection of foreigners/legal persons).

Albanian Law on Services excludes certain services from its scope of application; it does not require a general permit to invest/establish business in Albania. Law no79/2021 on Foreigners requires them though to have a permit stating that they are self-employed; EU/EFTA & CEFTA nationals are granted automatic entry (self-employed permit) through an electronic procedure of notification to the respective Albanian authority while being in Albania. Other foreigners need prior authorisation but are exempted from quotas.

Albania does not foresee any limitation to primary or secondary establishment; branches have the same legal personality as the parent company. Albania applies the non-discrimination principle (article 4 of the Law on Services) unless public interest justifies (principle of necessity) and the pursued activity cannot be achieved with a less restrictive measure (proportionality).

As regards the **Point of Single Contact**, the legal framework consists mainly of the Law on Services and Decision no. 1147 on the Unique e-Albania Governmental Portal State Database and on the



Approval of the Rules on the Functioning of the Single Point of Contact. It provides for an electronic portal embedded in e-Albania where services' providers can do all the necessary to start a business; it also provides information on formalities, contact details to start a business or an association, registering it and complaint mechanism. It is available in English and Albanian.

The Law on Services also stipulates the **screening of sectorial legislation**, further developed in Decisions on Council of Ministers no. 299 (methodology, authorities, reporting, drafting plan) and 300 (notification of new legislation, self-evaluation). Albania has so far identified service sectors and activities subject to screening and drafted a plan to revise sectorial legislation that shall be complete in 2024. Albania is supported by the GIZ SANECA project in this area.

Albania stated that it still has to align with the **cross-border provision of services** provided in Articles 16-18 of the Services Directive (plan to do so in 2025) as well as the multi-disciplinary activities and professional liability guarantee (accordingly Articles 23 and 25 of the Services Directive)..

Albania expects to fully align with Directive 2006/123/EC in 2025.

As regards the **Internal Market Information (IMI) System**, Albania stated that the relevant framework is the Law on Services, the Law no. 9880 on Electronic Signature and DCM no. 673 on the Reorganization of the National Agency of Information Society. Albania has not aligned with the *acquis* in this area (they foresee to do this in 2025) but it is willing to start negotiations to become a member of the IMI system

The institutional set up and administrative capacity are within the Ministry of Finance and Economy, National Business Centre (unified one-stop-shop for business registration and licensing), National Agency of Information Society and all responsible institutions for regulating access to/exercise of services activities (line ministries, independent and subordinate institutions and local government). Albania plans to further increase its administrative capacity in 2024-2025.

Regarding accelerated integration, Albania requested further participating in the single market in the area of freedom of establishment and freedom to provide services.

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

Overall, Albania is **partly aligned** with the EU *acquis* in the area of Services. The alignment with the cross-border of services provisions of the Service Directive still has to be undertaken. . The screening of legislation to identify barriers to the freedom of establishment and free movement of services with a view to further aligning its legislation with the Services Directive is partly done.

Regarding accelerated integration, the commission will explore further accelerated integration requests in the area of freedom of establishment and freedom to provide services.

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

, Albania is **partly aligned** with the EU *acquis* in the area of Services. Albania needs to complete the alignment of its legal framework with the Services Directive as well as to complete the screening of the Albanian legislation to identify all the possible barriers for services' providers.

## **III. POSTAL SERVICES**

### **a. Country presentation**

Albania's legal framework on postal services consists of Law no. 46/2015 on Postal Services in the Republic of Albania, , Law no. 9918/2008 on Electronic Communications, DCM no. 207 on the Approval of the Postal Services Policy Document and secondary legislation. Albania stated that its Law on Postal Services is fully aligned with the *acquis* as regards the Directive 97/67/EC as amended by Directive 2002/39/EC and Directive 2008/6/EC of the European Parliament and

of the Council.

Albania has gradually opened its postal sector to full competition abolishing the services reserved to the universal service provider in 2017, in line with the Postal Services Directive. There is currently one universal service provider, Albanian Post, with individual authorization issued by the national regulatory authority (AKEP), and 35 other postal service providers on the market with general authorizations. In 2021 the Regulation on cross-border parcel delivery services was transposed in Albanian legislation by the Instruction of Minister of Infrastructure and Energy No 5 of 25.6.2021. On the approval of the regulation on cross-border parcel delivery services Albania explained the scope of its universal service and the licensing regime, the complaints procedure, tariffs system and accounting separation of the universal service provider, and how it implements the Regulation on cross-border parcel delivery services .

The Authority for Electronic and Postal Communication AKEP (AKEP Authority for Electronic and Postal Communication) is a legally separate and operationally independent postal regulatory body in Albania with a staff of 85 employees. It monitors the postal market to ensure compliance with the EU postal rules and the provision of the universal service.

The central government (Ministry of Infrastructure and Energy, Finance and Economy, Commissioner for Consumer Protection, General Directorate Standards) is responsible for the postal sector policy. The postal sector strategy in Albania was approved in 2022 defining the vision for the development of the postal sector in the medium and long term. It focuses on providing postal services with high quality and reliability throughout the territory of the Republic of Albania based on new technologies and innovative solutions, as well as defining the objectives for the development of the postal sector for the period 2021-2026.

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

Overall, Albania is **fully aligned** to the EU *acquis* on postal services.

#### **C. SUMMARY OF FINDINGS – POSTAL SERVICES**

Albania is **fully aligned with the EU *acquis* as regards the Postal Services Directive and the Regulation on cross-border parcel delivery services in this area, it only**; In this context it needs to ensure compliance with the EU postal rules and provision of the universal service, and continue monitoring postal market developments .

### **IV. FIGHT AGAINST CORRUPTION – RIGHT OF ESTABLISHMENT AND FREEDOM TO PROVIDE SERVICES**

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

Albania criminalizes corruption as a serious crime, including its cross-border dimension. It has ratified the relevant international conventions against corruption; specific laws are in place to prevent corruption or to early detect it. Albania has also adopted specific legal acts to prevent money-laundering and ensures the confiscation and seizure of assets that are the result of corruption and organised crime. Albania has a cross-cutting strategy against corruption and an Action Plan 2020-2023; it applies several anticorruption measures (Law no. 131/2015 on the National Business Centre and a unified one-stop-shop for business registration and licensing/permits, including publication of any information related to registration and licensing). Albania has also undertaken the digitalization of the public services simplifying procedures and established procedures for addressing complaints. Furthermore, it has an updated register of requests and responses, a coordinator on the right of information and a transparency programme.

### **b. Commission assessment**

The Commission notes Albania's 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 – FIGHT AGAINST CORRUPTION**

Albania 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 Court of Justice of the European Union (CJEU) 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 – GENERAL FRAMEWORK

#### a. Country presentation

Free movement of capital in Albania is regulated by a number of core legal acts, including the Constitution of Albania, its laws on foreign investments, on the ratification of the Stabilisation and Association Agreement (SAA) with the EU, on strategic investments, and implementing legislation on activity in foreign currency. Albania currently has a number of Bilateral Investment Treaties (BITs), including with some EU Member States. Albania is aware that BITs may be in conflict with EU law and that some BITs may have to be terminated or amended upon accession to the EU. The responsible

bodies include the Bank of Albania (BoA), the Financial Supervision authority (AFSA), the state cadastre agency, and the ministries of finance and economy, internal affairs, agriculture and rural development, energy and infrastructure, and the ministry of justice.

There are no restrictions on Albanian nationals opening foreign exchange accounts abroad nor on foreign nationals transferring foreign currency to third countries beyond minor informational requirements for AML purposes. The SAA provides for safeguard clauses for exceptional circumstances, *i.e.* serious balance of payments difficulties.

In terms of insurance, individuals temporarily in Albania can remain insured in another country while full time residents must be insured in Albania. The legislation does not specify when and for how long exchange restrictions on payments and transfers for capital account transactions can be imposed. However, there is a requirement that restrictions be compatible with international obligations, which also includes the SAA. Albanian legislation provides for the definition of a local or foreign national as a “strategic investor” once a certain amount has been invested, and other conditions are fulfilled, and the Albanian state can expropriate private property in favour of large scale strategic investors.

Albania does not impose restrictions on inward or outward direct investments, however there are currently some legal restrictions in place on real estate, notably restricting the ownership of agricultural land, forests, meadows, and pastures and also specific investment requirements for the purchase of construction land. Albania is in breach of the SAA as regards prohibition of the acquisition of land by EU citizens. However the Law no. 8337, dated 30.4.1998, "On the transfer of ownership of agricultural land, forests, meadows and pastures," allows the rent up to 99 years for foreign natural and legal persons. Albania expects to repeal the current law restricting foreign ownership of agricultural land by 2025. The complexity of specific issues related with the process of drafting the law and finalization of preparatory phase of implementation, might impose the need for further negotiation before the full removal of restriction.

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

Existing Albanian legislation provides that, unless the process of compensation for previous owners is settled, agricultural land cannot be sold to foreign nationals. This legislation needs to be reformed to remove restrictions on acquisition by foreign nationals, notably EU citizens, for a fair market price. These provisions should have been addressed by 2016, in order to be in line with the SAA. This is an issue that has been raised in several SAA meetings and Albania needs to address this rapidly as it is in breach of the SAA.

Regarding Albania’s existing BITs, 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 their third-country counterparts are not willing to engage in their renegotiation or consensual termination. As a result, Albania should already try to align the texts of its BITs with third countries, as well as its policy regarding the conclusion of future BITs with the EU’s relevant policy and templates.

#### **C. SUMMARY OF FINDINGS – FREE MOVEMENT OF CAPITAL - GENERAL FRAMEWORK**

Albania is **partially aligned** with the EU *acquis* on free movement of capital. Albania should fully liberalise the sale and purchase of real estate, including agricultural land for EU citizens. It should also amend existing BITs with third countries to remove survival clauses prior to accession and ensure consistency with the EU’s relevant policy and requirements. Albania should ensure sufficient administrative capacity and coordination to implement the EU *acquis* on free movement of capital.

## II. PAYMENT SERVICES

### a. Country presentation

The Bank of Albania is the competent authority for the oversight and supervision of Albanian **payment systems and services**. In recent years, the National Strategy on Retail Payment Systems (2018-2023), which aims to modernise the retail payment systems in Albania, has promoted the development of the payments market and helped to increase the use of electronic payments. The Albanian Law on Payment Services entered into force in 2021, aiming to align national legislation with the Payment Services Directive 2, but excluding, inter alia, cross-border payment services and cross-border activities of institutions. National law has been partly aligned with the E-Money Directive 2 and the Single European Payments Area (SEPA) Regulation. Similarly to the alignment of national law with the Payment Services Directive 2, provisions dealing with cross-border situations are not included. The provisions of the Cross-Border Payments Regulation 2 and the Interchange Fees Regulation have not yet been implemented in Albania. The latter has been postponed due to the low level of card payment infrastructure and concerns that the regulation may negatively affect the future development of the market. Albania is also working on the creation and development of an instant payment solution.

In regard to accelerated integration, Albania requested participation in SEPA schemes..

### b. Commission assessment

Albania has made significant progress in recent years in the area of payment systems and its legislation is **partially aligned** with some of the relevant *EU acquis*, while it has not implemented the provisions of the *EU acquis* on cross-border payments and interchange fees. There are also shortcomings in the transposition of the Payment Services Directive 2, the E-Money Directive 2 and the SEPA Regulation on cross-border payment services and cross-border activities of institutions. Albania foresees full alignment by the time of accession to the EU. In view of the widespread use of electronic payments, Albania should ensure the implementation of rules on interchange fees in line with the relevant *EU acquis*, in order to reduce the cost of fees for merchants and to promote electronic payments and their competitiveness.

Regarding Albania'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 Albania's efforts to comply with the criteria of the EPC, including, inter alia, a high degree of alignment with the 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

Albania is <b>partially aligned</b> with some of the <i>EU acquis</i> on <b>payment services</b> . Albania should continue aligning with the <i>EU acquis</i> and ensure the implementation of the <i>EU acquis</i> on cross-border payments and interchange fees.
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## III. ANTI-MONEY LAUNDERING

### a. Country presentation

Albania maintains a broad definition of criminal activity and an all-crime approach to **money laundering** in its criminal code and has adopted specific laws on Anti-Money Laundering and Countering the Financing of Terrorism (AML/CFT) as well as laws on establishing a register of beneficial owners and register of bank accounts. A risk-based approach is applied which obliges certain entities to identify, document and mitigate AML related risks. The AML/CFT legislation is broad in scope and reporting entities include but are not limited to banks, insurers, real estate agents, lawyers, accountants, tax advisors, art brokers and any individual or natural legal person who trades

goods and services involving payments in cash in excess of 8 600 EUR. Reporting entities must submit suspicious activity reports (SARs) to the Albanian FIU no later than 72 hours after detection. From 2018 to 2022, on average 1 546 SARs were filed per year, the majority of which were filed by notaries and banks. Albania has now addressed all of the items on the Moneyval/FATF 2020 action plan, and in October 2023 was delisted from FATF’s ‘grey’ list of jurisdictions under increased monitoring.

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

Despite recent progress on alignment with the EU’s AML framework, Albania is partially aligned with the EU *acquis* in this area. In terms of the risk-based approach to AML, reporting obligations remain the responsibility of the reporting entities. The number of suspicious activity reports for lawyers is low and there have been none for gambling services providers thus far. Authorities were unclear if predicate offences have also resulted in parallel money laundering / terrorism financing investigations. Further work is necessary by authorities to ensure compliance with reporting obligations.

Regarding trusts, legislation provides that a trust can be client of a reporting entity, but according to authorities this has not happened in practice. Albania was delisted from FATF’s ‘grey’ list in October 2023, after having completed its FATF Action Plan. Albania should ensure that any future VTC law (including potential criminal amnesties) complies with the EU *acquis* and international standards. At the time of the bilateral screening meeting, Albania expressed the intention of reaching full compliance with FATF recommendations 7 and 15 in the course of 2023, but it remains only partially compliant.

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

Albania is **partially aligned** with the EU *acquis* on **money laundering**. Albania should continue aligning with the EU *acquis* in this area and refrain from establishing any scheme or other measure that might undermine alignment with the EU *acquis* and policies, including EU procedures and measures aimed at preventing money laundering and tax evasion.

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

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

Relevant primary legislation in Albania includes – among other provisions – Law no.8269/1997 on the Bank of Albania; Law no.9572/2006 on the Financial Supervisory Authority; Law no.53/2014 on Deposit Insurance; Law no.60/2016 on Whistleblowing and Whistle Blowers Protection’ and Law no.9367/2005 on the Prevention of Conflicts of Interest in the Exercise of Public Functions. Secondary legislation is divided among provisions dedicated to the Albanian Financial Supervisory Authority, the Bank of Albania and the Albanian Deposit Insurance Agency in their capacity as responsible institutions entrusted with fighting corruption. Additionally, Albania devised an Action Plan in Cross-cutting Strategy Against Corruption for the period 2023 – 2030. The various authorities will participate in the roundtable annual meeting focused on integrity, with the aim of strengthening institutional integrity and protecting public finances and assets. The specific objective of the strategy is the ‘protection of public finances and assets against abuse’.

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

The Albanian legislation provides corruption as a serious crime, including in its cross-border dimension. Albania 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. 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 Albania, 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. Therefore, focusing on implementation is key going forward.

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

Albania 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.



## 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 *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

Albanian law recognises the following main legal forms of business entities: limited partnership, private limited liability company without shares (LLC), general partnerships and joint stock company (JSC), which can be public or private.

#### I.A. DISCLOSURE REQUIREMENTS IN RESPECT OF COMPANIES AND BRANCHES AND THE USE OF DIGITAL TOOLS AND PROCESSES

##### a. Country presentation

Albania stated that it is aligned with the *acquis* in this area which is regulated by the Law no. 9723 on Business Registration.

All companies must register in the **commercial register** - including representative offices and branches of foreign companies - which is managed by the National Business Centre (NBC). Since May 2022, applications must be submitted electronically through the online government portal e-Albania. This no-cost process takes one working day, if all requirements are met. Companies are registered using a unique ID number. Documents submitted in paper format are converted and stored in electronic format, with no obligation on NBC to retain and archive these paper documents. Information on the commercial register is publicly accessible and free of charge – but with a nominal fee for certain information in paper form.

It is mandatory to disclose the identification data and signature samples of persons representing the company towards third parties. It is also mandatory to register any changes to the company, including wind up, merger, division, liquidation, and bankruptcy. Changes to company information are registered within 30 days from the change, whereas the *acquis* states normally within 21 days from receipt of the complete documentation regarding those changes. There is no requirement in Albanian law to disclose the names of disqualified directors.

Companies are obliged to disclose their financial statements in the commercial register no later than seven months from the closing date of each financial year; failure to do so can result in a fine of EUR 550.

Documents to be submitted are in the Albanian language, or in the case of documents of foreign jurisdiction, by a certified translation in Albanian. Information published by NBC is available in Albanian and English.

Regarding the EU **Business Registers Interconnection System (BRIS)**, Albania informed that currently all documents submitted to the commercial register are in pdf format, while financial documents are in xml format. It stated that some advance could be made in the next three years on having information in a database to be exchanged through BRIS, but that full interconnection with BRIS would be for the time of accession, following reflection on the technical specifications required.

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

Albania 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 interconnection with BRIS, Albania needs to align with the provisions on structured/machine-readable data and should refer to the Commission Implementing Regulation (EU) 2021/1042 on the technical specifications and procedures required, and on the timing for the registration of changes in the business registers.

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

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

The **formation and capital requirements** is governed by the Law no. 9901 on Entrepreneurs and Companies and Law no. 9723 on Business Registration. Albania stated that these laws are aligned with the relevant provisions of Directive (EU) 2017/1132. Formation of a company can be done online. The initial application for the registration can be submitted by the founders, or by any other authorised person. A notary may be authorised to register a new company directly through the e-Albania portal.

All business entities must register a list of mandatory company information with the commercial register. This information - and any subsequent changes - will remain publicly available, even after a company is stricken off the record of the business register. Administrators can be appointed by the company to act on its behalf. The main decision-making body of a limited liability company (LLC) and joint stock company (JSC) is the General Assembly of shareholders.

The minimum capital for setting up a LLC is less than 1 euro. For a private JSC the minimum capital is (approx.) EUR 30 000 while for a public JSC it is (approx.) EUR 86 000. Contributions for LLC and JSC can be only in cash, only in kind, or in both. Shares subscribed with contribution in kind must be paid in full before registration. Shares offered at a price higher than their nominal value must be fully repaid. The value of contributions in kind is decided by the shareholders, or, if they cannot mutually agree, by a licensed independent expert whose report must be published in the commercial register.

The company can distribute profits to the shareholders, only if after paying the dividend the company's assets fully cover its liabilities and the company has sufficient liquid assets to pay off the liabilities that become due within the next 12 months. Interim dividends cannot be distributed. In case of an unlawful distribution, the company may request its recovery based on the procedure described in the law.

The decision on capital increase or decrease is made by the General Assembly through a majority vote of three quarters of shareholders participating and must be registered in the commercial register. The pre-emption right can be exercised by shareholders at the time of making the capital increase or decrease, in proportion to the capital represented by their shares. It is possible to authorise an increase of capital up to a maximum amount and to empower the administrative body to carry out the operation.

