CONFERENCE ON ACCESSION TO THE EUROPEAN UNION – MONTENEGRO –

Brussels, 29 October 2026 (OR. en)

AD 87/26

LIMITE

CONF-ME 38

PUBLIC

ACCESSION DOCUMENT

Subject:	EUROPEAN UNION COMMON POSITION - Chapter 1: Free movement of goods

EUROPEAN UNION COMMON POSITION

Chapter 1: Free movement of goods

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 prejudge 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 the requirements set out in points 24, 28, 41 and 44 of the Negotiating Framework.

The EU expects 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 position AD 24/16 REV 1 CONF-ME 12 and its addendum AD 61/26 CONF-ME 25, accepts the *acquis* under chapter 1 as in force on 28 August 2026, and that it declares that it will be ready to implement it by the date of its accession to the European Union, with the exception of a number of requests for transitional measures and derogations.

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General obligations

The EU takes note of the significant progress achieved in the implementation of Montenegro's 2014-2018 Action Plan and the 2026 General Action Plan for **compliance with Articles 34 to 36 of the TFEU**, amending or repealing legal acts containing restrictions to free movement of goods or introducing the necessary mutual recognition provisions. Out of the almost 1 900 legal acts identified by Montenegro as containing provisions that may limit the free movement of goods, the vast majority (around 1 850 national legal acts), have been amended or repealed between 2014-2018. This includes 385 repealed legal acts as they contained obsolete or conflicting technical standards, and 154 repealed acts due to the alignment of Montenegrin legislation with the relevant EU *acquis*. The EU notes that in eight cases Montenegro identified the measure as possibly justified on the basis of Article 36 TFEU. The EU calls on Montenegro to amend the remaining 18 acts as necessary, by the end of 2026, in order to align them with the free movement of goods obligations derived from the EU Treaties. The EU welcomes Montenegro's adoption of legislation aligned with Regulation (EU)2019/515 on the mutual recognition of goods lawfully marketed in another Member State. The EU underlines that, from the date of accession, Montenegro needs to ensure that the principle of mutual recognition will be applied in full and that no measures having an equivalent effect to quantitative restrictions exist.

This fulfils the requirements of the **third closing benchmark** as set out in the EU common position (AD 12/17 CONF-ME 4).

The EU urges Montenegro to provide regular information on the developments and steps undertaken as regards further alignment of its legislation on general principles to the *acquis*.

Horizontal measures

The EU takes note that Montenegro has made significant progress with the alignment in the field of horizontal product legislation. The EU takes note of the adoption of key legal frameworks in the areas of standardisation, accreditation, metrology and market surveillance and on the notification of technical regulations.

PUBLIC

As regards standardisation, the EU takes note that Montenegro has adopted the Law on standardisation broadly aligning with Regulation (EU) 1025/2012 on European standardisation. The EU notes that through the recent amendments of the Law on standardisation in April 2026, Montenegro sought to address the recommendations from the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC). A peer review will be launched by CEN-CENELEC in the coming months to verify the Institute for Standardisation of Montenegro (ISME) compliance with CEN-CENELEC's membership criteria. The EU welcomes that ISME applied to join CEN-CENELEC and calls on Montenegro to finalise all the necessary procedures to become a full member of these bodies by end of 2026.

On conformity assessment and accreditation, the EU takes note of Montenegro's alignment with Regulation (EC) 765/2008 setting out the requirements for accreditation via its Law on accreditation of 2009, updated in 2015 and as further amended in April 2026. The EU notes that in September 2026 Montenegro adopted amendments to the Law on technical requirements for products and conformity assessment, aligning with Decision 768/2008/EC on a common framework for the marketing of products. The EU takes note that the Accreditation Body of Montenegro (ATCG) is a full member of the European cooperation for Accreditation (EA) since 2011. The EU welcomes that in 2023, the ATCG achieved the status of signatory to the European Accreditation Multilateral Agreement (EA MLA) in the following accreditation schemes: testing, calibration, medical examinations, inspection, and product certification. The EU notes that the peer evaluation, carried out in March 2026 in the context of maintaining ATCG's signatory status to the EA MLA, confirmed significant progress in the organisational structure, assessment planning, and implementation. However, a total of five non-conformities and six recommendations were identified. The EU calls on Montenegro to address the identified non-conformities as soon as possible.

