**TO:**

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**Subject: Medicines for Europe and European Business Association propose priority steps to continue the EU integration of the Ukraine's pharmaceutical industry**

Medicines for Europe representing generic, biosimilar and value-added medicine industries and European Business Association (EBA) as the largest union of businesses operating in the Ukraine's market are pay careful attention and support the Ukraine's accession process to the European Union. 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 pharmaceuticals[1].

In light of our commitment and the Ukraine's candidate status for EU membership, which imposes new obligations regarding the healthcare system and the pharmaceutical market compared to the previous

[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.

Association Agreement between the European Union and its Member States, on one, and Ukraine, of the other, we propose to structure the dialogue in view of the accession process. This will require extensive alignment of regulatory and market policies. A more structured series of exchanges, including engagement of the industry leadership, will serve as a catalyst to aid Ukraine in its crucial reform processes, which will contribute to preparing the country for the new EU-harmonized pharmaceutical regulation.

In this regard, we kindly ask you to consider the following directions as the most important priorities for potential cooperation between the EU and Ukraine, which we believe can be implemented before Ukraine's full accession to the EU, taking into account the ongoing active preparation of other sectors for inclusion in the EU Single Market[2]:

1. Strategic prospects

Ukraine's candidacy status for EU membership granted by the European Council decision on 23 June 2022 necessitates a complete re-evaluation of the regulation and strategy of the Ukraine's pharmaceutical market as it plans to become a part of the EU Single Market. This calls for the development of a vision for the Ukraine's place within the EU healthcare ecosystem and the Pharmaceutical Strategy for Europe. This consideration also owes to the presence of strong local pharmaceutical production capacities including active pharmaceutical ingredients (APIs), as a potential component to ensure the EU's security of supply and the availability of critical medicines, APIs and raw materials.

2. Reforming Ukraine's pharmaceutical regulatory agencies

We support the modernization of regulatory processes, in particular, via the creation of a new single regulatory agency as anticipated by the new Law of Ukraine *on Medicines* #2469-IX adopted 28 July 2022[3]. We suggest that the initial step should be the development and finalization of the concept of the new agency guided by principles of transparency, efficiency and profound consideration for Ukraine's future EU membership conditions. This will enable the selection of the most suitable EU member state agency as an operational example to follow within the technical support project (e.g. the Technical Assistance and Information Exchange Instrument (TAIEX) or Twinning), as anticipated by the Ministry of Health of Ukraine for implementation. Such an alignment is crucial for ensuring the best practices of access to safe, effective and quality medicines.

Furthermore, it is worth taking into account the recommendations within the EU Project by the European Bank for Reconstruction and Development *Advice on Regulatory Improvements in Ukraine's Pharmaceutical Sector*[4] and to extend the project in order to support the practical implementation of its recommendations (phases 3

[2] These include the preparation of a decision to grant EU internal market treatment for the purpose of roaming on public mobile communications networks (link) and the preparations on an Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) for the first three product sectors – products falling in the scope of the machinery, low voltage or electro-magnetic compatibility legislation (link).

[3] It should be noted that transforming the pharmaceutical- (and medical devices) related state bodies' activities into a single state regulatory body is anticipated by the Law of Ukraine *On Medicines* #2469-IX (link) which was adopted by the Verkhovna Rada of Ukraine on July 28th, 2022. It is stipulated now to enter into force 30 months after the end of the martial law. The Law is aimed at approximation of legislation and practices in the pharmaceutical sphere to the EU. However, support is needed to enable the relevant EU practices' enforcement. After its entry into force, it will entail revaluation and renewal of the legal framework, as follows: medicines' authorization, GMP and other GxP ("good practice" quality guidelines and regulations) requirements, bioequivalence, provisions on intellectual property protection, data exclusivity as well as renewal of the plan for Ukraine's joining the EU centralized and decentralized medicine authorization procedures and the EU centralized authorization procedure for CTs.

[4] https://moz.gov.ua/uploads/ckeditor/%D0%B4%D0%BE%D0%BA%D1%83%D0%BC%D0%B5%D0%BD%D1%82%D0%B8/%D0%9F%D0%BB%D0%B0%D0%BD%20%D1%80%D0%BE%D0%B7%D0%B1%D1%83%D0%B4%D0%BE%D0%B2%D0%B8%20%D1%96%D0%BD%D1%81%D1%82%D0%B8%D1%82%D1%83%D1%86%D1%96%D0%B9%D0%BD%D0%BE%D1%97%20%D1%81%D0%BF%D1%80%D0%BE%D0%BC%D0%BE%D0%B6%D0%BD%D0%BE%D1%81%D1%82%D1%96/20190329_InstitutionalCapacityBuildingPlan_UPDATED_ENG.pdf

and 4) in parallel with the Twinning project. This would make it possible to involve the best European experts not only in the assessment and exchange of experience between the agencies but also in the process of preparing the strategy for the creation of the new agency, as well as in the drafting and implementing the relevant regulations.

