

Screening report

Serbia

Chapter 28 – Consumer and health protection

Date of screening meetings:

Explanatory meeting: 4–5 December 2014

Bilateral meeting: 3–4 February 2015

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 including 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** includes legislation on product safety and the European Union's Rapid Alert System (RAPEX), cross-border enforcement cooperation, consumer redress, injunctions for the protection of consumer interests, sale of consumer goods and associated guarantees, unfair contract terms, price indications, *consumer rights*, distance marketing of financial services, consumer credit, misleading and comparative advertising, unfair commercial practices, timeshare, and package travel.

Insofar as **public health** is concerned, the *acquis* covers areas related to tobacco control, serious cross-border health threats including communicable diseases, blood, tissues, cells and organs, patients' rights in cross-border healthcare, medicinal products, cosmetics and medical devices 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 protection and health promotion, prevention and 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 access to consumer redress, including appropriate independent judicial and out-of-court dispute resolution mechanisms. It also encompasses consumer education, information and awareness-raising activities, and entails the active involvement of consumer representatives in the design and implementation of policies, thus ensuring a role for consumer associations.

II. COUNTRY ALIGNMENT AND IMPLEMENTATION CAPACITY

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

II.a. Consumer protection

Horizontal aspects

Serbia stated that a Strategy for Consumer protection for the period 2013–2018 was adopted in July 2013. Its aim is to provide consumers in Serbia with a high level of protection and to enhance the consumer protection system in line with EU standards and practices by 2018.

Concerning the institutional framework, the overall responsibility for general consumer protection policy lies with the Ministry of Trade, Tourism and Telecommunications and its Consumer Protection Department. The Market Inspection Department, comprising 45 market inspectors that focus on the law on consumer protection and 100 inspectors assigned to product safety at the time of the screening, is responsible for general supervision and prevention of unfair competition and consumer protection. Product Safety

in EU terms is covered by the Market Inspection Section. The Tourism Inspection Sector had, at the time of the screening, 75 tourist inspectors. Within the Government, since 2012, there is a National Council for Consumer Protection presided by the Minister responsible for consumer protection affairs as a consulting body. It consists of consumer protection experts and representatives of the Government, the private sector and consumer protection organisations. Currently this Council is being reorganised, pending the nomination to it of members of the new Consumer Council established in December 2014. Apart from the Ministry of Trade, Tourism and Telecommunications, the following institutions deal directly or indirectly with consumer protection issues: the Ministry of Health (including sanitary inspectors), the Ministry of Finance (Customs Administration and Tobacco Administration), the Ministry of Agriculture and Environment, the Ministry of Energy and Mining, the National Bank of Serbia, the Regulatory Agency for Electronic Communications and Postal Services, the Energy Agency, the Standardisation Institute, etc. According to Serbia, cross-border cooperation in the area of economic interests of consumers is becoming a priority in policy discussion with the countries in the region.

Serbia stated that the 2014 Law on Consumer Protection regulates consumer complaints and out-of-court settlement of consumer disputes. A Rulebook on the operation of alternative consumer dispute settlement entities was adopted in August 2015. According to the Law, out-of-court settlement of consumer disputes only applies in disputes where the value of the claim does not exceed EUR 4,000. Since August 2015 three out-of-court bodies have been registered and licensed by the Ministry of Trade, Tourism and Telecommunications, their contact details are published on the Ministry's website. The mediation procedure is free of charge for the parties involved.

Serbia stated that there are currently 28 registered consumer protection organisations in Serbia. Their tasks include filing actions for the protection of collective interests of consumers; to represent consumers' interests in judicial and out-of-court proceedings; to represent consumers' interests in consultative bodies in the field of consumer protection at national, regional and local levels, etc. A Consumer Council was established in December 2014, consisting of consumer protection organisations registered with the Ministry of Trade, Tourism and Telecommunications. Its aim is to encourage cooperation between consumer protection organisations. The Ministry of Trade, Tourism and Telecommunications has promoted the work of the consumer protection organisations through grants since 2008, notably in view of establishing regional advisory consumer centres. A National Consumer Complaint Register is operational since July 2014, it is not publicly accessible, but an annual report on its operations is publicly available and is published on the Ministry's website.

