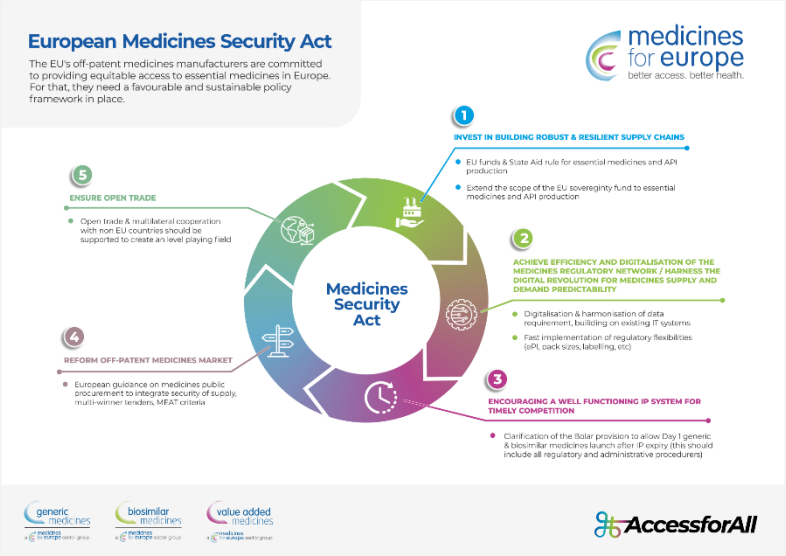
TOWARDS A EUROPEAN MEDICINES SECURITY ACT
to achieve open strategic autonomy in healthcare

Generic, biosimilar and value-added medicines are the backbone of equitable access and sustainable health systems in the European Union. Off-patent manufacturers supply over 70% of all medicines in Europe covering 80% of therapeutic areas. Between 70% and 90% of Covid-19 Intensive Care Unit (ICU) medicines were off-patent medicines. The industry employs over 190.000 people across Europe.



Medicines for Europe fully supports the EU's aim for **open strategic autonomy in healthcare** as well as the goal to make medicines affordable and available while delivering equitable access for all patients across Europe, as stated in the November 2020 European Pharmaceutical Strategy [1] and confirmed in April 2021 by the updated Industrial Strategy[2]. Despite the political commitment from EU leaders and institutions on medicines and active pharmaceutical ingredient (API) security, the European Commission has supported all 6 critical areas of dependencies identified by the updated industrial strategy (hydrogen, chips, raw materials and so on) except for essential medicines and APIs.

Medicines for Europe is calling on the European Commission to urgently adopt a new European **Medicines Security Act** to achieve European open strategic autonomy in healthcare to deliver equitable **access to high-quality, safe, effective and affordable medicines and APIs.**

The Act shall be based on five pillars:

1. Building a robust and resilient supply chain for essential medicines through **investments in EU-based manufacturing in order to reduce EU dependency on third-country manufacturing capacities**.

[1] Pharmaceutical Strategy for Europe
[2] Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery

2. Delivering affordable, equitable and fast access to medicines by ensuring a well-functioning **intellectual property (IP) system that encourages timely entry and an overall competitive environment for generic and biosimilar manufacturers**.
3. Achieving efficiency and digitalisation in the Medicines Regulatory Network by ensuring availability of essential medicines for all through the **adoption of short, medium, and long-term measures to prevent and mitigate the impact of medicines shortages in a sustainable manner**.
4. **Reforming broken off-patent medicine markets** by integrating supply security **into national policies** to prevent medicines shortages.
5. **Ensuring open trade and cooperation with non-EU countries.**

1. BUILDING A ROBUST AND RESILIENT SUPPLY CHAIN FOR APIS AND ESSENTIAL MEDICINES THROUGH INVESTMENT IN EU-BASED MANUFACTURING.

Covid 19 and the war in Ukraine have also highlighted fragilities in the European API and medicines supply chains and the need to remain competitive with non-European Countries. The staff working document of the EC structured dialogue on the security of medicines supply[3] recognised that when trade disruptions and unanticipated demand surges threaten the supply of critical medicines or their raw and packaging materials, and APIs, the existence of sufficient EU manufacturing capacity can contribute to reducing supply vulnerabilities and ensuring supply security. Several political calls have been made to stress the need for the sustainable European production of affordable medicines and building production capacity for critical products to respond to health crises (Versailles Declaration, Informal meeting of the Heads of State or Government, 10-11 March 2022[4] and the recent call for action by Health Ministers on the occasion of the EPSCO Council meeting on14 March 2023).

Investment in manufacturing technology (greening, digital, process technology, automation) and in production is needed to enable EU manufacturers to upgrade their technology to compete and to meet societal expectations for security, value-added innovation, and the environment and, at the same time, to ensure resilient medicines supply chains in case of a major crisis or emergency. To achieve this, **EU funds and State aid rules should be modified to include off-patent medicines and the API industry**, also by **extending the scope of the upcoming European sovereignty fund** and **creating new dedicated investment mechanisms for API, intermediaries, and finished products through DG HERA**. As a body in charge of scoping the API production capacities EU, DG HERA should have an important role in defining the distribution of investment support within European funding programs.

We additionally see a general shortage of skilled labour across Europe which is impacting the industry's ability to expand production. Support for closer links between education and the pharmaceutical sector to address these shortages is needed, with a particular focus on the

[3] Staff Working Document on Vulnerabilities of the global supply chains of medicines – Structured Dialogue on the security of medicines supply.
[4] Versailles Declaration, Informal meeting of the Heads of State or Government, 10-11 March 2022

environmental transition, the skills essential for quality requirements in the sector, and digitalisation automation and process automation.

