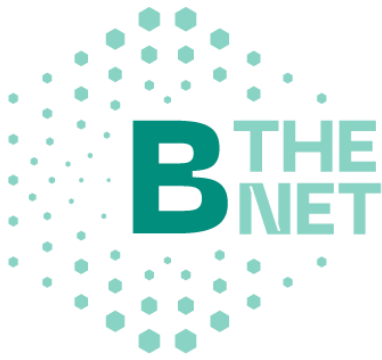




D2.18

Translational Event for Stakeholders M12

Accessibility to Veterinary Medicinal Products in Beekeeping in Europe

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Abstract	The beekeeping sector is an agricultural sector with a relatively small economic dimension in Europe. Except for some countries, especially those belonging to the European Mediterranean Sea region (Spain, Italy, Greece, etc.) and Germany, pharmaceutical industries often do not find an economic interest in developing the R&D needed to identify new drug candidates for Veterinary Medicinal Products (VMPs), or to request authorisation of new VMPs for the treatment of honey bees. Pharmaceutical suppliers do not find it profitable to import, even at the intra-community level, VMPs authorised in other countries due to the lack/scarcity of economic sales volume. The economic constraints are aggravated by the overall decrease in profitability that the beekeeping sector faces, deriving from a combination of factors, including increased colony losses and production costs, reduction in production due to the climate, and reduced selling prices. The current unfavourable circumstances often make beekeepers opt for the more economical options when treating their colonies against varroosis, with the increasing concern that synthetic acaricides might have an adverse effect on the health of the honey bees. Furthermore, many VMPs' active ingredients are basic, low-risk substances such as essential oils or organic acids, easily found in grocery shops and leaving no residues in the hives. In this

	situation, different countries have proposed diverse approaches to enable the accessibility of VMPs to beekeepers, and the EU eased the authorisation of VMPs for varroa treatment. The webinar brought together different scenarios at the EU level, drawing comparisons among Member States with different practical, on-field beekeeping dimensions (e.g., hobbyist beekeepers, professional beekeepers) and their approaches to making VMPs accessible to them. Following the presentations, discussion groups were organised to identify the limitations and challenges in different member states and propose solutions to enable more VMP accessibility to the beekeeping sector to treat varroosis.
Keywords	VMP, varroa, Europe, illegal use, availability

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The information and views set out in this report are those of the participants to the webinar and not necessarily reflect the official opinion of the European Union. Neither the European Union institutions and bodies nor any person acting on their behalf.

Table of Abbreviations and Acronyms

Abbreviation	Meaning
EMA	European Medicines Agency
EU	European Union
VMP	Veterinary Medicinal Product
USD	United States Dollars

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1 Executive Summary

Deliverable 2.18 presents the minutes of the first webinar for stakeholders of the European project B-THENET “BEST PRACTICES AND INNOVATIONS FOR A SUSTAINABLE BEEKEEPING” (GA N. 101059812). The webinar topic was the “Accessibility to Veterinary Medicinal Products (VMPs) for bees in Europe”.

This [B-THENET](#) webinar was held as a hybrid event in collaboration with the Nature and Apiculture weekend organised by the Romanian Federation of Beekeepers (ROMAPIS), who provided English-Romanian translation. Around sixty participants from all over Europe engaged in the webinar, while twenty-two participants met in person in Bucharest (Romania) at the Veterinary University. Participants included beekeepers, academia, public authorities, medicinal product distribution and veterinarians.

The programme included a presentation by the authorities of the European regulatory framework. It was followed by presentations of the crystallisation of such European framework in four different countries with different field realities: countries in which beekeeping is mainly a hobbyist occupation but with different importance at the national level (Belgium and Slovenia), and countries in which beekeeping is professionalised and has a large volume of participants (Romania and Spain). Finally, two companies commercialising VMPs for beekeeping presented their views and difficulties when introducing their products into the market.

The presentations served to identify two main limitations hampering the accessibility of beekeepers to VMPs to treat varroosis: the lack of economic interest by industry provided the small scale of the sector and the use of illegal products or formulations. These two issues served as topics for two brainstorming sessions on improving the situation.