Serbia indicated that awareness on consumer rights is at a low level in Serbia. Awareness raising activities, including several seminars and workshops notably in regional chambers of commerce, have been carried out in the area of consumer protection. Efforts are being made also to help consumer protection organisations.

Product safety related issues

Serbia stated that the Law on General Product Safety adopted in 2009 aims at aligning its national law with Directive 2001/95/EC on General Product Safety as well as with the Dangerous Imitations Directive 87/357/EEC. According to the Law, only safe products may be placed on the Serbian market and all economic operators responsible for product safety shall notify the competent authorities on dangerous products and cooperate with them to remove dangerous products from the market. Penalties up to EUR 40,000 are envisaged for any producer, distributor or responsible person for any breach of the

legislation. Serbia indicated that amendments to the legislation are foreseen in 2016 in order to ensure full alignment with the *acquis* on general product safety.

Serbia stated that it has aligned its legislation with the *acquis* on Liability for Defective Products (Directive 85/374/EEC) through its 2014 Law on Consumer Protection.

Serbia indicated that a key by-law for the enforcement of the Law on General Product Safety is the Regulation on the establishment of information on dangerous products which came into force in December 2009. Together with the 2009 Rulebook on the Form and Contents of the Notification of Dangerous products it aims at aligning with the rules for the future management of the Union Rapid Information System (RAPEX). A national rapid information exchange system similar to RAPEX providing information on dangerous products, known as NEPRO, was established in 2010. The national contact point is located in the Ministry of Trade, Tourism and Telecommunications. In 2010–2014 the relevant market surveillance authorities and Customs Administration officials had common trainings with market inspectors and sanitary inspectors in order to prepare for the application of risk assessment methods in accordance with RAPEX guidelines. The EU's RAPEX system is consulted on a daily basis. Serbia stated that the NEPRO system is a fully functioning system of exchange of information and that the EU's RAPEX system is consulted on a daily basis.

Serbia stated that a Law on Market Surveillance was adopted in 2011 and that the Strategy of Development of Quality Infrastructure 2015-2020, notably covering Market Surveillance, was adopted in October 2015. The Sector for Market Inspection within the Ministry of Trade, Tourism and Telecommunications had around 450 staff at the time of the screening, of which 100 market inspectors were in charge of control of compliance and safety of certain non-food products. Serbia stated that a Product Safety Council was established in 2013 in order to improve coordination and cooperation in the field of market surveillance, including representatives of market surveillance authorities and of Customs Administration. Also representatives of the Chamber of Commerce and consumer organisations participate in the work of the Council. Serbia indicated that information on market surveillance activities is published on a regular basis. Between 2013 and 2014 around 20 seminars/workshops were organised with economic operators and consumer organisations to discuss market surveillance issues.

At regional level, Serbia indicated that a network of contact points for information exchange on dangerous products has been established since 2013.

Non-safety related issues

Serbia indicated that several *acquis* elements are already in place through the Law on Consumer Protection (2014), such as *acquis* on consumer rights, unfair terms in consumer contracts, indication of product prices, sale of consumer goods and associated guarantees, unfair commercial practices, timeshares, package travel and injunctions. Provisions on indication of product prices are also included in the 2013 amendments to the Law on Trade and in the 2014 Rulebook on the manner and requirements for unit price indication for certain products. The 2011 Financial Services Consumer Protection Law, amended in 2014, is partly aligning with the *acquis* on consumer credit.

Serbia stated that its new Law on Advertising of February 2016 is designed to be aligned with the *acquis* on misleading and comparative advertising (Directive 2006/114/EC). Legislation on financial services consumer protection in the course of distance contracting is under preparation to align with the *acquis* on distance marketing of consumer financial

services. As regards Regulation (EC) No 2006/2004 on Cooperation between National Authorities responsible for the Enforcement of Consumer Protection Laws, Serbia indicated that the Single Liaison Office would be the Consumer Protection Department in the Ministry of Trade, Tourism and Telecommunications. According to Serbia, it has already increased its administrative capacity and it is anticipated that this level will be maintained through different trainings, TAIEX seminars and workshops, etc.

As regards administrative capacity in the area of financial services, Serbia stated that a Centre for Financial Consumer Protection and Education is in place in the National Bank of Serbia with 25 staff at the time of the screening (now 30) to address complaints by consumers and to ensure mediation.

