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Veterinary Medicinal Products

Preliminary project

Security of supply – veterinary medicinal products

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Contents

SUMMARY 2

1 BACKGROUND AND OBJECTIVES OF THE PRELIMINARY PROJECT 2

2 ANALYSIS OF GAPS IN VETERINARY MEDICINAL PRODUCT SUPPLY ON THE BASIS OF IMPORT NOTIFICATIONS (ART. 7 ET SEQ. VMPO) 3

2.1 OVERVIEW 3
2.2 LIVESTOCK 5
2.3 PETS 6
2.4 ASSESSMENT 8

3 KEY CAUSES OF CHALLENGING VETERINARY MEDICINAL PRODUCT SUPPLY SITUATIONS 8

4 POTENTIAL SOLUTIONS 9

4.1 FOPH REPORT ON DRUG SUPPLY BOTTLENECKS 2022 9
4.1.1 Cluster 1: Detailed optimisation of the existing system in Switzerland 9
4.1.2 Cluster 2: Further reaching modifications to the existing system in Switzerland 9
4.2 SPECIFIC IMPLEMENTATION PROPOSALS FOR VETERINARY MEDICINAL PRODUCTS FOR FURTHER INVESTIGATION 10
4.3 MEASURES THAT HAVE BEEN ASSESSED AND IMPLEMENTED 10
4.4 MEASURES THAT WERE ASSESSED BUT WILL NOT BE PURSUED 10

Summary

Like its human counterpart, veterinary medicine in Switzerland is facing an increasingly challenging supply situation and has experienced a spate of shortages in recent years. A preliminary project between the Federal Food Safety and Veterinary Office (FSVO) and Swissmedic analysed veterinary medicinal product supplies in Switzerland, assessed the causes of supply disruptions and outlined potential solutions. Some of these solutions have already been proposed for human medicinal products, while others have been designed specifically for veterinary medicinal products. When the preliminary project concluded, suggested solutions that were classified as relevant were proposed for closer examination and implementation in a subsequent project.

1 Background and objectives of the preliminary project

The supply situation for human and veterinary medicinal products in Switzerland is increasingly challenging, and there are repeated supply shortages. The causes of the shortages of veterinary medicinal products are diverse and the situation is similar to that in human medicine in terms of complexity. Furthermore, the veterinary medicinal products market is heavily fragmented (different target animal species, each with a wide range of therapeutic areas) and disproportionately smaller compared with the human medicinal products market.

Therapeutic products legislation currently provides a range of workarounds for challenging supply situations, such as the option of reclassification, veterinarians importing products from abroad and the manufacture of extemporaneous products. Given the growing accumulation of supply shortages, however, the current options for occasions when veterinary medicinal products are unavailable in Switzerland (either because they cannot be supplied or are simply not authorised) cannot provide satisfactory solutions in all cases.

The complex nature of veterinary medicinal product supply in Switzerland requires the involvement of various agencies, and one authority cannot determine the situation on its own. For this reason, a preliminary project undertaken jointly by the FSVO and Swissmedic was launched in spring 2024 to analyse the current situation and propose possible starting points for an improvement in the situation.

Preliminary project Security of supply – veterinary medicinal products – FSVO and Swissmedic

This preliminary project also investigated whether the *implementation proposals for the measures of the FOPH report on shortages in the supply of medicinal products*, which had been prepared for human medicinal products, might contain anything beneficial for the veterinary sector. The Federal Council noted the report in question in August 2024. In keeping with the One Health approach, and in the interests of increasing efficiency, implementation work will be coordinated between the human and veterinary medicinal product sectors and be interdisciplinary in nature.

The aims of the "Security of supply – veterinary medicinal products" preliminary project undertaken jointly by the FSVO and Swissmedic were:

- To analyse key gaps in veterinary medicinal product supply on the basis of existing import notifications (section 2)
- To determine the principal causes of challenging veterinary medicinal product supply situations (section 3)
- To outline potential solutions (section 4)

2 Analysis of gaps in veterinary medicinal product supply on the basis of import notifications (Art. 7 et seq. VMPO)

2.1 Overview

Veterinarians have the option of importing medicinal products from another country if no suitable alternative is authorised and available in Switzerland (Art. 7 Veterinary Medicinal Products Ordinance (VMPO, SR 812.212.27)). Veterinarians have been notifying the FSVO of cases where medicinal products have been imported since 1 July 2022. In certain cases, the FSVO also has to authorise import, depending on the country in which the product was authorised and other criteria.

