EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

POLAND25.EU

Theme 5: Availability and supply

Strengthening availability of medicines to protect public and animal health

Monica Dias (EMA)

Theme 5 – general considerations

Potential changes to the goals, objectives or narrative of the strategy

- Need for 'balanced' communication on shortages to avoid public concern (goal 1, objective 4)
- The document should adopt a more robust 'One Health' approach, integrating veterinary medicines more comprehensively and enhancing measures for emerging disease preparedness (narrative of the strategy)

To be considered in implementation actions

- Clear mission to progress on ongoing activities around mitigation and prevention of shortages of human medicines.
- Extent of shortage issues for veterinary medicines needs to be further assessed.
- Support to continue with a risk-based inspection approach incl. use of alternative inspection models, and to keep the GMP guidelines updated and harmonised in light of technological progress in manufacturing.

Theme 5 – Goal 1 (availability of medicines)

Strengthen the availability of medicines to protect public and animal health

1. Identify specific root causes of shortages for human and veterinary medicines and develop harmonised strategies to improve the prevention and management of shortages, particularly for critical medicines
2. Improve coordination of activities related to improving availability of human medicines and implement best practices in conjunction with stakeholders and international partners
3. Work with the European Commission to coordinate national and EU strategies for human medicines, including stockpiling, to reduce the possible impact of national measures on availability of medicines in other countries
4. Improve transparency and communication on both the launch of medicinal products and shortages with relevant stakeholders, including patients, healthcare professionals and HTA bodies

Theme 5 – Goal 1 (availability of medicines)

To be considered in implementation actions

- Further progress on the ongoing activities such as harmonisation of the implementation of shortage definition, including proportionate and risk-based shortage management
- Continue to facilitate the Voluntary Solidarity Mechanism
- Continue application of regulatory flexibilities
- Continue the exploration of further data exchange of the European Shortages Monitoring Platform (ESMP) with other IT systems
- Avoidance of duplication in shortage reporting
- Patient-level reporting of shortages

Theme 5 – Goal 1 (availability of medicines)

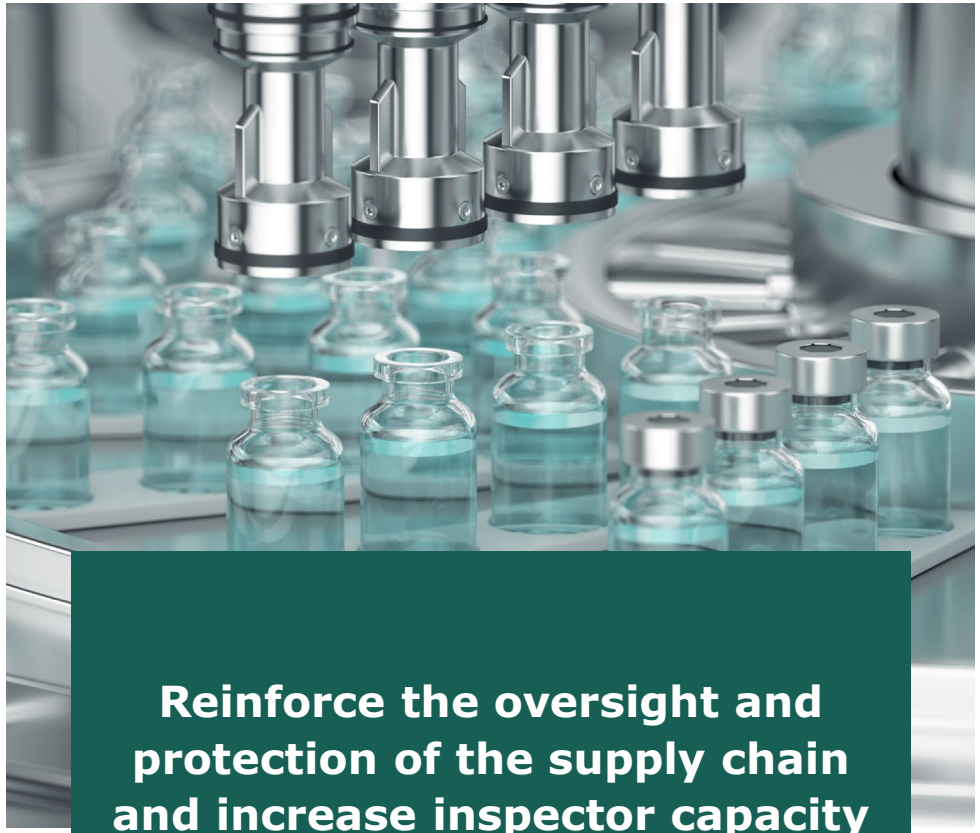
Comments outside the remit of medicines agencies

- Related to revision of pharmaceutical package / other EU policy initiatives / legislation:
  - Union list of critical medicines
  - Scope of Shortage Prevention / Mitigation Plans
  - Shortage reporting requirements
  - Usage of harmonised electronic package information
  - Strengthening regulation of supply chains, reshoring, reduction of dependence on third countries
  - Public health crisis activities
  - Consideration of specific populations (e.g. paediatric medicines)

Other comments

- Support for the significantly increased role of EMA in preventing and addressing shortages in recent years
- Welcomes strong focus on addressing medicine shortages and strengthening security of supply

Theme 5 – Goal 2 (supply chain)



Reinforce the oversight and protection of the supply chain and increase inspector capacity

5. Ensure sufficient numbers of trained inspectors are continuously available to perform legal duties (see section on sustainability of the network)
6. Use risk-based inspection planning, alternative inspection methodology and collaboration with international partners to better target oversight of the supply chain, including for key finished product and API manufacturers
7. Strengthen monitoring and oversight of the supply chain to prevent entry of falsified human medicines in the supply chain
8. Keep good manufacturing practice (GMP) requirements updated in light of technological progress in manufacturing (e.g. with respect to digital, IA and other technological systems).
9. Improve and inter-link information in current databases (e.g. EudraGMDP)

Theme 5 – Goal 2 (supply chain)

To be considered in implementation actions

- Harmonisation of interpretation of EU GMP guidelines
- Expand the data provided by Members States in the EudraGMDP database
- Monitor learnings from mutual recognition agreement (MRA) partners
- Standards for ensuring that new technology is implemented properly by industry

Theme 5 – Goal 2 (supply chain)

Comments outside the remit of medicines agencies

- Related to revision of pharmaceutical package / other EU policy initiatives / legislation:
  - Expanding MRA for vaccines and plasma-derived products, ATMPs

Other comments

- Relocate supply chains and production
- Step up EMA's global presence
- Focus on illegal supply chain is already addressed by the Falsified Medicines Directive
- Committed to promoting access to safe medicines, raising awareness about the dangers of unlawful medicines, and combating unsafe medicines
- Few incentives are available to companies to transition to manufacturing processes in line with EU standards while the EU Green Deal legislation has significantly increased requirements for companies to transition away from existing processes