II.b. Public health

Horizontal aspects

Serbia stated that its health system operates on the basis of the 2005 Laws on Healthcare and on Health insurance, along with the accompanying regulations. Both were amended in July 2014. In November 2010 Serbia adopted a Healthcare Development Plan 2010–2015. It aims inter alia at preserving and improving the state of health of Serbian citizens, providing fair and equal access to health care for all citizens, making the user (the patient) the focal point of the health care system, defining the role of the private sector in the provision of healthcare and improving human resources for health. Serbia indicated that total health expenditure was around 1.05% of the GDP in 2013. It also joined the EU Health Programme 2014-2020 on 18 February 2016

Serbia stated that a working group for developing an e-health National Plan was established in December 2014. An e-health unit was established in the Ministry of Health in June 2014 to deal with information technology development and regulation in the sector. Over the years, significant financial assistance has been provided in Serbia for development of e-health. Creation of a fully integrated health information system is the final goal. A committee was established in September 2014 and funding has been recently secured to this effect.

Overall responsibility for public health in Serbia lies with the Ministry of Health, the authority in charge of health policy, while the Public Health Institute is in charge of preserving and improving the health of citizens, with the National Health Insurance Fund managing the financing of the system. There is a network of health institutions consisting of 375 public health care facilities. A total of 147 health councils have so far been established throughout the country.

Serbia indicated that health workforce planning is covered by the Law on Health Care. As the workforce supply is considerable in Serbia (there have been more medical doctors than necessary), Serbia stated that it will consider a better coordination of the workforce planning between the Ministries of Education and Health.

Tobacco control

Serbia stated that the WHO Framework Convention on Tobacco Control (FCTC) was ratified by Serbia in February 2006. It provided the basis for the National Tobacco Control Strategy 2007–2015. Its objectives are to prevent future initiation of smoking (particularly among youth), to reduce smoking in all population groups, to reduce exposure to environmental tobacco smoke, to raise public awareness of the harmful effects of smoking

and exposure to tobacco smoke and to adequately regulate activities of the tobacco industry regarding production, advertising and sale of tobacco products. On the basis of a mid-term analysis performed in October 2013 supported by the WHO Office in Serbia, significant progress has been made, especially as regards legislation. Serbia stated that a new strategic document for tobacco control is foreseen to be adopted after 1 January 2016. Serbia indicated also that the provisions of the FCTC are taken into account in every revision of national legislation on tobacco.

Serbia indicated that its Law on Tobacco is partly aligned its national law with the *acquis* on tobacco control (including, in particular, the Directive (2014/40/EU), the new Tobacco Products Directive). A draft Law amending the Law on the Protection of the Population from Exposure to Tobacco Smoke is expected to be adopted in 2016. According to the Law on Consumer protection, tobacco products may not be sold to persons under 18 years of age whose identity needs to be checked by the trader – a novelty in the Serbian legislation. According to the Law on the Protection of the population from Exposure to Tobacco Smoke that entered into force in 2010 smoking is prohibited in all enclosed work places, public places as well as connected and associated areas apart from in designated hospitality facilities (see below), public transport, and in public places as well as in places for activities related to culture, sport and recreation, media, conferences and public meetings etc. However, the law currently allows smoking in designated hospitality facilities with a total functional surface of less than 80 m², including bars, cafés and restaurants. Draft laws on advertising and on protecting citizens from exposure to tobacco smoke were under preparation aiming to ban smoking in all public places, including in all hospitality facilities. Serbia indicated that it has yet to decide how it will fully align its national legislation to the new Tobacco Products Directive, including the use of the EU pictorial warnings.

As regards administrative capacity, Serbia stated that it has put in place a National Committee for the Prevention of Tobacco Use, an expert and advisory body of the Ministry of Health, as well as a National Office for smoking prevention. As regards future challenges, Serbia indicated enforcement of existing legislation and work of inspectors, ensuring resources for tobacco control activities including research, monitoring, promotion of stopping smoking, awareness raising campaigns, etc.