The capital cannot be decreased below the minimum basic capital required by law. A reduction of capital that changes the rights of a certain category of shares must be approved by those shareholders affected. There are safeguards for creditors whose claims are submitted within 90 days from publication of the decision to reduce the capital, such as the right to obtain security for claims.

The registered capital cannot be increased (either in cash or in kind) if the contributions for the previously subscribed shares have not yet been paid. The law has no cap on the increase of capital.

The law provides that shareholders are treated equally with the same rights and under the same circumstances.

Acquisition of own shares is prohibited. If a person does buy shares on behalf of a company, they are considered by law to have bought them on their own behalf. However, it is possible for a company to acquire its own shares if the company sells or cancels them within one year from the date of acquisition, including in the case of related party transactions. Acceptance of company's own shares as security is not regulated under national legislation, but such a situation is covered by the provisions on prohibition of purchasing own shares, at least during the enforcement of the security on shares.

A General Assembly must be convened if annual or interim accounts show losses amounting to 50% of the basic capital, or there is an indication that the company's assets cannot cover its liabilities within the next three months. The law does not specify the content of the decision to be taken, but if the capital is not restored following an assessment of the situation and subsequent measures taken by the company, then the company may file for bankruptcy.

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

Albania is **partially aligned** with the *acquis* on company formation and capital requirements.

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

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

The Law on Entrepreneurs and Companies provides that a LLC or a JSC may be a single-member company, which can be an individual or a legal entity. The sole shareholder is obliged to register in the commercial register and is responsible for exercising the rights and obligations of the General Assembly. All decisions must be recorded and kept at the company's head office. An individual managing a single member company cannot enter into contracts on loans or guarantees with the company; other contracts concluded must be recorded and kept at the company's head office, failure to do so is liable to a fine not exceeding ALL 15 000 (EUR 120).

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

Albania is aligned with Directive 2009/102/EC on Single-member Private Limited Liability Companies.

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

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

The Law no. 9901 on Entrepreneurs and Companies regulates **domestic mergers and divisions**. This applies to LLCs and both private and public JSCs who have been registered for at least one year. The restructure can be done by acquisition or through the creation of a new company. A company can be divided transferring all its assets and liabilities in favour of two or more existing or newly established companies. The main procedural steps are in line with the *acquis* regarding the draft terms of the agreement, the report of a licensed independent expert, publication in the commercial register at least one month before the General Assembly (GA), shareholders' rights to inspect the documents and acquire printed or electronic copies, approval by the GA and publication of the final decision. Any change in the value of assets/liabilities between the date of the draft terms and the date of the GA must be reflected in the final report, which is published in the commercial register. The law provides for an exemption of GA approval in the case of acquisition of one company by another which holds 90% or more of its shares.

The law has no specific provisions aligned with the *acquis* whereby creditors have access to administrative or judicial protection for violation of rights.

Albania informed that employee rights are covered by the general provisions of Albania's Labour Code. *This area is dealt with under Chapter 19 - Social Policy and Employment).*

Albania stated it is broadly aligned regarding domestic divisions. It informed that alignment is outstanding as regards other operations treated as mergers or divisions i.e. those concerning cash payment exceeding 10% or where the transferring companies or company being divided cease to exist. In this regard, Albania stated its commitment to assessing alignment needs and modalities within the next three years and explained it would require EU support for better understanding of the relevant *acquis* and best practices.

**Cross-border mergers** are regulated by the Law no. 110/2012 on Cross-Border Mergers of Commercial Companies. Albania stated this law is fully aligned with (EU) Directive 2017/1132. It applies when at least one of the companies is Albanian (LLC or public or private JSC). The law stipulates the procedural steps – these include drawing up the merger agreement, approval by the GA, and verification by the authorised notary who must issue a pre-merger certificate, certify the legality of the cross-border merger and ensure the publication in the commercial register. The law provides that the company arising from the cross-border merger cannot be declared as null and void. There are also provisions on the protection of creditors, employees and shareholders, as well as holders of special rights, which will need to be further aligned with the EU Company Law *acquis*, in particular as regards creditors’ protection.

Albania stated that there are no provisions in national law for **cross-border divisions or conversions**. Here again, Albania confirmed its commitment to assessing alignment needs within the next three years - including on employee and creditor protection - and signalled that it would need EU support in this regard.

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

Albania is **partially aligned** with the *acquis* on domestic mergers and divisions and cross-border mergers, but it is **not aligned** on cross-border divisions and conversions. It plans to fully align on domestic mergers and divisions by 2026, including the area of other operations treated as mergers and divisions; more specifically articles 116, 117, 158 and 159 of (EU) Directive 1132/2017. It also **needs to align with** amending Directive (EU) 2019/2121 paying close attention to employee, member, and creditor protection.

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

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

Albania stated there are no legal provisions as yet in domestic legislation on the Statute for a European company or the European Economic Interest Grouping (EEIG). Albania also stated there is no specific alignment with the Statute for a European Cooperative Society, although there may be partial alignment through Law 38/2012 on agricultural cooperation societies. For all three legal forms, Albania underlined its commitment to assess - within the coming three years - how *acquis* alignment might be achieved within the national regulatory framework, in particular regarding the business register and employee rights. In this context, Albania indicated it would need EU support for better understanding of the relevant *acquis* and best practice on implementation.

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

Albania has no alignment with Regulations (EC) 2157/2001 and (EEC) 2137/85 on the legal forms European Company and EEIG, nor with Regulation (EC) 1435/2003 on the Statute for a European Cooperative Society. Albania is encouraged to proceed with plans in the coming three years to assess how these legal forms can most suitably be provided for in domestic legislation.

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

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

The legal framework for **shareholders' rights and corporate governance** is the Law on Entrepreneurs and Companies and the Law on Business Registration. Albania considers it is fully aligned with Directive 2007/36/EC (Shareholder Rights Directive I [SRD I]). All shareholders are

identified and registered in the commercial register and can exercise their voting rights at the General Assembly. The Law provides for equal treatment of all shareholders; it specifies the mandatory contents of the notice of convocation and requires that documents with proposals of decisions must be accessible to shareholders at least 21 days before the meeting date (in line with the EU *acquis*). Participation by proxy is allowed if authorised by the shareholder and identification confirmed. Proxy voting is also allowed. There are procedures for voting electronically. Members representing at least 5% of the total votes of a company have the right to put items on the agenda. There are rules for reaching the quorum by simple or qualified majority.

Albania stated that it is not aligned with Directive (EU) 2017/828 regarding the encouragement of long-term shareholder engagement (Shareholder Rights Directive II [SRD II]) and explained that it needs to assess if alignment will be done through implementing legislation or through revision of the current Law. Albania said it expects to have a working plan and draft legislation with transposition tables by 2026, which will address SRD II issues, including remuneration policy for directors and the remuneration report. The date of entry into force will depend on implications with other national legislation and the code of administrative procedures.

Albania informed that to date there are no listed companies on the stock exchange and that there is no alignment with Recommendations 2005/162/EC on the Role of Non-executive or Supervisory Directors of Listed Companies or 2014/208/EU on the Quality of Corporate Governance Reporting (“comply or explain”). It confirmed its commitment to take concrete steps in this regard and apply the provisions of these recommendations by the time of accession.

As regards any **Corporate Governance Code(s)** (CGC), Albania stated that there is no CGC for listed companies, while there is a CGC for unlisted JSC which serves as a best practice reference with relevant principles. Albania informed that the Law on Entrepreneurs and Companies determines the standard rules for corporate governance models but does not oblige companies to adopt a CGC. The Albanian Financial Security Authority (AFSA) plans to set up a CGC by 2028.

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

On **shareholder’s rights**, Albania is **highly aligned** with SRD I but has no alignment with SRD II. Areas for attention include provisions on remuneration policy of directors and the remuneration report. Albania also needs to align with the provisions of Implementing Regulation (EU) 2018/1212. As Albania plans to establish a **corporate governance code** in the coming five years, it is advised to follow ongoing revisions to the OECD corporate governance principles. Albania should also introduce provisions to align with the Commission Recommendations on independent directors and board committees, and the quality of corporate governance reporting.

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

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

**Takeover bids** are regulated by Law no.10236/2010 on Takeover of Companies with Public Offer. AFSA is the competent authority responsible for the approval (or not) of takeover bids and for implementing financial sanctions for violations of the law.

Albania stated that this Law is largely aligned with the EU *acquis*, including the general principles and provisions (i.e. 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 company as a whole, no artificial increase or decrease to the price of the offeree company’s shares is allowed, and the takeover is launched only when the full financial payment is guaranteed). There are some minor areas where alignment is still required, in particular the definition of shares related to multifaceted voting.

Although Albania encourages companies to list, there are still no listed companies on the Albanian securities exchange market and thus it has no practical experience of implementing the Law. Full alignment with the *acquis* in this area is planned prior to EU accession.

## b. Commission assessment

Albania has a **high level of alignment** with the *acquis* on takeovers, and plans to fully align in this area before EU accession.

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

Albania is **aligned** with the *acquis* on single-member limited liability companies and has a **high level of alignment** regarding takeover bids, where it plans full alignment prior to EU accession.

Albania is **highly aligned** on disclosure requirements for companies and the use of digital tools and processes - which are already applicable on a national basis - but will 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.

There is also a **high level of alignment** with the Directive on shareholder rights in listed companies. However, there is **no alignment** with the amending Directive on the encouragement of long-term shareholder engagement or the 2018 Implementing Regulation. Albania also needs to introduce provisions to align with the Commission Recommendations on independent directors and board committees, and the quality of corporate governance reporting.

There is **partial alignment** with the *acquis* on company formation and capital requirements. Likewise, Albania is **partially aligned** with the *acquis* on domestic mergers and divisions and cross-border mergers, but it **still needs to align with** the *acquis* on cross-border divisions and conversions, as well as with the 2019 amending Directive, paying close attention to employee, member, and creditor protection.

Albania has yet to decide how the legal forms European Company, European Economic Interest Grouping, and European Cooperative Society can most suitably be provided for in domestic legislation, so as to ensure application of this *acquis* from the date of accession.

## II. COMPANY REPORTING

### II.A. CORPORATE ACCOUNTING

#### a. Country presentation

The area of corporate accounting is regulated by the Law on Accounting and Financial Statements which is based on EU Directive 2013/34/EU and amending Directive 2014/95/EU, Directive (EU) 2021/2101 and Regulation (EC) 1606/2002. Albania stated that the law is largely aligned with key provisions of the accounting directive, including requirements for preparing financial statements, definition of public interest entities (PIEs), thresholds for company size categories (on this Albania explained that further alignment would be achieved progressively to 2028), application of financial standards, consolidated financial statements, disclosure of financial statements, non-financial reporting, corporate governance statement, consolidated management report, and report on payments to government.

The National Accounting Council (NAC) is responsible for providing accounting standards. It translates International Financial Reporting Standards (IFRS) into Albanian and publishes them on the NAC website. NAC also issues guidelines for the preparation and content of the non-financial report. There are 16 national accounting standards (NAS), which are based on IFRS for SMEs and certain provisions of the EU accounting directive. NAS 1-14 apply to SMEs, NAS 15 provides for limited presentation and disclosure requirements for micro entities, and NAS 16 relates to non-profit organisations. There are currently six technical staff working at NAC. Albania stated that staff need more training and e-tools to function more effectively and be in line with EU standards and practices.

The law obliges PIEs to apply IFRS, while there is a derogation for small and medium sized PIEs who apply NAS. Within seven months from the reporting date, all companies must prepare their financial statements and submit the duly approved versions to the business register for publication. Micro

companies with an annual net turnover of less than ALL 5 000 000 (approx. EUR 40 000) are not obliged to publish financial statements. In this regard, Albania stated that further legislative amendments to align with the *acquis* in this area are postponed to 2028. Albania stated that small companies benefit from reduced disclosure requirements, in line with Directive 2013/34/EU. They are exempt from preparing a management report and also from preparing consolidated financial statements, except when one of the entities is of public interest. Large entities and PIEs active in the extractive and logging industry must compile and publish an annual report on payments made to government. Sanctions for the non-publication of financial statements are provided for in the Law on the national business register.

The law on ‘statutory audit and organisation of statutory auditor and certified accountant professions’ regulates which companies must appoint a statutory auditor; these being companies that apply IFRS, JSC applying NAS, and limited liability companies applying NAS over two consecutive years when they exceed certain criteria (turnover > circa EUR 80k, balance sheet > circa EUR 40k, number of employees > 50).

Albania indicated that its reform plans include regulatory framework amendments for further *acquis* alignment in this area, as well as strengthening the institutional role of NAC and increasing local and international cooperation on financial reporting.

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

Albania is **partially aligned** with the accounting Directive 2013/34/EU following a period of legislative reforms which can be found in the 2018 Law on Accounting and Financial Statements. Further alignment is required on issues regarding size criteria to define company categories and requirements for reporting on income tax information. Albania must ensure that financial statements for micro-companies that are incorporated as JSC, or other types of private LLC, are ultimately made available to the National Business Centre, and that the NAS applied by small and medium-sized public-interest entities comply with the provisions applicable to large companies. Albania also needs to align with the *acquis* on country-by-country reporting. Alignment in some of these areas is expected in 2028. Albania is encouraged to pursue its plans to strengthen capacities at the National Accounting Council and increase international cooperation with financial reporting regulators.

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

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

Albania’s Law no.25/2018 on Accounting and Financial Statements has certain provisions in line with Directive 2014/95/EU. Large companies of public interest, who exceed 500 employees, must include a non-financial report in the management report. Parent undertakings who are obliged to draw up consolidated financial statements must also prepare non-financial and corporate governance reports. SMEs with public interest are exempt from this obligation. The non-financial report should include information on key performance indicators. A statutory auditor or audit firm must verify that the non-financial report has been provided.

Although without definite plans, Albania intends to align with Directive (EU) 2022/2464 on corporate sustainability reporting, as well as with the *acquis*<sup>4</sup> requiring groups exceeding EUR 750 million to publish a country-by-country report, through amendments to the national laws on accounting and audit. This would also impact the institutional infrastructure responsible for introducing new reporting standards. In this regard, Albania underlined that capacity building for accountants and auditors would be an important element moving forward, as well as awareness raising amongst companies.

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

Albania is **partially aligned** with Directive 2014/95/EU on non-financial and diversity information (NFRD) by certain large undertakings and groups. Albania is **not aligned** with Directive

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<sup>4</sup> Directive (EU) 2021/2101 on disclosure of income tax information by certain undertakings and branches

2022/2464/EU on Corporate Sustainability Reporting (CSRD) which revises the NFRD. Albania aims to learn from best practice how the new sustainability standards will be implemented in other countries before defining which companies must use these standards and which body will be responsible. In this regard, it is advisable to focus on elements of NFRD that are common with the CSRD which will facilitate alignment with the CSRD in the future.

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

### **a. Country presentation**

**Reporting on capital markets** is regulated by Law no.62/2020 on capital markets and the Regulation on transparency requirements for listed companies. The Albanian Financial Supervisory Authority (AFSA) was established in July 2006 as an independent public institution reporting to the Albanian Parliament; one goal is to promote and maintain confidence and transparency of the securities market industry.

Albania explained that its capital market is at an early stage of development. There is one securities exchange operating which trades government securities only. To date there are no listed companies on the exchange and there is no officially appointed mechanism to store and safeguard information (although Albania stated that the Regulation does provide that regulated information shall be published at the national business centre).

Albania stated that the Regulation is **largely aligned** with Directive 2004/109/EC on transparency requirements for listed companies. It sets out obligations for biannual and annual reporting, including that they remain public for at least ten years. Annual reports must contain the financial statements, the auditor's report (if audited) and the management report; it should also include information on financial and operational performance and future development of the company. Issuers must publish on one of the media with the highest circulation in Albania. There are reporting exemptions for issuers exclusively of debt securities, as permitted by the Directive 2004/109/EC.

Albania stated it is partially aligned with the *acquis* concerning notification of the acquisition or disposal of major holdings. While national legislation provides for some level of sanctions for companies who fail to immediately publish information, Albania stated that the challenge of imposing such sanctions remains unknown for now (given there are no listed companies). Reports are published in the Albanian language only.

Albania stated that it plans to further align with the *acquis* in this area before the time of accession.

### **b. Commission assessment**

Albania 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 with Directive 2004/109/EC and ensure it is prepared to apply the relevant Commission Delegated Regulations<sup>5</sup> from the time of accession. Outstanding areas for alignment include the languages regime, the ability to act as a host member state, and to cooperate with other national competent authorities. It must also align national thresholds applicable to the notification of major holdings with EU provisions and verify that the national regime of sanctions applying to transparency on capital markets is aligned with the specific provisions of Directive 2004/109/EC. Furthermore, Albania must ensure that the obligation to draw up and publish interim financial reports addresses the consolidated level of a listed group. As Albania has no specific plans currently, alignment in this area is expected prior to accession.

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<sup>5</sup> Commission Delegated Regulations (EU) 2015/761, 2016/1437, and 2019/815



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

### **a. Country presentation**

**Statutory audit** is regulated by Law no.10091/2009 on statutory auditing and organisation of the audit and certified accountant profession, amended by Laws 10297/2010 and 47/2016. There are also several decisions by the Council of Ministers related to the Public Audit Oversight Body (POB) and Public Interest Entities (PIEs). From 2017-2022, twelve regulations have been approved to govern POB operations.

The POB was established as an independent regulatory body. It is funded from own sources (5/6) and the state budget (1/6), according to the annual budget law. The POB has ultimate responsibility for the quality assurance of statutory auditors and audit firms – including certification, registration and training programmes, and the system of inspections, investigations and sanctions. It supervises the application of the code of ethics requirements, which is drawn up in conformity with the Code of Ethics of the International Federation of Accountants (IFAC). Statutory audits are prepared in compliance with International Standards on Auditing (ISA). The professional body is responsible for the translation and publication of ISA in Albanian.

The law defines PIEs as listed companies, banks and non-bank institutions supervised by the Bank of Albania, insurance companies and companies managing pension and investment funds supervised by the Albanian Financial Supervisory Authority, and other state or private companies designated as such under decision number 17 of the Council of Ministers of January 2019. Albania stated that national legislation is aligned with the *acquis* regarding the appointment of audit committees and rotation requirements for PIEs.

National legislation provides that the quality assurance reviews of statutory audits of non-PIEs may be delegated to the professional body, who must report findings annually to the POB. The professional body can also conduct investigations independently, but only the POB can issue sanctions, which are published in the public register by the professional body. In certain instances the POB may engage external experts. Albania stated, however, that the POB lacks sufficient capacity and plans to address this issue in the future.

Quality assurance reviews are performed in an independent manner – based on risk assessment – at least every three years for the statutory audit of PIEs, and at least every six years for other entities.

Albania informed that it has already started drafting amendments to national legislation to achieve further *acquis* alignment in 2024, including the areas of statutory audit of PIEs, functions of audit committees, increasing POB capacities in terms of staffing and financing, and its ultimate responsibility as defined by the EU *acquis*. Albania also plans to improve the systems of professional education, and investigation and discipline, as well as increase international cooperation.

