CHESSMEN

Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network

SPEAKING THE **SAME LANGUAGE**

WP5 | Identifying the root causes of observed shortages of medicines

Causes of Shortages (Part 1)

The terms and definitions presented here are the result of the collaborative work carried out under Work Package 5.

They do not represent official definitions but rather proposed and agreed-upon interpretations that were considered for the work conducted within the project. These proposals aim to support future harmonisation efforts across the EU.

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Causes of Shortages (Part 1)

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MANUFACTURING ISSUES

Unforeseen disruptions within the manufacturing process caused by GMP compliance problems (API or finished product). Manufacturing issues also include capacity issues.

REFERENCE
HMA/EMA. (2020). Reader's guidance: SPOC system - Pilot phase.

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Causes of Shortages (Part 1)

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QUALITY ISSUES

Unforeseen disruptions within the manufacturing process leading to quality defects (API or finished product), including recalls.

REFERENCE

HMA/EMA. (2020). Reader's guidance: SPOC system - Pilot phase.

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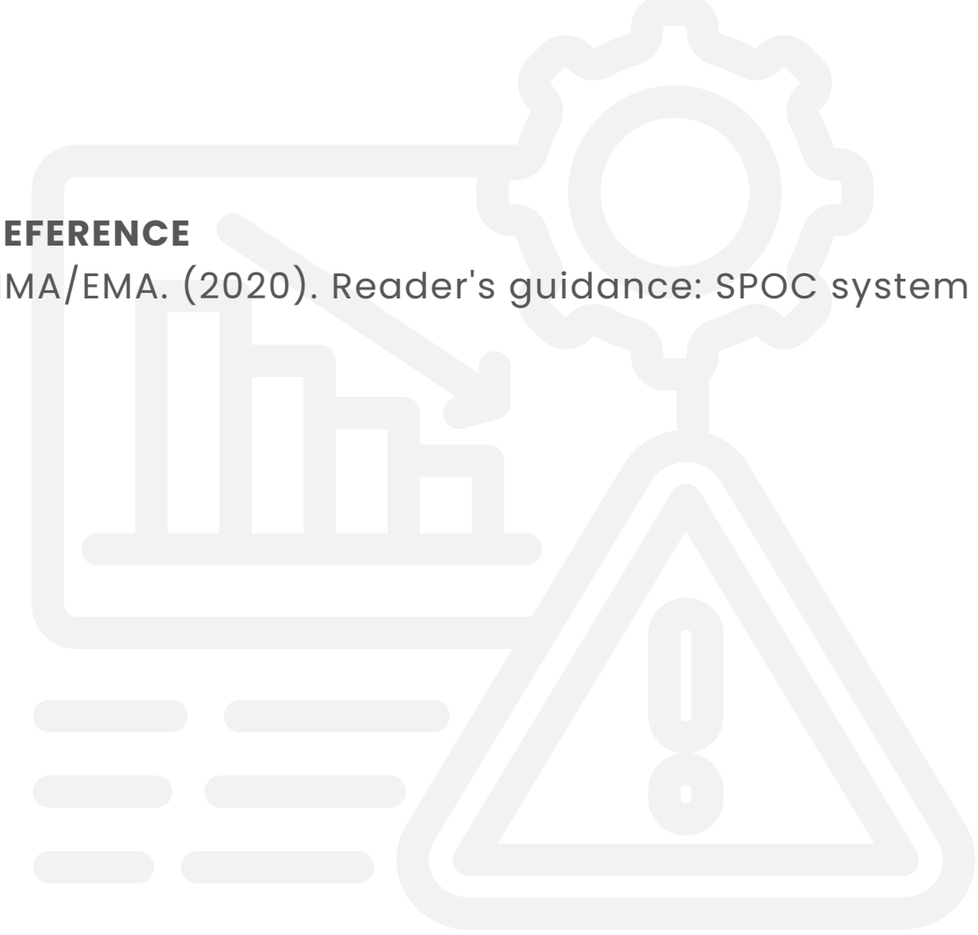
SAFETY AND EFFICACY ISSUES

If the medicinal product lacks therapeutic efficacy (or decrease efficacy) there are new safety risks identified requiring precautionary action, or the risk benefit balance of the medicine is no longer favourable.



REFERENCE
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UNEXPECTED INCREASED DEMAND

Unexpected increased demand due to previous Qdefects, due to market cessation/shortage of alternative products (e.g. generics), due to great awareness about a specific disease prevention or new treatment guidelines and/or recommendations of physicians'/veterinarians'/other healthcare professionals' organizations, change in reimbursement conditions, change in epidemiology.

REFERENCE
HMA/EMA. (2020). Reader's guidance: SPOC system - Pilot phase.