

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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STRONGER TOGETHER IN THE
FIGHT AGAINST COVID-19



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