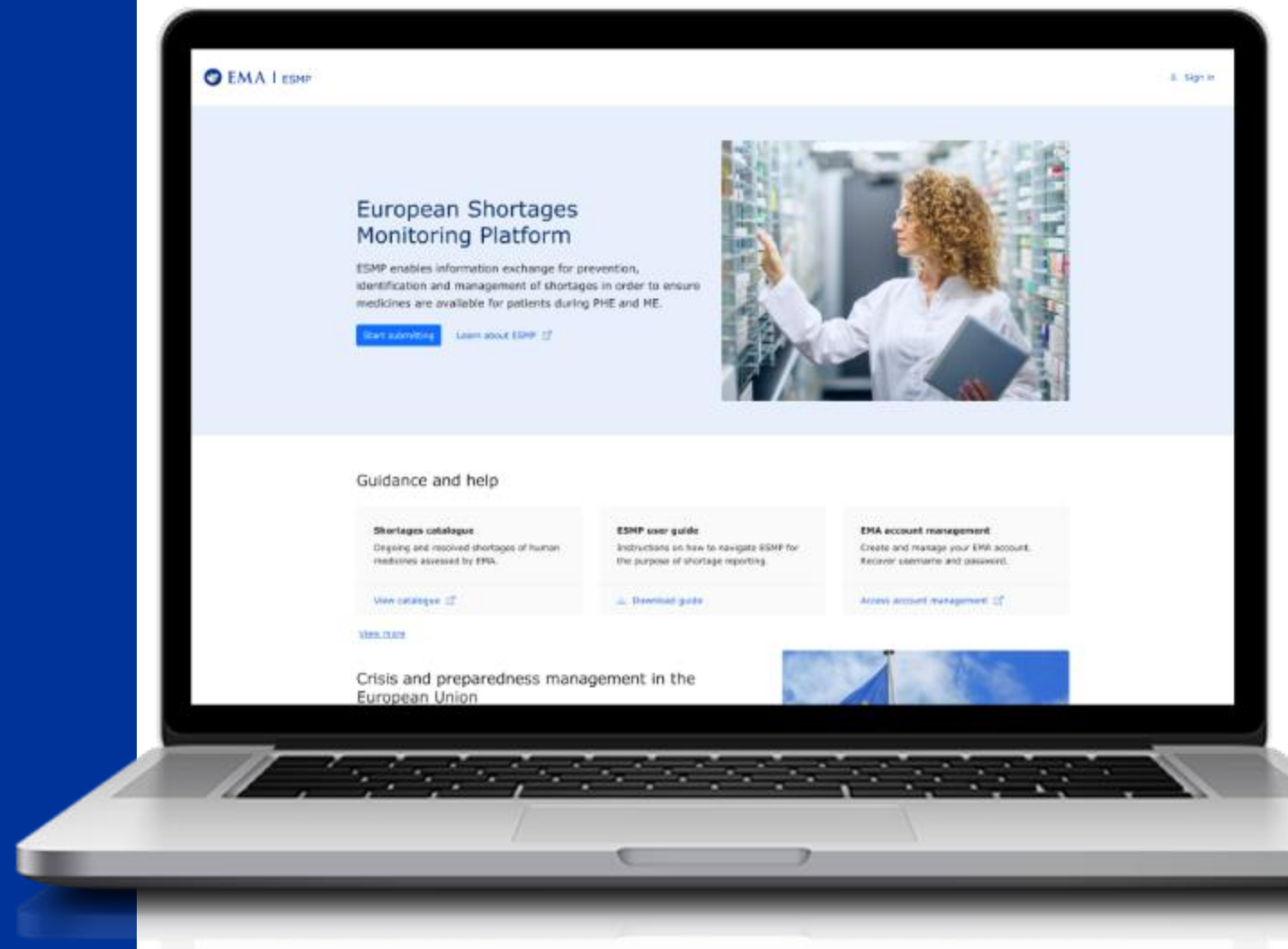


European Shortages Monitoring Platform (ESMP)

Training on readable IDs and general updates for industry

14 April 2026, 10:00 – 11:00 CEST



Goals and objectives



EXPLAIN THE NEW READABLE IDs FUNCTIONALITY

You will learn how to use newly introduced readable IDs in ESMP to verify the values you are submitting without the need to cross-reference external lists.



PROVIDE RELEVANT ESMP UPDATES FOR INDUSTRY

You'll get up-to-date information on the ESMP development progress and planned releases.



COLLECT FEEDBACK & ADDRESS QUESTIONS

You'll have an opportunity to ask questions to ensure your full readiness to use the readable IDs functionality in the ESMP and get information on other ESMP updates.

Housekeeping



Please note that **this session is being recorded and will be made available** through **EMA's corporate website (on the event page)** and **EMA's YouTube channel**

Participants can ask questions or give their input via the audience interaction tool **Slido**.



Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data**.

For more information on how EMA processes your personal data when using Slido, please refer to the specific sections on Slido in this [Data Protection Notice](#).



Agenda

- 1. Welcome and opening of the training session**
- 2. Training on readable IDs**
- 3. Q&A on readable IDs**
- 4. Overview of ESMP updates and upcoming developments**
- 5. General Q&A** through Slido
- 6. Closing remarks**

Send your questions via Slido



1. Join via the QR code or on www.slido.com with the session code #ESMP1404

2. Send or upvote the questions you want to hear answered

3. Questions will be shown on the screen and answered live in the Q&A session and the ESMP FAQ document updated with common questions

3

Introduction of readable IDs in submission templates

Sofia Zastavnik

Improving ESMP through feedback

Over the past 2 years, we've engaged ESMP users, capturing feedback to improve their experience.