An assessment of data from import notifications provided a first overview of the veterinary medicinal products that were most prone to shortages in Switzerland. The reasons for importing veterinary medicinal products (VMPs) were analysed – i.e. whether they had not been authorised in a suitable form in Switzerland or whether they had to be imported because of disruptions to distribution. The analysis did not provide any conclusions about the reasons for disruptions to distribution or why the veterinary medicinal products had not been authorised in the required form in Switzerland.

Subsequent analyses used FSVO data on import notifications/permits for the **period from 1 July 2022 to 30 June 2024** .

During this period, **7,411 cases of medicinal product importation** were notified to the FSVO or approved by the FSVO. Given that there are around 1,300 registered veterinary practices in Switzerland, that equates to a rounded average of three import notifications per practice and year. 3,489 cases of medicinal product importation were notified or approved for livestock (47%), 3,922 for pets (53%).

Figure 1 shows the reasons for importing in each case. According to Figure 1, the commonest reason for importing veterinary medicinal products for pets and livestock alike was the absence of a suitable authorised alternative in Switzerland (74% and 50% respectively).

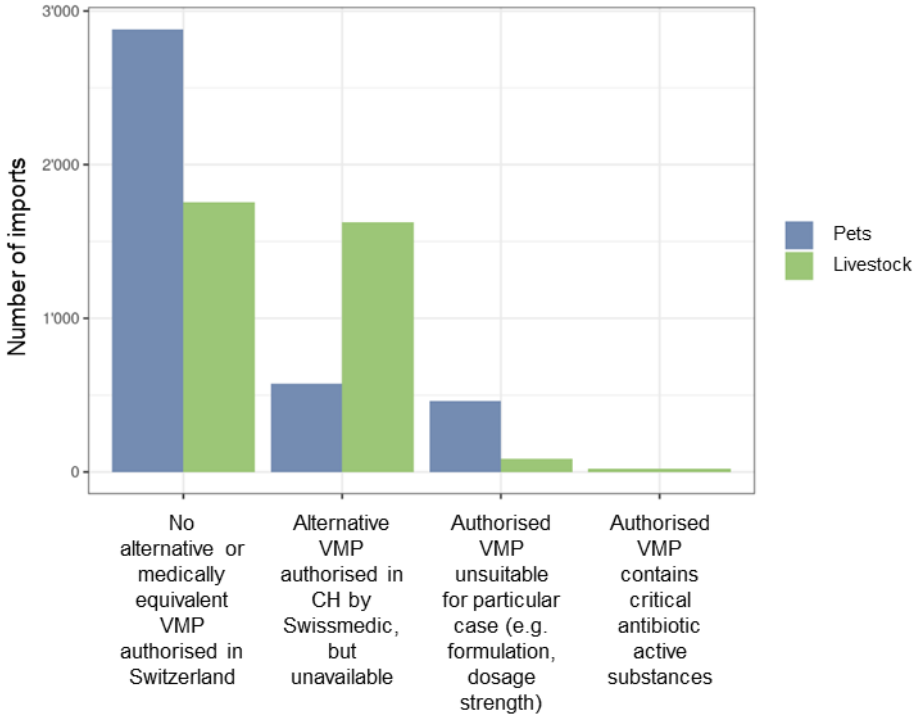


Figure 1: Reasons for importing veterinary medicinal products (VMPs)

The second commonest reason for importing was the unavailability of veterinary medicinal products authorised in Switzerland (47% for livestock, 15% for pets). Unsuitable pharmaceutical forms and dosage strengths also play a role, particularly for pets, where this is given as a reason for importation in 12% of cases.

Figure 1 does not take account of the quantity of veterinary medicinal products imported by veterinarians in each case. As a result, veterinary medicinal products imported in small quantities – for specialist treatments, for example – have been given the same weighting as veterinary medicinal products used in daily practice. The quantity/number of packs of veterinary medicinal products imported is shown in Figures 3 and 4 below.

