

# Time for the EU to take steps: a medicines security act is needed for health security

Brussels, 02 October 2023

The off-patent medicines industry provides 70% of medicines dispensed to patients in Europe covering over 80% of therapy areas. Generic, biosimilar and value added medicines make treatment options affordable, accessible, and available, so that patients can best manage their disease. These medicines also played a pivotal role during the covid outbreak, where between 70% and 90% of ICU medicines were off patent.

As highlighted in the “[Resilient EU2030](#)” report, recently published by the Spanish Presidency of the Council of the EU, the objective of the European Council meeting on 06 October is to strengthen supply chains, manufacturing capacity and ultimately, open strategic autonomy in the field of off patent medicines and API. Medicines for Europe and its members are natural partners who share these objectives and support the creation of a Medicines Security Act – which echoes the [Critical Medicines Act](#) called for by Member States - to deliver on this vision.

For it to be successful, Europe needs:

- Market and **procurement reform** that values security of medicines supply to prevent consolidation and avoid dependencies from other territories.
- **Investment** from EU funds and State Aid **in new manufacturing processes** that are more green and secure for essential medicines and API.
- **Digitalisation of the regulatory system** by using new and existing databases, such as the EU serialisation system. This will improve our ability to predict shortages and enable solidarity across Member States in managing those that do occur.
- A **clear IP system** that encourages day-1 launch of off-patent medicines which will prevent the forced delocalisation of off-patent medicines development and manufacturing. This is key for biosimilar medicines, where Europe is a pioneer and where there is potential to increase equitable patient access to medicines.
- **More cooperation** with major international manufacturing partners such as the US, India, and others.

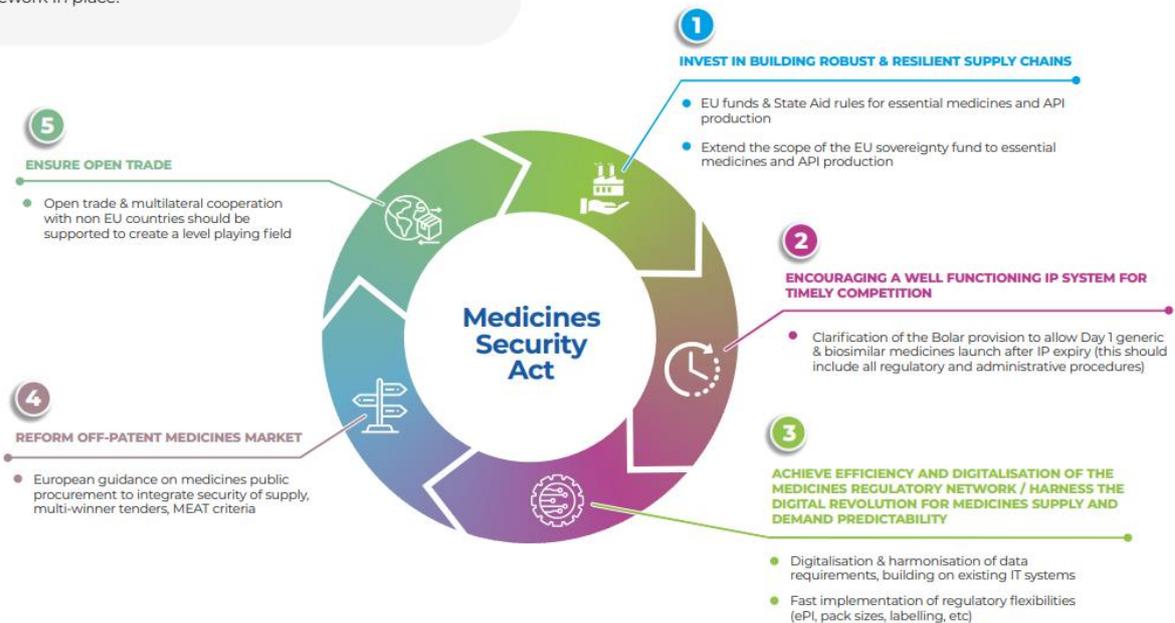
Commenting ahead of the European Council meeting and ahead of the upcoming European Commission communication on the availability of medicines, **Medicines for Europe President Elisabeth Stampa** said “*The discussion at the European Council could not be more timely. Increasing investment in API and medicines manufacturing is a completely aligned priority between EU heads of State and Medicines for Europe. My hope is to see actions on a concrete medicines security act, which, along with the revision of the EU pharmaceutical legislation, will support equitable access to and a more secure supply of off patent medicines, for the millions of patients who rely on them.*”

## Resource hub

Medicines for Europe proposal for a Medicines Security Act: [https://www.medicinesforeurope.com/wp-content/uploads/2023/05/Medicines-Security-Act-Draft\\_-final\\_v2.pdf](https://www.medicinesforeurope.com/wp-content/uploads/2023/05/Medicines-Security-Act-Draft_-final_v2.pdf)

## European Medicines Security Act

The EU's off-patent medicines manufacturers are committed to providing equitable access to essential medicines in Europe. For that, they need a favourable and sustainable policy framework in place.



## 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](http://www.medicinesforeurope.com) and on Twitter @medicinesforEU.