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Avian and pandemic influenza vaccines and influenza antivirals

Meeting

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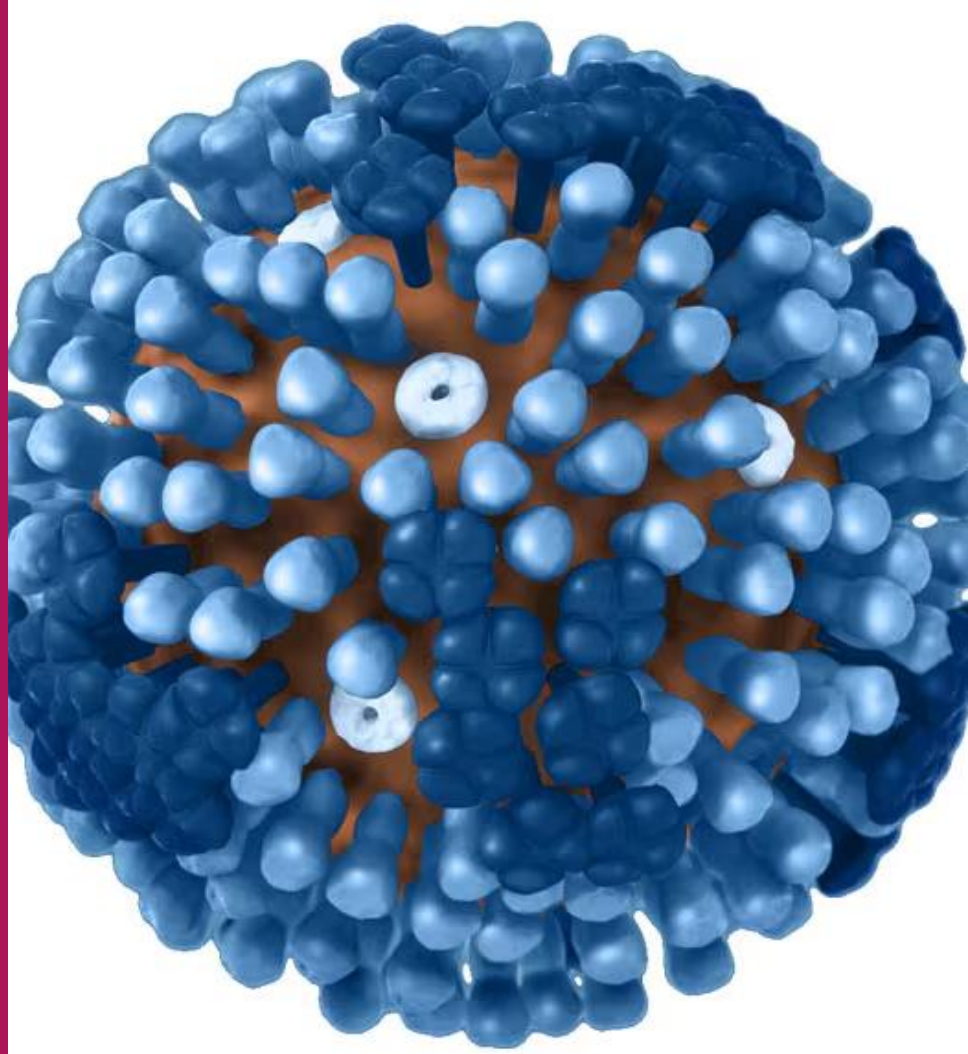

WHO Guidelines on regulatory preparedness:

for the oversight of pandemic or other emergency use Vxs in importing countries

WHO Technical Report Series, No 1054, Annex 2 (2024) replacing Annex 7 of TRS No 1004 (2017)

Scope:
Guidance to NRAs of vaccine-importing countries on the regulatory oversight of vaccines used during pandemics or other public health emergencies

General consideration	Risk-based considerations for regulatory evaluation and authorization		Post authorization activities	
Role of NRAs and regulatory preparedness	Selection of appropriate regulatory pathways and required documentation	Decision-making	Post-authorization changes	Importation, market surveillance and quality control, pharmacovigilance and release

TRS 1054, 2024, Annex 2

Reliance and Trust: the key to facilitate access to quality-assured health products

