

**CONFERENCE ON ACCESSION
TO THE EUROPEAN UNION
– ALBANIA –**

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ACCESSION DOCUMENT

Subject: EUROPEAN UNION COMMON POSITION
– Cluster 2: Internal Market

EUROPEAN UNION COMMON POSITION

(following Albania's Negotiating Position AD 1/25 CONF-ALB 1)

Negotiating Cluster: 2

Internal Market

Including chapters 1 - Free movement of goods, 2 - Freedom of movement of workers, 3 - Right of establishment and freedom to provide services, 4 - Free movement of capital, 6 - Company law, 7 - Intellectual property law, 8 - Competition policy, 9 -Financial services, 28 - Consumer and health protection

This position of the European Union is based on its general position for the Accession conference with Albania (AD 5/22 CONF-ALB 2), and is subject to the negotiating principles endorsed therein, in particular:

- any view expressed by either Albania or the EU on a specific chapter of the negotiations will in no way prejudice the position which may be taken on other chapters;
- agreements reached in the course of negotiations on specific chapters, even partial ones, may not be considered as final until an overall agreement has been reached for all chapters;

as well as to the requirements set out in points 2, 3, 5, 10, 14, 16, 23, 26, 31, 38, 39, 45, 46, 47 and 48 of the Negotiating Framework.

The EU encourages Albania to continue the process of alignment with the EU *acquis* and its effective implementation and enforcement, and in general to develop already before accession, policies and instruments as close as possible to those of the EU.

The EU notes that Albania, in its position AD 1/25 CONF-ALB 1 accepts the EU *acquis* under Cluster 2 as in force on 28 February 2025 and that it will be ready to implement it by the date of its accession to the European Union, except for those areas where it has requested a transition period in chapters 4, 9 and 28.

As an overall response to Albania's requests for transitional periods and derogations, the EU recalls its general negotiating 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 EU *acquis*. They must not involve amendments to the rules or policies of the EU, disrupt their proper functioning, or lead to significant distortion of competition.

1. Chapter 1 – Free movement of goods

The EU underlines that regarding **general principles** of the free movement of goods, Albania needs to align with the requirements of Articles 34-36 TFEU and relevant CJEU case law, ensuring it covers both the harmonised and the non-harmonised areas before accession. The EU recalls Albania needs to complete the introduction of mutual recognition clauses. The EU invites Albania to identify the contact point for technical regulations and ensure sufficient capacity in the relevant institutions.

The EU notes Albania's level of alignment with the EU *acquis* regarding **horizontal measures** on standardisation and accreditation and notes it needs to ensure full alignment. The EU welcomes the already established standardisation and accreditation bodies in Albania. The EU invites Albania to continue to address non-compliance issues and the recommendations signalled by CEN/CENELEC. The EU also notes Albania's partial alignment of national legislation with the EU *acquis* on conformity assessment, on metrology, on market surveillance, notification and on product liability. The EU also notes Albania needs to significantly reinforce human and financial resources regarding market surveillance. The EU underlines that Albania needs to expand market surveillance competences to cover all necessary sectors including chemicals, gas appliances, simple pressure vessels, aerosols, and pyrotechnic articles. The EU further notes that Albania does not have its own conformity mark. The EU also welcomes that Albania's national legislation already allows the use of the CE mark to goods placed on the market in Albania in sectors where the CE mark is foreseen by the EU *acquis*.

Regarding the **“New and Global Approach”**, the EU notes Albania’s level of legislative alignment with the EU *acquis* on electromagnetic compatibility (EMC), on low voltage equipment (LVD), on radio equipment (RED), on explosives for civil use, and on pyrotechnical articles, and notes it needs to ensure full alignment. The EU notes Albania’s partial alignment with the EU *acquis* on toys, on machinery, on outdoor equipment noise emissions (OND), on lifts, on personal protective equipment (PPE), on simple pressure vessels (SPVD), on construction products, on measuring units (MID), on non-automatic weighing instruments (NAWI), on pyrotechnical articles, on pre-packaged products, and on bottles used as measuring containers, and notes it needs to ensure full alignment. The EU recalls Albania needs to align its legislation on equipment and protective systems intended for use in potentially explosive atmospheres (ATEX), on eco-design, on gas appliances, on pressure equipment, on cableways, and on recreational craft. The EU underlines Albania needs to introduce sufficient administrative and implementing capacities to meet the obligations under the ‘New and Global Approach’ EU *acquis*. The EU also underlines the necessity to ensure sufficient levels of market surveillance and of conformity assessments.

Regarding the **“Old Approach” Product Legislation EU *acquis***, the EU notes Albania’s level of legislative alignment with the EU *acquis* on classification, labelling and packaging (CLP), and notes it needs to ensure full alignment. The EU notes Albania’s partial alignment with the EU *acquis* on REACH, on detergents, and on aerosol dispensers, and encourages it to ensure full alignment. The EU also notes Albania’s low level of legislative alignment with the EU *acquis* on drug precursors, and underlines that Albania needs to align its legislation with this EU *acquis* as well as on motor vehicles, on tractors (agricultural, forestry), on 2/3 wheeled vehicles, on non-road mobile machinery emissions, and on good laboratory practice (GLP). The EU also underlines Albania needs to ensure sufficient administrative capacity in all relevant ministries and other responsible bodies with high levels of integrity.