Serious cross-border health threats including communicable diseases

Serbia stated that the legal basis for the protection from communicable diseases in Serbia is the 2004 Law on Protection of the Population against Communicable Diseases, amended in April 2015, and the Rulebook on Reporting of communicable diseases and other cases laid down by the Law on Protection of the population from communicable diseases. The new law was adopted in March 2016 and it includes the EU list of diseases and EU case definitions.

At the time of Screening, Serbia stated that there was mandatory reporting of 70 communicable diseases. An early warning and response system (ALERT) has been put in place. Reports are provided on a weekly and monthly basis on overall trends of infectious diseases, as well as consolidated annual reports. The Institute for Public Health of Serbia is the focal point for epidemiological surveillance of communicable diseases. There is also a network of district coordinators and deputies for epidemic alert in place. A Communication centre for event-based surveillance was established in March 2010 for early detection, verification, risk assessment, early response and communication of public health events that may represent a threat to public health. It has links with the WHO and indirectly with the European Centre for Disease Prevention and Control (ECDC). A

Committee of the Ministry of Health for healthcare associated infections was established in 2003 and re-established in 2012. There is no national agency/body for patient safety in place yet.

A Commission/European Centre for Disease Prevention and Control (ECDC) assessment mission on communicable diseases in the framework of the enlargement process took place in October 2013, providing follow-up recommendations to optimise its communicable diseases system. Serbia developed an Action plan to follow-up on EU assessment recommendations which is the basis for further technical discussions with the Commission.

Serbia indicated that its future plans include the improvement of inter-sectorial cooperation through the establishment of a national inter-sectorial coordinating body in order to develop general and specific plans for preparedness and response to major threats to public health. The roll-out of an integrated health information system is a priority for the Ministry of Health as part of an overall healthcare reform. Strengthening administrative capacity is also considered necessary (this could include training of existing staff, hiring new staff, and workshops to inform staff on the *acquis* related to serious cross-border threats to health (Decision 1082/2013/EU)).

Blood, tissues, cells and organs

Serbia stated that its 2009 Law on Transfusiology Activity is partially in line with the *acquis* on blood (Directive 2002/98/EC). A working group has been formed in the Ministry of Health to amend it. There are currently 23 hospital blood banks and 47 blood establishments (a national blood transfusion institute in Belgrade, two blood transfusion centres in Novi Sad and in Niš and 44 blood establishments in general hospitals or clinical centres) in Serbia. Serbia stated that it is aware that this is a high number and plans to reduce them to 10 based on the implementation of a plan for the reorganisation of blood services in Serbia. The National Institute of Blood Transfusion keeps a register of serious adverse reactions and events that it delivers to the competent authority. TAIEX training has been provided in view of establishing a national quality system in the area of blood transfusion, a national centre for blood fractionation and a national haemovigilance system. Serbia indicated that it also plans to reorganise its blood transfusion service. The Institute of Blood Transfusion runs an awareness raising campaign with the aim of increasing the number of blood donors. According to Serbia, it is difficult to find regular blood donors.

In the area of tissues and cells, Serbia stated that the Law on Cell and Tissue Transplantation and the Law on Infertility Treatment with the Procedures of Biomedical Assisted Reproduction were adopted in 2009 and are partially in line with the *acquis* (including Commission Directives (EU) 2015/565 and 2015/565). Amendments to the legislation are foreseen to be adopted by the end of 2017 and 2016, respectively. A working group has been formed in the Ministry of Health to this effect. Tissue transplantation is carried out in seven institutions and hematopoietic stem cell transplantation in five institutions. Assisted reproductive technologies are performed in five public and ten private establishments in Serbia. Serbia indicated that it plans to establish a bank of reproductive cells, increase of capacities of tissue and biomedical assisted fertilisation establishments and work on awareness of the population about the benefits and importance of cell and tissue donation.

In the area of organs, Serbia stated that the 2009 Law on Organ Transplantation is partially in line with the *acquis*. It is foreseen to be amended by the end of 2017. There are five transplantation facilities and three transplantation programmes (heart, kidney and liver) in Serbia. In 2013, 95 transplantations were carried out. TAIEX training has been provided in

view of the establishment of a national system in the area of organ donation and transplantation. Serbia indicated that it intends to increase the number of donor hospitals and of trained health professionals for transplantation programme, and work on awareness of the population about the benefits and importance of organ donation.