2. DELIVERING AFFORDABLE, EQUITABLE AND TIMELY ACCESS TO MEDICINES BY ENSURING A WELL-FUNCTIONING INTELLECTUAL PROPERTY (IP) SYSTEM THAT ENCOURAGES TIMELY ENTRY AND AN OVERALL COMPETITIVE ENVIRONMENT FOR GENERIC AND BIOSIMILAR MANUFACTURERS.

The current European Intellectual Property System is conceived to stimulate innovation while ensuring timely competition. As stated in the 2015 Single Market Strategy, a **clarification of the Bolar exemption**[5] (part of the general pharmaceutical legislation) is a critical component to encourage generic and biosimilar timely competition. Therefore, it should be clarified that off-patent developers can plan and execute all aspects of the regulatory approval and administrative requirements (e.g. marketing authorisation, P&R listing, tender bids) for Day-1 of expiry and that API producers can supply and export for the purpose of seeking MA and for R&D purposes to encourage investment in EU APIs.

3. ACHIEVING EFFICIENCY AND DIGITALISATION OF THE MEDICINES REGULATORY NETWORK BY ENSURING THE AVAILABILITY OF ESSENTIAL MEDICINES FOR ALL THROUGH THE ADOPTION OF SHORT, MEDIUM AND LONG-TERM MEASURES TO PREVENT AND MITIGATE THE IMPACT OF MEDICINES SHORTAGES IN A SUSTAINABLE MANNER.

The problem of medicines shortages needs to be addressed at its core through effective monitoring of stockouts which lead to market concentration and decrease the competitiveness of generic actors.
To address this, we need:

- **To allow shortage monitoring through greater digitalisation and harmonisation of data requirements via an alignment between the EMA, National Competent Authorities (NCAs) and HERA to develop interoperable IT systems. At the same time, it is fundamental to build on existing data,** such as the European Medicines Verification System (EMVS) created with the Falsified Medicines Directive, in order to improve supply chain transparency and to enable pre-emptive actions by giving a supply/availability forecast of several weeks to the authorities (the ECDC is only able to forecast a maximum of 2 weeks ahead and this is not enough time for manufacturers to plan their supply chain).
- To achieve regulatory efficiency to facilitate the flow of products across EU markets by replacing paper leaflets with electronic product information (and delivering environmental benefits), harmonisation of pack sizes and labelling requirements, allowing marketing authorisation holders the same flexibilities as parallel traders to move products in a shortage, enabling efficient RUPs and fast-track API changes. The digitalisation of Patient Information Leaflets (PIL) will additionally facilitate faster response to stockouts inflicted by regulatory information changes or supply constraints e.g., pandemics.

[5] Medicines for Europe factsheet on Bolar exemption.

4. REFORM BROKEN GENERIC MEDICINE MARKETS BY INTEGRATING SUPPLY SECURITY INTO NATIONAL POLICIES TO PREVENT MEDICINES SHORTAGES.

As pointed out in the recent European Commission's studies on medicines shortages (Technopolis) the structural root cause of shortages of medicines is economic.
The Medicines Security Act would seek to prevent medicine shortages by learning from successful policies in countries such as Canada[6] and Australia[7] where they have introduced security of supply into their generic medicine market policies.
In recent years, European governments have designed pricing and reimbursement rules and procurement practices that aim to secure the lowest price possible. A downward spiral that is a result of applying lowest-price referencing, mandatory price reductions, clawback taxes, procurement price ceilings and many other tools, has jeopardised the sustainability of supply chains and security of supply.
We call on the Member States to revise existing pricing policies to ensure the healthy competitiveness and economic viability of generic medicines in Europe.
The study on best practices in public procurement of medicines (Gesundheit Österreich GmbH) confirms that the majority of tenders are awarded on the basis of lowest price-only, and that there is potential to use more MEAT criteria that would support more strategic procurement. A **comprehensive medicines procurement reform** is needed, with a strong focus on incorporating requirements for more diversified, multi-winner tenders and inclusion of MEAT criteria, to reward companies that invest in the twin-green and digital - transition, and security of supply. **Medicines for Europe calls on the European Commission to support Member States by issuing EU legal medicines procurement guidance on how to implement these practices into medicines procurement.**

5. ENSURING OPEN TRADE AND COOPERATION WITH NON-EU COUNTRIES.

The Covid-19 pandemic has confirmed the negative impact of protectionist and uncoordinated responses to health crises on critical global supply chains and equitable access to medicines. The European Union should remain a strong advocate of open trade and multilateral cooperation, while taking an assertive approach when necessary to combat unfair practices and ensure a level playing field, in line with the Trade Strategy adopted in 2021.

Limiting export restrictions and reducing trade barriers for medicines and APIs, increasing regulatory harmonisation through a comprehensive mutual recognition agreement and single development programmes and ensuring a good balance between intellectual property, competition and access to medicines in trade negotiations will foster better access to generic and biosimilar medicines, strengthen global supply chains and create new growth opportunities for EU manufacturers.

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[6] Medicines for Europe CreativCeutical study on "New pricing models for generic medicines (infographic & full study).
[7] Landmark new medicines agreements to bring significant benefits for Australian patients, Department of Health and Aged Care, Australia