The EU further underlines Albania needs to ensure sufficient levels of human and financial resources for sufficient market surveillance in all relevant sectors. The EU invites Albania to ensure that the adequate provision of the correct quality of fuels will be available when full alignment to the EU *acquis* on vehicles and non-road mobile machinery emissions is reached. The EU also invites Albania to examine if changes to roads and road “furniture” are needed to ensure the correct functioning of vehicle systems regulated in line with the EU *acquis*.

Regarding **procedural measures**, the EU welcomes Albania’s high level of legislative alignment with the EU *acquis* on crystal glass, on footwear, and on cultural goods unlawfully removed from the territory of an EU Member State, and notes it needs to ensure full alignment. The EU notes Albania’s partial alignment with the EU *acquis* on transparency in relation to pricing and reimbursement of medicinal products, on textile labelling, on firearms, and on the transfer of defence related products, and notes it needs to ensure full alignment in these areas as well. The EU invites Albania to improve the levels of human and financial resources to ensure sufficient levels of market surveillance. The EU also invites Albania to establish the necessary registers for the export, import and trade of cultural goods.

The EU calls on Albania to extend measures in the **fight against corruption** to all institutions involved in the free movement of goods.

2. Chapter 2 – Freedom of movement of workers

The EU welcomes Albania’s partial alignment with EU *acquis* in the area of **general principles of access to labour market**, specifically on the freedom of movement for workers concerning the right to enter, reside and work. The EU invites Albania to ensure that by the time of accession, EU citizens can access its labour market without any restrictions. The EU notes Albania also needs to ensure that, by the time of accession, restrictions of access to the public sector will only apply to posts which are directly related to the specific activities involving the exercise of public authority and the responsibility for safeguarding the general interest of the State. The EU also recalls Albania needs to designate an institution responsible for supporting EU mobile workers and guarantee adequate rights for EU citizens family members, be they EU or non-EU nationals. The EU also invites Albania to ensure that, by the time of accession, the restrictions of access to the public sector are in line with the CJEU case law.

The EU considers that **transitional measures** will be required to allow current Member States to apply measures restricting access to their labour markets for workers from Albania as well as in relation to the freedom to provide services involving temporary movement of workers. Under EU *acquis* the rights of nationals of a State which has acceded, who are already legally resident and employed in another Member State, are protected. Albanian nationals and their family members shall not be treated any less favourably than third country nationals when the latter are exercising their rights under the *acquis*. The EU will return to this issue at a later stage of the negotiations. The Commission will provide an impact assessment.

The EU welcomes Albania's partial alignment to the EU *acquis* on **supplementary pensions**. The EU notes that Albania is in partial alignment with the *acquis* regarding supplementary pensions. The EU invites Albania to fully align with the EU *acquis*, in particular on occupational pension schemes.

The EU welcomes Albania's good level of preparation regarding **EURES**. The EU invites Albania to ensure the adequate connection of private employment agencies to the system and to put in place the National coordination office.

The EU welcomes that Albania is partly aligned with the EU *acquis* establishing the **European Labour Authority**. The EU invites Albania to plan capacity building, both as regards IT and human capacities. The EU also invites Albania to continue fighting against undeclared work.

The EU welcomes Albania's partial alignment with the EU *acquis* on the **coordination of social security systems**. The EU notes that Albania benefits from a substantial experience of the basic mechanisms involved in social security coordination. The EU invites Albania to develop sufficient administrative capacity as well as deeper knowledge and further digitalisation to apply the EU *acquis* in this field. The EU also encourages further development in the area of social security coordination, including social security agreements with the EU Member States.

The EU positively notes that Albania has put in place specific measures in order to fight against corruption in the field of free movement of workers.

3. Chapter 3 – Right of establishment and freedom to provide services

The EU welcomes Albania's partial alignment to the EU *acquis* on **mutual recognition of professional qualifications**. The EU recalls Albania needs to complete the alignment of its legislation with the recognition of professional qualification *acquis*, mainly with the Professional Qualifications Directive ⁽¹⁾ and Lawyers Directives ⁽²⁾. The EU underlines Albania needs to eliminate all remaining nationality requirements needed for access to a profession. The EU also underlines that Albania needs to align the study programmes, under which qualifications for regulated (sectoral) professions are acquired in Albania, with the minimum training requirements of the EU *acquis* ⁽³⁾. The EU invites Albania to increase its administrative capacity to manage this field.

The EU welcomes Albania's partial alignment with the EU *acquis* in the area of **right of establishment and freedom to provide services**. The EU invites Albania to finalise the identification of all the possible barriers for services' providers and their elimination. The EU underlines Albania needs to complete the alignment of its legal framework with the Services *acquis* ⁽⁴⁾ to eliminate all barriers to access.