PUBLIC

The EU notes that Montenegro has aligned its legislation with Council Directive 85/374/EEC concerning the liability for defective products and the new product liability framework Directive (EU) 2024/2853. The EU encourages Montenegro to continue monitoring legislative developments, in particular, the upcoming "European Product Act Package" which aims to modernise the EU's product regulatory framework. The EU calls on Montenegro to monitor developments in this area and to ensure alignment with the outcome of the EU legislative process.

As regards metrology, the EU takes note that the Bureau of Metrology of Montenegro (BoM) is a full member of the European Association of National Metrological Institutes (EURAMET) since 2011, and that the accreditation of three laboratories - one for mass, one for length, and one for temperatures - has been achieved. The EU further notes that BoM is also a full member of the International Organisation of Legal Metrology (OIML) since January 2023. The EU notes that Montenegro has advanced its alignment on legal metrology. To this end, the EU welcomes that Montenegro is aligned with Council Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement as amended, with Directive 2014/31/EU on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments, with Directive 2014/32/EU on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments and Council Directive 75/107/EEC on the approximation of the laws of the Member States relating to bottles used as measuring containers, Directive 76/211/EEC on filling prepackages, Directive 2007/45/EC on the nominal quantities for pre-packed products and Directive 2009/34/EC relating to common provisions for both measuring instruments and methods of metrological control.

Concerning market surveillance, the EU notes that in April 2026, Montenegro adopted a new Law on market surveillance aligning with Regulation (EU) 2019/1020 on market surveillance and compliance of products. The EU calls on Montenegro to adopt its market surveillance strategy as soon as possible.

PUBLIC

As regards the European Conformity (CE) marking, the EU notes that since its independence Montenegro has never introduced its own national product conformity mark. Given its small domestic market and industrial production, Montenegro decided not to establish one. The EU notes that in the product sectors covered by the EU New Approach *acquis*, Montenegro unilaterally recognises the CE marking, meaning that products bearing the CE mark in accordance with harmonised EU legislation are considered compliant by Montenegro with its national product requirements and are allowed to be placed on the Montenegrin market. The current legal framework of Montenegro does not give the right to domestic manufacturers to affix the CE marking themselves under national legislation, as this matter is governed by European Union law. Montenegrin manufacturers have to use EU notified bodies to meet these requirements. The EU notes that these rules are laid down in the 2022 Decree on the method of recognising foreign conformity documents and conformity marks and the Law on technical requirements for products and conformity assessment (last amended in 2026). The EU notes that, in anticipation of Montenegro's accession to the EU, Montenegro introduced the compulsory use of the CE marking in national law in line with EU harmonised product rules, with the relevant provisions becoming applicable upon accession.

On the notification of technical regulations, the EU notes that the Law on technical requirements for products and conformity assessment and the related Decree on notification of technical regulations, standards, regulation on information society services and conformity assessment procedures, adopted in April 2026, is aligned with Directive 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services.

PUBLIC

The EU notes that in April 2026, Montenegro adopted Roadmaps covering Regulation (EU) 2024/2747 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market (IMERA), Regulation (EU) 2024/1735 on establishing a framework of measures for strengthening Europe's net-zero technology manufacturing ecosystem, Regulation (EU) 2024/3015 on prohibiting products made with forced labour on the Union market and amending Directive (EU) 2019/1937, Council Regulation (EC) 2679/98 of 7 December 1998 on the functioning of the internal market in relation to the free movement of goods among the Member States and Directive 2009/43/EC on simplifying terms and conditions of transfers of defence-related products within the Union. The EU urges Montenegro to implement such Roadmaps as soon as possible and before accession and to ensure the ability to enforce these Regulations as of the date of accession to the EU.

