

# **Screening report**

## **Montenegro**

### **Chapter 28 – Consumer and health protection**

**Date of screening meetings:**

Explanatory meeting: 19–20 February 2013

Bilateral meeting: 15–16 April 2013

## I. CHAPTER CONTENT

The *acquis* on consumer and health protection consists of regulatory measures, recommendations to Member States, coordination and support of Member States' activities as well as financial support. The Chapter covers the interests of the citizens as regards consumer policy, notably safety and economic interests, and public health.

The *acquis* in the area of **consumer protection** covers legislation in the field of consumer protection, including on product safety and the Union's Rapid Alert System (RAPEX), cross-border cooperation and enforcement, sale of consumer goods and associated guarantees, unfair contract terms, price indications, doorstep selling, distance selling, distance marketing of financial services, consumer credit, misleading and comparative advertising, unfair commercial practices, timeshare, package travel, injunctions for the protection of consumer interests and access to justice.

The *acquis* in the area of **public health** deals with issues related to tobacco control, communicable diseases, blood, tissues, cells and organs, patients' rights in cross-border healthcare, and also with mental health, drug abuse prevention, health inequalities, nutrition, alcohol related harm reduction, cancer screenings, healthy environments including prevention of injury, promotion of safety, active and healthy ageing as well as European action in the field of rare diseases.

Implementation and enforcement of consumer and health protection policies require adequate administrative capacities and infrastructure at national, regional and local level. As regards consumer protection, this refers to effective market surveillance and appropriate independent judicial and out-of-court dispute resolution mechanisms. It is also necessary to raise public awareness, consult with the public and involve consumers actively in effective policy implementation, thus informing and educating the consumer and ensuring a role for consumer associations.

## II. COUNTRY ALIGNMENT AND IMPLEMENTATION CAPACITY

This part summarises both the information provided by Montenegro and the discussion at the screening meeting. Montenegro indicated that it can accept the *acquis* regarding consumer and health protection and that it does not expect any difficulties to implement the *acquis* by the date of accession.

### II.a. Consumer protection

#### Horizontal aspects

Consumer policy in Montenegro has been set out in national consumer protection programmes since 2008. A Third National Programme of Consumer Protection (2012–2015) was adopted in October 2012, accompanied by an annual Action Plan for its implementation which is monitored by an inter-departmental Commission established in March 2013. It brings together representatives of the competent authorities of the State administration, consumer organisations and economy. An Annual Report on the Implementation of the National Programme of Consumer Protection for the period between July 2012 and June 2013 was adopted by the Government in October 2013.

Concerning the institutional framework, the overall responsibility for general consumer protection policy lies with a particular Department of Consumer Protection within the Ministry of Economy. An Administration for Inspection Affairs was established in 2012 by

merging 26 inspections from various ministries and other State administration bodies. 17 inspections are responsible for market surveillance and protection of consumers' health, safety and economic interests. They employ a total of 184 inspectors. In addition, the Ministry of Transport and Maritime Affairs with ten inspectors and the Ministry of Interior, operating with eight inspectors, have obligations as regards product safety while the Agency for Electronic Communications and Postal Services has a mandate as regards protection of the economic interest of consumers in the area of telecommunications and postal services.

A coordination body for market surveillance was established in October 2010, with the task to monitor implementation of the Strategy for market surveillance, coordinate market surveillance and to prepare the annual National Programme for Market Surveillance. A call centre and websites of the Administration for Inspection Affairs and of the Market Inspection aim at facilitating direct communication with citizens. In September 2013, a new IT platform was launched serving as a central hub for distributing consumer protection information and hosting software for management of notifications on dangerous products at national level, and as an IT facility for registering and handling consumer complaints by various bodies and NGOs. In 2012, 34 % of all complaints were related to tourism.

