EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Proposed reform of the pharmaceutical legislation

Overview of key elements of Chapter X - Availability and Security of Supply

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Presented by Klaus Kruttwig, Medicines and Medical Devices Shortages Specialist, EMA

Reasons for and objectives of the EU pharmaceutical legislation proposal

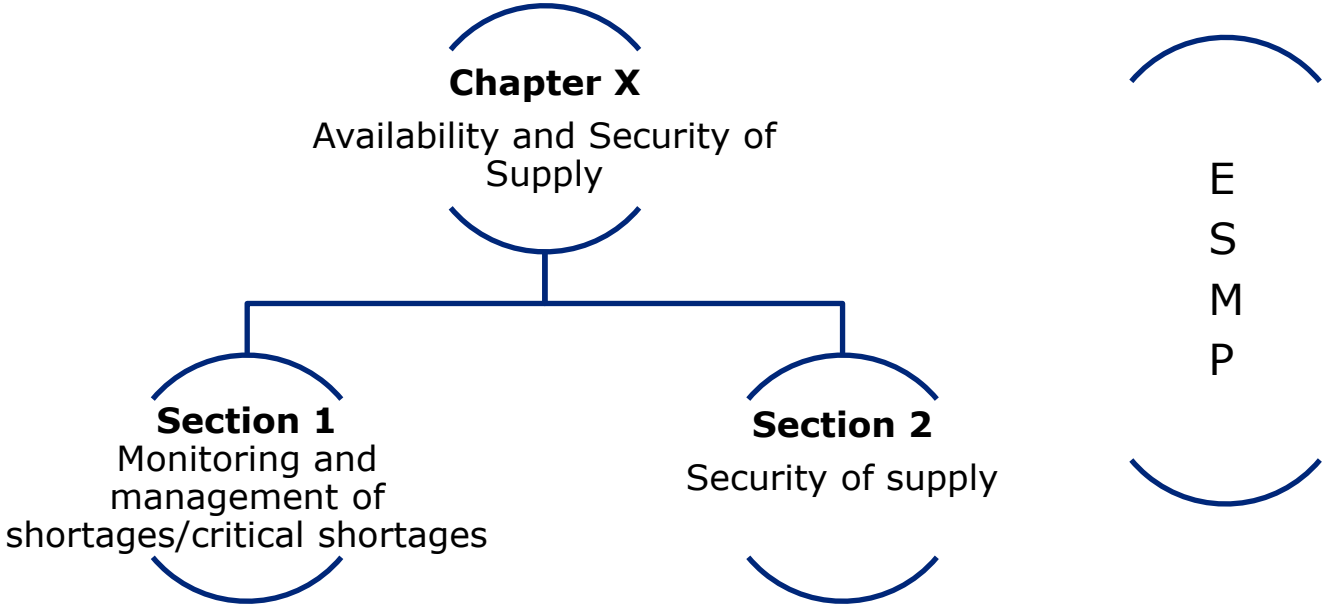
- Patient access to medicinal products across the EU and security of supply are growing concerns
- Shortages of medicinal products are a growing problem of for many EU/EEA countries
- The overarching aim of the reform is to ensure that patients across the EU have timely and equitable access to medicines.
- The proposal sets out a framework for the activities to be deployed by the Member States and the Agency to improve the EU's capacity to react efficiently and in a coordinated manner to support shortage management and security of supply of medicinal products, in particular critical medicinal products, to EU citizens, at all times.
- The proposal complements and further develops the core tasks already given to the Agency in the extension of its mandate (Regulation (EU) 2022/123) which was introduced as part of the EU's overall health response to the COVID-19 pandemic and the improved crisis management framework.

Proposed reform of the pharmaceutical legislation

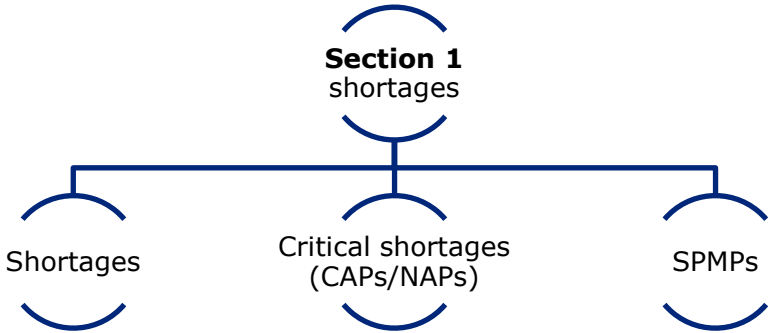
The **EU Pharmaceutical Reform** builds on the Pharmaceutical Strategy for Europe (2020), including the **structured dialogue** on the security of supply of medicines

