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Regulatory Science and Innovation Task Force

## EMA workshop on the Vulnerability Assessment with marketing authorisation holders responsible for a subset of critical medicines on the Union list – Questions and Answers

Date: 18/03/2026

Location: Online, 09:30–12:30 Amsterdam time (CET)

### Disclaimer

This document contains a list of all questions asked through Slido.com during the Vulnerability Assessment workshop held on 18 March 2026. The questions listed below were received from participants either before or during the workshop and have not been modified. The questions have been categorised and grouped by clusters for ease of reading. Questions that were submitted during the workshop, that were not in scope of the vulnerability assessment exercise are not addressed in this document. The responses represent the view of the MSSG Working Group on the Vulnerability Assessment Methodology at the time of the workshop and are not official statements by the European Medicines Agency nor its partners.

For detailed instructions on how to fill-in the data request template, please refer to the email circulated to all Marketing Authorisation Holders in scope of the 2026 Vulnerability Assessment Exercise, in particular the “ReadMe” guidance and the “Data Dictionary” worksheets in the data requests template.

Please see below an overview of the different clusters:

**General questions on the approach and the methodology:** These questions cover the approach and the methodology (starting from [page 3](#)).

**Benefits for marketing authorisation holders:** These questions relate to incentives, support measures, or mechanisms foreseen or envisaged under the new pharmaceutical legislation and proposed Critical Medicines Act (starting from [page 6](#)).

**Relationship between data request template and Shortage Prevention Plans (SPPs):** These questions concern the interaction, alignment, or dependencies between the data request template and the Shortage Prevention Plan (SPP) set out in Annex IV of the new pharmaceutical legislation (starting from [page 6](#)).

**Data request template:** These questions concern the structure, format, or use of the template for data collection (starting from [page 7](#)).



**Frequency of submissions:** These questions relate to how information, data, or submissions must be updated (starting from [page 13](#)).

**Marketing status/authorisation status of medicines in scope:** These questions relate to the marketing, authorisation, or regulatory status of medicinal products under the applicable legal framework (starting from [page 14](#)).

**Engagement with Marketing Authorisation Holders in scope of the exercise:** These questions address communication requirements, channels, or exchanges between stakeholders and competent authorities concerned (starting from [page 17](#)).

**Deadline for submission of data:** These questions relate to deadlines applicable to Marketing Authorisation Holders (MAHs) for submission of the data (starting from [page 18](#)).

Question from participant	Answer
<b>General questions on the approach and the methodology</b>	
Why do you need this level of detail?	The data requests to MAHs are based on the legal obligations set out in the new pharmaceutical legislation (NPL) and proposed Critical Medicines Act (CMA), to inform the vulnerability assessment.
How will critical vulnerabilities connect with third parties (Active Pharmaceutical Ingredient (API) manufacturers outside the European Economic Area (EEA)) be addressed?	The level of detail is required to inform both Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) recommendations under the NPL and relevant measures under the CMA to strengthen the security of supply of critical medicines in the Union.
For being competitive especially APIs are sourced in Asia. There is no production in Europe, or it is not competitive. Hence, we know that we are dependent on Asia, what will the EMA do here?	Detailed medicinal product data is required only in Sheet 1 of the excel template. The other sheets in the template cover high-level information, structured by distinct supply chain, without repeating full product-level detail.
I would like to know what the objective of all this work is?	
Are the Marketing Authorisation Holders (MAHs) required to submit the template?	
What lessons did you take from feedback from participants on resourcing in the pilot in 2024? This exercise seems to be much wider.	
Will there be an opportunity for MAHs to challenge the results of the vulnerability assessment in a structured way?	Marketing authorisation holders will be informed of the outcomes of the vulnerability assessment, at aggregate level. No re-examination of the outcome of the MSSG evaluation is foreseen.
How will this mandatory requirement be enforced? Via NCAs	The data requests to Marketing Authorisation Holders (MAHs), to inform the vulnerability assessment, are based on the legal

<sup>1</sup> [Structured dialogue on security of medicines supply - Public Health](#)

<sup>2</sup> [Assessment of the supply chain vulnerabilities for the first tranche of the Union list of critical medicines: Technical report - Public Health](#)

