

# Veterinary Medicinal Product in United Kingdom: A Regulatory View

## Abstract

Veterinary medicine is a field of the medicine that addresses disease, disorder and injury prevention, control, diagnosis, and treatment. It also covers animal husbandry, breeding, nutrition research and product development. The Veterinary Medications Regulation in the United Kingdom lays down legislative criteria for veterinary medicines manufacturing, classifying, supplying, marketing and use. In addition, the Veterinary Medicines Directorate is the national competent body, as well as an Independent Regulator. In the UK, there is an EU set of regulatory procedures covering veterinary medical products, including safety, licencing, and monitoring. The goal is to provide an overview of the wide range of regulatory checks that control the licencing, provision, and monitoring of veterinary pharmaceutical goods. These thorough inspections ensure that our animals' health and welfare are safeguarded by using safe, effective, and high-quality veterinary medicines, as well as by people and the environment.

## Keywords

Veterinary Medicines, Veterinary Medicines Directorate (VMD), Department of Environment, Food and Rural Affairs (DEFRA), Directives, Market Authorisation, Regulations.

## Introduction

The United Kingdom of Great Britain and Northern Ireland, once in a while known as the United Kingdom (UK) or Britain, is a sovereign country situated off the north-western shoreline of Europe's centre region. The United Kingdom is comprised of the island of Great Britain, the north-eastern piece of the island of Ireland, and a sprinkling of more modest islands dissipated all through the British Isles.

The United Kingdom is a constitutional monarchy and a unitary parliamentary democracy. Over several hundred years, the United Kingdom has evolved through a series of annexations, unions, and separations of constituent countries.

The United Kingdom has the fifth biggest ostensible GDP and tenth-biggest buying power equality economy on the planet (PPP). It has a prosperous economy and is positioned thirteenth on the planet as far as human turn of events. The United Kingdom was the world's originally evolved country and the biggest and most impressive force during the nineteenth and mid-20<sup>th</sup> century.<sup>21,22</sup>

- Capital city – London
- Official language – English
- Area – 93,628 square miles (242,500 km<sup>2</sup>).
- Population – 68,321,339
- GDP – \$3.12 trillion (nominal; 2021 est.), \$3.17 trillion (PPP; 2020)
- Currency – Pound sterling (GBP, £)

## Economy of United Kingdom

The economy of the United Kingdom is an all-around created social market and market-arranged economy. It has the fifth-biggest ostensible GDP, 10th biggest buying power



Figure 1: Map of United Kingdom Cities<sup>23</sup>



Figure 2: United Kingdom on Globe<sup>24</sup>

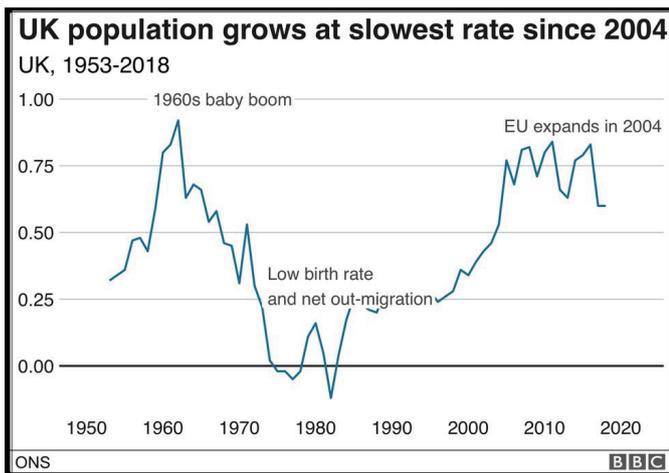


Figure 3: Population Growth in United Kingdom<sup>25</sup>

equality (PPP), and twenty-first-biggest GDP per capita on the planet, representing 3.3 percent of worldwide GDP.

The United Kingdom is comprised of England, Scotland, Wales, and Northern Ireland, and it is one of the world's most globalised economies. The United Kingdom was the fifth-biggest exporter and fifth-biggest merchant on the planet in 2019. It likewise had the third and fifth most noteworthy inward and outward unfamiliar direct speculations, separately. In 2020, exchange with the European Union's 27-part states represented 49% of commodities and 52 percent of imports in the United Kingdom.<sup>22</sup>

**Climatic Conditions of United Kingdom**

- The climate in the United Kingdom is mild.
- The UK experiences chilly, rainy winters and warm, wet summers.
- It lacks the extremes of heat and cold, drought, and wind found in other regions. Weather is also incredibly unpredictably unpredictable.

