Information from the Commission on antigen, vaccine, and diagnostic reagent banks

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DG SANTE – Unit G2 Animal health
European Commission

Outline

- AHL rules on antigen, vaccine, and diagnostic reagent banks
  - Union banks
  - National banks
- Proposed *modus operandi* for information sharing between Commission and Member States
- Next steps

AHL – Part III – Title I – Chapter 3 -

Antigen, vaccine and diagnostic reagent banks

AHL - **Article 48** - The establishment of **Union** antigen, vaccine and diagnostic reagent banks

1. For **listed diseases** referred to in **point (a) of Article 9(1)** in respect of which vaccination is not prohibited by a delegated act adopted pursuant to Article 47, the **Commission may establish** and **be responsible for managing Union antigen, vaccine and diagnostic reagent banks** for the storage and replacement of stocks of one or more of the following biological products:

(a) **antigens**;

(b) **vaccines**;

(c) vaccine master seed–stocks;

(d) diagnostic reagents.

AHL - **Article 48** - The establishment of **Union** antigen, vaccine and diagnostic reagent banks

2. The **Commission shall ensure** that the **Union** (…) **banks** (…):

(a) **store sufficient stocks of the appropriate type** of (…), **taking into account the needs of Member States** estimated in the context of the contingency plans provided for in Article 43(1);

(b) receive **regular supplies** and **timely replacements** of (…);

(c) are maintained and moved in conformity with the **appropriate biosecurity, biosafety and bio–containment requirements** laid down in (…);

AHL - **Article 48** - The establishment of **Union** antigen, vaccine and diagnostic reagent banks

3. The **Commission shall be empowered** to adopt **delegated acts** in accordance with Article 264 concerning:

(a) the **management, storage and replacement of stocks** of the Union (…) banks as provided for in paragraphs 1 and 2 of this Article;

(b) the biosecurity, biosafety and bio–containment requirements for the operation of those banks, (…).

Commission Delegated Regulation (EU) 2022/139 of 16.11.2021
(OJ L 23 of 2.2.2022, p. 1-10)

AHL - **Article 49** - Access to the **Union** antigen, vaccine and diagnostic reagent banks

1. The **Commission shall**, **upon request**, **provide for the delivery** of the biological products (…) from the Union (…) banks, provided that stocks are available, to:

(a) in the first place, **Member States**; and

(b) **third countries or territories**, provided that such delivery is **primarily intended to prevent the spread of a disease into the Union**.

AHL - **Article 49** - Access to the **Union** antigen, vaccine and diagnostic reagent banks

2. The Commission shall, **in the event of the limited availability of stocks**, **prioritise access** (…) based on:

(a) the **disease circumstances** under which the request is made;

(b) the **existence of a national antigen, vaccine and diagnostic reagent bank in the requesting Member State** or third country or territory;

(c) the existence of Union measures for compulsory vaccination laid down in delegated acts adopted pursuant to Article 47.

AHL - **Article 50** - Implementing powers concerning the **Union** antigen, vaccine and diagnostic reagent banks

1. The **Commission shall**, by means of **implementing acts**, lay down **rules for Union** (…) **banks**, (…):

(a) which of those biological products are to be included in the Union (…) banks and for which of the listed diseases (…);

(b) the types of (…) and in what quantities for each specific listed disease (…);

(c) the requirements concerning the supply, storage and replacement (…);

(d) the delivery (…) from the Union (…) banks to the Member States and to third countries and territories; (…)

Those implementing acts shall be adopted (…) Article 266(2).

Commission Implementing Regulation (EU) 2022/140 of 16.11.2021
(OJ L 23 of 2.2.2022, p. 11-21)

AHL - **Article 51** - Confidentiality of information concerning the **Union** antigen, vaccine and diagnostic reagent banks

Information on the **quantities and subtypes** of the **biological products** referred to in Article 48(1) stored in the **Union antigen, vaccine and diagnostic reagent banks** shall be **treated by the Commission as classified information** and **shall not be published**.

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AHL - **Article 52** - **National** antigen, vaccine and diagnostic reagent banks

1. **Member States** that have established **national antigen, vaccine and diagnostic reagent banks** for listed diseases referred to in **point (a) of Article 9(1) for which Union** (…) **banks exist**, shall ensure that their **national** (…) **banks comply with the biosecurity, biosafety and bio–containment requirements** laid down in (…).

2. **Member States shall provide the Commission with up–to–date information** on:

(a) the **existence or the establishment of the national** (…) **banks** referred to paragraph 1;

(b) the **types** of antigens, vaccines, vaccine master-seed stocks and diagnostic reagents and the **quantities** thereof held in such banks;

(c) any **changes in the operation** of such banks.

That **information** shall be **treated as classified information by the Commission** and **shall not be published.**

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AHL - **Article 52** - **National** antigen, vaccine and diagnostic reagent banks

3. The **Commission may**, by means of **implementing acts**, lay down **rules specifying the content, frequency and format of the submission of the information provided for in paragraph 2**.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Proposed *modus operandi* for information sharing between Commission and Member States

Proposed *modus operandi*

- Informal agreement in PAFF Committee - i.e. for now no need for a Commission Implementing Act based on AHL Article 52(3)
- Sharing of data between Commission and Member States on Union and national banks in full respect of AHL confidentiality requirements
- At face-to-face meetings of the AHW Section of PAFF (agenda point A)
- Once a year (e.g. in June or December – to be agreed)
- No publication of any PPT presentation on the Commission website (only CIRCA)
- Distribution of data on the banks on paper only (without any subsequent publication)

→ Allows for informed decision making by Commission and Member States, taking into account needs and current availabilities of banks

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Next steps

1st annual information sharing

- PAFF Committee meeting of June 2024 (tentative dates: 25-26 June)
- Face-to-face only meeting (no active participation via Interactio)
- Sharing of information from the Commission
  - PPT presentation (available on CIRCA but not to be published: which banks / cat. A disease / type of biological products) +
  - data on Union banks (distributed on paper to MSs, not to be published: quantities by serotypes as relevant, shelf life, manufacturer/product name, upcoming changes as relevant)
- Sharing of similar information by Member States on national banks
  - Oral "*tour de table*" +
  - data on national banks (distributed on paper to COM+MSs, not to be published)

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Comments / questions welcome !

Thank you

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