<sup>3</sup> [https://health.ec.europa.eu/document/download/3da9dfc0-c5e0-4583-a0f1-1652c7c18c3c\\_en?filename=hera\\_cma\\_strat-report\\_en.pdf](https://health.ec.europa.eu/document/download/3da9dfc0-c5e0-4583-a0f1-1652c7c18c3c_en?filename=hera_cma_strat-report_en.pdf)

Question from participant	Answer
inspections as majority of the MAs are other than centralized?	obligations set out in the new pharmaceutical legislation (NPL) and proposed Critical Medicines Act (CMA). MAHs are required to submit the requested information within the specified timeline. The
Will VA data become part of inspections?	legislation does not foresee that the data submitted will be part of inspections.
A lot of data is requested; would you also ask to companies what is needed in their view to ensure supply?	<p>The exercise is driven by the legal requirements set out in the NPL and proposed CMA, therefore inputs are structured and aligned with the legal obligations. The level of detail requested is designed to support a comprehensive assessment of supply risks, indirectly capturing relevant insights on supply security.</p> <p>The legislation also allows the possibility to request additional information from marketing authorisation holders, where necessary.</p>
Is the template mandatory only for the 19 International Non-proprietary Name (INNs)? Or for all critical medicines?	The template should be completed by all marketing authorisation holders responsible for the 19 INNs included in the current exercise. Beyond this exercise, the approach set out in the upcoming pharmaceutical legislation will apply to all critical medicines on the Union list of critical medicines.
You are mixing quantitative data with subjective assessments. How is this a robust approach?	<p>The vulnerability assessment methodology is intentionally designed as a hybrid model. Quantitative data on structural elements of the supply chain (such as manufacturing sites, flows, capacities and inputs) form the backbone of the assessment. Certain dimensions, including demand dynamics, operational practices and organisational processes, are difficult to quantify. In those cases, structured qualitative questions with clearly defined answer options are used, often supported by underlying quantitative components to help ensure consistency. Triangulation across multiple variables and sections is intended to support the robustness of the overall assessment.</p>
For some variables, especially in conditional vulnerabilities, there is a level of judgement (subjective assessments) involved. How will you ensure consistency?	<p>Consistency is supported through several mechanisms. Quantitative elements are incorporated wherever possible alongside qualitative questions, so that responses rely on data rather than perception alone. Qualitative questions use standardised answer options, which aim to reduce the likelihood of divergent interpretations across companies. Detailed guidance will be provided to analysts to support a harmonised interpretation across products. Additionally, triangulation across multiple variables and sections will be applied, helping to ensure that no single subjective input unduly influences the overall conclusion.</p>

Question from participant	Answer
<p>How will you detect and assess the quality level of the data obtained? Poor data quality will lead to incorrect analyses.</p>	<p>We rely on MAHs to provide accurate and complete information. To support this, a validated data collection template has been developed to minimise errors during submission. The European Medicines Agency (EMA) has extended Product Management Service (PMS) data submission deadlines for enrichment of structured Manufacturer's data and pack size for non-CAPs (part of <a href="#">Union list of critical medicines (ULCM)</a>) using Product User Interface (UI) and Active Pharmaceutical Ingredient (API) to June 2026.</p> <p>MAHs are required to enrich PMS with all required data. Also, throughout the process, MAHs are encouraged to engage with Rapporteurs and EMA coordinators in case issues are identified.</p>
<p>Are climate risks/vulnerabilities included in the assessment?</p>	<p>The vulnerability assessment intends to identify structural vulnerabilities in the supply chains of critical medicines. Climate-related risks and vulnerabilities are not directly captured as unique, time limited factors, however the potential impact of such risks may be captured in the assessment of certain elements (e.g. supply disruption notification process, geographical manufacturing areas, logistics sensitivity etc.).</p>
<p>Assuming that for a critical medicine many MAHs offer it and the market share is divided between them, hence all MAHs are dependent on one producer, will this be evaluated as well?</p>	<p>The vulnerability assessment methodology was designed to identify situations in which multiple marketing authorisation holders, responsible for a given INN plus pharmaceutical form and with market share distributed among them, are dependent on a single manufacturer of either API or finished product. This aspect is explicitly addressed through the requirement for comprehensive supply chain mapping as such scenarios represent a potential bottleneck within the supply chain.</p>
<p>We are also seeking clarity on the handling of commercially confidential information — particularly supplier names and locations — and how this data will be protected within EMA databases.</p>	<p>Data will be treated in accordance with applicable EU data protection legislation, including Regulation (EU) 2018/1725, and the Agency's established rules on confidential and commercially sensitive information.</p> <p>Data will be handled in an extremely confidential manner, and only a limited number of EMA and Member State National Competent Authority officials will have access. The Agency and the Member State National Competent Authorities are legally obliged to ensure the non-disclosure of information obtained in the context of their institutional activities. More specifically, the officials that will have access to the data under discussion are legally bound by the duty of non-disclosure foreseen under Article 76 of <a href="#">Regulation (EC) No 726/2004</a> and Article 17 of <a href="#">REGULATION No 31 (EEC), 11 (EAEC)</a>.</p>