The present deliverable gathers the information exchanged during the webinar.

2 Introduction

The beekeeping sector is an agricultural sector with a relatively small economic dimension in Europe. Except for some countries, especially those belonging to the European Mediterranean Sea region (Spain, Italy, Greece, etc.) and Germany, often, pharmaceutical industries do not find an economic interest in developing the R&D needed to develop new drug candidates for Veterinary Medicinal Products (VMPs) or to request for authorisation of new products to treat honey bees. Furthermore, there is a concern about the possible adverse effects of synthetic acaricides on honey bees. Pharmaceutical suppliers do not find it interesting to import, even at the intra-community level, VMPs authorised in other countries due to the lack/scarcity of economic sales volume. This, together with the lack of profitability of the sector coming from a combination of increased colony losses and costs of production, reduction in production due to the climate and reduced selling prices, make beekeepers often opt for the more economical option for treating their colonies against the Varroa mite.

Furthermore, many VMPs' active ingredients are basic, low-risk substances such as essential oils or organic acids, easily found in grocery shops.

In this situation, different countries have proposed diverse approaches to enable the accessibility of VMPs to beekeepers, and the EU eased the authorisation of VMPs for the treatment of varroosis.

The webinar was organised to share information related to the activities performed at the EU level within the regulatory framework of the VMP authorisation (European Medicines Agency, EMA), and the *status quo* in different Member States.

The experience of beekeepers as well as of two leading industries regarding the VMPs in Europe (VetoPharma and BeeVital) were gathered.

The use of illegal products and the poor distribution of VMPs were two issues identified for discussion, and a webinar session was dedicated to exchanging ideas on how to improve the current situation.

2.1 Participants/people we reached

The event ([Accessibility to VMP in beekeeping in Europe](#)) was organised as a hybrid event in collaboration with [ROMAPIS](#), a [Beelife](#) member from Romania. Twenty-two in-person participants were present in Bucharest (Romania), and around 60 participants participated online. Participants included beekeepers, academia, authorities, medicinal product distribution and veterinarians. The webinar was a joint event with the Nature and Apiculture Weekend organised by ROMAPIS in the AGROAPIS and APISANA projects' framework. Interpretation was provided in English and Romanian.

3 Programme

The webinar programme was as follows:

1. Welcome words and Introduction to the topic by moderator
2. The situation in the field
 - a. Presentation on the registration of veterinary medicinal products for bees - situation in Europe - Barbara Cyrus
 - b. Presentation at 3-4 countries:
 - i. Slovenia - Peter Kozmus
 - ii. Belgium - Ellen Danneels
 - iii. Romania - Cristina Surlea
 - iv. Spain - Juan Molina
3. Presentation from 2 companies
 - a. BeeVital - Dominik Nicolas Hohl
 - b. Veto-Pharma - Remi Padé
4. Discussion session
5. Wrap-up and closing of the webinar.

3.1 Presentations and information exchange

After the welcome words and introduction to the topic by Noa Simón, Scientific Director at BeeLife and a member of the Bee Health Committee of Apimondia, Dr Barbara Cyrus from the European Medicine Agency (EMA) presented the regulatory framework of VMPs in Europe, describing how the market authorisation process works and the active ingredients authorised for bee treatment. She also presented how pharmaceutical companies are incentivised to authorise products for minor species such as honey bees. The presentation can be accessed [here](#).

In the next presentation, the beekeeping sector's current situation, the European framework's crystallisation that occurs at the national level, and the corresponding sanitary system in 4 member states (Belgium, Romania, Slovenia, Spain) were presented. Four experts from each country presented the field situation in the four countries, the accessibility of VMPs to beekeepers, the main problems faced, and some proposals for solutions that could work at the national or the EU level.

