Session 4: Permanent withdrawals of medicinal products from the market

Moderator: Momir Radulovic (HMA)

Framing the session…(1/2)

- What is **in scope** of today's panel discussion:
  - Permanent withdrawals from the market **=** cessation of placing on the market (marketing cessation)
    - Definition: Withdrawals from the market **≠** shortages
  - Unavailability issues of both innovative **&** old, well-established medicines
  - Root cause: mostly commercial or business consideration, e.g.:
    - Small market sizes (low sales/profit),
    - Pricing /reimbursement,
    - Tendering (sole suppliers),
    - Reduced manufacturing capacity

A "withdrawal from the market" occurs when a MAH intends, either temporarily or permanently, to stop supplying a medicinal product. *(Directive 2001/83/EC)*

A "shortage" occurs when the supply of an authorized medicine - placed on the market - does not meet demand at a national level, whatever the cause. *(Regulation (EU) 2022/123)*

Framing the session…(2/2)

- What is **out of scope** of today's discussion:
  - Temporary withdrawals (as such discontinuations can lead to "shortages")
  - Quality/Safety/Efficacy reasons linked to "benefit-risk" assessment
  - Accessibility issues (more generally) are not to be addressed
- Session's **objective**:
  - Listen to each stakeholder group's feedback & raise awareness on the topic
  - Identify up to 3 key topics for future action (Roundtable)
  - Inform & refine HMA/EMA TF-AAM programme on the topic