Feedback highlights below from webinars and surveys reveal challenges with numerical RMS ID codes in standardised reporting:

“Initially, we encountered some challenges in understanding how to generate and manage the unique identification numbers required for submissions within the ESMP.”

“Simplification of the coding system, replacing complex codes with clearer, user-friendly labels.”

“The RMS number seems a bit unintuitive.”

“Could you introduce a simplified approach for identifying the appropriate RMS code?”

“As RMS identifiers are numbers it not easily detectable if a wrong identifier chosen for root cause. Has consideration been given to use text notation instead?”

Recap: Reporting instances to ESMP and RMS IDs



Data collection

- Shortage information
- Supply and demand of medicines
- i-SPOC Registration



MAH i-SPOCs



ESMP

In **normal circumstances**, MAHs will report shortages of centrally authorised products.

- **Routine shortage reporting** ←
- **Marketing status for CAPs** – submitted and maintained via IRIS

Submissions are **triggered by a potential or actual shortage** and MAHs need to keep the **entries up-to-date**, including the latest information.

During an **MSSG-led preparedness exercise**, MAHs follow the same submission process as during a crisis situation for a subset of products subject to close monitoring.

In a **crisis situation**, MAHs submit data on nationally and centrally authorised products in scope of a critical medicines list for a particular public health emergency.

- **Marketing status for CAPs** – submitted and maintained via IRIS
- **Marketing status for NAPs** ←
- **Availability information** ←
- **Manufacturing information**
- **Alternative therapies**

Submissions are **triggered by an MSSG announcement** and **frequency** of reporting is **defined by the MSSG**.

Highlighted datasets use RMS IDs in data submission

Readable IDs in ESMP submission templates: What it is

With readable IDs, ESMP users can now choose to insert clear identifiers and easily verify submissions directly, simplify checks, and improve confidence in submitted information.

Previously, ESMP templates only relied on numerical RMS ID codes for standardised reporting.



Main goal:

Enhance user experience with RMS IDs and simplify data verification.



Who is this feature for?

- MAHs of CAPs in submission templates for **routine CAP shortage reporting**.
- MAHs of non-CAPs and CAPs in submission templates for **MSSG-led preparedness reporting** and **crisis reporting**.



What is changing?

- > When users **UPLOAD**, they can input **numerical IDs** or **readable RMS IDs**
- > When users **DOWNLOAD** a reporting template, they will see **readable RMS IDs**.

ESMP data sets for MAH reporting – usage of RMS IDs

Normal circumstances	
EMA Ref	ESMP data element
Product information	
P1.1.2	Package PMS ID
P1.8	Country of authorisation
Shortage information	
S1.1	Shortage Status
S1.2	Shortage start date or expected start date
S1.3	Shortage end date or expected end date
S1.4	Point in supply chain at which disruption occurs
S1.5	Root cause of the shortage
S1.6.1	Countries in which manufacturing issues occur
S1.6.2	Countries in which increased demand occurs
S1.6.3	Countries in which distribution issues occur
S1.7	Root cause of the shortage - additional information
Prevention and mitigation	
S2.1	Shortage prevention and mitigation plans
S2.2	Shortage prevention and mitigation plans - ongoing and planned steps
Impact assessment	
S3.1	Affected population estimate
S3.2	Market share
S3.4	Shortage impact risk assessment
S3.5	Shortage impact risk assessment - additional information
Alternative therapies	
S4.1	Alternative therapies available?
S4.2	Alternative therapies
Additional information	
S5.1	Rapid Alert reference number
S5.2	Other authorities notified (e.g. other NCAs, EMA), including reference to Quality Defect report
S5.3	Reference to related pending regulatory action
S5.4	Required NCA actions, if any

Crisis and MSSG-led preparedness	
EMA Ref	ESMP data element
Product information	
P1.1.2	Package PMS ID
P1.8	Country of authorisation
Marketing status details	
P1.9	Marketing status
W1.1	Date of planned permanent withdrawal
W1.2	Planned withdrawal comment

EMA Ref	ESMP data element
Product information	
P1.1.2	Package PMS ID
P1.8	Country of authorisation
Shortage information	
S1.1	Shortage Status
S1.2	Shortage start date or expected start date
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S1.7	Root cause of the shortage - additional information
Shortage prevention and mitigation plans	
S2.1	Shortage prevention and mitigation plans
S2.2	Shortage prevention and mitigation plans - ongoing and planned steps
Market share	
S3.2	Market share
S3.3	Market share - additional information
Sales volume	
S6.1	Sales volume pre-PHE/ME
S6.2	Sales volume current
S.1.1 - S7.1.6	Sales volume forecast - Month 1 - Month 6
S7.2	Sales volume - additional information
Supply forecast	
S8.1.1 - S8.1.6	Supply forecast - Month 1 - Month 6
S8.2	Supply forecast - additional information
Stock information	
S9.1	Available stocks
S9.2	Desired safety stock
S9.3	Stocks - additional information

EMA Ref	ESMP data element
Product information	
P1.1.1	PMS ID
P1.3.1	Active substance SMS ID
Representative product	
X1.1	Representative product
Organisation information	
O1.1	Operation type ID
O1.3	ORG-ID (Manufacturer)
O1.5	LOC-ID (Manufacturer)
Manufacturing details	
M1.1	Manufacturing site status
M1.2	Is the site a contract manufacturer?
Alternatives sites	
M2.1	Alternative site LOC-ID
M2.2	Alternative site Country
Production plan and capacity	
M3.1	Unit of measurement
M3.2.1 - M3.2.6	Global Monthly Production plan - Month 1 - Month 6
M3.3	Global monthly production plan - additional information
M3.4	Average global monthly production output of previous year
M3.5	Peak global monthly production output of previous year
Alternative therapies	
P1.2.3	Invented name
P1.3.2	Active substance(s)
P1.6.2	Pharmaceutical form
Alternative therapies	
L1.1	Alternative therapies
L1.2	No alternatives

Disclaimer

All displayed RMS values are valid at the time of demonstration (14/04/2026).

