President of the European Commission, Ms. Ursula von der Leyen
Executive Vice President for A Europe Fit for the Digital Age, Ms. Margrethe Vestager
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Commissioner for Health and Food safety, Ms. Stella Kyriakides
Commissioner for Internal Market, Mr. Thierry Breton

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OPEN LETTER FROM THE EXECUTIVE COMMITTEE OF MEDICINES FOR EUROPE

Now or never: the EU needs an efficient and effective pharmaceutical strategy to deliver on equitable access and to secure medicines manufacturing and supply chains.

At the German EU Presidency Conference *'For a Healthy Europe'*, our President outlined our industry's call to shape a robust pharmaceutical strategy that delivers for patients and health systems in Europe.

The Corona virus crisis has clearly demonstrated the **key value of the off-patent medicines sector**, which worked day and night to supply hospitals everywhere in Europe with the medicines needed to treat Covid-19 infected patients (between 70% and 90% of ICU medicines were off-patent medicines). Our industry plays a critical role in public health and sustainability by supplying 67% of the dispensed prescription medicines in Europe.

At the same time, **the pandemic has shone a light on long-standing issues** related to the consolidation of pharmaceutical supply chains in Europe and globally and the rising cost of producing in Europe vs. decreasing prices for off-patent medicines. These factors are increasing our vulnerability to supply risks and shortages.

The **first step** should be to assess the reality of medicines manufacturing in Europe relative to our critical needs for medicines. Our industry is deeply rooted in Europe and employs 190,000 people in over 400 manufacturing sites for medicines and active pharmaceutical ingredients (API) and 126 R&D sites located in almost every single EU member state. Europe remains a leading producer of off-patent medicines and of API with around 35% of global API production compared to 25% in India, 33% in China and 12% for the US. Europe can build on its strong manufacturing footprint and on resilience measures to ensure security of supply during the Covid-19 crisis and for the future with a strong industrial policy that encourages investment in manufacturing and making supply chains resilient.

The forthcoming Pharmaceutical Strategy affords an opportunity to ensure security of supply and to strengthen Europe's medicines and API manufacturing while also improving equitable access to medicines. In line with the recent report by the European Parliament[1], **we see five key issues as priorities**:

* Supply security: since the 2009 financial crisis, all EU member states have pursued a strategy of procuring or reimbursing generic medicines at the lowest possible price without consideration for the need for manufacturers to continuously invest in manufacturing resilience and supply security or to adapt to the green and the digital transformation demanded by our society. This has led directly to consolidation and supply risks. In order to encourage more investments in manufacturing and resilience, the Commission

[1] Own initiative report "Shortage of medicines - how to address an emerging problem" – adopted on 17th September 2020.

can work with Member States to reverse this trend by agreeing and adopting **European guidelines for security of supply criteria to ensure that Most Economically Advantageous Tender (MEAT) criteria for medicine tenders is respected in the national procurement practices** and to adjust reimbursement policies for generic and biosimilar medicines.

* Sustainable and accessible pharmaceutical budgets: all EU Member States apply generic and biosimilar medicine policies to increase access to medicines and to keep budgets sustainable. The Pharmaceutical strategy can support Member States by **encouraging** generic and biosimilar medicine uptake immediately **at expiry of patents or exclusivities.** In many markets, the full potential of biosimilars remains untapped. The **EU intellectual property framework needs to be upgraded** in line with the 2015 Single Market Strategy which proposed a harmonisation of Bolar exemption to cover third party API suppliers.

* Making medicines regulation fit for the digital era: the Covid-19 crisis showcased the need for immediate **investments in the digitalisation of the medicines regulatory system** to accelerate the transfer of information between regulatory authorities and industry, to enable regulators to use that information for life-critical policies to prevent, monitor and mitigate shortages of medicines (linking regulatory and supply chain data), to reduce administrative red tape for industry and medicines agencies through regulatory optimisation (telematics) and to accelerate the delivery of critical patient safety information to patients (electronic product information).

* Keep and support manufacturing technology of European interest: as part of the EU Recovery Plan, there should be clear criteria to support investment in critical technology for medicine manufacturing. The criteria should address security of supply and pandemic/crisis planning as well as societal demands to upgrade medicines manufacturing for the environment and for more digital and automated production. The EU can build on its strong medicine manufacturing footprint to enable this transformation for greater security, environmental control and digitalisation.

* Aligning industrial and public health objectives: our industry's cooperation with the EU and Member States avoided a major shortage of emergency medicines when Covid-19 generated the biggest spike in patient demand ever experienced in Europe. This was achieved by tackling the industrial, regulatory (such as ad hoc regulatory flexibilities), budgetary (e.g. avoiding clawback measures) and logistic (closure of borders) barriers to producing and delivering medicines for European patients through action-oriented dialogue between industry and government. The complex challenges for the forthcoming pharmaceutical strategy: accessibility, affordability, innovation and security will require a major commitment from industry and different government departments and agencies which could be steered through a **Pharmaceutical Forum** involving Policy Makers, Regulators, Payers, Industry and other key stakeholders of the pharmaceutical chain, and at expert level, with the continuation of the **EMA/HMA supply chain committee** and participation of the industry in relevant committees, such as the Pharmaceutical Committee or the Health products procurement committee. This should build on the necessary *stability pacts* involving our industry in multi-annual pharmaceutical budget negotiations at national level.

We look forward to an ambitious pharmaceutical strategy proposal from the Commission and are engaged to achieve its core objectives of access, affordability, innovation and security in the interests of European public health.

The Executive Committee of Medicines for Europe
European Association of generic, biosimilar and value added medicines' manufacturers