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Brussels, 18th November 2020

SUBJECT: Call with Medicines for Europe on Covid-19 preparedness and future EU medicine policies

Dear Mr. Vandenberghe,

We would like to thank you for the very constructive meeting with the Medicines for Europe President and Executive members. Generic, biosimilar and valued added medicines, which represent almost 70% of dispensed prescription medicines in Europe, are essential for equitable access and for financial sustainability. Our members directly employ 190,000 people and operate 400 manufacturing and 126 R&D sites in Europe, investing up to 17% of their turnover in R&D.

European policies play an important role for sustainability and encouraging access to generic, biosimilar and value added medicines. As agreed, we would like to share some additional information both on Covid-19 preparedness and future EU policies:

Covid-19 preparedness:

- **European Strategic stockpiling**: should be targeted (based on a risk assessment to determine medicines or therapeutic focus areas) and proportionate (the size of the stockpiling should be defined per product to avoid overstocking waste).
- A **cost-effective stockpiling method should be adopted to absorb unforeseen market surges for a clear list of essential medicines for specific health emergency risks**. Any European reserve should avoid distorting the normal functioning and sustainability of the Internal Market and prevent the wasteful destruction of unused medicines (please find below a description of the UK strategic reserve model and its practical functioning).

- **Facilitate the movement of stock** from one country to another within EU, especially for medicines approved under national procedures (referred to as DCP or MRP medicines – around 90% of medicine registrations in Europe) and avoiding expensive and time consuming re-packaging. Some Nordic countries already enable this flexibility provided a medicines is already approved in another EU market. This simple change could significantly reduce the medicine shortages risks in many EU countries.

Policy priorities for EU pharmaceutical policy:

1. **European coordination** with stakeholders on policy. There should be more dialogue with industry at technical (pharmaceutical committee) and political (High Level Pharmaceutical Forum) levels to design effective policies for equitable access to medicines.

2. **Remove barriers to equitable access**. The EU should remove barriers to the timely access of generic, biosimilar and value added medicines at exclusivity expiry to ensure their widespread use to improve equity of access to essential medicines.

3. **Support innovation in well-established molecules**.
   By establishing a regulatory pathway for value added medicines the EU will improve treatments for patients that struggle with the management chronic and non-communicable diseases, like cancer.

4. **Tackle the root causes of medicines shortages by**:
   - ↳ issuing European security of supply and MEAT guidelines for medicines procurement based on best practice in member states;
   - ↳ rewarding and incentivising supply chain resilience which drive the right level of transparency to enable supply chains to act in the interest of patients;
   - ↳ enhancing a sustainable business environment for the off-patent medicines sector, by promoting the use of generic and biosimilar medicines as cost-effective therapy for many diseases

5. **Support EU leadership in medicines manufacturing by**:
   - ↳ clarifying what is critical for the EU in medicines supply and then conducting a gap analysis of Europe's production capabilities and technologies. For example, does Europe have sufficient sterile or biological medicine production capability for its security?
   - ↳ incentivising investments in green, digital and technological transformation for medicines (bulk and FDF) and active pharmaceutical ingredient (API) production with clear criteria in EU funds and state aid rules;
   - ↳ including medicines security of supply in a new medicines trade agenda – notably to avoid protectionist measures in the US and mitigate export restrictions from Asia in the future.

6. **Digital investments** are required for a **responsive medicines regulatory system**, therefore:
   - ↳ To improve the efficiency the regulatory agencies, the EU should invest in a **digital regulatory network** (**telematics**) for medicines based on harmonisation of requirements and system interoperability.
   - ↳ the digital framework should increase regulatory efficiency, progress medicines shortage monitoring and mitigation, improve information to patients (ex: **e-leaflets**) and advance the functioning of the Internal market.

7. **Ensure that intellectual property supports innovation but does not unduly restrict access to medicine,** The upcoming IP action plan and pharmaceutical strategy should:
    - ensure healthy competition at IP expiry by banning patent linkage;
    - harmonise the Bolar exemption to encourage investment in R&D and manufacturing in Europe;
    - ensure that any changes to the EU Supplementary Protection Certificate (SPC) do not unduly delay access to medicine in Eastern Europe;
    - address European Patent Office (EPO) dysfunctions that unnecessarily delay access to medicine.

We thank you again for your kind attention to our key issues. A detailed supportive explanation of Medicines for Europe policy recommendations is set out in Annex to this letter (please find it below).

We remain at your disposal for any further information you may need.