Question from participant	Answer
<b>Benefits for marketing authorisation holders</b>	
What benefits will get MAHs from the reports?	The objective of the vulnerability assessment is to inform policy measures, following the outcome of the assessment, that will support the security of supply of critical medicines in the European Union.
Subsequent to all implementation steps, what are the major changes that will be demanded for the MAH with critical medicines products and APIs that have been identified as highly vulnerable? What incentives will be given to Small and Medium-sized Enterprise (SMEs) considering that action would be needed to increase security stock.	Such measures include MSSG recommendations ( <a href="#">see MSSG guidance</a> ) set out in the new pharmaceutical legislation, in line with the MSSG toolkit. In addition, the outcomes of this vulnerability evaluation are required to implement key measures put forward in the proposed Critical Medicines Act (CMA), currently in the final stages of the co-legislative process, and certain measures under the proposed Critical Medicines Act (CMA), which also apply to SMEs. Measures in the proposed Critical Medicines Act include: the prioritisation of financial support for strategic projects that address a supply chain vulnerability and procurement related measures aimed at promoting diversification of suppliers where there is dependency on a single or a limited number of third countries, threatening the security of supply, established through a vulnerability evaluation. They may also include favouring suppliers that manufacture a significant portion of these critical medicines in the EU, where there is dependency on a single or a limited number of third countries, threatening the security of supply, established through a vulnerability evaluation when justified by a vulnerability analysis. These measures may be subject to change during the co-legislative process for the CMA.
What would be the action plan/ incentives for MAHs, following this assessment, especially for the most vulnerable INN?	
<b>Relationship between data request template and Shortage Prevention Plans (SPPs)</b>	
How will this assessment work next to the Shortage Prevention Plan (SPP). Will it both be needed? Or will SPPs (and Shortage Mitigation Plan (SMP) be replaced with the Supply Vulnerability Index (SVI)	The obligation to hold Shortages Prevention Plans is distinct from the vulnerability evaluation exercise.  Nevertheless, to minimise the impact on MAHs, the data request in the context of the vulnerability evaluation builds on the SPP requirement. The template therefore includes certain data elements required for the Shortage Prevention Plans set out in the new pharmaceutical legislation Shortage Prevention Plans (Annex IV, Part V).
Shall this methodology also be applied in the SPP or can the vulnerability assessment be reduced for products not include in the INN list?	The Supply Vulnerability Index is an indicator used within the methodology and forms part of the vulnerability assessment and does not replace any MAH data submission obligations as set out in the SPPs. The template also does not replace SPPs or SMPs.

Question from participant	Answer
<b>Data request template</b>	
When the template was created were MAHs asked what is needed from their perspective?	The template was circulated in advance of the workshop and comments were received from MAHs. These comments and those received during the workshop were taken into account and the template was further simplified before the formal data requests were sent to participating marketing authorisation holders by email on 31 <sup>st</sup> March, 1 <sup>st</sup> and 9 <sup>th</sup> April.
Do MAHs have to map the actors of the distribution chain?	The focus of the assessment is on the manufacturing supply chain and not on the distribution chain. Therefore, any actors in the distribution chain after the release of the finished product do not need to be mapped.
Should sales data be provided for the EU or global level (is EU breakdown is required)?	Sales data should be provided for the last full calendar year. For example, for this data request, data should cover from January 2025 to December 2025 and should be provided individually for each EU/ EEA country where the medicinal product is marketed.
Is the sales data required for the last calendar year i.e. 2025 or rolling year e.g. March 2025 to March 2026?	
When referring to the number of sold units in the last 12 months, should we consider the last calendar year (i.e. full year 2025)?	
Should all INNs be included in one single template (like in your example) or do we need to complete one template per INN	Both options are accepted. Companies can complete one template covering multiple INNs or separate templates for each INN, depending on internal convenience.
On the topic of product presentations, could you advise how MAHs should handle multi-strength or multi-pack presentations of the same product? Should each strength and pack size be reported separately, or can they be aggregated at the product level? Similarly, if the same manufacturing step is performed at	Each presentation and manufacturing site should be handled separately. For product presentations, each strength and pack size should be reported individually rather than aggregated at the product level. Similarly, when the same manufacturing step is performed at multiple approved sites, each manufacturing site should be recorded as a distinct entry.

