Collection: Illegal animal medicines: seizure and improvement notices and prosecutions

Updated: Updated for October 2018

Further information about seizure and improvement notices can be found in the Enforcement strategy for animal medicines

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Detailed guide: Apply for a Manufacturing authorisation for veterinary medicines

Updated: Updated register of specials manufacturing sites

Manufacturers are required to comply with the principles of Good Manufacturing Practice (GMP) where appropriate in relation to the following types of authorisation:

- manufacturing authorisation (ManA)
- manufacturing extemporaneous products (Specials) authorisation (ManSA)
- autogenous vaccine authorisation (AVA-I/S)
- non food animal blood banks authorisation (NFABBA)
- equine stem cell centre authorisation (ESCCA)
- exemptions for small pet animals (Schedule 6)

Guidance

For information about the requirements for veterinary only manufacturers.

Applications forms

- Application form for manufacturers authorisation
  (MS Word Document, 96.1KB)

- Application form for variation to manufacturers authorisation
  (MS Word Document, 101KB)

- Application form for manufacturers special authorisation
  (MS Word Document, 90.8KB)

- Application form for variation to manufacturers special authorisation
  (MS Word Document, 86KB)

- Application form for, or variation to schedule 6 manufacturer
  (MS Word Document, 68.7KB)

An application for a ManA or ManSA should be accompanied by a Site Master File.

To help process your application more efficiently you should provide, in addition to paper copies, an electronic copy of the application or any parts of it. These should be in MS Word if possible, although other formats are acceptable.

You must submit your application to the Veterinary Medicines Directorate (VMD).

Timelines

The VMD will validate your application within 10 days of receipt although this time will be extended if the VMD has to ask you for further information.

After validation we will carry out the pre-approval inspection within 90 days.

Fees

The VMD charges a fee for:

- a manufacturers authorisation
- a manufacturers authorisation variation
- the initial inspection of each site
- duplicate or multiple GMP Certificates
- on-going annual and inspection fees

The application and annual fees are not refundable or transferable.

Application refusal and appeals

We may refuse to grant an authorisation or may grant an authorisation that is different than that applied for. In such cases we will notify you.

Manufacturers of human and veterinary products

Where a site handles both human and veterinary medicines you should also refer to guidance published by the Medicines and Healthcare products Regulatory Agency (MHRA).

Any queries should be directed to the Regulatory Information Service on 020 3080 7400 or via their website.

Contact

You can contact the Inspections administration team by email at inspections@vmd.defra.gsi.gov.uk.or by phone on 01932 338426 or 338328.

EudraGMDP

Details of authorised manufacturing sites (ManA holders) and Good Manufacturing Practice (GMP) Certificates can be accessed by searching the European database, EudraGMDP. See
guide to using the EudraGMDP
(PDF, 87.4KB, 2 pages)

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Registers

Approved Specific Manufacturing Authorisations – AVAS

Approved Specific Manufacturing Authorisations – Non-Food Animal Blood Banks, and Equine Stem Cell Centre Authorisations

Authorised specials manufacturing sites

(PDF, 130KB, 3 pages)

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Guidance: Vaccination of dogs

Updated: Vaccines table updated

The Veterinary Medicines Directorate's (VMD) position on the authorised vaccination schedule for dogs has been published to help you make an informed decision on the vaccination schedule for your dog.

The table of vaccines lists vaccine products which have been authorised by the VMD.

Vets will use vaccination schedules that are based on the authorised summary of product characteristics (SPC).

However a vet may make the decision to use either a shorter or longer revaccination schedule based on the age, health, or vaccination history of the animal. This is considered to be off-label use of the product and the vet takes responsibility for the decision.

It is recommended that the course of action is agreed with the animal owner.

UK overseas intellectual property attaché network

Also referred to as Intellectual Property (IP) attachés, the IP liaison officers work with local UK Department for International Trade (DIT) and Foreign and Commonwealth Office (FCO) leads to provide support for UK businesses seeking advice on local IP matters.