Yours sincerely,

Adrian van den Hoven
Director General
Medicines for Europe

Annex

UK strategic reserve

From 2009 to 2019 the UK Government held a stockpile of approximately 400 essential medicines in the Essential Medicines Buffer Stock ("EMBS"). The list of medicines was drawn up by the DHSE, in conjunction with the NHS, and was designed to be ones most key to prevent death or admission to hospital.

This buffer stockpile was tendered under the following conditions:

- Awarded companies supplied stocks of medicines for one or more of approximately 400 lots of the essential/required medicines, which were purchased by the Department of Health.
- The awarded company was required to store the stocks of Department of Health-owned medicines in the UK over the duration of the tender (4 or 5 years).
- The awarded company was required to maintain a minimum shelf life for the relevant Department of Health-owned stock by releasing stock into the supply chain and replenishing with new stock.
- In the event of a supply shortage caused by a pandemic or other emergency, the company was required to release stocks into the supply chain for supply to UK customers and for delivery to the NHS, with the object of lessening any shortages of such medicines, and the contractor was required to purchase such stocks from the Department of Health for the purpose of such release.

Covid-19 preparedness: European strategic stockpiling of medicines

With Covid-19, Member States introduced many counterproductive stockpiling measures that undermined industry supply chains, threatened patient access and undermined EU solidarity. Disproportionate stockpiling requirements post-Covid-19 at national and/or EU level would further increase market consolidation and supply risks.

We recognise the positive role that emergency reserves can play in crisis situations provided they are proportionate, based on industry recommendations for good stock management, aligned with the principle of EU solidarity and economically sustainable. We support Commission policies to tackle national hoarding and other disproportionate restrictions to the free movement of goods. Regarding a possible future EU medicines reserve, we encourage the Commission to carefully design this policy together with medicine manufacturers. In particular, it would be important to:

- Agree on a list of essential medicines for the reserve, based on identified needs in a risk assessment.
- Establish a transparent process to purchase these medicines, identifying who will place orders, purchase the goods, hold the reserve, call off deliveries and under which conditions these medicines can be used. This process should clarify the tasks to be managed at country level and at EU Level involving the relevant supply chain actors.
- Establish clear responsibility for the costs associated with acquisition, distribution, storage and maintenance of these medicines. Maintenance rules should take account of product characteristics (e.g. shelf-life) as well as ownership of the financial risks of e.g. obsolescence and destruction.
- Reduce the regulatory complexity of managing a reserve of products which may have national licences (MRP/DCP) and labelling requirements. The EU regulatory system should be adapted to reduce this complexity (i.e. digital leaflets, simplified labelling, FMD serialisation issues).
- Avoid the wasteful destruction of medicines (which would only be needed in an emergency) by using best practice from across Europe regarding rolling reserves. As illustrated during our meeting, we enclose a cost-effective method used by the United Kingdom that could serve as a model of a future EU reserve.
- Although not directly linked, the EU joint procurement of ICU medicines also offers some future lessons. Notably, that the security of supply aspects should be critically reviewed in a dialogue with industry around issues such as double counting, improper quantification, lack of exclusivity clause and commitment to purchase, short submission deadlines, long response delays, among others.
- Close collaboration between authorities and industry to ensure the most efficient reserve definition based on supply chain parameters (part of Risk Assessment process by product / therapeutic area).

Policy priorities for EU pharmaceutical policy

1. **Dialogue with Industry**

During Covid-19, the Commission-Industry dialogue was critical to address the pandemic, avoid shortages and maintain EU solidarity. Going forward, the Commission should institutionalise this dialogue to tackle major pharmaceutical policy challenges and to ensure better implementation of policy across the whole EU.

2. **To deliver better access to medicines, there should be targeted measures for generic, biosimilar and value added medicines use in EU policies**

The Covid-19 outbreak showed the key role that generic, biosimilar and value added medicines play in ensuring equitable access to treatment and the sustainability of healthcare systems. The EU Pharmaceutical strategy

should include an **active policy of legislative and non-legislative measures to encourage greater access to and use of generic, biosimilar and value added medicines**. This should promote a sustainable approach to the life-cycle of off-patent medicinal products: stimulating the development, authorisation, manufacturing and innovation in known molecules.

The EU Pharmaceutical strategy should recognise that there are still hundreds of thousands of European patients without access to essential medicines (including life-saving medicines for cancer) even though less expensive generic and biosimilar medicines are available. The most effective tool for equitable access will be to remove barriers to access. For example, the strategy should ban evergreening practices and stimulate uptake where competition is weak such as biosimilar medicine markets. The evidence shows that biosimilar competition and use only occurs where it is encouraged by uptake measures to share the benefits with the healthcare community. This absence of competition leads to wasteful spending and to significantly lower patient access to biopharmaceuticals. This is evident in CEE countries in areas like cancer but also in Western EU markets for products with no uptake measures.