An Arbitration Board for *out-of-court settlement of consumer disputes* is in place since 2008 at the Chamber of Economy of Montenegro. It has 20 members (ten representatives from NGOs and ten representatives from the business sector) which are appointed for three years. 15 consumer complaints have been resolved since 2009. The Arbitration Board also organises training seminars for its members as well as media campaigns to raise public awareness of consumer rights and out-of-court settlement of consumer disputes. The draft Law on Consumer protection provides for appeals to the Arbitration Board to be free of charge. It also sets out improvements to the system of alternative consumer dispute resolution by establishing specialised internal structures for out-of-court settlement of consumer disputes in view of notably allowing consumers to choose specialised arbitrators of trust among the members of the Arbitration Board. The Banking Ombudsman participates in out-of-court settlement in the case of resolution of disputes between the consumers and banks and/or micro-credit financial institutions and credit unions.

There are two non-governmental organisations for consumer protection in Montenegro (CEZAP and ECOM), both based in Podgorica. The former was founded in 1999 and the latter in 2005; both 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. In May 2013, CEZAP filed the first collective lawsuit on behalf of 250 persons to protect their rights as regards consumer credits. A project has been launched by CEZAP to establish a permanent Consumer Protection Centre, increase the flow of consumer relevant information, analyse and raise awareness on unfair contract clauses and launch comparative product tests and research.

Montenegro stated that awareness raising activities have been carried out in the area of consumer protection, mainly by NGOs. Within an IPA 2010 project "Consumer protection and market surveillance" that ended in October 2013, a campaign on consumer protection was notably launched in February 2013 where information on consumer rights and mechanisms for their protection was broadcasted. There are also plans to include consumer protection issues in the school curriculum. Furthermore, the Ministry of Interior is planning to establish a working group to improve the protection of consumers in local government. CEZAP also participates in a project "European consumer bridge" financed by the EU, aiming at empowering consumers. Overall, Montenegro indicated that informing of consumers has increased significantly in recent years, but further efforts are necessary.

## Product safety related issues

The General Product Safety Law adopted in 2008 aims at aligning with EU Directive 2001/95/EC on *General Product Safety* as well as with the *Dangerous Imitations* Directive 87/357/EEC. Montenegro indicated that preparation of a new law has started in order to ensure full alignment with the *acquis* on general safety requirements, criteria and obligations of manufacturers and distributors as well as on exchange of information on dangerous products. The objective is to finalise the new draft legislation in the course of 2013 and adopt it in 2014.

Montenegro stated that EU Directive 85/374/EEC on *Liability for Defective Products* is aligned with through the Law on Contractual Obligations, adopted in 2008. Some of the missing provisions of the Law on Contractual Obligations, such as definition of damage, are regulated under the Law on Consumer Protection adopted in 2007. Montenegro indicated that there is a need to revise terminology used in the Law on Consumer Protection. This will be done through amendments to the Law foreseen to be adopted by the Parliament by the end of 2013. Montenegro also indicated that the Law would be aligned with Article 9(b) of the Directive providing for a threshold lower than € 500 for damage caused by a defective product, but that this provision would enter into force only upon accession in order to ensure a higher level of consumer protection in Montenegro until accession.

Montenegro indicated that the rules for the future *management of the Union Rapid Information System (RAPEX)* are in place through a decree on the exchange of information on products posing a risk adopted in 2010. The future national RAPEX contact point is planned to be located in the Market Inspection. Special software for the exchange of information on dangerous products at national level was put in place in 2013. Weekly reports on dangerous products can be found on the website of the Market Inspection Within the IPA project “Consumer protection and market surveillance”, an information system has been established with the aim to consolidate management of consumer complaints and monitoring of dangerous products on the entire territory of Montenegro. The system enables consumers to file a complaint or ask questions via an on-line application. Montenegro indicated that there are 50 market inspectors in the Market Inspection and that reactive market surveillance (upon reports by consumers, through monitoring RAPEX notifications published on the RAPEX website, data from other unsafe products databases, etc.) is a priority compared to proactive surveillance. Relevant staff has been regularly trained; several study visits have notably been carried out to Member States. A Memorandum of Understanding has also been signed between Market Inspection and Customs Administration in March 2012 in order to ensure the efficiency of the system for rapid exchange of information. Montenegro stated that when the Market Inspection suspects that a dangerous product could be placed on the Montenegrin market, it shall immediately inform the competent inspectorate and the Customs Administration thereof.

