	•	м •																											
D			P																										
	Dire	ktorat	et fo	r																									
	med	lisinsk	e pro	odı	ıkte	er																							
			R /	7																									
		S	$\mathbf{N}$		_	1																							
	Reg	gulat	oris	sk	inf	or	ma	asj	on	sm	øt	е																	
	8.m	gulat nai 20	025	•																									
		i Wilh																											
	Sen	iorråd	dgive	er,	en	het	t fo	r fc	orsy	/nir	igs	sikl	ker	het	og	till	ate	lse	r										
	SPC	)C-re	pres	ser	ntar	nt																							

## ESMP- European Shortages Monitoring Platform

## <u>HVA</u>

Plattform utviklet av EMA for å samle informasjon om tilgjengelighet, forsyning og etterspørsel. Hensikten med ESMP er å forebygge, oppdage og håndtere medisinmangler i EU/EØS-området.

Plattformen ble lansert februar 2025.





#### European Shortages Monitoring Platform

ESMP enables information exchange for prevention, identification, and management of shortages to ensure medicines are available for patients in the EU and EEA.

mitting Learn about ESMP 🗹







#### REGULATION (EU) 2022/123 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 25 January 2022

on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

(Text with EEA relevance)

#### THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

Having regard to the opinion of the Committee of the Regions (2),

Acting in accordance with the ordinary legislative procedure (3),

#### **HVORFOR**

ESMP er beskrevet i EMAs utvidede mandat- i forordning 2022/123 – artikkel 13

Article 13

#### European shortages monitoring platform

 The Agency shall set up, maintain, and manage an IT platform to be known as the European shortages monitoring platform ('ESMP'), which shall be linked to the database referred to in Article 57(1), point (1), of Regulation (EC) No 726/2004.

The ESMP shall be used to facilitate the collection of information on shortages of, supply of, and demand for medicinal products, including information on whether the medicinal product is placed or ceases to be placed on the market in a Member State.

- 2. The information collected through the ESMP shall be used to monitor, prevent, and manage:
- (a) actual or potential shortages of medicinal products on the critical medicines lists during public health emergencies and major events; and
- (b) actual or potential shortages of medicinal products that are likely to lead to a public health emergency or a major event in accordance with Article 4(2).

"The ESMP shall be used to facilitate the collection of information on shortages of, supply of, and demand for medicinal products, including information on whether the medicinal product is placed or ceases to be placed on the market in a Member State."



# ESMP- European Shortages Monitoring Platform

### **HVEM**

Følgende aktører skal rapportere til ESMP:

- MT-innehavere (MAH)
- Legemiddelmyndigheter (NCA)

MSSG spiller i tillegg en viktig rolle

Rapportering fordrer godkjent bruker hos EMA

### <u>NÅR</u>

Ulike data skal rapporteres av ulike aktører til ulike tidspunkt

HVEM

HVOR

HVA

3 ulike scenarioer beskrevet:

- Normaltilstand
- MSSG-definert beredskap
- Krise (Major Event (ME) eller Public Health Emergency (PHE))





	Routine shortage reporting	MSSG-led preparedness	Crisis
Available in:	Normal circumstances	Preparedness (PHE, ME)	Crisis (PHE, ME)
Purpose:	Early reporting of shortages to allow for efficient shortage prevention, management and mitigation	Specifically driven by the MSSG to address events that might lead to a PHE/ME	Focused on immediate actions to handle and mitigate the impact of ongoing or imminent crises, such as a PHE or ME
Submission trigger:	Potential or actual shortage of a marketing authorisation holders' product	MSSG announcement of preparedness exercise	EC recognition of a PHE/ME
Products in scope:	All centrally authorised products (CAPs)	List of medicines to be monitored for MSSG-led crisis preparedness (CAPs and NAPs)	List of critical medicines for a public health emergency/major event (CAPs and NAPs)
Frequency of reporting:	As required, updated when new relevant information is available	Defined by the MSSG	Defined by the MSSG
9		PHE: public health emergency ME: ma	ajor event



