



Report on EU best practice solutions and minimum common datasets

Work Package 7

Deliverable 7.2

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1. Introduction

Over the last years and especially within the COVID-19 pandemic the impact of medicines shortages reached the focus of both, the national and European Health authorities as well as stakeholders from the industry and the supply chain of medicines. Within the current EU4 health programme, the CHESSMEN JA is aimed at to harmonise the approaches, the data and wordings used in the management of shortages to reach a harmonised way of communication and the similar understanding and processing of the available data related to shortages.

The deliverable 7.2 on hand is, in line with the proposed goal of Work Package 7, an approach to review the existing IT Tools of the Member States with focus on best practices on data storage, data analysing and data submission. The main objective of this section is not to assess or evaluate existing practical solutions, but to collect information on the different systems used by Member States to manage shortages of medicines. This collection of information is important for a number of reasons. First and foremost, it provides a detailed overview of Member States' IT tools for managing medicines shortages. This report is the first compilation of information on these systems, their description and their use in the area of monitoring, preventing, mitigating, reporting and resolving medicines shortage situations. In addition, the information collected can support Member States that are currently developing their own IT systems for monitoring, reporting and managing medicines shortages by modelling them on harmonized practices already successfully used to manage medicines shortages.

Secondly, the underlying question of the minimum needed data to reach to reliable statements on shortage impact and criticality is addressed within this report. This topic is scheduled by defining a minimum common dataset in order to harmonise the documentation on shortages and to allow a simple data transmission, accumulation and evaluation towards the European Shortages Monitoring Platform (ESMP) of the European Medicines Agency (EMA). It should be emphasised that this report focuses on best practices in existing IT tools and does not cover best practices in monitoring, reporting and management, nor best practices in preventing and mitigating drug shortages, which is part of the work conducted within CHESSMEN Work Package 6 and 8.

Besides the step ahead to a harmonised way of shortage management, the data collected and the conclusions made for this report will also serve as an important footing for the scheduled conceptual platform for monitoring and managing drug shortages, which will be focus of the next report (deliverable 7.3) of Work Package 7 planned for 2025.

Although shortage-related deficiencies of medicines are a global phenomenon, this report and the identifications herein are focused on European processes, interfaces and data. The Joint Action CHESSMEN aims to harmonise and enhance the existing European measures to relief medicine shortages, improve patient healthcare and build up a well-networked basis at European level including healthcare facilities and other relevant stakeholders. The overarching goal of global connectedness is a future state-of-the-art solution to manage medicine shortages. In the process of interconnection of global systems, a comparison and harmonisation of the various global systems is of high importance and will be examined in future work. The European network achieved by this Joint Action will help to create a globally harmonised and effective network to improve the global access to medicines.



2. Methods

2.1 Identification of best practice solutions of existing IT tools

2.1.1 Existing data basis for identification of best practice solutions of existing IT tools

The data base for the identification of best practice solutions of existing IT tools is mainly based on information previously collected in the preparation of the deliverable 7.1, which critically analysed and discussed existing shortage platforms and the availability of shortage related data in Member States. Documents and information compiled by WP6 in deliverable 6.1 serve as one of the databases. This compilation includes reports on IT solutions in selected Member States, accessible data catalogues of Member States and other relevant documents related to drug shortages. (WP6 D6.1, 2023) In addition, the feasibility survey prepared for deliverable 7.1, which examines the availability of data collected by the shortage systems of the Member States, includes some information on the IT tools of the Member States and therefore also serves as one of the data bases for this report.

2.1.2 Creation of a survey for identification of best practice solutions of existing IT tools

Although the information collected in the previous feasibility survey included specifications of some Member States' IT tools, it was not comprehensive enough to cover the information needed to identify best practice solutions of existing IT tools. For this reason, a new, detailed feasibility survey was developed to allow Member States to describe in detail their systems for dealing with drug shortages (see Annex 1). The survey was developed by analysing the documents identified by WP6 and deriving questions from them regarding IT tools. In addition, findings from the previous report were used as a basis as well, e.g. by asking if and from which systems stock data is obtained, and by focusing on questions that require a machine-to-machine approach.

This survey focuses on the benefits of these systems and concludes with highlights and best practices of the strategies implemented by Member States to address drug shortages. In addition, the survey explicitly included and encouraged Member States that do not currently have a variety of IT tools or have IT systems under development to submit their best practices and describe their ways of managing medicines shortages.

The survey was divided into different sections and requested information on, for example, the technical structure of the electronic shortage system, the collection and quality of data related to shortages and the provision and accessibility of data to relevant stakeholders. Moreover, the survey has been designed in such a way that the large amount of generated data can be used in the next deliverable 7.3 (*Development of a concept platform to monitor and manage medicines shortages*).

2.1.3 Analysis of existing IT solutions at national and EU level

The survey was circulated to all Member States participating in WP7 and 18 completed surveys from 17 Member States were received. Three countries did not complete the survey for different reasons. One Member State completed the checklist twice due to the separation of the national competent authorities responsible for medicines and vaccines. Both of these national competent authorities share common IT tools, so answers of the survey could partly be combined and other answers could be considered separately. Therefore, the sample size varies from n=17 and n=18. 11 out of 17 Member States have indicated that they have an electronic shortage system. Due to the consideration of the separated/combined information of the Member State with two national competent authorities, the sample size varies between n=11 and n=12 systems/IT-tools. Each sample size per calculation is listed in the chapter 3.1.1.

The details of the checklists were combined in an Excel master template. The individual subgroups of the survey: electronic shortage system – technical setup, electronic shortage system – additional functions, data quantity, data quality, data accessibility and further information are examined separately in the analysis. As the survey is very extensive and detailed, as described above, and can also be used to prepare deliverable 7.3, the most important information from the survey has been selected to identify best practice. Within the analysis, the responses from each Member State have been anonymised. In some cases, the answers have been shortened or edited to make them easier to understand (see chapter 3.1).

2.2 Identification of the minimum common dataset

For the identification of the minimum common data set, the core data set defined in deliverable 7.1 was used as a main source. (WP7 D7.1, 2023) For the definition of the core data set, a survey has been conducted which focused on the data collected within the national shortage platforms. The survey considered the aspects, which were of interest in the documents provided by WP 6 and in the Mpox and COVID-19 templates, which the EMA provided for the NCA reporting during the pandemics. In the end, the core data represents a streamlined and compromised data set able to cover the most important aspects of information on ongoing shortage situations and to supply an adequate amount of data for the shortage management.

To expand the core dataset to the minimum common dataset, it was aligned with the missing data points of interest of Mpox and COVID-19 templates. Beyond that, the proposal for a Regulation on the authorisation and supervision of medicinal products for human use was searched for possible requirements, which could derive from the potential legislation. (European Council, 2023)

The final assessment of the minimum common data set will also take into account the outcome of the deliverable 7.1 survey with focus on the ability of the Member States to collect the data on a national legal basis. By using this data already prepared in different context, the proposal on the minimum common data set did not require a revised survey.

3. Results

3.1 Identification of best practice solutions on the existing IT tools

3.1.1 Survey for the identification of best practice solutions on the existing IT tools

3.1.1.1 Technical setup of the electronic shortage system

In the survey, 11 out of 17 Member States indicated that they have an electronic shortage system in place which is equal to 65% (Table 1).

Question	Criterion	Sample Size (n)	Total Number	%
<i>Does your country have an electronic shortage system?</i>	Yes	17	11	65%

Table 1: Survey result - Does your country have an electronic shortage system?

Out of the 11 Member States that report having an electronic shortage system, the system is hosted internally by 8 Member States (Table 2) and 82% of the Member States electronic shortage systems are updated live/daily (Table 3).

Question	Criterion	Sample Size (n)	Total Number	%
<i>Who is hosting the shortage reporting system (internally by NCA or externally by a service provider)?</i>	Internally	11	8	73%

Table 2: Survey result - Who is hosting the shortage reporting system (internally by NCA or externally by a service provider)?

Question	Criterion	Sample Size (n)	Total Number	%
<i>How frequently are the data updated in your shortage system?</i>	Live/daily	11	9	82%

Table 3: Survey result - How frequently are the data updated in your shortage system?

According to the survey, there is a wide range of formats, in which the shortage report can be saved as. The answers given are summarized listed in Table 4. The most frequent mentioned answers are: pdf, xml, text, html, Excel formats and structured databases.

In what format is the shortage report saved as?
<ul style="list-style-type: none"> • Online database or export in Excel format
<ul style="list-style-type: none"> • Pdf, saved as: document, structured data in, MS SQL database
<ul style="list-style-type: none"> • For NCA users: csv, html • For external users: xml and xls
<ul style="list-style-type: none"> • XML and/or PDF formats • The information in the report document is converted to structured form in an SQL database.
<ul style="list-style-type: none"> • Text file format
<ul style="list-style-type: none"> • SQL database • Export can be done in any format. XML format on website
<ul style="list-style-type: none"> • XML format
<ul style="list-style-type: none"> • A statement in an application by a MAH
<ul style="list-style-type: none"> • Structured data in databases
<ul style="list-style-type: none"> • Relation database; format JSON - JSON is a lightweight data interchange format that is often used for structured data storage.
<ul style="list-style-type: none"> • Pdf
<ul style="list-style-type: none"> • The platform allows the data to be exported as an Excel file. • HTML format or plain text .txt • graphic Dashboard .pdf

Table 4: Survey result - In what format is the shortage report saved as?

64% of the Member States stated, that the electronic shortage report can be edited retrospectively after transmission (Table 5).

Question	Criterion	Sample Size (n)	Total Number	%
After submission of the shortage report: can the shortage report be edited (e.g. if there are missing/incorrect entries)?	Yes	11	7	64%

Table 5: Survey result - After submission of the shortage report: can the shortage report be edited?

11 out of 12 national competent authorities' electronic shortage systems are connected to internal systems/databases which equals to 92%. Furthermore, 7 out of 12 electronic shortage systems are connected to external systems/databases which corresponds to 58% (Table 6). A listing of internal systems/databases connected with the shortage systems and the data being transferred into the shortage system from internal systems is shown in Table 7.

In Table 8 is a listing of external systems/databases connected with the shortage system and data being transferred towards external systems. In all cases, there is no established data transfer of data from the external systems into the shortage systems.