At regional level, Montenegro indicated that their Market Inspection has established good cooperation with their Slovenian counterparts and has established communication with their counterparts in Serbia and the former Yugoslav Republic of Macedonia, and that cooperation with other countries of the region is also in place. Notably, Montenegro uses the databases of other countries of the region (Bosnia and Herzegovina, Croatia) in order to detect dangerous products. The establishment of a network of cooperation of bodies in charge of market surveillance in the region is under preparation through a regional project funded by Germany that started in June 2013 until February 2015.

Overall, Montenegro indicated that in the future cooperation with the Customs Administration will be further improved. Also more seminars could be organised for staff involved.

### Non-safety related issues

Montenegro indicated that several *acquis* elements are already in place through the Law on Consumer Protection (2007), the Law on Contractual Obligations (2008) and the Law on Internal Trade (2008), such as *acquis* on *unfair terms in consumer contracts*, *distance contracts*, *contracts negotiated away from business premises*, *misleading and comparative advertising*, *indication of product prices*, *sale of consumer goods and associated guarantees* and on *timeshares* (the old Directive 94/47/EC). *Unfair commercial practices* are only partially covered. The Law on Tourism aims at aligning with the *acquis* on *package travel*. *Distance marketing of consumer financial services* is covered by regulations on the securities market.

According to Montenegro, a new Law on Consumer protection is under preparation, with planned adoption by the Parliament in 2013. It will aim at generally aligning with the new *acquis* on *consumer rights* (through alignment with Directive 97/7/EC on distance selling and with Directive 85/577/EC on doorstep sale), with the *acquis* on certain aspects of the sale of consumer goods and associated guarantees, on unfair terms in consumer contracts, on price indications, on unfair commercial practices, on distance marketing of consumer financial services, on *injunctions* as well as on new *acquis* on timeshares. Full alignment with the *acquis* on consumer rights is foreseen to be achieved by the end of 2014 through further amendments to the Law on Consumer Protection. Furthermore, a Law on Prohibition of Misleading Advertising is under preparation aiming at alignment with the *acquis* on misleading and comparative advertising. Amendments to Law on Tourism are to be adopted by the Parliament by the end of 2014 in order to complete legal alignment with the *acquis* on package travel. A Law on *consumer credits* was adopted by the Parliament in July 2013 aiming at completing legal alignment with the old *acquis* (Directive 2008/48/EC) in this area. It is foreseen to align with the new *acquis* (Directive 2011/90/EU on credit agreements for consumers) through secondary legislation.

As regards the EU Regulation (EC) No 2006/2004 on *Cooperation between National Authorities responsible for the Enforcement of Consumer Protection Laws*, Montenegro indicated that elements of this Regulation will be included in the new Law on Consumer protection.

## **II.b. Public health**

### Horizontal aspects

The Health Care Policy in Montenegro until 2020 aims to extend life expectancy, improve the quality of life, reduce health inequities and integrate Montenegro's health system with European and global health development processes. The development of the health sector in Montenegro is guided by a Master plan for 2010–2013 which puts an emphasis on reform of secondary and tertiary levels of healthcare. E-health is on its way to being fully integrated in the health sector, helping to make the healthcare systems interoperable. Medical doctors, for example, are already using the electronic Health Card which will be regulated by law by the end of 2014. Although there is no national e-health strategy as such, a section on e-health is included in the National Strategy for Information society development 2012–2016.

Main legislation in this area is the Law on Health Care (2012) and the Law on Health Insurance (2012). Concerning the institutional framework, the main actors are the Ministry of Health (MoH), the Health Insurance Fund of Montenegro and a network of health institutions consisting of public health care institutions (18 public health centres, seven general hospitals and three special hospitals as well as the Institute of Public Health of Montenegro) and private health care institutions with which the Health Insurance Fund has concluded a contract on providing health care arising from compulsory health care. As regards the health workforce, the Government adopted a Human resources plan for 2013–2022 at the beginning of 2013. It sets out the objective to meet with EU standards on the number of doctors by 2027, and the continuous education and training of doctors, including an increase of the number of students in the Faculty of Medicine. Montenegro also indicated that a future challenge for the country will be medical education in Montenegro, as currently, apart from specialisation in radiology and radiotherapy, students mostly undergo medical training in Serbia.

