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SCIENCE MEDICINES HEALTH

Update on the new Medicine Shortage Communication (MSC) process and template

PCWP/HCPWP and all eligible organisations meeting
20 November 2024

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Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)

EMA MSSG Medicine Shortage Communication (MSC)

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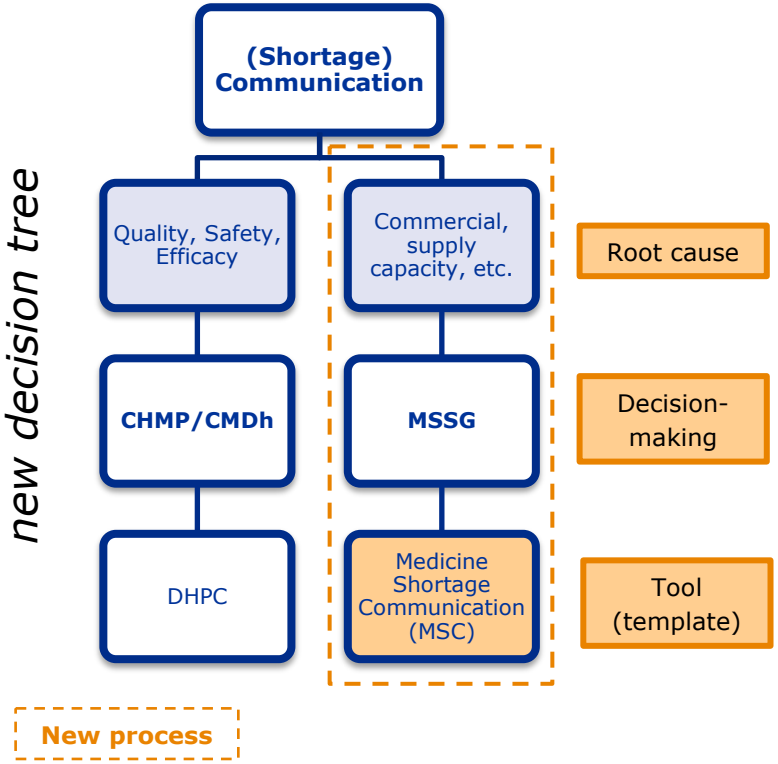
Streamline and improve (shortages) communication to HCPs in EU



Recent challenges (with shortage DHPCs):

- The processes at **national level** of a DHPC are based mainly on what is needed for **pharmacovigilance** activities
- **Concerns** on endorsing wording, e.g. market withdrawals linked to commercial decisions

Proposal (principles of the new process):

1. Communications that only **concern supply or shortages**, without an associated Q/S/E issue, would be endorsed by **MSSG** (***new:*** **MSC template**).
2. All other communications (including Q/S/E-related DHPCs that also impact supply or availability) would continue through the **existing DHPC process** without change (under remit **CHMP/CMDh**).

1 New process for Medicine Shortage Communications (MSC)

“To be” MSC approval process (by EMA MSSG)

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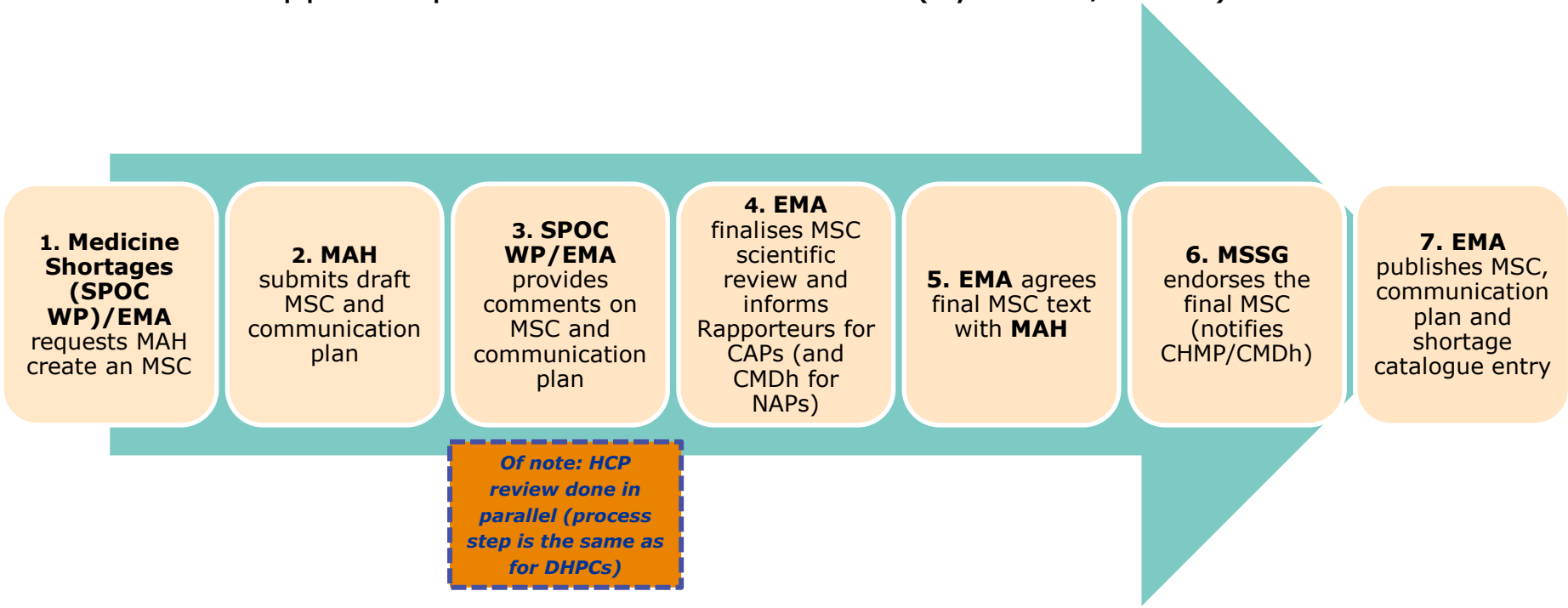
Mirrors current approval process for DHCPs review (by CHMP/CMDh)