Figure 2 shows that the number of registered cases of importation has increased since the roll-out of the "VMP Import" electronic reporting system in July 2022, reaching a peak in the winter of 2023-24.

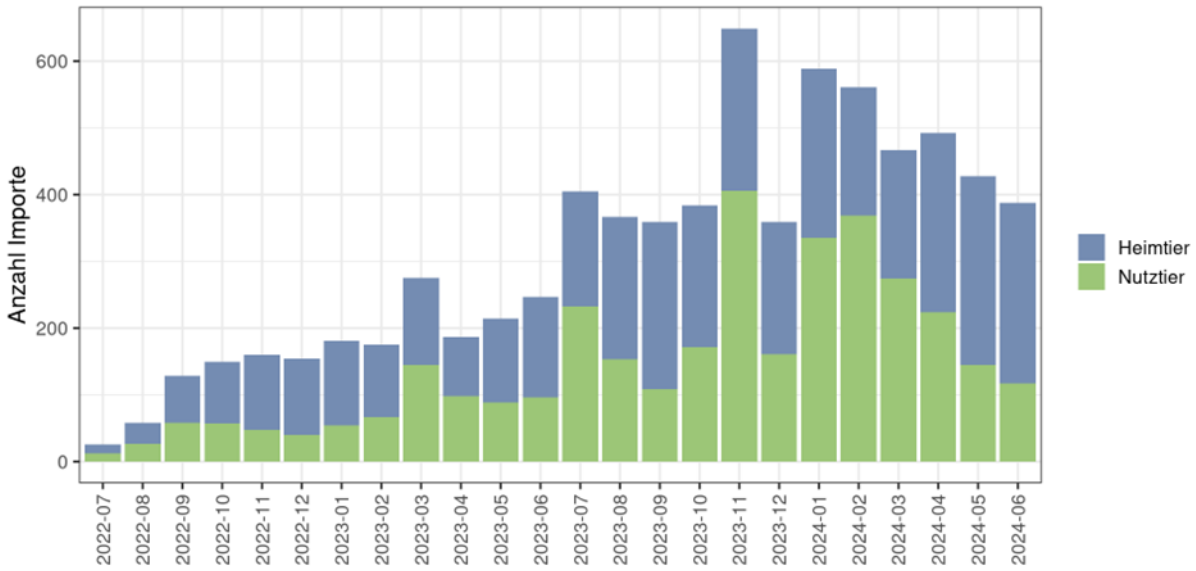


Figure 2: Number of imports over time by the two categories of animal

The initial increase in cases of importation may be attributable to the fact that veterinarians first had to familiarise themselves with the new system. Since the special permits issued by Swissmedic and the Institute of Virology and Immunology were valid at the same time (until 31 August 2023 and 31 October 2022 respectively), these may have had an effect too. The peaks in the winter of 2023-24 are attributable to the unavailability of a Swiss wholesaler for a period of several months, as a result of which several vital veterinary medicinal products, especially for livestock, could not be supplied for a period several of months and had to be imported from abroad. The peak in March 2023 is due to an acute disruption in supplies of a vaccine for bovine keratoconjunctivitis caused by *Moraxella bovis* infection.