The weather in the United Kingdom is not always consistent. The climate in London, which is located in the south-east of the United Kingdom, is warm and dry in the summer and cold and dry in the winter. Cumbria, in England's mountainous north-west, has colder winters and more rain.

**Big variations in how economies are recovering from pandemic**

Percentage change in GDP compared with pre-pandemic level (Q4 2019 v Q1 2021)

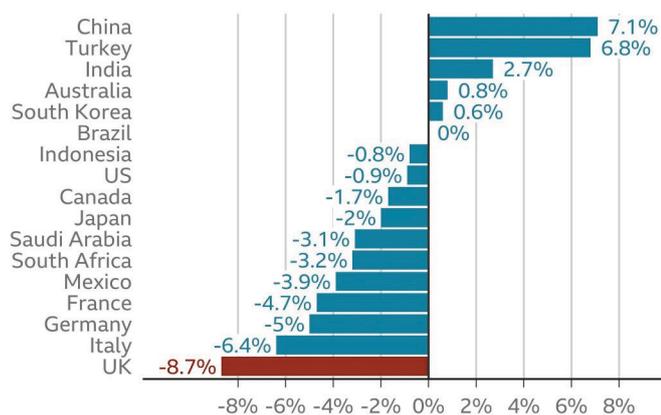


Figure 4: Economy Comparison<sup>26</sup>

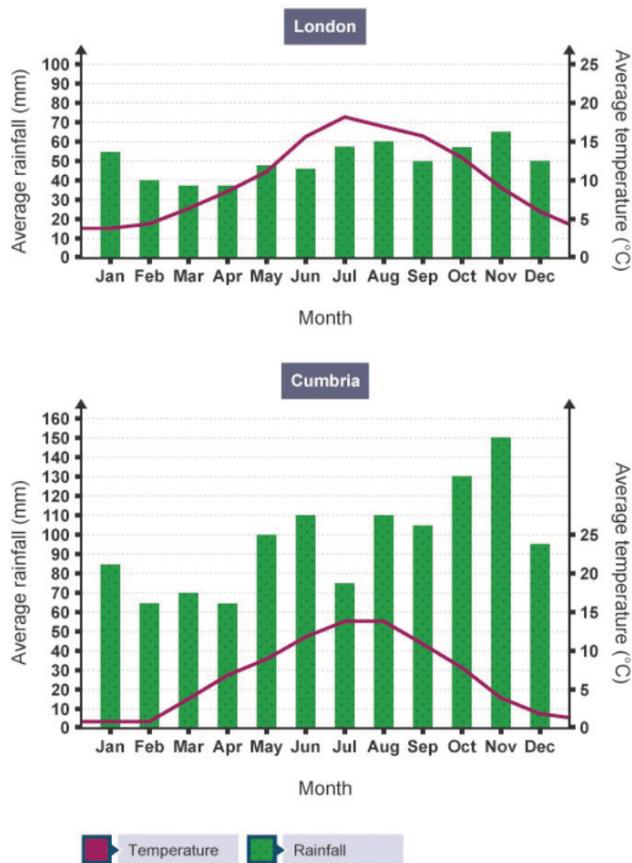


Figure 5: Climatic Conditions in United Kingdom<sup>27</sup>

**The United Kingdom's climate is separated into four main regions:**

South East	cold winters, warm and dry summers
South West	mild and very wet winters, warm and wet summers
North West	mild winter, cool summers and heavy rain all year
North East	cold winter, cool summers and steady rain all year

**ICH Stability Zones – Zone I [Temperate Zone]**

**Long Term Stability Testing Conditions –**

Climatic Zones	Temperature	Humidity	Minimum Duration
Zone I	21°C ± 2°C	45% RH ± 5% RH	12 Months



### Accelerated and Intermediate Stability Testing Conditions –

Climatic Zones	Temperature	Humidity	Minimum Duration
Accelerated Ambient	40°C ± 2°C	75% RH ± 5% RH	6 Months
Accelerated Refrigerated	25°C ± 2°C	60% RH ± 5% RH	6 Months
Accelerated Frozen	5°C ± 3°C	No Humidity	6 Months
Intermediate	30°C ± 2°C	65% RH ± 5% RH	6 Months



Figure 6: A domestic cat being operated on by a veterinarian<sup>19</sup>

### Veterinary Medicine, the Branch of Science that Deals with Animals

Veterinary medicine is the branch of medicine concerned with animal disease, disorder, and injury prevention, control, diagnosis, and treatment. Aside from that, it deals with animal husbandry, breeding, nutrition research, and product creation. Veterinary medicine covers a large range of animal species, both domesticated and wild, as well as a wide range of diseases that can affect them.