Principles

Enablers

- TRUST
- CONVERGENCE & HARMONIZATION
- INFO SHARING AND DIALOGUE among regulators
- ECONOMIC OR LEGAL INTEGRATION
- STAKEHOLDERS ENGAGEMENT

GRelP: Good Reliance Practices

WHO Good Reliance Practices in the regulation of medical products: high level principles and considerations (2021)

Vaccines for Avian Influenza

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Zoonotic Influenza Vaccine Seqirus

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Zoonotic influenza vaccine (H5N8) (surface antigen, inactivated, adjuvanted)

Medicine | Human

Authorised
This medicine is authorised for use in the European Union

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Overview

Zoonotic influenza vaccine Seqirus is a vaccine used in adults to protect against flu caused by H5 strains of the influenza A virus (also known as avian influenza or bird flu). Bird flu is a zoonotic infection (an infection that can spread from animals to humans).

Zoonotic influenza vaccine Seqirus contains a flu strain called A/Astrakhan/3212/2020 (H5N8)-like strain (CBER-RG8A) (clade 2.3.4.4b) and is based on parts of influenza virus that has been inactivated (killed) so that it does not cause any disease.

How is Zoonotic influenza vaccine Seqirus used?

How does Zoonotic influenza vaccine Seqirus work?

1. NAME OF THE MEDICINAL PRODUCT

Zoonotic Influenza Vaccine Seqirus suspension for injection in pre-filled syringe
Zoonotic influenza vaccine (H5N8) (surface antigen, inactivated, adjuvanted)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (haemagglutinin and neuraminidase)* of strain:

A/Astrakhan/3212/2020 (H5N8)-like strain (CBER-RG8A) (clade 2.3.4.4b) 7.5 micrograms** per 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks
** expressed in micrograms haemagglutinin (HA).

Adjuvant MF59C.1 containing per 0.5 ml dose:

squalene (9.75 mg), polysorbate 80 (1.175 mg), sorbitan trioleate (1.175 mg), sodium citrate (0.66 mg) and citric acid (0.04 mg).

Zoonotic Influenza Vaccine Seqirus may contain trace residues of egg and chicken proteins, ovalbumin, kanamycin, neomycin sulphate, formaldehyde, hydrocortisone and cetyltrimethylammonium bromide which are used during the manufacturing process (see section 4.3).

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection (injection).
The vaccine is a milky-white liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Zoonotic Influenza Vaccine Seqirus H5N8 is indicated for active immunisation against H5 subtype influenza A viruses in adults 18 years of age and above (see sections 4.4 and 5.1).

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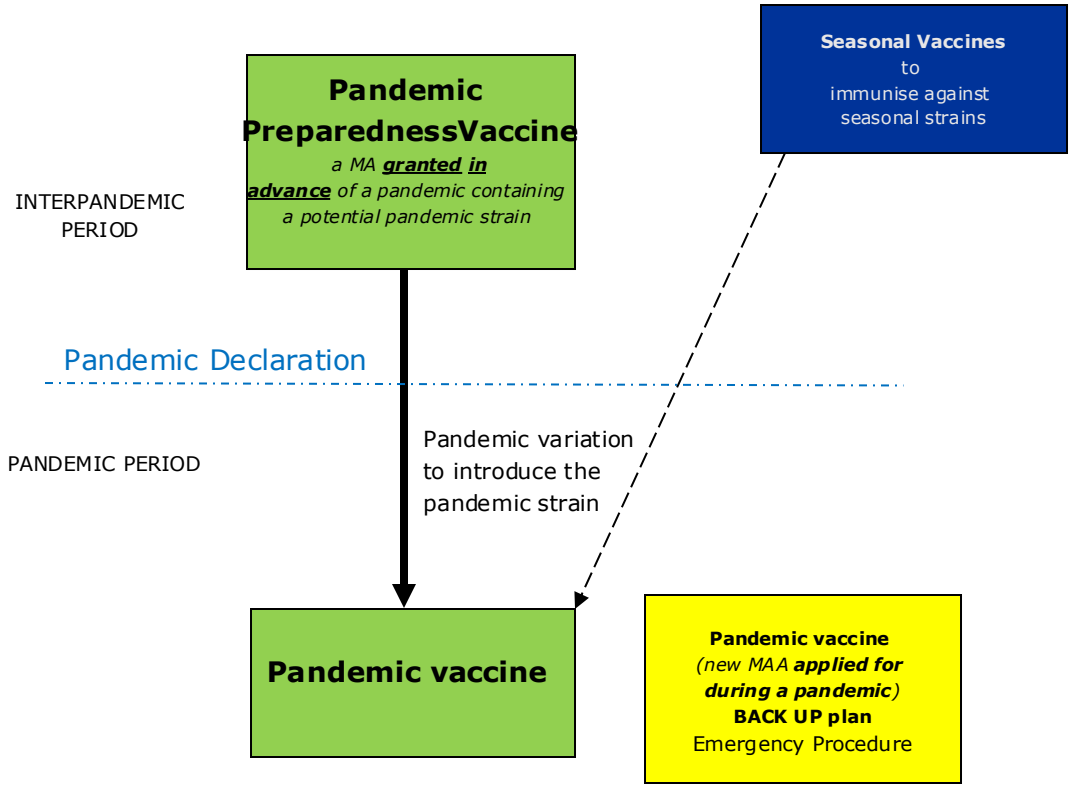
Pandemic preparedness vaccines H5N1 (humans)

