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Subject: European Union Common Position
- Chapter 28: Consumer and health protection

EUROPEAN UNION COMMON POSITION

Negotiating Chapter 28: Consumer and health protection

This position of the European Union is based on its general position for the Accession Conference with Montenegro (AD 23/12 CONF-ME 2), and is subject to the negotiating principles endorsed therein, in particular:

- any view expressed by either party on a chapter of the negotiations will in no way prejudice the position which may be taken on other chapters;
- agreements – even partial agreements – reached during the course of the negotiations on chapters to be examined successively may not be considered as final until an overall agreement has been established;
- as well as to the requirements set out in points 24, 28, 41 and 44 of the Negotiating Framework.

The EU encourages Montenegro to continue the process of alignment with the EU *acquis*, noting that additional *acquis* may enter into force before accession, to ensure its effective implementation and enforcement, and develop already before accession, policies and instruments as close as possible to those of the EU.

The EU notes that Montenegro, in its negotiating positions AD 23/14 CONF-ME 18 and AD 10/26 CONF-ME 9, Montenegro accepts the *acquis* under chapter 28 as in force on 30 March 2026, and that it declares that it will be ready to implement it by the date of its accession to the European Union.

Consumer protection

On **product-safety related issues**, Montenegro adopted the Law on General Product Safety aligning with Regulation (EU) 2023/988, which repeals Directive 2001/95/EC and Council Directive 87/357/EEC.

The EU notes that Montenegro adopted implementing legislation on the functioning and operation of the Rapid Alert System and on the Information Exchange System for Products Presenting a Risk, based on its Law on General Product Safety. The EU calls on Montenegro to complete its alignment with Commission Implementing Regulation (EU) 2024/2639 on roles and tasks for the Safety Gate Rapid Alert System single national contact points by day of accession.

The EU welcomes the amendments of Montenegro's Law on Market Surveillance of Products to ensure its alignment with Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products. Product safety is also regulated through Montenegro's Law on Technical Requirements for Products and Conformity Assessment.

In the area of economic interests of consumers (formerly referred to as non-safety related issues), the EU welcomes the adoption of the Law on consumer protection in February 2026 which increased Montenegro's alignment with the EU acquis in the area, including Directive 2011/83/EU on consumer rights as required by the dedicated closing benchmark under this chapter. The EU invites Montenegro to prepare to share its first Alternative Dispute Resolution national report (an obligation for EU Member States every four years) which should include information on current challenges in ensuring an effective out-of-court dispute resolution mechanism for domestic and cross-border consumer disputes. The EU also expects Montenegro to establish a European Consumer Centre on its territory by the time of accession.

The EU welcomes that Montenegro's new Law on Consumer Protection also ensured alignment with selected provisions of Regulation (EU) 2017/2394 on cooperation between national authorities responsible for the enforcement of consumer protection laws. These include provisions on the single liaison office, as well as minimum investigative and enforcement powers and cooperation between authorities competent for supervising the enforcement of consumer protection legislation. The EU calls upon Montenegro to operationalise the single liaison office upon accession. Montenegro has also adopted the implementing regulations for Regulation (EU) 2017/2394, which will apply from the date of accession.

Before accession, Montenegro is expected to continue and complete alignment of its legislation with the evolving EU *acquis* in the area of consumer protection and product safety. This in particular concerns amendments to the new Law on Consumer Protection in order to align it with Directive (EU) 2023/2673, Directive (EU) 2024/1799, Directive (EU) 2024/825, including Commission implementing Regulation 2025/1960, and Directive 2025/2647. This also concerns amendments to the Law on Consumer Credit in order to align it with Directive (EU) 2023/2225 and amendments to the Law on Tourism and Hospitality ensuring full alignment with the new Package Travel Directive (i.e. amending Directive (2015/2302/EU)).

As regards administrative capacity, the EU notes that Montenegro has continually strengthened the role and effectiveness of the Council for Consumer Protection since its establishment in 2014. As for capacity for the implementation of EU consumer protection *acquis*, the EU notes Montenegro's comprehensive administrative structure of the institutions in charge of strategic planning and policy development, and the institutions responsible for the enforcement of consumers' interests. The EU expects Montenegro to further advance with the recruitment of additional market surveillance inspectors and enhance the knowledge and skills of the personnel in the bodies and authorities responsible for the proper implementation of consumer protection legislation. In addition, the EU recommends that Montenegro strengthen the engagement of local governments in consumer protection and ensures sustainable and predictable financial support for consumer organisations and out-of-court consumer dispute resolution mechanisms.

The EU urges Montenegro to implement its adopted Action Plan, which, guided by the recommendations of the 2026 peer review report, foresees measures to address the remaining gaps in capacity to implement and enforce the EU *acquis* on consumer protection and product safety by the date of accession. Notably, Montenegro commits in this Action Plan to ensuring competent authorities have sufficient resources to participate in the consumer protection cooperation activities foreseen in Regulation (EU) 2017/2394 and on product safety.

