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

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WP5 | Identifying the root causes of observed shortages of medicines

The basics of medicine availability

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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SHORTAGE

A situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State or of a CE-marked medical device does not meet demand for that medicinal product or medical device at a national level, whatever the cause.

REFERENCE
REGULATION (EU) 2022/123 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

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DEMAND

The request for a medicinal product or a medical device by a healthcare professional or patient in response to clinical need; the demand is satisfactorily met when the medicinal product or the medical device is acquired in appropriate time and in sufficient quantity to allow continuity of the best care of patients.

REFERENCE

REGULATION (EU) 2022/123 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

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SUPPLY

The total volume of stock of a given medicinal product or medical device that is placed on the market by a marketing authorisation holder or a manufacturer.

REFERENCE

REGULATION (EU) 2022/123 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

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MEDICINAL PRODUCT

Any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.

REFERENCE

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.