Session 4: Permanent withdrawals of medicinal products from the market

Network priorities to 2025: TF AAM workplan

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Network priorities to 2025: TF AAM workplan

Outline

1. Industry reporting obligations (legal basis)
2. Impact to public health and vulnerabilities
3. “As is” TF-AAM work programme (2021-2025)
4. Solutions for Regulators to mitigate potential impact
5. “Focused discussion” – 3 key topics for future action

Legal basis

- What is the meaning of *"cessation of placing on the market"*:
  - Chapter 1 of volume 2A of the Notice to Applicants as:

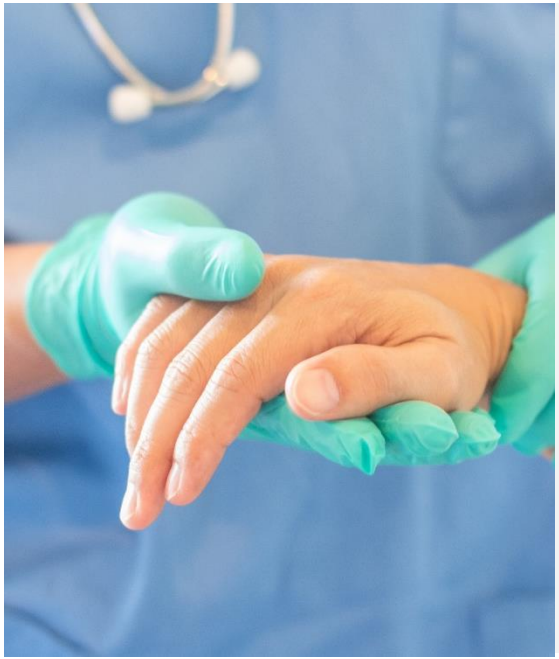
    "Cessation of release into the distribution chain" with the consequence that the concerned product may **no longer be available** for the supply to the patients.

- Industry's reporting obligations:
  - Article 13(4) of Regulation (EC) No 726/2004:

    "MAHs are required to inform EMA if their CAP ceases to be placed on the market of a Member State, either temporarily or permanently".
  - Article 23a) of Directive 2001/83/EC, as amended:

    "If the product ceases to be placed on the market of a MS, either temporarily or permanently, the MAH shall notify the NCA no less than two months before the cessation of placing on the market".

Impact to public health and vulnerabilities



- Impact (on patients):
  - No/limited therapeutic alternatives
  - Switching patients over to alternatives may lead to adverse reactions/ medication errors
  - Aggravation of patient's health (as a result of missing dose)
- Vulnerable populations:
  - Suffering from life-threating and/or rare conditions
  - Paediatrics, elderly, mental health patients

“As is” TF-AAM work programme (2021-2025)

In 2019:

Survey report on handling of withdrawals from the market by NCAs developed by TF-AAM

(internal use by NCAs only – see main conclusions, next slide)

Planned action (until 2025):

Development of best practices on processes in place to withdraw medicines permanently from the market

There is no published guidance for MAHs on identification/reporting of temporary/permanent withdrawals from the market (contrary to shortages)

Solutions for Regulators to mitigate potential impact

"Toolkit" of actions* undertaken at national/EU level (non-exhaustive):

- Working with MAHs to:
  - manage existing stocks, and
  - expedite/anticipate future supplies,
- Working with clinical experts on guidance and protocols (for therapeutic alternatives)
- Fast-tracking regulatory procedures (accelerated TTs)
- Reach out to alternative MAHs to meet additional demand
- Working with parallel importers to obtain unauthorised medicines

**Based on NCA survey report on handling of withdrawals from the market conducted in 2019*

“Focused discussion” –3 key topics for future action

Company-driven (economic) decisions of withdrawals from the market should carefully consider the needs of patients to avoid having a negative impact on EU public health.

Question:

What actions can be undertaken to enable early dialogue before Industry’s decisions are taken?

Improving transparency and enhancing communication routes is acknowledged between regulators and external stakeholder organisations, including HCPs, industry and patient groups.

Question:

What other tools can be explored to allow HCPs and patients to obtain information early?

The permanent market withdrawal of a medicine directly impacts the delivery of healthcare in the respective healthcare system.

Question:

What are opportunities to engage early with decision-makers in healthcare systems, to discuss and assess the consequences of a withdrawal from the market by a company early?

Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union