The EU welcomes Albania's alignment with the EU *acquis* in the area of **postal services** as regards the Postal Services ⁽⁵⁾ and cross-border parcel delivery services ⁽⁶⁾ *acquis*. The EU invites Albania to ensure compliance with the EU postal rules and provision of the universal service and continue monitoring postal market developments.

The EU positively notes that Albania has put in place specific measures in order to **fight against corruption** in the right of establishment and the freedom to provide services.

⁽¹⁾ Directive 2005/36/EC

⁽²⁾ Directive 98/5/EC and Council Directive 77/249/EEC

⁽³⁾ Directive 2005/36/EC as amended

⁽⁴⁾ Directive 2006/123/EC

⁽⁵⁾ Directive 2008/6/EC

⁽⁶⁾ Regulation (EU) 2018/644

4. Chapter 4 – Free movement of capital

The EU notes Albania's partial alignment with the EU *acquis* on **free movement of capital**. The EU also underlines that it is the responsibility of Albania to ensure that upon accession all its bilateral investment treaties between Albania and third countries, are in conformity with the *acquis*. The EU underlines Albania needs to terminate its bilateral investment treaties with EU Member States, including the legal effects of sunset clauses, upon accession. The EU invites Albania to ensure sufficient administrative capacity and coordination to implement the EU *acquis* on free movement of capital.

The EU underlines Albania needs to lift all existing discriminatory conditions for EU Member State citizens who intend to purchase agricultural land in Albania, as compared to those for Albanian citizens. The EU stresses that these restrictions are not in line with the *acquis* and are incompatible with the Stabilisation Association Agreement (SAA), which provides that as regards the acquisition of real estate in its territory, Albania shall ensure the same treatment of nationals of the Member States of the European Union as compared to its own nationals.

The EU takes note of Albania's request of seven years following the date of its accession to the EU or until 31 December 2037 with a safeguard clause to extend it for three years, during which it would maintain the existing restrictions on the acquisition of agricultural land including forestry for EU/EEA and third country nationals legal and natural persons.

The EU notes the information submitted in support of its request. The EU nevertheless considers that more detailed information will be required before the EU can take a position on this request. The EU invites Albania to provide more information in particular regarding the:

- a. State of play and planned measures to improve legal certainty as regards the ownership structure of agricultural land. This includes harmonisation of land register and cadastral data in line with the interim benchmarks in Cluster 1 and planned stages for settlement of currently unresolved ownership rights.
- b. Size and distribution of agricultural undertakings.
- c. Current ownership structure of agricultural land stressing if any is owned or leased to foreigners.
- d. Plans for the privatisation of State-owned agricultural land.
- e. Current and planned restrictions after accession in the acquisition of land for EEA and third country nationals.

The EU notes Albania's partial alignment with some of the EU *acquis* on **payment services**. The EU also notes Albania needs to continue aligning with EU regulatory framework on payments . The EU underlines Albania needs to finalise alignment with the *acquis* on payment services ⁽⁷⁾ and e-money ⁽⁸⁾. The EU recalls Albania needs to align with the *acquis* on cross border payments and interchange fees.

The EU notes that Albania is partially aligned with the EU *acquis* on **anti-money laundering** ⁽⁹⁾. The EU underlines Albania needs to continue aligning with EU regulatory framework on anti-money laundering including transfer of funds ⁽¹⁰⁾. The EU also notes Albania's uneven track record on the field of money-laundering. The EU recalls Albania needs to reach complete alignment with the EU *acquis* in this area. The EU underlines Albania needs to demonstrate a solid track record on countering money-laundering and terrorist financing.

⁽⁷⁾ Directive (EU) 2015/2366
⁽⁸⁾ Directive 2009/110/EC
⁽⁹⁾ Directive (EU) 2015/849
⁽¹⁰⁾ Regulation (EU) 2023/1113

The EU notes that regarding **fight against corruption in the area of free movement of capital** Albania has a range of specific anti-corruption measures in place.

5. Chapter 6 – Company law

The EU welcomes Albania's broad alignment with the EU *acquis* in the area of **company law and corporate governance**. The EU notes Albania's high level of alignment with disclosure requirements for companies and the use of digital tools and processes, while it invites Albania to align with EU *acquis* provisions on structured/machine-readable data to eventually be able to interconnect with the EU Business Registers Interconnection System (BRIS). The EU underlines that Albania needs to finalise alignment with the *acquis* on company formation and capital requirements, on domestic mergers and divisions, and on cross-border mergers, divisions and conversions, including provisions covering the protection of employees, members, and creditors. The EU also notes Albania's high level of alignment with shareholder rights in listed companies⁽¹¹⁾. The EU underlines Albania needs to align with the amending Directive on the encouragement of long-term shareholder engagement ⁽¹²⁾, including the corresponding implementing rules. The EU further notes Albania needs to introduce provisions to align with the Commission Recommendations on independent directors and board committees, and the quality of corporate governance reporting. The EU also invites Albania to align with the Statute for a European company or the European Economic Interest Grouping (EEIG). The EU further notes Albania needs to align with the Corporate Sustainability Due Diligence Directive⁽¹³⁾.