Question	Criterion	Sample Size (n)	Total Number	%
<i>Is there an interface connecting your shortage system with other internal systems/databases?</i>	Yes	12	11	92%
<i>Is there an interface connecting your shortage system with external systems/databases?</i>	Yes	12	7	58%

Table 6: Survey result - *Is there an interface connecting your shortage system with other internal and/or external systems/databases?*

Is there an interface connecting your shortage system with other internal systems/databases? If yes, which internal systems/databases are connected with the shortage system?	Is there an interface connecting your shortage system with other internal systems/databases? If yes, which data are transferred into the shortage system?
<i>Internal regulatory database</i>	<i>Product data (code, commercial name, etc) of products with active MA</i>
<i>eForm Temporary product shortage notifier interfaced with central and integrated case tracking, workflow and document management system</i>	<i>The pdf of the notification and the accompanying data</i>
<i>Every information to registered and authorized medicinal products (e.g. billing information, contact details of the marketing authorization holder, GMP/GDP details) are stored in the internal system, this information is interlinked with the shortage notification</i>	<i>Name of the medicinal product, Procedure number of the shortage notification, MR/DC/CP number, Marketing authorisation holder, Active substance, ATC code, Domain (human/veterinary), Dosage form, Applicant, Prescription-only, SAP product (for billing), Priority (internal classification), PIP code of not available packs (depending on selection during notification), PIP code of limited available packs (depending on selection during notification), Pharmaceutical form, Strength, Legal base of the authorisation, Hospital product (not fully implemented yet), ICU product (not fully implemented yet), Risk class (not fully implemented yet), Settlement (for billing), Psychotropic (yes/no), Narcotic drug (yes/no)</i>
<i>Medicinal Products Registry, Analysis and reporting software, Organisation registry, Diary system, eServices, Integration products, Logging systems, User management system, Mail system.</i>	<i>Medicinal product information, marketing status information, information package sizes, organisational information. The system also generates information on substitutable alternatives to facilitate the manual process of evaluating the impact and options of how to mitigate the medicinal shortage, based on data from other systems.</i>

<i>Our case management system that is also used for regulatory procedures.</i>	NA
<i>Marketing authorization registry. Shortage registry is formed from shortage notifications.</i>	<i>Information for identifying the medicinal product in the package level is transferred to shortage reporting system.</i>
<p><i>The Shortage system is connected with the internal system for the acceptance, evaluation and publication of shortages. The shortage system is the Webservice-Provider, the internal system is Webservice consumer.</i></p> <p><i>The system for the acceptance, evaluation and publication of shortages is connected with the agency's website and generates HTML-fragments fetched by the agency's homepage</i></p>	<p><i>System for the acceptance, evaluation and publication of shortages: Shortage notifications for human vaccines</i></p>
<i>Online medicinal product information center</i>	None
<p><i>Drug database Open Data Catalogue Overview Market Report Electronical prescription system</i></p>	NA
<p><i>The shortage system is connected with the internal database of marketing authorisation applications</i></p>	<p><i>The MAH can search and choose the respective medicinal product for which a shortage report should be created via processing number, marketing authorisation number or medicinal product name in the shortage system.</i></p> <p><i>These information are transferred from the internal marketing authorisation database into the electronic shortage system.</i></p> <p><i>The following information is transferred into the shortage system:</i></p> <ul style="list-style-type: none"> <i>product name</i> <i>processing number</i> <i>marketing authorisation number</i> <i>specific number for each MAH</i> <i>name and address of the MAH</i> <i>pack size/code/quantity</i> <i>active ingredient</i> <i>strength</i> <i>pharmaceutical form</i>

<p><i>Agency's medicines database.</i></p> <p><i>The medicines database contains all information about the registered medicines. The shortage system gives information to Agency's medicines database about the start and end date of a shortage.</i></p>	<p><i>The shortage system receives information about medicines (name, active substance, dosage, pharmaceutical form, package information, MAH holder, registration number, type of procedure, etc.).</i></p>
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Table 7: Survey results - Which internal systems/databases are connected with the shortage system? Which data are transferred into the shortage system?

<p>Is there an interface connecting your shortage system with external systems/databases? If yes, which external systems/databases are connected with the shortage system</p>	<p>Is there an interface connecting your shortage system with external systems/databases? If yes, which data are transferred into the shortage system?</p>
<p><i>Social insurance system</i></p>	<p><i>None, the social system only reads the information of the shortage notifications</i></p>
<p><i>Notifications of upcoming and ongoing shortages are published as open-source data which is utilized by several actors:</i></p> <ul style="list-style-type: none"> <i>- service which enables future integration in prescription systems - Electronic Healthcare Record</i> <i>- Information regarding shortages from medicinal product agency is visible on affected products. Separate pages for health care professionals vs the public</i> 	<p><i>None – all data is outgoing.</i></p>
<p><i>Public shortage information is published on webpage as an open data from where different entities can download the information.</i></p>	<p><i>NA</i></p>
<p><i>Prescription systems</i></p> <p><i>National electronic shortage system is connected with the following platforms:</i></p> <ul style="list-style-type: none"> <i>- Electronic prescription platforms</i> <i>- Hospital's management platforms</i> <i>- Pharmacy's management platforms</i> <i>- Wholesalers's management platforms</i> <i>- Insurance companies</i> <i>- Other entities of the Health Ministry</i> 	<p><i>None</i></p> <p><i>One way from national system to other platforms</i></p>
<p><i>eForm "Temporary product shortage notifier"</i></p> <p><i>Only notification reception, no outward communication</i></p>	<p><i>The pdf of the notification and the accompanying data</i></p>

<i>Public shortage information is published in Agency's webpage as an open data from where different entities can download the information.</i>	NA
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Table 8: Survey results - Which external systems/databases are connected with the shortage system? Which data are transferred into the shortage system?

5 out of 12 national competent authorities systems are able to analyse the shortage data automatically (Table 9). This corresponds to 42%. A detailed description of the automated analysis is shown in Table 10.

Question	Criterion	Sample Size (n)	Total Number	%
<i>Is there any automated analysis of the shortage data reported?</i>	Yes	12	5	42%

Table 9: Survey result - Is there any automated analysis of the shortage data reported?

If yes, please describe the process of the automated evaluation:	If yes, how are the automated analysed data presented (for example graphic, listings)?
<p><i>The system generates information regarding possible alternatives (substitutable medicines, packages within the same package group or alternative pack-sizes) or if there has been a decision to withdraw marketing authorization.</i></p> <p><i>The system updates this information once per day so that published information is up to date.</i></p> <p><i>(In addition the assessors may add information regarding other possible alternatives or relevant mitigation actions).</i></p> <p><i>The assessors analyse the current situation and reports to stakeholders and other agencies.</i></p>	<p><i>Listing in published information of all shortages (Excel-file).</i></p> <p><i>Graphics can be viewed in a statistics tool internally for analysis purposes.</i></p>
<p><i>A filled Excel template can be automatically generated from the shortage system.</i></p> <p><i>The Excel is filled with all shortage notifications over a selected time period and includes the information of the mandatory data fields from the shortage report.</i></p>	<p><i>Graphics of number of notifications per month or year and reported causes.</i></p>

<i>Filters can be applied as appropriate to analyse specific data.</i>	
<i>Automated categorization of criticality of vaccine shortages after data transfer from shortage portal</i>	<i>Only NCA internally in the form of categorization for criticality assessment</i>
<i>Monitoring and statistics</i>	<i>Graphic and listings</i>
<i>For the evaluation of the impact of the shortages there is an automated algorithm. Nonetheless, there is the need to assess every shortage in a case-by-case scenario. The algorithm is an addition tool to consider on the evaluation.</i> <i>Information regarding shortages is automatically updated on a dashboard and presented graphically.</i>	<i>Both listing and graphics are possible.</i>

Table 10: Survey results - Process of the automated data evaluation and kind of presentation.

According to the survey, there are only 25% of the national competent authorities who have a separate system for entities beside MAHs for shortage reporting (Table 11).

Question	Criterion	Sample Size (n)	Total Number	%
<i>Is there a separate system for entities beside MAHs for shortage reporting?</i>	Yes	12	3	25%

Table 11: Survey result - Is there a separate system for entities beside MAHs for shortage reporting?

67% of the national competent authorities report the use of alternative IT tools beside the shortage system that are relevant for monitoring supply shortages (Table 12). A detailed listing can be found in Table 13.

Question	Criterion	Sample Size (n)	Total Number	%
<i>Are there alternative IT tools in place beside the shortage system that are relevant for monitoring supply shortages?</i>	Yes	12	8	67%

Table 12: Survey result - Are there alternative IT tools in place beside the shortage system that are relevant for monitoring supply shortages?

Are there alternative IT tools in place beside the shortage system that are relevant for monitoring supply shortages? If yes, please describe these alternative IT tools.
<ul style="list-style-type: none"> • <i>Online service for MAHs to report sales data periodically.</i>
<ul style="list-style-type: none"> • <i>Pharmacy sale statistics is used as a complement to assess the medicinal shortage situation. Website</i>
<ul style="list-style-type: none"> • <i>Stock information (wholesalers, pharmacies, hospital pharmacies)</i>
<ul style="list-style-type: none"> • <i>Form for the public to report unavailability's of vaccines (pharmacists, physicians, patients)</i>
<ul style="list-style-type: none"> • <i>Database with information on the sales of medicines charged to the National Health System</i>
<ul style="list-style-type: none"> • <i>TRACStocks– tool implemented by industry associations to collect data on stocks and supplies</i>
<ul style="list-style-type: none"> • <i>In cooperation with an external service provider tools for monitoring of market shares, pharmacy data (sell-in/sell-out), prescription data;</i> <p><i>List of certain FDF for which data on production, stocks and sales volumes are to be submitted on a legal and regular basis. Tool that summarises information on critical medicines from the internal database for marketing authorization to gain a quicker overview on available medicines.</i></p>
<ul style="list-style-type: none"> • <i>Data warehouse and Dashboard</i>

Table 13: Survey result – Description of alternative IT tools.

3.1.1.2 Additional functions of the electronic shortage systems

Within the surveys subgroup: electronic shortage system – additional functions, special features of the electronic shortage systems during shortage reporting and processing are queried.

According to the survey, 82% of the Member States with an electronic shortage system indicate, that functions to ease the reporting of shortages are available (Table 14). The detailed functions e.g. automated data by a connection to internal databases to ease the report are listed in Table 15.

Question	Criterion	Sample Size (n)	Total Number	%
<i>Are there functions to ease the report (e.g. automatic filling of data from previous reports or other connected databases)?</i>	Yes	11	9	82%

Table 14: Survey result - Are there functions to ease the report?