### **b. Commission assessment**

Albania has a **high level of alignment** with Directive 2006/43/EC and amending Directive 2014/56/EU, as well as with Regulation (EU) 537/2014. Since 2018, Albania is building a track record of quality assurance inspections, investigations, enforcement, and sanctions, and is already drafting legislative amendments to achieve further *acquis* alignment in 2024. Albania is encouraged to follow through with its plans to strengthen capacities of the public audit oversight body (POB) in terms of staffing and funding, as well as those of the professional body.

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

Albania has a **high level** of alignment with the *acquis* on statutory audit; it should continue, however, to **further strengthen capacities** of the public audit oversight body in terms of staffing and funding, as well as those of the professional body. **Further alignment is needed** to align with the *acquis* in the areas of accounting and transparency requirements for listed companies. Albania **also needs to align** with the *acquis* on country-by-country reporting, and the 2022 Directive on corporate sustainability reporting.

### **III. FIGHT AGAINST CORRUPTION – COMPANY LAW**

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

Albania informed it is drafting a new crosscutting anti-corruption strategy which will also tackle integrity in the business sector, and mentioned the business registry as one area that can be vulnerable to corruption.

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

In general, Albania needs to pursue better governance in the private sector to promote integrity, transparency and the fight against corruption.

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

Albania is working to improve the structures to fight against corruption in company law.
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## 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

Albania is **moderately prepared** on Chapter 7 and does not expect difficulties to implement the relevant EU *acquis*.

The National Strategy for Intellectual Property 2022-2025 is aimed at (a) improving the legal framework (notably through amending the Copyright Law and through a legal reform in industrial property rights); (b) developing and strengthening institutions; (c) improving inter-institutional cooperation and coordination; (d) raising public awareness; and I the potential identification of geographical indications and designations of origin. Most of the legislative gaps are indicated in the National Plan for European Integration (NPEI), to be addressed within 2023-2025. Albania is part of 23 international agreements in the field of Intellectual Property Rights (IPR), 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). Albania also expressed its intention to adhere to the Singapore Treaty, the Nairobi Treaty, and the Marrakesh Treaty.

Regarding accelerated integration, Albania requested to participate in the Commission's projects dedicated to SMEs and youth; to participate in the European Union Intellectual Property Office (EUIPO) Observatory; to benefit from the IP Education Tools offered by the EUIPO; and to participate as observer in the Group of Experts on Industrial Property Policy (GIPP).

## b. Commission assessment

Albania has reached a **high level of alignment** with the EU *acquis* in the area of intellectual property law. It is encouraged to continue with the current trend of progress. Albania has also demonstrated that it has the basic administrative structures to manage and enforce IPR.

The adoption of the National Strategy for Intellectual Property 2022-2025 was a positive development in this regard, as it provides the timeframes for alignment with the EU *acquis* on IPR. However, ensuring full alignment and an effective implementation of the remaining partially- or non-transposed provisions within the given timeframes will highly depend on the good functioning and the capacity of the administrative structures dealing with IPR and its enforcement.

Regarding the **accelerated integration** requests, the Commission looks favourably to Albania's participation as an observer in the GIPP. The Commission will explore Albania's participation in the projects dedicated to SMEs (such as the IP SME Fund) and youth. The Commission will further explore Albania's participation in the EUIPO Observatory and the request to benefit from the IP Education Tools offered by the EUIPO to Member States. The Commission notes that cooperation activities such as foreseen in Article 152 of the EU Trade Mark Regulation or under Regulation (EU) No 386/2012 can only concern Member States. In this regard, the Commission encourages exchanges with the EUIPO, for example through the Memorandum of Understanding.

## C. SUMMARY OF FINDINGS – HORIZONTAL ASPECTS

Albania has reached a **high level of alignment with the EU *acquis* in the area of intellectual property law**. The country demonstrated that it has the basic administrative structures to manage and enforce IPR. However, ensuring full alignment and an effective implementation will highly depend on the good functioning and the capacity of the administrative structures dealing with IPR and its enforcement.

## II. COPYRIGHT AND RELATED RIGHTS

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

#### a. Country presentation

The **legal framework** on copyright and related rights is based on Law no. 35/2016 on Copyright and Other Related Rights (Copyright Law) as amended by Law no. 37/2022 and complemented by 17 sublegal acts. Albania indicated that the Law is largely aligned with the EU *acquis*.

Albania is a party to six international agreements on copyright and related rights.<sup>6</sup> It is not a party to the Beijing Treaty on Audiovisual Performances, nor to the Brussels Convention and the Marrakesh VIP Treaty.

The main body in the area of copyright and related rights is the Copyright Directorate (CD), an official public and state institution within the Ministry of Culture. Its mandate derives from the Copyright Law, as amended. It is divided into the Monitoring Sector and the Registration Sector, and is composed of one director, one head of sector, and four experts. Its main responsibilities include proposing, drafting and implementing the strategies and policies for the protection, exercise and enforcement of copyright and related rights, promoting awareness campaigns and training, registration and transferring of copyright and related rights, and managing the licensing process and monitoring of

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<sup>6</sup> Albania is a party to the following international agreements on copyright and related rights: Berne Convention for the Protection of Literary and Artistic Works; World Intellectual Property Organisation (WIPO) Convention; WIPO Copyright Treaty; WIPO Performances and Phonograms Treaty; Convention for the Protection of Producers of Phonograms; and Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations.

Collective Management Organisations (CMOs). The CD offers all its four services online, through the e-Albania platform, administered by the National Agency of Information Society (NAIS).

The provisions in the field of satellite broadcasting and cable retransmission are implemented by the CD and Audio-visual Media Authority (AMA), which applies administrative fines, whereas the State Inspectorate for Market Surveillance (SIMS) supervises the market. In the area of collective management of copyright and related rights, the Monitoring Sector of the CD, composed by two experts and one head of sector, proposes the licensing of CMOs and monitors their activity, while SIMS can take measures against CMOs. The National Copyright Council is in charge of deciding on the methodology and tariffs, when there is no decision between CMOs and users. The Board of Arbitration provides for alternative dispute resolution for technological protection measures, while providing for the possibility to go to court. Albania registered three fines and four CMOs so far, as well as seven court cases in the last one and a half years.

Regarding its implementation track record, the CD has amended the Copyright Law in 2022, adopted a sublegal act on licensing of CMOs, drafted three sublegal acts, concluded numerous meetings on methodology and tariffs for royalties, licensed four CMOs and monitored them yearly, and certified 1 513 copyright certificates. During 2020-2022, seven databases and 10 computer programs were registered. In 2022, there were 17 requests for information on public domain works. It also organised 16 staff trainings and six seminars for copyright users. The current focus of the CD is placed in strengthening its administrative capacities, namely through restructuring, trainings, and inter-institutional cooperation. The authorities are focused on raising awareness among institutions and stakeholders.

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

Albania has reached a **high level of alignment** with the EU *acquis* on copyright and related rights. However, work remains to be done in the upcoming years. Albania needs to put in place the necessary implementing legislation for the 2022 amendments to the Law on Copyright and Other Related Rights. The remaining legal gaps are expected to be addressed in the amendments to the Copyright Law foreseen until 2025, which should lead to full alignment in this field.

The necessary structures to ensure **administrative capacity** to implement and apply the EU *acquis* in the area of copyright and related rights are in place. Nonetheless, further improvement of cooperation between the different bodies and institutions is needed, particularly in improving the track record of effective implementation of the legislation and through improving training of staff, judges, and prosecutors.

## **II.B. COPYRIGHT IN THE INFORMATION SOCIETY**

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

Albania 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) through the Copyright Law and five other laws<sup>7</sup>. It declared to be fully aligned with the list of exclusive rights of authors and certain related rights and on exceptions and limitations, namely through a mandatory exception for temporary copies, exceptions for the reproduction of works for private and personal use, for educational or research purposes and for the purpose of public information, among others. Albania provides legal protection of technological measures and rights management information and is fully aligned on sanctions and remedies. The country is not aligned with Directive (EU) 2019/790 on Copyright and Related Rights in the Digital Single Market and amending Directives 96/9/EC and

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<sup>7</sup> The five laws include: Law No. 7895, Criminal Code of the Republic of Albania; Law No. 8116, Civil Code of the Republic of Albania; Law No. 8485, Code of Administrative Procedures; Law No. 8116, Code of Civil Procedure of the Republic of Albania; and Law No. 7905, Criminal Procedure Code of the Republic of Albania.

2001/29/EC, which will be included in the NPEI for alignment until 2025.

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

The Copyright Law, as amended, is **partially aligned** with Directive 2001/29/EC. Albania should observe the provisions laid out in Article 16 of the Directive (EU) 2019/790 on the Digital Single Market. Albania needs to make the necessary distinctions between ‘compensation’ and ‘remuneration’ overall and where relevant. Albania is expected to align, by 2025, with Directive (EU) 2019/790 related to the Digital Single Market, within the timeframe provided by its NPEI.

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

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

Albania stated that it is **highly aligned** with Council 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), with the exception of the articles addressed exclusively to Member States. It has aligned with the definition of communication to the public by satellite, with the author’s exclusive right to authorise the initial broadcasting, and with acquisition of rights. It is also aligned with the definition of cable retransmission, and with the principles of mediation and good faith during negotiations. It provides for mandatory collective management (with a possibility to opt-out) for both broadcasting via satellite and cable retransmission for members and non-members. The National IP Strategy 2022-2025 aims at improving institutional cooperation with the Audio-visual Media Authority on the application of the Copyright Law by broadcasters and cable operations and revising the remunerations tariffs. Albania **intends to align** with 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) by 2025.

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

Albania is **highly aligned** with Directive 93/83/EEC. Albania is expected to align, within the timeframe provided by its National IP Strategy (2025), with the SatCab II Directive (EU) 2019/789.

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

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

Albania informed about its **partial alignment** with 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. The Copyright Law does not provide for the multi-territorial licensing of rights in musical works for online use, the creation of independent management entities (IMEs), nor the development of digital music services. Further alignment is planned for 2025, notably Article 5(5) of the Directive (not in the Copyright Law but used in practice), IMEs and multi-territorial licensing. The scheme for the collection and distribution of compensation related to the exceptions for private copying and for reprography is not yet in place. It plans to approve the sublegal acts on, *inter alia*, the one-stop-shop for collecting and distributing remunerations ‘Sporteli Unik Për Administrimin E Të Drejtës Së Autorit’ (S.U.A.D.A.), and on the licensing and monitoring of collective management organisations.

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

Albania is **partially aligned** with Directive 2014/26/EU. Albania needs to provide, in particular, for the multi-territorial licensing of rights in musical works for online use, for the alignment with Article 5(5) of the Directive (especially in the area of on payment of royalties due to a right-holder of acts which occurred before the termination of the authorisation or the withdrawal of rights took effect, or under a license granted before that), and for the creation of independent management entities (IMEs) within the established timeframe (i.e. by 2025). Additionally, Albania needs to approve the sublegal acts on the licensing and monitoring of CMOs and on the one-stop-shop for collecting and distributing

remunerations for all types of rights (including audio-visual and music), S.U.A.D.A., to improve implementation of collective rights management.

## **II.E. DATABASES**

### **a. Country presentation**

Albania declared to be **fully aligned** with Directive 96/9/EC on the Legal Protection of Databases, by providing copyright protection and *sui generis* protection for substantial qualitative and/or quantitative investments. It acknowledged that the non-inclusion of the element related to obtaining the data in its Copyright Law could be an error. Registration of databases is voluntary.

### **b. Commission assessment**

Albania has achieved a **high level of alignment** with Directive 96/9/EC.

## **II.F. TERM OF PROTECTION**

### **a. Country presentation**

Albania stated it has **fully aligned** with Directive 2011/77/EU amending Directive 2006/116/EC on the Term of Protection of Copyright and Certain Related Rights, with the exception of the articles applicable to Member States only. Works are protected during the author's life and up to 70 years after his death. For performers, the term of protection is 70 years after the first interpretation, whereas for producers of a phonogram and of a film is 70 and 50 years after the first fixation, respectively. Rightholders can dispute any decision that a work is considered to be in the public domain.

### **b. Commission assessment**

Albania has achieved a **high level of alignment** with Directive 2011/77/EU, except for the provisions that are applicable for Member States only.

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

### **a. Country presentation**

Albania stated its **full alignment** with Directive 2001/84/EC on the Resale Right for the Benefit of the Author. A royalty cannot be less than EUR 500, and a derogation is foreseen in the event that the transaction involves more than one art dealer, for individual and joint payment obligations.

### **b. Commission assessment**

Albania has achieved a **high level of alignment** with Directive 2001/84/EC on the artist's resale right.

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

### **a. Country presentation**

Albania confirmed its **full alignment** with Directive 2006/115/EC on Rental Right and Lending Right and on Certain Rights Related to Copyright in the Field of Intellectual Property. The exclusive right to authorise or limit the public lending right is only applicable to authors and the inclusion of related right-holders will be addressed in the amendments to the Copyright Law. It provides for a right to equitable remuneration for rental for an author who has waived his rental right to a phonogram or film producer and for a derogation from the lending right. The procedure for an equitable remuneration for public lending will apply upon accession to the EU.

### **b. Commission assessment**

Albania is **partially aligned** with Directive 2006/115/EC. However, it needs to grant the exclusive right to authorise or limit the public lending right to related authors. This is planned in the amendments to the Copyright Law. A procedure for the equitable remuneration of authors for public

lending also needs to be put in place.

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

### **a. Country presentation**

Albania acknowledged its **partial alignment** 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, except for the articles addressed to Member States only. The Association of the Blind of Albania contributes to the administrative capacity in this field. Albania will focus on aligning with 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**

Albania is **partially aligned** with Directive (EU) 2017/1564. The country is expected to adhere to the Marrakesh Treaty as soon as possible and align with Regulation (EU) 2017/1563.

## **II.J. ORPHAN WORKS**

### **a. Country presentation**

Albania stated that it is **highly aligned** with Directive 2012/28/EU on Certain Permitted Uses of Orphan Works. It has not aligned with the articles addressed to Member States only. A work that is classified as orphan work in the EU is considered an orphan work in Albania, without the need for diligent search in the latter. Phonograms are not part of the Copyright Law yet. The CD and the NAIS are creating an online database on orphan works. Albania adopted the by-law on the procedure and fair compensation for the use of orphan works in November 2023. It also intends to amend the relevant articles to include phonograms and to cooperate with the EUIPO on the database.

### **b. Commission assessment**

The country is **partially aligned** with Directive 2012/28/EU on orphan works. Albania is expected to include the provisions for phonograms in the planned amendments to the Copyright Law. Furthermore, it is expected to draft and approve the by-law for the online database on copyright works, including orphan works.

## **II.K. PORTABILITY**

### **a. Country presentation**

Albania acknowledged that it is **not aligned** with Regulation (EU) 2017/1128 on Cross-Border Portability of Online Content Services in the Internal Market. While discussions are ongoing to decide on the leading institution, this area will likely be included in the amendments to the Copyright Law, foreseen for 2025.

### **b. Commission assessment**

Albania 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**

Albania stated that it is **fully aligned** with Directive 2009/24/EC on the Legal Protection of Computer Programmes. Inter-institutional cooperation on the implementation of this right needs to be improved.



### b. Commission assessment

Albania has achieved a **high level of alignment** with Directive 2009/24/EC.

## II.M. SEMICONDUCTORS

### a. Country presentation

The country is **partially aligned** with Council Directive 87/54/EEC on the Legal Protection of Topographies of Semiconductor products, with the exception of the articles exclusively addressed to Member States.

### b. Commission assessment

Albania is **partially aligned** with Directive 87/54/EEC.

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

Albania has a **high level of alignment** with the EU *acquis* on **copyright and related rights**. However, it has yet to adopt the implementing legislation for the 2022 amendments to the Law on Copyright and Other Related Rights. The amendments to the Copyright Law, foreseen by 2025, are expected to lead to full alignment in this field. The necessary structures to ensure **administrative capacity** to implement and apply the EU *acquis* in copyright and related rights are in place. Nonetheless, further improvements are needed in terms of institutional cooperation and of effective implementation of the legislation.

Albania has a **high level of alignment** with the EU *acquis* on **broadcasting via satellite and cable retransmission (SatCab I)**. It has also achieved a **high level of alignment** with the EU *acquis* on **databases**, on the **term of protection**, on the **artist's resale right**, and on **computer programmes**.

Albania'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**, on **collective management of copyright and related rights**, on **rental and public lending rights**, on **orphan works** and on **semiconductors**. Albania is also **partially aligned** with EU *acquis* **implementing the Marrakesh Treaty**. The country is expected to adhere to the Marrakesh Treaty as soon as possible and start aligning with Regulation (EU) 2017/1563.

However, Albania is **not aligned** with the EU *acquis* on **copyright and related rights in the Digital Single Market** and 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 expected to do so by 2025, in line with its National IP Strategy. Albania is also **not aligned** with the EU *acquis* on **cross-border portability of online content**.

## III. INDUSTRIAL PROPERTY RIGHTS

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

#### a. Country presentation

The overarching legal act in the field of industrial property rights is Law no. 9947 on Industrial Property, as amended in 2021 (the IP Law) and complemented by 12 sublegal acts. Albania indicated that its industrial property legislation has a **high level** of alignment with the EU *acquis* and that it is planning a legal reform, to adopt separate laws for each industrial property right. This reform is planned in the National IP Strategy 2022-2025 and in the NPEI 2023-2025. The exhaustion of rights regime is national and foreseen in the IP Law. Albania is a party to 17 international agreements on

industrial property rights.<sup>8</sup>

The main body in the area of industrial property rights is the General Directorate of Industrial Property (GDIP), a public institution under the Ministry of Finance and Economy (MFE). Its mandate derives mainly from the IP Law, as amended. It is divided into one Supervisory Council (five members), one director-general, four departments, and seven sectors. Out of 39 employees, 16 are examiners. Its main responsibilities include the registration, administration, protection, and promotion of IP objects, drafting IP-related legislation, and organising trainings and awareness-raising activities. It provides 155 online services, through the e-Albania platform. It is also responsible for granting, registering, issuing, rejecting and publishing a supplementary protection certificate. Any person can submit an application or bring an action for a declaration of invalidity of the certificate before the GDIP.

On the implementation track record of the GDIP, the register of IP objects has seen an increasing trend, and that the annual budget has also increased, with the exception of 2022 for both cases. In the period 2018-2022, there were 4 198 applications for patents, out of which only 74 were national applications. During the same period, Albania registered 17 194 trade mark applications, out of which 6 184 were national applications, and 766 applications of industrial designs, out of which only 115 were national. The country also highlighted numerous awareness-raising workshops with stakeholders, the IP pre-diagnostic tool, the new strategy for the Training Centre, among others. During the same period, Albania organised 128 in-house trainings and 46 abroad for IP staff, with international assistance (including via TAIEX and EU Twinning). It also strengthened its training centre and established cooperation with, *inter alia*, public institutions, universities, SMEs, and chambers of commerce. Its future focus is placed in implementing the legal reform in the IP field and reinforcing 58pprox.58nings, including of staff, judges and prosecutors.