### Tobacco control

Montenegro indicated that the *acquis* on tobacco control has been aligned with through the Law on Restriction of Tobacco Products Use (2011). This Law bans smoking in all hospitality establishments (bars and restaurants), except for designated hotel rooms. However, under the Law on Excise taxes, smoking may be allowed in case the owner of the establishment pays 1 €/m<sup>2</sup> to the tax authority on a monthly basis. This provision is in force until 1 January 2014. Since the entry into force of the Law on Excise taxes in June 2012, also inspection activities on supervision of the use of tobacco products in restaurants have been put on hold. The procedure for concluding a licensing agreement for use of EU pictorial warnings has been initiated.

The WHO *Framework Convention on Tobacco Control (FCTC)* was ratified by Montenegro in 2005.

### Communicable diseases

Montenegro stated that the legal basis for the protection from communicable diseases in Montenegro is the Law on Protection of the population from communicable diseases (2012) and the Rulebook on the Method of reporting communicable diseases, nosocomial infections, conditions and death of people suffering from communicable diseases. The 2012 Law expanded the list of communicable diseases in line with the recommendations of the WHO and the EU Commission and ECDC (European Centre for Disease Prevention and Control). The Law recognises an obligation to define cases of reporting infectious diseases that might constitute a threat to global public health, in line with the International health regulations. Also, a national coordination body was established with the view of eradicating certain infectious diseases and reporting to the competent authorities on facts relevant for occurrence, elimination, eradication and maintaining a disease free status at the country level. Montenegro indicated that an advisory body for immunisation is to be established. The Law prescribes also an obligation to establish a Commission for control of hospital infection and expert teams for surveillance, prevention and elimination of hospital infections.

The Public Health Institute gathers information on epidemiological surveillance of communicable diseases and informs WHO and other relevant international institutions within 24 hours, in case of outbreak. Reports are provided on a weekly and monthly basis on overall trends of infectious diseases, as well as consolidated annual reports. An integrated healthcare information system is in place and controls are intensified in the summer season.

A system for early warning and emergency response (ALERT) is in place and Montenegro indicated that the surveillance network has yielded good results.

Montenegro indicated that there are no national guidelines on healthcare associated infections. A national commission on hospital infections is in place, but has not met so far. According to Montenegro, the majority of small laboratories suffer from lack of adequate equipment. There is also a lack of an adequate system of coordination between laboratories as well as insufficient quality control. Montenegro stated that there is no capacity to test all suspect cases in Montenegro, but an agreement is in force with Italy and Serbia for testing.

Montenegro indicated that a reform of the surveillance system has started in the form of a pilot project that is foreseen to be completed by the end of 2014. Capacity building is to be strengthened: all coastal public health centres are foreseen to have their own epidemiological units by 2016/2017, the public health centre of Niksic is foreseen to be strengthened by 2017 and the centres of Kotor, Herceg Novi, Budva and Plijevlja after 2020. Also all laboratories are foreseen to be connected to primary healthcare centres.

#### Blood, tissues, cells and organs

Montenegro stated that a Law on *Blood* provision was adopted in 2007 establishing the Institute for Blood Transfusion in Montenegro. Blood collection is carried out by the Institute with nine organisational units. Data on blood traceability are kept for at least 30 years. Records on adverse reactions and events are kept, but there is no organised reporting. In 2012, two regular supervisory activities over blood establishments were performed by the Institute and one over collection centres. Montenegro plans to organise training for health inspectors in the future with Taiex assistance. A new Law on Blood provision is foreseen to be adopted by the end of 2013 followed by seven implementing Rulebooks foreseen to enter into force in the first quarter of 2014. The Sector for Biomedicine (bioethics, pharmaceuticals and transplantation programmes) in the MoH with five staff members is foreseen to become the National Competent Authority in this area. It is also foreseen to improve the system of blood traceability and strengthen the national hemovigilance system through this Law.