3. Alignment of regulatory requirements to enable GMP mutual recognition.

We would welcome more engagement and dialogue between the EU member GMP (Good Manufacturing Practices) inspection bodies and the Ukrainian GMP inspection authorities. This will facilitate a closer alignment of relevant GMP standards for Ukraine to get prepared for the future audit requirements. The involvement of both parties could fast track this important area of pharmaceutical regulation. As stated above, the establishment of the new single regulatory agency is to ensure full regulatory and practical compliance with the EU regulations, particularly in the area of GMP. This will create a stronger foundation for mutual recognition of GMP documents between the EU and Ukraine. Facilitation is possible in this respect via the Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) for GMP in medicinal products specifically. In our opinion, the issue is possible to be treated separately from other ACAA related commitments between the EU and Ukraine. Ukrainian inspection bodies' full access to EudraGMDP database is also one of the issues with a potential for current facilitation.

4. Digitalisation

Both Ukraine and the EU are known to have been heavily investing in the digitalisation of the regulatory processes. Harmonizing standards and creating clear processes for manufacturers to submit data to the agency systems is essential for Ukraine. Furthermore, interoperability ought to be in place. We encourage a dialogue on key digital projects such as the electronic common technical document (eCTD), Identification of Medicinal Products (IDMP)/substance, product, organisation and referential (SPOR) data management, and electronic product information (ePI) to enable Ukraine's aligning with the EU standards and processes in view of its future EU accession and upgrade the relevant procedures as much as possible.

5. Counterfeit medicines

We recognise the need for Ukraine to combat counterfeit medicines and support verification system developments. It is fundamental to avoid any duplication of the EU and Ukraine's IT systems to optimize costs. Equally as important is to avoid technical errors (i.e., software/hardware connections of end users) not to undermine the benefits of verification and not to jeopardise the investment performed. Facilitating communication to ensure Ukraine's joining the European Medicines Verification System (EMVS) is vital for its fight against counterfeit medicines. We also see opportunities for the facilitated integration of Ukraine into the EU safety and quality systems, such as EudraVigilance (pharmacovigilance) and Eudra-GxP (quality compliance).

6. Healthcare access

We support the reconstruction of Ukraine's healthcare infrastructure including pharmaceutical manufacturing facilities damaged during the war, as well as the prospective start of new clinical trials and resumption of patient screening within the ongoing ones. We also encourage the development and implementation of new tools to improve patient access to effective medicines, medical devices, which is critical for the healthcare effectiveness. Encouraging Ukraine's participation in the EU National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR) for the best procurement practices and other initiatives dealing with the essential medicine supply to all patients in need is essential. Integration of Ukraine into the EU pharmaceutical industrial policy initiatives such as the Medicines Security Act and the Important Projects of Common European Interest (IPCEI) is highly beneficial.

7. Intellectual property rights (IPR)

We would like to highlight the need to intensify the EU-Ukraine dialogue to ensure Ukraine's legislation approximation to the EU including access to generic and biosimilar medicines after IP protection expiry in line with the current EU law, in particular:

1) There is a need to align the Ukraine's legislation on the Bolar exemption with the EU pharmaceutical legislation. In our opinion, the current (Law *On Medicines* #123/96-BP of 4 April 1996 and general IPR legislation) and future (Law *On Medicines* #2469-IX of 28 July 2022) Ukraine's legislation allows granting marketing authorisation to generic products only if additional obligations are imposed or in exceptional circumstances, and in practice the courts considered marketing authorisation applications as patent infringements. We would strongly recommend an alignment with the language used in art. 10(6) of Directive 2001/83/EC, which specifies that conducting the necessary studies and trials with a view to obtaining a market authorisation and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products. In particular, the unconditional marketing authorisation issue should be considered within the scope of the Bolar exemption. This is a key to ensure legal certainty and timely patient access to generic and biosimilar medicines immediately after expiry of relevant patents. Also, some of current Ukraine's legislative provisions have a link in between the marketing authorization process and the patent rights of the reference product owner, thus representing a clear patent linkage unlike the EU law which does not allow it. Patent linkage has a potential impact on preventing the entry of generic and biosimilar medicinal products to the market immediately after substance patents expire.
2) We would like to underline the need to clarify that the martial law should not extend the patent terms unlike it is in the current Ukraine's legislation. It would ensure the improved access to treatment for patients of Ukraine.
3) In view of the general perspective, there is a need to update the IPR legislation in the pharmaceutical sector in Ukraine to incorporate the amendments under current EU consideration as well as update and align Ukrainian court practice with EU to ensure the due enforcement of IPR including, inter alia, the right to defend the preliminary injunction claims.

As a summary, we do believe that the fast-track of Ukraine's capabilities of EU integration and the follow-up activities will much contribute to the significant improvement of patient access to pharmaceutical products, foster investments in the pharmaceutical R&D and manufacturing and ensure the sustainable supply of pharmaceutical products to both Europe and Ukraine.

We kindly request your support and contribution to the vision as described above and believe it will come true. We take this opportunity to re-affirm our solidarity with the Ukrainian people.

Yours respectfully,

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