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

Albania has reached a **high level of alignment** with the EU *acquis* on industrial property rights. Albania is expected to make significant progress in addressing the remaining gaps in legislation and achieve full legislative alignment with the legal reform of the IP Law and division into specific laws for each industrial property area, as foreseen in the National IP Strategy 2022-2025.

Regarding implementation, the necessary structures to ensure administrative capacity to implement the EU *acquis* in the area of industrial property rights are in place, notably through the GDIP. Nonetheless, further strengthening of cooperation and coordination between the different bodies and institutions and training of staff, judges, and prosecutors is needed, particularly for the implementation of the legislation regarding SPCs and for the enactment of the legal reform on IP rights.

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

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

Albania informed that it is **partially aligned** with Directive (EU) 2015/2436 to Approximate the Laws of the Member States Relating to Trade Marks, through the IP Law and the Decision of the Council of Ministers (DCM) no. 315/ for the Approval of the Regulation for Trade Marks, as amended. It has fully aligned with several articles from the Directive (as well as some substantive provisions from the Regulation). The IP Law provides for trade marks with reputation/well-known trade mark as relative grounds for refusal. It is not aligned with the provisions that were added in the current Directive (EU) 2015/2436. Albania is partially aligned with the absolute grounds for refusal. The new draft Law on Trade Marks is expected to enter into force by the end of 2024 and to achieve full alignment.

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<sup>8</sup> Albania is a party to the following international agreements on industrial property rights: Paris Convention; Convention on the Establishment of WIPO; European Patent Convention (EPC); The Hague Agreement on Industrial Designs; Geneva Act; Madrid Agreement; Protocol of the Madrid Agreement on trade marks; Nice Convention; Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS); Budapest Treaty; Strasbourg Agreement; Agreement on Patent Rights of the WIPO; International Convention for the protection of new varieties of plants; London Agreement; Locarno Agreement; Vienna Agreement; and the Lisbon Agreement.

### **b. Commission assessment**

Albania is **partially aligned** with the EU legislation on trade marks. While it has aligned with the earlier Directive 2008/95/EC to Approximate the Laws of the Member States Relating to Trade Marks, it still needs to bring it fully in line with Directive (EU) 2015/2436. While the Albanian legislation already includes the majority of absolute and relative grounds for refusal, it still needs to include further additional absolute and relative grounds for refusal foreseen in that Directive. Albania also needs to provide for an invalidity ground of bad faith. Albania is expected to align with Directive (EU) 2015/2436 in the new Law on Trade Marks, planned to enter into force by the end of 2024. However, Albania 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**

The Albanian IP Law and DCM no. 270/2018 for the Approval of the Regulation for Industrial Designs are the main legislation in the field of legal protection of industrial designs. It is **partially aligned** with Directive 98/71/EC on the Legal Protection of Designs (as well as some substantive provisions of the Council Regulation (EC) No 6/2002 on Community Designs) while most of the articles that have not been aligned with are those applicable to Member States only. The legislation does not provide for the protection of unregistered designs. It noted that a registered design right is not eligible for protection under the Copyright Law. A new Law on Industrial Designs aimed at aligning with the remaining provisions is planned until 2025.

### **b. Commission assessment**

Albania has a **high level of alignment** with the EU legislation on industrial designs. It needs to provide for a design protected by a design right to be eligible for protection under the Copyright Law as well. Albania will only be able to be part of the EU-wide industrial design system after EU accession.

## **III.D. PATENTS**

### **a. Country presentation**

Albania informed about its **full alignment** with Regulation (EC) 1610/96 Concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products, **partial alignment** with Regulation (EC) No 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products, and its **non-alignment** with Regulation (EU) 2019/933 amending Regulation (EC) No 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products (SPC waiver). The latter two are foreseen to be fully aligned with in the specific Law on Patents, until 2024.

The IP Law is **partially aligned** 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. The Court of Tirana may, upon request, grant a compulsory license for patents and SPCs relating to the production and selling of pharmaceutical products to export to countries with public health problems. Further alignment will be addressed in the new Law on Patents, until 2024. Albania informed that it is **fully aligned** with Directive 98/44/EC on the Legal Protection of Biotechnological Inventions (Biotech Directive) except for the provisions applicable to Member States only.

### **b. Commission assessment**

Albania is **fully aligned** with Regulation (EC) 1610/96 and is **partially aligned** with Regulation (EC) 469/2009. It is **not aligned** with Regulation (EU) 2019/933 (SPC waiver) for medicinal products. It is expected to achieve further alignment through the specific Law on Patents expected within the framework provided by the National IP Strategy by 2024. Albania is also **highly aligned** with the Biotech Directive. While the Albanian law already has some provisions on compulsory licensing, the country is **partially aligned** with Regulation (EC) 816/2006 on Compulsory Licensing of Patents.

### III.E. TRADE SECRETS

#### a. Country presentation

Albania informed that it is **fully aligned** with Directive (EU) 2016/943 on the Protection of Undisclosed Know-How and Business Information (Trade Secrets) Against their Unlawful Acquisition, Use And Disclosure, with the exception of the articles applicable to Member States only and adjustments regarding general provisions, proportionality, limitation period, provisional and precautionary measures, conditions, safeguards, alternative measures, and injunctions and corrective measures in order to account for certain national procedural rules.

#### b. Commission assessment

Albania is **fully aligned** with Directive (EU) 2016/943 on trade secrets, with slight adjustments on procedural aspects. Albania needs to ensure that the proportionality principle under that Directive is duly applied.

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

Albania has a **high level of alignment with the EU *acquis* on industrial property rights**. It is expected to achieve full legislative alignment with the legal reform of the IP Law and division into specific laws for each industrial property area, as foreseen in the National IP Strategy 2022-2025. Albania has the necessary structures to ensure **administrative capacity** to implement the EU *acquis* in this area. Nonetheless, further strengthening of institutional cooperation and training is needed.

On **patents**, Albania is **fully aligned** with the EU *acquis* on the creation of an **SPC for plant protection products**. and **partially aligned** with the EU *acquis* on the **SPC for medicinal products**. It is **not aligned** with the **SPC waiver for medicinal products**. Albania is also **highly aligned** with the EU *acquis* on **biotechnological inventions**. However, it is **partially aligned** with the EU *acquis* on **compulsory licensing of patents**.

Albania is **fully aligned** with the EU *acquis* on **trade secrets**.

Albania has a **high level of alignment** with the EU *acquis* on **industrial designs**.

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

### IV. ENFORCEMENT

#### a. Country presentation

Albania declared its **full alignment** with Directive 2004/48/EC on the Enforcement of Intellectual Property Rights (IPRED) through the Albanian Civil Code, Code of Civil Procedure, Criminal Code, IP Law, Copyright Law, and Law no. 8488/1999 for the Protection of the Topography of the Integrated Circuits. Albania has joined important international agreements for the implementation of IPR, and is a member of WIPO, INTERPOL, the World Customs Organisation, and EUROPOL.

Provisional and precautionary measures can be issued against the alleged infringer. Furthermore, Albania is aligned with the right of information, corrective measures, and with the provisions on damages. The Criminal Code also foresees criminal sanctions from the infringement of IP rights and copyright.

The main administrative bodies dealing with IPR policy making are the Copyright Directorate, within the Ministry of Culture, and the General Directorate of Industrial Property, integrated in the MFE. Their main task is to provide for the strategic and regulatory framework on IPR and ensure and monitor their implementation. Enforcement is ensured by the State Inspectorate for Market Surveillance, the General Directorate of Customs/IPR Directorate, the General Directorate of State Police, the courts, and the Audiovisual Media Authority. Albania also created an interinstitutional

working group for Chapter 7, led by the MFE.

The authorities dealing with administrative offenses in the field of IPR (besides the judicial authorities) are the General Directorate of Customs, the SIMS and the AMA, which inspects and can prohibit reproduction. In terms of criminal offenses, the General Directorate of State Police and the State Prosecutor are the main figures and act *ex-officio*. Albania also noted the also cooperation with other institutions, such as the General Directorate of Taxes. During 2019-2022, the SIMS carried out 1 645 inspections on copyright and related rights and 189 sanctions, as well as 135 inspections on IP rights and 46 sanctions. In 2018-2022, the General Directorate of Customs suspended 30 717 goods through applications, and 37 982 *ex-officio*. During the same period, AMA issued 48 financial measures.

Concerning the judicial authorities, the Courts of First Instance of General Jurisdiction are the competent court for all the litigations in the fields of copyright and industrial property. The appeals of decisions of the National Council of Copyright are taken before the Administrative Court of First Instance. In terms of civil cases at the Supreme Court, Albania registered, in 2018-2022, three open cases for infringement of the reproduction right, four open cases for infringement of the distribution right, and one closed case for infringement of the right of public presentation of visual art. On the First Instance Court on IPR disputes, in 2017-2021, there was a total of 80 cases. In 2021, the number of concluded and unfinished cases was even. In the same period, Albania registered 21 convictions for criminal offences in the IPR field and a total of 72 IPR cases, out of which 37 have been concluded.

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

Albania is **partially aligned** with the IPRED Directive on enforcement of IPR. Close alignment between the provisions aligned with through Law no. 997/2008 and Law no. 35/2016 needs to be ensured, where appropriate.

With regards to the legislation, there is a need to pay particular attention to and ensure an effective alignment with the relevant enforcement legal rules and measures present in Directive 2004/48/EC in the process of the legal reform of the IP Law in the respective IP laws. The legal reform of the IP Law and the amendments to the Copyright Law are planned in the National IP Strategy 2022-2025 and in the NPEI 2023-2025 with clear timelines. These amendments need to preserve or improve enforcement in the area of copyright and related rights.

Regarding enforcement in practice, the number of court cases remains low. Although the number of inspections and sanctions by SIMS on IP rights has risen considerably in 2022, it remains very low, especially compared to those on copyright.

The numerous awareness-raising and training initiatives that took place and that are foreseen are positive steps towards effective implementation. Continuing these initiatives will remain crucial for effective implementation of IPR legislation. Further improving training of staff, judges and prosecutors, and reinforcing human resources are key for IPR enforcement.

#### **C. SUMMARY OF FINDINGS – ENFORCEMENT**

Albania is **partially aligned with the IPRED Directive on enforcement of intellectual property rights**. Albania needs to improve the enforcement of IPR, in particular regarding the number of court cases and the number of inspections and sanctions on industrial property rights. Further improving training of staff, judges and prosecutors, and reinforcing human resources are key for IPR enforcement.

### **V. FIGHT AGAINST CORRUPTION -- INTELLECTUAL PROPERTY LAW**

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

Albania has ratified several international conventions against corruption and adopted specific legislation on the prevention of corruption and money-laundering, including in the field of IPR. The CD acts on the basis of the Order of the Ministry of Culture no. 93/2020 on ethical and anti-corruption activities at the Ministry of Culture, that provides for an internal audit mechanism, the Law on the

Right of Information, among others. Its anti-corruption measures include the ethical and anti-corruption structure within the Ministry, one anti-corruption coordinator, and one coordinator for the right of information. The anti-corruption track record of the CD includes provisions on equal and transparent tariffs for copyright use, rules on responsibility for CMOs on non-ethical and corruptive actions related to S.U.A.D.A., two administrative investigations of the CD during 2021-2022, and the provision of four online services.

The GDIP has approved an Ethical Code (Decision no. 5/2022 for the Approval of the Ethical Code for the General Directorate of Industrial Property, Chapter V Gifts and Favours). The GDIP offers 155 online services. It has an anti-corruption coordinator and a coordinator for the right to information. In 2022, it received 14 requests under this right, and gave 14 responses. It also provides an online register of authorised representatives and reports. However, it does not have a whistle-blower unit. The IP Law provides for external financial audit, in which context the GDIP prepares yearly financial statements. The SIMS, the General Directorate of Customs, and the General Directorate of State Police have also reportedly incorporated anti-corruption measures.

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

The existence of specific anti-corruption measures in the main bodies dealing with IPR and its enforcement, supported by legal acts, in addition to the overall anti-corruption efforts of Albania, are a positive sign that, if duly implemented, sets the country in the path towards the prevention of corruption in IPR. Therefore, focusing on implementation of these measures is key.

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

**Albania has specific measures in place to prevent corruption in the main bodies dealing with IPR and its enforcement, supported by legal acts.** It has adopted specific legislation on the prevention of corruption and money-laundering, including in the field of IPR.

## H) CHAPTER–8 - COMPETITION POLICY

The competition *acquis* covers **anti-trust, 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 **anti-trust**, 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 of the 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 anti-trust 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 139/2004 and the Implementing Regulation 802/2004. 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 of the 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 *acquis* under this chapter is directly linked to Alba'ia's obligations under Article 71 of the Stabilisation and Association Agreement between the EU and Albania (SAA) presently in force.

### I. LEGAL FRAMEWORK FOR COMPETITION POLICY

#### I.A. ANTITRUST

##### a. Country presentation

The **legal framework** is based on the Law on Protection of Competition (LPC), which aims to protect fair and effective competition in the market, defining the rules of conduct by undertakings, as well as the institutions responsible for protection of competition and their competences. According to Albania, the LPC is fully aligned with Articles 101 and 102 of the TFEU and other relevant acts of the *acquis* in this area.

The LPC was adopted in 2003 and subsequently amended in 2010. The Albanian Competition Authority (ACA) is in charge of implementing the LPC and is empowered to approve regulations and guidelines to this end. It is composed of the Competition Commission, a collegial decision-making body of the authority and the Secretariat, the administrative body of the ACA.

The LPC contains the main rules on restrictive agreements and abuse of dominant position. Article 4 of the LPC prohibits restrictive agreements, while Article 5 exempts restrictive agreements when they fulfil conditions similar to those laid down in Article 101(3) TFEU. The *de minimis* rule is also included in the Competition Law, allowing exemption from prohibition for agreements that do not significantly affect market competition. Undertakings must notify the ACA of any restrictive

agreements, which will then determine if these agreements are prohibited under the LPC.

Albania states that as regards prohibition of abuse of the dominant position, Articles 8 and 9 (ex-post analysis) and Articles 69 and 70 (ex-ante analysis) of the LPC are aligned with Article 102 TFEU. A non-exhaustive list of criteria for determining the existence of a dominant position or prohibited abusive behaviour is provided by the Competition Law. Abusive behaviour examples include fixing unfair sale or purchase prices and adopting discriminatory practices.

Secondary legislation provides further **substantive rules** and guidance on how competition rules should be applied. In this respect, Albania considers that it has aligned its framework with several Commission Regulations, including on the application of Article 101(3) of the TFEU to categories of technology transfer agreements to categories of specialization agreements; categories of research and development agreements, as well as with the Commission Guidelines on the applicability of Article 101 of the TFEU to horizontal co-operation agreements. Albania has yet to fully align its secondary legislation with the EU *acquis*, including with Commission Regulation of 10 May 2022 on the application of Article 101(3) TFEU to categories of vertical agreements and concerted practices (Vertical Block Exemption Regulation (VBER)), and the Commission Guidelines on Vertical Restraints (Vertical Guidelines) of 2022.

It is stated that Article 9 of the LPC and the Guidelines adopted by the ACA On the assessment of the dominant position and the abuse of the dominant position is aligned aligned with the Communication from the Commission providing guidance on its enforcement priorities in applying Article 102 TFEU to exclusionary abusive conduct by dominant undertakings.

As regards **procedural rules**, Albania states that its legislation is aligned with the Commission's Implementing Regulation No 773/2004, relating to the conduct of proceedings. It is also aligned with Guidelines on the method of setting fines and the Commission notice on immunity from fines and reduction of fines in cartel cases. However, the country has yet to align with amendments introduced in 2015 to the above-mentioned Commission notice.

Albania considers that the ACA has procedural rules and investigative powers that are similar to the powers granted to the Commission and EU national competition authorities. Upon approval from the Competition Commission, ACA Secretariat may initiate a preliminary investigation by its own initiative (*ex officio*) or following a complaint submitted by concerned or third parties related to the prevention, restriction or distortion of competition. When signs of restriction of competition are observed, the in-depth investigation procedure is initiated. The in-depth investigation may be conducted up to 6 months (which can be extended).

In order to carry out the investigation, the ACA may issue requests for information. The ACA may also carry out unannounced on-site inspections at companies' premises (so called "dawn-raids"). When the ACA finds that there is an infringement of the LPC in the area of restrictive agreements or the abuse of a dominant position, it adopts a decision obliging the companies concerned to stop the infringement. To ensure the prohibition of the infringement, the Competition Commission, may impose on companies any remedies necessary, including remedies of a structural nature.

For infringement of competition rules, the ACA may impose administrative fines, 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 ACA for leniency and cooperate fully with the authority's investigation of the cartel.

## **b. Commission assessment**

As regards antitrust, the Albanian legislative framework has a **high level of alignment** with the primary *acquis* in this area. The **substantive rules** laid down in the Law on Competition Protection are directly based on Articles 101 and 102 of the TFEU and other relevant acts of the *acquis* in this



area, with the exception that Article 4 of the LPC is applied via notifications and decisions by the ACA, whereas Article 101 is directly applicable. Secondary legislation provides further substantive rules and guidance on how competition rules should be applied and are generally aligned with the EU acquis. There are certain acts of the EU acquis, with which the Albanian secondary legislation is not yet aligned, including the Commission Vertical Block Exemption Regulation 2022/720 and Vertical Guidelines of 2022 (2022/C 248/01, C/2022/4238).

The **procedural rules** in the area of antitrust have a **high level of alignment** with the EU *acquis*. In this respect, the relevant rules are aligned with the Commission Regulation relating to the conduct of proceedings, the Guidelines on the method of setting fines and the Commission notice on immunity from fines and reduction of fines in cartel cases of 2006. The country still needs to align with amendments introduced in 2015 to the Commission notice on immunity from fines and reduction of fines.

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

## **I.B. MERGERS**

### **a. Country presentation**

Albania considers that its competition legislation is broadly in line with Council Regulation (EC) No139/2004 (the Merger Regulation). The LPC lays down the conditions under which mergers can be allowed.

As regards **substantive rules**, Albania stated that it has aligned its framework with several Commission guidelines including the Commission guidelines on the assessment of horizontal and non-horizontal mergers. However, its secondary legislation remains to be aligned with the Commission guidelines and communications including the Notice on Case Referral in respect of concentrations.

According to Albania, as regards **procedural rules**, the LPC is aligned with the Commission Regulation (EC) No 802/2004 implementing Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the Implementing Regulation) and its annexes. However, it still remains to be aligned with the amendments introduced to the Implementing Regulation by the Commission Regulation (EU) No 1269/2013 of 5 December 2013.

The ACA has investigative powers considered similar to the powers granted to the Commission and national competition authorities by the TFEU, Council Regulation (EC) N°1/2003 (the antitrust Implementing Regulation), the Merger Regulation and other EU legislation.

The merger control procedures in the LPC provide that concentrations must be notified to the ACA for authorisation if they meet specific notification thresholds during the previous financial year. Notifications must be submitted within 30 days of the conclusion or signature of the relevant agreement and the announcement of any public bid.

