

The European resilience to medicines' shortages through the pandemic

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Abstract

The shortage of medicines has increased worldwide, reducing the ability of national healthcare systems to find solutions to ensure patients' access to pharmacological therapies. Shortages can be traced to supply-related causes (e.g., manufacturing issues, regulatory issues, distribution) and demand-related ones (e.g., parallel trade, price and reimbursement policies, tendering). Moreover, extraordinary natural or geopolitical events (e.g., COVID-19 outbreak, Brexit, 2021 Suez Canal obstruction) can stress the resilience of the pharmaceutical manufacturing and distribution chains worldwide [1]. Even if globalized players control the research and manufacturing of raw materials and medicinal products, the activities of regulatory authorities are still based on national or supranational (i.e., European Union) frameworks. Moreover, the heterogeneity of the National healthcare systems and the fragmentation of the National regulatory frameworks can be itself a cause of medicine unavailability and/or can limit the development of proper problem-solving strategies. It is the case of market distortions caused by the different reimbursement and price policies among European member states.

In 2019, the EMA and the HMA released two guidelines on shortages definition, notification and communication to promote information sharing and cooperation among European pharmaceutical stakeholders, regulators and professionals [1]. Moreover, National and Industrial Single Points of Contact (SPOC) have been created to facilitate sharing of the information and the coordination of emergency plans among the EMA, the Competent National Authorities (CNAs), and pharmaceutical industries.

However, harmonized and practical shortage risk-assessment metrics are still needed to promote stronger cooperation among European Countries. Although several measures have been proposed by regulators and professional associations, most of them are designed to face specific shortages' root causes and cannot be applied widely. In this context, the application of harmonized algorithms able to determine the shortage/unavailability impact on public health can be useful to identify the most critical medicinal products and to improve the cooperation at National and European levels, permitting CNAs, healthcare professionals (e.g., pharmacists) and other stakeholders to adopt the most appropriate problem-solving strategies [1].

1 U.M. Musazzi, D. Di Giorgio, P. Minghetti. New regulatory strategies to manage medicines shortages in Europe. *Int. J. Pharm.*, 579, 2020, 119171, <https://doi.org/10.1016/j.ijpharm.2020.119171>.