Serbia stated that in general, the areas of blood, tissues, cells and organs are the areas of the health sectors in Serbia that need the most reforms to bring them in line with EU Standards. The Directorate of Biomedicine in the Ministry of Health is the Competent Authority since 2010. It has eight employees. An inspection process has only recently been initiated, but no inspectors had been appointed by April 2016. Currently, the inspection tasks are carried out by the Health inspection. EU funding is foreseen for the training of the inspectors.

Patients' rights in cross-border healthcare

Serbia stated that the 2013 Law on Patients' rights and a Rulebook on conditions and manner of referring of insured persons for treatment abroad aim at regulating some aspects in this area. Serbia indicated that 16 bilateral agreements with Member States contain provisions on healthcare, i.e. on health insurance, and eight agreements have been concluded with Member States on the use of the European Health Insurance Card. Under the Law on Health Insurance, health care protection abroad is possible only in case of emergency medical services. However, in August 2014, a budgetary fund was established to provide additional resources for treatment of diseases or injuries that cannot be successfully treated in Serbia. The diagnosis and treatment of patients with rare diseases or patients who need diagnostic tests or therapy that cannot be provided in Serbia, can receive it abroad. Serbia stated that it has a long tradition and experience in the application of international agreements. It does not expect problems with regard to application of the EU rules on patients' rights in cross-border healthcare.

Medicinal products, cosmetic, and medical devices

Serbia stated that the 2012 Law on medicines and medical devices and the accompanying Rulebooks aim at aligning its national law with the *acquis* in this area. Additional amendments are intended in order to align it further with the *acquis* in the areas of market authorisation, orphan medicines, medicines for paediatric use, pharmacovigilance (including Directive 2010/84/EU & Regulation (EU) No 1235/2010/EU).

Serbia stated that a medicinal product may only be placed on the Serbian market through national authorisation by the Medicines and Medical Devices Agency of Serbia. The Agency may exceptionally authorise the import of medicines without marketing authorisation through an administrative procedure. In 2014, the Health Insurance Fund decreased the price of a number of medicinal products by 30–50%. In 2013 the status of privately owned pharmacies was aligned with that of state-owned ones. The Ministry of Health has called for improved cooperation with pharmaceutical companies, many of which have not yet registered all the required medications in Serbia. A new reference laboratory for the identification and testing of controlled psychoactive substances was opened in December 2013.

Serbia indicated that the competent institution responsible for the authorisation of human and veterinary medicines is the Medicines and Medical Devices Agency of Serbia, which was founded in 2004. It has in total 173 staff. The Ministry of Health supervises medicinal products for human use through its Group for medicines and medical devices (3 staff) and the Inspection of medicines and medical devices (9 staff).

Serbia stated that it foresees to amend its Law on Safety Items for General Use by the end of 2018 aiming at aligning with the *acquis* on cosmetics (Regulation (EC) No 1223/2009). This will entail training for all staff involved in cosmetic products control, including in the accredited laboratories. Serbia will also create its national system of notification before allowing cosmetic products to enter the EU. In the area of medical devices, Serbia stated that the current legislation on medicines and medical devices is foreseen to be amended in 2016 in view of aligning with the *acquis*, providing that current provisions not aligned with the *acquis* will be repealed by the time of accession.

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, Serbia stated that a Law on the Protection of People with Mental Illness and Rulebooks on detailed conditions for use of physical restraint and seclusion of persons with mental illness who are undergoing treatment in psychiatric institutions as well as on detailed conditions for the establishment of organisational units and conducting community mental health care were adopted in 2013. A Strategy for the Development of Mental health care was adopted in 2007. According to national law, physical restraint and seclusion can only be used in emergencies, for the purpose of ensuring the physical security of the given person or provided that all less restrictive interventions have been previously exhausted or have proven to be ineffective. As regards community mental health care, Serbia indicated that it was aiming at a further reduction of capacities in psychiatric hospitals and at development of a network of community mental health care units. Currently, there are five community mental health centres in Serbia. Health workers have been trained in particular on the legal framework regarding the prevention, treatment and rehabilitation of persons with mental health problems. Educational material is under preparation on the rights of hospitalised psychiatric patients.