Question from participant	Answer
multiple approved sites, is it required to report each site individually, or can they be grouped under a single manufacturing operator entry?	
In case the line is dedicated to more medicinal product how should this considered?	In case the production line is dedicated to more than one medicinal product, the information should be reported separately for each medicinal product in scope (use separate row for each medicinal product). Capacity, utilisation and ramp-up should be estimated for the respective share of the line dedicated to this product. The objective is to capture effective capacity and flexibility available for each medicinal product rather than the total capacity of the line.
Should the lead time include the time needed to release product to the market?	The lead time should include the full time from production start to product availability for the market. It should not include downstream distribution to wholesalers, hospitals or pharmacies. The focus is on the manufacturing lead time up to a releasable finished product.
Will all data also be pre-populated for Nationally Authorised Products (NAPs)?	A template with certain information pre-populated will be shared with marketing authorisation holders responsible for both nationally authorised medicines and centrally authorised medicines in scope of the exercise, including information from EMA systems, such as EMA's substance, product, organisation and referential (SPOR) data, where available. This Q&A Document is a complementary source of information, in addition to the "Read Me" guidance and "Data Dictionary" in the data request template and will be updated periodically.  As for manufacturing table, EMA intends to provide pre-populated templates based on PMS data where this is available.
Which fields will be provided pre-populated?	
A pre-filled Excel file will be provided, is that correct?	
In the manufacturing table, could columns F and subsequent be prefilled with MA data already held by the agency, for verification and possibly addition where needed? Objective: maximise process efficiency, limit redundant inputs and human error.	
Are ophthalmic forms considered integral drug device combination products?	A medical device is considered integral to a medicinal product where, in accordance with Article 1(9), second subparagraph of Regulation (EU) 2017/745, the following three cumulative conditions are met:

Question from participant	Answer
	<ul style="list-style-type: none"> <li>• The medical device and the medicinal product are placed on the market in such a way that they form a single integral product.</li> <li>• The device is intended for single use only</li> <li>• The device is intended exclusively for use with the specific medicinal product in that combination</li> </ul>
<p>If the MAH has two legal entities in different countries who are MAHs for the same INN do both entities have to submit data or is it the entity defined as the head office in EudraVigilance.</p>	<p>The preferred approach would be to submit one consolidated response. This should be reflected in the reply to EMA.</p>
<p>On adding rows, do we add new row in sheet called market &amp; product for each strength of the product?</p>	<p>Each product strength must be reported as a separate row in Sheet 1. Data is collected at product (PMS ID) level to enable pre-population and data consistency, even though analysis is performed at INN and pharmaceutical form level. Differences between strengths should be captured in Sheet 1, while supply chain sheets (2, 3 and 4) can be grouped by products with identical supply chains. Marketing authorisation holders responsible for medicines on the Union list of critical medicines will be required to submit the template to inform the vulnerability assessment, upon request, based on the prioritisation approach. The template will not need to be completed for medicines not included on the Union list of critical medicines.</p>
<p>Regarding the Excel sheet 1, why is this information not available from the Health Authority?</p>	<p>The information in worksheet 1 (MARKET AND PRODUCT information) will contain information on all CAPs and NAPs with a valid marketing authorisation, held by that marketing authorisation holder. The medicinal product elements will be pre-populated using data held in PMS. Mistakes and/or blanks are possible, and EMA invites MAHs to correct any discrepancies in PMS. The information is in principle available at Member State level, however, it is currently not possible to easily use the National Competent Authority systems for verification for this exercise, due to the accelerated timeline and the fact that EMA and NCA systems are not yet fully interoperable. MSSG may review and update the template and/or the methodology following the 2026 exercise, based on lessons learned. Participating marketing authorisation holders will receive feedback accordingly. This will ensure the methodology is robust and informed by reliable data.</p>
<p>If this exercise were to show that certain datapoints are not feasible</p>	<p>MSSG may review and update the template and/ or the methodology following the 2026 exercise, based on lessons</p>