The strategy should also recognise value added medicines innovation which is needed to improve treatments for patient with chronic and non-communicable diseases, like cancer (e.g. improvement of adherence or possible reduction in hospital visits through reformulation or combination with digital delivery), deliver on high unmet medical need (e.g. repurposing known medicines for Covid-19 treatments) at sustainable cost for health systems. The strategy should encourage this innovation and the necessary R&D investments required to deliver significant additional benefits for public health.

3. **Reforming tender systems to support supply security and long-term competition**

The pharmaceutical strategy will tackle **medicine shortages**. There is abundant evidence[1] that points to the economic factors driving industry consolidation in the off-patent sector – thereby increasing supply risks. We anticipate that the Commission's investigations into the root causes of shortages will confirm this.

The current economic model for off-patent medicines in Europe does not reward investments in security of supply. Since the 2009 financial crisis, all EU member states have pursued a strategy of procuring generic medicines at the lowest possible price without consideration of the need 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 of manufacturing and supply risks. **To encourage more investments in manufacturing and resilience, the Commission can work with Member States to reverse this trend by agreeing and adopting European guidelines for medicines procurement for long term sustainability and workable Most Economically Advantageous Tender (MEAT) criteria for medicine tenders.** The EU can also benefit from best national procurement practices to adjust the number of tender winners to allow multiple manufacturers to continue supplying each market. Some issues that should be address include: Automatic reopening of tenders upon market entry of generic/biosimilar, multi-winner tenders, volume and timing commitments within framework agreements, Environmental criteria, Product characteristics, supply chain resilience, dual sourcing. They are outlined in the enclosed position paper.
In addition, EU guidelines should encourage procurers of medicine to investigate *abnormally low tender bids* as per Article 69 of Directive 2014/24/EU and the Guidance on the participation of third country bidders and goods in the EU procurement market by the European Commission.

[1] Reading list | Medicines shortages ;
The Economist intelligence unit report "addressing medicine shortages in Europe";

Joint procurement of generic medicines provides questionable additional value to patients, healthcare professionals or payers. Our experience with the ICU medicines joint procurement shows that joint procurement only adds complexity when applied to generic medicines that frequently have national marketing authorisations. Thus, the time necessary to prepare and enact a joint procurement that takes all these into consideration greatly exceeds that of national (or regional) procurers and thus nullifies the very security objectives being pursued under EU law.

If the European Union continues with joint procurement in future crisis situations, the criteria cited above for national procurement should be included. Furthermore, as already mentioned in our letter on "Second wave pandemic preparedness: procurement principles" it is crucial to take into account:

- Coordination and clarity between the European Commission, national governments, regulatory authorities and the industry. Indeed, it is important to know if national authorities want to use this procurement process as opposed to other national contracts currently in place or to be launched in the near future. In some cases, relevant government agencies were not even aware of the joint tender to which the country had signed up.
- Inventory transparency: to plan stocks, industry needs more transparency on the available medicine stocks that governments have either in state warehouses or in wholesaler warehouses for a second or third wave risk. We are aware that there are, for example, large volumes of compounded medicines with very short stability periods (likely too short to serve a second or third wave).
- Standardised epidemiological, hospitalisation and intensive care occupancy data: all member states should share standardised data to allow accurate modelling of the disease's spread. The ECDC should collect and share the data promptly with industry.
- Firm undertaking by member state buyers: without purchase commitments, joint procurement can lock in stock that may never be used for patients or may disincentivise companies from participating in the market. In addition, the joint procurement of ICU medicines launched during the summer periodhas, in some cases, added further uncertainty as some member states have deliberately chosen to launch two tenders simultaneously – the joint procurement and a national procurement procedure.
- Appropriate procurement timelines: given the emergency of the situation, the procurement process and manufacturing lead times should be included.

The pharmaceutical market is highly regulated, with each member state implementing strong price controls. For generic and biosimilar medicines in particular, price regulation frequently includes some form of reference pricing to prices of direct competitors in the same market (internal reference pricing) or to prices in other markets (external reference pricing). These practices, coupled with government dictated price cuts create a downward price pressure that does not allow manufacturers to adjust prices to reflect regulatory costs, changes in the cost of goods, or other cost factors. This contributes to consolidation of the market and undermines supply security.