The EU notes that the alignment of the above-described legislation and ongoing and planned administrative capacity building on consumer protection fulfils the requirements of the first closing benchmark set in document AD 32/14 CONF-ME 26.

Public health

The EU recalls that the efficiency, financial sustainability and effectiveness of the healthcare system in Montenegro is key to good quality, reliable, affordable and equitable public healthcare. The EU recalls the importance of health equity, effective health promotion and diseases prevention, particularly with regard to all health determinants, gender equality, and active and healthy ageing.

In the field of **tobacco control**, the EU welcomes Montenegro's adoption of primary and secondary legislation intended to align with the EU *acquis* and expects Montenegro to ensure full alignment with all EU tobacco control *acquis* by the time of accession along with comprehensive capacity for proper implementation and enforcement. Montenegro adopted the Law on Restricting the Use of Tobacco Products intended to align with Directive 2014/40/EU on the manufacture, presentation and sale of tobacco and related products and Council Recommendation 2003/54/EC on the prevention of smoking and on initiatives to improve tobacco control. The EU urges Montenegro to align with Council Recommendation of 3 December 2024 on smoke- and aerosol-free environments replacing Council Recommendation 2009/C 296/02. The EU calls on Montenegro to amend the Law on Restricting the Use of Tobacco Products to align with the Commission Delegated Directive (EU) 2022/2100 as regards the withdrawal of certain exemptions for heated tobacco products.

In the area of **communicable diseases**, the EU welcomes Montenegro's adoption of the Law on the Protection of the Population from Communicable Disease and relevant implementing legislation to align with Decision 2000/57/EC on the early warning and response system and Decision (EU) 2018/945 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions.

The EU calls on Montenegro to swiftly and effectively implement its Action Plan for the Prevention of and Preparedness for Responding to Cross-Border Health Threats of December 2025, which defines measures to strengthen institutional, administrative, and technical capacities, as well as coordination and reporting obligations towards the EU. The EU notes Montenegro's commitment to align this Plan with the EU's Prevention, Preparedness and Response Plan (PPR) adopted on 28 November 2025 and to adopt the law transposing Regulation (EU) 2022/2371. Montenegro has been a signatory to the Joint Procurement Agreement on Medical Countermeasures since 2020 and is already eligible to participate in joint procurement procedures.

The EU welcomes Montenegro's progress in strengthening its epidemiological surveillance system through the enhancement of diagnostic and laboratory capacities, the development of sentinel surveillance, the establishment of national contact points, and participation in European disease surveillance networks. In line with the above-mentioned Action Plan, the EU expects Montenegro to ensure, by the date of accession, the necessary capacities to fully apply the relevant EU *acquis*, including obligations related to reporting, information exchange, and coordinated response to serious cross-border health threats.

The EU notes that the adoption of the above-described legislation and ongoing and planned administrative capacity building fulfils the requirements of the second closing benchmark set in document AD 32/14 CONF-ME 26.

In the overall area of **substances of human origin**, the EU notes Montenegro's satisfactory level of alignment. On **organs**, the EU welcomes Montenegro's amendments to the Law on Removal and Transplantation of Human Organs for Medical Treatment Purposes and its relevant implementing legislation, which align with Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation and Commission implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation.

Additionally, the EU welcomes that Montenegro's Law on the Removal and Transplantation of Human Tissues and Cells for Treatment Purposes, Law on Medically Assisted Reproduction and relevant implementing legislation aligns with Directive 2004/23/EC and Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC on human tissues and cells.

The EU also welcomes that Montenegro's Law on blood supply, and relevant implementing legislation, are aligned with Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and the relevant EU implementing *acquis*.

The EU notes that regarding Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application, which will repeal and replace EU Directives on 2002/98/EC and 2004/23/EC which will become applicable from August 2027, Montenegro adopted an action plan for alignment with the above-mentioned regulation. This action plan includes strengthening of administrative capacity and oversight to implement the Regulation by the date of accession. The EU calls on Montenegro to effectively implement the action plan and to update it on a six-monthly basis.

The EU urges Montenegro to adopt the Law on the implementation of Regulation (EU) 2024/1938, establishing a single authority for substances of human origin with the powers, independence and adequate resources needed to carry out the oversight activities. The EU notes the commitment from Montenegro to put into immediate operation a functioning vigilance system for substances of human origin that tracks serious adverse reactions and events (SARE) and ensures adequate communication to and follow-up by the Ministry of Health, when this has been implemented. The EU expects Montenegro to demonstrate and evidence that this system is operational by reporting on the number of notifications in the system and by the follow-up of these notifications in the Action Plan.