Are there functions to ease the report (e.g. automatic filling of data from previous reports or other connected databases)? If yes, please explain.
<ul style="list-style-type: none"> • <i>Internal regulatory database connection</i>
<ul style="list-style-type: none"> • <i>e.g.: copying address data (headquarters, mailing address) product name packsize name MAH Registration number</i>
<ul style="list-style-type: none"> • <i>Product search in eService. Information regarding package identification number and if the product has been marked as marketed or not in the registry for marketing information (managed by another agency). Pre-population of eService forms at report updates with previously notified data. In one notification several strengths and packages can be included, and prognostic dates can be specified for each package. Some types of information concerns all included packages selected, for example the cause of the shortage.</i>
<ul style="list-style-type: none"> • <i>Automatic filling of data from previous reports</i>
<ul style="list-style-type: none"> • <i>The package information in the shortage reporting system is filled automatically.</i>
<ul style="list-style-type: none"> • <i>Automatic filing data from drug database</i>
<ul style="list-style-type: none"> • <i>When indicating the CIP code (Presentation Identifier Code), the name of the medicine, ATC code, active substance and presentation are automatically filled.</i>
<ul style="list-style-type: none"> • <i>At the beginning of the transmission of the initial report, a list appears with the data that was deposited with the central registration for the shortage system. The MAH can search and choose the respective medicinal product for which a shortage report should be created via processing number, marketing authorisation number or medicinal product name in the shortage system. These information are transferred from the internal marketing authorisation database into the electronic shortage system.</i>
<ul style="list-style-type: none"> • <i>Some information regarding the medicine is filled automatically, for example type of procedure. Some information is already paired and the MAH only has to select the respective presentation, for example the fields: active substance, dosage, pharmaceutical form and commercial name are paired. Some fields open a drop-down list and the selection must be done through the listing. MAH can submit multiple shortages on a single notification. Nonetheless, every notification has to be filled separately.</i>

Table 15: Survey results - Functions to ease the report.

Regarding data submission, 91% of Member States with an electronic shortage system report that submitting organisations receive assistance/explanation when entering data (Table 16). In addition, submitting organisations can add their own comments to the shortage report within each Member States

electronic system (100%, Table 16). In almost all electronic shortage systems (91%), data is entered by submitting entities using both free text and multiple choice fields (Table 16).

Question	Criterion	Sample Size (n)	Total Number	%
<i>During submission of data, does the submitting entity get help/explanations how/what to fill into the requested data fields (e.g. short description/explanation/expected information for the respective field)?</i>	Yes	11	10	91%
<i>Can the submitting entity in the shortage report comment on entered data (e.g. elaborate on cause of shortage)?</i>	Yes	11	11	100%
<i>Are the data for the shortage report requested in a free-text field or are there multiple-choice fields (e.g. to increase consistency and comparability of collected data)?</i>	Both	11	10	91%

Table 16: Survey results - During submission of data, does the submitting entity get help/explanations how/what to fill into the requested data fields? Can the submitting entity in the shortage report comment on entered data? Are the data for the shortage report requested in a free-text field or are there multiple-choice fields?

9 out of 12 national competent authorities with an electronic shortage system have the opportunity to add information into the electronic shortage report, which equals to 75% (Table 17). The information added on a regular basis according to the survey are listed in table 18. The majority of Member States have indicated that the inclusion of a criticality assessment may be one of the possible options (Table 18).

Question	Criterion	Sample Size (n)	Total Number	%
<i>Is it possible for the authority to add information into the electronic shortage report (e.g. criticality assessments)?</i>	Yes	12	9	75%

Table 17: Survey result - Is it possible for the authority to add information into the electronic shortage report?

Is it possible for the authority to add information into the electronic shortage report (e.g. criticality assessments)? If yes, which information are added on a regular basis?
<ul style="list-style-type: none"> Internal assessment (for the purpose if and why a parallel export ban is issued), Emails, other relevant documents
<ul style="list-style-type: none"> In the shortage management system, the assessor can add information regarding criticality, interactions with the company and other relevant information for the assessment.
<ul style="list-style-type: none"> Criticality assessment can be added.

<ul style="list-style-type: none"> • <i>Categorization of criticality of vaccine shortage, publication of vaccine alternatives, link to NITAG recommendations</i>
<ul style="list-style-type: none"> • <i>Criticality assessments, alternative treatments' information (e.g. sales and stock data), emails received related to the shortage...</i>
<ul style="list-style-type: none"> • <i>List of substitute medicine product and/or note</i>
<ul style="list-style-type: none"> • <i>Information shared with the notifier:</i> <ul style="list-style-type: none"> - <i>Classification of impact</i> - <i>Classification of mitigation measure</i> <p><i>Information exclusively internal:</i></p> <ul style="list-style-type: none"> - <i>Justification of impact;</i> - <i>Internal notes.</i>

Table 18: Survey result - Which information are added on a regular basis into the shortage report?

According to the survey, data on shortages are available in English for 64% of Member States with an electronic shortage system (Table 19).

Question	Criterion	Sample Size (n)	Total Number	%
Are shortage data available in English in your Member State?	Yes	11	7	64%

Table 19: Survey result - Are shortage data available in English in your Member State?

3.1.1.3 Data quantity within the electronic shortage systems

The surveys subgroup: Data quantity, is intended to give an impression of the scope of data available in the electronic shortage systems. 100% of the Member States' electronic shortage systems include data that is mandatory for the submission of the shortage report (Table 20). Further, 91% stated that voluntary information can be added (Table 20). With regard to the question of how long the shortage reports are kept, 64% of the Member States indicated that the reports are kept permanently or that no time limit has been set (Table 20).

Question	Criterion	Sample Size (n)	Total Number	%
Is there data that is mandatory for the submission of a shortage report?	Yes	11	11	100%
Are there possibilities to add voluntary data to the shortage report?	Yes	11	10	91%
How long are shortage reports saved in your shortage system internally?	No limit/permanently	11	7	64%

Table 20: Survey results – Mandatory data for submission of shortage report, possibilities to add voluntary data into the shortage report and duration of storage internally.

3.1.1.4 Data quality within the electronic shortage systems

The surveys subgroup: Data quality, is intended to give an impression on the current quality of shortage related data within the used IT tools/systems. This subgroup analysis is not limited to Member States with an electronic shortage system. In some cases, Member States without an electronic shortage system but with another data collection system are also included.

47% of Member States report having a system to check the quality of shortage data transmitted (table 21). 2 out of 11 Member States with an electronic shortage system indicate that an interface between the shortage system and the respective QS system is available (Table 21). In both cases, the interface is internal (Table 21). Descriptions of the systems to check the quality of submitted shortage data are listed in Table 22.

Question	Criterion	Sample Size (n)	Total Number	%
<i>Is there a system to check the quality of submitted shortage data?</i>	Yes	17	8	47%
<i>If yes, is an interface between the shortage system and the respective system available for an automated data check?</i>	Yes	11	2	18%
<i>If yes, which interface is used? Is the interface internal or external?</i>	internal	2	2	100%

Table 21: Survey results – Availability of a system to check the quality of submitted shortage data, availability of an interface and kind of interface.

Is there a system to check the quality of submitted shortage data? If yes, please describe.
<ul style="list-style-type: none"> Manually via IQVIA
<ul style="list-style-type: none"> Data entry validation in the eService. XML-schema to validate data constraints and datatypes.
<ul style="list-style-type: none"> Only the medicine name/strength/MAH/ National authorisation code or EMA authorisation number is validated since a case needs to be created in our case management system manually based on this information from the shortage report
<ul style="list-style-type: none"> Medicine package information is based on medicines registry and shortage can be reported only for marketed packages. <p>System do not allow you to inform shortages for same periods (no double notifications). If shortage ends earlier or lasts longer, you need to update the ongoing shortage information.</p>
<ul style="list-style-type: none"> Notification can be done only for active medicine product, Estimated resumption date is later than Valid from (date)
<ul style="list-style-type: none"> Only manually in some cases via external service provider Tools/ Market shares can be checked via an external service provider market data

- Some fields are mandatory.
Some fields open a drop-down list and the selection must be done through the listing.
However, it is mainly a manual validation.

Table 22: Survey results – Systems to check the quality of submitted shortage data.

33% of all Member States, participating in the survey have a system in place to collect information on stocks of medicines (Table 23). Information on the systems in detail are listed in Table 24. 67% of these systems collected information on selected medicines and 33% of all medicines (Table 23). None of the systems are connected to an electronic shortage system of the Member States (Table 23).

Question	Criterion	Sample Size (n)	Total Number	%
Do you have a system in place to collect information on stock of medicines?	Yes	18	6	33%
If yes, is information collected on all medicines or only on selected medicines/medicines that are in a shortage situation?	Selected	6	4	67%
If yes, is information collected on all medicines or only on selected medicines/medicines that are in a shortage situation?	All	6	2	33%
If yes, is there an interface connecting the shortage system with the respective system?	Yes	4*	0	0%

Table 23: Survey results – Systems to collect information on stock of medicines, kind of medicines and interfaces of the respective system with the shortage system. *(4 of the 6 Member States with a system to collect information on stock of medicines do have an electronic shortage system, whereas 4 is the sample size, having the opportunity to connect the systems via an interface.)

Do you have a system in place to collect information on stock of medicines? If yes, please describe.	If yes, who do you collect the information from (e.g. MAH/wholesalers/pharmacies etc.)?
<ul style="list-style-type: none"> • Wholesaler, pharmacy and hospital pharmacy stock levels are reported daily or every other day. 	<ul style="list-style-type: none"> • Wholesaler, pharmacy and hospital pharmacy
<ul style="list-style-type: none"> • National competent authority may require MAH to provide information on the stock of a medicinal product. During the pandemic, a weekly report on the stock of certain medicinal products was reported. 	<ul style="list-style-type: none"> • MAH. Under certain circumstances, we also collect information from wholesalers.
<ul style="list-style-type: none"> • The Electronic Reporting System for stock of medicines included in National catalogue of medicines prices – prescription only mentioned 	<ul style="list-style-type: none"> • For all manufacturers, importers, wholesalers, pharmacies and hospitals

<ul style="list-style-type: none"> System established during the Covid-19 pandemic. We collect the stock of medicine at a wholesaler and pharmacy level, as well as at the hospital pharmacies. 	<ul style="list-style-type: none"> Wholesalers, pharmacies and hospital pharmacies.
<ul style="list-style-type: none"> Tool implemented by industry associations 	<ul style="list-style-type: none"> MAHs
<ul style="list-style-type: none"> According to national legislation, there is a FDF list for which regular data transmission by MAH's is considered necessary to assess the supply situation. The following data must be transmitted on a regular basis: data on production, stocks and sales volumes. The FDF data have to be uploaded by each MAH to a SFTP server in csv format. This process/system is not connected with NCA's electronic shortage system, since realised in cooperation with an external service provider. 	<ul style="list-style-type: none"> MAHs, Wholesalers (different way of data collection)

Table 24: Survey results – Systems in place to collect information on stock of medicines.