RMS values might be updated and change over time.

Please refer to the **ESMP implementation guide** or [SPOR site on referential values](#) to ensure you are using the latest version of RMS identifiers.

Point in supply chain at which disruption occurs

RMS values (1/2)

RMS List: 200000028549

Routine shortage reporting
 Crisis and MSSG-led preparedness
 > Availability information

AS IS

Available for insertion and download in ESMP

Numerical ID	Term name
200000028583	Active substance intermediate
200000028584	Active substance
200000028585	Supply of raw materials, excipients, packaging components
200000028586	Finished product manufacturing
200000028587	Primary packaging
200000028588	Secondary packaging

TO BE

Available for insertion and download* in ESMP

Numerical ID	Readable ID	Term name
200000028583	ActSubInt	Active substance intermediate
200000028584	ActSub	Active substance
200000028585	SupplyRawExcPack	Supply of raw materials, excipients, packaging components
200000028586	FinProdMan	Finished product manufacturing
200000028587	PriPack	Primary packaging
200000028588	SecPack	Secondary packaging

Point in supply chain at which disruption occurs

RMS values (2/2)

RMS List: 200000028549

Routine shortage reporting
 Crisis and MSSG-led preparedness
 > Availability information

AS IS

Available for insertion and download in ESMP

Numerical ID	Term name
200000028589	Batch control testing
200000028590	Batch release
200000028591	Importation
200000028592	Distribution of released products
200000028593	Not related to supply chain issues
200000028594	Other

TO BE

Available for insertion and download* in ESMP

Numerical ID	Readable ID	Term name
200000028589	BatchCtrlTest	Batch control testing
200000028590	BatchRelease	Batch release
200000028591	Importation	Importation
200000028592	DistrRelProd	Distribution of released products
200000028593	NotSupplyRel	Not related to supply chain issues
200000028594	Other	Other

Shortage root cause RMS values (1/3)

RMS List: 200000028648

AS IS

TO BE

Available for insertion and download in ESMP

Numerical ID	Term name
200000028689	Manufacturing issues - Manufacturing issues preventing production/release
200000028690	Manufacturing issues - Restrictions on people
200000028691	Manufacturing issues - GMP non - compliance
200000028692	Manufacturing issues - Capacity issues
200000028694	Quality issues - Suspected defective product preventing release of batches to the market
200000028695	Quality issues - Suspected defective product requiring batch recall
200000028697	Regulatory issues - Marketing authorisation restricted/suspended
200000028698	Regulatory issues - Regulatory approval delay

Available for insertion and download* in ESMP

Numerical ID	Readable ID	Term name
200000028689	ManufProdRel	Manufacturing issues - Manufacturing issues preventing production/release
200000028690	ManufPeople	Manufacturing issues - Restrictions on people
200000028691	ManufGMPNonComp	Manufacturing issues - GMP non - compliance
200000028692	ManufCapacity	Manufacturing issues - Capacity issues
200000028694	QualDefProdPreventRelease	Quality issues - Suspected defective product preventing release of batches to the market
200000028695	QualDefProdRecall	Quality issues - Suspected defective product requiring batch recall
200000028697	RegMaRestSus	Regulatory issues - Marketing authorisation restricted/suspended
200000028698	RegApprDelay	Regulatory issues - Regulatory approval delay

Shortage root cause RMS values (2/3)

RMS List: 200000028648

AS IS

Available for insertion and download in ESMP

Numerical ID	Term name
200000028700	Unexpected increased demand - Consumer driven stockpiling
200000028701	Unexpected increased demand - Member State driven stockpiling
200000028702	Unexpected increased demand - Changes in prescribing behaviour
200000028703	Unexpected increased demand - Change in use (off label or through changes in MA)
200000028704	Unexpected increased demand - Increased demand due to unavailability from other MAHs
200000028706	Distribution issues - Air transport
200000028707	Distribution issues - Sea transport
200000028708	Distribution issues - Land transport

TO BE

Available for insertion and download* in ESMP

Numerical ID	Readable ID	Term name
200000028700	UnexIncDemCoStock	Unexpected increased demand - Consumer driven stockpiling
200000028701	UnexIncDemMsStock	Unexpected increased demand - Member State driven stockpiling
200000028702	UnexIncDemChangePre sBeh	Unexpected increased demand - Changes in prescribing behaviour
200000028703	UnexIncDemChangeInUse	Unexpected increased demand - Change in use (off label or through changes in MA)
200000028704	UnexIncDemUnavailOtherMah	Unexpected increased demand - Increased demand due to unavailability from other MAHs
200000028706	DistrAir	Distribution issues - Air transport
200000028707	DistrSea	Distribution issues - Sea transport
200000028708	DistrLand	Distribution issues - Land transport

Shortage root cause RMS values (3/3)