New and Global approach product legislation

As regards the new and global approach product legislation, the EU takes note that Montenegro has made good progress towards alignment with the EU new and global approach product *acquis*, notably with Regulation 2016/424 on cableway installations, Regulation 2016/426 on gas appliances, Directive 2014/33/EU on lifts and safety components for lifts, Directive 2014/68/EU on pressure equipment, Directive 2014/29/EU on simple pressure vessels, Directive 2014/34/EU on equipment and protective systems intended for use in potential explosive atmospheres (ATEX), Regulation 2019/1009 on fertilisers, Regulation 1223/2009 on cosmetic products, Regulation 305/2011 and Regulation 2024/3110 on construction products, Directive 2014/35/EU on low voltage equipment, Directive 2013/53 recreational and personal watercraft, Directive 2014/28/EU on civil explosives, Directive 2013/29/EU on pyrotechnic articles, Regulation 2025/2509 on the safety of toys, Directive 2000/14/EC related to outdoors noise emissions, Regulation 2016/425 on personal protective equipment, Directive 2006/42/EC on machinery, Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment, Regulation (EU) 2026/405 on detergents and surfactants and Directive 2014/30/EU on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

The EU also notes that Montenegro has adopted secondary legislation aligning with Directive 2009/125/EC regarding the establishment of a framework for the setting of eco-design requirements for energy related products. The EU notes Montenegro's two-step approach to alignment with the EU new and global approach product *acquis*, adopting the Law on technical requirements for products and conformity assessment (last amended in 2026) as primary legislation for most of the above-mentioned cases, while adopting specific secondary legislation to complete alignment of the specific technical requirements of the Directives or Regulations in question.

Concerning the EU medical device *acquis* under the new approach, the EU welcomes that the Law on medical devices and the Law on administrative procedure and related rulebooks are aligned with Regulation 2017/745 on medical devices and Regulation 2017/746 on in vitro diagnostic medical devices.

The EU invites Montenegro to continue to align with the EU *acquis* in this area, and to finalise the alignment, as soon as possible before accession, with Regulation (EU) 2024/1781 on ecodesign requirements for sustainable products.

Old approach product legislation

As regards the EU old approach product legislation, the EU takes note of Montenegro's good progress on alignment with the EU *acquis,* notably in the area of aerosol dispensers (Council Directive (EC) 75/324/EEC), and good laboratory practice and related inspections (Directive 2004/9/EC and Directive 2004/10/EC), key chemical legislation such as REACH (Regulation (EC) No 1907/2006) and CLP Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures and Regulation 273/2004 on drug precursors.

PUBLIC

As regards Regulation (EC) 1907/2006 (REACH), the EU notes that Montenegro has made significant progress in preparing for its implementation, including by adopting relevant legislation in line with REACH. The EU calls on Montenegro to continue with preparations for implementation of the REACH Regulation in particular as concerns its participation in the mechanisms established by the Regulation, such as the organs and committees of the European Chemicals Agency. The EU notes that Regulation (EC) 1907/2006 is also addressed under chapter 27 Environment and that Montenegro may request a transitional arrangement within that chapter. As regards, alignment with CLP, the EU notes that Montenegro has made significant progress notably through the establishment of the legal and initial operational arrangements for the poison centre and emergency health response required under the CLP framework, and expects Montenegro to be fully prepared to implement it by the time of accession. The new Law on chemicals, adopted in July 2026, formally designates the Centre for Hospital Epidemiology and Toxicology as the body responsible for receiving information related to emergency medical response and that a 24-hour telephone service is available to healthcare professionals and members of the public providing access to clinical toxicology advice in cases of poisoning or suspected poisoning. The EU notes that work is ongoing to adopt further bylaws particularly concerning alignment with Annex VI and Annex VIII of the Regulation and calls on Montenegro to finalise this work as soon as possible, before accession. The EU notes that Montenegro is aligned with Regulation 273/2004 on drug precursors via its national Law on monitoring and control of the manufacture and trade in certain substances that can be used in the manufacture of narcotic drugs and psychotropic substances was adopted in June 2026. The EU notes that in June 2026, Montenegro adopted the Law on the homologation of vehicles, vehicle systems, components and separate technical units aligning broadly with the overarching EU Regulations in the field of motor vehicles and thereby establishing a vehicle homologation system in Montenegro.

