How to assess the impact of medicines shortages in the European Union?

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Abstract number: 2SPD-030

Medicines shortages have been spreading in European countries with a substantial impact on the capability of national healthcare systems in ensuring the continuity of care. Shortages sometimes originate from unpredictable and multifactorial causes, which may be supply-related or demand-related. In 2019, the EMA and HMA joint task force released two guidance on the shortage notification for manufacturers and the communication to the public [1]. However, rational and practical shortage risk-assessment metrics are still needed to support regulators, manufacturers and other healthcare professionals in facing the crisis [2].

OBJECTIVE OF THE PRESENT WORK

to propose a risk-assessment tool for health professionals, regulatory agencies and other stakeholders to triage a shortage impact on public health regardless of its root cause or the affected healthcare setting.

When a medicinal product is placed on the market

Shortage alert

How to define the shortage effects?

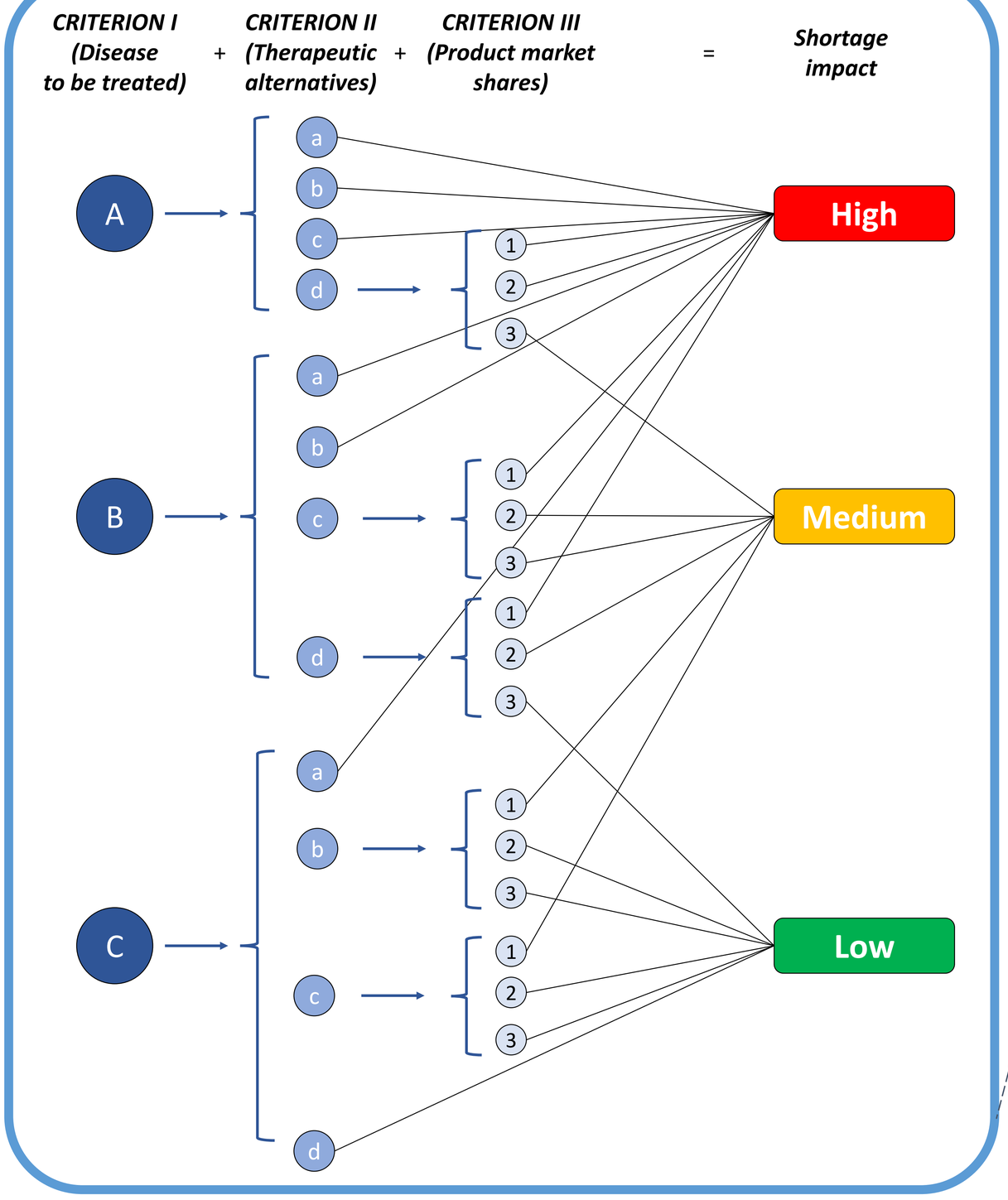
Adopting an algorithm to define the shortage impact on patient health

How to prevent/mitigate shortages?

- Improving manufacturer resilience
- Improving economic sustainability
- Blocking exportation/ Facilitating importation

↑ *Efficacy of adopted strategies*

Communication to public/Cooperation among all the stakeholders and European Countries



CRITERION I

The seriousness of the therapeutic indications can be determined following the principles of VEN (Vital-Essential-Nonessential) analysis [3]. In this light, a medicinal product can be classified as:

A. a product for life-supporting, life-sustaining or rare diseases,
B. a product for serious or debilitating diseases (acute or chronic),
C. a product for other conditions.

If the same medicinal product is indicated for the treatment of more than one disease, the most severe and low prevalent one should be considered.

CRITERION II

The shortage impact on public health is also influenced by the existence of therapeutic alternatives on the market. Consequently, the scores for criterion II are:

a) not more than two medicinal products containing drug substances in the same ATC level III (same therapeutic/pharmacological subgroup) or IV (same chemical/therapeutic/pharmacological subgroup),
b) more than two medicinal products for the same ATC level III, but not for the same ATC level IV,
c) more than two medicinal products containing drug substances in the same ATC level IV, but no generic products are available for the same ATC level V (same chemical substance or therapeutic moiety),
d) more than two generic products for the same ATC level V.

CRITERION III

The higher the market shares of a medicine (expressed as annual volumes), the higher the potential risks for the public health. The Criterion III scores are:

1) market shares higher than 50% of the entire national market,
2) market shares between 25-50%,
3) market shares lower than 25%.

CONCLUSION

Although further studies in real-world settings are needed to fully validate the procedure, it is a proof of concept for promoting cooperation and harmonized solutions to medicine shortages. The most critical medicinal products can be selected in advance by competent authorities and stakeholders, improving the resilience of the healthcare systems.

CONFLICT OF INTEREST: This scientific proceeding does not imply any current or potential conflict of interest with the Administration of affiliation; the view and opinions expressed are those of co-author and should not be attributed to AIFA.

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