Question from participant	Answer
to obtain based on the available inputs, would the template be adjusted accordingly?	learned. Participating marketing authorisation holders will receive feedback accordingly. This will ensure the methodology is robust and informed by reliable data.
In the Excel template, Sheet 1 "Market & Product", Column W, how do you define "new technology"?	'New technology' refers to a technology that is novel to industry practice, not yet widely adopted, or considered innovative enough to warrant additional regulatory attention.
In the manufacturing operators and supply flows tabs (worksheets 2 and 3 respectively), is it necessary to repeat the information for each individual country when referring to decentralised procedures (DCPs), given that the identifier for each row requires the medicinal product name as per the SmPC in the local language?	In sheet 1. "MARKET & PRODUCT" in column L, MAHs are requested to report the marketing status of the product, indicating in which EU/EEA countries the product is placed on the market using the drop-down menu. MAHs are requested to include a new row for each EU/EEA country in which the product is marketed. For each row, the name of the medicinal product of the corresponding Summary of Product Characteristics (SmPC) or other regulatory documents, shall be indicated in line with the local language of the country where the product is authorised.
For DCPs, should the manufacturing operator and supply flow information be repeated for each country, since the row identifier requires the product name in the local SmPC language?	Column "M" should reflect the total number of units sold per presentation (as per ISO IDMP guide definition) of the medicinal product in the EU/EEA in the last full calendar year (Jan 2025–Dec 2025).
Do the "marketed countries" listed in columns L and M refer only to EU countries, or to all countries where the company is the MAH?	
According to the instructions this exercise is to be completed at pharmaceutical-form level, certain sections of the template request information on strength. If the responses differ between presentations of the same pharmaceutical form, should the information be provided per presentation instead?	Information of worksheet 1 "Market & Product" will be pre-populated at pharmaceutical form level, which includes strength. For subsequent sheets, data should be reported per distinct supply chain; where supply chains are identical across pharmaceutical forms and strengths, this can be indicated accordingly. If a supply chain is different at active substance, pharmaceutical form and strength level these need to be separate entries.  The inclusion of strength reflects data pre-population at PMS ID level (pharmaceutical form + strength).

Question from participant	Answer
Does worksheet 2 (manufacturing operators) is this requiring only API, manufacturing, packaging? Is release required?	In worksheet 2 "MANUFACTURING OPERATORS ", all the manufacturing steps shall be considered, including batch release. Please note that the manufacturing site refers to any location worldwide where manufacturing operations (including production, quality control, and primary/secondary packaging,) take place for medicines intended for the EU market.
For CMOs, should MAHs report only the approved GMP sites listed in the dossier, or also subcontracted operations not directly included in the marketing authorisation?	In addition, MAHs are requested to provide details of all manufacturing sites involved in the production of the medicinal product. This includes indicating, in column J, whether each site operates as a Contract Manufacturing Organisation (CMO) or not. Both GMP sites and subcontracted operations not directly included in the marketing authorisation can be included.
One API manufacturer informed that they are not exporting the API to EU anymore. As of now, the API manufacturer is still registered in our dossier. How can we display this situation in the table?	In this case the API manufacturer should still be listed in the sites as it remains part of the registered supply chain, however, please indicate in worksheet 2 "MANUFACTURING OPERATORS", column N that the site is inactive and in sheet 3" MANUFACTURING SUPPLY FLOWS" report 0% supplier share from this API site.
When we talk about production processes, do we also include packaging processes?	In worksheet 3 "MANUFACTURING SUPPLY FLOWS"all the materials needed for the manufacturing (not downstream distribution) supply-chain stages of the final medicinal product (e.g. API, intermediate product, bulk product, packaging component), will have to be included, indicating their role in the supply chain of the final medicinal product. MAHs should gather all relevant information from their CMOs.
The assessment has to be filled out for all production steps - API, excipients, production of the bulk and also separately for the packaging? Hence, the suppliers of API, CMOs, Excipients have to provide the MAH with this information?	"Manufacturing supply flows" refer to the movement of materials and products between manufacturing sites across the manufacturing supply chain. The downstream supply chain (i.e. distribution after the final product has been manufactured and released) should not be considered. For all distinct supply chains for the products in scope in your portfolio, you should insert all manufacturing supply flows.
In "Manufacturing Supply Flow" should packaging materials considered?	In case there are multiple manufacturing supply flows for a product (row), please use/add a new row for each manufacturing supply flow for a given product, repeating the product information in columns A-D for that given product.
Should we submit the API supply chain as well?	
Ref. sheet 3 Manufacturing Supply Flow if the bulk is manufactured and packed in the same site how should this be considered?	