PUBLIC

The EU notes that work is also ongoing to complete alignment with the technical and implementing requirements stemming from Regulations (EU) 2018/858 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, (EU) 168/2013 on the approval and market surveillance of two or three-wheel vehicles and quadricycles, (EU) 167/2013 on the approval and market surveillance of agricultural and forestry vehicles and (EU) 2016/1628 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, including their implementing and delegated acts. The EU calls on Montenegro to finalise this work and to adopt the necessary secondary legislation to complete alignment with the relevant acquis as soon as possible and before accession.

The EU also notes Montenegro's significant progress in aligning with the *acquis* on pharmaceuticals (medicinal products for human use and for veterinary use), which is also part of the EU old approach *acquis* for Montenegro as detailed hereunder.

Procedural Measures

The EU notes that Montenegro has aligned with the *acquis* on textiles (Regulation 1007/2011) and footwear labelling (Directive 94/11/EC), crystal glass (Council Directive 69/493/EEC), transparency of measures regulating pricing and reimbursement of medicinal products as detailed above, on the control and acquisition and possession of weapons (Directive 2021/555) and on the return of cultural objects unlawfully removed from the territory of a Member State (Directive 2014/60/EU). The EU urges Montenegro to complete its alignment with the EU *acquis* on simplifying terms and conditions of transfers of defence-related products (Directive 2009/43/EC).

These developments **fulfil the requirements of the second closing benchmark on progress towards alignment with the horizontal legislation**, **Old and New Global approach product** *acquis* and procedural matters as set out in the **second closing benchmark** in the EU common position (AD 12/17 CONF-ME 4).

The EU invites Montenegro to provide regular information on the developments and steps undertaken as regards further alignment of its legislation on horizontal measures to the EU *acquis*, the Old, New and Global approach product *acquis* and on procedural measures.

On the EU *acquis* on **medical products for human use and for veterinary use,** the EU notes the significant progress made by Montenegro in aligning its legislation. In particular, in February 2026 Montenegro adopted the new Law on medicines and related secondary legislation, thus aligning with the core EU pharmaceutical *acquis,* including Directive 2001/83/EC on medical products for human use, as last amended, and as complemented by a large number of related implementing and delegated legislation, and Regulation (EU) 2019/6 on veterinary medicinal products, which repealed Directive 2001/82/EC, and related implementing and delegated acts. The EU notes that the Law on administrative procedures and subsequent decrees are aligned with Council Directive 89/105/EEC concerning the transparency of measures regulating the prices and reimbursement of medicinal products in European Union Member States. This facilitates obtaining an overview of national price and reimbursement agreements, including their application and the criteria on which they are based, making this information publicly accessible to all persons affected by the pharmaceutical market.

The adoption of the above-mentioned legislation fulfils the requirements of the **first closing benchmark** as set out in the EU common position (AD 12/17 CONF ME 4).

The EU calls on Montenegro to align with the remaining applicable legislation including implementing and delegated acts in the EU *acquis* on medicinal products for human and for veterinary use as soon as possible and latest by the date of accession. The EU expects Montenegro to provide regular updates on the progress made concerning the alignment and implementation of EU *acquis* on medicinal products for human use, and on veterinary medicinal products. On the latter, the EU expects updates on the adoption of national rules or procedures that are laid down in Regulation (EU) 2019/6. These include national rules on the retailing of veterinary medicinal products, procedures for the implementation of the use of veterinary medicinal products outside of the marketing authorisation, procedures for suspending, revoking, or varying the terms of marketing authorisations or the penalties applicable to infringements of the Regulation.

PUBLIC

The EU underlines that as from the date of accession, Montenegro must ensure compliance with and application of the clinical trials Regulation (EU) 536/2014 and its delegated acts, Regulation (EC) 726/2004 establishing a European Medicines Agency**,** the EU *acquis* on the fees and charges payable to the European Medicines Agency (EMA) (Regulation 2024/568), as well as with legislation on the EMA's reinforced role in crisis preparedness and management (Regulation (EU) 2022/123). The EU calls on Montenegro to ensure alignment with the "variations framework" of medicinal products for human use in line with Regulation (EC) 1234/2008.

To help preventing falsified medicines from entering the legal supply chain and to avoid disruption in the supply of medicinal products, the EU calls on Montenegro to promptly establish a repository system to enable the end-to-end verification and decommissioning of product unique identifiers as laid down in Delegated Regulation (EU) 2016/161. In addition, the EU calls on Montenegro to ensure the application of Implementing Regulation 699/2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity. The EU will closely monitor progress to this end.