For the 'CA's assessment of concentrations, the LPC establishes both preliminary and in-depth procedures. In preliminary proceedings, the ACA examines the notification to determine if the concentration could substantially restrict market competition, especially as a result of creating or strengthening a dominant position. Following preliminary proceedings, the ACA may either allow the concentration subject to certain conditions or initiate in-depth proceedings. During in-depth

proceedings, the ACA evaluates whether the concentration significantly restricts competition, particularly due to the creation or strengthening of a dominant position. When the Competition Commission finds that the concentration shows such indications it may decide to authorize it based on conditions and obligations or open an in-depth investigation. The ACA has three months to adopt a decision either approving the merger, possibly with conditions, or blocking it.

#### **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 necessarily 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 LPC and its secondary legislation have a **high level of alignment** with the EU *acquis* in this area. The **substantive rules** are directly based on the Merger Regulation and other EU *acquis*.

The **procedural rules** in the area of mergers **have a high level of alignment** with the Implementing Regulation. However, Albania still needs to align its framework with the amendments introduced to the Implementing Regulation by the Commission Regulation (EU) No 1269/2013 of 5 December 2013.

The ACA is entrusted with powers similar to those of the Commission or to those that national competition authorities of the Member States.

Albania has yet to align its secondary legislation with EU soft law tools such as the Commission guidelines and communications including the Notice on Case Referral in respect of concentrations, Guidance on the preparation of public versions of Commission Decisions adopted under the Merger Regulation, and the Explanatory note on Best Practice Guidelines.

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

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

The **definition of State aid**, allowed State aid and not allowed State aid are laid down in the Law on State Aid (LSA), adopted in 2005 and subsequently amended. Albania considers that these definitions reflect Article 107 of the TFEU.

As regards **procedural rules**, Albania states its legal framework is partially aligned with Council Regulation No 1589/2015 laying down the rules for the application of article 108 of the TFEU and certain other EU *acquis* on State aid procedure, including Commission Regulation (EU) 2015/2282 as regards the notification forms and information sheets.

The Law on State Aid provides for an ex-ante control: the State aid grantor is under the obligation to notify State aid to the State Aid Commission (SAC), which is the authority in charge of the application of the LSA. The SAC 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 SAC is responsible for ordering the recovery of any unlawful and incompatible aid that was granted, with interests.

The notification obligation applies to all aid measures, except *de minimis* aid. Albania states that the rules for granting *de minimis* aid are partly harmonised with the EU *acquis*. Albania has not yet aligned its legislation with the Commission Regulations on the calculation of certain time limits, handling of complaints, and identification and protection of confidential information.

Albania has stated that the Law on State Aid is partially aligned with the Commission Regulation 651/2014 declaring certain categories of aid compatible with the internal market in application of Art.107, 108 of the TFEU (the General Block Exemption Regulation). In line with the General Block Exemption Regulation, certain aid measures do not have to be notified by Member States provided that they fulfil specific conditions. In order to raise awareness of State aid rules among aid grantors

and ensure their effective implementation, Albania explained that aid measures that could potentially benefit from this block exemption shall nonetheless be notified to the SAC.

Albania has not yet aligned its legislation with the EU *acquis* on **horizontal aid** in the areas of research and development and innovation aid, risk capital aid, important projects of common European interest, training aid and employment aid.

As regards State aid rules on Services of general economic interest (SGEI), Albania stated that its legal framework is partly aligned with the Commission Decision on the application of the European Union State aid rules to compensation granted for the provision of SGEI and Commission Regulation on the application of Art.107, 108 of TFEU to de minimis aid granted to undertakings providing SGEI. It still needs to align with the Communication from the Commission on EU framework for State aid in the form of public service compensation.

In the area of regional aid, Albanian legal framework is partially aligned with the Commission Guidelines on regional State aid. Albania 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.

Albania 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**, Albania stated that its legal framework is not yet aligned with the Commission Notice on State aid in the form of guarantees as well as the EU *acquis* concerning short-term export credit insurance.

As regards the reference/discount rate, Albania highlighted its plans for full approximation of the Communication from the Commission of 19.1.2008 on the revision of the method for setting the reference and discount rates<sup>9</sup>.

Albania noted that the conditions under which the sale of publicly owned land does not represent State aid are yet to be harmonised with the EU *acquis*. 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. Albania has not yet aligned its framework with the Commission Staff Working Document (2014)179 Common methodology for State aid evaluation.

In the area of **sectoral aid**, Albania explained that the national framework (including sectoral guidelines) for financing of the public broadcasters, granting of State aid for production of films and other audiovisual works, granting aid for the deployment of broadband networks are broadly aligned with the EU *acquis* in these areas.

As regards postal sector, Albania indicated that its legislation is partially 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<sup>10</sup>.

As regards aid to coal sector, Albania stated that its legislation is not aligned with the Council Decision on State aid to facilitate the closure of uncompetitive coal mines or Commission Communication relating to the methodology for analysing State aid linked to stranded costs.

Similarly, in the area of steel sector, Albania declared it still needs to align with the Communication from the Commission C(2002) 315 on Rescue and restructuring aid and closure aid for the steel sector. It was noted that the SAC has not taken any decision on granting aid for steel sector.

In the areas of transport and infrastructure, Albania has yet to align its framework with the EU *acquis*,

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<sup>9</sup> OJ C 14, 19.1.2008, p. 6–9

<sup>10</sup> OJ C 39, 6.2.1998

including with 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 **definition** of State aid in the Albanian legislation is broadly in line with Article 107 TFEU.

Albanian **procedural rules** on State aid control are **partially aligned** with the EU *acquis*. The enforcement powers of the State Aid Commission as laid down in the Law on State aid broadly reflect those of Commission when carrying out the control of State aid granted by Member States. In particular, the Law on State aid includes a standstill clause for notified aid, pending the decision of the SAC and provides for the possibility of recovering incompatible State aid.

Further alignment is necessary with the Council Regulation laying down the rules for the application of article 108 of the TFEU and Commission Regulations and Notices, including on the calculation of certain time limits, handling of complaints, where the country is still not aligned.

Albania has **not aligned** its legislation with the EU *acquis* on **horizontal aid** in the areas of research and development, innovation aid, risk capital aid, important projects of common European interest, training aid and employment aid. In the area of regional aid, Albanian legal framework is partially aligned with the Commission Guidelines on regional State aid.

The Albanian rules on State aid for environmental protection and energy aid are not in line with the EU *acquis*. Albania also needs to align its framework with the Guidelines on State aid for Rescue and Restructuring.

As regards **specific aid instruments**, the rules on State aid in the form of guarantees, short-term export credit insurance and measures relating to direct business taxation are **not aligned** with the EU *acquis*. The rules on reference/discount rates are partially in line, are in line with EU rules.

As regards the reference/discount rate, Albania has yet to fully align its legislation with the Communication from the Commission on the revision of the method for setting the reference and discount rates.

Albania noted that the conditions under which the sale of publicly owned land does not represent State aid are yet to be harmonised with the EU *acquis*. 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. Albania has not yet aligned its framework with the Commission Staff Working Document Common methodology for State aid evaluation.

In the area of **sectoral aid**, Albania has **partially aligned** its legal framework with the EU *acquis* concerning financing of the public broadcasters, granting of State aid for production of films and other audiovisual works, granting aid for the deployment of broadband networks.

As regards postal sector, Albania is partially 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 and steel sector, Albania has yet to align its legislation with the respective EU *acquis*. In the areas of transport and infrastructure, Albania has yet to align its framework with the EU *acquis*, including with Commission Guidelines on State aid to airports and airlines and to maritime transport as well guidelines on State aid for railway undertakings.

### **I.D. LIBERALISATION**

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

Albania indicated that the application of the LPC does not include exceptions for particular sectors or types of enterprise and it is applicable to all undertakings, which directly or indirectly have or may have an influence in the market. That includes public undertakings and undertakings that have been granted by the state exclusive or special rights as well as undertakings entrusted with the operation of

services of general economic interest or having the character of a revenue-producing monopoly insofar that in law or in fact their activity is not obstructed.

Albania considers the rules on the financing of services of general economic interest are partially aligned with the *acquis* in this area. In particular, the government decision on determination of criteria, intensity and procedure for granting and authorisation in the form of compensation of the services of the general economic interest is partially aligned with the Commission Decision of 20 December 2011 on State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest. Albanian legislation is not aligned yet with the Commission Directive 2006/111/EC on the transparency of financial relations between Member States and public undertakings as well as on financial transparency within certain undertakings.

Albania indicated that the LPC does not contain any discriminating provisions according to the origin of capital (being foreign or domestic) and in general that, the Albanian legislation that regulates the production and marketing of products (including services) does not contain discriminatory provisions between domestic undertakings and foreign undertakings.

#### **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 Albanian system currently is not yet aligned with EU rules. Albania needs to fully align its legislation with the EU *acquis* relating to the aid in the form of compensation to 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 high level of alignment with the EU *acquis*. The substantive rules are largely based on Article 101 and 102 TFEU, the Merger Regulation and other EU regulations. Albania 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 this law, they are unable to perform the tasks or activities assigned to them by the public authority. Nonetheless, the system currently in place is not yet aligned with EU rules - Albania 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 ACA is the only institution that applies antitrust and merger rules in Albania. It is in charge of applying the LPC and is an independent public entity and has been performing its tasks since 2004.

The ACA is accountable to the Albanian parliament, to which it submits annual reports on its activity. The decision-making body of the ACA is the Competition Commission, composed of five members and headed by a Chairman. Members are appointed by the Parliament for a period of five years and have the right to be re-appointed not more than twice consecutively.

The Secretariat of the ACA is headed by a Secretary General. It comprises five Directorates: Production Markets Surveillance, Non-Production/ Services Markets Surveillance, Market Analysis and Methodologies, Legal Integration and Juridical Affairs as well as Human Resources, Budget and Communication. The ACA has 49 staff, mainly economists and lawyers. The ACA has its own independent budget, which is funded by the State budget in line with the Albanian legislation. The ACA has a Strategic Management Group that proposes the amount of budget every year to the Ministry of Finance and Economy, which is later approved by the Parliament of Albania.

During 2017-2022, the ACA adopted 54 decisions concerning prohibited agreements, 65 decisions concerning the abuse of dominant position and 170 decisions authorising concentrations. In that period it imposed fines amounting to approx. EUR 2.6 million.

In line with the LPC, an appeal may be filed against the decision of the ACA Competition Authority before the District Court of Tirana within 30 days from the announcement of the decision. The appeal does not suspend the application of ACA's decision. The District Court of Tirana may decide for a suspension of the whole or part of these measures. Appeals against judgements of the District Court of Tirana may be filed before the Court of Appeal.

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

The ACA, which has been performing its tasks since 2004 as a public independent authority, is a well-established institution with procedural rules and investigative powers similar to those of granted to the Commission and national competition authorities of Member States. With 49 employees, mainly lawyers and economists, it is well equipped to fulfil its tasks. Its administrative capacities should be further strengthened, in particular through continuous training of its staff. The ACA also needs to continue to strengthen its enforcement record, in particular in the imposition of fines and in the fight against cartels and should make additional efforts in the area of competition advocacy. Albania needs to ensure that the recommendations of the ACA on draft legislation having an impact on competition are properly taken into account. The judiciary's capacity to assess complex competition cases also needs to be reinforced.

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

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

The State Aid Commission (SAC) is the decision-making authority that implements State aid rules in the country. The Commission is composed of five members, chaired by the Minister in charge of economy. The other members are appointed by the Council of Ministers, on the proposal of the Minister of Finance and Economy, Minister responsible for European Integration, Minister of Justice and a representative of civil society.

The SAC is attached to the Ministry of Finance and Economy. Its secretariat is within the Sector of Business Promotion in the Department of Development of Economic Policies in the Ministry of Finance and Economy<sup>11</sup>. The secretariat has only 3 posts, 1 of which remain vacant. Its administrative capacities to fulfil its tasks are insufficient. In 2022, the SAC issued four decisions approving the aid.

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<sup>11</sup> By order of the Minister of Minister of Finance and Economy no. 170, dated 20.07.2023 "On the establishment of the administrative structure for the control of state aid" is operational the administrative structure for the control of state aid with three officials: the Director of the Directorate of Business Promotion Policies, the Head of the Competitiveness Sector and the Specialist of the Analyses Sector.

So far, the SAC has not issued any negative decision. Decisions of the SAC may be appealed before the Administrative Court.

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

The SAC cannot be considered as an operationally independent authority within the meaning of Article 71(4) of the SAA given its direct links to the Ministry of Finance and Economy, an aid granting authority. The Chair of the SAC is the Minister of Finance and Economy and his Ministry nominates another member of the SAC. Furthermore, the secretariat of the SAC, which assists the SAC in investigating State aid and preparing decisions, is part of the Ministry of Finance and Economy. The capacity and enforcement record of the SAC and its secretariat are insufficient. The State aid authority urgently needs additional qualified staff, in order to be in a position to build a solid enforcement record. The Commission notes that very few aid measures are notified and approved by the SAC before being granted. Albania needs to significantly improve its enforcement record in the field of State aid.

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

Albania has sufficient implementation and enforcement capacity in the areas of antitrust and mergers. However, in the area of State aid the implementation and enforcement capacity is insufficient. The ACA is a well-established and operationally independent institution based on the assessment of the organisational structure with investigative powers similar to those of Commission and national competition authorities of Member States. The ACA should continue to strengthen its administrative capacity, notably through relevant training of its staff, with a view to building strong enforcement record. As regards State aid, the State Aid Commission cannot be considered as an operationally independent authority within the meaning of Article 71(4) of the SAA, The SAC has yet to establish a solid track enforcement record in the area of State aid. The prerequisite for that is strengthening the administrative capacities of the institution.

### **III. THE FIGHT AGAINST CORRUPTION – COMPETITION POLICY**

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

In the area of the fight against corruption, Albania indicated provisions of the Law on the Prevention of Conflict of Interest in the Exercise of Public Functions as well as the Law on whistle-blowing and whistle-blower protection.

As regards the decision making of the ACA, the LPC excludes Members of the Commission from taking part in a case where he/she has an interest or he/she has represented one of the concerned parties. Furthermore, the ACA adopted the Regulation on the prevention of conflict of interests and on the declaration of assets during the exercise of public functions in the Competition Authority as well as the Code of Ethics of the Competition Authority.

The ACA is part of the Inter-Sectoral Anti-Corruption Strategy 2023-2030, holding the role of the Anti-corruption Coordinator. Regarding the action plan on the anti-corruption strategy, the ACA organized a roundtable with the regulatory institutions regarding bid rigging in procurement procedures in December 2022.

In collaboration with the Public Procurement Agency in Fighting Bid Rigging, the ACA adopted guidelines on public procurement and competition protection, integrity of the public procurement process in December 2022.

### **b. Commission assessment**

Albania has in place a legal framework for fighting and preventing corruption in the competition policy area as described above under country presentation with specific provisions on corruption in the area of competition policy.

The ACA has an important role in the Inter-Sectoral Anti-Corruption Strategy 2023-2030, as the Anti-corruption Coordinator.

As regards combatting bid rigging Albania has laid the foundation by adopting the guidelines in cooperation with the Public Procurement Agency and raising awareness in this area through the roundtable with the regulatory institutions. The ACA, in cooperation with the Public Procurement Agency, needs to obtain sufficient resources to ensure effective enforcement of competition rules in the public procurement sector.

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

Albania has a legal framework in place for fighting corruption in the area of competition policy. The ACA plays an important role in the Inter-Sectoral Anti-Corruption Strategy 2023-2030. The ACA needs to have sufficient resources in the fight against bid rigging to ensure enforcement of guidelines on public procurement and competition protection.



## 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 BONDS

#### a. Country Presentation

Regarding **covered bonds** Albania has not yet aligned its legislation with Directive (EU) 2019/2162 on covered bonds and covered bond public supervision (the Covered Bonds Directive), or with the provisions of Directives 2009/65/EC 2014/59/EU which it amends. It plans to ensure full alignment by the end of 2027. The competent body is the AFSA, in cooperation with the Ministry of Finance and Economy and the BoA.

#### b. Commission Assessment

Albania is **not aligned** with the EU *acquis* on covered bonds and covered bond public supervision.

### I.B. INVESTMENT FIRMS

#### a. Country Presentation

Albania's national legislation regarding **investment firms** was reviewed recently to introduce capital requirements with a **high level of alignment** with Regulation (EU) 2019/2033 on the prudential requirements of investment firms. It is only partially aligned with Directive (EU) 2019/2034 on the prudential supervision of investment firms, due to the limited complexity and dimension of the sector; aspects such as governance requirements are not yet covered by national legislation. Albania will in the next years validate the appropriateness of the regulation recently in place and full alignment in this area is envisaged at the latest upon accession

#### b. Commission Assessment

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

### I.C. CAPITAL REQUIREMENTS

#### a. Country Presentation

Regarding **Capital Requirements** Directive (CRD) and Capital Requirements Regulation (CRR) Albanian National legislation and standards for banks in Albania have a high level of alignment with Directive 2013/36/EU (CRD) and with Regulation 575/2013/EU (CRR)<sup>12</sup>. An independent assessment of Albania's current regulatory and supervisory framework for banks concluded in the first half of 2022 resulted in a rate of equivalence of 83%, however, incorporation of some of the latest adopted reviews of the EU *acquis* in this area (Regulation (EU) 2019/876, or CRR II and Directive (EU) 2019/878, CRDV) is still outstanding. Albania is also aware of the planned amendments proposed by the 2021 Banking Package (legislative proposals to further amend the CRR and the CRD, or CRR III and CRD VI) to these two pieces

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<sup>12</sup> Directive 2013/36/EU on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC and Regulation (EU) No 575/2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012

of the EU *acquis*, and it will plan its additional steps for full alignment once these have been adopted. The Bank of Albania (BoA) ensures the supervision of banks, including branches of foreign banks in Albania and branches of the banks licensed by BoA operating outside the territory of Albania. The BoA's Supervision Department is the sole responsible for the licensing and regulation processes, as well as on-site and off-site inspections. Overall, Albania has been gradually aligning its national framework for banks with the international standards of Basel II and Basel III, and therefore to the EU *acquis* which is largely aligned with these international standards. The pace of this alignment depends on Albania's assessment of the level of development and complexity, and the needs of their banking system.

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

Albania has a **high level of alignment** with the EU *acquis* on prudential requirements for banks.

### **I.D. DGS AND INVESTOR COMPENSATION SCHEMES**

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

Regarding **deposit guarantee schemes**, Albania's legislation is partially aligned with the EU *acquis* on deposit guarantee schemes. Non-aligned areas include the maximum level of coverage, the types of depositors excluded from coverage, a lack of pre-set target level of the ex-ante fund, the use of risk-based premiums, the pay-out period and protection of temporary high balances. Full alignment is envisaged at the latest by the time of Albania's eventual accession to the EU. The Albanian Deposit Insurance Agency (ADIA), established in 2002, is responsible for the ex-ante deposit insurance scheme for depositors in banks and saving and loan associations (SLAs). ADIA is chaired by the Governing Council (representatives of BoA, Ministry of Finance and Economy (MFE) and auditors institute) and participates in the Financial Stability Advisory Group alongside BoA, MFE and AFSA.