In the area of drug abuse prevention, Serbia indicated that a new Strategy for Drug Abuse Suppression (2014–2021) and its accompanying Action plan (2014–2017) were adopted in December 2014. Serbia stated that the Strategy is in line with the EU Strategy on drugs (2013–2020) and EU Action plan on drugs (2013–2016). A Rulebook on drug abuse prevention, treatment and rehabilitation is under preparation. An Office for Combating Drugs was established in July 2014. It has been staffed and furnished, and is now operational. A National Monitoring Centre for Drugs and Drug Addiction has been established in the Ministry of Health as the national focal point for cooperation with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Serbia indicated that it is foreseen to increase the availability of treatment, strengthen programmes for rehabilitation of drug addicts, improve cooperation with local authorities and all relevant stakeholders in the Strategy, and train existing staff in the area of drug abuse prevention.

As regards health inequalities, Serbia stated that on the basis of the Law on Health Insurance every citizen is entitled to healthcare in Serbia and emergency healthcare is provided to all citizens (healthcare provision to non-registered and non-insured residents is limited to emergency services). Specific Roma health mediators were introduced in 2008. The objective is to increase the number of insured persons, vaccinated children, systematic check-ups, the number of people using services of counselling centres and preventive health centres, knowledge of disease prevention, family planning and nutrition, etc. In 2014, 75 health mediators were working in 60 Serbian municipalities. Serbia indicated that it is foreseen in the future to develop a new comprehensive National Strategy of Public health addressing reduction of health inequalities, with a special focus on Roma and vulnerable groups including migrants and refugees (see under Chapter 23). It is also

foreseen to have a system for monitoring the health status of the population through special surveys in place by 2017.

Serbia indicated that there is no national action plan on nutrition and physical activity. A Rulebook on requirements related to nutrition in kindergartens and a National programme for childhood obesity are under preparation. An action plan for food and nutrition was drafted in 2007 and a national action plan against obesity in 2012, but they were not adopted. Nevertheless, Serbia indicated that several activities have been carried out in this area, such as health promotion activities at national level to improve dietary habits including decrease of salt consumption, public health campaigns, different surveys on dietary habits, etc. Serbia is a member of European Salt Action Network since 2014. Serbia stated that a double burden of malnutrition/under nutrition vs. obesity needs to be tackled in Serbia. A 2014 national survey on nutrition showed that 54.7% of the Serbian population is overweight or obese.

In the area of alcohol related harm reduction, Serbia indicated that a National Programme for Prevention of Alcoholism was under preparation.

As regards cancer screening, Serbia stated that a national programme entitled “Serbia against Cancer” was adopted in 2009. National programmes for early cervical, colorectal and breast cancer detection were adopted in 2013. A cancer screening office (Office for prevention of malignant diseases) was established in 2013 at the Institute of Public Health of Serbia to coordinate, organise, monitor and evaluate the implementation of cancer screenings. It reports to the Ministry of Health and also coordinates training and awareness raising activities. Serbia indicated that it plans to improve the legal framework on cancer control and to strengthen administrative capacity in this area, inter alia to increase the number of healthcare institutions capable of implementing the cancer screening programmes by 30% in 2015 and to develop an electronic IT system for the monitoring of the implementation of the screening programmes in 2015–2016.

In the area of healthy environments, Serbia indicated that legislation has been adopted in the area of electromagnetic fields. A Programme was adopted for systematic testing of non-ionising radiation in the environment for 2013–2014. In the field of prevention of injury and promotion of safety, Serbia stated that there is no overall national strategy on injury prevention, nor is there a national agency/body responsible for patient safety. Occupational injuries are addressed via the 2005 Law on Health and Safety at Work and the Strategy on Health and Safety at Work for the period 2013–2017. A reporting system for adverse events is partially in place.

A new Law on the Prevention and diagnosis of genetic diseases, genetic anomaly and rare diseases was adopted in January 2015. It identifies and defines for the first time the concept of rare diseases and genetic research related to rare diseases in Serbia. A Strategy and an Action plan on rare diseases are under preparation. Serbia stated that there are currently five centres of expertise for rare diseases in Serbia. Public health institutes are required to keep registers of persons suffering from rare diseases, but work is ongoing to establish a National registry of rare diseases. In August 2014, a budgetary fund was established to provide additional resources for treatment of rare diseases that cannot be successfully treated in Serbia. First patients were allowed to be treated abroad since January 2015. A national organisation for rare diseases in Serbia was founded in 2010 as an umbrella organisation that gathers together patients’ associations and individuals with various rare diseases. Serbia stated that Ministry of Health has had a very intensive and successful cooperation with the national organisation.