22% of all Member States participating in the survey have a system in place to collect information on demand of medicines (Table 25). Detailed information on the systems are listed in Table 26. In most cases, all information on demand is collected for all medicines (Table 25) and in no case, there is an interface connecting the shortage system with the demand system (Table 25).

Question	Criterion	Sample Size (n)	Total Number	%
Do you have a system in place to collect information on demand of medicines?	Yes	18	4	22%
If yes, is information collected on all medicines or only on selected medicines/medicines that are in a shortage situation?	Selected	4	1	25%
If yes, is information collected on all medicines or only on selected medicines/medicines that are in a shortage situation?	All	4	3	75%
If yes, is there an interface connecting the shortage system with the respective system?	Yes	4	0	0%

Table 25: Survey results – Systems in place to collect information on demand of medicines, kind of medicines and interfaces of the respective system with the shortage system.

Do you have a system in place to collect information on demand of medicines? If yes, please describe.
<i>Wholesaler sales are collected twice in a month</i>
<i>Only historical data on sales which were extrapolated</i>
<i>We regularly check the National Prescription System data, where we can see the monthly sales of medicines charged to the National Health System.</i>
<i>Not directly, however we so have systems to monitor past demand. Future demand is calculated based on past figures.</i>

Table 26: Systems in place to collect information on demand of medicines.

According to the survey 11% of the participating Member States have a system in place to analyse stock/demand/other relevant data to make forecasts for preventive or mitigative measures on shortages (Table 27). In both cases, there is no interface connecting the electronic shortage system with the respective system. Short descriptions of the systems are shown in Table 28.

Question	Criterion	Sample Size (n)	Total Number	%
<i>Do you have a system in place to analyse stock/demand/other relevant data to make forecasts for shortage preventive or mitigative measures?</i>	Yes	18	2	11%
<i>If yes, is there an interface connecting the shortage system with the respective system</i>	Yes	2	0	0%

Table 27: Survey results - systems in place to analyse stock/demand/other relevant data to make forecasts for shortage preventive or mitigative measures and availability of an interface.

Do you have a system in place to analyse stock/demand/other relevant data to make forecasts for shortage preventive or mitigative measures? If yes, please describe.
<i>Stock data is uploaded by pharmaceutical companies on a third party platform that exploits the data into tables and Excel sheets forecasting stock.</i>
<i>The specific FDF-data are transmitted by the MAH. NCA is the data owner but an external service provider processes and prepares the data in a NCA-specific dashboard</i>

Table 28: Survey results - systems in place to analyse stock/demand/other relevant data to make forecasts for shortage preventive or mitigative measures.

3.1.1.5 The public data accessibility

The survey's subgroup on public data accessibility queries the procession of shortage data for public access. 61% of the Member States participating in the survey publish the shortage report publicly (Table 29). 45% of these Member States prepare the data for example graphically (Table 29). Information on how the data are prepared can be found in Table 30.

Only 1 Member State has a separate access point for healthcare professionals on shortage data with information beyond the public view with more information and provides the following information "All trading notifications are visible from MAHs" (Table 29).

Question	Criterion	Sample Size (n)	Total Number	%
<i>Is the shortage report published publicly?</i>	Yes	18	11	61%
<i>Are the public shortage report data prepared for example graphically?</i>	Yes	11	5	45%
<i>Is there a separate access point for shortage data with information beyond the public view with more information, e.g. for doctors, pharmacists or similar professionals?</i>	Yes	18	1	6%

Table 29: Survey results - *Is the shortage report published publicly? Are the public shortage report data prepared for example graphically? Is there a separate access point for shortage data with information beyond the public view with more information, e.g. for doctors, pharmacists or similar professionals?*

Are the public shortage report data prepared for example graphically? If yes, how are the data prepared?
<i>Preparation status sheet</i>
<i>Graphics with text and diagrams on number of shortages, causes and different type of statistical data is published every quarter on the Agency's website.</i>
<i>Shortage search is provided and open data source</i>
<i>In the report published by NCA every six months.</i>
<i>Listing</i>

Table 30: Survey results – *Preparation of shortage data.*

3.1.1.6 Further questions on shortage systems

The survey's subgroup: further questions includes on the one hand information on used Excel sheets in the context of shortage management and on the other hand questions on best practice solutions which might not be covered by the surveys questions so far.

7 out of 18 Member States use Excel templates for the management of shortage data (Table 31). Processes in which the Excel templates are involved and if these can be automatically filled or read out are shown in Table 32.

Question	Criterion	Sample Size (n)	Total Number	%
Are Excel templates used in your Member State for the management of shortage data (e.g. for data transfer)?	Yes	18	7	39%

Table 31: Survey result – use of Excel templates within the Member State.

Are Excel templates used in your Member State for the management of shortage data (e.g. for data transfer)? If yes, please briefly describe the process.	If yes, are the Excel templates automatically filled or read out? Please describe.
MAH report shortages in medicine shortage eService, provided by the agency. This information is handled in the Medicine Shortage Registry. From here, shortage data can be exported/transferred to Excel.	Yes. Previously described regarding publication of shortages: Medicinal shortages are available in the XML-files (since 2018).
A filled Excel template can be automatically generated from the shortage system. The Excel is filled with all shortage notifications over a selected time period and includes the information of the mandatory data fields from the shortage report Filters can be applied as appropriate to analyse specific data.	See first column
At the moment for merging data from different sources to make analysis and to make graphic figures. This changes, when Power BI comes.	No
For the reporting of the shortages, MAH/representative send the information to the NAMMDR using an xls. format	Not automatically
According to national legislation, there is a FDF list for which regular data transmission by MAH's is considered necessary to assess the supply situation. The FDF data have to be uploaded by each MAH to a SFTP server in csv format.	Ideally the data collection is programmed by the MAH's IT department and automatically retrieved, stored in csv utf-8 format and uploaded to the external service provider's server.
An Excel database is used to manage all shortage information. The system is manual and reporting of shortages from stakeholders can come via a form, an email and even phone. However, the details requested will be the same in all cases. It is not for the purposes of data transfer.	Some columns are free text, some are drop-down.

<i>We have electronic platforms. However, exported Excel files are still used for data transfer or to facilitate the analysis.</i>	<i>Yes, Excel files are exported from the electronic platform fully filled.</i>
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Table 32: Survey result – use of Excel templates within the Member State.

Best practices on the Member State’s shortage systems/IT tools that deserve special mention and which are not covered by the survey are listed in Table 33.

Are there any best practices on your Member States shortage systems/IT tools that deserve special mention and which are not covered by the survey? If yes, please describe.
<p><i>Agency’s structured systems for “information flow” from receiving report of medicine shortage to publish to the public:</i></p> <ol style="list-style-type: none"> <i>1. Medicine Shortage eService</i> <i>2. Medicine Shortage Registry</i> <p><i>--> The utilisation of standardised headings for all information that is given on alternative medicines, provide good quality in the open source data provided, as well as the possibility to analyse shortages and get statistics.</i></p> <ol style="list-style-type: none"> <i>3. Medicine Shortage Analysis</i> <i>4. Medicine Shortage Public Information on the web and as open data</i>
<i>Very well working system for shortage reporting (SAHA SA), that has gotten thanks from MAH and their representatives.</i>
<i>Collaboration with NITAG in automated form if required.</i>
<i>Our shortage IT tool sends automatic messages to the MAH or local representative to remind them that the shortage re-supply date has passed and that they have not reported the end of the shortage.</i>
<p><i>Standardized data formats.</i></p> <p><i>RESTful API integration.</i></p> <p><i>Real-time data updates.</i></p> <p><i>User-friendly web interfaces.</i></p> <p><i>Secure data access and storage.</i></p> <p><i>These practices can enhance efficiency and interoperability in shortage management systems.</i></p>
<i>The Electronic Reporting System for stock of medicines included in National catalogue of medicines prices – prescription only.</i>

Yes. NCA's Information System for Health Technologies Assessment system is only used for the submission and management of shortages notified by the MAH or its representatives.

In addition, as referred above, there is the possibility for the notification of unavailabilities (not shortages) by wholesalers, pharmacies, healthcare professionals and citizens. These notifications are compiled daily in an Excel file. This compilation is a manual procedure.

Wholesalers and pharmacies have the obligation to notify these unavailabilities of medicines to Agency until 24 hours after the identification of the lack of medicine.

Pharmacies must notify these unavailabilities when the lack of the medicine results in the incapacity to satisfy a prescription/request from the citizen in a period of 12 hours.

Healthcare professionals and citizens also have the possibility to notify these unavailabilities as an optional procedure.

Table 33: Survey results – Description of best practices on the Member States shortage systems/IT tools that deserve special mention and which are not covered by the survey.

3.1.2 Best practices of the Member State's systems extracted from 7.1 Survey

The feasibility survey which was circulated within the preparation of deliverable 7.1 includes a question regarding best practice of the Member States systems that should be considered in the current context. The answers were screened and selected to meet the criteria of best practices regarding IT systems. The survey's answers are listed in Table 34 and have also been anonymised.

Is there a best practice in your Member State's system that should be considered?
<ul style="list-style-type: none"> <i>Our national medicinal product database is a single point of action for the whole lifecycle of the medicinal product.</i>
<ul style="list-style-type: none"> <i>Data-driven system that has been architected to provide the best possible overview over the stocks of medicine at the major medicine resellers in the Member State. The best practice take-away is to identify the supply chain of medicine and monitor the stocks in a way that enables you to react before a shortage becomes a problem. This includes expanding the dataset with data pertaining to medicine consumption, as well as supply – converted to a unified figure such as the WHO DDD. Additionally, the system needs to be flexible enough to enable adjusting the metamodel to any needs that might arise, such as for example a pandemic or natural disaster. This way medicine shortage is monitored at different key points in the supply chain.</i>
<ul style="list-style-type: none"> <i>Data combining with machine to machine. No manual work / Excel.</i>
<ul style="list-style-type: none"> <i>Have a maximum of autofills to avoid mistakes; Pop ups to better define expectations</i>

<ul style="list-style-type: none"> • We aim that our new system allows to comply with the standards developed by the International Organization for Standardization for the identification of medicinal products (IDMP).
<ul style="list-style-type: none"> • Yes, we have a guideline that explains how to use the shortage reporting system in the management of shortages of medicinal products and a users manual.

