Medicines are manufactured for patients not for stockpiles: the EU must act!

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To tackle shortages, some EU Member States (France, Germany, Czech Republic, Austria, Greece, Denmark and Poland) are increasingly instructing medicine manufacturers to stockpile, undermining EU solidarity and counter-intuitively exacerbating the risk of shortages. Stockpiling mandates prevent manufacturers from reallocating medicines to another EU country to solve a shortage. They also undermine the economic viability of many inexpensive generic medicines by adding warehouse costs and increasing the risk of wasteful stock write-offs. This contributes to an already consolidated market with fewer and fewer companies marketing Europe's essential medicines.[1]

In practice, national stockpiles undermine access to essential medicines in Europe. A six-month stockpile of antibiotic medicines in Germany would equate to one-quarter of the EU supply. This six-month worth of stock can equate to the combined supply needed for eleven smaller EU member states[2].

The Health Emergency and Response Authority (HERA) has announced a new EU reserve strategy which must tackle this issue urgently. Medicines for Europe outlines its vision for this policy in its position paper on stockpiling, which states that:

- The European Commission should strictly monitor national requirements to prevent disproportionate and extensive national stockpiling.
- The European Voluntary Solidarity Mechanism should enable manufacturers to efficiently reallocate stocks from one country to another to tackle a shortage. Nine out of ten shortages are in a single EU Member State, according to the Technopolis study. This will require more transparency of the EU market and greater use of the real time data on demand and supply found in the European Medicines Verification System.
- EU strategic reserves, co-funded by the EU and Member States, could be agreed with manufacturers based on rolling stocks which would reduce wasteful write-offs and dramatically lower costs for taxpayers. These reserves should be targeted, proportionate and transparent.
- Regulatory changes, such as electronic product information or digitalisation of the regulatory network, could support supply chain agility and should therefore be introduced.

[1] A recent study shows that 26% of generic medicines have disappeared from the EU market over the last 10 years and the situation is worse for antibiotics (-31%) and for certain generic cancer medicines (-38%).
[2] Calculations according to the IQVIA MIDAS database figures for 2022. Estimated supply for EU member states: Bulgaria, Poland, Romania, Croatia, Czech Republic, Estonia, Latvia, Lithuania, Hungary, Slovakia, Slovenia

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- Including supply security in market policies, as in the future EU guidance on medicine procurement and adjustments to reference pricing policies, will encourage more investment in manufacturing and diversification.

For more information and to access the full position paper, please visit https://www.medicinesforeurope.com/wp-content/uploads/2024/04/240327_Position-paper-stockpiling_FINAL3.pdf

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.
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