



# **Shortages of Medicine**

## **A European Problem**

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# Shortages of Medicine: An Old Problem Flaring Up



The number of shortages increased 20-fold between 2000 and 2018 and has increased 12-fold since 2008.

In its resolution of 2 March 2017, the EP already called for:

- A better definition of the concept – and an analysis of the causes – of shortages of medicine
- A mechanism whereby medicine shortages across the EU can be reported upon on an annual basis
- A review of the statutory basis of the EMA, and to give consideration to enhancing its remit to coordinate pan-European activity aiming at tackling medicine shortages in the Member States

The pandemic only showed the symptoms of an already existing structural problem. In response the EP started an initiative report.

# Shortages of Medicine – Initiative Report in a Nutshell



In September 2020 the EP formalised its position.

The report recommends that the European response to medicine shortages must be based on three pillars:

- A return to health sovereignty by securing supplies;
- Stepping up European action to better coordinate and,
- Supplement Member State health policies, enhance cooperation between them, and return EU health sovereignty through closer European integration.

# Securing Supplies



- Making security of supply a priority criterion in tendering procedures with the Commission recommending the best offer to the Member States.
- The creation of one or more non-profit European pharmaceutical undertakings capable of producing certain medicines of strategic importance for health care in emergencies in the case of a single production line or an ingredient that is particularly difficult to obtain or no longer profitable for pharmaceutical companies to manufacture.
- Diversification of manufacturers and supply chain to secure supply and produce active ingredients in the European Union, and investing in research, innovation.

# More Vigorous Action at European Level to Better Coordinate and Supplement Member State Health Policies



- The creation of a European reserve of medicines of strategic importance for health care along the lines of the 'RescEU' mechanism set up by the Commission. The aim here is to develop a number of health strategies at European level, with a joint reserve of priority medicines and vaccines, with harmonised prices, to enable Member States to deal with supply problems.
- Strengthening of EU purchasing power through joint procurement to reduce costs of medicines and items of equipment. It is easier to negotiate with suppliers when representing 446 million consumers.
- Greater transparency in the distribution chain with the introduction of centralised management, obtaining more information from all stakeholders, making pharmaceutical companies, manufacturers and distributors more accountable, alongside the management and marketing authorities, particularly as regards 'strategic' medicine stocks, given that pharmaceutical supply chains generally operate on a 'just-in-time' basis.

# Closer Cooperation between Member States



- Real-time management of medicine stocks in each Member State and prevention of stockpiling. The Commissioner responsible for health should oversee a task force working in conjunction with the EMA, national agencies and manufacturers, in order to anticipate heavier demand on stocks and regulate the movement of medicines within the single market in accordance with the needs of each Member State.
- The introduction of simplified legislation and more flexible regulatory measures to allow for new manufacturing sites, multilingual packaging, different pack sizes and electronic package leaflets. - As a pharmacist, I´m not so happy with this.
- The introduction of digital tools for the sharing of information regarding stock levels and shortages of medicine and medical equipment in the Member States.

# Shortages of Medicine – Key Issues



## Monitoring:

- Involving different stakeholders (from API producers to hospital pharmacists) along the supply chain
- Notifications from market authorisation holders alone is not enough and comes often too late
- Member states should have common definitions of “shortages” and strategies
- EMA should have central role in monitoring
- We need a holistic approach

# Shortages of Medicine – Key Issues



- **Diversification :**

Changing of public procurement/tendering – setting new parameters (e.g. security of supply, environmental & social standards) instead of cheapest offer wins.

- **N-1 redundancy as conditionality for market authorization:**

Identifying alternatives for each component of the supply chain akin to the principle of N-1 redundancy in electrical grid operation.

- **Access and affordability:**

We need an action plan for compulsory licensing schemes and also make sure that exploitative business models can be prevented.

# Shortages of Medicine – Key Issues



## European solidarity:

- Joint procurement instead of every MS for themselves, cooperation instead of competition
- Harmonised shortage prevention and management plans, ensuring that national initiatives on stockpiling do not create shortages in other Member States
- EU contingency reserve of medicines and the establishment of one or more European non-profit pharmaceutical entities - to operate in the public interest in the manufacturing of medicines

# Shortages of Medicine – Key Issues



## **More competencies and resources for EU health policy:**

Shame that EU4Health reduced to 5.1 billion (instead of 10.4) – EU health policy was a neglected sector. We need more coordination!

## **Drawing attention to the “One Health” approach:**

We are only as healthy as our environment - e.g. Antimicrobial Resistance (AMR):

- Don't overuse antibiotics in agriculture (change from industrial farming)
- Implement environmental criteria into the GMP to ensure right treatment of waste(water) in pharma production sites worldwide

# Shortages of Medicine



- Shortages are a common European problem, for which we need to find common answers. Solidarity is key.
- We need to involve stakeholders not only alongside supply chains but also in the whole health sector to guarantee an effective monitoring and to come up with holistic solutions.
- Only returning the API production to Europe is not a solution in itself. We have to change the way our tendering/procurements work and focus on other criteria than just prices.
- Aligning our health policies on a „One Health“ approach will also bring benefits considering shortages.

**Thank you for your attention!**



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