



UEMO STATEMENT

LESS (MEDICINES) ARE MORE (TROUBLING)

Running Out of Medicines - Why there are Drug Shortages and what it means for General Practice/Family Medicine

This important topic was the subject of the two-day meeting on March 1 and 2, 2023, regarding shortages of medicines, bringing together General Practitioners/Family Doctors, Hospital Consultants, researchers, pharmacists, representatives of the pharmaceutical industry, veterinarians and members of the EU Commission (DG SANTE and HERA).

The causes of shortages can include manufacturing problems leading to delays or interruption in production, shortages of raw materials, increased demand for medicines, distribution problems, labour disruptions, natural disasters, the recent pandemic context, and the current geopolitical and socio-economic contexts (i.e. inflation surge).

There are already attempts to create structures to assess the impact of drug shortages on patients and five essential elements have recently been identified: 1) the existence of an alternative product, 2) the disease in question, 3) susceptibility, 4) costs and 5) the number of affected patients. By ranking these elements, an indication of the impact can be obtained. (1)

The EMA meeting benefitted from the multidisciplinary nature of the participants and many innovative ideas were discussed.

Among them were the following

- The EMA has a Shortage Catalogue for human medicines on its website and there are efforts to coordinate a similar list for Veterinary Medical Products.
- Good and reliable data is essential, both in order to give warning of shortages and to mitigate the effects of poor supply.
- The EMA has created a Single Point of Contact for member states to report incipient supply problems



There were breakout sessions on Immunoglobulins, Biosimilars and Veterinary Medical Products and groups, including UEMO, reported on how the withdrawal of drugs affected them.

- Guidance documents are generic and refer more to the organization and communication between entities. Practical recommendations that are aligned with the principles of evidence-based medicine -and developed by scientific societies or entities are necessary. The EMA has also published guidance documents for patients' and healthcare professionals' organisations with key principles and examples of good practices to prevent and manage shortages of human medicines. (2) Moreover, the Scottish Government has developed a number of recommendations on how to deal with shortages. (3)

Shortages need to be identified as early as possible and the response must be swift, with clear indications of alternatives for the various possible clinical settings.

We must not forget the fact that shortages have a real effect on the doctor-patient relationship, particularly in Primary Care (4). At the EMA meeting, UEMO stated that in General Practice/Family Medicine the withdrawal of a drug because of changes in the risk/benefit profile is understood and approved. It is not the prime reason for shortages in the field of family medicine.

Even when the drug is withdrawn for commercial reasons (low volume, high cost, or shortage of ingredients) withdrawal seems a safer process than the possibility of an uncertain and unreliable supply.

Europe has largely adopted a "Just In Time" policy for drugs with pharmacies relying on daily distribution and deliveries. For example, in the UK there are, in pharmacies, six days' worth of drugs, so there is a negligible stockpiling of medication.

In general, shortages in the community ('setting) are about supply issues and increased demand, as in the recent amoxicillin and amoxiclav shortage, especially in paediatric formulations, with a surge in Strep A infections.

They reflect directly on the doctor/patient relationship and on the continuity of patient care.



UEMO considers that it is important to have early warning of possible shortages since this can prompt measures, such as rationing, dose reduction or the use of alternative treatments in order to mitigate the impact of the nonavailability of drugs.

It is also important to have reliable information on available alternative treatments. This needs to be specific and locally relevant. Often the message is that, for instance, beta-blockers are in short supply but ACE inhibitors are available. It is more useful if the information is more specific (e.g. atenolol is in short supply) and of local significance (e.g. ramipril is available in local pharmacies). These measures will do much to mitigate the effects of drug shortages in general practice/family medicine.

UEMO are happy to continue working with the European Medicines Agency and other partners on this important topic.

References:

- (1) Doerine J. Postma, Peter A. G. M. De Smet, Kim Notenboom, Hubert G. M. Leufkens and Aukje K. Mantel-Teeuwisse: Impact of medicine shortages on patients - a framework and application in the Netherlands. Postma et al. BMC Health Services Research (2022) 22:1366
- (2) <https://www.ema.europa.eu/en/news/towards-better-prevention-medicine-shortages-eu>
- (3) NHS Community Pharmacy Website (scot.nhs.uk)
- (4) Iacobucci G. Drug shortages leave primary care staff exposed to abuse from frustrated patients BMJ 2022; 377 :o1100 doi:10.1136/bmj.o1100