- Veterinary science serves to human wellbeing both straightforwardly and by implication by observing and controlling zoonotic sickness (irresistible illness passed from nonhuman creatures to people). They likewise assist with food security by observing and treating animals, just as psychological well-being by guaranteeing that pets are solid and enduring.
- Veterinary researchers every now and again team up with disease transmission experts and other wellbeing or regular researchers, contingent upon the kind of work they do. Ordinarily, veterinarians are ordered by law to really focus on the prosperity of creatures. To keep creatures protected and solid, veterinarians analyse, treat, and care for them.<sup>18</sup>

The Veterinary Medications Regulation (VMR) establishes legal criteria for the manufacture, classification, supply, marketing, and use of veterinary medicines in the United Kingdom. Furthermore, veterinary medical products (VMPs) are subject to a number of EU regulatory regulations, including safety, licencing, and monitoring.<sup>1</sup>

The Veterinary Medicines Directorate is the UK's national competent authority and independent regulator (VMD). The European Pharmaceuticals Agency (EMA) is in charge of scientific review and monitoring of medicines at the EU level.<sup>1</sup>

Before gaining a Marketing Authorisation (MA) or a licence for sale and supply in the UK, all authorised veterinary medications for animals must go through a rigorous regulatory clearance process.<sup>1</sup>

Each permitted veterinary medicinal product must fulfil the requisite standard of safety, efficacy, and quality, as determined by scientific research conducted by animal medicine businesses and subsequent examination by independent regulatory authorities. This guarantees that

### Discussion: Factsheet

Product	Veterinary Medicines
Country of Filing	U.K.
Regulating Agency	Veterinary Medicines Directorate
Department	Department of Environment, Food and Rural Affairs [DEFRA]
Regulatory Classification	Veterinary Medicinal Product
Definition of Veterinary Medicinal Product	Any drug or mixture of chemicals that can be employed in animals or given to them with the objective of restoring, correcting, or modifying physiological functioning by pharmacological, immunological, or metabolic action, or performing a medical diagnostic.
Form	Application forms (Annex A or on the VIVID's website): <a href="https://www.gov.uk/government/collections/veterinary-medicine-licence-application-forms">https://www.gov.uk/government/collections/veterinary-medicine-licence-application-forms</a>
Mode of submission	Submission through electronically (e-mail to): <a href="mailto:borderline@vmd.defra.gsi.gov.uk">borderline@vmd.defra.gsi.gov.uk</a> or in duplicate hard copy to the Enforcement team.
Directive 2001/82/EC	The Veterinary Medicinal Products Directive (as amended) establishes restrictions for the manufacture, authorization, marketing, distribution, and post- authorization surveillance of veterinary pharmaceuticals in all European Member States.
Licensing	£4,915,000 (paid for by the veterinary pharmaceutical industry)
Statutory Residues	£3,693,000 (paid for by the food industry)
Non-statutory residues	£1,054,000 (paid for by Defra)
Policy	£2,298,000 (paid for by Defra)
Validity	5 years

Table 1: Factsheet on Veterinary Medicinal Products in U.K

animal medicines are both safe and effective, as well as meeting quality standards.<sup>1</sup>

In the United Kingdom, antibiotics are only available on prescription from a veterinary surgeon; as a result, all antibiotics are POM-V (prescription only drugs – through a veterinary surgeon).<sup>1</sup>

All veterinary medications obtained and used in food-producing animals must be documented on the farm, according to the VMR. When farm animals are given veterinary medications, a mandatory residue surveillance programme is used to ensure the safety of the food they generate (meat, milk, eggs, etc.). This initiative ensures that the UK meets an EU regulatory need to test samples for veterinary medication residues.<sup>1</sup>

Pharmacovigilance is a continual process of veterinary drug safety and efficacy monitoring that enables the safe use of effective medicines.<sup>1</sup>

Only licenced veterinary medications are allowed to be used in the United Kingdom. The VMD's enforcement division takes pre-emptive action in the case of a breach of the VMR, which may include criminal prosecution.<sup>1</sup>

The Veterinary Medicines (Regulation (EU) 2019/6) will modernise the current enactment in the European Union (EU) on veterinary medication authorisation and utilisation when it produces results on January 28, 2022. It contains further measures to work on veterinary drug accessibility and security, just as expanding EU antimicrobial obstruction endeavours. The European Medicines Agency (EMA) is working intimately with the European Commission and other EU accomplices to plan for the Regulation's execution.

