

UK AUTHORISED PRODUCTS

The Legality of Veterinary Medicines and Record Keeping

Jason Learner, Technical Advisor, National Bee Unit

There appears to be some lack of clarity about the use of hive cleaning products which are currently available on the market. Products which claim to treat or prevent disease must be authorised in accordance with the Veterinary Medicines Regulations (VMR) before they can be placed on the market. If they have not been authorised in accordance with the VMR, then the medicine should not be used.

Authorised Products in the UK

For those who are unsure, the products in the table are currently authorised for use in the UK and are available without veterinary surgeon involvement or prescription as they carry the AVM-GSL ('over the counter' medicine) distribution category. They can be purchased online or from your usual supplier.

To view the Summary of Product

Characteristics (SPC) for these products please go to the Product Information Database on the Veterinary Medicines Directorate (VMD) website: www.vmd.defra.gov.uk/ProductInformationDatabase/ Click on 'Product Search' and select 'Bees' from the Species drop-down list. The SPC gives specific information such as special warnings both for the intended species and the person administering the medicine. Further information on varroacides can also be found in the *Managing Varroa* booklet, available from BeeBase (<https://secure.fera.defra.gov.uk/beebase/index.cfm?pageid=93>) and click on the 'Managing Varroa' link to open the pdf file.

Products Authorised in the EU

The following link to the VMD website lists bee products authorised in Europe which have been approved for import under a Special Import Certificate (SIC): http://www.vmd.defra.gov.uk/vet/bee_authorized.aspx

Varroa treatment products currently authorised for use in the UK

Product Name	Active Ingredient
Apiguard [®] gel (25% Thymol) for beehive use	thymol
Apilife Var [®] bee-hive strip for honey bees	camphor (racemic) eucalyptus oil menthol levo thymol
Apistan [®] 10.3% w/w bee hive strip	tau-fluvalinate
Bayvarol [®] 3.6 mg bee-hive strips for honey bees	flumethrin
MAQS [®] beehive strip	formic acid 95% w/w
Thymovar [®] 15 g bee-hive strips for honey bees	thymol



We need to keep varroa mite levels down as low as possible to help our bees thrive

However, if you wish to import a different product, you may still apply for an SIC.

The VMD has canvassed the EU Member States, including the European Fair Trade Association (EFTA) countries, for information regarding products which they have authorised for use on honey bee colonies. Details of these products can also be found on the VMD website using the following link: http://www.vmd.defra.gov.uk/vet/bee_europe.aspx

How to Get Hold of Products Authorised in the EU

European Union legislation (Directive 2001/82 as amended), transposed into national legislation (Veterinary Medicines Regulations 2013), permits the importation of products authorised in other Member States under the prescribing Cascade, when the need to do so arises. However, this can



Clare Worring

Some of the varroa treatments authorised for use in the UK

Borderline Products

In October 2013, under its 'Classification of Borderline Products', the Federal Agency for Medicines and Health Products (FAMHP) ruled that, within the EU, products intended for the cleansing of beehives to minimise acarids would be considered veterinary medicinal products.

VMD recently carried out a review of the 'most popular' unauthorised products available for use by beekeepers in the UK. Nine manufacturers have been identified who supply the UK market.

Three are located in the UK; the others are in Europe and the US. These manufacturers will be asked either to submit an application for a Marketing Authorisation for their products or to change their product labelling and associated literature to remove any claims relating to treatment or prevention of acarid infestation.

The VMD does not wish to remove these products from the market and it is anticipated that companies will choose to amend their labelling. It is hoped that both the UK and non-UK companies will cooperate in making the changes as soon as possible.

With regard to products held in stock, no product recalls will be requested and products already within the retail chain will remain on sale. It is hoped that allowing a sell-through period will limit any possible commercial or financial impact on the industry or any welfare concerns of beekeepers caused by lack of product availability.

Misuse

If you believe a product is being misused or marketed incorrectly, then you should contact the VMD Enforcement team at enforcement@vmd.defra.gsi.gov.uk

Record Keeping Requirements

The Veterinary Medicines Regulations 2013 (VMR) require the keeper of a food-producing animal, including bees, to maintain records of the purchase of medicinal products to include:

- the name of the product
- the batch number
- the date of acquisition
- the quantity acquired
- the name and address of the supplier.

When the medicine is administered to the bees, the keeper must further record:

- the name of the product
- the date of administration
- the quantity administered
- the withdrawal period
- the identification of the animals treated (in the case of bees, the hive number or identifier).


Finally, when disposing of unused medicine the beekeeper must note:

- the date of disposal
- the quantity of product involved
- how and where it was disposed of.

These records must be kept for five years following the administration of the medicine, even if the animals concerned are no longer in the keeper's possession, eg, the colony has died out, been split, swarmed, sold or given away.

Record keeping is necessary to ensure traceability of medicines and to enable product recall, particularly for medicines used to treat animals entering the food chain.

Record-keeping Card

A medicines record card can be found on the public pages of BeeBase (<https://secure.fera.defra.gov.uk/beebase/index.cfm?sectionid=109>). This link will take you to the Veterinary Medicines pages which outline all the information that needs to be kept on a medicines record card. At the bottom of the page, you will find a link that enables you to download and print out your own blank records. 

A record card you can download from BeeBase

VETERINARY MEDICINE ADMINISTRATION RECORD - TO BE KEPT FOR 5 YEARS										
NAME:		ADDRESS:								
APIMARY ANIMELLOCATION:		POST CODE:								
TO BE COMPLETED AT TIME OF PURCHASE				TO BE COMPLETED AT TIME OF ADMINISTRATION						
Name and Address of Supplier of product				Date of purchase	Quantity	Date of administration	How used/used	Quantity of bees administered	Withdrawal period	Date & time of next administration
Name	Address	Product	Quantity	Date	Quantity	Date	Quantity	Days	Time	

Manufacturers are required to keep proof of purchase and a record of purchase, administration and disposal of all veterinary medicines for a minimum of 5 years. Blank records are available from Veterinary Medicines Directorate, Woodham Lane, New Year, Addicks, Surrey KT11 3LJ. Telephone: 01292 208911. National Bee Unit © Crown copyright