Dr Peter Kozmus (Slovenian Beekeepers Association, leader of the breeding programme for the Carnolian bee and the Vice-President of Apimondia), presented the actual situation for Slovenia (presentation available [here](#)): due to the small market size, VMPs' prices are high, diversity of products is reduced, and pre-ordering in advance is required. On top of that, the formulations available are inadequate for the national hive model, which influences the products' efficacy and makes the posology adaptation necessary.

Dr Ellen Danneels (Honeybee Valley, Belgium) presented the Belgian state of affairs, describing a situation in which the government recognises the limitations faced by the beekeeping sector and allows a certain degree of tolerance, enabling alternative ways for the beekeepers to access VMPs (the presentation is available [here](#)): the cascade system (but not enough veterinarians are specialised in bee health) pushes veterinarians to work as distributors of VMPs, products bought online or across the borders in France, Germany, Luxembourg or the Netherlands.

Dr Cristina Șurlea (University of Agronomic Science and Veterinary Medicine, Bucharest; collaborator of ROMAPIS (Federation of Romanian Beekeepers)), presented the Romanian situation (the presentation is available [here](#)). A highly professionalised sector where the circulation of unauthorised treatments seems to be the main problem was described. Given the border-sharing with non-EU countries, there is a high probability of smuggling VMPs not authorised in the EU, with active ingredients that can be risky to the honey bees, contaminating the beekeeping products with residues potentially having a negative impact on consumers', beekeepers' and environmental health. Intensive training programs for beekeepers, bee health workers and advisors and collaboration with veterinarians were proposed.

Dr Juan Molina (Spanish Association of Veterinarians Specialised in Bee Health (AVESPA)) presented the national situation (the presentation is available [here](#)). A highly regulated beekeeping sector involving advisors who are veterinarians specialised in bee health was reported. However, the deviation from the norm remains the main problem: homemade treatments with (un)authorised active ingredients that beekeepers can access online. Investing more into research to achieve a diversified selection of VMPs available for the treatment of varroosis was proposed. The Spanish system provides 2 subsidised varroa treatments/colony/year, which is a positive measure that has reduced the need to seek illegal uses of veterinary formulations.

Dominik Hohl (CEO of the company BeeVital) presented the experiences gained on the authorisation of VarroMed®, the first VMP for treating honey bees (the presentation is available [here](#)), which has a centralised marketing authorisation valid for the entire EU. The pros (simplified paperwork and procedure) and cons (lengthy and costly process) of the procedure were presented. Suggestions were made for improving the process of authorisation, such as having a "honey bee VMP" professional contact at EMA, creating a VMP regulation specific for bees, harmonising the dispensing regulations across the EU, and proposing to incentivise the use of authorised products vs. illegal ones, via subventions or strict sanctions for illegal uses.

Remi Padé, coordinator of the Bee Innovation projects at Veto-pharma, described the company's efforts in developing new VMPs for bee health and engaging with the beekeeping sector to bring new products into the market. Specifically for varroa treatment, they have been studying 40 molecules in the last 3 years and collaborating with beekeepers once the VMP was tested and formulated. However, developing a new VMP for varroa treatment is a time-

consuming and cost-intensive (between 2 and 5 million USD) process. The steps to be taken by the industry during the registration process were described in detail. The presentation is available [here](#).

3.2 Discussion session

The information exchange was followed by a discussion session in which the participants sought to brainstorm and propose improvements to the system to ease the accessibility of VMPs in beekeeping. The original plan was to create two parallel breakout sessions where two different topics were discussed simultaneously. However, the hybrid and bilingual nature of the event made it impossible to divide the audience. As a result, all the participants contributed to the discussion of both topics proposed: (1) How to ensure accessibility to VMPs in countries where beekeeping is small-scale, and the distribution of VMPs is limited?; (2) How to deal with illegal use of VMPs?

(1) How to ensure accessibility to VMPS in countries where beekeeping is small-scale and the distribution of VMPs is limited?