In the area of *tissues and cells*, Montenegro stated that the Act on Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment and the Law on Infertility Treatment with Assisted Reproductive Technologies (ART) were adopted in 2009. Also, a number of implementing rulebooks have been adopted in this field. Transplantations are carried out only in the Clinical Centre of Montenegro, and ART procedures in one public (Cetinje General Hospital) and three private institutions. Montenegro indicated that the organs transplantation process is only starting to be developed. So far, with assistance from Croatian experts, four kidney transplantations from a living donor have been performed, while removal and transplantation of human body parts from deceased donors have not been performed yet. A National Commission for the development of a transplantation programme and promotion of organ donation in Montenegro is in place. Montenegro indicated that regular supervision is carried out over providers of ART. However, there is no vigilance and traceability in the area of tissue transplantation. Montenegro indicated that it intends to organise a workshop on transplantation through Taiex assistance in 2013 as well as training for health inspectors in the future. Montenegro indicated that in the area of *organs*, legislation is foreseen to be adopted in 2013 and the overall legal alignment to be completed in this field in 2015. For example, traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and

distribution of human tissues and cells are foreseen to be introduced for the first time in 2015.

#### Patients' rights in cross-border healthcare

Montenegro stated that ex-Yugoslav citizens are already familiar with the contents of the *acquis* in this area, as at the time it was possible to travel freely for healthcare treatment in ex-Yugoslavia. Montenegro described the different groups of bilateral agreements on social insurance that are in place as well as the system of prior authorisation before Montenegrin citizens can travel abroad for healthcare due to the limited budget of the Health Insurance Fund. Montenegro also stated that modern technologies (e-health) will be a challenge to ensure the overall functioning of the system. Montenegro indicated that legal alignment in this area is foreseen to be completed by accession through amendments to the Law on Healthcare Insurance by the end of 2018.

#### Mental health, drug abuse prevention, health inequalities, nutrition, alcohol related harm reduction, cancer screenings, healthy environments including prevention of injury, promotion of safety and rare diseases

As regards *mental health*, a Law on the Protection and Enforcement of the Rights of Mentally Ill was adopted in 2005 and amended in June 2013. A Strategy for Improvement of Mental health was adopted in 2004 and an Action Plan for the Promotion of Mental Health in Montenegro 2011–2014 is under implementation. A Commission on Mental Health, a professional advisory body, as well as a National Focal Point on Mental health are in place. There is one Special Hospital for Psychiatry Dobrota in Kotor and Departments for Psychiatry within the Clinical Centre of Montenegro in Podgorica and the General Hospital in Nikšić. Centres for mental health exist also within the primary healthcare centres. As regards community-based services, Montenegro stated that there are seven regional centres and teams of mental health professionals operating. A project is ongoing in cooperation with WHO on provision of home services for mentally ill. Capacity-building is also being improved through IPA assistance focusing on staff training, including in community mental health care. Montenegro indicated that it tries to be active in the area of mental health at international level. It also stated that even if its budget allocated to this area is less than 5 % of the State budget in the area of health, it is still more than in some countries of the region.

In the area of *drug abuse prevention*, Montenegro indicated that amendments to the 2011 Law on the Prevention of Drug Abuse were adopted in July 2013. A Strategy for the Prevention of Drug Abuse 2013–2020 and an accompanying Action Plan 2013–2016 are in place. Montenegro indicated that it suffers from an insufficient capacity for treatment of drug abusers; on the other hand, NGOs play an active role in this field.

As regards *health inequalities*, Montenegro reported about measures taken to improve access to healthcare for minorities, especially Roma. Measures are aimed at improving health of the Roma population, at encouraging and directing members of the Roma population to choose their doctor and a paediatrician for their children, at upgrading knowledge of medical experts concerning the special characteristics of the Roma population and at educating members of the Roma population on rights to healthcare. The process of introduction of health mediators has been launched. There is also a very good cooperation with NGOs to address health issues of minorities.

Montenegro indicated that an Action Plan for *Nutrition* and Food Safety (2010–2014) is in place. A national initiative to reduce salt intake was adopted in December 2012. A Specialised Service for Nutrition, an out-patient clinic, receives between 800 and

1000 patients per year for counselling on individual diets, etc. There is no national data on overweight and obesity, but this is planned in the future.