The EU recalls that medicinal products for human use that are not authorised under any EU/EEA legislation cannot bear the EU safety features and shall not be decommissioned. In addition, the EU expects that Montenegro puts in place the necessary measures to prevent these medicinal products from entering the rest of the EU internal market.

The EU notes that in its negotiation position, AD 24/16 REV 1 CONF-ME 12 and its addendum AD 61/26 CONF-ME 25, Montenegro requested the **transitional periods** listed below for the implementation of the EU *acquis* on medicinal products for human use and for veterinary use under this chapter. The EU recalls its general position that transitional measures are exceptional, limited in time and scope, and accompanied by a plan with clearly defined stages for the application of the *acquis*. These transitional requests must not involve amendments to the rules or policies of the EU, disrupt their proper functioning, or lead to significant distortion of competition.

The EU notes that Montenegro has requested a **transitional period of three years** from the date of accession to derogate from the application of Article 6(1) of Directive 2001/83/EC on the community code relating to medicinal products for human use, as last amended, and which states "*No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EC) No 726/2004 [...]"*. The EU considers that such a transitional period is acceptable as far as it concerns medicinal products for human use which have been granted a national marketing authorisation by the competent authority of Montenegro and are listed in Montenegro's negotiating position AD 24/16 REV 1 CONF-ME 12 and its addendum AD 61/26 CONF-ME 25. The EU recalls that marketing authorisations covered by this derogation shall not benefit from mutual recognition in the Member States in accordance with Article 28 (2) of Directive 2001/83/EC before these products have been authorised according to Directive 2001/83/EC. Until such authorisation is granted, those medical products for human use shall not be subject to parallel trade to another EU Member State.

The EU notes that Montenegro has requested a **transitional period** of three years from the date of accession to derogate from the application of Article 5(1) of Regulation (EU) 2019/6 on veterinary medicinal products. The EU recalls that Article 5(1) lays down that "*a veterinary medicinal product shall be placed on the market only when a competent authority or the Commission, as applicable, has granted a marketing authorisation for that product in accordance with Article 44, 47, 49, 52, 53 or 54*". The EU considers that such transitional period is acceptable as far as it concerns medicinal products for veterinary medicinal products that have been granted a national marketing authorisation by the competent authority of Montenegro and are listed in Montenegro's negotiating position AD 24/16 REV 1 CONF-ME 12 and its addendum AD 61/26 CONF-ME 25. The EU recalls that marketing authorisations covered by this derogation shall not benefit from mutual recognition in accordance with Articles 51 and 52 of Regulation (EU) 2019/6 before these products have been authorised in accordance with Regulation (EU) 2019/6. Until such authorisation is granted, those veterinary medicinal products shall not be subject to parallel trade to another EU Member State pursuant to Article 102 of that Regulation.

PUBLIC

The EU notes that Montenegro has requested a **one-year phasing-out period** from the date of accession for existing stocks of veterinary medicinal products without a national marketing authorisation granted by Montenegro, which were lawfully imported into Montenegro before the accession date, by way of derogation from Article 106(1) of Regulation (EU) 2019/6 on veterinary medicinal products. The EU recalls that Article 106(1) lays down that *"veterinary medicinal products shall be used in accordance with the terms of the marketing authorisation"* and that derogations contained in Regulation (EU) 2019/6 to Article 106(1) may allow, in exceptional circumstances, the use of veterinary medical products that are not authorised in the Union. The EU considers that such phasing out period is acceptable. The EU requires that Montenegro puts in place the necessary measures to prevent these goods from entering the rest of the EU internal market.

The EU notes Montenegro's request for a **transitional period of 18 months** from the date of accession to exempt it from applying Article 104 of Regulation (EU) 2019/6 on veterinary medical products, which regulates the retail of veterinary medicinal products at a distance. The EU considers this request acceptable. The EU calls on Montenegro to adopt the necessary secondary legislation during the transitional period to enable the retail of veterinary medicinal products at a distance in accordance with EU standards, and to put in place the necessary measures to prevent the entry of falsified veterinary medicinal products in the legal supply chain and their distribution within the EU internal market. The EU recalls that the possibility to offer veterinary medicinal products by means of information society services is provided for by Regulation (EU) 2019/6 and that it may create new business opportunities for retailers established in Montenegro.