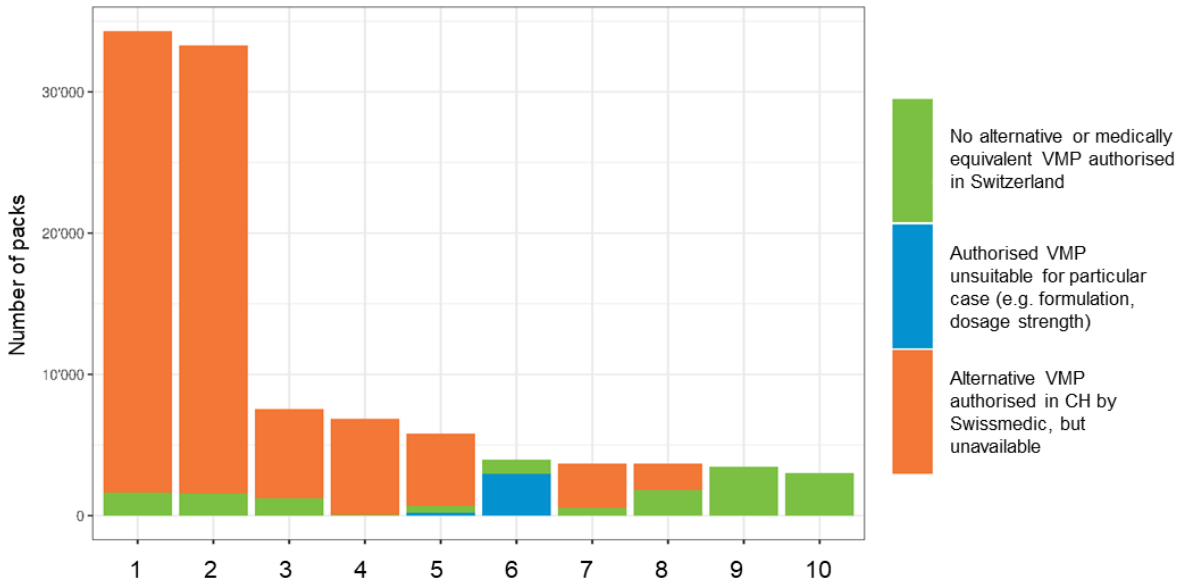
In many cases, the imported veterinary medicinal product is not authorised for the relevant indication and/or species in the country in which it was sourced either. 30% of all medicinal products imported for pets are reclassified, the corresponding figure for livestock is around 8%.

Medicinal products authorised in neighbouring countries were preferred for both pets and livestock, with Germany as the key source by a substantial margin (48% for pets, 54% for livestock).

Commonly imported medicinal products are dealt with in more detail below.

2.2 Livestock

In the majority of cases, supply shortages are the original reason for importing the ten most frequently imported preparations for livestock (see Figure 3).



1 Solutions for infusion or injection containing calcium and other active substances
2 Solution for infusion containing calcium and other active substances
3 Solution for injection containing vit. E and sodium selenite
4 Solution for injection containing calcium and other active substances
5 Solution for injection containing iron
6 Oral flunixin meglumine gel
7 Solution for infusion containing sodium hydrogen carbonate
8 Udder injector containing benzylpenicillin procaine monohydrate
9 Solution for injection containing toldimfos sodium
10 Attenuated live avian encephalomyelitis virus

Figure 3: Most frequently imported veterinary medicinal products (VMPs) for use in **livestock** (number of packs) with reason for importation

The four most commonly imported preparations for livestock include three comparable veterinary medicinal products – solutions for infusion and injection containing calcium and other active substances. A total of 74,448 packs of these products was imported because supplies of alternative products authorised in Switzerland were interrupted for several months.