The Regulation's principal objectives are to:

- promote the development of novel veterinary medications, notably those aimed at niche markets (minor use and minor species).
- streamline pharmacovigilance standards, for example, to improve the functioning of the internal market for veterinary medications by simplifying the regulatory environment and decreasing administrative cost for pharmaceutical businesses manufacturing veterinary medicines.
- improve EU antimicrobial resistance efforts by passing specific measures to ensure the responsible and appropriate use of antimicrobials in animals, such as reserving some antimicrobials for human sickness treatment.<sup>2</sup>

Regulation (EU) 2019/6 amends Regulation (EU) 726/2004 on veterinary medicine authorisation and supervision, which

**Benefits and EMA Responsibilities**

<b>Benefits of the veterinary regulation<sup>2</sup></b>	Increased availability and access to safe and high-quality medicines for veterinarians, farmers and pet owners to treat and prevent animal diseases
	Reduced administrative burden and better incentives for pharmaceutical companies developing new and innovative veterinary medicines, benefiting in particular micro, small and medium-sized enterprises (SMEs)
	New and enhanced rules to keep antimicrobials (including antibiotics) effective based on a 'One health' approach for the benefit of animal and public health and every EU citizen
<b>EMA is also responsible for<sup>2</sup></b>	Revising its procedures and regulatory and scientific guidance documents, in line with the Regulation and its implementing and delegated acts
	Leading the implementation of Information Technology (IT) systems required by the Regulation, including the Union Product Database, which will provide information on all authorised veterinary medicines and their availability in EU Member States
	Implementing the outcomes of the implementing and delegated acts

Table 2: Benefits and EMA Responsibilities on Veterinary Medicinal Products

**The Veterinary Medicines Regulations, 2013<sup>3</sup>**

Introductory Text	Part 1
	Part 2
	Part 3
	Part 4
	Part 5
Schedule 1	Marketing Authorisations
Schedule 2	The manufacture of veterinary medicinal products
Schedule 3	Classification and supply, wholesale dealers and sheep dip
Schedule 4	Administration of a veterinary medicinal product outside the terms of a marketing authorisation
Schedule 5	Medicated feeding stuffs and specified feed additives
Schedule 6	Exemptions for small pet animals
Schedule 7	Fees

Table 3: Contents of the Veterinary Medicines Regulations, 2013

presently supervises the centralised marketing authorisation system for both human and veterinary medications.

In December 2018, the European Parliament and the European Council enacted Regulation (EU) 2019/6. It will take effect on January 28, 2022.<sup>2</sup>

**The Veterinary Medicines Directorate (VMD)<sup>4,5</sup>**

- A. Authorisation requirements
- B. Post authorisation requirements
- C. Manufacturing
- D. Selling/Marketing
- E. Using medicines
- F. Import/Export
- G. Other

**A. Authorisation Requirements<sup>6</sup>**

**I. Product Types:**

Pharmaceutical and biological products are divided into two categories.

Biological goods contain active compounds that are created or extracted from a biological source and require a combination of physiochemical and biological tests, as well as the production process and its control, to characterise and determine quality.

Biological veterinary drugs include the following items:

- An immunological veterinary drug given to animals in order to create active or passive immunity, diagnose immunity in order to desensitise them to allergens, or cause an impact based on antigen-antibody interactions.
- Veterinary medications made from plasma and blood
- Veterinary pharmaceuticals that come within Part A of Annex A to Regulation No. 2309/93

## II. Authorisation Routes:

There are five ways to get an MA in the UK, or parts of them:

- GB MA. – National
- NI MA. – National
- Centralised European procedure which will include NI
- Mutual Recognition European procedure with NI as concerned member state
- Decentralised European procedure with NI as concerned member state

These pathways govern the rules, methods, processes, and timeframes used in processing an application for a new MA. The authorisation is only valid in the territories for which it was granted, and it is subject to all applicable rules.

## III. Legal Bases:

There are numerous legal bases for requesting an MA, each reflecting the type and content of data needed to support an application.

## IV. Distribution Categories:

POM-V will be the distribution category for an extraordinary MA. For PMAs, if the product satisfies the following conditions, the distribution category can be modified from POM-V to POM-VPS:

- Has been on the market for at least a year and is currently selling well exclusively makes preventative claims
- It has a low risk of adverse events (AE) and is suspected of being ineffective (SLE)

A MAPI product's distribution category will be the same as the parent product's distribution category.