Regarding **investor compensation schemes** Albania's Law on Capital Markets is partially aligned with the EU *acquis* on investor compensation schemes. The establishment of an investor compensation scheme (ICS) in Albania is provided for in the Law on Capital Markets (2020) and is still not functioning (ICS to enter into force in May 2025). The compensation fund will be established and managed by a company authorised by the Albanian Financial Supervisory Authority, or by the Authority itself. Compliance at a larger extent will be achieved with the establishment of further rules on the administration of the Albanian ICS which is envisaged to take place prior to the entering into force of the ICS (May 2025). Full alignment is envisaged at the latest by the time of Albania's eventual accession to the EU.

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

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

### **I.E. RECOVERY AND RESOLUTION**

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

Regarding **recovery and resolution framework for banks** (BRRD) Albania's legislation is partially aligned with the EU *acquis* on *the recovery and resolution framework for banks*. The Albanian regulatory framework for recovery and resolution is aligned with the provisions of Directive 2014/59/EU (BRRD 1). Albania has not yet aligned with Directive (EU) 2019/87 (BRRD 2). BoA is the supervisory and resolution authority responsible for the recovery and

resolution. No date for full alignment is planned yet.

Regarding **reorganisation and winding up** of credit institutions Albania's legislation is partially aligned with Directive 2001/24/EC on the reorganisation and winding up of credit institutions. BoA is the competent authority for placing a bank under compulsory liquidation. The BoA fulfils its supervisory function through the Supervision Department. Full alignment is foreseen at the latest by the time of Albania's eventual accession to the EU.

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

National legislation is **partially aligned** with the EU *acquis* on the recovery and resolution framework for banks, and on the reorganisation and winding up of credit institutions.

### **I.F. SUPERVISION OF FINANCIAL CONGLOMERATES**

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

Regarding **supervision of financial conglomerates** Albania's legislation has not incorporated yet the EU *acquis* on supervision of financial conglomerates laid down in Directive 2002/87/EC (FICOD). Only some minor concepts and definitions pertaining to the supervision of financial conglomerates are included in Albania's Banking Law, such as those related to intra-group transactions and close links. There are five banking and financial groups under consolidated supervision of BoA, based on the definitions enshrined in the banking law and its implementing legislation. Full alignment is foreseen at the latest by the time of Albania's eventual accession to the EU.

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

Albania is **not aligned** with the EU *acquis* on the supervision of financial conglomerates.

### **I.G. SUMMARY OF FINDINGS – BANKS AND FINANCIAL CONGLOMERATES**

Albania is **partially aligned** to the EU *acquis* on banks and financial conglomerates. Albania's administrative and technical capacities are satisfactory to perform current regulatory and supervisory tasks. However, the capacities will need to be strengthened further to account for the expanding responsibilities that the EU *acquis* entails

## **II. INSURANCE AND OCCUPATIONAL PENSIONS**

### **II.A. SOLVENCY OF INSURERS**

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

Regarding the **solvency of insurers**, the insurance market in Albania is still at an early stage of development of the Solvency II directive (Directive 2009/138/EC). There are eight non-life and four life insurance companies. The non-life market has 87% of the total assets, and the remaining 13% of total assets is covered by the life insurance market. Compulsory insurance dominates the market, accounting for 62% of the total gross written premiums (GWP), among which motor liability insurance makes a large part. The draft law that will amend the legislation on voluntary pensions is currently in the Albanian Parliament. Albania's insurance market showed resilience to major shocks, including the 2019 earthquake and the COVID-19 pandemic. Its regulatory framework is designed to be highly aligned with the Solvency I regime. Implementation of Solvency II is one of the key priorities of AFSA's strategy to

prepare the country for EU accession, its high-level roadmap foresees that step-wise implementation of Solvency II, over around seven years, will start in 2023.

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

Albania has a **high level of alignment** with the Solvency I regime but is **not aligned** with Solvency II regime.

### **II.B. SUSTAINABILITY FACTORS AND RISK AND PREFERENCES**

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

Regarding **sustainability factors and risk and preferences** Albania is not aligned with the EU *acquis* on sustainability factors, risks and preferences. AFSA plans to conduct market assessment on the development of insurance-based investment products and the integration of sustainability factors, risks and preferences as well as contribute to market capacity building. There is as yet no planned date for full alignment.

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

Albania is **not aligned** with the EU *acquis* on sustainability factors, risks and preferences.

### **II.C. MOTOR INSURANCE**

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

Regarding **motor insurance** Albania's regulatory framework is partially aligned with the EU *acquis* on 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). Deviations to the EU *acquis* concern minimum amounts for the sum insured, compensation of injured parties in cases of bankruptcy/winding up procedures of insurers and a standard template of policyholders' claims-history statement. Albania's Law on Compulsory Insurance in the Transport Sector governs liability insurance towards third parties in the transport sector up until claim resolution and compensation's disbursement. AFSA is the competent body for the regulation and supervision of all insurance companies operating in Albania. AFSA also supervises the Albanian Insurance Bureau, which oversees insurance green cards and the insurance compensation fund. Full alignment is foreseen at the latest by the time of Albania's accession to the EU.

#### **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, and the enforcement of the obligation to insure against such liability.

### **II.D. INSURANCE DISTRIBUTION**

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

Regarding **insurance distribution** National legislation is not aligned with the current EU *acquis* on insurance distribution under Directive 2016/97/EU (it was designed to align to the previous EU *acquis*). Deviations include the responsibilities and obligations of the ancillary intermediaries, standardising the information included in the insurance product information document (IPID) for non-life products, distribution channels, product oversight and governance (POG) and requirements for insurance-based products. AFSA is the sole authority for the registration, regulation, and supervision of insurance intermediaries. The current legal base sets the requirements on professionalism, ethics, and reliability to be met by

intermediaries, it also sets two categories of intermediaries, i.e. agents and brokers. It establishes different roles for both categories, clarifying that insurers are responsible for the actions or omissions of the agent in relation to the insured and brokers are under obligation to provide objective information about insurance products in a comprehensible form to allow an informed decision. Full alignment is foreseen by 2030.

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

Albania is **not aligned** with the EU *acquis* on insurance distribution.

### **II.E. OCCUPATIONAL PENSIONS**

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

Regarding **occupational pensions** Albania is partially aligned with Directive 2016/2341 on the activities and supervision of institutions for occupational retirement provision (IORP II). Deviations concern the non-coverage of cross-border activities, sponsor undertaking definition and activity, key functions and key person/personnel of management company and depositaries, outsourcing the fund management activity, remuneration policy, and statement of investment policy principals. AFSA is the sole regulatory and supervisory authority of the voluntary pension fund market. Currently, there are four management companies, four voluntary pension funds, and three depositaries operating in Albania. Further alignment is ongoing.

#### **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** Albania's regulatory framework is designed to be highly aligned with Council Directive 91/674/EEC on the annual accounts and consolidated accounts of insurance undertakings. Its Law on Accounting and Financial Statement redefines the general principles and rules for the drafting and components of financial statements and the applicable accounting standards. Layouts for the balance sheet as well as profit and loss reporting of insurance companies are aligned with the European framework.

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

Albania has a **high level of alignment** the EU *acquis* on the annual accounts and consolidated accounts of insurance undertakings.

### **II.G SUMMARY OF FINDINGS – INSURANCE AND OCCUPATIONAL PENSIONS**

Albania is **partially aligned** to the EU *acquis* on insurance and occupational pensions. Albania must take the necessary steps to strengthen administrative capacities in view of increasing responsibilities and future obligations deriving from the application of the evolving EU *acquis*.

### III. FINANCIAL MARKET INFRASTRUCTURE

#### III.A. SETTLEMENT FINALITY

##### a. Country Presentation

Regarding **settlement finality** Albania is partially aligned the EU *acquis* on settlement finality in payment and securities settlement systems. Albania's payment system law foresees that all the systems should be licensed, regulated and overseen by BoA. BoA cooperates with AFSA on clearing and settlement systems for securities. The concept of interposable systems has been introduced. Further alignment will be ensured, but no specific date for this is foreseen yet, and some elements will only be applied only upon Albania's accession to the EU.

##### b. Commission Assessment

National legislation is **partially aligned** with the EU *acquis* on settlement finality in payment and securities settlement systems.

#### III.B. FINANCIAL COLLATERAL

##### a. Country Presentation

Regarding **financial collateral** Albania's regulatory framework is partially aligned with Directive 2002/47/EC on financial collateral arrangements. Its Law on Payments Systems governs all cases of financial collateral agreements in Albania. Credit claims are not covered by Albania's regulatory framework due to the country's early stage of market development. Further alignment will be ensured, but no specific date for this is foreseen yet.

##### b. Commission Assessment

National legislation is **partially aligned** with the EU *acquis* on financial collateral arrangements.

#### III.C. CENTRAL SECURITIES DEPOSITORIES

##### a. Country Presentation

Regarding **central securities depositories** Albania is partially aligned with the EU *acquis* on improving securities settlement in the European Union and on central securities depositories; While the definition of central securities depository and the list of their core services is fully aligned with the EU *acquis*, many other elements, including those related to internalised settlement, provision of services in another Member States and relations with third countries, are not yet aligned. Further alignment is foreseen in 2024, in particular as regards banking-type ancillary services and review and evaluation provisions, full alignment is foreseen by Albania's accession to the EU.

##### b. Commission Assessment

National legislation is **partially aligned** with the EU *acquis* on central securities depositories.

#### III.D. SECURITIES FINANCING TRANSACTIONS

##### a. Country Presentation

Regarding **securities financing transactions** Albania's regulatory framework is designed to be highly aligned with the EU *acquis* on transparency of securities financing transactions and of reuse. Deviations include an absence of definitions for counterparties, financial counterparties and trade repositories, and of an obligation of a counterparty to report to a trade

repository, obligations for the registration of a trade repository and obligations on transparency and availability of data held, as well as an absence of detailed requirements on the transparency of the reuse of financial instruments received as collateral by the counterparties. Full alignment is foreseen by the time of Albania's accession to the EU. AFSA is the sole authority for the regulation and supervision of the securities market and activities of this market, including the activities of other subjects related to the investments in securities which operate in this market and of management companies of CIU. AFSA also has the power to impose administrative sanctions and other administrative measures on the service providers on the capital market and on management companies of CIU.

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

Albania has a **high level of alignment** with the EU *acquis* on transparency of securities financing transactions and of reuse.

### **III.E. OTC DERIVATIVES, CENTRAL COUNTERPARTIES, AND TRADE REPOSITORIES**

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

Regarding **OTC derivatives, Central Counterparties and Trade repositories** Albania is partially aligned with the one of the pieces of EU *acquis* on OTC derivatives, central counterparties and trade repositories, but not with the rest of the relevant EU *acquis*. Further alignment on authorisation and organisational requirements of central counterparties is foreseen in 2024. Full alignment is foreseen by the time of Albania's accession to the EU.

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

National legislation is **partially aligned** with the EU *acquis* on OTC derivatives, central counterparties and trade repositories.

### **III.F. SUMMARY OF FINDINGS – FINANCIAL MARKET INFRASTRUCTURE**

Albania is **partially aligned** to the EU *acquis* on **financial market infrastructure**. Further capacity building in these areas is necessary to account for the expanding responsibilities that the EU *acquis* entails.

## **IV. SECURITIES MARKETS AND INVESTMENT SERVICES**

### **IV.A. MARKETS IN FINANCIAL INSTRUMENTS**

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

Regarding **markets in financial instruments** Albania national legislation is designed to be highly aligned with the EU *acquis* on MiFID II and to ensure conformity with European standards, however, it is not aligned with the EU *acquis* on MiFIR in relation to the requirements for systematic internalisers. AFSA is the responsible body for the authorisation and supervision of the relevant regulated activities, banks providing investment services also need BoA authorisation on services and activities specified in the legal base. Further alignment is foreseen with the approval of a number of drafted regulations by the end of 2024, full alignment is foreseen by the time of Albania's eventual accession to the EU.

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

Albania is **partially aligned** with the EU *acquis* on MiFID II. Albania has a **low level of alignment** with the EU *acquis* on MiFIR.



## IV.B. MARKET ABUSE

### a. Country Presentation

Regarding **market abuse** Albania is partially aligned with the EU *acquis* on market abuse, further alignment is foreseen by the end of 2024. AFSA has the power to impose administrative sanctions or to take administrative measures in case of infringement of market abuse rules, to conduct inspections, to conduct administrative investigations, to suspend the listing of any financial instruments or prohibit their trading, and to request the freezing of assets. The Commission pointed out that the Listing Act review is currently underway. In this regard, amendments will be introduced in the Market Abuse Regulation.

### b. Commission Assessment

National legislation is **partially aligned** with the EU *acquis* on market abuse.

## IV.C. BENCHMARKS

### a. Country Presentation

Regarding **benchmarks** Albania's legislation is not aligned with the EU *acquis* on benchmarks, and there are no administrators for the provision of a benchmark and no index provider in Albania. Some alignment to this EU *acquis* is foreseen by the end of 2026, full alignment is foreseen by the time of Albania's accession to the EU.

### b. Commission Assessment

Albania is **not aligned** with the EU *acquis* on benchmarks.

## IV.D. ALTERNATIVE INVESTMENT FUND MANAGERS

### a. Country Presentation

Regarding **alternative investment fund managers** Albanian national legislation is designed to have a high level of alignment with the EU *acquis* on alternative investment fund managers. AFSA is the sole authority entrusted with the regulation and supervision of the collective investment undertakings' market. Aside from requirements for EU Member States, deviations to the EU *acquis* are that Alternative Investment Funds (AIF) can be offered only to professional and/or qualified investors. Cross-border activity is conducted through the recognition process of the AIF Manager and the AIF, which is finalised with a positive or negative decision by AFSA. Full alignment is foreseen by the time of Albania's accession to the EU.

As the EU legislation in this field is evolving, Albania committed to monitor the changes in the EU *acquis*.

### b. Commission Assessment

Albania has a **high level of alignment** with the EU *acquis* on alternative investment fund managers.

## IV.E. PROSPECTUSES

### a. Country Presentation

Regarding **prospectuses** Albania's legislation is designed to have a high level of alignment with the EU *acquis* on prospectuses, though it deviates with regard to the introduction of a base prospectus, the EU growth prospectus, and the simplified disclosure regime for secondary issuances. It is partially aligned with the EU *acquis* on the format, content, scrutiny

and approval of the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market. AFSA is the competent authority. Full alignment is foreseen by the time of Albania's accession to the EU. Albania is following the evolution of *EU acquis* in this field.

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

Albania has a high level of alignment with the EU *acquis* on prospectuses.

### **IV.F. UCITS**

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

Regarding **UCITS** full alignment is foreseen by the time of Albania's accession to the EU *acquis* on coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS), to which it is currently partially aligned. Deviations to the EU *acquis* concern the requirements relevant to EU Member States and that cross-border activity is enabled via the recognition process of a management company or CIU, such recognition depends on a positive or negative decision by AFSA, the competent authority. Full alignment is foreseen by the time of Albania's accession to the EU.

Regarding cross-border distribution of UCITS full alignment is foreseen by the time of Albania's eventual accession to the EU *acquis* in this area. Deviations to the EU *acquis* concern the cross-border activity which is conducted through the recognition process of a management company, alternative fund manager or CIU with public offer and registration of foreign AIF. This depends on a positive or negative decision by AFSA, which is the competent authority. Further alignment is foreseen during 2024.

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

National legislation has a **high level of alignment** with the EU *acquis* on coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS). It is **partially aligned** with the cross-border distribution of UCITS.

### **IV.G. PAYMENT ACCOUNTS**

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

Regarding **payment accounts** Albania has a **high level of alignment** to the EU *acquis* 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). Further alignment is taking place during 2024. BoA is building its capacity in these areas, notably to increase staff capacities on consumers interest protection with respect to payment accounts as well as enhance communication and interactions with licenced and supervised entities.

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

Albania 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** Albania's legislation is partially aligned with Directive

2014/17/EU on credit agreements for consumers relating to residential immovable property (the Mortgage Credit Directive – MCD). Deviations to the EU *acquis* include the definition of mortgage credit agreement, requirements for the establishment and supervision of credit intermediaries and appointed representatives, and standards for advisory service. BoA is the competent body. Further alignment is foreseen. There is as yet no planned date for full alignment.

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

National legislation is **partially 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**

Albania is **partially aligned** to the EU *acquis* on **securities markets and investment services**. Further administrative capacity building is needed to account for increasing responsibilities and future obligations deriving from the implementation of the EU *acquis*. It is crucial for Albania 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**

Sustainable finance is very new to the Albanian financial market, but policy awareness is growing among relevant authorities in Albania.

Regarding Regulation (EU) 2020/852 – (Taxonomy Regulation) Albania is not yet aligned. Full alignment is foreseen by the time of Albania’s accession to the EU.

Regarding Regulation (EU) 2019/2089 Albania has not yet aligned with the EU *acquis* on EU Climate Transition Benchmarks, EU Paris-aligned Benchmarks and sustainability-related disclosures for benchmarks. Sustainable finance is very new to the Albanian financial market, but policy awareness is growing among relevant authorities in Albania. Full alignment is foreseen by the time of Albania’s accession to the EU.

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

Albania is **not yet aligned** with the EU *acquis* on taxonomy, or on EU Climate Transition Benchmarks, EU Paris-aligned Benchmarks and sustainability-related disclosures for benchmarks.

### **c. SUMMARY OF FINDINGS – SUSTAINABLE FINANCE**

Albania **is not yet aligned** with the EU *acquis* on **sustainable finance**.

### **VI. FIGHT AGAINST CORRUPTION – FINANCIAL SERVICES**

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

Albanian legislation qualifies corruption as a serious crime, including in its cross-border dimension. Albania 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. The relevant primary legislation in Albania includes a Law on the Financial Supervisory Authority, a law on whistleblowing and the protection of

whistle-blowers and on the prevention of conflicts of interest in the exercise of public functions. Albania adopted an Action Plan and Cross-cutting Strategy Against Corruption 2023–2030. The various authorities will participate in the roundtable annual meeting focused on integrity, with the aim of strengthening institutional integrity and protecting public finances and assets. The specific objective of the strategy is the protection of public finances and assets against abuse.

Albania considers that 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, 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. Albania sees implementation as the key to make further progress.

**b. Commission assessment**

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 ALBANIA, 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.

Focusing on implementation of relevant domestic legal provisions as well as international conventions should be Albania’s priority going forward.

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

Albania has anti-corruption measures in the main bodies dealing with financial services and with its enforcement.

## J) CHAPTER 28 - CONSUMER AND HEALTH PROTECTION

The EU *acquis* in the area of **consumer protection** covers legislation that protect consumers' economic interests and rights, and in relation to product safety, dangerous imitations and liability for defective *products*. It also comprises of Safety Gate, the EU's rapid alert system for dangerous non-food products, the EU's Rapid Alert System. EU *acquis* and standards also cover cooperation and enforcement of consumer protection laws, the pricing of products, sale of consumer goods and associated guarantees, 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 Albania is set out in its cross-cutting strategy on consumer protection and market surveillance 2023-2030. The basic legal framework in this area are Albania's Law 9902/2008 on Consumer Protection (amended by Laws 15/2013 and 71/2018) and relevant implementing legislation, its Law 10480/2011 on General Safety of Non-food Products. The Ministry of Finance and Economy (MFE) has overall responsibility for general consumer protection policy, alongside the Ministry of Tourism and Environment and the Bank of Albania (BoA). Implementation of consumer policy and legislation is ensured by the Consumer Protection Commission (CPC), the State Inspectorate of Market Surveillance (SIMS), the Financial Supervisory Authority (AMF), alternative dispute resolution (ADR) bodies in regulated sectors, local government, and the legal authorities. Albania has not yet aligned to Regulation 2017/2394 (EU) on co-operation between national authorities responsible for consumer protection.