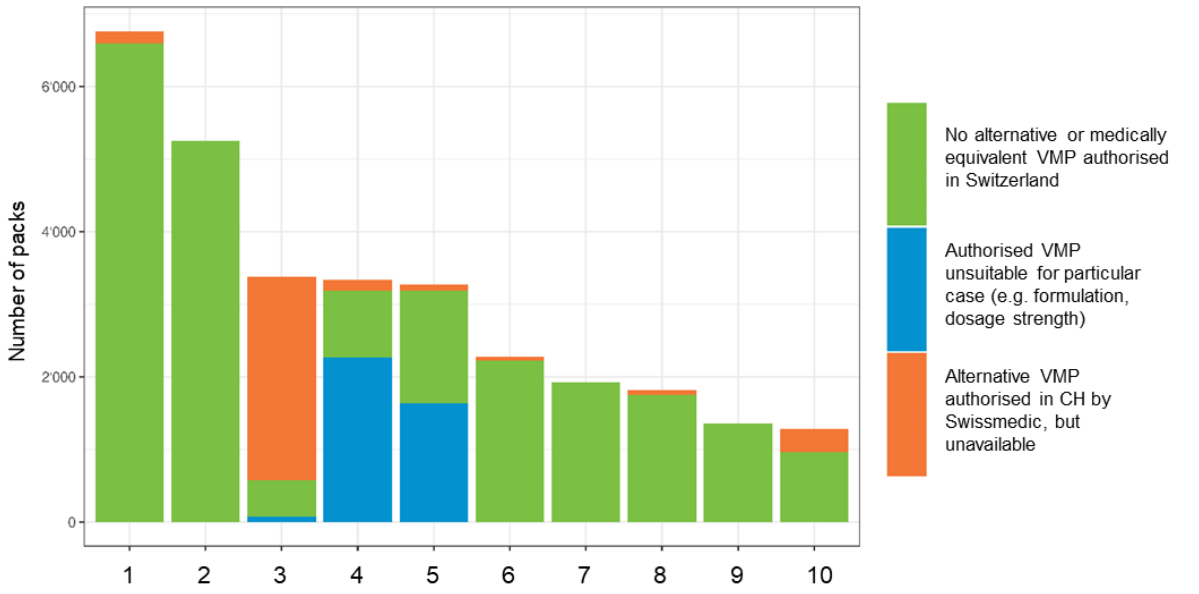
Furthermore, solutions for injection containing vitamin E and sodium selenite (7,569 packs) were imported. Here again, this was due to supply disruption.

The fifth most frequently imported product was a solution for injection containing iron (5,800 packs), once more in response to the unavailability of the veterinary medicinal product authorised in Switzerland.

In sixth place is an oral gel containing flunixin meglumine (3,979 packs imported). This veterinary medicinal product was imported to use in working horses. Three preparations containing the same active substance are authorised in Switzerland, but all are for injection. Various oral anti-inflammatories are available, but these contain different active substances. This veterinary medicinal product was also frequently imported for horses kept as pets (3,275 packs).

2.3 Pets

Figure 4 shows that in volume terms and in the majority of cases, veterinary medicinal products imported for pets are not authorised in Switzerland in the desired form and supply interruptions play a less important role.



1	Oral sucralfate suspension	6	Oxytetracycline eye ointment
2	Nitroscanate tablets	7	Liquid dilution for injection containing Renes bovis gl., Viscum album and other active substances
3	Oral omeprazole suspension	8	Topical ointment containing nystatin, neomycin sulphate, thiostrepton and triamcinolone acetonide
4	Furosemide tablets	9	Powder for solution for injection containing ampicillin and sulbactam
5	Oral flunixin meglumine gel	10	Topical cream containing neomycin sulphate and prednisolone acetate

Figure 4: Most frequently imported medicinal products for use in **pets** (number of packs) with reason for importation

The majority of medicinal products are imported either for reclassification because, as in Switzerland, they are not authorised abroad for the relevant species or because the active substances are authorised in Switzerland as veterinary medicinal products, but not in the pharmaceutical form or dosage strength needed for specific indications. The fact that supply interruptions are less frequently a problem than with veterinary medicinal products for livestock could be due to the fact that several comparable products are often on the market for pets. Moreover, if they are not authorised for veterinary medicine, they are often authorised for human medicine and can be reclassified.

The medicinal product most frequently imported for pets was a medicinal product authorised abroad for humans (6,758 packs). This oral sucralfate suspension was imported for administration to dogs, cats and horses. No comparable veterinary or human medicinal product is authorised in Switzerland. The veterinary medicinal products authorised in Switzerland for similar indications (e.g. protecting the stomach and preventing or treating gastrointestinal ulcers) all contain proton pump inhibitors or H2 receptor antagonists. Given that the same sucralfate preparation was imported for working horses (an additional 2,788 packs), demand for this preparation appears to be high.

The second most frequently imported veterinary medicinal product for pets were nitroscanate tablets (5,250 packs). The veterinary medicinal product containing this active substance used to be authorised in Switzerland for worming dogs, but has been displaced by more modern active substances. In the meantime, the medicinal product is only authorised abroad. However, it was imported to treat ornamental fish.

The third most commonly imported preparation is an oral suspension of omeprazole (3,374 packs). This was imported for horses because both alternatives containing the same active substance that were authorised in Switzerland were unavailable.