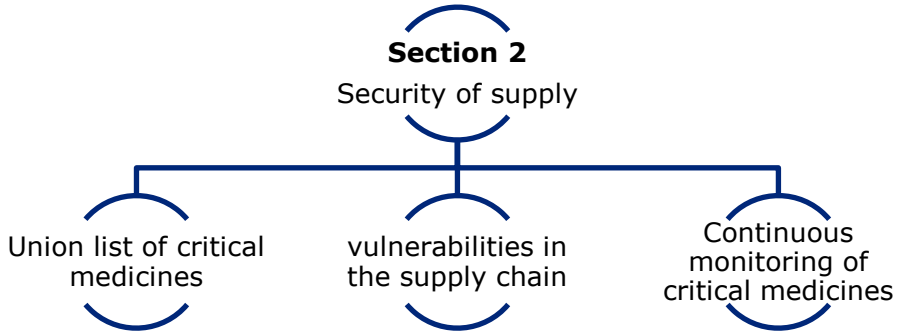
- *1 of the 6* ***key political objectives*** *focuses on shortages/availability*

Chapter X of the proposed Regulation sets out the rules on **shortages**



Chapter X: Availability and Security of Supply





Key points addressed:

- *Improved **coordination, monitoring and management** of shortages, in particular critical shortages (MS and EMA)*
- ***Earlier** and **harmonised notification** of shortages and withdrawals*
- *Stronger coordinating role for **EMA** & more powers for **MS** and **Commission***
- *Establishment of the Union list of critical medicines*
- *Shortage Prevention and Mitigation Plans*
- *Expansion of the scope of the ESMP*

Relevant definitions

- ‘shortage’: a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State.
- ‘critical shortage’ means a critical shortage in the Member State for which coordinated Union level action is considered necessary to resolve that shortage in accordance with this Regulation.
- ‘Critical shortage in the Member State’: A shortage of a medicinal product, for which there is **no appropriate alternative** medicinal product available on the market in that Member State, and that shortage **cannot be resolved**.
- ‘critical medicinal product’: A medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients and identified using the methodology pursuant to Article 130(1), point (a).

Section 1: Monitoring and management of shortages/critical shortages

- **Obligation** on **MAHs and wholesalers** to ensure appropriate and **continued supplies**
- **Shortage prevention plans** for all medicines **and Shortage mitigation plans** for shortages
- Notification of **market cessations, withdrawals, suspensions and shortages** (temporary disruptions)
- Shortage monitoring by both NCAs and EMA,
- Establishment of the MSSG **list of critical shortages** and recommendations
- MAH obligations to provide information, based on MSSG recommendations, comply and report on measures taken
- Commission role in implementing measures, taking MSSG recommendations into account
- Possibility for wholesale distributors and other actors to report shortages - can provide any information on shortages requested by NCAs or EMA

Section 2: Security of supply

- Establishment of **Union list of Critical Medicinal Products** by **EMA,** including evaluation of **vulnerabilities** with respect to the **supply chain**
- MAHs and other actors shall **submit information on critical MPs**
- **MSSG recommendations** on appropriate **security of supply** measures to MAHs, the Member States, the Commission or other entities
- Responsibility of MAHs to provide information to EMA, take MSSG recommendations into account, comply with measures taken at EU or national level and report on measures they have taken
- Role of the **Commission**, including a provision on Commission adoption of an implementing act to improve security of supply of certain medicines on the Union list of Critical Medicinal Products, directed towards on MAHs, wholesale distributors or other relevant entities

Summary

- **New EU pharmaceutical legislation** proposal currently under negotiation, together with the initiatives foreseen in the **European Commission Communication on tackling medicine shortages in the EU** will further reinforce security of supply for critical medicines and prevention of shortages.
- Security of supply and shortage prevention and management is a key focus
- Foresees a stronger coordinating role for EMA, and more powers for Member States and the European Commission
- Expansion of the scope of the European Shortages Monitoring Platform (ESMP)

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
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