Albania is aligned with the EU *acquis* on single-member limited liability companies. The EU recalls Albania needs to finalise alignment with the EU *acquis* regarding takeover bids.

⁽¹¹⁾ Directive 2007/36/EC

⁽¹²⁾ Directive (EU) 2017/828

⁽¹³⁾ Directive (EU) 2024/1760

The EU notes that in the field of **company reporting** Albania has a high level of alignment with the EU *acquis* on statutory audit. The EU invites Albania to continue to further strengthen capacities of the public audit oversight body in terms of staffing and funding, as well as those of the professional body to ensure that quality assurance, investigations and sanctions concerning the statutory audits, in particular those of public-interest entities, are carried out by the competent authority responsible for audit oversight. The EU underlines that Albania needs to further align with the EU *acquis* in the areas of accounting and transparency requirements for listed companies, on country-by-country reporting⁽¹⁴⁾, and on corporate sustainability reporting⁽¹⁵⁾, and the size-criteria ⁽¹⁶⁾.The EU also underlines that Albania needs to align its capital markets legislative framework with reporting requirements⁽¹⁷⁾.

The EU calls on Albania to pursue better governance in the private sector, to promote integrity, transparency and the **fight against corruption in the area of company law**.

6. Chapter 7 – Intellectual property law

The EU welcomes Albania's high level of alignment with the EU *acquis* in the area of intellectual property law. The EU also positively notes Albania has the basic administrative structures in place to manage and enforce intellectual property rights. The EU invites Albania to ensure good functioning and sufficient capacities of the administrative structures dealing with intellectual property rights and its enforcement.

⁽¹⁴⁾ Directive 2016/881/EU

⁽¹⁵⁾ Directive (EU) 2022/2464

⁽¹⁶⁾ Directive (EU) 2023/2775

⁽¹⁷⁾ Directive 2013/50/EU

The EU welcomes Albania's high level of alignment with the EU *acquis* on **copyright and related rights**. The EU recalls Albania needs to finalise the alignment in the area of intellectual property rights, in particular on copyright and related rights. The EU invites Albania to further improve institutional cooperation and effective implementation of the legislation. The EU also notes that Albania is partially aligned with the EU *acquis* on the harmonisation of certain aspects of copyright and related rights in the information society, on collective management of copyright and related rights, on databases, on the protection term, on resale rights, on rental and public lending rights, on orphan works and on semiconductors. The EU also invites Albania to adhere to the Marrakesh Treaty. The EU underlines Albania needs to align with the EU *acquis* on copyright and related rights in the Digital Single Market, to the rules applicable to certain online transmissions of broadcasting organisations and retransmissions of television and radio programmes (SatCab II), and to the rules on cross-border portability of online content.

The EU positively notes Albania's high level of alignment with the EU *acquis* on **industrial property rights**. The EU invites Albania to further strengthen institutional cooperation and training. The EU also notes that in the area of supplementary protection certificates (SPC), Albania is fully aligned with the EU *acquis* on plant protection products and partially aligned on medicinal products. The EU notes Albania's high level of alignment with the EU *acquis* on biotechnological inventions. The EU invites Albania to further align on compulsory licensing of patents and on trade secrets.

The EU also invites Albania to complete the legislative alignment with the EU *acquis* on SPCs for medicinal products. The EU underlines that the planned amendments shall *inter alia* provide that, as from the date of Albania's accession, it shall be considered that the first authorisation to place a medicine or a plant protection product on the market shall be the date of issuing such authorisation in the first Member State of the EU. The EU recalls that under the *acquis*, the relevant date is the date of issuing such authorisation in the EU/European Economic Area (EEA). The EU also underlines the importance that products protected by a valid basic patent in the EU at the date of Albania's accession – including pharmaceutical and plant protection products – are eligible for SPCs.

The EU underlines the importance of measures ensuring the unitary character of the EU trademark and of the EU design.

The EU recalls that pursuant to the EU Trademark Regulation, from the date of accession of a new Member State, an EU trademark registered or applied for pursuant to this Regulation before the date of accession shall be extended to the territory of the new Member State.

The EU recalls that EU/EEA exhaustion of rights is a fundamental principle that underpins the single market, and that must be complied with by all Member States upon accession.

The EU notes Albania's partial alignment on **enforcement** of intellectual property rights. The EU invites Albania to improve the enforcement of intellectual property rights, in particular regarding the number of court cases and inspections and sanctions on industrial property rights. The EU also invites Albania to further improve the training of staff, judges, and prosecutors, and to reinforce human resources.

The EU notes that regarding **fight against corruption in the area of intellectual property rights**, Albania has a range of specific anti-corruption measures in place and underlines the importance of implementing these.