RMS List: 200000028648

AS IS

TO BE

Available for insertion and download in ESMP

Numerical ID	Term name
200000028709	Distribution issues - Export restrictions
200000028710	Distribution issues - Import restrictions
200000028712	Commercial reasons - Pricing and reimbursements
200000028713	Commercial reasons - Insolvency
200000028714	Commercial reasons - Prioritisation of other markets
200000028715	Commercial reasons - Business strategy (other)
200000043380	Other

Available for insertion and download* in ESMP

Numerical ID	Readable ID	Term name
200000028709	DistrExport	Distribution issues - Export restrictions
200000028710	DistrImport	Distribution issues - Import restrictions
200000028712	ComPricing	Commercial reasons - Pricing and reimbursements
200000028713	ComInsolvency	Commercial reasons - Insolvency
200000028714	ComPrioOtherMarkets	Commercial reasons - Prioritisation of other markets
200000028715	ComBusinessStrat	Commercial reasons - Business strategy (other)
200000043380	Other	Other

Shortage mitigation and prevention plan RMS values (1/2)

RMS List: 200000028617

Routine shortage reporting
 Crisis and MSSG-led preparedness
 > Availability information

AS IS

TO BE

Available for insertion and download in ESMP

Numerical ID	Term name
200000028633	Alternative active substance manufacturer
200000028634	Alternative finished product manufacturer
200000028635	Alternative batch control site
200000028636	Alternative batch release site
200000028637	Supply of product in foreign language labelling
200000028638	Supply of alternative unauthorised product
200000028639	Release of product with minor quality defects
200000028640	Increase production capacity of current site(s)

Available for insertion and download* in ESMP

Numerical ID	Readable ID	Term name
200000028633	AltActSubMan	Alternative active substance manufacturer
200000028634	AltFinProdMan	Alternative finished product manufacturer
200000028635	AltBatchCtrlSite	Alternative batch control site
200000028636	AltBatchRelSite	Alternative batch release site
200000028637	SupForeignLang	Supply of product in foreign language labelling
200000028638	SupUnauthProd	Supply of alternative unauthorised product
200000028639	RelProdQualDef	Release of product with minor quality defects
200000028640	IncProdCurrentSite	Increase production capacity of current site(s)

Shortage mitigation and prevention plan RMS values (2/2)

RMS List: 200000028617

Routine shortage reporting
 Crisis and MSSG-led preparedness
 > Availability information

AS IS

Available for insertion and download in ESMP

Numerical ID	Term name
200000028641	Supply of other presentation(s) of the same product
200000028642	Use of exceptional change management process (ECMP)
200000028643	Resolve manufacturing or quality issue(s)
200000028644	Change mode of transportation
200000028645	Expedited shipment and shipment under quarantine
200000028646	Prioritisation of supplies to critical customers
200000029652	Alternative sources of raw/starting materials
200000028647	Other

TO BE

Available for insertion and download* in ESMP

Numerical ID	Readable ID	Term name
200000028641	OtherPresSameProd	Supply of other presentation(s) of the same product
200000028642	ECMP	Use of exceptional change management process (ECMP)
200000028643	ResManIssues	Resolve manufacturing or quality issue(s)
200000028644	ChangeTransport	Change mode of transportation
200000028645	ExpedShipment	Expedited shipment and shipment under quarantine
200000028646	PrioSupCritCustom	Prioritisation of supplies to critical customers
200000029652	AltRawMaterial	Alternative sources of raw/starting materials
200000028647	Other	Other

Shortage impact risk assessment RMS values

RMS List: 200000033599

AS IS

Available for insertion and download in ESMP

Numerical ID	Term name
200000033600	High
200000033601	Medium
200000033602	Low

TO BE

Available for insertion and download* in ESMP

Numerical ID	Readable ID	Term name
200000033600	High	High
200000033601	Medium	Medium
200000033602	Low	Low

Marketing status for NAPS RMS values

RMS List: 100000072052

AS IS

TO BE

Available for insertion and download in ESMP

Numerical ID	Term name
100000072074	Not marketed
100000072083	Marketed
200000026055	Never marketed
230000000000	Temporarily unavailable

Available for insertion and download* in ESMP

Numerical ID	Readable ID	Term name
100000072074	Not marketed	Not marketed
100000072083	Marketed	Marketed
200000026055	Never marketed	Never marketed
230000000000	Temporarily unavailable	Temporarily unavailable

Readable IDs in normal circumstances



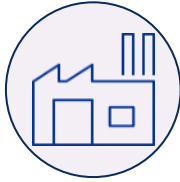
CAPs Holders in submission templates for **routine CAP shortage reporting**

ESMP Data Element impacted

Routine Shortage Reporting

- › **Shortage information:** Point in supply chain at which disruption occurs, Root cause of the shortage
- › **Prevention and mitigation:** Shortage mitigation and prevention plan
- › **Impact Assessment:** Shortage impact risk assessment

Readable IDs in MSSG-led preparedness and crisis



MAHs of non-CAPs and CAPs in submission templates for **MSSG-led preparedness reporting** and **crisis reporting**

