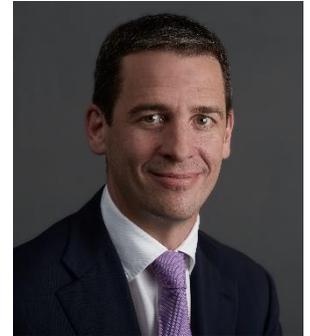


Statement from the President

Now or never: pragmatism & ambition needed in EU pharma strategy to deliver on Europe's medicines manufacturing

Medicines for Europe is ready with realistic policy proposals to secure manufacturing resilience and supply for patients across Europe, says President Christoph Stoller



Berlin, 07 October 2020, speaking at ['For a Healthy Europe'](#), a ProGenerika-German EU Presidency event

The upcoming EU pharmaceutical strategy provides a one of a kind opportunity to strengthen Europe's role as a global player for medicines manufacturing. The COVID-19 crisis has shone a light on a long-standing issue: the pharmaceutical supply chain is increasingly consolidated, and Europe is gradually losing its pharmaceutical productions, opening up areas of vulnerability which leads in severe cases to shortages. This cannot continue, and solutions must be found.

The first step must be to assess the reality of medicines manufacturing in Europe. Across Europe, our industry has manufacturing sites, working day and night, to produce the essential ingredients and finished products needed to make the medicines in our cabinets, pharmacies and in our hospitals.

In fact, the off-patent medicines sector can count on 190,000 people at over 400 manufacturing and 126 R&D sites in Europe, developing and manufacturing the medicines that patients across Europe needs. Additionally, Europe still accounts for around 35% of API worldwide production (25% India, 33% China, 12%US)¹. Nevertheless, the sector has been consolidated over time and various aspects of the supply chain have become globalised as a result of sustainability challenges faced by our industry.

But medicines are not like any other commodity. Disruptions in global supply have a much more profound impact on people's lives than other goods. In that sense, we broadly support the EU's vision for securing supply and strengthening medicines manufacturing in Europe through its upcoming pharmaceutical strategy. What concerns Medicines for Europe members is that we take this unique moment to put in place the right solutions that will make a tangible and systemic difference for the long term.

As the association representing the medicines manufacturers who provide for almost 70% of dispensed medicines in Europe, Medicines for Europe has defined where action is needed to help achieve this goal:

- **First** – Healthcare systems' unsustainable preference for the lowest cost generic option without regard for companies' investments to secure supply or pursue Europe's key transformative priorities like the Green agenda, is playing against the ambition to secure manufacturing in Europe and therefore a more resilient supply chain. This must change by reforming tender policies and

¹ Data sources: Charles River Associates and GDUFA

designing new pricing models which encourage investments in security of supply and manufacturing resilience, covering the whole value chain from APIs to finished products.

- **Second** – Use the power of digitalisation and telematics to create regulatory environment which is flexible enough to ensure fast transfers of information between the industry and regulators and to approve fast shipment of medicines between member states to address shortages;
- **Third** – Upgrading the single market IP framework by implementing measures such as a broad Bolar exemption which extends to third party API suppliers;
- **Finally**, and leveraging the COVID19 lessons learned, we need at European Level a platform where policy makers, payers, regulators, industry and other actors of the pharmaceutical supply chain can meet regularly to develop and implement sustainable policy reforms, and not a talking shop, so that patients get the medicines they need.

If one positive has come from the COVID-19 crisis, it has been the power of collaboration. When faced with an urgent crisis, industry and Governments worked together to manage the risk and reduce the impact. This should not be confined to crises only. Building manufacturing capacity in Europe is a long term goal, and one which cannot be accomplished by any one actor alone. At Medicines for Europe, we are ready to contribute to an EU pharma strategy that works, that makes sense, and that delivers for patients and health systems in Europe. It's now or never!

- Christoph Stoller

President, Medicines for Europe (Teva)

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.