In fourth place among the most frequently imported preparations are furosemide tablets for dogs and cats (3,336 packs). In addition to preparations containing comparable active substances, an alternative product containing the same active substance and for the same species is authorised in Switzerland. According to the import notifications, however, this veterinary medicinal product cannot be used in

many cases because the dosage strength is too high for lighter dogs and cats of average weight. This is an understandable reason because the preparation authorised in Switzerland is suitable for animals with a body weight of 20 kg or more. To complicate matters the Information for healthcare professionals states that the tablets should not be divided. The preparation is often used for long-term treatment of heart or kidney failure in dogs and cats.

The fifth most frequently imported medicinal product for pets is an oral gel containing flunixin meglumine (3,275 packs). It is the same veterinary medicinal product as that in sixth place for livestock. Further information on the medicinal product can be found in the relevant section.

The sixth most commonly imported product for pets was an eye ointment containing oxytetracycline (2,279 packs). This is not authorised in Switzerland for either humans or animals. Furthermore, other countries have authorised it only for humans but not for animals. This ointment is often used in livestock too (1,866 packs).

2.4 Assessment

The analysis of the most frequently imported veterinary medicinal products indicates that medicinal products for **pets** are imported primarily because no suitable alternative is authorised in Switzerland (Figure 4). Furthermore, the medicinal products most commonly imported for use in pets are medicinal products that are also authorised abroad for humans or a different species. Medicinal products for **livestock** were primarily imported because of disruptions to supplies of authorised medicinal products (Figure 3).

There was no comparative analysis of the number of authorisations in Switzerland relative to European countries with a similar market size. Such comparisons are not suitable for analysing supply disruptions, since authorisation does not mean that products are actually on the market. This is particularly relevant to centralised EU authorisations, where authorisation is automatically valid in all EU countries, but medicinal products are only placed on the market in countries where there is commercial interest (veterinary medicinal products have to be distributed in the respective national languages in the EU too). Moreover, a comparison of this type would be an extremely complex undertaking because the way that authorisations are counted is not systematic. For example, one authorisation covering several dosage strengths of an active substance and several target animal species may be issued, or one authorisation per dosage strength and/or target animal species. One of the factors on which this depends is how, and in which order, authorisation applications are submitted.

3 Key causes of challenging veterinary medicinal product supply situations

The causes listed in section 2 aside, it can be assumed that the reasons for supply shortages of veterinary medicinal products are in most cases the same as for human medicinal products. The *FOPH report on drug supply bottlenecks 2022* cites the following causes for shortages of human medicines on the basis of earlier reports:

a. Business decisions
    a. Lean management (just-in-time production)
    b. Relocation of production facilities to other countries
    c. Lack of/inadequate investment
b. Production-related reasons
    a. Production problems
    b. Limited production capacity
    c. Lack of raw materials
c. Changes in demand
    a. Unexpected rise in demand

   b. Increase owing to medicinal product resistance
   c. Pricing geared to excessive production volumes
   d. Medicinal products not reimbursed by health insurers
d. Cost grounds
   a. Manufacturers' liquidity problems
   b. Excessive price pressure
e. Market access
   a. Gaining access to the market is too costly/laborious
   b. The market is too small
   c. Restrictive state authorisation policy

For its depiction of the medicinal products supply situation in Switzerland, the FOPH report referred to above explores the reasons why supplies of vital human medicinal products are disrupted. The reason for each disruption to supplies of a vital human medicinal product has to be reported to the Federal Office for National Economic Supply.

In the absence of a reporting obligation for vital veterinary medicinal products, a comparable analysis for veterinary medicinal products is **not possible**.

4 Potential solutions

4.1 FOPH report on drug supply bottlenecks 2022

A detailed description of the measures and implementation proposals can be found in the *FOPH report on drug supply bottlenecks 2022* and the document *Implementation proposals for the measures of the FOPH report on shortages in the supply of medicinal products* (See the "Documents" tab on the Federal Office of Public Health web page).

The implementation proposals were reviewed from a One Health perspective in the course of the preliminary project to assess their relevance to veterinary medicinal products. The proposals that were classified as relevant are listed under 4.1.1 and 4.1.2. These should be further pursued for veterinary medicinal products by participation in working groups with the FOPH.

