

Joint Action (JA) on regulatory flexibilities, including magistral preparations - 1/3

- New JA stemming from the recent Commission Communication “Addressing medicines shortages in the EU” *.
- Proposed to be funded under EU4Health WP2024.
- As experience has shown during COVID-19 regulatory flexibilities can be an important tool to manage and mitigate shortages of critical medicines.
- Regulatory flexibilities can facilitate:
 - *the quick authorisation and roll-out of alternatives;*
 - *upscaling of production or approval of alternative suppliers of raw materials or finished products;*
 - *temporarily extending shelf-life;*
 - *redistribution of medicines between Member States*
 - *magistral preparations.*

* <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2023:672:REV1>



Joint Action (JA) on regulatory flexibilities, including magistral preparations – 2/3

This new Joint Action aims to support National Competent Authorities (NCAs) in a **concrete way** to mitigate the shortages of critical medicines in the EU, where necessary :

- Collect **knowledge and regulatory experience** on such measures
- **Foster collaboration and best practice sharing** between members of the EU regulatory network
- Promote **effective use of regulatory flexibilities** at national level
- Develop where necessary proposals for **guidance for the implementation** of such flexibilities at national level in line with EU legislation



Joint Action (JA) on regulatory flexibilities, including magistral preparations – 3/3

- This JA aims to provide support to NCAs **based on the experiences and challenges encountered.**

To ensure the JA is beneficial to NCAs please let us know:

1. in which areas you consider there is a need to:
 - a) Collect knowledge and regulatory experience
 - b) Foster more collaboration and best practice sharing
 - c) Develop proposals for guidance for the implementation of such flexibilities at national level
2. in which areas have you encountered challenges in implementation?