Question from participant	Answer
<p>In the Manufacturing Supply Flows section, does EMA expect a complete supply chain mapping (from API to intermediate, finished product and distribution), or only those critical steps impacting shortages?</p>	
<p>Should we state information in the different sections on the suppliers of the different excipients too or only for the ones we consider as critical?</p>	<p>In worksheet 4. "CRITICAL KEY INPUTS", in column F, MAHs are requested to provide information only for key inputs, as defined in the proposed Critical Medicines Act, that are considered critical by the marketing authorisation holder, rather than all key inputs. This includes key inputs that are essential for the manufacturing process, including for examples critical packaging materials, excipients, solvents, reagents and consumable, excluding the active substance, and where there is an identified vulnerability or supply risk (e.g. limited suppliers, long lead times, no substitutes), based on MAH's internal risk assessment.</p> <p>Routine or non-critical excipients with no identified risk do not need to be included.</p>
<p>Regarding Section 4, does "critical key inputs" include only API, excipients, and primary packaging, or also consumables such as filters, tubing, and single-use bags? Also, in the Manufacturing Supply Flows section, is full supply chain mapping expected, or only critical shortage-relevant steps?</p>	
<p>Regarding Section 4, how does EMA define "critical key inputs"? Should this category include only API, excipients, and primary packaging, or are consumables such as filters, tubing, and single-use bags also expected to be reported?</p>	
<p>In worksheet 5 "Stock Management", should stock levels be reported as actual physical inventory, average monthly stock, or weeks of supply? Additionally, when determining seasonality impact in cases where reliable historical demand data is not available (for example, with new products), what approach should MAHs take?</p>	<p>In worksheet 5 "STOCK MANAGEMENT ", the requested data focus on the frequency of stock levels monitoring. In particular, in column G you will find a drop-down menu with four options (e.g. daily, weekly, monthly, less frequent). Regarding seasonality in worksheet 1 "MARKET &amp; PRODUCT ", MAHs are asked to assess whether demand is relatively stable throughout the year, it shows moderate seasonal variation, or it shows strong seasonal variation, based on how peak demand compares with the average monthly demand during a typical year.</p>

Question from participant	Answer
<b>Frequency of submissions</b>	
How often will this report be done? and how frequently are MAHs expected to provide data for the vulnerability assessment?	The legislation does not specify a frequency for conducting vulnerability assessments. The process will start with the first set of INNs and will proceed on a phased basis for critical medicines on the Union list. Vulnerability assessments will be prioritised using EMA/MSSG procedures and criteria, in line with the new pharmaceutical legislation.
This will give only a snapshot. How would you address changes of data over time?	
How frequently must MAHs update the Annex III dataset if there are no changes in the supply chain, and what about minor updates such as supplier relocation? If an API or excipient is sourced from a single supplier globally, should this be classified automatically as high vulnerability, even if long-term supply contracts are in place? How often will this report be done? and how frequently are MAH expected to provide data for the vulnerability assessment?	The methodology has been agreed by MSSG, with input from industry. Please complete the data request form.  The objective of this assessment is to identify potential structural vulnerabilities across critical medicines, in line with the applicable legislative framework.  For the purpose of the 2026 exercise, MAHs are expected to submit all available information by 29 May 2026. The vulnerability assessment will be completed based on the data submitted by marketing authorisation holders. MAHs will have a dedicated Rapporteur and EMA coordinator assigned for each INN. Questions can be submitted via a functional mailbox: <a href="mailto:vulnerabilityassessment@ema.europa.eu">vulnerabilityassessment@ema.europa.eu</a> , and a user guide and data dictionary will be provided together with the formal data request. No further requests for updates are anticipated during the exercise.
How often should the data be updated? How often will this report be done? and how frequently are MAH expected to provide data for the vulnerability assessment?	
Can you please confirm what are the timelines of the exercise?	
If there are changes in the data provided over time, will the data need to be shared with EMA, or is this a one-time exercise? How frequently must MAHs update the Annex III dataset if there are no changes in the supply chain, and what about minor updates such as supplier relocation? If an API or excipient is sourced from a single supplier globally, should this be	