Administrative capacity

The EU takes note of the actions undertaken by Montenegro to strengthen its administrative capacity, in particular by increasing the staffing levels in the standardisation, accreditation, metrology and market surveillance bodies. The EU notes that the implementation and enforcement of the free movement of goods, including market surveillance, runs across multiple Ministries. The EU calls on Montenegro to establish a coordination body for market inspections as soon as possible, by end of 2026.

PUBLIC

The EU underlines the importance of quality infrastructure bodies ISME, ATGC and BoM for the proper functioning of the internal market, as they play a key role in implementing the EU *acquis* in question. The EU urges Montenegro to continue reinforcing the administrative capacity of the aforementioned key bodies and key Ministries in terms of resources and staffing, in particular for inspections, to ensure full implementation of the *acquis* by the date of its accession to the EU.

The EU notes that Montenegro adopted a comprehensive administrative capacity strengthening plan, for the purpose of implementing closing benchmark 4 of chapter 1 adopted by Montenegro in July 2026, to continue to reinforce the staffing levels over the period until at least 2028. The EU calls on Montenegro to hire and train the additional staff to fill the vacancies identified in the administrative capacity strengthening Plan for 2026, by end of December 2026. The EU will monitor these merit-based recruitments closely. The EU urges Montenegro to make available the necessary financial resources identified, to ensure adequate implementation of this staffing plan, including for the development of IT systems/platforms necessary for cooperation with and reporting to the EU. The EU also acknowledges the tangible progress made by Montenegro in aligning its administrative capacities in the areas of medicinal products for human use and for veterinary use, as well as medical devices, including *in vitro* diagnostics. The administrative capacity strengthening plan addresses key regulatory and operational challenges in these sectors, setting out clear timelines, recruitment targets, and capacity-building measures. The EU notes that while many structural and preparatory steps have taken place, notably in the area of market surveillance of medicines by CinMed as well as the actions taken by ISME and ATGC, sustained implementation remains key to ensure full enforcement of the acquis upon accession. In particular, the EU expects Montenegro to have in place, by the date of accession, the necessary technical arrangements, including IT systems, to enable connection to and effective use of the European database on medical devices (EUDAMED). The EU will monitor the implementation of Montenegro's administrative capacity strengthening plan closely and any follow up needed following the monitoring mission by the Commission.

PUBLIC

The EU notes that Montenegro has initiated concrete measures to reinforce operational capacities in the areas of medicinal products for human use and for veterinary use, including the recruitment of additional technical and administrative staff to manage essential functions, such as the evaluation of marketing authorisation applications and official controls on the use of veterinary medical products. While these efforts are encouraging, further progress is needed to ensure that personnel are fully equipped to handle legal updates, IT systems/platforms requirements (including preparedness for EU databases connectivity to allow cooperation with and reporting to the EU), and cross-cutting administrative tasks. In this regard, the EU encourages Montenegro to accelerate the delivery of regular training, including through EU support projects like Twinning to strengthen capabilities in market surveillance, conformity assessment procedures, oversight of notified bodies, and the prevention of falsified medicines entering the legal supply chain. For clinical trials, this may include trainings on practical implementation of the Clinical Trials Information System (CTIS) including assessment and authorisation procedures.

The EU will continue to closely monitor progress through regular updates and reporting from Montenegrin authorities. Montenegro will need to ensure that all administrative capacities in all these sectors are fully operational by the time of EU accession.

The EU notes that on anti-corruption measures, integrity plans are in place across all key institutions, including the Administration for Inspection Affairs, the Ministry of Economic Development, the Bureau of Metrology, the Institute for Standardisation, the Accreditation Body of Montenegro (ATCG), and the Institute for Medicines and Medical Devices (CInMED).

This **fulfils the requirements of the fourth closing benchmark** on administrative capacity to implement and enforce the legislation in all horizontal areas affecting the free movement of goods as set out in the EU common position (AD 12/17 CONF-ME 4).