4. Support EU leadership in API and medicines manufacturing to ensure security of supply and competitiveness at global level

EU **API and** medicine manufacturers are important contributors to a global medicines supply chain. While we support measures to encourage manufacturing in Europe, we believe in open markets. The EU medicines manufacturing strategy should focus on and ensure manufacturing security and security of the supply chain, both on API and medicines manufacturing, rather than on small subsets of molecules or API by:

a. Defining a clear list of objectives for the security of medicines supply and manufacturing.

b. Assessing/mapping the strengths and weaknesses of the European API and medicines manufacturing footprint. The focus should be on **critical classes of medicines needed rather than single molecules, the technological capabilities and adaptability of our factories** and the central supply chain for Europe as a whole (not done member state by member state which increases industry effort for no gain).

c. While rejecting national protectionism, the EU should introduce **strong economic incentives** (**for both medicines and active pharmaceutical ingredient manufacturing** in Europe as well as **an expanded scope and harmonised Bolar exemption**, whose fragmentation forces investments in API production outside of Europe.

d. **Increase the resilience of manufacturing and supply chains** by:
   a. Integrating manufacturing and resilience criteria in procurement/purchasing – to change the lowest price policies of payers.
   b. Increasing cooperation with trade partners on GMP mutual recognition, environmental and other regulatory standards to create a level playing field while increasing resources for inspections in third countries.
   c. Adapting the EU trade agenda to focus on accessible, secure and open medicines supplies

5. Making medicines regulation fit for the digital era by implementing a digital regulatory infrastructure

We support the policy of "*a Europe Fit for the Digital Age*", because experience shows that the EU has been extremely slow implementing digital projects in pharmaceuticals. We first need the **digitalisation of the regulatory system so that medicines data can be collected EU-wide**. This requires the digital interconnection of all national medicine agencies with the European Medicines Agency (EMA) and the connection to already existing medicines data bases like the European medicines verification system (EMVS) to enable the EU and members states to collect more accurate information to proactively manage critical shortage situations.

The Covid-19 crisis showcased the need for immediate investments in the digitalisation of the medicines regulatory framework (regulatory authorities are not yet interconnected and some of them still share information by paper). There has been some regulatory flexibility demonstrated by Health Authorities as a result of the pandemic crisis in a move towards acceptance of electronic documentation/ signatures, however recently some Health Authorities have reverted to requesting original signature/paper copies, notarised documents. The pandemic has highlighted the weaknesses/inefficiencies/administrative burden in the current regulatory system and the urgent need to streamline regulatory processes so that regulatory data is only submitted once and is readily accessible both by the EMA and National Competent Authorities.

A digital medicines regulatory network should:

- accelerate the transfer of harmonised information between regulatory authorities and industry,
- enable regulators to use information for life-critical policies to prevent, monitor and mitigate shortages of medicines (linking regulatory and supply chain data),
- reduce administrative red tape for industry and medicines agencies through regulatory optimisation (telematics and variations to MA systems)
- accelerate the delivery of critical safety information to patients (e-leaflets/electronic product information) which would also reduce the overall environmental footprint of the industry.

- Increase regulatory flexibility to respond in emergency situations such as rapid authorisation procedures as was required during Covid-19

The Commission can speed up the digitalisation of the EU Regulatory system by providing some EU funding to member state medicine agencies to invest in an EU-wide digital regulatory system as small budgetary constraints have been a major factor of delay. Any funding should be provided with clear obligations to deliver IT projects in a timely and efficient manner based on a coherent project-management plan.

6. Intellectual Property Action Plan

Medicines for Europe looks forward to an Intellectual Property (IP) Action Plan for a well-functioning IP system in Europe to stimulate innovation through incentives and competition. The IP system should be fine-tuned to ensure the quality of patent granting, avoid fragmentation or the risks that regulatory standards collide with IP rules. These IP specific aspects are fully described in a Medicines for Europe White Paper "Anatomy of a failure to launch: A review of barriers to generic and biosimilar entry and the use of competition law", the paper explores the role of inappropriate use of IP in blocking access to generic and biosimilar medicines that you can find also attached to this letter.

To stimulate immediate competition in the off-patent market, the IP Action Plan should include the following fundamental elements:

To tackle fragmentation in the IP system:

- Harmonising and enlarging the Bolar exemption as posited in the 2015 Single Market Strategy
- If proposed, careful calibration of a Unitary SPC to avoid any unintended effects on access to medicines
- Ban all forms of Patent Linkage in EU legislation
- Ensure consistent EU application of IP Enforcement Directive on Damages for generic/biosimilar companies where off-patent competition is delayed.

To increase quality & accountability of the IP system at the European Patent Office (EPO):

- Raise quality (vs. quantity) of patents granted and granting procedures;
- Change EPO internal rules to remove the abuses of divisional patents;
- Ensure political accountability of patent granting bodies – especially the EPO.