Can only be used during a declared pandemic, subject to strain change via pandemic variation

- **Adjupanrix** (split virion, inactivated, adjuvanted with AS03), containing antigen of A/VietNam/1194/2004 (H5N1), GSK, authorised in 2008
- **Pandemic Influenza Vaccine H5N1 Baxter AG,** (whole virion, inactivated), containing antigen of A/Vietnam/1203/2004 (H5N1) - Resilience Biomanufacturing Ireland Limited, authorised in 2009
- **Foclivia** (influenza virus surface antigens, inactivated), containing antigen of A/VietNam/1194/2004 (H5N1), Seqirus, authorised in 2009
- **Pandemic influenza vaccine H5N1 AstraZeneca** (reassortant influenza virus (live attenuated, nasal) of the following strain: A/Vietnam/1203/2004 (H5N1) strain), AstraZeneca, authorized in 2016

Routes for approval of pandemic vaccines in case of pandemic



- Pandemic Preparedness Vaccines are so far the quickest path to approve pandemic vaccines
- **4 platforms authorised** to be varied after pandemic strain identified
- seasonal vaccines could be varied to pandemic vaccines but scientifically can pose constraints
- Pandemic vaccines also approvable during a pandemic via emergency procedure but likely late for first wave based on 2009 experience

Antivirals against pandemic influenza

- **Tamiflu** (oseltamivir in 30mg, 45mg and 75mg hard capsules, Roche): *treatment (all ages including full term neonates) and prevention of influenza (> 1 year of age and older), post-exposure prevention of influenza in infants less than 1 year of age during a pandemic influenza outbreak*

- **Ebilfumin** (oseltamivir, Actavis Group (same strength, presentation and indication as above)

- **Relenza** (Zanamivir inhalation powder, pre-dispensed, GSK):*treatment of both influenza A and B in adults and children (≥ 5 years) who present with symptoms typical of influenza when influenza is circulating in the community. Post-exposure prophylaxis of influenza A and B in adults and children (≥ 5 years) following contact with a clinically diagnosed case in a household. Prophylaxis of influenza A and B during a community or pandemic outbreak.*

- **Dectova** (Zanamivir solution for infusion with 2 strengths, GSK): *treatment of complicated and potentially life-threatening influenza A or B virus infection in people aged ≥6 months when:*
  - *The patient's influenza virus is known or suspected to be resistant to anti-influenza medicinal products other than zanamivir, and/or*
  - *Other anti-viral medicinal products for treatment of influenza, including inhaled zanamivir, are not suitable for the individual patient*

- **Xofluza** (Baloxavir marboxil in film-coated tablets of 20-40-80mg, Roche): *treatment of uncomplicated influenza and post-exposure prophylaxis in people aged 1 year and above*