They also:

- raise awareness of IP through business outreach. This includes briefing business delegations, joint webinars with DIT and local trade associations

- liaise with host governments and stakeholders about local and international IP frameworks / environment

Contact details

Kayleigh Nauman: Attaché North America

Career history: Before joining the Intellectual Property Office (IPO), Kayleigh worked for a Member of Congress in the US House of Representatives. There, she managed a diverse portfolio, working on intellectual property, trade, and telecommunications; developing and writing legislation; and supporting Congressional oversight of executive agencies. Previously, Kayleigh worked in local and state government in Wyoming, USA. She is a Fulbright Scholar and holds an MPhil from Emmanuel College at the University of Cambridge, UK.

Focus in North America: Supporting the IPO's input into any Free Trade Agreement (FTA) with the United States and providing insight into US IP policies and IP discussions they may have with global trading partners. Kayleigh also focusses on building cooperation between the US and UK on IP matters such as global treaties, simplifying international patent procedures and approaches to IP enforcement. Finally, Kayleigh can provide IP advice and support to UK businesses operating or trading with the US, Canada and Mexico.

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Christabel Koh: South East Asia

Joined IPO: August 2013

Career history: Prior to working for the UK Government, Christabel spent six years at the IP Office of Singapore and the IP Academy, last serving as an Assistant Director of Special Projects. In her roles she focused on international cooperation, IP capacity building and monitored IP developments. She also co-founded Just Tee It in 2007, an online golf portal. Her roles covered product development, marketing channel management and enhancing customers' digital experience. She holds a MSc in Technopreneurship and Innovation from Nanyang Technological University in Singapore and University of Washington, Seattle, WA.

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Desmond Tan: South East Asia

Joined IPO: April 2018

Career history: Prior to joining the Intellectual Property Office (IPO), Desmond was Senior Assistant Director with the Intellectual Property Office of Singapore (IPOS) for five years, covering various portfolios such as

strategy and policy, industry development and planning, capacity building, as well as a stint in media engagement. Desmond holds a Degree in Aeronautical Engineering from the Nanyang Technological University, Singapore.

Focus in SE Asia: The IP landscape is SE Asia is diverse and evolving rapidly. Based in Singapore, the team provides regional IP support to UK businesses operating in or venturing to SE Asia. The team also works with the local governments and associations to develop a pro-business IP environment for the region.

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Cerian Foulkes: China

Joined IPO: April 2019

Career history: Prior to joining the Intellectual Property Office (IPO), Cerian was Senior Innovation Policy Officer for the UK government's Science and Innovation Network in China. Previous to this, she worked in the China team of the UK's Research Councils and in the auto industry. Cerian has lived and worked in China for over nine years and is fluent in Mandarin.

Focus in China: China's IP framework is fast developing and the UK is a key international partner. Cerian and her team in Beijing and Shanghai, provide direct support to UK companies with concerns across the IP spectrum, particularly in supporting enforcement outcomes. The team also works closely with a number of Chinese government agencies on IP, to share UK expertise and best practice. This work is part of wider engagement by the UK IPO with China, including the annual UK-China IP Symposium and technical exchanges.

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Angelica Garcia: Brazil

Joined IPO: August 2016

Career history: Lawyer with a LL.M in IP & International Trade from Queen Mary University, London. She was formerly Director of Marketing & Business Development for ACE Aceleratech start-up accelerator in Brazil and Latin America and worked on Deloitte's German-Brazilian Desk. Most recently she worked for the Department for International Trade (formerly UKTI) of the British Government.

Focus in Brazil: Assisting UK companies that have IP issues in Brazil and working closely with Government to ensure that there is a strong IP framework. This includes outreach with both officials and business, highlighting the benefits of a strong IP system. Specific areas of interest include addressing backlogs in patents and trade marks, Geographical Indications (GIs), pharmaceuticals and IP enforcement.

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India

Post currently vacant.

Useful guides

Guidance: IsItWaste tool: for advice on the by-products and end of waste tests

Updated: We've updated information on how to use our Definition of Waste Service to get an opinion on whether your waste derived material can be classed as non-waste.

Use the user guide to:

- access the IsItWaste tool
- do a self assessment to help you decide whether your material is likely to be waste
- ask the Environment Agency Definition of Waste Service for an opinion

The IsItWaste tool is for England only. It's based on English and Welsh case law. Northern Ireland and Wales may have similar tools.