

TO

Ms. Marta KOS
Commissioner for Enlargement
European Commission

Mr. Gert Jan KOOPMAN
Director-General
Directorate-General for Enlargement and the Eastern Neighbourhood
European Commission

Ms. Sandra GALLINA
Director-General
Directorate-General for Health and Food Safety
European Commission

C/C
Ms. Katarina MATHERNOVA
Ambassador of the European Union to Ukraine

Mr. Viktor LIASHKO
Minister of Health of Ukraine

16 October 2026

Subject: Strengthening Ukraine's Pharmaceutical Regulatory System through the Establishment of the New National Competent Authority

Dear Commissioner Kos,
Dear Director-General Koopman,
Dear Director-General Gallina,

Medicines for Europe, representing the European generic, biosimilar and value-added medicine industries, the European Federation of Pharmaceutical Industries and Associations (EFPIA), representing the biopharmaceutical industry operating in Europe, European Business Association (EBA), one of the largest union of businesses operating in the Ukraine's market, and the Association of Pharmaceutical Research and Development (APRAD), representing leading pharmaceutical companies active in the research and development of new medicines (together - the Associations), closely follow and support Ukraine's accession process to the European Union (hereinafter - EU). We are committed to fostering cooperation with the EU, Ukraine's institutions and key stakeholders to support the Ukraine's integration into the EU single market for pharmaceuticals¹.

Against this background, we welcome the efforts undertaken by the Government of Ukraine to implement the new pharmaceutical legislation and prepare for the establishment of the new National Competent Authority (hereinafter - "the NCA", also referred to as "the state control authority" or "the

¹ In particular, on 22 June 2023, Medicines for Europe and the EBA signed a Memorandum of Understanding to support and take forward the accession process, https://www.medicinesforeurope.com/wp-content/uploads/2023/06/MOU_PR.pdf.

Ukrainian Pharmaceutical Agency”) foreseen under the Law of Ukraine “On Medicines” No.2469-IX of 28 July 2022, which enters into force on 1 January 2027² (with certain provisions applicable from 1 January 2028). We also highly appreciate the close cooperation between the Ukrainian authorities and European institutions in this area, including the ongoing Twinning project “Support the establishment of the state control authority for medicines and medical devices”³ and the establishment of the Strategic Advisory Working Group (Advisory Board) on the establishment of the Ukrainian Pharmaceutical Agency⁴. These initiatives create a unique opportunity to ensure that the NCA is built from the outset according to the highest European standards.

As strong supporters of Ukraine's EU accession process, we believe it is essential that this reform succeeds and contributes to the broader objective of integrating Ukraine into the European regulatory and economic space. For this reason, we respectfully recommend that several key principles be considered during the establishment of the NCA.

First, we strongly believe that the selection of the Head of the NCA and its senior management should be conducted through transparent, merit-based and competitive procedures. We appreciate that similar approaches have been successfully implemented during the establishment and reform of other Ukrainian public institutions with strong European support⁵, and we hope that this aspect will be maintained. Ensuring the independence, professionalism and credibility of the NCA from its inception will be essential for building trust among patients, healthcare professionals, regulators and industry.

With regard to staffing, we recognise the significant practical challenges associated with launching a fully operational NCA within an ambitious timeframe. We understand that the complete recruitment of an entirely new workforce through open competition may not be feasible in the short term and that the temporary transfer of qualified personnel from existing institutions may be necessary to ensure business continuity and uninterrupted performance of regulatory functions.

At the same time, such transfers should be regarded as a transitional measure. We recommend establishing transparent competency assessment, qualification validation and integrity screening procedures for all personnel transferred from existing authorities, with a clearly defined timeframe for completion following the launch of the NCA⁶. In our view, all transferred staff should undergo such assessment within a reasonable and predetermined period, for example, within the first year of operation of the NCA, in order to ensure that the institution is ultimately staffed on the basis of competence, professionalism, accountability, staff integrity and incorruptibility as the core priorities.

We would also encourage consideration the independent participation of experts nominated by Ukraine's international partners in both the leadership selection process and the design of the staff assessment procedures, building on successful practices applied in other key institutional reforms.

Transparent and merit-based appointment procedures are also an important anti-corruption safeguard, helping to ensure the integrity, independence, and credibility of the NCA while minimising the risks of undue influence and conflicts of interest in regulatory decision-making.

Second, the NCA should be designed as a modern, efficient and financially sustainable institution. From an industry perspective, it is critically important that the NCA operates according to clear and predictable procedures, has a coherent organisational structure, avoids unnecessary duplication of functions, maintains proportionate staffing levels and ensures extensive use of digital technologies and invests in their upgrades. The objective should not simply be to recreate existing structures and functions under a new name, but rather to establish a regulator that represents a genuine step forward towards European best practices in governance, transparency and efficiency.

Third, all regulatory procedures should be aligned as closely as possible with the corresponding

² <https://zakon.rada.gov.ua/laws/show/2469-20#Text>

³ https://www.bmeia.gv.at/fileadmin/user_upload/Zentrale/Europa/EU-Twinning/April-Juni_25/Twinning-Fiche-Ukraine_UA_24_UF_HE_01_25.pdf?utm_source

⁴ The Advisory Board was established to provide strategic guidance on the creation of the Ukrainian Pharmaceutical Agency in the pharmaceutical sector, bringing together recognised international and national experts, including: Emer Cooke (EMA), Lembit Rägo (CIOMS/WHO), Rainer Becker (DG SANTE), Krzysztof Landa, Robin Martz (U.S. Embassy in Kyiv); Mykhailo Radutskyi (Parliament of Ukraine), Olha Stefanyshyna (Parliament of Ukraine), Anka Feldhusen (Business Ombudsperson); Petra Doerr (EDQM).