Albania recognises that it needs to reinforce its human resources and their capacities in many of these bodies, and the coordination between these bodies, in order to be able to fully implement the EU *acquis*. Albania has established a round table on consumer and health protection, which includes chambers of commerce, civil society, consumer organisations, academia and experts. Albanian businesses and consumer protection bodies need to strengthen their expertise in regard to consumer protection. There are several non-governmental organisations for consumer protection in Albania, which together have over 50 members. Their tasks are to participate in public hearings on draft legislation; to provide advice/opinions to consumers; to organise trainings and to inform the general public on different matters.

The supervision department of BoA is responsible for is responsible for licencing, regulation and on- and off-site supervision of banks, non-bank financial institutions, saving and loans associations and their unions. Albania is currently negotiating to join the EU consumer protection programme, under the EU Single Market Programme.

## **b. Commission assessment**

Albania's consumer protection system is **partly aligned** with EU consumer *acquis* and standards. A general framework exists via national laws on consumer protection, on general safety of non-food products, and on market surveillance, and the relevant implementing legislation. Enforcement of consumer rights is ensured by CPC, SIMS, AMF, ADR bodies in regulated sectors, local government, and the legal authorities.

Albania should reinforce its human resources and their capacities in many of these bodies, and the coordination between these bodies. Albania is **not yet aligned** to the EU *acquis* on co-operation between national authorities responsible for consumer protection. Some level of awareness raising of consumers on their rights, support for consumer NGOs, and awareness raising with the general public, is ensured via a round table on consumer and health protection.

## **I.B. PRODUCT SAFETY RELATED ISSUES**

### **a. Country presentation**

Albania's Law 10480/2011 on the General Safety of Non-food Products is aligned at a high level with Directive 2001/95/EC on general product safety, deviations from the EU *acquis* are those on provisions relevant to EU Member States. Albania has a high level of alignment with the Directive 1987/357/EEC on dangerous imitations, apart from the aspects pertaining to EU Member States and the Council. Albania is at a limited level of alignment to the EU *acquis* on product liability - its legislation does not cover agricultural products (which the EU *acquis* covers), and some definitions are not yet aligned – full alignment is foreseen in 2026.

With regard to the Safety Gate, full alignment with the relevant legal requirements is foreseen by the time of Albania's accession to the EU. The Ministry of Finance and Economy (MFE) is the responsible body for product safety. Implementation is ensured by SIMS and by the Customs service. SIMS largely ensures its inspection procedures via its online e-inspection platform, to guarantee transparency and digitization of the documentation and the storage of inspection data. SIMS performs documentary, physical and laboratory checks according to established standard operating procedures/ relevant legislation. SIMS takes decisions on the temporary prohibition of products on the market, their permanent prohibition, and on the destruction of products. SIMS works in cooperation with customs authorities, and can impose fines to economic operators. SIMS has competence with regard to online trading.

### **b. Commission assessment**

Albania has a **high level of alignment** with the EU *acquis* on general product safety and on dangerous imitations. With regard to the Safety Gate is **partly aligned** with the relevant legal requirements, and has a **low level of alignment** to the EU *acquis* on product liability. The Ministry of Finance and Economy (MFE) is the body with overall responsibility for product safety. Implementation is ensured by SIMS and by customs. Implementing capacity should be reinforced in several sectors.

## **I.C. NON-SAFETY RELATED ISSUES**

### **a. Country presentation**

Albania has a low level of alignment with Directive 2019/2161/EU on the better enforcement and modernisation of Union consumer protection rules, alignment is currently foreseen in 2025. It is also at a low level of alignment with Directive 2020/1828/EU on representative actions for the protection of the collective interests of consumers, areas not yet or only partly aligned mostly concern the aspects of redress. MFE is the responsible body for both of the above, and is planning further alignment of both in 2024-25. CPC ensures implementation.

On Directive 2011/83/EU on consumer rights, Albania's national legislation has a high level of alignment. Deviations mainly concern non-obligatory articles and aspects only applicable to EU

Member States. MFE is the responsible body, CPC ensures implementation. Albania has a track record of implementing its respective national law.

Albania has a high level of alignment with Directive 2002/65/EC on distance marketing of consumer financial services. Deviations to the *EU acquis* concern distance contracts, and aspects only applicable to EU Member States. MFE is the responsible body, CPC and AMF are responsible for its implementation. There are currently insufficient resources allocated to this area, and Albania recognises that capacity building is necessary.

Albania is partly aligned with Directive 93/13/EEC, as amended, on unfair terms in consumer contracts, deviations from the *EU acquis* include some missing text and language that goes beyond the *EU acquis*, and articles that only apply to EU Member States. Further alignment is foreseen in 2024-2025. MFE is the responsible body, CPC ensures implementation. There are currently insufficient resources allocated to this area, and Albania recognises that capacity building is necessary.

Albania is partly aligned with Directive 98/6/EC on the indication of the prices of products offered to consumers. Deviations from the *EU acquis* include indications of the selling price and price per unit, regarding products sold in bulk, advertisement, and articles that only apply to EU Member States. MFE is the responsible body, SIMS ensures implementation. Staff recruitment and capacity building is necessary in this area.

As regards Directive 2019/771(EU) on certain aspects of the sale goods, national legislation is partly aligned. Full alignment is foreseen by the end of 2025. Albanian legislation has aspects that do not comply with the *EU acquis* concern on the supply of consumer goods, right of redress, guarantees, and the binding nature. MFE is the responsible body, SIMS ensures implementation, which have capacity shortcomings – recruitment of more staff is foreseen in 2023 and 2024.

In regard to Directive 2005/29/EC on unfair business-to-consumer commercial practices, and its amending acts, Albania is partly aligned. Shortcomings include some definitions, an aspect on the scope and another on the code of conduct. Further alignment is foreseen 2024-2025 MoFE is the responsible body, CPC and AMF are responsible for its implementation.

On Directive 2006/114/EC on misleading and comparative advertising, Albania's national legislation has a very low level of alignment. Provisions on business-to-business relations, and also available facilities, enabling the courts, voluntary control, misleading advertisements and aspects only relevant to EU Member States are not yet aligned. MFE is the responsible body, CPC ensures implementation. Albania acknowledges that there is a need to improve the institutional set-up and functioning; needs for further capacity is under assessment.

Albania is not yet aligned with Directive 2019/770/EU on certain aspects concerning contracts for the supply of digital content and digital services, nor is it aligned to Directive 2019/771(EU) on contracts for the sale of goods. Alignment is foreseen by the end of 2025.

Albania is partly aligned with Directive 2008/122/EC on timeshare, long-term holiday product, resale and exchange contracts. Deviations include some non-included articles and paragraphs. Further alignment is foreseen 2024-25. MFE is the responsible body, CPC ensures implementation. On Directive (EU) 2015/2302 on package travel and linked travel arrangements, Albania is partly aligned due to alignment to previous *EU acquis*. The Ministry of Tourism and Environment is the responsible body, enforcement is the responsibility of the National Coast Agency, which is responsible for implementation. Further alignment is also foreseen in 2024-25.

On Directive 2008/48/EC on credit agreements, Albania is partly aligned via its Laws on Consumer Protection, Law on Banks, and implementing legislation on consumer credit and banking rules. Deviations to the *EU acquis* currently include some of the scope and definitions, which need to be amended, as well as aspects regarding open-ended agreements, linked credit agreements. Albania has

aligned in regard to information to be included in advertising, some aspects of pre-contractual information, and the borrowing rate, while it has not aligned with some articles notably applicable to EU Member States. Supervision is ensured by the BoA, which regularly published information on related complains and the results of its inspections on its website. Further capacity building of staff is necessary to ensure full implementation. Albania was reminded that this part of the EU *acquis* was currently being revised.

Albania 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 4, which is foreseen to be adopted and enter into force in 2024.

Albania's Law on Consumer Protection and DCM 1089/2022 is partly aligned with Directive 2013/11/EU on alternative dispute resolution for consumer disputes, deviations to the EU *acquis* concern cross-border disputes and ADR functions. MFE is the responsible body. CPC and the MFE ADR general directorate are responsible for implementation. The CPC is established under the consumer protection (CP) law. The CPC has five members, two from MFE, two from Ministry of Justice, and one from civil society. There is also a water regulatory authority and an energy regulatory authority for related regulatory issues, which have mediation roles in case of related consumer issues.

The Albanian Financial Service Authority (AFSA) covering complaints in this sector. The Authority of Electronic and Postal Communications (AKEP) is the regulatory authority responsible for ADR in regard to the electronic communications and postal services sectors. BoA is the ADR body in regard to the banking and financial services sector, and plans to establish an additional unit to address this. The Albanian Authority on Civil Aviation (AACAA) deals with ADR issues in the aviation sector. Overall the Albanian authorities are already addressing and resolving a certain volume of ADR related complaints.

Albania should ensure its alignment with the latest EU *acquis* on *consumer protection*, and ensure the necessary capacity to ensure it, including with regard to market surveillance in all relevant sectors.

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

In the area of non-safety related issues Albania has a **high level of alignment** with the EU *acquis* on distance marketing of consumer financial services, and on comparability of fees relating to payment accounts, payment account switching and access to payments accounts and access to payment accounts with basic features.

Albania is **partly aligned** with the EU *acquis* on unfair terms in consumer contracts, on the indication of the prices of products offered to consumers, on alternative dispute resolution for consumer disputes, on the sale consumer goods, on unfair business-to-consumer commercial practices, on timeshare, long-term holiday product, resale and exchange contracts, on package travel and linked travel arrangements, and on credit agreements.

Albania has a **low level of alignment** with the EU *acquis* on the better enforcement and modernisation of Union consumer protection rules, on representative actions for the protection of the collective interests of consumers, and on misleading and comparative advertising.

Albania is **not aligned** with the EU *acquis* on certain aspects concerning contracts for the supply of digital content and digital services, or on contracts for the sale of goods.

There are currently insufficient resources allocated to most of the non-safety consumer areas.

#### **I. D. SUMMARY OF FINDINGS - CONSUMER PROTECTION**

Albania has a <b>high level of alignment</b> with the EU <i>acquis</i> on <b>general product safety</b> and on <b>dangerous imitations</b> . It is <b>party aligned</b> with the legal requirements with regard to the <b>EU Safety</b>
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**Gate** and has a **low level of alignment** to the EU *acquis* on **product liability**.

Albania has a **high level of alignment** with the EU *acquis* on **distance marketing of consumer financial services, and on comparability of fees relating to payment accounts, on payment account switching and access to payments accounts and access to payment accounts with basis features**.

Albania is **partly aligned** with the EU *acquis* on **unfair terms in consumer contracts, on the indication of the prices of products offered to consumers, on alternative dispute resolution for consumer disputes, on the sale of goods, on unfair business-to-consumer commercial practices, on timeshare, long-term holiday product, resale and exchange contracts, on package travel and linked travel arrangements, and on credit agreements**.

Albania has a **low level of alignment** with the EU *acquis* on **the better enforcement and modernisation of Union consumer protection rules, on representative actions for the protection of the collective interests of consumers, and on misleading and comparative advertising**.

Albania is **not yet aligned** with the EU *acquis* on **certain aspects concerning contracts for the supply of digital content and digital services, and on contracts for the sale of goods**. Albania is also **not aligned** to the EU *acquis* on **co-operation between national authorities responsible for consumer protection**.

Albania should ensure capacity building in order to ensure the necessary capacities to ensure this in all relevant consumer areas.

## **II. PUBLIC HEALTH**

### **II.A. HORIZONTAL ASPECTS**

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

The legal base for healthcare is part of the fundamental law of Albania, (Article 55 of the Constitution states that Citizens equally enjoy the right to health care from the state. Everyone has the right to health insurance according to the procedure established by law). The main legislation on health are the Law 10138/2009 (amended) on Public Health and the Law 10383/2011 on Health Insurance respectively as well as Law 10107/2009 on Health Care, Law 55/2022 on Hospital Care, Law 44/2012 on Mental Health, Law 105/2014 on Medicines, Law 19/2014 on Medical Devices, Law 147/2014 on Medical Emergency Services, and Law 138/2014 on Palliative Care. Health care policy in Albania is set out a National Health Strategy 2022-2030, and ongoing action plans on noncommunicable diseases, health promotion, cancer, and sexual and reproductive health. There are also a large range of national programmes on vaccinations, and on dental, cancer, and vision screening.

Adult life expectancy is the highest in the region, and there have been improvements in healthcare results in several other areas. Despite increases in wages, emigration of doctors and other healthcare workers remains significant. Albania 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 and Social Protection.

With regards to the EU4Health programme, Albania stated that it intends to apply to join the programme. It signalled that its strategic goals are investing in people's health over the life cycle, progress towards universal health coverage, strengthening integrated health system, strengthening the system response to emergencies, and digital health.

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

Albania has a basic legal framework for healthcare in place, which is set out in the Albanian constitution, the Law on Public Health and on the Law on Health Insurance respectively. Healthcare policy is set out in quite a comprehensive set of policy documents, including the 2022-2030 National

Health Strategy and in ongoing action plans on non-communicable diseases, health promotion, cancer, and sexual and reproductive health. There are also a large range of national programmes on vaccinations, and on dental, cancer, and eye/vision screening. Albania is a signatory and user of the EU Joint Procurement agreement for medical countermeasures, and it plans to apply to join the *EU4Health programme*.

## **II.B. eHEALTH**

### **a. Country presentation**

Albania's legal base for *eHealth* is partly aligned to the EU *acquis*, and is set out in implementing legislation (DCMs 673/2017, 507/2017 and Order 277/2020) under its Laws on Health Care and on Medicines and Pharmaceutical Services. Albania has an e-prescription system covering the description, registration, execution and reimbursement of prescriptions. There is also an e-warehouse system for pharmaceutical products. Albania has an e-visit system to record patients visits to primary healthcare centres, and e-referral system to digitalise referrals, an e-report system to automate electronic medical reports, which enables electronic reports to employers and employees, which includes e-signatures by doctors. In regard to inter-operability for exchange of data, Albania's systems are based on the previous generation of the EU inter-operability platform - it is planned to update to the current EU system by the end of 2024.

Via Albania's e-government portal (e-Albania) citizens can ask for e-health services, including appointments, changing doctors, registering for and recording COVID-19 vaccines, online records of chronic diseases, appointments, and some third-party services (such as import and export of medicines. Albania estimates that more than 4 million paper prescriptions have been eliminated (replaced by e-prescriptions) every year. Future plans include IT systems in regional hospitals (by end 2024) and a medical register for nurses, doctors, dentists and pharmacists (by the end of 2024), and upgrading the e-HR systems for health centres and family doctors (by end 2025). With regard to health data, Albania intends to align to GDPR by the end of 2025.

### **b. Commission assessment**

Albania's national legislation is partly aligned to Regulation (EU) No 282/2014<sup>13</sup>. Albania has an extensive ehealth system in place, covering e-prescription, an e-warehouse system for pharmaceutical products, an e-visit system to record patients visits, an e-referral system to digitalise referrals, and an e-report system to automate electronic medical reports, which enables electronic reports to employers and employees, which includes e-signatures by doctors. While the system in principle allows citizens to use the ehealth system to book appointments and access their health records online, the high-speed internet coverage needs to be developed as it is not available everywhere, and many patients could therefore have issues accessing ehealth services, particularly in rural areas.

## **II.C. MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE**

### **a. Country presentation**

There are seven companies producing medicinal products for human use in Albania. They are all inspected every two years in regard to compliance. Albania's legal base under its Law on Medicines and Pharmaceutical Services is partly aligned to the EU *acquis* on medical products for human use, except with regard to the EU *acquis* on orphan medicines, on medicinal products for paediatric use, and on advanced therapy products to which Albania is not aligned. Albania accepts medicinal products for human use in Albania that have been market of an EU Member State or by the EU Medical Agency (EMA). All such products are recorded in a national register. Further alignment to some of the *acquis*

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<sup>13</sup> As well as Commission Implementing Decision 2011/890/EU providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth, Council Conclusions 2017/C 440/05, and COM/2018/233 on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society.

is foreseen in 2024. The responsible authority is the Ministry of Health and Social Protection, it is implemented by the National Agency of Medicines and Medical Devices, which inspects manufacturers. Most medicines used in Albania come from the EU.

There are two manufacturers of veterinary medical products in Albania. Albania's legal base for medicines for veterinary use is its Law on Veterinary Services which is partly aligned to the previous EU *acquis* on this, however it is not aligned to the latest EU *acquis*. Full alignment to the current EU *acquis* is foreseen in 2024. Veterinary medical products are authorized for placement on the market if they are certified for placement on the market of an EU Member State or by the EU Medical Agency (EMA). All such products are recoded in a national register. The Ministry of Agriculture and Rural Development is the responsible body; its State Commission of Veterinary Medical Products is responsible for approving such products for placement on the market. This is a new sector for the ministry, it intends to fill vacancies by the end of 2023. Tests are ensured by the Albanian veterinary and Food Safety Institute. The National Authority of Veterinary and Plant Protection ensures market control of veterinary medical products, while border controls are ensured by the national food authority. There are legal obligations on retailers and wholesale bodies to record detailed documentation on the sale of such products. All relevant economic operators are controlled at least twice a year. In 2022, there were 48 inspections of wholesalers, and 444 on veterinary pharmacies. Albania is not aligned to the EU *acquis* on medicated animal feed.

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

National legislation is its Law 26/2017 on Cosmetic Products, which is **partly aligned** to the EU *acquis* on medical products for human use. It is not aligned in regard to the EU *acquis* on orphan medicines, on medicinal products for paediatric use, and on advanced therapy products. Albania's legislation is not aligned to the current EU *acquis* on medicines for veterinary use. Both medicinal products for human use and medicinal products for veterinary use are authorized for placement on the Albanian market if they have been placed on the market of an EU Member State and/or are authorised by the EU Medical Agency (EMA). All such products are recoded in a national register.

### **II.D. COSMETIC PRODUCTS**

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

Albania's national legislation is designed to have a high level of alignment with Regulation 1223/2009/EC on cosmetic products and Regulation 2022/1181 on cosmetic products that contain more than 0.001% of formaldehyde. It is not aligned in regard on definitions, nanomaterials, and other aspects, and partly aligned on notification. The responsible body is the Ministry of Health and Social Protection, market surveillance is ensured by the state health inspectorate. There are already around 90 persons identified in Albania established in the territory that is responsible for the safety of the product and its compliance with all the requirements of the EU Cosmetic Regulation. Full alignment is foreseen by the end of 2026.