Question from participant	Answer
classified automatically as high vulnerability, even if long-term supply contracts are in place?	
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How often should the data be updated?	
<b>Marketing status/authorisation status of medicines in scope</b>	
For the 19 INNs currently under evaluation, if they are in the registration process to obtain a marketing authorisation in the EU, can the review process be expedited? We would also like confirmation as to whether information related to UK licences is out of scope, considering the templates reference only EU/EEA. This is particularly important since some of our UK licences are currently part of ongoing EU procedures.	<p>All medicinal products included on the Union list of critical medicines are in scope of the vulnerability assessment. This is limited to medicines with a valid marketing authorisation in EU/EEA.</p> <p>Where a medicine is not marketed, all relevant, available manufacturing data should be submitted, and the marketing authorisation holder should reflect that the medicine is not marketed in their reply.</p> <p>If the marketing authorisation has been fully withdrawn and the product no longer holds a valid marketing authorisation in the EU or any EU/ EEA country, it should not be included.</p> <p>If the product will be withdrawn from a national market but the marketing authorisation remains valid, it should be included.</p>
Will products authorised in the United Kingdom/Northern Ireland	The template also captures information on the likelihood of discontinuation and the strategic importance of the product within

Question from participant	Answer
as a CMS in MRP/DCP procedures (thus being present in the PMS) be in the scope of this exercise?	the MAH's portfolio in the conditional vulnerabilities' worksheet. However, if relevant information can be provided for medicines under development, this could be considered in the scope of the MSSG recommendations.
If we are developing any of those products listed now, would there be any support from EMA we can have for any more prompt registration?	The exercise is legislation-driven, so inputs are structured. However, the level of detail requested is designed to support a comprehensive assessment of supply risks, indirectly capturing relevant insights on supply security.  At this stage, MAHs are expected to complete and submit the full template. The current exercise does not foresee a simplified or accelerated route for voluntary vulnerability designation.
Have there been considerations to create an accelerated, simplified route for an MAH to voluntarily and proactively apply for a vulnerability designation? Sometimes it is quite obvious.	The exercise is legislation-driven, so inputs are structured. However, the level of detail requested is designed to support a comprehensive assessment of supply risks, indirectly capturing relevant insights on supply security  Marketed country is the country where the product is placed on the market and available for patients and healthcare professionals to be used in treatments.
Marketed country — is this a country with the product physically available on the market or just with a valid MA?	
Will the vulnerability assessment also apply to medicines that are not marketed?	
A MAH with an INN on the vulnerability list but with the product not marketed in EU is still required to complete and submit the template with structured supply chain data?	
Should information be included if a product is under termination (being withdrawn)?	
For one of the substances on the list, we do not have a marketing authorisation now. But the initial submission will be done soon. Do we have to fill in the data of this medicine into the template too?	

Question from participant	Answer
Should we consider withdrawn applications for exclusion from this request, since those products are not being commercialised?	
The data needed should be populated for the registered products OR only for the marketed ones?	
What about medicinal products that have been newly approved and have not yet been placed on the market? Should be included in table?	
In case of non-marketed products, for certain questions data will not be available. Is that OK?	
If the manufacturing agreement with a manufacturer has been terminated by the MAH, but the marketing authorisation has not been withdrawn, is the MAH still required to include and submit all related data for that product in the template?	
Some information will not be available for CMOs. How shall we deal with missing information?	If input is needed by third parties such as CMOs and API suppliers, the MAH will have to request the information from those sources to complete the template.
How should we proceed when for example the contract API manufacturer is not providing the required data? Can the columns be left unfilled in this case?	If by the deadline of 29 May some data requests are still pending, MAHs should engage with the Rapporteur and EMA coordinator as to why the data is not currently available. Any outstanding information should be submitted as soon as possible.  We confirm that the responsibility for providing Vulnerability Assessment data lies with the MAHs, in line with the upcoming legal obligations in the new pharmaceutical legislation.
Regarding the manufacturing operators which are requested in sheet 2 of the template, what should be entered if information cannot be provided from the CMO?	The MAH information included in the template refers to the EU-level MAH, rather than the national MAHs.