7. Chapter 8 – Competition policy

The EU notes that, regarding the **legal framework for competition policy**, antitrust has a high level of alignment with the primary EU *acquis* but there are certain acts with which Albanian legislation is not yet aligned. The EU also notes that full alignment with provisions of Directive 1/2019 (except the cross-border aspects) remains to be achieved into national legislation. The EU also notes, within the context of the possibility for Member States to have national rules on merger controls, Albania's high level of alignment on merger control, whilst some elements of procedural rules and EU soft law remain to be further aligned. The EU further notes Albania's definition of State aid is broadly in line with the EU *acquis*. The EU underlines that Albania's State aid rules are not aligned or are only partially aligned with the EU *acquis* in all areas, including the procedural rules, horizontal and sectoral aid instruments as well as specific aid instruments.

The EU further notes that Albania is not aligned with the EU *acquis* in the area of liberalisation, relating to services of general economic interest, and the applicable transparency rules. The EU recalls that Albania needs to complete legislative alignment with the EU *acquis* in the legal framework for competition policy including through primary and secondary legislation.

The EU welcomes, regarding the **institutional framework and implementing capacity**, the existence in terms of organisational structure of a well-established and operationally independent and functioning Competition Authority. The EU underlines the importance of full legislative alignment to guarantee the independence, resources, powers and procedures of the Competition Authority to ensure effective enforcement. The EU notes that Albania's administrative capacity in the areas of antitrust and mergers is sufficient. The EU also underlines that Albania's Competition Authority needs to continue strengthening its administrative capacity, notably through relevant training of its staff. The EU recalls Albania needs to continue building a strong enforcement record in the area of competition.

The EU notes that regarding State Aid, Albania has a State Aid Commission. The EU underlines that Albania needs to transform the State Aid Commission into an operationally independent authority within the meaning of the SAA. The EU also underlines the need to have sufficient implementation and enforcement capacity in the area of State aid including the need to strengthen the administrative capacity of the State Aid Commission. The EU recalls that Albania needs to establish a solid track record of enforcement in the area of State aid, including alignment of existing aid measures with the EU *acquis*, also following commitments undertaken under the SAA.

The EU notes that Albania has a legal framework in place for **fighting corruption in the area of competition policy**. The EU calls on the Albanian Competition Authority to build up sufficient resources in the fight against bid rigging to ensure the enforcement of guidelines on public procurement and competition protection.

8. Chapter 9 – Financial services

The EU notes that Albania is partially aligned to the EU *acquis* on **banks and financial conglomerates**. The EU welcomes Albania's high level of alignment on capital requirements. The EU recalls Albania needs to align with the latest version of the Capital Requirements Directive and the Capital Requirements Regulation. The EU underlines that Albania needs to align with the EU *acquis* on the prudential requirements for investment firms and financial conglomerates. The EU also underlines that Albania needs to align with the EU *acquis* on the area of deposit guarantee schemes particularly on the size and types of depositors covered. The EU also notes that on recovery and resolution framework Albania is aligned with the first Banking Resolution and Recovery Directive ⁽¹⁸⁾. The EU also recalls Albania needs to align with the second Banking Resolution and Recovery Directive ⁽¹⁹⁾. The EU further underlines that Albania needs to further strengthen its supervisory capacities to account for the expanding responsibilities that the EU *acquis* entails.

The EU takes note of Albania's request to exclude Savings and Loans Associations (SLAs) from the application of all EU provisions relating to credit institutions through an amendment of Article 2 of the Capital Requirements Directive ⁽²⁰⁾. The EU also notes that Savings and Loan Associations represent 0.77% of the Albanian banking sector assets.

The EU notes the information Albania submitted in support of its request. The EU considers that more detailed information will be required before the EU can take a definitive position on this request, regarding the:

- a. Capital requirements and current supervision levels and practices for SLAs;
- b. Product range offered by SLAs;
- c. Types of clients using SLAs;
- d. Territorial footprint of SLAs.

⁽¹⁸⁾ Directive 2014/59/EU

⁽¹⁹⁾ Directive (EU) 2019/879

⁽²⁰⁾ Directive 2013/36/EU

The EU notes that Albania is partially aligned to the EU *acquis* on **insurance and occupational pensions**. The EU also notes that Albania is aligned with the solvency I regime. The EU underlines that Albania needs to align with the solvency II regime. The EU underlines Albania needs to finalise alignment with the motor insurance *acquis* ⁽²¹⁾. The EU recalls Albania needs to align its legislation on insurance distribution with the *acquis*.

The EU notes that Albania is partially aligned to the EU *acquis* on **financial market infrastructure**. The EU welcomes Albania's alignment with the EU *acquis* in the area of transparency of securities financing transactions. The EU underlines Albania needs to align with settlement finality and financial collateral. The EU underlines that Albania needs to meet, at the latest by the time of accession, the requirements laid down in the latest version of European Market Infrastructure Regulation ("EMIR") ⁽²²⁾. Albania will also need to meet the requirements of latest version of the central securities depositories regulation (CSDR) ⁽²³⁾.

The EU notes that Albania is partially aligned to the EU *acquis* on **securities markets and investment services**. The EU welcomes the high level of alignment on prospectuses and alternative investment fund managers. The EU also notes Albania's partial alignment with MiFID II. ⁽²⁴⁾ The EU recalls Albania needs to align with MiFIR ⁽²⁵⁾. The EU invites Albania to align on UCITS and AIFMD. The EU further notes Albania needs to align with the mortgage credit *acquis* ⁽²⁶⁾.