ESMP Data Element impacted

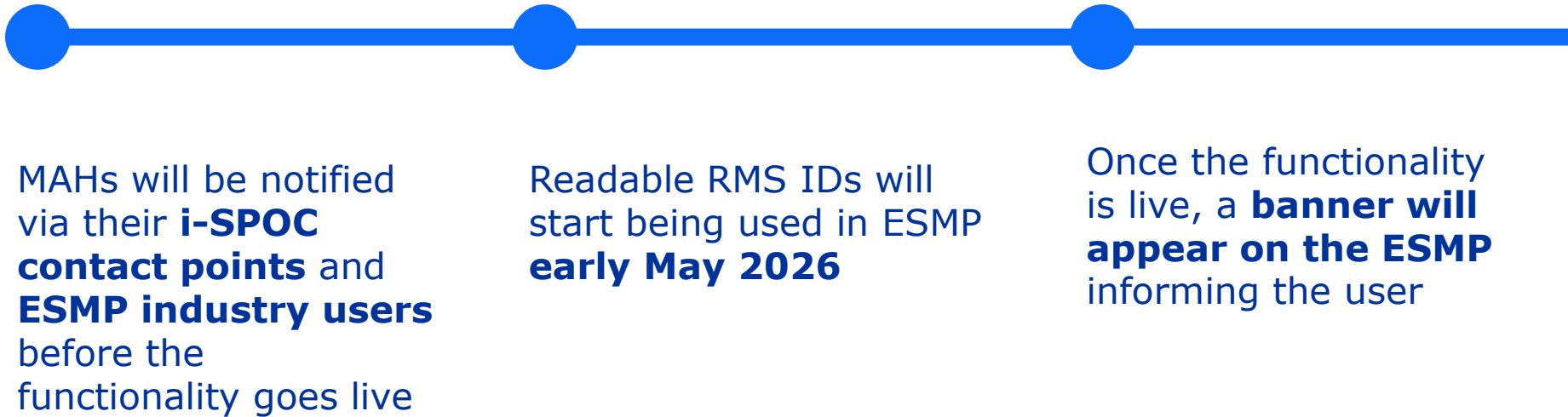
- > **Marketing status for NAPs**
 - > Marketing status
- > **Availability information**
 - > Point in supply chain at which disruption occurs, Root cause of the shortage, Shortage mitigation and prevention plan
- > **Manufacturing information**: Not impacted
- > **Alternative therapies**: Not impacted

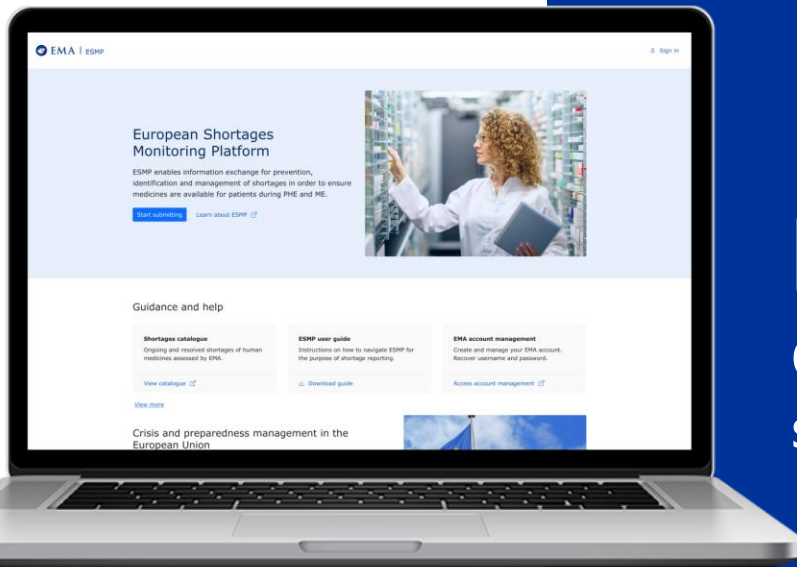


Remarks and tips & tricks

- Where multiple values can be inserted, they need to be **separated by semicolons**.
- Readable IDs are **not case-sensitive** (i.e. you can input them in lowercase, uppercase, or combination).
- When **reporting** user can choose if inputting RMS numerical IDs or readable IDs. Either way when the user **downloads** a reporting template, it will contain readable IDs.

Release timeline





Let's see how it works: practical examples

Overview of the readable IDs in an ESMP
submission template

Disclaimer

All the information used in the demonstration displayed is fictional and made for the purpose of this training.

Example of a file populated with readable RMS IDs - for upload in ESMP

1	N	O	P	Q	R	S	T	U	V	W	X	Y
1/202	26/02/2022	Other	DistrLand			CZ	Distribution disrupted	OtherPresSameProd	Steps taken to ensu	15590	62	High
2/202	05/02/2022	BatchCtrlTest	UnexIncDemMsStock		DE		Germany facing unexpe	RelProdQualDef	Manufacturing incre		47	Medium
2/202	29/03/2022	ActSub	ComPricing				Company decision ma	ResManIssues	Pricing discussions		62	Medium
7/202	11/09/2022	BatchRelease;ActSubInt	Other;ComPricing				Manufacturing issues i	AltActSubMan;Other	Alternative substan	60000	100	High
7/202	31/10/2022	ActSub;SupplyRawExcP	ManufPeople;RegMaRestSus	LU;MT			Manufacturing issues i	AltActSubMan	Alternative substan		100	Medium
5/202	21/07/2022	PriPack;SecPack;BatchC	ManufGMPNonComp;QualDefProdRecall	LU;MT			GMP non-compliance i	IncProdCurrentSite;RelF	the current site is b	150000	100	Low
7/202	21/07/2022	Importation;DistrRelPro	ManuCapacity;QualDefProdPreventRelea	LU;MT			Capacity on manufacatu	ECMP;ResManIssues;CI	the manufacturing i		100	High
7/202	21/07/2022	BatchRelease;DistrRelP	RegApprDelay;UnexIncDemMsStock;Unex		BE;MT		The delay in the regulat	ExpedShipment;AltRawf	the shipping is bel		100	Medium
7/202	08/05/2022	DistrRelProd;Other	DistrImport;DistrLand;DistrAir;DistrExpor		BE;MT	BE;MT	Distribution has been h	AltActSubMan	an alternative manu		100	Medium
3/202	12/02/2022	SupplyRawExcPack	RegMaRestSus				Supply has been disrupt	AltActSubMan	an alternative manu	279800	2	High

