KYRIAKIDES GEORGOPOULOS
LAW FIRM

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Good Practices for Industry for the Prevention of Human Medicinal Product Shortages

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BY IRENE KYRIAKIDES, VICTORIA MERTIKOPOULOU, AITHRA-VALENTINA ANTONIADOU

EMA has recently published a guidance with Good Practices for Industry for the Prevention of Human Medicinal Product Shortages providing the following ten (10) recommendations for marketing authorization holders (MAHs), wholesalers, distributors and manufacturers.

Recommendation 1

MAHs, manufacturers and wholesalers, should notify the national competent authorities in case of a potential or actual shortage as soon as possible and in advance of any (potential/actual) shortage.

That way by taking actions at an early stage, shortages and their respective impact on patients and healthcare professionals may be avoided. Any shortage update (e.g. extension/reduction of the shortage period) should be reported in a timely manner to allow the re-evaluation of the shortage impact.

Recommendation 2

Increase transparency as regards shortage information between different stakeholders mitigating and preventing shortages while ensuring healthcare professionals have the time to identify and source alternative medicinal products.

Recommendation 3

MAHs should increase the accuracy of notification details along with follow-up communications where needed, enabling stakeholders to understand the situation, to assess the impact and adopt prevention or mitigation measures.

Recommendation 4

MAHs, manufacturers and wholesalers, should each have a shortage prevention plan specific to their role focusing on the vulnerabilities in the supply chain and the ways of addressing such risks. In particular, the shortage prevention plans should refer to the following aspects:

- MAHs shortages prevention plan: general oversight of the medicinal products supply at a global and national level.
- Manufacturers shortage prevention plans: manufacturing capabilities, sourcing raw materials, market trends, marketing activities and supply of the manufactured medicinal products.
- Wholesale shortages prevention plans: vulnerabilities from medicinal products receipt, storage and delivery.

Recommendation 5

MAHs, manufacturers and wholesalers should each have a shortage management plan to respond to issues resulting in shortages.

Each shortage management plan, depending on the stakeholders' role, should identify red flags and risks as regards the continuous availability of medicinal products. The effectiveness of such

mitigation plans and the controls intended to prevent supply interruptions should be formally and periodically evaluated.

It should be noted, however, that neither shortage prevention plans nor shortage management plans are mutually exclusive.

Recommendation 6

Optimize pharmaceutical quality systems to strengthen the reliability and resilience of supply chains throughout the lifecycle of medicinal products.

Good Manufacturing and Distribution Practices (GxPs) provide for standard for quality. However, MAHs should pay equal attention to all medicines, regardless of the stage in the lifecycle of the medicine.

For that reason, MAHs and manufacturers should adapt product quality reviews (PQRs) to assess the robustness of the supply chain arrangements and controls.

ICH guideline Q10 on Pharmaceutical Quality System sets a framework beyond just adherence to GxPs, describing the use of knowledge management and quality risk management as well as the opportunities to demonstrate quality systems effectiveness, while ICH guideline Q128 sets a framework facilitating the management of post-approval changes more predictably and efficiently, promoting continuous improvement to ensure reliable supplies of medicinal products.

Industry stakeholders should promote continuous improvement of the GxP environment/framework and post-authorization changes to strengthen the reliability and resilience of supply chains and prevent shortages.

Recommendation 7

Increase resilience in the supply chain, considering known vulnerabilities. MAHs and manufacturers should have enough stock of products for unexpected delays during manufacturing site changes or ownership transfers.

Recommendation 8

Improve communication between stakeholders. MAHs and manufacturers should adopt two-way communication systems and their cooperations/communications should also cover potential or actual shortages.

Recommendation 9

Promote fair and equitable distribution to meet patients' needs. Medicinal Products stockpiling leads to a disrupted supply chain. On the one hand, stakeholders should not order or dispense bigger amount of stock than normal in case of a potential or actual shortage, while on the other hand MAHs should allocate their stock between countries considering patients' needs and not just economic factors.

Recommendation 10

Take appropriate steps to minimize the risk of parallel trade or export exacerbating shortages.

Even though the free movement of medicinal products is a legitimate business practice, in case of shortages the exportation of medicinal products may worse the extent of a shortage in the source country, albeit it is unlikely that exports alone can cause shortages.

Competent authorities should impose restrictions on parallel trade, if justified and proportionate under the applicable legislation, and stakeholders active in parallel trade should monitor the shortages situation, and, in cases of an identified risk to public health, inform and seek advice from the competent authorities of the exporting Member State.

In light of the above, it is apparent that the shortages challenges and the importance of addressing such shortages have been recognized across the EU over the last few years. Stakeholders should adopt and implement

(additional) prevention strategies and mitigation measures to minimize the risk of major shortages and a future public health crisis.

For further information on guidance for the prevention of shortages, please visit the following websites:

- Good Practices for Industry for the Prevention of Human Medicinal Product Shortages, European Medicines Agency, 2023
- Good Practice Guidance for Patient and Healthcare Professional Organizations on the Prevention of Shortages of Medicines for Human Use, European Medicines Agency, 2022

Contact Us

Irene Kyriakides
PARTNER
i.kyriakides@kglawfirm.g

Victoria Mertikopoulou
PARTNER
v.mertikopoulou@kglawfirm.gr

Follow Us

ATHENS OFFICE

28, Dimitriou Soutsou Str.,
115 21 Athens

T +30 210 817 1500
F +30 210 685 6657-8
E kg.law@kglawfirm.gr

THESSALONIKI OFFICE

31, Politechniou Str.,
551 34 Thessaloniki

T +30 2310 441 552
E kg.law@kglawfirm.gr

www.kglawfirm.gr