PUBLIC

The EU invites Montenegro to keep it regularly informed of the developments and steps undertaken in reinforcing the administrative capacities in terms of staffing and resources in all the areas covered under this chapter.

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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 implement and enforce the *acquis* in this chapter and the completion of the legislative alignment. 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 in the strengthening of its administrative capacity.

The EU notes that Montenegro, in its negotiating position AD 24/16 REV 1 CONF-ME 12 and its addendum AD 61/26 CONF-ME 25, accepts the *acquis* under chapter 1 as in force on 28 August 2026, and that it declares that it will be ready to implement it by the date of its accession to the European Union, with the exception of a number of requests for transitional measures and derogations.

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

Furthermore, the EU recalls that there may be new *acquis* between 28 August 2026 and the date of accession.

PUBLIC

List referred to in Article [XX] of the Act of Accession: transitional measures

[XX]. FREE MOVEMENT OF GOODS

32001 L 0083: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

By way of derogation from the requirements for obtaining a marketing authorisation for human medicinal products laid down in Article 6(1) of Directive 2001/83/EC, marketing authorisations for medicinal products, which are not subject to Article 3(1) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency and which are on the list (List 1 in the Appendix to this Annex as provided by Montenegro in its negotiating position AD 24/16 REV 1 CONF-ME 12 and its addendum AD 61/26 CONF-ME 25 issued under Montenegrin law prior to the date of accession shall remain valid until they are renewed in compliance with the Union *acquis* or until three years from the date of accession, whichever is earlier.

The marketing authorisations covered by this derogation shall not benefit from mutual recognition in accordance with Article 28 (2) of Directive 2001/83/EC in the Member States as long as these products have not been authorised according to that Directive. Until such authorisation is granted, those medicinal products for human use shall not be subject to parallel trade to another EU Member State.

PUBLIC

The national marketing authorisations granted under Montenegrin national law before accession and not covered by this derogation and every new marketing authorisation shall, as of the date of accession, be in compliance with Directive 2001/83/EC.

3201 R 0006: Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

a) By way of derogation from the requirement of obtaining a marketing authorisation laid down in Article 5(1) of Regulation (EU) 2019/6, marketing authorisations for veterinary medicinal products, which are not subject to Article 42(2) of that Regulation, and which are on the list (List 2 in the Appendix to this Annex as provided by Montenegro in its negotiating position AD 24/16 REV 1 CONF-ME 12 and its addendum AD 61/26 CONF-ME 25 issued under Montenegrin law prior to the date of accession shall remain valid until they are granted in compliance with the Union *acquis* or until three years from the date of accession, whichever is the earlier.

The marketing authorisations covered by this derogation shall not benefit from mutual recognition in accordance with Articles 51 and 52 of Regulation (EU) 2019/6 in the Member States as long as these products have not been authorised according to Regulation (EU) 2019/6. Until such authorisation is granted, those veterinary medicinal products shall not be subject to parallel trade to another EU Member State pursuant to Article 102 of that Regulation.

The national marketing authorisations granted under Montenegrin national law before accession and not covered by this derogation and every new marketing authorisation shall, as of the date of accession, be in compliance with Regulation (EU) 2019/6.

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b) By way of derogation from the requirement to use veterinary medicinal products in accordance with the terms of the marketing authorisation laid down in Article 106(1) of Regulation (EU) 2019/6, stocks of veterinary medicinal products without a national marketing authorisation granted by Montenegro that were lawfully imported before the accession date and are still present in Montenegro may continue to be used in Montenegro for a one-year period from the date of accession. These veterinary medicinal products shall not enter the rest of the EU internal market.

c) By way of derogation from Article 104 of Regulation (EU) 2019/6, the application of the provisions on the retail of veterinary medicinal products at a distance in Montenegro is suspended for a period of 18 months from the date of accession. Such derogation shall not prevent persons permitted to supply veterinary medicinal products in a Member State in accordance with Article 103(1) of Regulation (EU) 2019/6 from offering veterinary medicinal products not subject to a veterinary prescription by means of information society services to natural or legal persons established in Montenegro in accordance with Article 104(1) of that Regulation.

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