In the area of *alcohol related harm reduction*, a National Strategy for the Prevention of Alcohol Abuse and Alcohol-related Disorders in Montenegro 2013–2020 was adopted by the Government in October 2012. Advertising of alcohol is banned (except for wine and beer) and the limit for alcohol consumption when driving is 0.5 ‰.

As regards *cancer screenings*, national programmes for early cervical, colorectal and breast cancer detection exist and screenings are being started. A National Cancer Control Plan has been adopted, cancer being the second leading cause of death in Montenegro after circulatory diseases. Efforts to raise awareness of early detection of breast and cervical cancer are ongoing. Montenegro indicated that screenings are carried out on a voluntary basis, and it is difficult to mobilise the public. However, the aim is to reach a 75 % coverage in all screenings. Montenegro also stated that the establishment of the National Cancer Register is in progress and foreseen to be operational by 2015.

In the area of *healthy environments*, Montenegro indicated that its legislation is partly in line with the *acquis* on electromagnetic fields. Legal alignment in this area is foreseen to be completed by July 2015.

In the field of *prevention of injury and promotion of safety*, Montenegro indicated that a Strategy for the promotion of the health of employees and safety at work in Montenegro 2010–2014 has been adopted with an accompanying action plan. A wide spectrum of institutions is involved in the activities. The MoH has also established a Commission for quality and safety where also NGOs are associated through the NGO Society for quality and safety of patients.

A National Strategy for *Rare Diseases* in Montenegro 2013–2020 was adopted by the Government in January 2013. According to Montenegro, 6–8 % of the population are affected by rare diseases. Montenegro stated that there is currently a lack of appropriate registration and unified monitoring of rare diseases at national level and insufficiently raised awareness on rare diseases. The objective is to improve the prevention of rare diseases with genetic origin by organising extensive “screening” programmes. Moreover, a National Reference Centre for Rare Diseases is foreseen to be established; it will be responsible for the implementation of the Strategy in this area. Supervision and evaluation of the implementation of the Strategy will be carried out by the National Council for Rare Diseases foreseen to be established within the MoH. Also national public campaigns for raising general and professional awareness on the importance of rare diseases are planned as from the beginning of 2014.

### **III. ASSESSMENT OF THE DEGREE OF ALIGNMENT AND IMPLEMENTING CAPACITY**

Overall, Montenegro has already reached a good level of alignment with the *acquis* in the area of consumer and health protection. A lot of legislative work is currently being carried out in both areas. A new Law on Consumer Protection is under preparation aiming at aligning with most of the *acquis* concerning non-safety related issues. This will be followed by a new Law on General Product Safety. In the area of public health, a new Law on Blood provision is under preparation. Legal alignment in the area of tissues and cells is foreseen to be finalised in 2015. Administrative capacity-building needs to continue in both areas and due attention needs to be paid to *acquis* enforcement and application of EU technical standards, in particular in the area of public health.

### **III.a. Consumer protection**

#### Horizontal aspects

Montenegro is undertaking all efforts to develop a consumer protection system in line with the EU consumer protection strategies and values. A general framework is in place. Enforcement of consumer rights needs to be further improved. Although substantial efforts have been made to raise awareness of consumers on their rights, support for consumer NGOs and awareness raising with the general public, *inter alia* about the out-of-court settlement of consumer disputes, need to continue.

#### Product safety related issues

In the field of general product safety, Montenegro has already reached a good level of alignment. Attention needs to be paid to the revision of the current legal framework in order to complete legal alignment in the areas of general product safety, dangerous imitations and liability for defective products. Legal alignment remains to be completed also in the area of child-resistant and novelty lighters. As regards market surveillance, the number of published notifications on dangerous consumer products is rising. Efforts need to continue to ensure due functioning of market surveillance, including coordination between different stakeholders and technical training of market inspectors.