Table 34: Feasibility survey D7.1 results – Description of best practice in your Member State's system that should be considered.

3.1.3 Documents selected by WP6 to identify best practice solutions on IT tools

In order to identify the best practice solutions of IT tools, the documents selected by Work Package 6 were also analysed. As noted in deliverable 7.1, it is possible that the selected documents on best practice in IT tools do not reflect the current state of the systems.

The documents were reviewed and much of the information is already covered by the survey on identification of best practice solutions on the existing IT tools. The key points of the selected documents on best practice solutions on IT tools are detailed guidelines provided to users and two systems for collecting information on medicines stocks, which are covered by the survey as well.

3.2 Identification of the minimum common dataset

3.2.1 Alignment of the core dataset to the COVID-19/Mpox template

Like stated in section 0 of the report on hand, the core data set defined within the deliverable 7.1 sources serves as a basis for the definition of the minimum common data set. To provide a confound overview the core dataset is presented in the table below (Table 35).

Core data	Availability in % of MSs	Core data	Availability in % of MSs
MAH company name	100	Alternatives available (yes/no)	89
Trade name / product name	100	(Expected) End date of shortage	89
Pharmaceutical form	100	Shortage status (actual, potential, resolved)	78
Strength	100	ATC code	67
(Expected) Date of the beginning of shortage	100	Market sales volume of the medicinal product	50
Cause of shortage	100	Marketing status of the medicinal product (marketed/not marketed)	44

Shortage notification date	100	Risk assessment of the impact of shortage	39
National authorisation code or EMA authorisation number	94	Market share data of the medicinal product (hospital and ambulatory markets)	39
Email address of the contact person	89	Volume of prescriptions	11
Active substance	89	Information on the forecast of demand	6
Pack size	89		

Table 35: Identified core preparedness dataset for the data transfer from NCAs to ESMP and data availability in percent in the 18 participating Member States. (WP7 D7.1, 2023)

The defined core dataset was set against the template for COVID-19 and Mpox, which was structured into four sections: product information, Member State vaccine/drug needs, Member State stock information and additional shortage information. Different subdivisions of these parts were used to map the critical availability of vaccines and medicines in the Member States during the pandemics. Table 36 below exemplarily shows the general data structure and relevant data elements of the EMA COVID-19 template, the template for NCA reporting on Mpox was structured the same way.

EMA COVID-19 PHE NCA reporting template
Product information
Product name
International non-proprietary name (INN) or common name
ATC code
Active substance
Units
Mass of the active substance(s) in mg
Route of administration
Additional information
Reporting country
Information on the national vaccination strategy
Member States demand
Estimation PHE patient need (6 months)
Estimation of new hospitalised patients (6 months)
Estimation of new pre-hospitalised patients foreseen to be treated (6 months)
Estimation number of patients to be vaccinated (6 months)

Estimation of average use			
Average daily dose of active substance needed	Average therapy duration (days)		Average use per adult patient
Planned minimum stock			
Member States supply			
MS available stock			
Hospital stock	Community pharmacy stock	Wholesale distributor stock	Current strategic reserve
Planned strategic reserve			

Table 36: Data structure and elements of the COVID-19 PHE NCA reporting template that was used by the EMA during the COVID-19 crisis for data query. (European Medicines Agency, 2023)

With respect to the specified subgroups within the template, the core dataset (Table 35) was adjusted into four data types: general information, product information, shortage details and Member State needs. The provisional data structure of the core dataset is presented below (Table 37).

Data structure core dataset			
General information			
MAH company name		Email address of the contact person	
Product information			
Trade name / product name	ATC code		Pack size
Strength	National authorisation code or EMA authorisation number		Pharmaceutical form
Active substance	Marketing status of the medicinal product (marketed/not marketed)		Market share data of the medicinal product (hospital and ambulatory markets)
Shortage details			
Shortage notification date	(Expected) Date of the beginning of shortage		(Expected) End date of shortage
Shortage status (actual, potential, resolved)	Cause of shortage	Risk assessment of the impact of shortage	Alternatives available (yes/no)
Member States need			
Market sales volume of the medicinal product	Volume of prescriptions		Information on the forecast of demand

Table 37: Data elements of the core dataset classified into data types resulting in a data structure similar to that of the COVID-19 NCA reporting template.

As highlighted above, the data elements of the core dataset provide an overview of the shortage situation, product information and information on the medicinal need in the Member States that is core focus of preventive and mitigative measures. The complimentary information for these measures on the stock situation along the supply-chain for the medicinal product was not included in the core dataset so far. Stock related details are important for the determination of the drug supply in the Member States and can help to predict the course of the dynamic shortage situation. For this reason, the core dataset is extended by data elements that query the stocks of the product in the supply-chain and other supply related information. The data elements adopted from the COVID-19 NCA reporting template which have not been included yet into the core dataset are presented below (Table 38).

Supplementary data elements		
Member States supply		
Currently available stock at pharmaceutical companies	Currently available stock at hospitals	Currently available stock at pharmacies
Currently available stock at wholesalers	Currently available stock strategic reserve	
Planned minimum stock at pharmaceutical companies	Planned minimum stock at hospitals	Planned minimum stock at pharmacies
Planned minimum stock at wholesalers	Planned minimum stock strategic reserve	
Information on the forecast of supply		

Table 38: Supplementary data elements adopted from the COVID-19 NCA reporting template.

The data elements in Table 38 were assigned into a data type to comply with the data structure as shown in Table 37. As the data elements focusing on the supply and stocks had no suitable existing data type, a new data type that concentrates on the information and the supply and stocks was added to the data types of the core dataset and named 'Member States supply'.

The proposed minimum common dataset consists of the core dataset that has been identified in the deliverable 7.1 and the additional data elements extracted from the COVID-19 NCA reporting template. The identified minimum common dataset will serve together with the deliverable 7.1 as a basis for the discussion of general data transfer from the Member States to the ESMP and the development of ESMP preparedness features. The proposed minimum common dataset is presented below (Table 39).

Minimum common dataset		
General information		
MAH company name	Email address of the contact person	
Product information		
Trade name / product name	ATC code	Pack size

Strength	National authorisation code or EMA authorisation number		Pharmaceutical form
Active substance	Marketing status of the medicinal product (marketed/not marketed)		Market share data of the medicinal product (hospital and ambulatory markets)
Shortage details			
Shortage notification date	(Expected) Date of the beginning of shortage		(Expected) End date of shortage
Shortage status (actual, potential, resolved)	Cause of shortage	Risk assessment of the impact of shortage	Alternatives available (yes/no)
Member States need			
Market sales volume of the medicinal product	Volume of prescriptions		Information on the forecast of demand
Member States supply			
Currently available stock at pharmaceutical companies	Currently available stock at hospitals		Currently available stock at pharmacies
Currently available stock at wholesalers		Currently available stock strategic reserve	
Planned minimum stock at pharmaceutical companies	Planned minimum stock at hospitals		Planned minimum stock at pharmacies
Planned minimum stock at wholesalers		Planned minimum stock strategic reserve	
Information on the forecast of supply			

Table 39: The minimum common dataset combines the core dataset from the deliverable 7.1 and the supplementary data elements adopted from the COVID-19 NCA reporting template.

3.2.2 Availability of the minimum common dataset in Member States

The evaluation of the feasibility study in deliverable 7.1 showed that the data situation in the 18 participating Member States is very diverse. There is a wide variety in the systems used, the information collected and the legal obligations in the Member States, which answered the survey. In particular, the provision of shortage-related information shows large differences in the availability of data in the Member States. The table below shows which percentage of Member States are able to provide the data of the minimum common dataset based on the survey conducted for deliverable 7.1 (Table 40).

Availability of minimum common dataset in Member States (%)			
General information			
MAH company name	100	Email address of the contact person	89
Product information			

Trade name / product name	100	ATC code	67	Pack size	89		
Strength	100	National authorisation code or EMA authorisation number	94	Pharmaceutical form	100		
Active substance	89	Marketing status of the medicinal product (marketed/not marketed)	44	Market share data of the medicinal product (hospital and ambulatory markets)	39		
Shortage details							
Shortage notification date	100	(Expected) Date of the beginning of shortage	100	(Expected) End date of shortage	78		
Shortage status (actual, potential, resolved)	78	Cause of shortage	100	Risk assessment of the impact of shortage	39	Alternatives available (yes/no)	89
Member State need							
Market sales volume of the medicinal product	50	Volume of prescriptions	11	Information on the forecast of demand	6		
Member State supply							
Currently available stock at pharmaceutical companies	22	Currently available stock at hospitals	6	Currently available stock at pharmacies	6		
Currently available stock at wholesalers	6		Currently available stock strategic reserve	6			
Planned minimum stock at pharmaceutical companies	0	Planned minimum stock at hospitals	0	Planned minimum stock at pharmacies	0		
Planned minimum stock at wholesalers	0		Planned minimum stock strategic reserve	0			

Information on the forecast of supply ¹	17
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Table 40: The minimum common dataset and its availability in the 18 participating Member States queried in the feasibility survey for deliverable 7.1. (WP7 D7.1, 2023)

The overview of data availability in Table 40 shows that Member States are only able to provide a fraction of the shortage-related data requested. Although most Member States have access to general or product information and shortage details like the cause and duration of the shortage, only a few Member States can provide extensive detailed information like the available stocks, demand, forecasts and production plans.

The feasibility survey for deliverable 7.1 also queried whether the participating Member States could provide information that focus on the stocks and supply from other system or in individually defined cases. The potential data availability of the supplementary data elements from Table 38 in the 18 surveyed Member States for deliverable 7.1 is shown below (Table 41).

Data element	Availability in % of MSs	Data element	Availability in % of MSs
Currently available stock at pharmaceutical companies	22	Planned minimum stock at pharmaceutical companies	0
Currently available stock at hospitals	6	Planned minimum stock at hospitals	0
Currently available stock at pharmacies	6	Planned minimum stock at pharmacies	0
Currently available stock at wholesalers	6	Planned minimum stock at wholesalers	0
Currently available stock strategic reserve	6	Planned minimum stock strategic reserve	0
Information on the forecast of supply	17		

Table 41: Data availability of the supplementary data elements from in the 18 Member States that participated in the feasibility survey of deliverable 7.1. (WP7 D7.1, 2023)

¹ In deliverable 7.1 „Information on the forecast of supply” was labeled as “Forecast of supply for the medicinal product (projected deliveries)”.