4.1.1 Cluster 1: Detailed optimisation of the existing system in Switzerland

- Implementation proposal 4: Improve coordination and cooperation
- Implementation proposal 5.1: Extend mandatory stockpiles to additional medicinal products
- Implementation proposal 9.1: Simplify the out-of-stock application process
- Implementation proposal 11.1: Simplified authorisation under Art. 14 para. 1 let. a$^{\text{bis-quater}}$ of the Therapeutic Products Act (TPA)

4.1.2 Cluster 2: Further reaching modifications to the existing system in Switzerland

- Implementation proposal 16.1: Procurement by the Confederation under capacity agreements
- Implementation proposal 15.2: Verify fulfilment of supply criteria (option 2: financial rewards for secure supplies)
- Implementation proposal 17: Production by the Confederation (in severe shortages)
- Implementation proposal 10.1: Create new legislation to permit the time-limited importation of unauthorised medicinal products

- Implementation proposal 11.2: Simplified authorisation procedure under Art. 13 TPA

As regards the implementation proposals from **Cluster 3** (International/multilateral solutions), no decision on whether Swissmedic and/or the FSVO would take part in working groups with the FOPH had been taken at the time the preliminary project concluded.

4.2 Specific implementation proposals for veterinary medicinal products for further investigation

The preliminary project identified various implementation proposals that are specific to veterinary medicinal products and which should be examined in greater depth in a follow-on project and with the affected stakeholders' involvement if appropriate. The implementation proposals include, for example, reporting supply disruptions, assessing existing authorisation procedures, requirements for packaging elements (medicinal product information and packaging), requirements planning for supplying the Swiss market, wholesaling among veterinarians and the procurement of essential veterinary medicinal products for an epidemic. The follow-on project is scheduled to commence in the second quarter of 2025.

4.3 Measures that have been assessed and implemented

Two measures specific to veterinary medicinal products that were identified during the preliminary project have already been implemented. The first involved Swissmedic making the veterinary medicinal products industry aware of the option of using out-of-stock applications. If a veterinary medicinal product that is authorised in Switzerland is unavailable for a limited period of time owing to supply shortages (stock-out situation), the marketing authorisation holder can request permission to place the foreign version of the identical product (qualitative and quantitative composition) on the Swiss market for a limited period of time. The request for temporary placement on the market can be approved if availability of the veterinary medicinal product is important on treatment grounds, it can be assumed that there is no additional risk in terms of medicinal product safety and no equivalent alternative product is available in Switzerland.

The second involved the FSVO making cantonal veterinary services aware that the option of "veterinarians helping each other out with veterinary medicinal products" is available provided it does not develop into regular trading.

4.4 Measures that were assessed but will not be pursued

Following assessment by the FSVO and Swissmedic, it was decided not to pursue several measures as part of the follow-on project. This includes "direct adoption of EU authorisations". Reason: Ready-to-use veterinary medicinal products may not be placed on the market in Switzerland until they have been authorised by Swissmedic. This is in line with the requirements in all developed industrial nations, including all EU countries. Switzerland currently has no way of contributing to EU authorisation procedures because it has no association with the EU and corresponding bilateral treaties are not in place.

Unilaterally adopting EU authorisations would make Switzerland the only European country to adopt authorisations unseen even though it is not an EU member and thus plays no role in the scientific assessment and decision-making process. As a further consequence of unilateral adoption, it would no longer be possible to adequately guarantee drug safety and consumer protection in Switzerland. Market surveillance for the purpose of ensuring compliance and enforcing therapeutic products legislation cannot be delegated to foreign authorities and must remain the prerogative of the authorities in Switzerland as a sovereign constitutional state. Having considered these public health and political aspects, the Federal Council categorically rejected unilateral recognition of foreign authorisations when it enacted the TPA.

However, Swissmedic has been taking account of European authorisation decisions for many years. The veterinary medicinal products industry makes extensive use of the established procedures for doing so under Art. 13 and 14 para. 1 let. a$^{bis - ter}$ TPA.