The following ideas/proposals came into the discussion:

- Allow beekeepers' associations to buy and distribute VMPs under the supervision of veterinarians or veterinary associations specialising in bee health.
- Make the role of beekeeper associations more prominent in the distribution of VMPs.
- Promote the role of veterinarians in apiculture.
- However, some participants thought that veterinarians should not be obliged to directly distribute the medicines to beekeepers. It should be the task of pharmacists. This option, however, entails higher prices where it is available (e.g., Belgium).
- Another way to improve the availability of VMPs could be to allow beekeeping equipment shops to sell low-risk, non-prescription VMPs. Several member states, including Germany, Austria, Holland, and others, already do so successfully.
- Beekeepers are livestock growers and should be regularly controlled by the relevant authorities.
- Beekeepers should be able to buy authorised products from other EU countries.

(2) How to deal with illegal use of VMPs?

The following ideas/proposals came into the discussion:

- At the EU level:
 - Accelerate and facilitate risk assessment by EMA and authorisation by the EU.
 - Obligation for a centralised authorisation process that will make all the VMPs legal across the EU.
- At Member State level:

- Reduce the prices for authorised VMPs, subsidise them (in case the invoices are presented), control the use of VMPs and strictly fine those who use unauthorised products.
- Reconsider the VAT rate applied to VMPs for bee health and reduce it so that the price can be reduced.
- Increase the number of alternative/cheaper treatment possibilities by
 - improving relations/cooperation/exchanges among Member States on honey bee-related VMPs and
 - giving the possibility to beekeepers to use all VMPs that are authorised elsewhere in the EU Member States without the need for the adoption of the cascade principle.
- Understand the reasons behind illegal use: price/higher effectiveness of illegal products/fake claims on effectiveness? Depending on the reasons, take action.
- Increase resources for controlling illegal uses or distribution of VMPs.
- Impose a fine to shops selling VMPs that are not registered for honey bees.
- Support breeding honey bees that can cope better with the Varroa mite and support the distribution of such queens among the beekeeping sector.
- Increase awareness of policy-makers involved in elaborating national rural development programmes about alternative treatments.
- At the local level:
 - Promote the collaborative and synchronised varroa treatment approach.
 - Education and training of veterinarians, advisors and beekeepers via specialised magazines, social media, training courses, trusted sites, etc.
 - Improving trust between veterinarians and beekeepers.
 - Beekeepers should focus on prevention rather than cure (train them on biotechnical measures, resistant varieties/breeds, etc.)
 - Harmonise authorisation and distribution regulation among Member States, and harmonise the methods for veterinary prescription throughout the EU, e.g., VMPs based on organic compounds do not need veterinary prescription anywhere in the EU or can be sold over the counter while VMPs with high environmental risk or potential risk of contamination of beekeeping products, need a prescription.
 - E-prescriptions (easier to track how much VMPs are sold).
- At international/national fairs, salespersons should clearly indicate if the product is registered in the customer's country.

As shown before, the discussion lasted much longer than expected but rendered a rich exchange of ideas. The webinar was finalised with the promise to distribute the summary included in this



deliverable among the participants.

4 Conclusions

This first B-THENET webinar versed on the accessibility of VMPs for bees in the EU. The problems experienced by the beekeeping sector throughout Europe seem similar but also country-specific, depending on the profile of the beekeeping sector in each country. However, due to the relatively reduced economic contribution of beekeeping in comparison with other agricultural sectors, the investments made towards the development of R&D, official controls, and distribution lack appropriate consistency. As a result, the sector in each country has tried to solve the situation in a wide diversity of manners.

Two main issues related to the accessibility of VMPs in European beekeeping were revealed in this webinar:

1. The lack of interest in pharmaceutical distribution of VMPs in countries where beekeeping is conducted on a small-scale.
2. Illegal use of VMPs in countries where the beekeeping sector is more professionalised.

Participants commented that, given the circumstances, the beekeeping sector and its associations should be given a more prominent role in the distribution of VMPs, if possible, under the supervision of a veterinarian. It was also suggested that once VMPs are authorised in one country of the EU, the procedure to allow access to a VMP in other Member States of the EU should be made easier and that harmonisation in the implementation of official procedures should happen throughout the EU.

5 Appendix

The video recording of the webinar is available [here](#).



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