4. Discussion

4.1 Identification of best practice solutions of existing IT tools at national and EU level

With the help of the analysed survey of the current and the previous report and the evaluation of the documents identified in Work Package 6, the following options can represent a selection of best practice solutions on IT tools, divided into their subgroups.

4.1.1 Best practices on IT tools: Technical setup of the electronic shortage system

In addition to setting up an electronic shortage platform, the majority of Member States host the shortage platform internally (Table 1 and Table 2). Internal hosting can be advantageous in order to make adjustments and adaptations to the system quickly and transparently. Internal hosting also ensures independence in data security and data safety, which are steadily rising topics in importance.

In almost all Member States with an electronic shortage system, the shortage data is updated at least daily or live (Table 3), ensuring that the most up-to-date information is always available to NCA's shortage assessors and for public. Also, this contributes to a maximum of transparency it also brings along questions of a fast data processing and assessment which raise the needs for automatised solutions in shortage management.

According to the survey, there is a wide range of formats, in which the shortage report is saved as. The most frequent mentioned answers are pdf, xml, text, html, Excel formats and structured databases (Table 4). There is no specific format that has become established in the majority of Member States. In general, preference should be given to formats that are machine-to-machine compatible and can be processed automatically to ensure a minimum workload to summarise the data needed for transmission from NCAs to EMA via ESMP.

The majority of the Member States indicated, that a submitted shortage report can still be edited (Table 5). According to the survey, there is no clear trend as to whether the changes are made by the NCA or by the submitting entities. There are advantages and disadvantages in both cases. If data can only be edited by the NCA afterwards, data sovereignty is no longer with the submitting entities, although the NCA could make adjustments quickly and would always know which data have been updated. On the other hand, if only the submitting entities can edit the data, there could be time delays and the NCA would always have to be informed during processing whether data have been edited. Furthermore, the possibility to add specific data to a shortage notification e.g. on criticality of the shortage would need an explicit possibility for the NCA to make adjustments or adding. Otherwise, those kinds of data would be needed to add manually to shortage notifications, which would cost an additional investment of time.

Almost all national competent authorities with an electronic shortage system are linked to an internal database/system via an interface (Table 6). By linking the shortage system to internal databases, a large amount of data can be transferred automatically (Table 7), improving data quality and reducing workload. According to the survey, the shortage system is for example linked to the internal database of marketing

authorisation applications. More than half of the Member States indicated, that an interface connecting the shortage system with external systems/databases is available (Table 6). In order to increase the amount of data, especially with regard to the minimum common data set, and to save time, it could be beneficial to transfer data from external systems into the internal shortage system. However, according to Table 8, this is not the case in any of the Member States. The time saving mentioned above is also becoming increasingly important due to the growing number of supply shortages and the resulting increase in the workload of the NCAs. An automated shortage analysis would be a good measure to counteract this. An automated analysis of the shortage data is possible in less than half of the national competent authorities (Table 9). Although not many national competent authorities have yet established automated evaluation, it can be seen as best practice due to large amounts of time, which can be saved. Unfortunately, there is only one Member State with an adequate system in place that generates information regarding possible alternatives (substitutable medicines, packages within the same package group or alternative pack-sizes). Another national competent authorities' system can do an automated categorization of criticality of vaccine shortages (Table 10). Furthermore, there is a system where information regarding shortages are automatically updated on a dashboard and presented graphically (Table 10). An automated algorithm is available in a national competent authorities' system for assessing the impact of shortages. However, each shortage needs to be assessed on a case-by-case basis. The algorithm is an additional tool to be considered in the assessment (Table 10). The results of the analysis can be prepared as graphics or text for example (Table 10).

More than half of the national competent authorities indicated, that alternative IT tools are in place beside the shortage system that are relevant for monitoring supply shortages (Table 12). The alternative IT tools are used for example, to collect stock data, report sales data or the tools also represent a data warehouse or a dashboard (Table 13). Overall, IT tools that also contribute to data quantity with regard to the minimum common dataset can be considered advantageous, as they can also be used automatically or connected to other systems with an interface if necessary. This point was also raised by one Member State when asked whether further best practices should be considered (Table 33). It was noted that the aim should be to combine data on a machine-to-machine basis, without manual work or Excel spreadsheets.

4.1.2 Best practices on IT tools: Additional functions of the electronic shortage systems

In the electronic shortage system of almost all Member States there are functions to ease the report (Table 14). By simplifying reporting, data quality can be increased by avoiding mistakes and the workload of the submitting entity can be reduced. Functions to ease the report might be automatic filling of data from medicinal product database or form previous reports (Table 15). As described above, there is usually an interface between the shortage system and the internal medicinal product database. In almost all Member States with an electronic shortage system, the submitting entity get help/explanations within the system how/what to fill into the requested data fields (Table 16). This improves the data quality as well. In addition, there are also Member States that provide detailed guidelines to the submitting entities (Table 33).

Moreover, in all Member States with an electronic shortage system, the submitting entity can comment on entered data of the shortage report (Table 16) and in most of the Member States shortage systems, there are multiple-choice and free-text fields (Table 16). Multiple choice fields may help to increase consistency and comparability of collected data and in free-text fields, additional information may be added by the submitting entity.

More than half of the national competent authorities do have the possibility to add information into the electronic shortage report (Table 17). The information, which are added on a regular basis are listed in Table 18. According to the survey, the criticality assessment is most frequently included in the shortage report, which might increase data consistency and also allows information to be bundled so that data is less scattered. Regarding other Member State best practices that should be considered (Table 33), one Member State noted that their shortage system sends automatic messages to the MAH or local representatives to remind them that the shortage re-supply date has passed and that they have not notified the end of the shortage. This automated approach is also a best practice for keeping the shortage data up to date and reducing the workload of the NCAs.

Data on shortages are available in English in the majority of Member States (Table 19). This is an advantage with regard to the minimum common dataset and a harmonised data transmission.

4.1.3 Best practices on IT tools: Data quantity within the electronic shortage systems

In each Member State are data that is mandatory for the submission of a shortage report (Table 20), which enhances the data consistency and also forms an important basis for (partially) covering data of the minimum common dataset. Furthermore, there are in most of the Member States possibilities to add voluntary data to the shortage report and the shortage reports are saved without a limit (Table 20). Unfortunately, the voluntary nature of the transmission of some data is a weakness, as it is unlikely that this data will be regularly transmitted to NCAs. On the other hand, the permanent storage of shortage reports is a great advantage, as it allows historical data to be combined and analysed. However, the length of time for which this data is stored is partly dependent on legal requirements and cannot be determined arbitrarily.

4.1.4 Best practices on IT tools: Data quality within the electronic shortage systems

Less than half of the Member States indicate that they have a system to check the quality of submitted data (Table 21). Even if the majority did not or had not the possibility to implement a system to check the data's quality, it has a major benefit. An example of a quality-check systems is according to the survey the data entry validation via XML-schema to validate data constraints and datatypes. It was also noted that some data quality checks can only be carried out manually, e.g. using tools from external service providers (Table 22) whereby an automated check is to be favoured. Overall, it should be noted that basic data on medicinal products are easier to verify, for example through links to internal systems. Complex data such as the market share are more difficult to verify when included in the report.

One third of the Member States have a system in place to collect information on stock of medicines (Table 23). The data are mainly available for selected medicinal products (Table 23). Unfortunately, there is no interface between the stock information systems and the shortage systems (Table 23). Nevertheless, the

availability of a system on stock information is a best practice solution regarding the requirements of the minimum common dataset and the machine-to-machine transmitting approach. Three Member States collect the stock of medicine at a wholesaler and pharmacy level, as well as at the hospital pharmacies (Table 24). As part of the previous survey from deliverable 7.1, one of the respective Member States had noted with regard to best practices to consider that their “data-driven system has been architected to provide the best possible overview over the stocks of medicine at the major medicine resellers in the Member State. The best practice take-away is to identify the supply chain of medicine and monitor the stocks in a way that enables you to react before a shortage becomes a problem. This includes expanding the dataset with data pertaining to medicine consumption, as well as supply – converted to a unified figure such as the WHO DDD. Additionally, the system needs to be flexible enough to enable adjusting the metamodel to any needs that might arise, such as for example a pandemic or natural disaster. In this regard, [our system] could monitor both medicine and medical devices as was relevant for the COVID-19 pandemic. This way medicine shortage is monitored at different key points in the supply chain”. Another Member State has a tool on stock data which is implemented by industry associations (Table 24), where information on medicinal products with historical shortages and/or risk of shortages are collected from MAHs. The data are updated in real-time. MAHs send their levels of stocks through the platform/Tool that provides an overview of levels of stocks for essential medicines, accessible by companies and health authorities. MAHs can also send their levels of stocks directly to the NCA in an Excel sheet format. Upon their reception, the NCA will proceed to an analysis of the data and underline whether the level of stock is critical or not.

One fifth of the Member States have a system in place to collect information on demand of medicines without medicinal product specification (Table 25). There is no interface between the system in question and the shortage system. As mentioned above, data on the availability of a system on demand information is a best practice solution with respect to the requirements of the minimum common data set and the machine-to-machine transfer approach. One Member State has indicated that the wholesaler sales are collected twice in a month (Table 26).

Two Member States indicated that they have a system in place to analyse stock/demand/other relevant data to make forecasts for shortage preventive or mitigative measures (Table 27). In one of the two Member States systems, stock data is uploaded by pharmaceutical companies on a third party platform that exploits the data into tables and Excel sheets forecasting stock. In this case, it is also the Member State that has the above-mentioned stock level tool, which was implemented by industry associations. The other Member State described that specific finished dosage form data are transmitted by the MAH. NCA is the data owner but an external service provider processes and prepares the data in a NCA-specific dashboard (Table 28). With regard to systems for stock data, demand data and systems to make forecasts for shortage preventive or mitigative measures, maximum benefit would be achieved if these systems could be linked to other internal systems like the shortage system and if the analysis of the data could be automated without much manual effort.

4.1.5 Best practices on IT tools: The public data accessibility

In more than half of the Member States, the shortage report is published publicly and the public shortage data are prepared graphically (Table 29). The possibilities to prepare the data are for example: Graphics with text and diagrams on number of shortages, causes and different type of statistical data is published

every quarter on the agency's website (Table 30). The simplified and transparent presentation of shortage data enables the public to be informed about current shortages in a comprehensible manner. Again, it can be recommended as a best practice to automate the evaluation and presentation of the data in order to reduce the workload within the NCAs.