⁵ For example, the selection procedures for the leadership of the National Anti-Corruption Bureau of Ukraine (NABU), the Specialised Anti-Corruption Prosecutor's Office (SAPO).

⁶ Similar re-certification and assessment mechanisms have been introduced in the context of the reform of the Bureau of Economic Security of Ukraine (ESBU) and the customs administration, including the involvement of independent commissions and international experts to strengthen institutional capacity, integrity and public confidence.

procedures applied within the EU. Any deviations from the EU legislation and regulatory practices should remain exceptional, objectively justified and accompanied by a clear roadmap for future convergence. Regulatory predictability and alignment are essential prerequisites for future participation in the European medicines regulatory network and for facilitating Ukraine's gradual integration into the EU Internal Market.

Importantly, the establishment of the NCA is not solely an administrative or technical reform. It is also a strategic economic reform with direct implications for investment, competitiveness and patients' access to medicines. The structure, effectiveness and credibility of the NCA will directly influence the investment climate and attractiveness of the Ukrainian pharmaceutical market, the ability of companies to launch and supply medicines, the level of regulatory burden faced by manufacturers and ultimately the timely availability of safe, high-quality and affordable medicines for Ukrainian patients. A modern and effective NCA can facilitate market access, encourage competition, attract investment and strengthen supply chain resilience.

This issue is particularly important giving the financing model envisaged under the new legislation. The reform introduces significantly broader funding mechanisms for the NCA, including annual contributions from regulated operators to support the performance of regulatory and state control functions. While the industry supports a sustainable financing model for an effective regulator, such a model also creates legitimate expectations regarding efficiency, transparency, accountability and value for money. As the pharmaceutical industry will make a substantial and ongoing financial contribution to the functioning of the NCA, the allocation and use of these resources should be guided by the principles of good governance, proportionality and effective public administration.

In this context, ensuring a proportionate organisational structure, efficient allocation of resources, transparent decision-making, clear performance indicators and measurable regulatory outcomes becomes not only a matter of good governance, but also a key element of regulatory credibility. The level of financing foreseen by the reform should be matched by a corresponding level of institutional performance, service quality and responsiveness to the needs of patients, the healthcare system and economic operators. The business community's willingness to support the financing model envisaged by the legislation will ultimately depend on the NCA's ability to demonstrate tangible improvements in regulatory performance and public value. Conversely, weaknesses in governance, staffing or procedures could create unnecessary barriers to market entry, increase costs and have a negative impact on patient access to treatment.

For these reasons, *we respectfully encourage the European institutions to consider recognising the establishment of the NCA as one of the benchmarks in Ukraine's accession process, notably under Chapter 28 "Consumer and Health Protection" which is part of Cluster 2 "Internal Market". Such recognition would also contributing to the effective implementation of Ukraine's broader Internal Market obligations.*

In our view, the successful establishment of the NCA should be reflected in the screening, monitoring and benchmarking framework applied to Ukraine's accession process. Progress should not be measured solely by the formal creation of the institution, but also through clear qualitative and operational indicators demonstrating that the NCA is capable of effectively implementing the EU pharmaceutical acquis and functioning according to European standards.

We would respectfully suggest that the European institutions consider the following benchmark indicators when assessing progress in this area:

- establishment of a fully operational NCA with sufficient administrative, technical and scientific capacity to effectively implement and enforce the EU pharmaceutical acquis;
- transparent, merit-based and competitive appointment of the NCA's leadership, ensuring its independence, staff integrity, accountability and public trust;
- timely adoption and implementation of secondary legislation required under the Law of Ukraine "On Medicines" No.2469-IX of 28 July 2022 and aligned with the EU pharmaceutical acquis, together with the harmonisation of regulatory procedures and decision-making processes with EU legislation, guidelines and regulatory practices;
- establishment of transparent governance, budgeting and performance-monitoring mechanisms, ensuring efficient, proportionate and accountable use of public and industry-funded resources;

- merit-based recruitment of the NCA's personnel through transparent and competitive procedures as the general rule, while permitting the temporary transfer of qualified staff from existing regulatory bodies only as an exceptional transitional measure, subject to mandatory competency assessment and attestation within a defined period following the establishment of the NCA;
- introduction of EU-aligned reliance and recognition mechanisms, including for Good Manufacturing Practice (GMP) inspections and certificates, where appropriate and consistent with EU legislation and international commitments.

We believe that the successful achievement of these objectives would make the new NCA a strong example of institution-building within Ukraine's accession process and a tangible demonstration of the country's commitment to the European principles of good governance, transparency, accountability, integrity, regulatory excellence and effective integration into the EU Internal Market.

The Association remains fully committed to constructive cooperation with European and Ukrainian partners and stands ready to provide any further information that may be useful.

Thank you in advance for your consideration and continued support.

Yours respectfully,

Adrian van den Hoven
Director General
Medicines for Europe



Nathalie Moll
Director General
European Federation of Pharmaceutical
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Ganna Derevyanko
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