The EU notes that Albania is not yet aligned with the EU *acquis* on **sustainable finance**. The EU invites Albania to align with the Taxonomy Regulation ⁽²⁷⁾.

The EU positively notes that Albania has specific measures in place to **fight against corruption** in the main bodies dealing with financial services and their related legislative enforcement. The EU underlines the importance of the continued fight against corruption in the financial services area.

⁽²¹⁾ Directive 2009/103/EC

⁽²²⁾ Regulation (EU) No 648/2012

⁽²³⁾ Regulation (EU) No 909/2014

⁽²⁴⁾ Directive 2014/65/EU

⁽²⁵⁾ Regulation (EU) No 600/2014

⁽²⁶⁾ Directive 2014/17/EU

⁽²⁷⁾ Regulation (EU) 2020/852

9. Chapter 28 – Consumer and health protection

The EU notes that in the field of **consumer protection**, Albania has a high level of alignment to the EU *acquis* on general product safety and on dangerous imitations. The EU invites Albania to align with the EU *acquis* on EU Safety Gate and product liability. The EU underlines Albania's high level of alignment to the EU *acquis* on distance marketing of consumer financial services, comparability of fees relating to payment accounts, payment account switching and access to payments accounts. The EU also notes Albania's partial alignment to the EU *acquis* on unfair terms in consumer contracts, the indication of the prices of products offered to consumers, alternative dispute resolution for consumer disputes, on the sale of goods, on unfair business-to-consumer commercial practices, timeshare, long-term holiday product, resale and exchange contracts, on package travel and linked travel arrangements, and on credit agreements.

The EU underlines Albania needs to align with the EU *acquis* on the better enforcement and modernisation of Union consumer protection rules, representative actions for the protection of the collective interests of consumers, and on misleading and comparative advertising. The EU invites Albania to align with the EU *acquis* on certain aspects concerning contracts for the supply of digital content and digital services, on contracts for the sale of goods, and on promoting the repair of goods. The EU also underlines Albania needs to strengthen capacities and allocate sufficient resources to the bodies responsible for consumer protection and align with the EU *acquis* on co-operation between national authorities responsible for consumer protection.

The EU notes that regarding **public health**, Albania's legislation is designed to be fully aligned with the EU *acquis* on prevention of smoking and on smoke-free environments, however this has now been replaced with EU *acquis* on smoke-and aerosol-free environments. The EU invites Albania to align to EU interoperability standards and data protection standards regarding health data. The EU also notes Albania's level of alignment with the EU *acquis* on communicable diseases, and notes that Albania needs to complete this. The EU also invites Albania's to align with the EU *acquis* on audio-visual media services.

The EU recalls Albania needs to align with the EU *acquis* on the manufacture, presentation and sale of tobacco and related products, advertising of tobacco products, and with all other EU *acquis* on tobacco control. The EU also notes Albania's partial alignment to the EU *acquis* on medicinal products for human use (including Clinical Trials, Good Manufacturing and Good Distribution Practices, as well as requirements for Wholesale Distributors), on blood, tissues, and cells and on the adequate preparation for the entry into force of Regulation (EU) 2024/1938 on substances of human origin (SoHO), on mental health, and on patients' rights in cross-border healthcare. The EU underlines that Albania needs to complete its alignment in these areas and also align with the EU *acquis* on orphan medicines, medicinal products for paediatric use, advanced therapy products, and veterinary medicinal products. The EU underlines that authorisations for medicinal products for human and veterinary use granted before accession have to be upgraded to comply with the level of quality, efficacy and safety in accordance with the relevant EU *acquis*. The EU further invites Albania to improve the health of vulnerable population groups, ensuring equal access to quality health services for such populations. The EU also invites Albania to strengthen administrative and technical capacities in the area of public health including in the areas to address drug abuse prevention, nutrition, harmful alcohol consumption, prevention of injury and promotion of safety.

The EU notes that Albania is requesting a transitional period of three years following its accession to the European Union until 31 December 2033 to adhere to the requirements established by Directive 2001/83/EC for the authorisation, manufacture, distribution, and pharmacovigilance of medicinal products for human use within the European Union. The EU also notes that no such transition period is requested for veterinary medicinal products.

The EU recalls that compliance with the EU *acquis* on, and the availability of, medicinal products are important to ensure the safety of human health in the EU. The EU further notes that the request of Albania does not relate only to authorisation requirements, but also to other aspects regulated by EU law on medicinal products, including pharmacovigilance.