4.1.6 Best practices on IT tools: Further aspects on shortage systems

Around one third of the Member States use Excel templates for the management of shortage data (Table 31). When using Excel templates, it can be identified as best practice that automated filling and reading of the templates should be possible in order to keep the workload low and the data quality high (Table 32).

One aspect of the best practices to be considered in Table 33 is the according to a NCA, the agency's structured systems for "information flow" from receiving report of medicine shortage to publish to the public. The utilisation of standardised headings for all information that is given on alternative medicines, provide good quality in the open source data provided, as well as the possibility to analyse shortages and get statistics. Another Member State has indicated different practices, which can enhance the efficiency and interoperability in shortage management systems such as standardized data formats which also match the approach of the minimum common dataset, RESTful API integration, real-time data updates to increase the data quality, user-friendly web interfaces for easy and correct data transmission and secure data access and storage.

However, it should be noted that not all of the EU Member States were included in this analysis with regard to the best practice solutions identified for IT tools. It should also be noted that IT tools outside the EU were also not taken into account, which means that some good practices may not have been considered in this analysis. Nevertheless, a large number of best practice solutions on IT tools could be identified.

4.2 Identification of minimum common dataset

The minimum common dataset that will be the main focus point for the further discussion and conceptualisation of the preparedness features and the harmonised data transfer from the Member States to the ESMP was identified in this report. During the identification process different shortcomings related to the data elements of the minimum common dataset were analysed and evaluated.

The screening of the proposal for a Regulation on the authorisation and supervision of medicinal products for human use showed that there is no explicit data stated that is to be provided by the NCAs, however the proposal states that the obligations of NCAs are to be expanded. It is envisaged that the new regulation aids in the harmonisation of the rules for the monitoring and reporting of current or potential shortages of medicinal products. This includes the procedures and the respective tasks, as well as obligations of concerned bodies (e.g. NCAs). The minimum common dataset that is proposed in this report can be used as a guideline for the discussion of legislative aspects to define clear data requirements and processes that are necessary to establish a European and national shortage management and address medicines shortages. In this context also the financing of the new systems and processes must be clarified. Although the Joint Action provides a concept and framework for the shortage-management systems and

processes, financing aspects must be discussed at the relevant institutions of the participating Member States.

The scope and data structure of the identified minimum common dataset were aligned to the relevant data elements of the COVID-19 and Mpox reporting templates. In the conceptualisation of the ESMP it must be discussed if the proposed minimum common dataset contains sufficient data elements to be able to describe comprehensively the drug shortage situation and to prepare measures to manage these situations. Hereby it must be noted, that in addition to the NCAs the MAHs supply the ESMP with shortage-related information and thus potentially missing information from the NCAs could be covered by the MAHs. This aspect must be considered in the conceptualisation process of the ESMP.

In the context of the extent of the minimum common dataset and the data transfer, it must be discussed whether for every shortage the complete minimum common dataset has to be transferred. For example, a reduced data transfer (e.g. without information on forecasts) could possibly be reasonable for shortages that are only short-dated and have a confirmed end date. Naturally, with an established machine-to-machine setup, the complete data transfer should be pursued, but during the setup of the automated systems a reduced data transfer can lessen the resource demanding collection of data by Member States that are in the process of shortage system automatisation. It is important for a harmonised approach that every Member State has the same concept of the minimum common dataset and ideally has an automated machine-to-machine setup that is able to transfer the data elements of the minimum common dataset to the central shortage management system.

Apart from the identification of the extent and the structure of the minimum common dataset the individual establishment of clear definitions for the data elements present in the minimum common dataset plays a decisive role in the initiation of the harmonised data transfer from the Member States to the ESMP. Specifically the unified definition of data elements in the data types product information, shortage details, Member States' need and Member States' supply and the use of these definitions by the Member States is essential for a harmonised approach. To establish an overview of a shortage situation, it is essential to identify clearly the medicinal products that are in the focus of the shortage report. The minimum common dataset includes the data elements "trade name / product name", "ATC code", "Pack size", "Strength", "National authorisation code or EMA authorisation number", "Pharmaceutical form" and "Active substance" to identify the product in question. However, currently there is a general problem when the provided information by different Member States is compared and analysed. First and foremost, a common language for the data elements must be determined. As EMA is an international agency, it is logical to use an international auxiliary language such as English as a common ground for communication. Although data elements "ATC code" and "Active substance" that are subject to international numbering and categorisation requirements would then be identical in all Member States, there could still be a difference in data submitted for the data elements "Strength", "Pack size", "National authorisation code or EMA authorisation number" and "Pharmaceutical form". For these data elements, the harmonisation of units and definition is essential. On the subject of units, the MAHs are discussing a possibility to standardise specification of units that can be adopted in the shortage report. A possible way to harmonise the definition of the data collected for the identification of medicinal products is to use the substance, product, organisation and referential (SPOR) master data catalogue. This catalogue was developed by the EMA to facilitate the reliable exchange of medicinal product information in a robust and consistent manner. In this catalogue, the EMA implements the standards developed by the International

Organization for Standardization (ISO) for the identification of medicinal products (IDMP). The two SPOR services Substance Management Service (SMS) and Product Management Service (PMS) contain harmonised data and definitions to identify uniquely at the same time the ingredients and materials of a medicinal product and the medicinal product based on regulated information such as marketing authorisation, packaging and medicinal information. The implementation of the SPOR master data catalogue would assist the establishment of a common ground for the comparability of medicinal product information between different Member States.

Similar considerations apply to the data elements in the data type shortage details, Member States' need and Member States' supply. The calculations of data elements such as market share and volume of the medicinal product, volume of prescriptions and forecast of demand and supply must either be performed in a uniform way in all the Member States' systems or be obtained from a common source to harmonise the data submission and make the data of different Member States comparable. It must be noted however, that a strong dependency of shortage details on a single source should be avoided, as this is a threat identified in the SWOT analysis of the deliverable 7.1. Systems and procedures that independently confirm the data and alleviate the dependency should be considered and established. The specific procedures for the calculation and acquisition of the shortage details above rely heavily on the requirements by ESMP and should be discussed intensively when a basic ESMP system frame has been developed. For data elements regarding the drug shortage cause and the risk assessment of the impact of the shortage situation standardised definitions are equally required. The harmonisation of the key definitions will enable the analysis of the shortages of different Member States. The Work Package 5 of the CHESSMEN Joint Action discusses the key definitions related to shortages of medicines. The finalised definition of shortage related terms will aid in refining the management of shortages and support the choice of suited preventive and mitigating measures to resolve or prevent existing and emerging drug shortages.

Apart from the inhomogeneous shortage-related definitions, a major obstacle for a harmonious data transfer approach poses the inconsistent availability of data in the Member States. Although there are data elements of the minimum common dataset that are readily available by a larger percentage of Member States, there are also data elements that are unavailable in almost all Member States. Most Member States have access to key and basic information details on the product and common aspects of the shortage situation. Information that is more detailed however, especially the information from data elements of the minimum common dataset adopted from the COVID-19 and Mpox template that centre on comprehensive information on stocks and supply, is currently mostly uncollectable in the Member States.

One of the reasons for the current data situation in the Member States are missing legal frameworks that impede the accumulation of drug shortage related information that is required for the clear shortage situation overview and the development of targeted measures to mitigate or prevent drug shortages. Furthermore, there are Member States have not yet set up systems to collect relevant shortage information to provide the data for the minimum common dataset. The collection and analysis of data without an automated system is difficult and most often due to high workload not possible. The consolidation of relevant shortage data from multiple sources can be possibly be a problem as well. In the identification of best practices, several Member States that have multiple electronic systems and sources to collect data were identified (Table 7 and Table 12). A larger amount of additional systems and sources

to collect information can be beneficial for the data situation in the Member State, however data from different sources can be difficult to merge and potentially important shortage information can be omitted. In this context, for the discussion of general data transfer and the development of ESMP preparedness features aspects regarding the interface between the NCAs and ESMP have to be discussed. The identification of best practices in section 3.1.1.1 Table 4 shows that the shortage reports from the NCAs are saved in a variety of data formats. For a harmonised approach of data transfer from the NCAs to the ESMP, a data format must be chosen that is to be used by all Member States. The data transfer of the minimum common dataset in a unified format would harmonise the documentation on shortages and allow a simple data transmission, accumulation and evaluation.

5. Next steps

First, the data and results provided will flow into the upcoming deliverable of WP7, which aims to characterize a concept platform for shortage reports and supplementing data for shortage management. Moreover, the concept platform should also cover the important questions of the possibilities of data submission to ESMP. The presented report therefore also got into the possibilities of the Member States to export the needed data and transmit them via machine-to-machine approaches. Secondly, all Member States can use the provided report to adjust their own shortage systems to the needs and scope for an automatised data submission to EMA. This also applies to Member States without any IT system so far, as they can develop an adequate system in line with the best practices already available in the Member States and also with the extent of data needed to completely fulfil the upcoming requests of the EMA. Last but not least, the report can also serve to get new approaches on the national management of shortages if the best practice solution of other Member States can serve as models for others.

Surveys on the identification of best practice solutions on the existing IT tools received after report preparation will be analysed and included into the next deliverable as well.

Regarding the minimum common dataset, it was illustrated that the main problem remains to arise from missing data, which clearly restrict the way a comprehensive assessment can derive out of it. Therefore, it has to be pointed out, that the legislation is needed to be adjusted to allow NCAs to request the data defined in the minimum common data set from the stakeholders.

6. Overall Conclusion

Both parts of this report, the best practices on IT solutions and the minimum common data set, are important checkpoints for a harmonised approach to identifying, preventing and mitigating shortages. With regard to the proposal for a Regulation on the authorisation and supervision of medicinal products for human use, the requirements for NCAs to provide comprehensive data may increase. (European Council, 2023) Therefore, the status quo described in this report may serve various purposes for further approaches in the technical set-up of Member States.

6.1 Identification of best practice solutions of existing IT tools at national and EU level

By analysing the different shortage systems of the Member States, it was possible to identify a large number of best practices for different system features.

A very important aspect of best practice is the general automation of shortage systems. On the one hand, automated assessment of shortage notifications will be of great benefit in reducing the workload of Member States. To date, there are only a few and non-harmonised approaches to automated assessments in Member States, but these serve as first examples of best practice.