III. ASSESSMENT OF THE DEGREE OF ALIGNMENT AND IMPLEMENTING CAPACITY

Overall, Serbia has reached a satisfactory level of alignment with the *acquis* in the area of consumer and health protection. A new law on Consumer Protection was adopted in 2014 aiming at aligning national legislation with most of the *acquis* concerning non-safety related issues. A new law on General Product Safety is under preparation. In the area of public health, a new law on the protection of the population against communicable diseases was adopted in 2015. Legal alignment remains outstanding in the areas of blood, tissues, cells, organs and pharmaceuticals. Administrative capacity-building needs to continue in both areas. Particular attention needs to be paid to the *acquis* on the enforcement and the application of EU technical quality and safety standards, in particular in the area of public health. The overall financial sustainability of the public health system needs to be strengthened.

III.a. Consumer Protection

Horizontal aspects

Serbia is undertaking 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 and the implementation of consumer policies need to be further improved. The national consumer complaint register needs to become publicly accessible. Cooperation between line ministries and consumer organisations still needs to be reinforced, as does cooperation between consumer protection organisations themselves. Support for consumer NGOs and awareness raising with the general public, including on out-of-court settlement of consumer disputes, needs to continue. Rules on out-of-court settlement of consumer disputes concerning the monetary threshold imposed for the introduction of a claim need to be brought in line with the *acquis*.

Product safety related issues

In the field of general product safety, legal alignment remains to be completed. Efforts need to continue to ensure adequate 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, Serbian legislation is partially aligned with the *acquis*. Legal alignment remains to be completed *inter alia* on consumer rights and is yet to be confirmed in the area of misleading and comparative advertising. At the time of accession, Serbia will also need to be able to ensure adequate enforcement capacity and 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 the Single Liaison Office.

III.b. Public Health

A basic framework and infrastructure in the area of public health are in place in Serbia. However, further capacity-building is necessary in terms of administrative capacity, including training of health workforce, and equipment. Considering the considerable amount of future pensioners, rejuvenation of the health workforce should be taken up in the workforce planning to guarantee continuation of public health functions as well as better coordination of the workforce planning between the Ministries of Education and Health.

The new e-health unit in the Ministry of Health needs to become operational. It is important that the Serbian eHealth agenda is aligned with the agenda of the e-health Network set up under Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. The overall financial sustainability of the health sector remains seriously endangered by the poor financial situation of the Public Health Fund. A shortage of medical and administrative staff in primary healthcare centres poses difficulties especially in rural areas and when hiring of new employees in the public sector is currently frozen. In general, effective health promotion is important, particularly with regard to all health determinants as well as active and healthy ageing.

Tobacco control

Serbian legislation in this area is partially in line with the *acquis*. Legal alignment remains to be completed as regards the use of EU pictorial warnings. Advertising of tobacco products is prohibited in general with a few small exceptions (i.e. trade publications). Legal alignment has also begun for the new Tobacco Products Directive (Dir. 2014/40/EU). Serbia is encouraged to implement further aspects over the coming years, including reporting and regulation of ingredients, labelling and packaging, and provisions on tobacco-related products such as e-cigarettes.

Serbian legislation is well aligned with the Recommendation on smoke-free environments. There is also a high degree of alignment with the Recommendation on the Prevention of Smoking and Initiatives to improve Tobacco Control but we suggest Serbia considers prohibiting tobacco distance sales, the use of promotional items and tobacco samples, introducing information measures concerning expenditure for advertisement, marketing and promotion and restricting sponsorship on all kind of different events.

Serious cross-border health threats including communicable diseases

In this area, further alignment of the national legislation with the *acquis* is necessary. Surveillance and response capacity, including microbiology laboratory capacity, remains limited and requires modernisation. A centralised health information and communication system has to be developed. This should incorporate different systems, such as early warning and rapid alert system (EWRS) or integrated laboratory data and reporting, and connect clinical centres with e.g. secondary health care institutions, public health institutes as well as private healthcare providers.