#### Non-safety related issues

In the area of non-safety related issues, Montenegrin legislation is partially aligned with the *acquis*. Montenegro is well aware of the requirements by the *acquis* on the basis of a screening of the national legislation in relation to 11 EU Directives carried out in 2010. Attention needs to be paid now to the revision of the current Law on Consumer Protection which aims at completing legal alignment in many areas, such as the new *acquis* on consumer rights, the *acquis* on certain aspects of the sale of consumer goods and associated guarantees, on unfair terms in consumer contracts, on price indications, on unfair commercial practices, on distance marketing of consumer financial services, on injunctions as well as on new *acquis* on timeshare. Legislation remains to be adopted also in the areas of misleading and comparative advertising and package travel in order to complete legal alignment in these fields. In the area of consumer credits, Montenegrin legislation appears to be in line with the old *acquis* (Directive 2008/48/EC). However, legislation still remains to be brought in line with the new *acquis* (Directive 2011/90/EU on credit agreements for consumers). Montenegro has an adequate alternative dispute resolution mechanism in place in the area of consumer credits, as required by the *acquis*; in addition to an arbitration board that handles consumer credit related complaints there is also a system of out-of-court settlement of consumer disputes with a more general scope. At the time of accession, Montenegro will also need to be able to ensure the application of the EU Regulation on Consumer protection cooperation, in particular regarding the minimum powers of enforcement authorities and the designation process for the competent authorities and Single Liaison Office.

### **III.b. Public Health**

The development of the health sector in Montenegro is guided by a Master plan for 2010–2013 which is broadly in line with the EU Health strategy. The basic framework and infrastructure are in place. However, further capacity-building is necessary in terms of administrative capacity, including training of health workforce, and equipment. Furthermore, future medical education will be a challenge, as students currently for the most part undergo medical training in Serbia. In order to ensure education and training according

to European standards; it would be better, in the future, to collaborate closely with, for example, a Member State in the region, in case it is not possible to provide full curricula in Montenegro. Implementation of e-health continues to be slow; efforts need to be stepped up in this respect. It is important that the Montenegrin eHealth agenda is aligned with the agenda of the eHealth Network set up by the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. In general, effective health promotion is important, particularly with regard to all health determinants as well as active and healthy ageing.

### Tobacco control

Montenegrin legislation in this area is in line with the *acquis*. However, enforcement of the Law on Restriction of Tobacco Products, which extends the areas where smoking is prohibited, continues to pose challenges, especially in restaurants. Inspections that have been put on hold since June 2012 need to resume. A licensing agreement for the use of EU pictorial warnings remains to be concluded.

It would be advisable to have legislation to remove tobacco products from self-service displays in retail outlets, to prohibit the sales of sweets/toys which resemble tobacco in the context of the prevention of tobacco sales to children and adolescents, to introduce the use of price measures to discourage tobacco product consumption and to introduce measures to protect against exposure to second-hand smoke as part of the implementation of the EU *Recommendation on the Prevention of Smoking and Initiatives to improve Tobacco Control* and the *Recommendation on smoke-free environments*.

### Communicable diseases

In the area of communicable diseases, Montenegro has already reached a good level of alignment. EU case definitions still need to be fully adopted and used in national surveillance. Detailed specifications of the notifiable diseases are listed in the Law on Protection of the population from communicable diseases rather than in the supporting Rulebook. This makes alterations and amendments to the list relatively inflexible and rapid reaction to a new disease threat could be more difficult. The EU case definitions of special health issues: nosocomial infections and antimicrobial resistance (AMR) (Decision 506/2012) are missing from the surveillance guidelines. The EU case definitions on health associated infections (HAI/AMR) should also be added to the guidance document.

In general, implementation and enforcement of the adopted legislation remains a challenge. A Commission assessment mission on communicable diseases carried out in June 2013 has provided follow-up recommendations to optimise the communicable diseases system in Montenegro. Overall, the legal basis, national structures and resources are generally in place and are being strengthened. However, national plans, guidelines and protocols should be developed in several fields: preparedness and response planning, outbreak investigation, risk assessment, risk management, crisis communication, etc.

