

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

Second edition

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Digital information exchange for monitoring and reporting medicines shortages

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Joint Action CHESSMEN – Work Package 7

- The general objective of this WP is to develop a European IT concept model to monitor and manage medicines shortages, considering as a priority the gathering of existing tools/good practices already developed at EU Member State level
- Making such a reporting system competently available for Europe means a significant strengthening of availability and a forward-looking management of possible constraints



CHESSMEN – Work Package 7

- With a view to optimising accessible tools, an IT platform concept will be developed and made available for future development at European level
- In particular, which core data are required there for the various users is part of the specifications to be made
- Therefore, WP7 will propose an efficient merging of the available systems and information sources of Member States, with an inclusive approach



European IT concept model

- Surveys have shown that almost all Member States in Europe have a system in place to prevent, avoid or mitigate shortages
- The different and diverse valid data sources implemented in each Member State are at least partially interoperable
- Such an approach will be complex and will need to be scaled up to provide each user with the information they need in their field of activity



European IT concept model

- In this context, it is important to avoid the creation of new instruments
- Priority should be given to the harmonisation and re-use of existing instruments
- The system should make the most of the existing structure and provide information on demand, with specific roles for each actor
- In addition, WP7 should enable Member States to set up their own system compatible with the **European Shortages Monitoring Platform (ESMP)** to be developed by the EMA as a central EU system



Objectives and activities – Work Package 7

- SWOT analysis of IT solutions at EU and MS level for shortage reporting and monitoring
 - Assessment of the status of shortage reporting systems in MS
 - Study the availability of data in MS
- Review existing IT tools in MS
 - Identify best practices for data submission, analysis and storage
- Identification of a minimum common data set
 - Provide a basis for further discussion and design of ESMP preparations
 - Characteristics for harmonised data transmission



The main results available so far

- In most cases internal electronic shortage platforms with daily updates of the shortage data
- Shortage data available in English in the majority of Member States
- Most Member States have a history of shortage data (usable for analysis and forecasting)
- Alternative IT tools relevant for shortage monitoring available in more than half of Member States (e.g. stock data collection systems, sales data reporting, data warehouse, shortage dashboard)
- No standardisation of IT format for shortage reports



Where we are now...

- SWOT analysis of the IT solutions at EU and MSs - **done**
- Identification of best practice solutions and minimum common datasets – **done**
- Development of a concept platform to monitor and manage medicines shortages – **development phase**



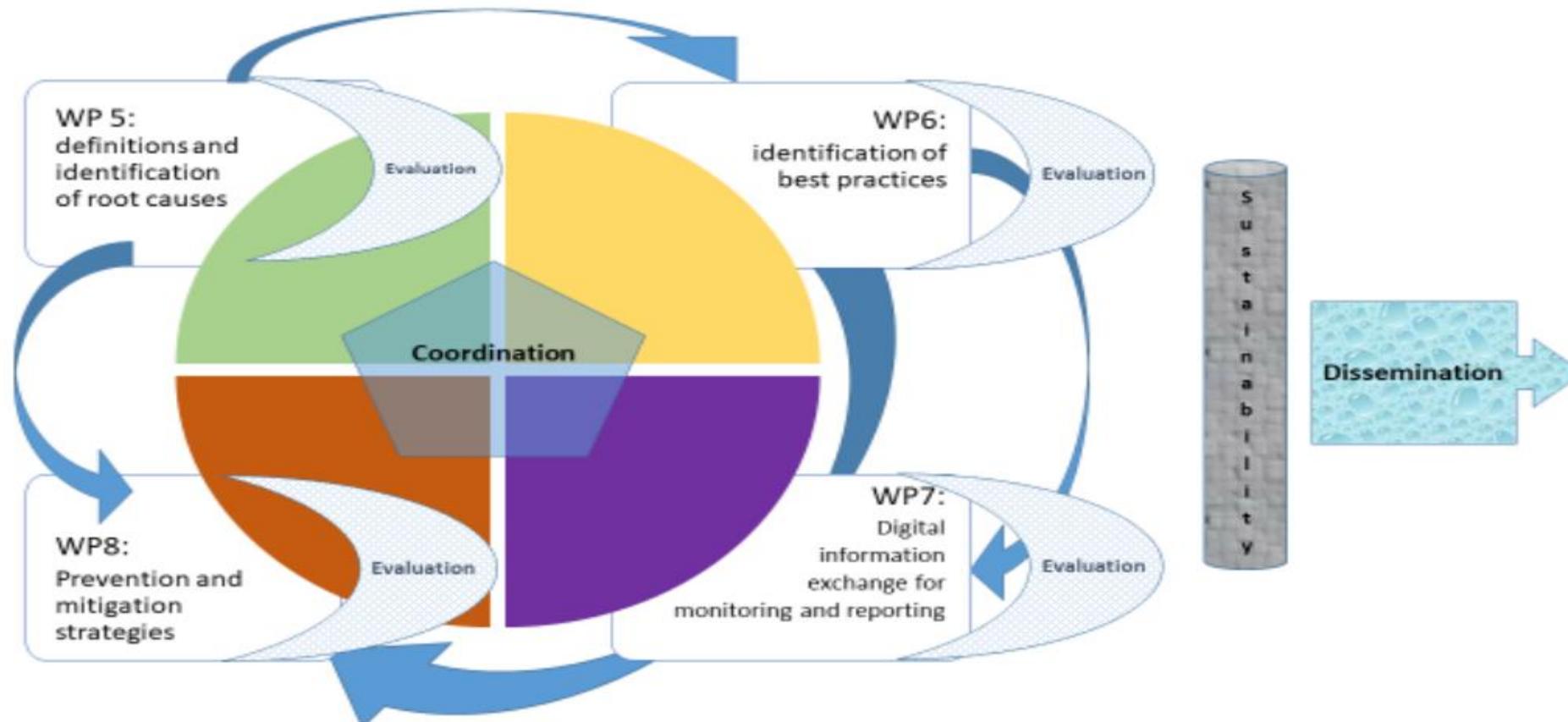
Target corridor

The system should then actively involve pharmacies (community and hospital pharmacies), the medical profession, the wholesalers, the pharmaceutical industry and the authorities at national and European level.

The system should provide for specific roles for each actor, use the existing structure as fully as possible and provide information in line with the structure as possible and provide information as needed.



Coherent structure for WP5, WP6, WP7 & WP8 – Overview



Thanks for your time and attention.

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