KEY POINTS

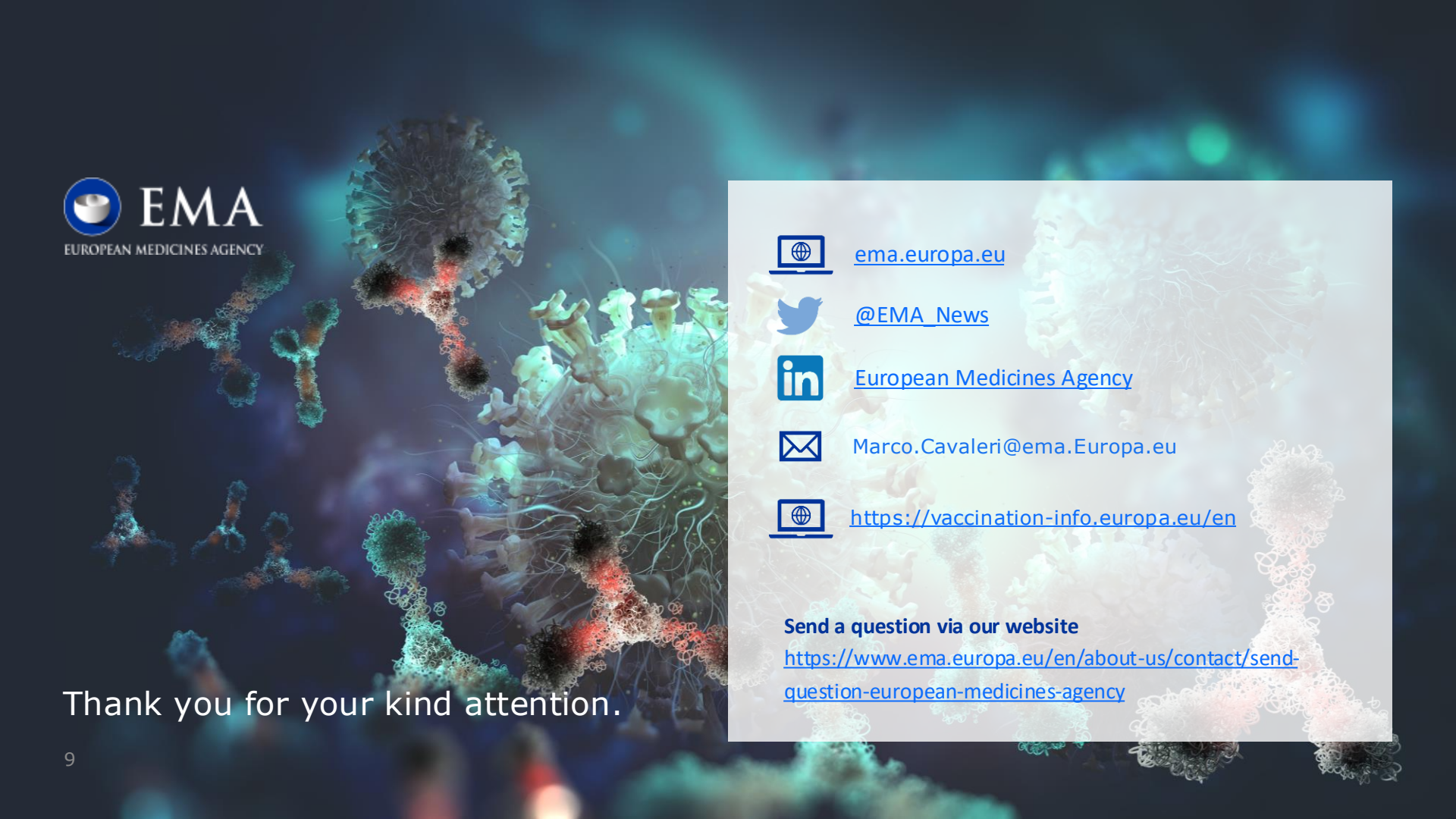
- Pathways for regulatory approval of zoonotic and pandemic preparedness vaccines available in the EU since before 2009 H1N1 pandemic
  - *3 zoonotic flu vaccines and 4 pandemic preparedness vaccines approved*

- Check if vaccine composition update is needed: is there cross-immunity? Across ages?

- Timelines for update of vaccine composition in case of a pandemic and release of commercial batches up to 6 months or more - need to address bottlenecks, e.g. reagents and potency assays

- New technologies are emerging –innovation in technology vs antigen selection, e.g. mRNA vs new antigens – speed, trust in safety, correlates of protection

- Antivirals are available for use especially for prophylaxis and early treatment while waiting for vaccines availability: check susceptibility profile and clinical trials set up



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