Proposed MSC template

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Medicine Shortage Communication

<Date>

<Name of medicinal product (active substance, presentation, formulation): supply shortage>

Dear Healthcare Professional,

<Name of marketing authorisation holder(s)>, is notifying healthcare professionals about a shortage of [name of medicine]

Overview of situation

- **<Brief description of the shortage situation, including reason and actions taken by the MAH>**
- **The shortage affects <some> <all> of the EU countries where the product is marketed including [**name of country**]**
- **The shortage is expected to continue until [**insert date**]**
- **<The shortage is not due to any safety, efficacy or quality concerns with [**name of medicine**]**

Mitigation measures

In order to manage the shortage, the MAH is engaging with <the European Medicines Agency> and the [National Competent Authority] on mitigation measures.

During the shortage, healthcare professionals should:

- **<not prescribe [**name of medicine**] to new patients <to conserve / guarantee supply for patients who are already taking this medicine and who do not have suitable alternatives.> < prescribe a reduced dose if this is an option >** *(this is not a comprehensive list and other measures may be applicable and if so reflected in this section).*
- **<Consider prescribing [**describe alternative medicine *(this is usually a reference to another medicine of the same class rather than a specific medicine and can be tailored according to the national situation)*,or alternative formulation**]**
- **[**Describe any additional clinical recommendations**]**
- **<For additional information consult EMA's shortage catalogue, <your country's shortage register** *(if available)* **or > your national competent authority.>**

Background on the shortage

Guidance: This section may include the following information:

[Description of the therapeutic indication of the medicinal product, a description of the root cause of the shortage]

[Important details about the shortage such as the duration and mitigating actions taken]

[The reason for disseminating the MSC at this point in time]

[Any evidence supporting the recommendation]

[A statement on any previous MSC/DHPCs related to the shortage that have recently been disseminated]

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

***Annexes** (if applicable)*

<Link/reference to other available relevant information, such as information on the website of a competent authority>

Communication Plan for Medicine Shortage Communication

MSC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	
Marketing authorisation holder(s)	
Purpose of the communication	
MSC recipients	
Member States where the MSC will be distributed	

Timetable *[Delete steps which are not applicable]*	**Date**
MSC and communication plan (in English) agreed by MSSG	
MSC and communication plan (in English) sent for information to CHMP / CMDh	
Submission of translated MSC to the national competent authorities for review	
Agreement of translations by national competent authorities	
Dissemination of MSC	

Pilot phase

Duration: to allow MAHs and NCAs to get familiar with the new template, it is proposed that the MSC pilot phase will take 6 months (October 2024 and March 2025).

Scope: all critical shortages not related to Q/S/E, following a SPOC WP request

Benefits: This will allow the Regulatory Network to:

1. Identify potential issues with implementation/dissemination of MSC at national level
2. Further adjust involvement of Rapporteurs/CHMP/CMDh in case of clinical recommendations
3. Adjust the template and/or process based on experience.

Q/S/E – Quality, Safety, Efficacy
MAH – marketing authorisation holder

Summary and next steps

Summary:

- Implement MSC through a **pilot** for critical shortages unrelated to quality, safety, or efficacy issues, under **MSSG** governance.
- **Consultation with the HCPs** remains unchanged (same process as for DHPCs).
- Anticipated **numbers of MSCs** (same criteria as for DHPCs, i.e. SPOC WP request)
- MSCs are published on the EMA website

Delivery plan (Q4 2024)

September:

- *MSSG agreed to the pilot phase to implement the MSC template and process.*
- *Update to Industry Standing Group (ISG)*

October:

- Launch of pilot phase

November:

- Update to HCP/PCWP

Adjust template if needed and "Go–live" in **April-May 2025**

Any questions?

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