The EU also recalls that any transitional period should not compromise safety of medicinal products available in other EU member states and that proper guarantees, such as exclusion of incompliant medicines from mutual recognition in other EU Member State, are to be considered. In order to fully assess this request and its scope, the EU invites Albania to provide additional information on:

- a. Estimated impact on the Albanian pharmaceutical industry.
- b. Number of medicinal products which are:
 - i. Registered in Albania but not authorised in the EU;
 - ii. Registered in Albania and authorised in the EU in the centrally authorised procedure;
 - iii. Registered in Albania and authorised in one of the national authorisation procedures of Member States (also dynamic scenario numbers – expected numbers at the moment of accession, if possible).
- c. As regards the adjustment of national registration of medicines with requirements for the EU marketing authorisations, provide information on how varying level of complexity of different authorisation routes under the EU *acquis* has been taken into account in assessing the impact on the Albanian industry and national administration.

- d. On the provision of critical medicines to patients in Albania and the current EU,
- e. On the extent the composition of domestic and non-EU sourced medicines currently authorised to be placed on the Albanian market are identical to that in medicines authorised by the Commission to be placed on the EU single market.
- f. Albania's procedures and market for veterinary medicinal products, on which Albania also needs to be aligned with the relevant EU *acquis*, and for which authorisations need to comply with that *acquis*.

The EU positively notes that Albania has the institutional framework in place to **fight corruption** in the area of consumer and health protection and expects Albania to ensure good levels of integrity in these areas.

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In view of the present state of preparations, the EU notes that, on the understanding that Albania has to continue to make progress in the alignment with and implementation of the EU *acquis* covered by the following chapters, these may only be provisionally closed once it is agreed by the EU that the following benchmarks are met:

Chapter 1 – Free movement of goods

- Albania has an advanced level of alignment with the introduction of mutual recognition clauses, and the necessary amendments to domestic legislation and administrative practices, complying with the obligations stemming from Articles 34-36 of the TFEU.
- Albania has aligned with the EU *acquis* on horizontal product legislation and demonstrates an advanced level of alignment with the EU product *acquis* of this chapter, particularly in those sectors where alignment is so far insufficient or limited.

- Albania demonstrates that it has sufficient administrative capacity with high standards of integrity to properly implement and enforce, by the time of accession, the legislation in all horizontal areas affecting the free movement of goods (including standardisation, accreditation, metrology, conformity assessment and market surveillance) as well as the EU product *acquis* in this chapter.

Chapter 2 – Freedom of movement of workers

- Albania demonstrates that it has sufficient structures and enforcement capacity to fully implement the *acquis* on freedom of movement for workers by the time of accession.

Chapter 3 – Right of establishment and freedom to provide services

- Albania has adopted and presented to the European Commission a list of regulated professions within the meaning of the relevant EU *acquis*, specifying the activities covered by each profession and the justifications on the regulations.
- Albania has aligned the study programmes, under which qualifications for regulated professions are acquired in Albania, with the minimum training requirements of Directive 2005/36/EC and its relevant amendments.
- Albania has aligned the horizontal regulation on services by incorporating the Services Directive⁽²⁸⁾ and demonstrates further progress in the alignment of sectoral legislation and on the related administrative capacity.
- Albania has aligned with the *acquis* repealing any nationality requirements for access and exercise of service activities, except for nationality requirements justified and proportionate according to Article 51 TFEU. These amendments need to be applicable at the latest by the date of accession.

⁽²⁸⁾ Directive 2006/123/EC

Chapter 4 – Free movement of capital

- Albania has aligned with the *acquis* with respect to capital movements and demonstrates it will be able to fully implement it by accession, ensuring that all remaining restrictions are removed.
- Albania has aligned with the EU *acquis* in the field of payments notably as regards payment services in the internal market (Payment Service Directive as amended), cross border payments and Single European Payments Area *acquis*⁽²⁹⁾ and demonstrates it will be able to fully implement it by accession.
- Albania has aligned with the EU *acquis* in the area of prevention of money laundering and terrorist financing (notably Anti Money Laundering Directive, Anti Money Laundering Regulation and Transfer of Funds Regulation, as amended). Albania demonstrates sufficient administrative capacity to properly implement and enforce the relevant Anti Money Laundering / Counter Terrorism Financing legislation and obligations, and demonstrates tangible progress towards a solid track record. Albania demonstrates that it will be ready to fully implement the *acquis* from the day of accession.

Chapter 6 – Company law

- Albania has aligned its legislation with the general provisions of the EU *acquis* on company law and the establishment and functioning of limited liability companies, domestic mergers and divisions and cross-border conversions, mergers and divisions.
- Albania has aligned its legislation with Shareholder Rights Directive as amended⁽³⁰⁾, Takeover Bids Directive, and ensures it will be able to implement the Corporate Sustainability Due Diligence Directive⁽³¹⁾ from the date of accession.

⁽²⁹⁾ Regulation (EU) No 260/2012

⁽³⁰⁾ Directive (EU) 2017/828

⁽³¹⁾ Directive (EU) 2024/1760

- Albania has aligned its Law on Capital Markets, and relevant implementing legislation, with the *acquis* which includes the latest version of the Transparency Directive ⁽³²⁾, and it also has aligned its financial reporting regime, including implementing legislation, with the *acquis* which includes the Accounting Directive ⁽³³⁾ as amended ⁽³⁴⁾.
- Albania has aligned its statutory audit legislation, including implementing legislation, with the latest version of the Audit Directive. Particular attention should be paid, when organising the system of public audit oversight, to ensure that quality assurance, investigations and sanctions concerning the statutory audits, in particular those of public-interest entities, are carried out by the competent authority responsible for audit oversight.