*the colouring has been applied to the table for demonstration purposes only

Example of a file populated with numerical and readable RMS IDs - for upload in ESMP

N	O	P	Q	R	S	T	U	V	W	X	Y	
ag	Shortag	Point in supply chain	Root cause of the shortage	Countri	Countri	Countri	Root cause of the sho	Shortage prevention	Shortage prevent	Affected	Market s	Shortage impact risk asses
/202	26/02/202	200000028594	DistrLand		CZ		Distribution disrupted c	200000028641	Steps taken to ensu	15590	62	200000033600
/202	05/02/202	200000028589	UnexIncDemMsStock		DE		Germany facing unexpe	200000028639	Manufacturing incre		47	200000033601
/202	29/03/202	200000028584	ComPricing				Company decision mad	200000028643	Pricing discussions		62	200000033601
/202	11/09/202	200000028590;200000	200000043380;ComPricing				Manufacturing issues r	200000028633;200000	Alternative substan	60000	100	200000033600
/202	31/10/202	200000028584;200000	ManufPeople;RegMaRestSus	LU;MT			Manufacturing issues r	200000028633	Alternative substan		100	200000033601
/202	21/07/202	200000028587;200000	200000028691;200000028695;2000000	LU;MT			GMP non-compliance c	200000028640;200000	The current site is b	150000	100	Low
/202	21/07/202	200000028591;200000	200000028692;200000028694;2000000	LU;MT			Capacity on manufacat	200000028642;200000	The manufacturing i		100	High
/202	21/07/202	200000028590;200000	RegApprDelay;UnexIncDemMsStock;Unex		BE;MT		The delay in the regula	200000028645;200000	The shipping is bei		100	Medium
/202	08/05/202	200000028592;200000	200000028710;DistrLand;DistrAir;DistrE		BE;MT	BE;MT	Distribution has been h	AltActSubMan	An alternative manu		100	Medium
/202	12/02/202	200000028585	RegMaRestSus				Supply has been disrup	AltActSubMan	An alternative manu	279800	2	High

*the colouring has been applied to the table for demonstration purposes only

Example of a file downloaded from ESMP

Downloaded files will always **display the readable RMS IDs**, even if the upload was done using numerical RMS IDs

M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z
Shortag	Shortag	Point in supply chain	Root cause of the shortage	Countri	Countri	Countri	Root cause of the sh	Shortage prevention	Shortage prevent	Affected	Market s	Shortage impact risk asses	Shortage i
0/01/202	26/02/20	Other	DistrLand			CZ	Distribution disrupted	OtherPresSameProd	Steps taken to ensu	15590	62	High	Risk consi
5/12/202	05/02/20	BatchCtrlTest	UnexIncDemMsStock		DE		Germany facing unexe	RelProdQualDef	Manufacturing incre		47	Medium	Medium ri
3/12/202	29/03/20	ActSub	ComPricing				Company decision ma	ResManIssues	Pricing discussions		62	Medium	Medium ri
1/07/202	11/09/20	BatchRelease;ActSubIn	Other;ComPricing				Manufacturing issues i	AltActSubMan;Other	Alternative substan	60000	100	High	Risk is hig
1/07/202	31/10/20	ActSub;SupplyRawExc	ManufPeople;RegMaRestSus	LU;MT			Manufacturing issues i	AltActSubMan	Alternative substan		100	Medium	No other f
3/05/202	21/07/20	PriPack;SecPack;Batch	ManufGMPNonComp;QualDefProdRecal	LU;MT			GMP non-compliance i	IncProdCurrentSite;RelF	The current site is b	150000	100	Low	Other alter
1/07/202	21/07/20	Importation;DistrRelPr	ManuCapacity;QualDefProdPreventReleas	LU;MT			Capacity on manufacatu	ECMP;ResManIssues;Cl	The manufacturing i		100	High	No other a
1/07/202	21/07/20	BatchRelease;DistrRelF	RegApprDelay;UnexIncDemMsStock;Unex		BE;MT		The delay in the regulat	ExpedShipment;AltRaw	The shipping is bel		100	Medium	Consider
1/07/202	08/05/20	DistrRelProd;Other	DistrImport;DistrLand;DistrAir;DistrExp		BE;MT	BE;MT	Distribution has been	AltActSubMan	An alternative manu		100	Medium	Consider
4/09/202	12/02/20	SupplyRawExcPack	RegMaRestSus				Supply has been disrupt	AltActSubMan	An alternative manu	279800	2	High	Number o

*the colouring has been applied to the table for demonstration purposes only

Interact and send your questions via Slido



1. Join via the QR code or on www.slido.com with the session code #ESMP1404

2. Send or upvote the questions you want to hear answered

3. Questions will be shown on the screen and answered live in the Q&A session and the ESMP FAQ document updated with common questions



Q&A

on Readable IDs

Moderated by Stephanie Marschler

4

Overview of ESMP updates and upcoming developments

Sofia Zastavnik, Stephanie Marschler

Updates on European Shortages Monitoring Platform (ESMP) expansion

● Q1 2026

EMA : ESMP – EMVS Gap Analysis presented to EMVO Board

● Q2 2026

NCAs : Voluntary Solidarity Mechanism requests submitted via ESMP

NCAs : Critical shortages reported via ESMP

○ Q3 2026

EMA : Testing and automation of the methodology to identify vulnerabilities in the supply chains of medicines on the Union list of critical medicines

○ From Q3 2026

Expansions to ESMP based on the **New Pharma Legislation** and delivering enhancements based on users' feedback



Expected outcome: Enhance shortage management capabilities, thereby strengthening the EU Network's ability to make faster and more accurate strategic decisions.