<b>S</b>	
EUROPEAN MEDICINES AGENCY	

	MSSG-led preparedness	Crisis
Available in:	Preparedness (PHE, ME)	Crisis (PHE, ME)
Purpose:	Specifically driven by the MSSG to address events that might lead to a PHE/ME	Focused on immediate actions to handle and mitigate the impact of ongoing or imminent crises, such as a PHE or ME
Submission trigger:	MSSG announcement of preparedness exercise	EC recognition of a PHE/ME
Products in scope:	List of medicines to be monitored for MSSG-led crisis preparedness (CAPs and NAPs)	List of critical medicines for a public health emergency/major event (CAPs and NAPs)
Frequency of reporting:	Defined by the MSSG	Defined by the MSSG
10	PHE: pub	emergency ME: major event



### Data collection in the ESMP: MAH submissions





#### Data collection

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



In normal circumstances, MAHs will report shortages of <u>centrally authorised products</u>.

- Shortage information
- Shortage prevention and mitigation plans
- Shortage impact assessment
- Alternative therapies

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 <u>nationally and centrally authorised products</u> <u>in scope</u> of a critical medicines list for a particular public health emergency or major event.

- Shortage information
- Shortage prevention and mitigation plans
- Marketing status
- Market share, sales volume and sales forecast
- Manufacturing information including production plan, capacity and alternative sites
- Alternative therapies

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

# Ressurser

• EMAs nettside for European Shortage and Monitoring Platform

https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortagesavailability-issues/european-shortages-monitoring-platform#reporting-via-esmp-70290

## • ESMP FAQ

https://www.ema.europa.eu/en/documents/other/frequently-asked-questions-european-shortagesmonitoring-platform-esmp\_en.pdf

#### • ESMP

Introductory webinar on the European Shortages Monitoring Platform (ESMP)

### • ESMP User guide for MAHs

https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmpuser-guide-marketing-authorisation-holders\_en.pdf

#### • EU forordning 2022/123:

European Shortages Monitoring Platform | European Medicines Agency (EMA)



· · · · · · · · · · ·	•••••	· · · · · · · · · · · · · · · · · · ·	· · · · ·
dmp.no			
	· · ·		
helsenor			
	aktoratat f	ar madicinaka praduktar	
f in Dire	ektoratet f	or medisinske produkter	
f in Dire	ektoratet f	or medisinske produkter	
f in Dire	ektoratet f		
• • • • • • • • • • • • • • • • • • •	ektoratet f	• • • • • • • • • • • • • • • • • • • •	· · · · · ·
• • • • • • • • • • • • • • • • • • •		· · · · · · · · · · · · · · · · · · · ·	
Image: second		$\begin{bmatrix} & & & & & & & & & & & & & & & & & & &$	
		· · · · · · · · · · · · · · · · · · ·	  t for · · · ·
		$\begin{bmatrix} & & & & & & & & & & & & & & & & & & &$	· · · · · · · · · · · · · · · · · · ·

٠	•	•	•	٠	•	٠	•	٠	٠	•	•	•	٠	•
٠	•	•	•	•	•		•	•	٠	•	•	•	•	•
٠	•	•		•	٠		٠	٠	٠	٠	•	•	۲	•
•	٠	٠	٠	٠	•		•	•	•	۲	•	٠		•
•	•	•	•	•	Dire	ektor	atet	for	٠	•	•	•	٠	•
•	•	٠	•	٠	me	disin	ske p	orodı	ukter	•	•	•	é	•
•	•	•	•	•,•	•		•	•	•	•	•	•	•	
•	•	•	•	٠	•		•	•	٠	•	•	•	•	•
•	•	•	•	•	•	•	•	•	•	•	•	•	•	<b>e</b> r