Chapter 7 – Intellectual property law

- Albania undertakes all necessary legislative amendments to ensure EU/EEA exhaustion of rights in all areas from the date of accession.
- Albania has aligned its legislation with the *acquis* on intellectual property rights, in particular on copyrights and related rights, industrial property rights and Intellectual Property enforcement.
- Albania ensures a sufficient administrative capacity to register intellectual property rights and provides a track record of effective enforcement by the relevant administrative authorities, and through civil and, where appropriate, criminal justice.

Chapter 8 – Competition policy

- Albania has aligned with the EU *acquis* covered by the chapter on competition policy.
- Albania has built up sufficient administrative and judicial capacity in the area of antitrust, mergers and State aid control, including through ensuring the operational independence of the State Aid Commission.

⁽³²⁾ Directive 2004/109/EC

⁽³³⁾ Directive 2013/34/EU

⁽³⁴⁾ by the country-by-country Directive, the corporate sustainability reporting Directive, and the size-criteria Directive (Directive 2023/2775/EU)

- Albania has demonstrated a solid enforcement record in the area of antitrust and mergers, including a track record of effective and efficient administrative and judicial follow-up of infringements, including through imposition of deterrent sanctions, where appropriate.
- Albania has demonstrated a solid enforcement record in the area of State aid control, including a track record of ex-ante notification of aid, thorough assessment and effective alignment of aid measures and schemes with the *acquis*, as well as effective and efficient administrative and judicial follow-up, including through recovery of illegal and incompatible aid where applicable.

Chapter 9 – Financial services

- Albania has an advanced level of alignment with the *acquis* in the field of banking and financial conglomerates, notably in relation to capital requirements, supervision of financial conglomerates, deposit protection and reorganisation and winding up of credit institutions and has demonstrated the capacity to fully align with the *acquis* before the accession and to implement and enforce it from the day of accession.
- Albania has an advanced level of alignment with the *acquis* in the field of insurance (including Solvency II) and occupational pensions, notably as regards life insurance, reinsurance, insurance distribution, and motor vehicle liability insurance, and has demonstrated that it will be ready to implement the *acquis* from the day of accession.
- Albania has an advanced level of alignment with the *acquis* in the field of financial market infrastructure, including clearing and settlement, notably as regards settlement finality and financial collateral arrangements, and in the field of securities markets, investment services, and investment management, notably as regards Markets in Financial Instruments framework, prospectus, transparency, and market abuse, and regarding investment management, and has demonstrated that it will be ready to implement the *acquis* from the day of accession.

- Albania has an advanced level of alignment with the *acquis* in the field of digital finance, notably as regards operational resilience and crypto assets and has demonstrated that it will be ready to implement the *acquis* on digital finance and sustainable finance from the day of accession.
- Albania has demonstrated the robustness and independence of regulatory and supervisory institutions with high standards of integrity - in line with the requirements of the various sectoral legislations - with sufficient administrative capacity for the implementation and enforcement of the *acquis* in the field of financial services.

Chapter 28 – Consumer and health protection

- Albania has an advanced level of alignment with the EU general product safety and consumer protection *acquis* (including EU *acquis* on private enforcement, on guarantees and on digital content), ensuring the protection of consumer interests of consumers, their safety, capacity building for their consumer organisations, effective enforcement and the right to redress. Albania demonstrates the adequate administrative structures with high standards of integrity and enforcement capacity, including necessary levels of independence, to implement them correctly by the time of accession.
- Albania has an advanced level of alignment with the EU legislation and international obligations on tobacco control as well as its full and due implementation and enforcement.
- Albania has aligned with the EU *acquis* on patients' rights in cross-border healthcare, substances of human origin, medicinal products for human and veterinary use, cosmetics, and medical devices, has an advanced level of alignment with all other EU *acquis* on public health, and demonstrates that it has the necessary levels of administrative capacity and integrity, including a sustainable supervision system/authority, to properly implement and enforce the EU public health *acquis* in all these fields.

Monitoring of progress in the alignment with and implementation of the EU *acquis* and relevant European standards 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 Albania's administrative capacity, its capacity to complete legal alignment in all sectors under this cluster, as well as further progress in implementation and enforcement. Particular consideration needs to be given to the links between the present cluster and other negotiation clusters. A final assessment of the conformity of Albania's legislation with the EU *acquis* and relevant European standards as well as 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 cluster, and which is to be provided to the Conference, the EU invites Albania to provide regularly detailed written information to the Stabilisation and Association Council on progress in the implementation of the EU *acquis*.

In view of all the above considerations, the Conference will have to return to this cluster at an appropriate moment.

Furthermore, the EU recalls that there may be new EU *acquis* between 28 February 2025 and the conclusion of the negotiations.