On organs, Montenegro has adopted the Law on the Removal and Transplantation of Human Organs for Medical Treatment Purposes and the relevant implementing legislation for alignment with Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 establishing EU-wide standards for the quality and safety of human organs intended for transplantation and Commission implementing Directive 2012/25/EU of 9 October 2012 establishing procedures for the exchange of human organs intended for transplantation between EU member states.

The EU also notes that Montenegro's Law on Mandatory Health Insurance has achieved a good level of alignment with Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare and with Commission implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State. The EU urges Montenegro to ensure information to citizens on the recognition of medical prescriptions and to establish a National Contact Point on cross-border healthcare.

Regarding administrative capacities, the EU encourages Montenegro to build upon the staffing, technical, and organisational capacities of the Department of Public Health, Department of Transplantation and Department of Biomedicine which are responsible for implementing legislation in the field of substances of human origin, notably by recruiting skilled staff for each of the 13 positions Montenegro envisages, of which 8 are current filled.

In the field of **mental health**, the EU notes that Montenegro is participating in an EU4HEALTH Joint Action on the mental health of vulnerable groups. The EU recalls that Montenegro should continue ensuring community-based services as an alternative to institutionalisation and the allocation of sufficient financial resources in mental health care. Overall, it is encouraged that Montenegro pays due attention to the Commission Communication on a comprehensive approach to mental health (COM/2023/298).

The EU takes note that activities are ongoing in the area of **nutrition**, including the promotion of infant and young child feeding guidelines (0–24 months) and nutrition standards for preschool institutions. Montenegro carried out numerous promotional activities on breastfeeding and nutrition of pregnant women and children, as well as trainings for patronage and paediatric teams.

In the field of **non-communicable diseases**, the EU encourages Montenegro to use as reference the recent Commission Communication on an EU cardiovascular health plan (COM(2025) 1024)) on prevention, early detection and screening, treatment and care (including rehabilitation).

The EU recalls the importance of **alcohol related harm reduction**, and the **prevention of injury** and **promotion of safety**, including actions supporting healthy diet and adequate physical activity for all the population, in particular for children.

In the area of **drug abuse prevention**, the EU notes that Montenegro adopted a Strategy on Drugs 2024–2027, together with the Action Plan 2024–2025, in line with EU policies and international obligations and adopted relevant bylaws in this area.

Montenegro has national **cancer** screening programmes for breast, colorectal and cervical cancer in place, which are partially aligned with the Council Recommendation of 9 December 2022 on strengthening prevention through early detection: ‘A new EU approach on cancer screening’ 2022/C 473/01. The EU encourages Montenegro to fully align with this EU *acquis* and to take further efforts to increase the invitation coverage of these programmes.

On **digital health**, the EU takes note of Montenegro's national digital health development strategy. The EU encourages Montenegro to share information with it on its monitoring efforts on the ongoing implementation of Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space.

In the area of **health inequalities**, the EU takes note of Montenegro's activities to improve the health of vulnerable population groups, notably maternal and child healthcare. Regarding ethnic minorities such as Roma, the EU notes that Montenegro has established six job positions for Roma mediators in the field of health care. In the field of **healthy environments and risk assessment**, the EU requests that Montenegro keep it informed on progress on implementing its national legislation designed to be aligned with the EU *acquis* on exposure to electromagnetic fields (Council Recommendation 1999/519/EC).

The EU notes that the adoption of the above-described legislation and ongoing and planned administrative capacity building fulfils the requirements of the third closing benchmark set in document AD 32/14 CONF-ME 26.

In view of the above considerations, the EU notes that, at this stage, this chapter does not require further negotiations.

Monitoring of progress in the alignment with and implementation of the EU *acquis* will continue throughout the negotiations. The EU underlines that it will devote particular attention to monitoring all specific issues mentioned above with a view to ensuring Montenegro's administrative capacity, its ability to enforce the *acquis* in this chapter, and the completion of the legislative alignment, and its capacity to apply EU quality and safety standards in the area of public health and consumer protection.

Particular consideration needs to be given to the links between the present chapter and other negotiation chapters. A final assessment of the conformity of Montenegro's legislation with the EU *acquis* and of its implementation capacity can only be made at a later stage of the negotiations. In addition to all the information the EU may require for the negotiations in this chapter, and which is to be provided to the Conference, the EU invites Montenegro to provide regularly detailed written information to the Stabilisation and Association Council on progress in the implementation of the *acquis* and strengthening of its administrative capacity.

In view of all the above considerations, the EU will, if necessary, return to this chapter at an appropriate moment.

The EU notes that Montenegro, in its negotiating positions AD 23/14 CONF-ME 18 and AD 10/26 CONF-ME 9, accepts the *acquis* under chapter 28 as in force on 30 March 2026. The EU furthermore notes that Montenegro declares that it will continue the alignment process with the *acquis* and that it will be ready to implement it by the time of its accession to the European Union.

Furthermore, the EU recalls that there may be new *acquis* between 30 March 2026 and the conclusion of the negotiations.