On the other hand, the focus will be on best practices for the machine-to-machine approach, which should allow automated data transfer from Member States' systems to the ESMP. In addition, the connection of the shortage systems to internal or external systems via interfaces plays an important role, as resources can be saved by automating the data transfer and improving the quantity and quality of Member States' data required for the ESMP transmission. Internal database links between Member States and their shortage systems are widely used as best practice, while links to external sources allowing data transfer to the shortage systems, including data from the minimum common dataset as stock or demand data, are not available.

However, the establishment of largely automated shortage notification systems will require many human and financial resources, which not all Member States may be able to provide in the short term.

6.2 Identification of minimum common dataset

The identified minimum common dataset has been built from data elements aimed at providing sufficient categorisation of drug shortages and data to prepare measures to manage these shortage situations. The structure and scope of the minimum common dataset was based on the well-established COVID-19/Mpox template. The minimum common dataset consists of 33 data elements providing information on the general shortage situation, the product information and information needed for mitigation and prevention measures. Based on previously collected information on availability of shortage data from the Member States surveyed, several major shortcomings of the European data situation were identified. Of the 33 data elements, only 7 can currently be provided by all Member States. Comprehensive and detailed information on shortages is not available in most Member States. For the effective use of the minimum common dataset or other datasets derived from it, the current data situation in the Member States needs to be improved through measures such as changes to the current legal framework or increased networking of relevant stakeholders. In addition, definitions and units related to scarcity need to be harmonised so that information can be compared and used across Member States. By addressing these shortcomings, the future automated data collection and analysis would help to reduce drug shortages in a consistent way.

7. Bibliography

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8. Annex

7.1 Annex 1: Survey: Identification of best practice solutions on the existing IT tools

This survey is aimed to provide an option for Member States to comment on their multitude of systems (e.g. service portals, platforms, networks) used to collect and process information in relation to shortage situations. Hereby, the focus should be on the description of the best practices and the advantages of these systems. Please note that an isolated Excel template does not count as an IT tool. If an Excel template is used as a database from which data is automatically transferred into an IT tool or if a filled Excel template is automatically generated from an IT tool, the Excel template can be considered as an IT tool.

The answers of the MSs in this feasibility survey will be critically analysed and utilised for the identification of best practice solutions in the existing IT tools at national and European level. In case of questions or suggestions, please contact: JAWP7Shortages@bfarm.de

Please complete and send the survey back until 3rd November 2023.

Table 1: General Information

General Information	
Member State (MS)	
National competent authority	
MS's contact person for questions - Name	
E-Mail address	

Table 2: Electronic shortage system - Technical Setup

Electronic shortage system - Technical Setup		
1. Does your country have an electronic shortage system?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2. Name of your electronic shortage reporting system.		
3. Who is hosting the shortage reporting system (internally by NCA or externally by a service provider)?		
4. How frequently are the data updated in your shortage system?		

Electronic shortage system - Technical Setup	
5. In what format is the shortage report saved as?	
<i>5.1 If stored in a text file format, what text file format is used?</i>	
<i>5.2 If not stored in a text file format, how is the information of the shortage report stored?</i>	
<i>5.2.1 Can the information of the shortage report be transformed into a text file format without difficulties?</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>
6. After submission of the shortage report: can the shortage report be edited (e.g. if there are missing/incorrect entries)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>6.1 If yes, who can edit the shortage report?</i>	
<i>6.2 If not, how are mistakes/incorrect entries managed (e.g. deletion of wrong report and creation of new one)?</i>	
7. Is there an interface connecting your shortage system with other <u>internal</u> systems/databases?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>7.1 If yes, which internal systems/databases are connected with the shortage system?</i>	
<i>7.2 If yes, which interface is used?</i>	
<i>7.3 If yes, which data are transferred into the shortage system?</i>	
<i>7.4 If yes, which data are transferred from the shortage system into other internal systems?</i>	
8. Is there an interface connecting your shortage system with <u>external</u> systems/databases?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>8.1 If yes, which external systems/databases are connected with the shortage system?</i>	

Electronic shortage system - Technical Setup	
8.2 <i>If yes, which interface is used?</i>	
8.3 <i>If yes, which data are transferred into the shortage system?</i>	
8.4 <i>If yes, which data are transferred from the shortage system into external systems?</i>	
9. Is there any automated analysis of the shortage data reported?	Yes <input type="checkbox"/> No <input type="checkbox"/>
9.1 <i>If yes, please describe the process of the automated evaluation.</i>	
9.2 <i>If yes, how are the automated analysed data presented (for example graphic, listings)?</i>	
10. What entities beside MAHs can submit a shortage report (for example physicians, public, pharmacists)?	
10.1 <i>Is there a separate system for entities beside MAHs for shortage reporting?</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>
10.1.1 <i>If yes, please describe the system.</i>	
10.1.2 <i>If yes, is the system connected with the shortage platform via an interface? Which interface?</i>	
11. Are there alternative IT tools in place beside the shortage system that are relevant for monitoring supply shortages?	Yes <input type="checkbox"/> No <input type="checkbox"/>
11.1 <i>If yes, please describe these alternative IT tools.</i>	

Table 3: Electronic shortage system - Additional functions

Electronic shortage system - Additional functions		
1. Are there functions to ease the report (e.g. automatic filling of data from previous reports or other connected databases)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<i>1.1 If yes, please explain.</i>		
<i>1.2 If an automatic filling of data is available, which data are filled in?</i>		
2. During submission of data, does the submitting entity get help/explanations how/what to fill into the requested data fields (e.g. short description/explanation/expected information for the respective field)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3. Is it possible for the authority to add information into the electronic shortage report (e.g. criticality assessments)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<i>3.1 If yes, which information are added on a regular basis?</i>		
4. Are the data for the shortage report requested in a free-text field or are there multiple-choice fields (e.g. to increase consistency and comparability of collected data)?		
5. Can the submitting entity in the shortage report comment on entered data (e.g. elaborate on cause of shortage)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6. Are shortage data available in English in your Member State?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<i>6.1 If yes, which data?</i>		

Table 4: Data quantity

Data quantity	
1. Is there data that is mandatory for the submission of a shortage report?	Yes <input type="checkbox"/> No <input type="checkbox"/>
1.1 <i>If yes, what are the mandatory data?</i>	
2. Are there possibilities to add voluntary data to the shortage report?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2.1 <i>If yes, which data?</i>	
3. How long are shortage reports saved in your shortage system internally?	

Table 5: Data quality

Data quality	
1. Is there a system to check the quality of submitted shortage data?	Yes <input type="checkbox"/> No <input type="checkbox"/>
1.1 <i>If yes, please describe.</i>	
1.2 <i>If yes, is an interface between the shortage system and the respective system available for an automated data check?</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>
1.3 <i>If yes, which interface is used? Is the interface internal or external?</i>	
2. Do you have a system in place to collect information on stock of medicines?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2.1 <i>If yes, please describe.</i>	
2.2 <i>If yes, is information collected on all medicines or only on selected medicines/medicines that are in a shortage situation?</i>	

2.3 <i>If yes, who do you collect the information from (e.g. MAH/wholesalers/pharmacies etc.)?</i>	
2.4 <i>If yes, how frequently are the data updated?</i>	
2.5 <i>If yes, is there an interface connecting the shortage system with the respective system?</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>
2.5.1 <i>If yes, please describe. Is the interface internal or external?</i>	
3. Do you have a system in place to collect information on demand of medicines?	Yes <input type="checkbox"/> No <input type="checkbox"/>
3.1 <i>If yes, please describe.</i>	
3.2 <i>If yes, is information collected on all medicines or only on selected medicines/medicines that are in a shortage situation?</i>	
3.3 <i>If yes, who do you collect the information from (e.g. MAH/wholesalers/pharmacies etc.)?</i>	
3.4 <i>If yes, how frequently are the data updated?</i>	
3.5 <i>If yes, is there an interface connecting the shortage system with the respective system?</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>
3.5.1 <i>If yes, please describe. Is the interface internal or external?</i>	
4. Do you have a system in place to analyse stock/demand/other relevant data to make forecasts for shortage preventive or mitigative measures?	Yes <input type="checkbox"/> No <input type="checkbox"/>

4.1 <i>If yes, please describe.</i>	
4.2 <i>If yes, where do you get the data from (e.g. own system or external service providers)?</i>	
4.3 <i>If yes, is there an interface connecting the shortage system with the respective system?</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>
4.3.1 <i>If yes, please describe. Is the interface internal or external?</i>	

Table 6: Data accessibility (public)

Data accessibility (public)	
1. Is the shortage report published publicly?	Yes <input type="checkbox"/> No <input type="checkbox"/>
1.1 <i>If yes, which information are published?</i>	
2. How frequently are shortage reports published publicly?	
3. Is there a separate access point for shortage data with information beyond the public view with more information, e.g. for doctors, pharmacists or similar professionals?	Yes <input type="checkbox"/> No <input type="checkbox"/>
4. Are the public shortage report data prepared for example graphically?	Yes <input type="checkbox"/> No <input type="checkbox"/>
4.1 <i>If yes, how are the data prepared?</i>	
5. How long are the shortage reports shown publicly?	
5.1 <i>If the shortage report is outdated, is the data still available at the website?</i>	

Table 7: Further questions

Further questions	
1. Is there any option to enhance the facilities of the reporting system in case of crisis or public health emergencies?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>1.1 If yes, please describe.</i>	
2. Are Excel templates used in your Member State for the management of shortage data (e.g. for data transfer)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>2.1 If yes, please briefly describe the process.</i>	
<i>2.2 If yes, are the Excel templates automatically filled or read out? Please describe.</i>	
3. Are there any best practices on your Member States shortage systems/IT tools that deserve special mention and which are not covered by the survey? If yes, please describe.	

4. In deliverable 7.1, mandatory data that should be transmitted to the ESMP as a priority preparedness dataset were identified. Where do you get the preparedness data from? Please add the internal and external sources to the corresponding data listed below.

Core Data – (preliminary) Preparedness Dataset	Source
MAH	
Product name	
Pharmaceutical form	
Strength	
(Expected) Date of the beginning of shortage	
Cause of shortage	
Shortage notification date	
National authorisation code/EMA authorisation number	
E-Mail of MAH contact person	
Active substance	
Pack size	
Alternatives	
Expected end date of shortage	
Shortage status	
ATC Code	
Volume of sales	
Marketing status	
Risk assessment of impact of shortage	
Market share of the product	
Volume of prescriptions	
Demand data/Forecast of demand	

5. Which internal/external sources are taken into account in case of crisis reporting? Please list.