The surveillance and response capacity is still limited, in particular regarding human and material resources. Surveillance system should be developed as an electronic surveillance reporting system formalised and implemented across the entire health sector, including the Clinical Centre of Montenegro. Reports should contain analysis and interpretation of data and be published on the website of the Public Health Institute. The inadequacy of national laboratory capacity for detection and further characterisation of pathogens/diseases under mandatory reporting needs to be addressed, with appropriate referral agreements with competent laboratories within the EU/EEA networks, instead of relying exclusively on

capacity in Serbia. To this end, cooperation with EU networks should be established. Representatives should be identified for cooperation with the Commission and the ECDC. Also logistics and infrastructure of crisis management need to be strengthened. High-quality tools should be available in order to make efficient communication possible with the Commission, ECDC, neighbouring countries and other international partners. The public health microbiology laboratory system needs to ensure business continuity – reagents, equipment and staff – and use an infrastructure that is suitable for quality testing in accordance with biosafety standards, in particular towards the safety of health care workers. A system for quality assurance should also be established. As a small country, it is unlikely that Montenegro will be able to meet all European standards, but at least minimum standards need to be applied. For example, as regards laboratory capacity, a potential cost neutral solution could be to have two-three primary laboratories and a central laboratory performing microbiology reference services. Testing standard operational procedures (SOPs) and algorithms should be implemented. The transport system should be in place to support timely and safe distribution of specimens/isolates.

As regards human resources, sustainability of the number and the qualifications of the epidemiology workforce are essential. Regular training and simulation exercises for national health crises should be conducted, including major epidemics. Participation of public health professionals from municipality and national levels in regular training and international missions needs to be actively supported, in order to increase their knowledge and experience in investigating and managing large or complex outbreaks. Montenegro also needs to align its data protection legislation with the *acquis*.

#### Blood, tissues, cells and organs

In the area of blood, tissues and cells, Montenegrin legislation is partially aligned with the *acquis*. A detailed timeline for adoption of legislation is in place in view of completing legal alignment in these areas. Overall, administrative and technical capacities in these areas need to continue to be strengthened after the Sector for Biomedicine in the MoH with five staff members becomes the National Competent Authority in these areas. Upgrading and restructuring of facilities for handling blood, blood components, tissues and cells will continue to be necessary in order to meet the EU technical standards.

#### Patients' rights in cross-border healthcare

Legal alignment remains to be completed in this area. This will in particular require putting in place legislation regarding: 1) reimbursement of costs of healthcare received abroad by Montenegrin citizens, with particular regard to treatments covered; levels of reimbursement; authorisation procedures; rules applicable to planned and unplanned healthcare; information to patients; 2) healthcare provided to nationals from EU Member States, with particular regard to: access to healthcare; tariffs charged; access to patient records; information to patients about patient safety standards in place; any differences between the treatments of planned or unplanned healthcare; 3) establishment of a National Contact Point that provide information to patients (i.e. on patients' rights, entitlements, levels of reimbursement; authorisation procedures, complaint and redress procedures, quality and safety standards, status of healthcare providers); 4) recognition of medical prescriptions (e.g. by pharmacists) issued in a country other than Montenegro, including measures on content of medical prescriptions (which information items shall appear on prescriptions to identify prescriber, patient, prescribed product, etc.).

Mental health, drug abuse prevention, health inequalities, nutrition, alcohol related harm reduction, cancer screenings, healthy environments including prevention of injury, promotion of safety and rare diseases

In the area of mental health, an adequate legal framework is in place. 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.

In the field of drug abuse prevention, efforts have been made 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 needs to be stepped up, including at local level.

In the area of health inequalities, activities need to continue to improve the health of vulnerable population groups, such as Roma, as discrimination remains prevalent in access to healthcare.

Activities are ongoing in the area of nutrition, alcohol related harm reduction, prevention of injury and promotion of safety on the basis of different strategies in force. Adoption of the National Strategy for Rare Diseases in Montenegro 2013–2020 in January 2013 is a welcome initial step to start activities in the area of rare diseases.

Council Recommendation of December 2003 on cancer screening is to a large extent implemented in Montenegro. Efforts to raise awareness of early detection of breast and cervical cancer have continued and screening programmes are being started. However, further efforts are necessary to establish appropriate administrative and technical capacity-building for organisation and implementation of the National Cancer Control Plan.

In the area of healthy environments, legal alignment remains to be completed with the *acquis* on electromagnetic fields.