The Consumer Voice in Europe

EMA GOOD PRACTICE GUIDANCE FOR COMMUNICATION ON MEDICINES' AVAILABILITY ISSUES

BEUC comments

Contact: Jelena Malinina – health@beuc.eu

BEUC, The European Consumer Organisation appreciates the opportunity to comment on the draft *Good practice guidance for communication on medicines' availability issues* developed by the European Medicines Agency (EMA) and Head of Medicines Agencies (HMA) taskforce on availability of authorised medicines for human and veterinary use.

Why it matters to consumers

Medicines shortages is a growing problem in Europe: a report published by the European Association of Hospital Pharmacists in November 2018 showed that almost 92% of the 1,666 responding pharmacists in 38 European countries had experienced problems sourcing medicines.[1] Medicine shortages can have a significant impact on patients and consumers, including failure to treat conditions, delayed treatment, or the prescription of less effective treatment.[2] As such, it is crucial that shortages are uniformly defined and investigated to find their common causes and possible solutions.[3]

Effective communication is key

Shortages can be caused by one or a combination of problems: in manufacturing (i.e. shortage of raw materials), distribution and supply (i.e. parallel trade from a low-price to a high-price market in the EU), or economics (i.e. the financial crisis, pricing policies, or marketing strategies). Given the complexity of the system and variety of causes for medicines shortages, there is no easy fix to the issue. Nonetheless, effective communication in the supply-chain is a prerequisite for addressing medicines shortages. BEUC therefore welcomes EMA's intention to provide clear and harmonised guidance for communication on medicines shortages both at national and EU levels.

While the draft guidelines correctly outline the key elements of successful communication on shortages, such as harmonised formats of reporting, key elements to report on, timing of publication, *etc.*, we would also welcome a recommendation on how to achieve closer collaboration with stakeholders, including patient organisations and healthcare professionals. We would likewise recommend including consumer groups into these categories as shortages often occur among wider population groups which are not necessarily diseases-specific. In addition, BEUC suggests adding the following to the section 'information to be published in the catalogue': actions undertaken to mitigate/solve a shortage.

Communication must be built on common terminology

While the guidance establishes good practice for communication, one critical element is missing: a formal definition of what should be considered a medicine shortage and data requirements for associated issues.

---

[1]   European Association of Hospital Pharmacists, 2018:
      www.eahp.eu/sites/default/files/report_medicines_shortages2018.pdf
[2]   De Weerdt, E., Simoens, S., Casteels, M. et al. Appl Health Econ Health Policy (2017) 15: 441.
      https://doi.org/10.1007/s40258-016-0264-z
[3]   See BEUC, Access to medicines, November 2015: https://www.beuc.eu/publications/beuc-x-2015-104_access_to_medicines.pdf

Harmonised communication on shortages at the EU level will not be effective unless a clear and widely used formal definition(s) is developed. At present, formal and legally binding definitions of drug shortages does not exist in most EU countries (with the exception of Belgium, France, Italy and Spain).[4] Absence of definitions, as well as inconsistencies and incomparability of existing definitions across different systems and countries, are likely to hinder comprehensive reporting, communication, and comparative analyses of the problem of drug shortages, as well as the scale and effects of shortages. To address this problem, BEUC recommends that the guidelines should be promoted together with efforts to develop a harmonized definition (or set of definitions) of medicine shortages, possibly within the framework of the EU pharmaceutical legislation.

Such a formal definition should however not be created with an aim to *legally* replace existing descriptions of shortages. Given the variety and diversity of national healthcare systems, a '*one size fits all'* approach should be avoided, as it might not meet the needs of various systems. However, the definition of shortages should aim at harmonization of the key criteria and definitions of major problems associated with medicine shortages. We welcome the EMA-HMA's taskforce's work in this area, and once a definition is agreed, we believe it should be promoted as a prerequisite of improved communication on shortages between and within the Member States.

A common European approach to shortages is needed

Depending on the cause of shortage it may affect more than one country and it can pose significant cross-border threats. Consequently, in addition to a commonly agreed terminology, there is a need to develop an EU-wide centralised monitoring system to collate the reports from the national systems and also to identify common causes of shortages in the Member States. Such a database could be coordinated by EMA-HMA and should be open for healthcare professionals, patients in order to notify and learn about ongoing shortages.

The common system could also serve as a tool to ensure better compliance of pharmaceutical manufacturers and pharmaceutical full-service healthcare distributors with Directive 2001/83/EC[5]. This would facilitate appropriate and continued availability of medicinal products and provide a mandatory pre-notification of disruption of supply in the case of permanent or temporary medicines shortages.

Conclusions

All in all, BEUC welcomes EMA-HMA workstream on medicine shortages, and encourages EMA-HMA to continue promoting a harmonised approach among the Member States. While it is important to take into account the differences of national healthcare systems, medicine shortages often become a cross-border issue that requires a joint response. Thus, there is a strong need for developing a commonly agreed terminology and obtaining a uniform definition for a medicine shortage. Timely communication and early warning system could significantly improve the current situation with medicines shortages in Europe.

ENDS

---

4   Bochenek Tomasz et al. Systemic Measures and Legislative and Organizational Frameworks Aimed at Preventing or Mitigating Drug Shortages in 28 European and Western Asian Countries m Front. Pharmacol., 2018, https://doi.org/10.3389/fphar.2017.00942

5   Directive 2001/83/EC on the Community code relating to medicinal products for human use. https://ec.europa.eu/health/sites/health/files/files/eudralex/vol1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf