

Safety Surveillance of COVID-19 vaccines

Member States Briefing

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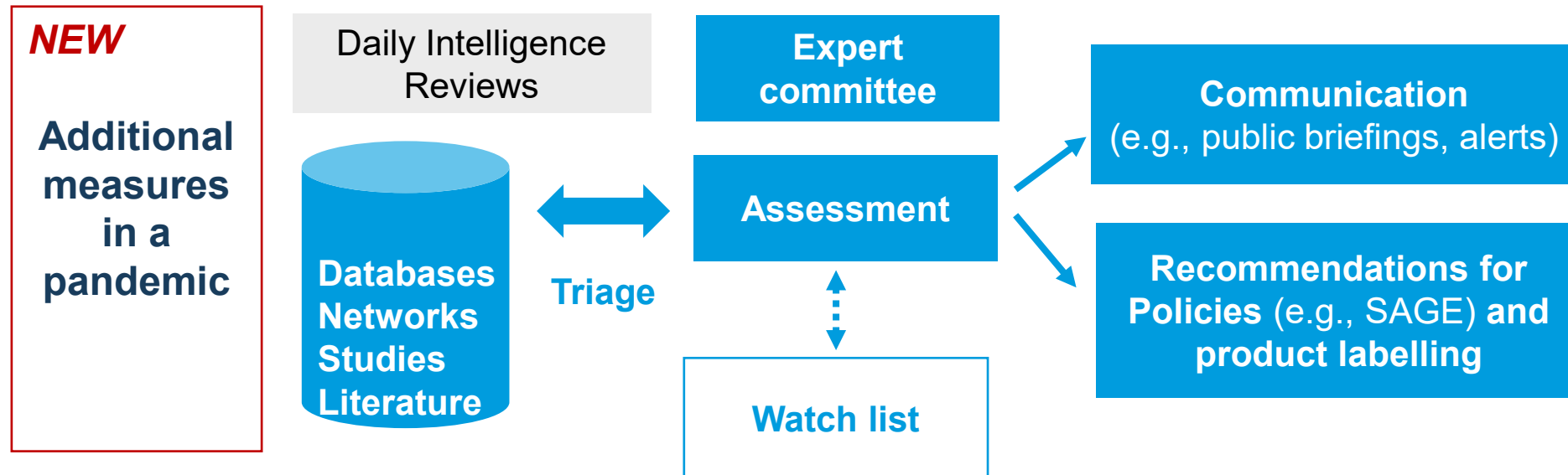
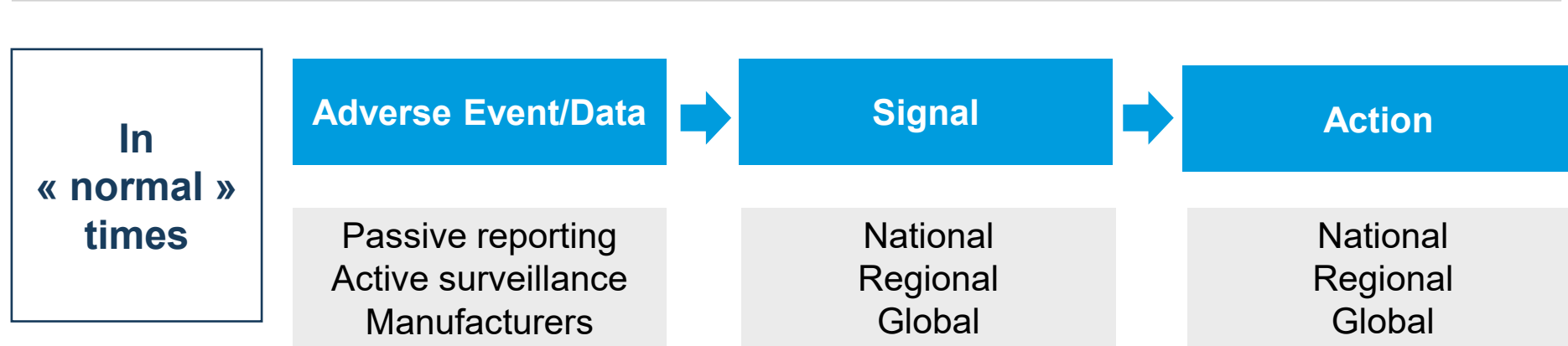
This presentation aims at answering 3 specific questions



1. What is the latest information on the COVID 19 vaccine safety – focus on AstraZeneca Vaccine
2. What are the key recommendations from WHO, UK and EMA ?
3. What are the next steps?

Pharmacovigilance System at work

Safety surveillance of vaccines



Key take-aways

- **More pro-active**
- **Enabling real-time data collection and assessment**
- **Leveraging more data sources** (incl. informal sources such as social networks)
- **Greater coordination and joint action** (e.g., through regulatory networks)
- **Ongoing evaluation and adjustment** to meet evolving needs

Blood coagulation events with Astra Zeneca Vaccine from some regions and countries

UK – Review of data as on 31 March

- 20.2 million doses of the COVID-19 Vaccine AstraZeneca
- 79 reports of blood clotting cases with low levels of platelets
- Risk of clots is 4 people in a million who receive the vaccine

EMA –Review of data as on 22 March

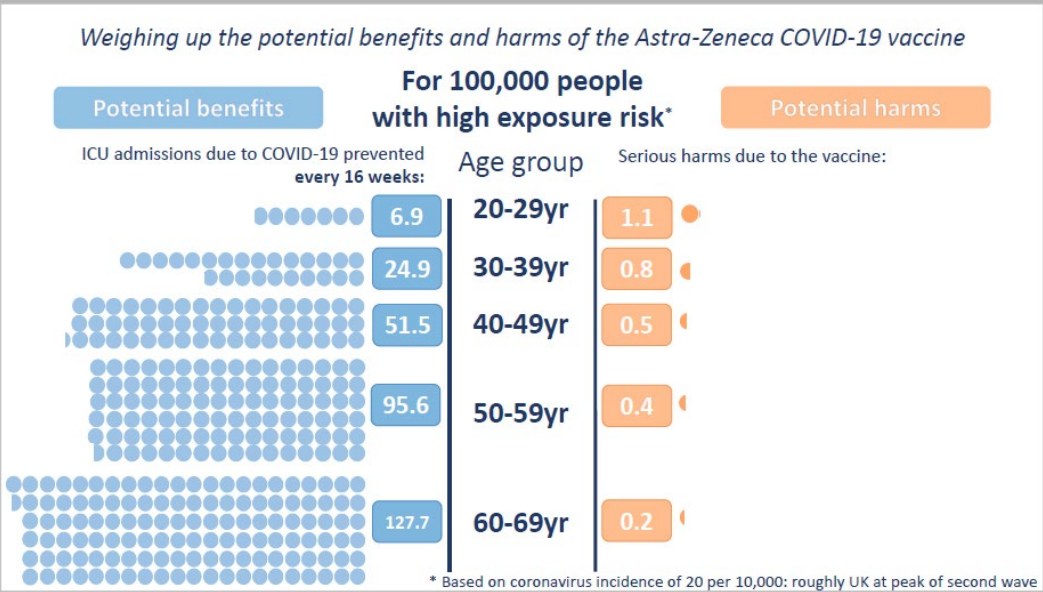
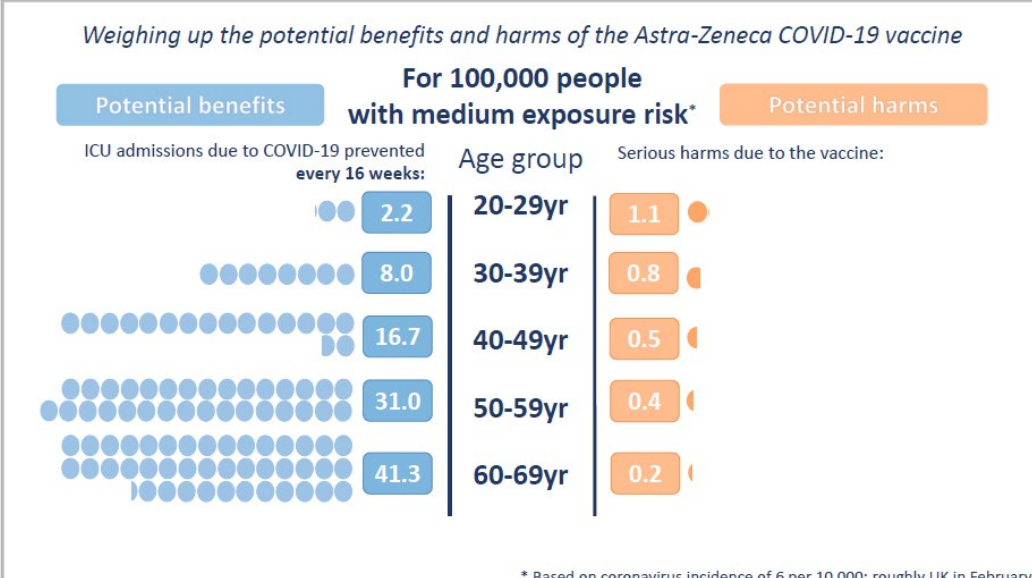
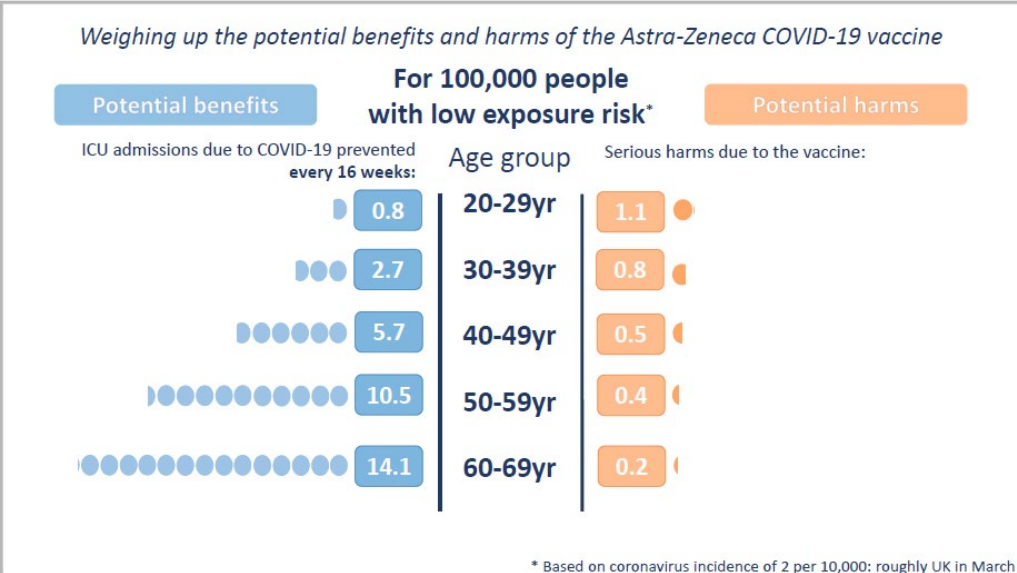
- 62 cases of cerebral venous sinus thrombosis (CVST) and 24 cases of splanchnic vein thrombosis (Eudravigilance data)
- Out of 24 million people vaccinated in EEA and UK

Global AZ-based

- A total of 158,396 Million doses have been distributed
- 9 cases compatible with cerebral venous thrombosis and/or thrombosis + thrombocytopenia
- Argentina, Bangladesh, Brazil, Egypt, India, Mexico, Oman, Saudi Arabia, UAE

Potential benefits of the Astra-Zeneca COVID-19 vaccine continue to outweigh risks

<https://www.gov.uk/government/news/mhra-issues-new-advice-concluding-a-possible-link-between-covid-19-vaccine-astrazeneca-and-extremely-rare-unlikely-to-occur-blood-clots>



Recommendations and Next Steps

1

Benefits of AstraZeneca vaccine continues to outweigh risks

2

UK MHRA and EMA – updates to Labels and information for health professionals

Section 4.4 on warnings and precautions

Section 4.8 on Undesirable Effects (thrombosis with thrombocytopenia as a rare adverse reaction)

3

WHO

- **Rare thrombotic events with or without thrombocytopenia plausible**
- **Need harmonized definitions, guidance on diagnosis, further investigations needed on risks factors**

4

Next steps

- **Support countries in active surveillance and studies**
- **Harmonise case definitions and develop clinical guidance**
- **GACVS continues to meet**
- **Updating safety information on SmPC and PIL**