Question from participant	Answer
How can MAH honestly get this production capacity etc. when product is externally supplied?	
What happens if we can't get responses from our manufacturers in time?	
The template can only be completed with the input from CMOs and API supplier, are there templates available that can be forwarded to CMOs and API suppliers?	
If any of the information requested in the template is not available and cannot be retrieved, what should be MAH do?	
In cases where MAH and the manufacturer are not the same legal entity (same company/ potentially competitors), how do you intend to ensure the security of sensitive manufacturing and sales data (tabs 3 and 4)? If I understand correctly, the responsibility for providing VA data lies with the MAH.	
When using a CMO for manufacturing we do not have very detailed information of production like production line number.	
When a product has more MAHs in different countries, which MAH should be reported in the cover page?	
<b>Engagement with Marketing Authorisation Holders in scope of the exercise</b>	
Is there the opportunity to raise questions to EMA during	Marketing authorisation holders in scope of the exercise will have a dedicated Rapporteur and EMA coordinator assigned for each INN.

Question from participant	Answer
preparation without going via Service Desk?	Questions can be submitted via a functional mailbox: <a href="mailto:vulnerabilityassessment@ema.europa.eu">vulnerabilityassessment@ema.europa.eu</a> , and a user guide and data dictionary will be provided together with the formal data request.
Will the reports or outcomes be available for pharmaceutical companies or only for authorities?	Where possible, aggregated outcomes and reports will be made available to participating marketing authorisation holders, protecting commercially confidential information against unjustified disclosure, as foreseen under Chapter X of the upcoming new pharmaceutical Regulation. Feedback will also be provided to participating marketing authorisation holders involved in this exercise.
Who are your contact points in the companies? Will the pre-filled template be shared with this workshop participants?	The main contact points should be the Industry Single Points of Contact (iSPOC) registered with EMA, in accordance with Regulation (EU) 2022/123. For those MAHs who have not fulfilled the legal obligation to register an iSPOC or where the iSPOC is no longer valid, EMA and Member State National Competent Authorities (NCAs) provided alternative contact details. Where no contacts were available, publicly available sources were used.
If the iSPOC is not part of at the time of the submission deadline, can another authorised person (e.g. the Head of Supply Chain) submit the completed template instead? If so, what is the preferred submission channel (e.g. email), or is there an alternative process recommended by EMA?	The template has been provided to MAHs using the contact points. MAHs may nominate an alternative contact point for the exercise, and the template may be shared internally within the organisation to allow another person to submit on behalf of the iSPOC. However, iSPOC contacts should be updated in line with the requirements set out in Regulation (EU) 2022/123. All submissions must be made via EudraLink, to ensure that confidential information is shared securely.
<b>Deadline for submission of data</b>	
Is there any possibility to adjust the deadline to beyond 30 April?	The timelines have been agreed by MSSG, to ensure finalisation of the exercise by the end of 2026, in preparation for the new pharmaceutical legislation and the Critical Medicines Act, so that the measures can be effectively implemented. Nevertheless, we understand the concerns that have been expressed by the industry regarding the original deadline. Therefore, the deadline for data submission has been extended until from 30 April to 29 May 2026.
The time allowed vs effort seems incorrect. Gathering of the data by MAH's is at least as much effort as the assessment/report writing phases — arguably its significantly harder. Yet MAH's have only 5 weeks to collect all the data vs 4.5 months for Assessments and 3 months for report writing.	MAHs are required to submit the completed template by the deadline. If by the deadline of 29 May some data requests are still pending, MAHs should engage with the Rapporteur and EMA coordinator as to why the data is not currently available. Any outstanding information should be submitted as soon as possible.
Why are we not being given more time to gather and date the data.	This will ensure outcomes and reports are available to inform policy measures under the new pharmaceutical legislation and

Question from participant	Answer
This compromises the accuracy of the data.	proposed Critical Medicines Act. MSSG may review and update the template and/or the methodology following the 2026 exercise, based on lessons learned. Participating marketing authorisation holders will receive feedback accordingly. This will ensure the methodology is robust and informed by reliable data.
1 month to collect the data but 5 months to analyse the data! Do you plan further interactions with each MAH upon the data completed?	
April is the financial year end for many companies. This will significantly restrict access to key information/functions like Finance. Can the timeline be extended/postponed for MAH for this — and gained back somewhere else in the year?	
If not all information is gathered by deadline for April 30, do we still submit the partial information or how should this be handled?	
What are the consequences for the MAH of not meeting the deadline of 30.04.2026 or for providing incomplete data?	