2026 CAP MAH Adoption Survey on ESMP



Goals

The objective of the survey was to assess two critical aspects:

- Gather **feedback on current users' experience** so far with the platform.
- Gather feedback on **future users' readiness to use ESMP** when needed.



Target audience

195 respondents composed by both CAP and non-CAP holders. 75% of which already have a ESMP role.



Positive results

- **Most current users** find the ESMP **easy to navigate** (61% plus 24% neutral) and **perform reliably** (57% plus 21% neutral) for routine shortage reporting.
- Concerning **guidance resources**, most future users (77%) know where to find them, while most current users (73%) found them useful to use the ESMP successfully.



Areas of improvement

- Requests for **improved functionalities** are mentioned (e.g. addition of dropdown menus and dashboards).
- Requests for **harmonisation of EU definitions**.

Addressing Key Perception Gaps

Feedback

Existing solution

“SPOC-only access restrictions hinder stakeholder collaboration on the ESMP portal”

Each company can have **as many ESMP users as they need**

“Limited system interoperability”

The ESMP Application Programming Interface (**API**) for **MAHs routine shortage reporting was released** in 2025

“Shortages reported for over two years cannot be updated or closed without altering the Start Date to an incorrect value”

The **shortage start date** has been updated and can **now support dates prior to 2019**

“Dedicated FAQ section would have been helpful”

FAQ section is available on the ESMP guidance, training materials and events webpage on EMA website

“Contact points for ESMP support are not specified”

Multiple contact points available: **EMA Service Desk** for technical questions, **AskEMA** for general questions, the **EMA Account Management Portal**, access, account, and registration

What we're working on next for user experience improvements

MAH survey and **direct user experience testing conducted**, priority areas highlighted by users

- **Easy access** to your reported **active shortage details** - allowing users to download all current or potential shortages in a format that can be used for reporting.
- More **user-friendly error messages** that suggest course of action.
- Improving the **success rate** of uploading a file, clearer indication of mandatory versus optional fields.
- Explore options to make submission template easier to use – **dropdown menus** with RMS identifiers, **quick access tools** to clarify **conditionality rules** between data elements and possible values.

Insertion of manufacturing information: a deep dive



WHO?

Marketing Authorisation Holders



WHEN?

In case of a **crisis situation** or **MSSG-led preparedness** action for CAPs and NAPs.



WHAT?

The data submission pathway requires a set of information, **including manufacturing** details such as the production plan, capacity, and alternative sites.

Demonstrated in the EMA Q1 Quarterly System Demo in March – recording available



WHAT'S NEW?

Manufacturing sites of **NAPs** stored in **PMS** are **automatically pre-populated in the ESMP submission template** for manufacturing information.

All manufacturing sites for NAPs are maintained exclusively in PMS.

Key deadlines for MAHs for manufacturer data submission to PMS:

- June 2026 for non-centrally authorised products (non-CAPs) featured on the [Union list of critical medicines](#)
- December 2026 for all other non-CAPs
- Check full details on data submission deadlines on PMS page on the EMA corporate website.

Updates and tips in routine CAP shortages reporting (1/2)



Updates

- **Weekly reminders** being sent to MAHs for **outdated shortage records** from 20 April (see next slides).
- Amendment to shortage start date restrictions: **Earliest possible shortage start date** is now **01/01/2019**
 - long-term shortages can now be entered and maintained in the ESMP.
 - communication and request for specific shortage cases will follow.

Tips

- 1 To avoid submission issues when updating shortages notifications, **generate** the ESMP submission template **from ESMP and select only the affected product** from the list of your organisation's products.
- 2 Keep product/country rows with shortage status "No shortage" per product in submission file.
→ **Do not delete** rows of the same product in countries without shortages.

Updates and tips in routine CAP shortages reporting (2/2)

- 3 **Choose most applicable RMS IDs** and describe further in related free text fields, rather than inserting “Other”, and include as much information as available in the free text fields to avoid follow-up emails.
- 4 Reminder regarding **shortage statuses** (template column L) in ESMP:
 - > A ‘*Potential*’ shortage should be updated to ‘*Actual*’ when the shortage becomes actual.
 - > A ‘*Potential*’ shortage should be updated from ‘*Potential*’ to ‘*Resolved*’ when the shortage was prevented and did not occur.
 - > An ‘*Actual*’ shortage should be updated to ‘*Resolved*’ when the shortage is closed,
 - > Update also correct shortage start and end dates plus any additional relevant information.
 - > **Do not update a potential or actual shortage to ‘*No shortage*’!**
 - > Exception: shortage information was submitted in error, e.g. different product or different country.
- 5
 - Where possible, submit one **comprehensive update** per submission per product.
 - > High-quality, well-timed updates support faster assessment and reduce follow-up queries.

Reminders for outdated shortage records

Automated reminder to review and update reported shortage information for specific authorised product in ESMP

- Reminder is sent when the ESMP detects at least one open shortage record for a product:
 - Potential shortages: outdated expected shortage start date;
 - Actual shortages: outdated expected shortage end date.