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

Albania's legislation is partly with the EU *acquis* on cosmetic products - it is not aligned in regard to definitions and on nanomaterials, and partly aligned on notification.

### **II.E. MEDICAL DEVICES**

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

Albania's Law 89/2014 on Medical Devices, an amending law (Law 21/2020) and implementing legislation is designed to partly align to Regulation 2017/745/EU on medical devices and Regulation 2017/746/EU on in vitro diagnostic medical devices. Non-aligned aspects include identification and traceability of such devices, conformity assessment, re-processing of single use devices, market surveillance, and cooperation with EU Member States. Full alignment is foreseen during 2024. The registration process is completely online in Albania. The responsible bodies are the Ministry of Health

and Social Protection and the National Agency for Medicines and Medical Devices. The authorities signalled that they would like to be able to join the expert group on medical devices.

Regarding accelerated integration, the Albania asked to participate in the expert group on medical devices as an observer.

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

National legislation is partly aligned to the EU *acquis* on medical devices and on in vitro diagnostic medical devices. Albania's registration process for medical devices is ensured completely online.

The Commission took note of Albania's request on accelerated integration, and evaluates it positively. Albania may now request to join the expert group on medical devices as an observer.

### **II.F. TOBACCO CONTROL**

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

Albania has three laws covering tobacco control. These are its Law on Public Health, Law on the Protection of Health from Tobacco Products, and a Law Ratifying the WHO Framework Convention on Tobacco Control (FCTC), and several pieces of implementing legislation. These are designed to be fully aligned with Council Recommendations 2003/54/EC on and 2009/C 296/02 on the prevention of smoking and on smoke-free environments respectively. They are partly aligned to Directives 2010/13/EU on audio-visual media services, 2014/49/EU on the manufacture, presentation and sale of tobacco and related products, 2003/33/EC on advertising of tobacco products, and Delegated Directive 2014/109/EU establishing the library of picture warnings to be used on tobacco products. Full alignment is planned by 2025, by when Albania also intends to ratify the WHO convention to eliminate the illicit trade in tobacco products.

The responsible bodies for tobacco control in Albania are the Ministry of Health and Social Protection, and the Institute of Public Health, and there is an Inter-sectoral Committee for the Protection of Health from tobacco which also includes other ministries, inspection authorities, and the Tirana Police service. The State Health Inspectorate is responsible for enforcement. Albania uses a wide array of monitoring of tobacco consumption, including surveys and studies, including studies of smoking by school-age children. Albania's legal base treats electronic cigarettes and heated tobacco products in the same way as cigarettes. There are annual anti-smoking campaigns, including a new one aimed at school-age children. Advertising of tobacco and tobacco products is banned. Albania encourages non-smoking by enforcing legislation banning smoking in public places, and by awareness-raising campaigns.

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

Albania's legislation is designed to be fully aligned with the EU *acquis* on prevention of smoking and on smoke-free environments. It is partly aligned with the EU *acquis* on audio-visual media services, on the manufacture, presentation and sale of tobacco and related products, on advertising of tobacco products, and on establishing the library of picture warnings to be used on tobacco products. Advertising of tobacco and tobacco products is banned. Although it is a member of the WHO's Framework Convention on Tobacco Control, Albania has not yet acceded to the WHO's Framework Convention Protocol to Eliminate Illicit Trade in Tobacco Products, nor ensured their full implementation.

### **II.G. BLOOD, TISSUES, CELLS AND ORGANS**

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

Albania's legislation on *blood* are its Laws 9739/2007 and 505/2017 on the Organisation of Transfusion Service and related implementing legislation, which have a high level of alignment to the EU *acquis* on blood. Further alignment is planned by the end of 2025. The Ministry of Health and Social Protection is the competent body. Albania has a National Blood Transfusion Centre (NBTC), regional blood centres, and collection and distribution blood banks, 31 structures in total. The current

national health strategy (see above) foresees this to be rationalised to five blood establishments and 26 hospital blood banks. Albania is planning to establish a national information system to ensure full traceability.

Albania's legislation on the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, and on the quality and safety of human organs intended for transplantation consists of its Law 10454/2011 on this and DCMs 617/2012 and 206/2013, as well as Ministerial Orders 416/2011 and 103/2014, which are partly aligned to the relevant EU *acquis*. Full alignment is foreseen by 2030. Albania also plans to review its legislation on information procedures for the exchange with EU Member States of human organs intended for transplantation. The Ministry of Health and Social Protection is the competent body. Control is ensured by the State Health Inspectorate, inspection staffing requires strengthening. Albania has a kidney transplant programme in place, as well as a national protocol on this. Albania does not yet have the capacity for transplants from deceased donors or for corneal donations.

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

In the area of blood, tissues and cells, Albanian is **partly aligned** with the EU *acquis*. Shortcomings include aspects on the competent authority for hemovigilance and the organisation of hemovigilance network at national level, and on non-conformity, corrective and preventive actions, equipment and materials. Non-aligned aspects include the education and qualification of responsible persons, the qualification and training of staff dealing with procurement, processing, preservation, storage, and distribution of tissues and cells. Administrative and technical capacities in these areas are not yet sufficient to implement the *acquis*, and neither are the facilities for handling blood, blood components, tissues and cells adequate to meet the relevant EU technical standards.

### **II.H. COMMUNICABLE DISEASES AND HEALTH SECURITY**

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

Albania's legal base in regard to communicable diseases is its Law 15/2016 on the Prevention and Fight Against Infections and Communicable Diseases, which is designed to be aligned with all EU decisions and recommendations on health threats, preparedness response and planning, patient safety, antimicrobial resistance, cross border health threats, vaccination, influenza vaccination, and on One Health. Albania has established a communicable disease surveillance system, an integrated digitalized system that includes reporting, case-based and laboratory investigation, outbreak investigation, contact tracing, syndromic and event-based surveillance. This was launched in 2018 and notably used during COVID-19. The ministry of health and social protection is the competent body. Albania already participates in the EU laboratory network.

Albania as a national approved One Health Action Plan on antimicrobial resistance and there is an operational paper-based surveillance system for AMR, including priority bacteria (digitalization is underway), as well as a separate digitalized surveillance system for health care associated infections. A One Health digital surveillance platform has been established, which links human and veterinary systems. Antimicrobial consumption is monitored through a system that combines data from health Insurance Fund and drug control centre, as well as surveys.

Albania plans to align to the EU *acquis* on cross-border health threats, notably Commission Implementing Decision (EU) 2018/945 on the communicable diseases and related special health issues to be covered by epidemiological surveillance, by the end of 2023. Albania already reports to the to the European Centre for Disease Prevention and Control (ECDC) via the TESSy database, and will report to ECDC on its preparedness plan.

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

Albania has a **high level of alignment** to the EU *acquis* on communicable diseases, apart from on case definitions, and is partly aligned with the EU *acquis* on cross-border health threats. Though national structures are in place and human and material, implementing resources are limited. National plans, guidelines and protocols are yet to be developed in several fields including preparedness and response planning, outbreak investigation, risk assessment, risk management, and crisis communication. A

surveillance system is yet to be developed, and a formal electronic surveillance reporting system has not yet been put in place across the entire health sector. The national laboratory capacity is not yet adequate; this should be addressed.

### **III.I. PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE**

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

Albanian healthcare system is legally obliged to apply the principles of universality, access to good quality care, equity and solidarity, and non-discrimination regarding nationality. The competent authorities are the ministry of health and social welfare, and the healthcare insurance fund. Upon requests for prior authorization made by an insured person with a view to receiving cross-border healthcare, the state of affiliation the conditions are met, the prior authorization shall be granted pursuant to certain conditions. Albania has agreements in place on this with several EU Member States already, including Belgium, Luxembourg, Germany, the Czech Republic, and Hungary, and negotiations with others are ongoing.

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

Albania is partly aligned to the EU *acquis* in this area. Further alignment remains to be done in regard to the reimbursement of costs of healthcare received abroad by Albanian citizens. Albania is also yet to cover healthcare provided to nationals from EU Member States. Albania also needs to establish a National Contact Point to provide information to patients, and ensure the recognition of medical prescriptions issued in a country other than Albania, including measures on content of medical prescriptions.

### **III.J. HEALTH INFORMATION**

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

Albanian legislation is partly aligned to the EU *acquis* on health information. Data is stored in 39 disease registers, including surveillance data on communicable diseases, and on the activities of health institutions, by the State Statistical Office (INSTAT). Data is also stored in the national ehealth portals (*see above, section I.A eHealth*). Albania's list of indicators is based on European core health indicators (ECHI) adopted for Albania. Weekly, monthly and yearly reports are produced, including on communicable diseases.

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

National legislation is partly aligned to the EU *acquis* on health information. Some data on diseases, including communicable diseases, is being collected and stored.

### **III.K. CANCER SCREENING**

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

Albania has a national cancer screening control plan. It is fully aware of the new EU approach to cancer screening, and plans to align to it. Albania expects an increase in its cancer cases. Albania recognises that its cancer registries need to be updated. Albania plans to join in the European Network of Cancer Registries. The most frequent cancer types in Albania are lung and breast cancer.

Albania has been working with EU Member States to establish a cervical cancer screening programme. It has also started a breast cancer screening programme. A colorectal cancer screening programme is available for all residents 35-70 and there is a national cancer control plan 2022-2030 covering prevention, screening, early diagnosis, treatment, palliative care, information systems, and coordination.

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

Albania has started *cancer screening* to try to ensure the early detection of breast and cervical cancer continue. It has yet to ensure the necessary levels of administrative and technical capacity to ensure this.

## **II.L. MENTAL HEALTH**

### **a. Country presentation**

Albania's main legal basis on mental health is its Law on Mental Health, Laws on Inclusion, Social Assistance, Social Care, and Rights and Treatment are also relevant. The National Mental Health Strategy 2013-2022 ended at the end of 2022 and a new Mental Health Case Action Plan is under development that is foreseen to take the latest EU *acquis* on mental health into account. The Institute of Public Health is the responsible institution. Albania's healthcare services operator and its four regional directories and 36 local units that have mental health sectors are responsible for the implementation and relevant legislations in mental health, in cooperation with local actors.

### **b. Commission assessment**

In the area of *mental health*, national legislation is partly aligned with the EU *acquis*. Plans exist for further capacity-building in this area, especially as regards staff training. Measures are being taken to introduce community-based mental health services as an alternative to institutionalisation.

## **II.M. HEALTHY ENVIRONMENTS**

### **a. Country presentation**

Albania's national legislation is designed to be fully aligned with the EU *acquis* on exposure to electromagnetic fields. The Albanian Radiation Protection Commission is the responsible body; each subject/person that performs activities with non-ionized radiation sources are obliged to be approved by this body.

### **b. Commission assessment**

In the area of healthy environments, Albania is partly aligned with the EU *acquis* on exposure to electromagnetic fields, and it is implementing controls in this area.

## **II.N. RARE DISEASES**

### **a. Country presentation**

On rare diseases, Albania has designed its legal basis to be aligned to the relevant EU *acquis*. Actions in regard to rare diseases are foreseen in the national 2021-2030 National Health Strategy, the National Health Promotion Action Plan, in health insurance coverage, and in its decision on medical reimbursement. Each paediatric service, at hospital level, has a database of patients followed at national level for such diseases.

### **b. Commission assessment**

National legislation is designed to be fully aligned to the relevant EU *acquis*, which are included in the legal bases for health insurance and the reimbursement of medicines. Albania's national health strategy 2021-2030 includes activities on rare diseases. The country is yet to develop national guidelines on this and is also yet to extend coverage of the reimbursement for orphan medicines.

## **II.O. HEALTH INEQUALITIES**

### **a. Country presentation**

As regards health inequalities, the Albanian Constitution stipulates in Article 55 that "Citizens enjoy in an equal manner the right to health care from the state" and "Everyone has the right to health insurance pursuant to the procedure provided by law". These principles are designed to be reflected in the national legal base, notably in the Albanian Law Against Discrimination. Albania's Law on Compulsory Health Care guarantees free access to all medical services (primary and hospital level of care and reimbursement drug list) for uninsured persons. The ongoing Albanian Primary Healthcare Strategy (2020-2023) includes a priority to vulnerable groups and supporting these groups within the communities through health services. The action plan on health promotion targets vulnerable groups of the Albanian population, including women and girls, children in need, the Roma community, persons with disabilities as well as marginalized groups. Albania's action plan for equality, inclusion and participation of Roma and Egyptians 2021-2025 also includes health related measures. During the

height of the COVID-19 pandemic, social support and payments were provided to the marginalized population in urban and rural areas, through a network of support from central and local government institutions. Health centres close to Roma and Egyptian settlements lacking access to health facilities, serving the entire population of the area, the Roma, Egyptians and non-Roma.

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

In the area of health inequalities, activities are being implemented that are designed to improve the health of vulnerable population groups, including Roma, though discrimination remains prevalent in access to healthcare. There is only a limited focus on improving the health of vulnerable population groups, ensuring equal access to quality health services for such populations, including Roma and Egyptian minorities, older people, people with pre-existing mental health problems, with disabilities, and rural or remote populations, notably women and girls.

### **II.P. HEALTH LIFESTYLES – ALCOHOL AND DRUG ABUSE PREVENTION**

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

Albania's National Health Strategy 2021-2030 includes specific objectives and interventions related to the promotion of a healthy lifestyle and ensuring a healthy environment. The national legal base includes a Law on the Protection of Minors from Alcohol Use, and a Law on the "War Against Drugs". The Ministry of Health and Social Protection is the responsible body. The health promotion action plan 2022-2030 includes measures aimed at substance use, including a specific focus on school-age children, aimed at prevention of tobacco, alcohol, and illicit drug use.

Albania adopted a Strategy for the Prevention and Reduction of Alcohol-related Damages (2017-2021) that aims to prevent or minimize the harm that alcohol causes to the individual, the family and the community in the context of developing a safe and healthy drinking culture. Data cited by Albania shows the prevalence of alcohol consumption in the last month by 15-year-old youth is 16% among girls and 31% among boys. The same dataset shows lifetime prevalence of cannabis use among young people aged 15 is 3% among girls and 13% among boys. Albania is implementing harm reduction programmes, whose measures include methadone-maintenance therapy (MMT); needle-and-syringe-exchange programs (NSEP); HIV testing and counselling; STI testing and treatment; basic medical support; distribution of condoms and lubricants; and peer education and distribution of materials on information, education, and communication (IEC). aiming to reduce the negative consequences on the health status of people who inject drugs (PWID). Albania signed a working agreement with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in 2019

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

In the field of *drug* abuse prevention, efforts are ongoing as regards substitution treatment for drug abusers and the establishment of a substance abuse register that may help monitor needs for treatment and care. Capacity for drug abuse prevention should be stepped up, including at local level. Albania is implementing actions on nutrition, alcohol related harm reduction, prevention of injury and promotion of safety on the basis its relevant ongoing strategies.

### **II.Q. SUMMARY OF FINDINGS – PUBLIC HEALTH**

The basic legal framework for healthcare is set out in the Albanian constitution. Albania is a signatory of the EU Joint Procurement agreement for medical countermeasures. Albania needs to align to EU interoperability standards and to the GDPR in regard to health data. Albania's legislation is **designed to be fully aligned** with the EU *acquis* on **prevention of smoking** and on **smoke-free environments**. Albania has a **good level of alignment** with the EU *acquis* on **communicable diseases**, apart from on case definitions. Relevant resources need to be reinforced.

Albania's legislation is **partly aligned** with the EU *acquis* on **audio-visual media services, on the manufacture, presentation and sale of tobacco and related products, on advertising of tobacco products, and on establishing the library of picture warnings to be used on tobacco products.**



Albania also to accede to the WHO's FCTC Protocol to Eliminate Illicit Trade in Tobacco Products. Albania is also **partly aligned** to the EU *acquis* on **medicinal products for human use**, in particular with the EU general pharmaceutical *acquis*, and with the EU *acquis* on **cosmetics**. Albania is **partly aligned** with the EU *acquis* on **blood, tissues and cells**, and on **mental health**. Albania is **partly aligned** with the EU *acquis* on **patient's rights in cross-border healthcare**. Administrative and technical capacities in these areas need to be strengthened.

Albania is **not aligned** with the EU *acquis* on **orphan medicines**, on **medicinal products for paediatric use**, and on **advanced therapy products**. Albania is also **not aligned** to the current EU *acquis* on **medicines for veterinary use**.

On *health inequalities* Albania needs to continue to focus on improving the health of vulnerable population groups, ensuring equal access to quality health services for such populations, including Roma and Egyptian minorities, older people, people with pre-existing mental health problems, with disabilities, and rural or remote populations, notably women and girls. Albania needs to increase its capacities to address *drug abuse prevent, nutrition, alcohol related harm reduction, prevention of injury and promotion of safety*.

### III. FIGHT AGAINST CORRUPTION - CONSUMER AND HEALTH PROTECTION

#### a. Country presentation

There is Albanian legislation in place on ethical rules in the public administration, and implementing legislation in place on the approval of the rules for the application of the principles of ethics, classification of the external activities and the value of gifts that may be administered during the activity of the public administration servants. The Consumer Protection Commission (CPC) has a dedicated website which is, *inter alia*, designed to ensure transparency, access to information and accountability. Members of CPC sign a personal impartiality declaration for the duration of their mandate. All CPC decisions and its yearly reports are published online, and it can be used by consumers to make online complaints. SIMS also publishes its programmes, reports, and work plans on its website, and has its own transparency programme. SIMS is subject to national legislation on the prevention of conflict of interests in the exercise of public functions. SIMS has its own ethical code, as does the customs authority. Albanian Financial Services Authority (AFSA) also enables online complaints, where its charter of consumer and investor rights is published is also available, and has a toll-free contact number. Provisions addressing conflicts of interest regarding BoA are included in the law on the Bank of Albania, the Statute of BoA, and the Code of ethics on BoA. MFE, SIMS, BoA, customs and AFSA each have their own whistle blower units/entities. MFE, BoA, and AFSA each have internal audit units. There is a dedicated Anti-corruption Inspector in the cosmetics sector. All national pharmaceutical manufacturers are inspected every two years for compliance, and for veterinary medicine stocks, a complete review of quantities bought, sold, and in stock is kept and all detected discrepancies are recorded. The national Agency of Medicines and Medical devices has a transparency programme, an electronic register of requests and responses, a coordinator on the right of information, a whistle blower unit, and online templates of denunciation for internal or external whistle-blowers.

#### b. Commission assessment

Albania has established quite a range of anti-corruption measures in regard to consumer protection, notably in regard to transparency and the provision of information. Many entities involved in consumer protection have measures against conflict of interests in place, and several also have internal whistle blower entities. In regard to public health Albania has a specific is a dedicated Anti-corruption Inspector in the cosmetics sector. There are also systems in place to control pharmaceutical manufacturers and to track veterinary medicine stocks, which are potentially important measures against corruption. The national Agency of Medicines and Medical devices has a range of anti-corruption and whistle blower provisions in place. Therefore, focusing on the full and adequate implementation of this range of anti-corruption measures is key going forward.

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

Albania has the institutional framework in place to fight corruption in the area of consumer and health protection. Albania needs to ensure that these are all fully and correctly implemented.