To: [redacted]@minvws.nl]
From: [redacted]
Sent: Tue 7/28/2020 9:43:32 AM
Subject: FW: Medicines for Europe feedbacks on the Pharmaceutical Strategy
Received: Tue 7/28/2020 9:43:33 AM
Medicines for Europe-Policy Roadmap for Medicines ManufacturingLeadership July 2020.pdf
Medicines for Europe-Lessons learned from COVID19 policy paper.pdf

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Van: [redacted]@minbuza.nl>
Verzonden: maandag 27 juli 2020 14:38
Aan: [redacted]@minvws.nl>
Onderwerp: FW: Medicines for Europe feedbacks on the Pharmaceutical Strategy
Urgentie: Hoog

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From: [redacted]@medicinesforeurope.com>
Sent: dinsdag 7 juli 2020 11:00
To [redacted]@medicinesforeurope.com>
Subject: Medicines for Europe feedbacks on the Pharmaceutical Strategy
Importance: High

medicines for europe
better access. better health.

Subject	Medicines for Europe feedbacks on the Roadmap on the pharmaceutical strategy "safe and affordable medicines (new EU strategy)"
Informed	Health responsible - Permanent Representations to the European Union
Attachements	• Lessons leaned from Covid-19 • Policy Roadmap for Medicines Manufacturing Leadership

Medicines for Europe believes that to deliver **equitable patient access to medicines** and contribute to **healthcare system sustainability,** the pharmaceutical strategy should prioritise **sustainable economic, regulatory and industrial off patent medicines policies. Generic, biosimilar and value added medicines (almost 70% of EU prescription medicines) are critical to access and to public health**, as demonstrated by our industry's role in dramatically increasing the supply of medicines for Covid-19. To align public health and industrial policy agendas, the strategy will need to be based on a structured dialogue between industry, supply chain actors and the EU Institutions and national authorities. Paying lip service to transparency will not suffice.

A sound functioning of the internal market can be achieved by promoting healthy competition, removing barriers that delay off-patent medicines market entry at loss of exclusivity, allowing for rapid and sustainable uptake of medicines with robust policy frameworks. For biosimilar medicines, efforts should target countries or segments where biosimilar uptake is low. In fields of high unmet need such as orphan diseases, the removal barriers to follow-on competition, the need to harmonised rules such as the Bolar Directive and an EU ban on patent linkage are essential to grant access to therapies for more patients.

To reinforce *the mechanisms for cooperation and coordination between regulatory authorities,* it should boost the **optimisation of regulatory system to focus finite resources on access. Concretely, this includes** the implementation of the European Network telematic strategy; the reduction of redundant administration (amend variations regulation); shifting resources to essential tasks such as regulatory oversight and plant inspections; the implementation of electronic product information and the simplification multilingual packs.

Regarding the **availability of medicines**, the EU should address the root causes of medicines shortages, which are economic (price-only procurement criteria; reference pricing policies; clawback policies; arbitrary price-cuts), high regulatory burden (Falsified Medicines Directive implementation; Brexit), unforeseen surges in demand (as experienced during COVID-19). **By securing existing and encouraging new investments in off-patent medicine manufacturing,** EU policies should cover public sustainable procurement practices, pharmaceutical regulation, new pricing models and reimbursement (via Transparency Directive) and **state aid** should secure and incentivise investment in supply reliability and in high-technology medicines manufacturing in Europe at national level while stimulating multi-source medicine competition at expiry of exclusivities.

The COVID-19 outbreak has demonstrated the **resilience of the European off-patent medicines industry which was able to massively scale up supply to address demand surges.** Therefore, the strategy should **support the global competitiveness of the** industry by building on existing pharmaceutical manufacturing capacity (over 400 off-patent medicines manufacturing sites in EU) to further increase security and resilience of supply. It should also create strong incentives for finished products and API in Europe while rejecting national protectionism that would undermine the Internal Market and European solidarity. Supply chain resilience and regulatory cooperation should also be part of a **new medicines trade agenda** based on security, access and mutual openness with key trading partners. Advancing **single global development** of generic and biosimilar medicines is also of critical importance. Finally, the strategy should also recognise value added medicines innovation which is needed to improve treatments for patient with chronic and non-communicable (i.e. cancer) diseases, deliver on high unmet medical need (e.g. repurposing for Covid-19 treatments) at sustainable cost for health systems. The strategy should lay the foundation to sustain this innovation for public health.

Please find enclosed two policy documents that Medicines for Europe has developed that are the support for our feedbacks to the Pharmaceutical strategy Roadmap:

* **Medicines for Europe Lessons Learned from Covid-19 policy paper**. We believe that the COVID-19 outbreak in Europe has catalysed some long-standing issues in the functioning of pharmaceutical policy, as well as the impact this can have on patient access and hospital and pharmacy supply. These lessons should be included in the upcoming pharmaceutical strategy.
* **Policy Roadmap for Medicines Manufacturing Leadership** that includes short, medium and long term policies for a stronger and resilient medicines and active pharmaceutical ingredient manufacturing ecosystem.

You can also find our feedbacks directly on the European Commission website.

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

I wish you a very nice day,

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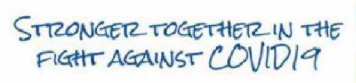

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Transparency register: (10)(2e)
medicines for europe