Weekly reminders sent every Monday from EMA-IRIS@ema.europa.eu.

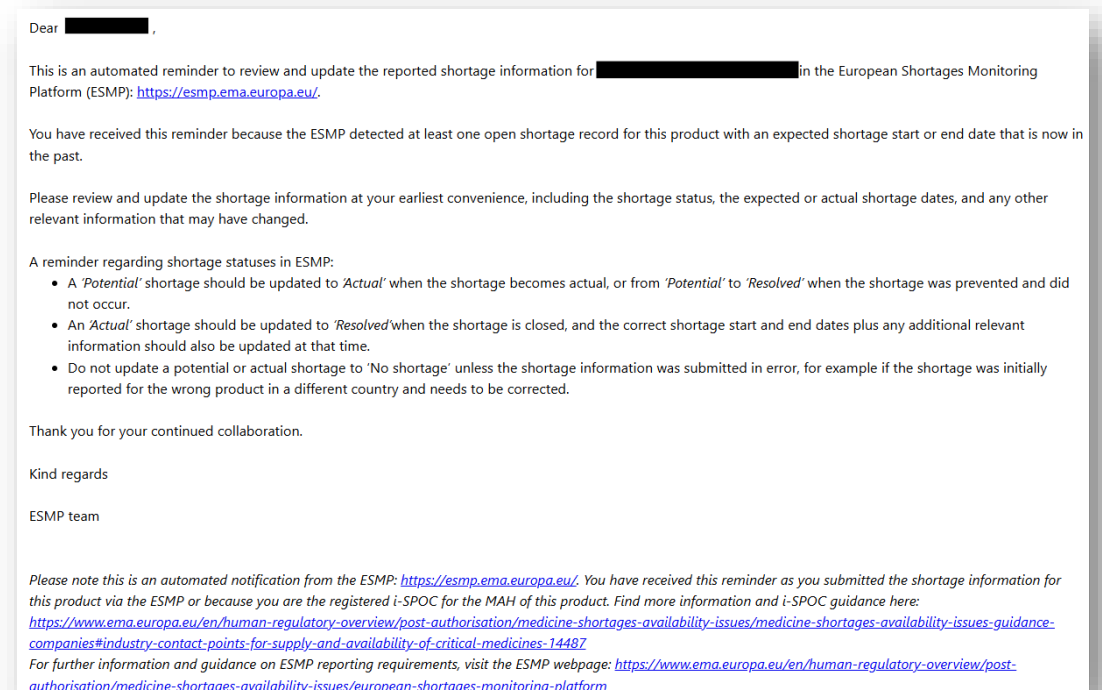
Sent to ESMP user that submitted the shortage(s) report & MAH's i-SPOC is copied.

Subject line includes required action and product name, MAH name, IRIS reference number
→ Do not change the subject line if responding to the email.

Reminder includes link to ESMP platform for easy access.

MAH to **review and update the shortage information:**

- shortage status;
- expected or actual shortage dates;
- any other relevant information that may have changed.





Q&A

Moderated by Stephanie Marschler

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Closing remarks

Sofia Zastavnik

Useful links and resources

! All documents and videos mentioned below (and more) are published and linked on the dedicated [ESMP guidance, training materials and events webpage](#) on the EMA corporate website.

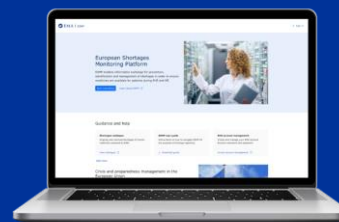


[User guide \(MAHs\)](#)

Comprehensive **step-by-step guidance** to fulfil reporting requirements and data analysis.

New version with readable IDs to be available

Central **hub for information** around the ESMP.



[ESMP portal](#)

[Implementation guide](#)



Detailed **technical specifications** and reporting data guidelines to ensure accurate submissions.

New version with readable IDs to be available

Structured **visual guides** to support you in following ESMP reporting processes.



[ESMP webpage](#)

[Training recordings and video tutorials](#)



Support

- **For ESMP questions/ issues:**

- [ESMP section of the EMA Service Desk portal \(Service Now\)](#) → report issues related to accessing the ESMP, seeing unexpected data, uploading data or the system performance
 - [Report an issue with ESMP](#) to create a ticket for the issue you are experiencing
 - [Request information about ESMP](#) to create a ticket for the question you have

Depending on the issue or question, select one of the **different service offerings**:

- ESMP MAH routine CAP shortage reporting
- ESMP MAH Crisis/MSSG-led preparedness submissions
- ESMP other (topics covering multiple aspects and/or general nature)



Please provide a clear description of the issue and provide screenshots or the generated PDF as attachment as these can help to solve the query a lot faster.

- **For other questions/ issues:**

- [EMA Service Desk](#) for technical questions on the use of the portal and for reporting faults
- [EMA account management portal](#) for access, account, and registration requests
- [Ask EMA](#) for general questions not related to a specific submission/procedure

Wrap up

Thank you for your participation! Today we covered:

- 1 *Detailed walk-through of readable IDs functionality introduced in ESMP templates*
- 2 *Overview of main recent and planned updates on ESMP development*
- 3 *Overview of updates and reporting tips in routine CAP shortages reporting*



Your feedback matters

- Please spare **a few minutes to complete the feedback survey** in Slido, sharing your feedback on today's event.
- **Your input will guide us in tailoring next sessions** to better meet your needs and preferences.



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