Data analysis is a major problem: the regional level has epidemiological data but lack the capacity to analyse, while the national level could have the knowledge but lack data. Human resource management and organisational strengthening are required, but are difficult to achieve, given also the horizontal hiring freeze for the public administration.

A national plan of human resources in the health sector needs to be implemented and actions to restructure and strengthen the workforce should continue. New programmes of specialisation and professional development should be developed. More attention needs to be given to effective and sustainable financing of disease-specific strategies, including the national HIV/AIDS strategy, future action plan and awareness-raising. The risk of a rise in communicable diseases for which vaccines are available is real. Less than 95% of the population is vaccinated against the 10 most common diseases. Additional work is needed in particular on surveillance of antimicrobial resistance, development of an antimicrobial resistance action plan and inter-sectorial cooperation, especially since the scale of the problem requires cooperation with the EU and with the WHO to contribute to the global action plan on antimicrobial resistance

Blood, tissues, cells and organs

In the area of blood, tissues and cells, Serbian legislation is partially aligned with the *acquis* and work on this is continuing at a steady pace with support from Member State experts. 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.

In terms of administrative capacity, the roles and responsibilities of the Directorate of Biomedicine as competent authority need to be clearly defined in the revised legislation. Sufficient resources will then need to be at its disposal to ensure oversight of the sector and complete the establishment of authorisation, inspection, reporting and vigilance systems. In the sector itself, upgrading and restructuring of facilities for handling blood, blood components, tissues and cells will be necessary in order to meet the EU technical quality and safety 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 Serbian 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 Serbia, including measures on content of medical prescriptions (which information items shall appear on prescriptions to identify prescriber, patient, prescribed product, etc.).

Medicinal products, cosmetics and medical devices

Legal alignment remains to be completed in the area of medicinal products, in particular as regards human medicinal products, the rules on import as well as good clinical practice and clinical trials, as regards the veterinary medicinal products the rules on variations of market authorization (MA) and maximum residue limits (MRL). Further strengthening of the administrative capacity is required to implement the pharmaceutical legislation, including Regulation (EU) no 536/2014 on clinical trials which recently became applicable in the EU¹. All Serbian marketing authorisations have to be in accordance with the rules and provisions of the EU legislation in this field.

Legal alignment also remains to be completed with regard to cosmetics. This is foreseen by the end of 2018, which will mean Serbia will need to ensure training for all staff involved in cosmetic products control and the creation of a national system of notification will be necessary. Legal alignment also remains to be completed with regard to medicines and its law on medical devices, which is foreseen during 2016.

¹ The Regulation on clinical trials became applicable on 28 May 2016.

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

The legal framework in the area of mental health is comprehensive. Community-based mental health services need to be further supported as an alternative to institutionalisation.

In the field of drug abuse prevention, drug consumption in Serbia has been increasing in recent years. A stronger focus on drugs prevention and treatment is needed. The national focal point for cooperation with EMCDDA needs to become fully operational and needs to strengthen its capacity to adequately perform data collection and reporting.

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. In particular, support for the work of Roma health mediators needs to be continued.

Activities are ongoing in the area of nutrition, alcohol related harm reduction (including the drafting of a National Programme of Prevention of Drug and Alcohol Abuse 2016-2020), prevention of injury and promotion of safety. A study on population health conducted in 2014 showed an increased number of smokers, obese and alcohol consumers. The 2014 national survey on nutrition showed that 54.7% of the population is overweight or obese. In this context efforts are needed to develop public health initiatives or policies on breastfeeding promotion and on maternal nutrition during pregnancy, which will be included in the future National Programme for the Prevention of Childhood Obesity. Furthermore, disease prevention strategies should be established to fight malnutrition and lack of physical activity, to improve citizens' health and provide affordable healthcare in the long run. Implementation of the strategic and legal framework in the area of rare diseases needs to be ensured.

As regards cancer screening, the legal framework and administrative capacity need to be improved. Adequate training of personnel is a prerequisite for high quality screening, as well as sufficient human and financial resources. In the area of healthy environments, due implementation of legislation needs to be ensured.