

The supply of plasma-derived medicinal products in the future of Europe

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Reducing the likelihood of medicines shortages via preventive and mitigation strategies

CHESSMEN –joint action

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AIMS of WP8 on preventive and mitigation strategies against medicines shortages

- Formulating a National Shortage Prevention and Mitigation Plan(NSPMP, for National Competent Authorities)based on the best practices and literature
- Producing a good practice guidance for stakeholder dialogue platforms for supply chain stakeholders, patients and healthcare providers at Member State level as part of the NSPMP
- Elaborating an Implementation Plan for NSPMP in co-operation with the EMA SPOC WP (supervision and recommendations for stakeholder dialogue platform)
- Position paper of recommendations for minimum standards



Preventive measures to be concentrated on

- Stakeholder Dialogue
 - Setting up co-operation structures, targeted communication, supply chain and healthcare platforms, reviewing guidance on communication, awareness campaigns on national and EMA shortage catalogues
- Lists of critical or strategic products
 - Taking part in forming Union and national level critical medicines lists
- Medicines supply reserves, national stockpiling and stockholding obligations
 - Joint action on stockpiling strategies, development of guidelines
- Financial measures
 - Co-operation with pricing, reimbursement and procuring agencies on national level (NCAPR-experts on EU-level) on rational use of medicines and activities to encourage the availability
- Shortage Prevention Plan
 - Preparing in possible changes in Pharma legislation and participating in development of guidance as necessary
- Regulatory Procedures
 - Accelerating regulatory processes and considering MSSG Toolkit recommendations on National level, joint action on regulatory flexibilities



Mitigation measures to be concentrated on

- Collaboration and consultation with external stakeholders
 - Agile procedures of communicating shortages of critical medicines with supply chain actors, healthcare professionals and patient representatives,
 - listings of available alternatives for e.g. interchangeable products open to all
 - informing healthcare professionals and media about the underlying background issues to control disruptions originating from the demand side
- Assessing the potential impact of a shortage
 - Setting up systems for monitoring and analysing the incoming data about shortages and availability of medicines
 - Common approach for reporting of uniformly categorized shortages through IT-assisted systems
- Export bans and restrictions
 - Common understanding in MSs on this mitigation measure and effects on both demand and supply side



Working in co-operation with

- EMA/HMA Taskforce on Availability of Authorised Medicines Thematic Working Groups 1+2 work
 - Union Critical Medicines List
 - Shortage Prevention and Mitigation Plan
 - Good Practice Guidance for Communication
 - Good Practice Guidance for Patient and Healthcare professionals Organisations
- EMA SPOC Working Party
 - Implementation plan for NSPMP in general
- Other work packages of Chessmen to elaborate the NSPMP



Thank you

