1 General questions

1.1 What will the vaccine licences look like? How will they be issued (still as a paper version)?

In future, the authorisation certificates for all veterinary medicinal products will be in the Swissmedic format and will be downloadable from the Portal.

1.2 Will the current authorisation numbers remain unchanged?

Yes.

1.3 Currently, "IVI Nr./No. IVI:" is stated in the IHP and package leaflet. Will that continue to be the case?

No. "IVI" should be replaced with "Swissmedic" by the authorisation holder at the next available opportunity (outside of changes, also independently; see also question 3.3).

2 Questions on medicinal product information

2.1 Will it be possible to have two rather than three languages for space reasons without submitting an application, as is currently the case with IVI?

No. In future, Swissmedic practice will apply for vaccines. The authorisation holder must submit an application if the Information for healthcare professionals cannot be printed in three languages for technical reasons. The VMPC will also continue to be published in three languages in all cases.

2.2 Section 2: Will the following headings continue to be used, where applicable?

"**Active substances**"
"Adjuvants"
"Excipients"

Yes.

2.3 Section 2: Should definitions according to the pharmacopoeia still be used and previously differing quantities be changed?

E.g. CCID50: The statistically determined quantity of a virus required to infect 50% of inoculated tissue cultures.

Yes, with the required application for variation, if applicable.

2.4 Section 4.6:

Will frequencies according to the frequency model and the frequency model itself continue to have to be stated, even if this information was previously not stated for older products?

Frequencies must be stated according to the model.
For the model itself, the following applies according to the IHP template:
In the case of few adverse effects with frequencies or adverse effects without frequencies, the listing of the list of incidences above can be omitted and the relevant incidence only noted in brackets following the adverse effect.
Example: "Rare: Allergy (more than 1 but fewer than 10 in 10,000 treated animals)".

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2.5 Sections 5.1 and 5.2
Do both sections still have to be included and labelled as "not applicable"? Do current "Properties/effects" have to be incorporated under other relevant sections or deleted?

Yes, headings with numbers must not be deleted. Scientific immunological properties can be listed where applicable in section 5 "Pharmacological properties" directly under the ATCvet Code (but with no statements of a promotional nature).

2.6 Section 6.5: Do the standards developed with us on implementation of the revision continue to apply:
First give details of the composition of the container and then list the pack sizes below?
Examples:
Glass type I bottles or PET bottles
Pack sizes:
Glass type I bottle, 20 ml (20 doses)
PET bottle, 50 ml (50 doses)

Yes, the clear presentation should not only continue but can also be adopted for pharmaceuticals in future.

2.7 Section 6.5: Can the following abbreviations/descriptions continue to be used?
Glass type I or II (use Roman numerals)
PET
HDPE (high-density polyethylene)
MLP (multi-layered plastic)

Yes, the abbreviations/descriptions are always admissible (also for pharmaceuticals).

2.8 Section 6.5: Should only pack sizes that are actually available on the market continue to be listed (even if documentation for other pack sizes was submitted with the initial registration)?

No, in future all pack sizes according to the authorisation may be listed (in line with Swissmedic practice).

2.9 Section 7: Can only the name and location of the authorisation holder continue to be stated, without full address details (street and postcode)? Remark: The full address is not required for human medicinal products either.

Yes, with immediate effect, the company name and location (registered office according to the entry in the Commercial Register) are also sufficient for pharmaceuticals.

3 Questions on packaging

3.1 Primary and secondary packaging: Do excipients subject to compulsory declaration still need to be stated for vaccines?

No, only adjuvants need to be stated on the packaging in addition to the active substances; all other ingredients only need to be stated in section 2 of the Information for healthcare professionals (subject to declaration = excipients relevant for safe use).

3.2 EAN codes have not been included on the secondary packaging of vaccines to date. Will this continue to be the case?

The EAN code is also not mandatory for veterinary medicinal products authorised by Swissmedic. If no EAN code is shown, the authorisation number is not integrated into this. Instead, "Swissmedic NNNNN nnn" (NNNNN = authorisation number, nnn = packaging code) is stated somewhere on the packaging.

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Note: Packaging codes are new for IVMP: They appear on authorisation certificates and once known, can be incorporated into the text at the next available opportunity independently by the company (similarly to the replacement of “IVI” before the authorisation number by “Swissmedic”). (See question 3.3)

3.3 Implementation time limit for changes to packaging after transfer of responsibility from IVI to Swissmedic.

An extraordinary implementation time limit of two years applies for modification (reprinting) of packaging for immunologicals after their transfer from IVI to Swissmedic. The packaging must therefore fully comply with the requirements of Art. 12 in conjunction with Annex 6 of the Therapeutic Products Licensing Requirements Ordinance (TPLRO, SR 812.212.22) by 1 January 2025 at the latest.

3.4 The revisions to the IHP/packaging materials that have to be made independently due to the transfer from the IVI to Swissmedic also need to be made in the Veterinary medicinal products compendium (VMPC). How does this process work (procedure for variations with no official decision from Swissmedic)? New from May 2023

The modified texts should preferably be sent to the VMPC together with the current Swissmedic authorisation certificate – particularly when the modifications go beyond a change of the authorisation number and packaging codes (e.g. change of the medicinal product name according to the current authorisation certificate issued by Swissmedic). Please copy in tam@swissmedic.ch.

3.5 Regarding product names that do not meet the Swissmedic requirements, can these be changed independently in accordance with the documentation? We will have to modify all IHPs with the new Swissmedic pack size numbers anyway, and it would make sense to be able to correct the product names at the same time to avoid further expenses and effort. New from May 2023

As an exception, the change of veterinary medicinal product name to the name stipulated as part of the transfer to Swissmedic according to the current authorisation certificate can be implemented independently. (See also question 3.4).

3.6 We have invested a lot of work in revising documentation with the IVI in recent years. Of course, we have not been able to review the composition of all of our products (and do not want to have to do this...). However, from a rough examination, we have noticed that the units are different (usually U rather than the previous name according to the authorisation) and numbers are not shown in subscript/superscript. We seem to remember that you mentioned at the event that there are technical problems/database problems here. New from May 2023

The active substance composition is now only being shown generically (U rather than as a differentiated unit). Precise information can be found in the approved IHP. The authorisation certificates generally have no legal relevance. The current official decision – that issued by the IVI as long as there is no official decision from Swissmedic – in conjunction with the approved information for healthcare professionals is always legally relevant.

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