# HMA/EMA Task Force on Availability of Authorised Medicines

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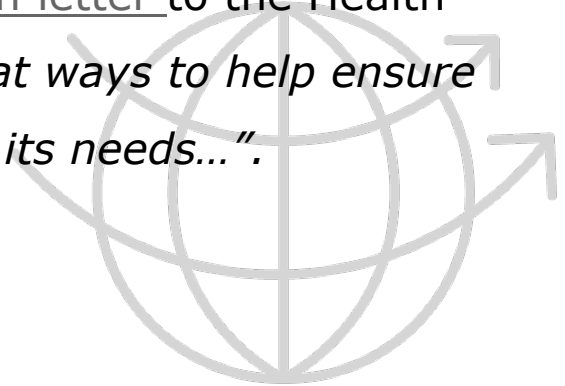
# Background (1/3)

- **Shortages of medicines:** global problem and on the rise in Europe
- **Causes are varied**: manufacturing or quality related (GMP), increased demand, economical (commercial reasons, P&R)
- Significant impact on **patients and healthcare systems** due to:
  - medicines rationing
  - delay of critical treatments
  - use of alternatives that may be less efficacious or increase risk of medication errors and adverse events

# Background (2/3)

❑ Improving the **availability of medicines** authorised in the European Union (EU) was recognised as **priority topic in EU Medicines Agencies Network Strategy to 2020** (published in 2015) and is a **strategic Focus Area** to be featured in the EU Medicines Agencies Network Strategy to **2025**.

❑ The president of the European Commission in her Mission letter to the Health Commissioner, Mrs Stella Kyriakides, asked her to *…"look at ways to help ensure Europe has the **supply of affordable medicines** to meet its needs…"*.



# Background (3/3)

- **HMA/EMA TF-AAM** was established in 2016 with the aim to:

  1. assess reasons why authorised medicines are not marketed in MSs
  2. establish definitions and metrics to enhance shortage management
  3. improve sharing of information among EU regulatory authorities
  4. develop communication strategies within the Network and with other actors in the healthcare system

- The mandate of the TF-AAM was extended in December 2019 for **another 3 years**.
  - Co-chairmanship: Kirstin Raudsepp (EE) and Noel Wathion (EMA)

- **The scope relates to: 1)** *medicines authorised but* **not marketed** *(or no longer marketed), and* **2)** *medicines authorised* **affected by supply disruptions.**

# Main achievements and progress on key activities (1/2)

1. HMA/EMA workshop on availability of authorised medicines (November 2018 multi-stakeholder meeting). Workshop report published in the EMA and HMA websites (**February 2019**)
2. Publication of Guidance on detection and notification of shortages for MAHs (**July 2019**). Implementation of the guidance is currently foreseen after Q2 2020.
3. Publication of Good practice guidance for EU authorities on public communication on medicines' availability issues (**July 2019**)
4. Pilot phase of the SPOC system for sharing of information among EU regulatory authorities started on **9 April 2019.** Phase 1 (information sharing) finished in August 2019 and Phase 2 (EU coordinated actions on shortages) is foreseen to start after Q2 2020.

# Main achievements and progress on key activities (2/2)

5. Publication of the proposed metrics of shortage (**December 2019**) following adoption by the EMA Management Board. Will be tested in a pilot phase together with the guidance for MAHs (after Q2 2020).

6. EU Regulator's manual is currently under development and once finalised will become the reference material for all EU regulators (**to be finalised at the end of 2020).**

7. Publication of information on national shortages for each MS. A list of national *shortage registers* for all MSs is compiled in the EMA and HMA websites.

8. Development of concept paper on best practices to prevent shortages (drafting started in **Q1 2020**)

# Any questions?

## Further information

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