HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

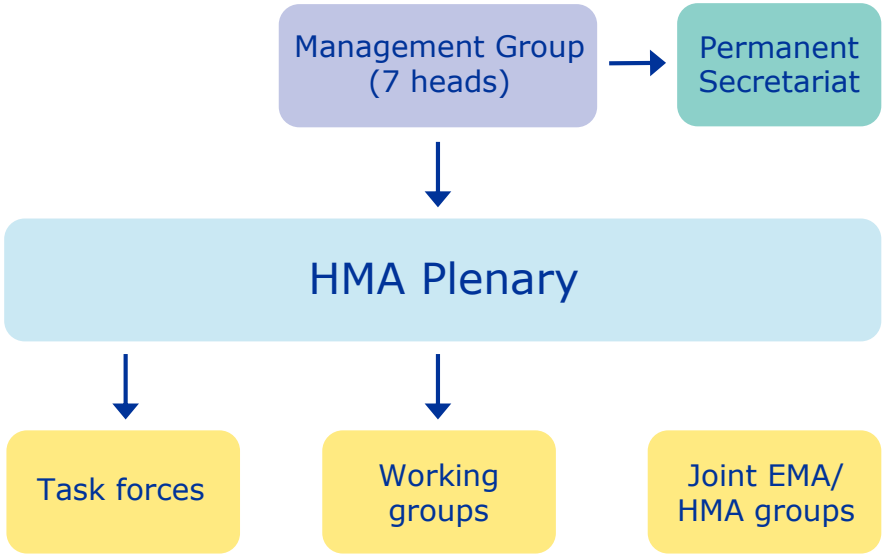
Ongoing actions for vaccine roll out at national level – Denmark as a Case

Nikolai C. Brun on behalf of Heads of Medicines Agencies (HMA)
Danish Medicines Agency, Director of Division, Chief Medical Officer

Outline

1. Heads of Medicines Agencies (HMA): a short introduction
2. Organisation of vaccine roll out in Member States – an overview
3. Surveillance of side effects of COVID-19 vaccines
4. Knowledge of effectiveness and safety of COVID-19 vaccines
5. Promoting trust in Health Authorities through open and transparent communication

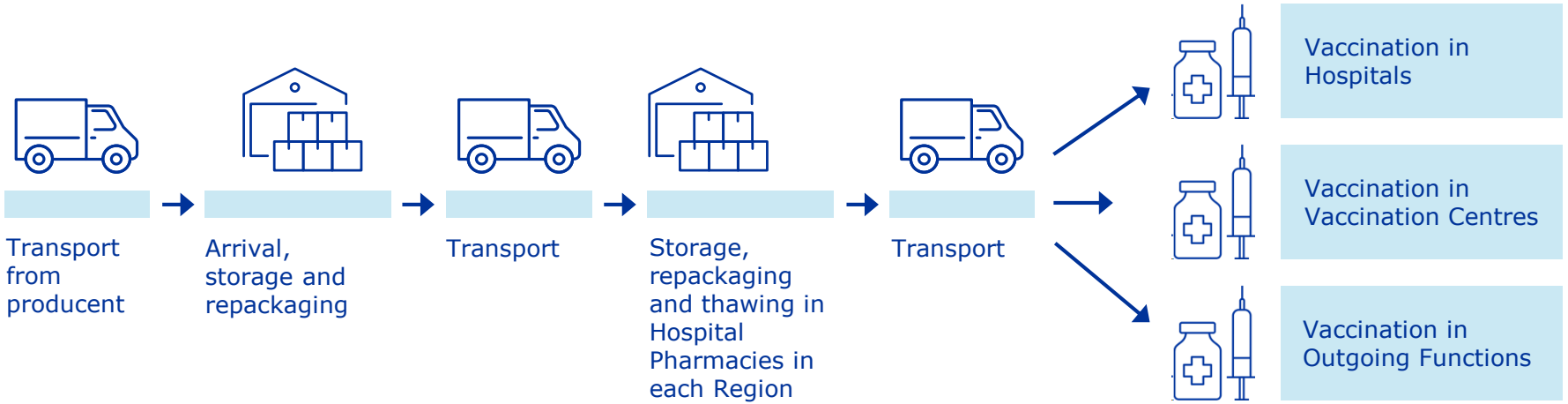
Heads of Medicines Agencies (HMA): a short introduction



- Coordinating role for National Competent Authorities (NCAs)
- Protecting and promoting public health in Europe
- Foster an effective and efficient European medicines regulatory system

Organisation of vaccine roll out in Member States

AN OVERVIEW USING DENMARK AS AN EXAMPLE



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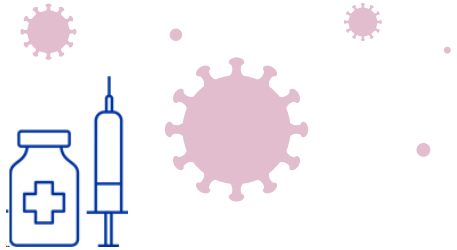
Organisation of vaccine roll out in Member States

AN OVERVIEW USING DENMARK AS AN EXAMPLE

Vaccines delivered to Member State



Distributed from Health Authorities to the Regions by selected target groups

- Selected citizens in nursing homes in areas with high incidence*
- Selected citizens > 65 at high risk of servere course with COVID-19*
- Selected front line staff at hospitals and nursing homes*

The vaccines assigned are distributed by regions according to target groups at the individual vaccination sites

- Hospitals
- Vaccination Centres
- Outgoing Functions

* Phase 1 in roll out

Surveillance of side effects of COVID-19

OBJECTIVES AND ACTIONS

- Ensure a strong set-up for reporting adverse reactions and monitoring the vaccines
- Healthcare professionals and citizens should be able to easily report suspected side effects at national level
- Healthcare professionals and citizens should have the necessary information to be able to report
- Focus on high quality of adverse reaction reports - crucial for signal monitoring
- Stricter reporting obligation to be considered at national level
- Studies to monitor the effectiveness and safety of vaccines

Knowledge of effectiveness and safety of COVID-19 vaccines

- The companies will continue to provide study results and data as they continue to be generated
- In addition, independent studies of COVID-19 vaccines coordinated at EU level which will give more information on the vaccine's long-term safety and effectiveness
- Member States may also carry out their own additional studies at national level using national cohorts (e.g. in Denmark ENFORCE study)
- Member States may also use other means to gather data in real time and complement routine pharmacovigilance actions such as:
  - National Health Registries
  - electronic health records and
  - in future, use of AI based Signal Generation – early identification of unknown side effects and identification of unreported side effects

Promoting trust in Health Authorities through open and transparent communication

OVERALL VISION

- Member States steping up communication efforts to support an informed debate on vaccines – an informed basis knowledge for everyone
- Everyone has a right to be informed – information on how the vaccines has been developed, approved and is being monitored
- Efforts are being made at national level to reach as many citizens as possible

Everyone has a right
to be informed.

Thank you