Draft guidance for industry to improve reporting & best practice

Multi-stakeholder meeting with the HMA/EMA Task Force on availability of authorised medicines
9 November 2018

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Agenda

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- Who is responsible for monitoring supply and reporting shortages?
- When should a notification be made?
- Who should be notified?
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- Proposed template for shortage notification

Introduction

The HMA/EMA Task Force on availability of medicines has developed **draft industry guidance** for **reporting** of **shortages** of medicinal products in the Union (EU/EEA).

What issues should be reported?

- **Shortages** within the EU/EEA that are **ongoing** or that are **expected to occur** in the future, irrespective of the criticality of the medicine.

- **Restriction of supply** imposed by the competent authority of any country in which a **quality defect** has been **identified**.

Who is responsible for monitoring supply and reporting shortages?

Shortages are a **multi-stakeholder responsibility**, requiring the co-ordinated involvement of all stakeholders **across the supply chain**.

Marketing Authorisation Holders, and the **distributors**, within the limits of their responsibilities, should ensure **appropriate and continued supplies** to pharmacies and persons authorised or entitled to supply medicinal products so that the **needs of patients** in the Member State in question are **covered**.

Marketing Authorisation Holders are in the best position to assess relevant information, as they have full visibility of their stock, both national and global. They should report all confirmed impending or anticipated medicine shortages.

When should a notification be made?

- Marketing Authorisation Holders and parallel traders should notify EU competent authorities of any situation **when supply cannot or will not meet demand at national level**, irrespective of the criticality of a medicine.

- Notification shall occur as soon as the shortage or the potential shortage **has been confirmed** and, other than in exceptional circumstances, **no less than two months before the interruption** in the placing on the market of the product.

Who should be notified?

- For **all authorised medicinal products**, shortage notifications should be sent to the **impacted national competent authorities**.

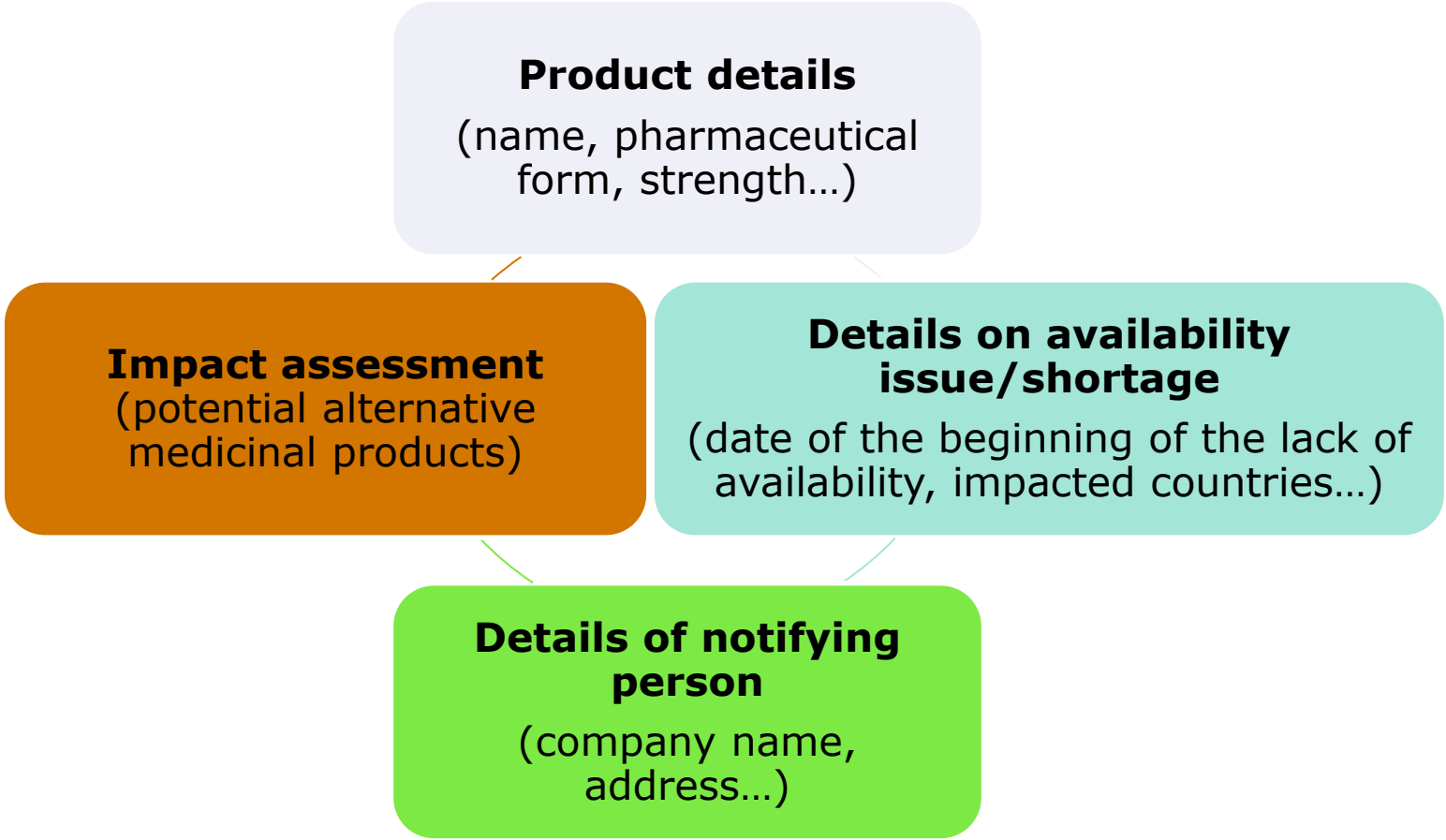
- For **centrally authorised products**, shortage notifications should be sent to **EMA** as well as the **impacted national competent authorities**.

What information should be notified?

HMA/EMA Task Force has developed **draft template** of proposed information to be included within shortage notifications:

- The information provided in the notification is used by the competent authority for **triaging** and **assessment** of the situation. The information should therefore be as **accurate** and **up-to-date** as possible, all while being **comprehensive** and **concise** at the same time.
- Some information may not be available at the time of the notification but it **should not delay it**. New information should be provided as soon as it becomes available.

Proposed template for shortage notification



Best practice - example

Cancer medicine used to treat a type of blood cancer

- Several batches failed quality testing and were not released.
- Manufacturing was temporarily suspended.

MAH's proposal was discussed between EMA and relevant EU competent authorities. It was agreed to:

- Accept importation of alternative product
- Inform healthcare professionals in writing about the stock-out and what actions to take.

- 19 EU countries were affected.
- In order to ensure supply, MAH proposed importing an alternative product from outside the EU.

Information on shortage was published on the EMA catalogue and updated once the shortage was resolved.

Any questions?

Further information

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See websites for contact details

European Medicines Agency www.ema.europa.eu

Heads of Medicines Agencies www.hma.eu

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