## V. Product Authorisation Number

An approved item in the UK will have an authorisation number went before by the image Vm on item documentation and naming. This means that the item has been tried and approved for use as per the headings in the item writing.

The MAH organisation number is the initial five numbers, trailed by an item number all together. The principal number of the item number component will be the region recognisable proof number:

- 4 – UK wide – Pre 2021 authorisations retaining a UK wide authorisation and these product numbers start with the number 4
- 3 – NI MA – For MAs authorised in NI only
- 5 – GB MA – For MAs valid in GB only

Focal authorisations gave by the European Commission (EC) are legitimate in all EU part states, including Northern Ireland, and will be appointed an EU MA number.

## VI. UK Public Assessment Reports (UKPARs)

In most cases, a public assessment report (PuAR) will be published on the VMD's Product Information Database (PID), along with the SPC, label text, and a post-authorisation assessment (PAA). Since a product was initially approved, the PAA has kept track of all applications submitted for it.

### B. Post Authorisation Requirements<sup>7</sup>

Guidance:

- Apply for special batch control of a pharmaceutical veterinary medicine
- Submit an application for a batch release of an immunological veterinary medication.
- Veterinary Pharmacovigilance Responsibilities for Authorisation Holders

### C. Manufacturing<sup>8</sup>

Guidance:

- Veterinary medicine manufacturing authorizations
- Production and distribution of medicated feedstuffs

### D. Selling/Marketing<sup>9</sup>

Guidance:

- Medicines for tiny pets are exempt from approval.
- Authorisation from a veterinary medicine wholesaler
- Approval of facilities for the retail distribution of veterinary pharmaceuticals by appropriately authorised individuals (SQP)
- Veterinary practitioners' registration and inspection

### E. Using Medicines<sup>10</sup>

Guidance:

- The cascade: giving unapproved medications
- Veterinary medicine
- Horse medicine
- Controlled drugs
- Bee medicine availability in the UK

### F. Import/Export<sup>11</sup>

Guidance:

- Importing a veterinary medicine into the United Kingdom
- Exporting drugs and medicines: specific rules

### G. Others<sup>12</sup>

Guidance:

- File an appeal against a VMD regulatory decision.

### European Medicines Agency (EMA), Veterinary Medicines Regulatory Information<sup>13</sup>

This section contains information about veterinary medication regulation in the European Union (EU). It is especially relevant to the centralised procedure, in which the European Medicines Agency (EMA) plays a crucial role.

The navigation menu is divided into three categories, each of which corresponds to one of the essential stages in the lifespan of a pharmaceutical product:

- A. Research and development, including maximum residue limits (mrls);
- B. Marketing authorisation.
- C. Post-authorisation.



**A. Research and Development**

The European Medicines Agency (EMA) prompts and helps organisations that are exploring and creating veterinary prescriptions. This remembers logical and administrative data for how to plan and direct clinical preliminaries, consistence guidelines, setting up greatest build-up limits for prescriptions and biocides, advancement backing, and impetuses for organisations creating drugs for minor use/minor species (MUMS)/restricted business sectors.<sup>14</sup>

**B. Marketing Authorisation**

The European Medicines Agency (EMA) is liable for coordinating intelligent assessments of bound together promoting authorisation applications (MAA). The united displaying authorisation, once yielded by the European Commission, is authentic in all European Union (EU) Member States, Iceland, Norway, and Liechtenstein.<sup>15</sup>

**C. Post-Authorisation**

The European Medicines Agency (EMA) prompts drug organizations whose therapeutic items have been endorsed in Europe on logical and administrative issues. This is alluded to as the item lifecycle's post-approval stage.

This information outlines marketing authorisation holders' responsibilities in areas such as pharmacovigilance, applying to vary a marketing authorization, submitting product data to the EMA, and reporting product defects or recalls.<sup>16</sup>

**Summary and Conclusion**

The Veterinary Medicines Regulation in the United Kingdom builds up authoritative prerequisites for the assembling, arrangement, supply, showcasing, and utilisation of veterinary medications. The Veterinary Medicines Directorate (VMD) is the public capable position and free controller in the

**Key Regulations<sup>17</sup>**

Legal controls on veterinary medicines	<ul style="list-style-type: none"> <li>The Veterinary Medicines Regulations (VIR) 2013, as revised, stay in power in the United Kingdom for the guideline of veterinary prescriptions.</li> <li>The Northern Ireland Protocol (the Protocol) expresses that Northern Ireland will keep on being dependent upon EU law.</li> </ul>
Future Veterinary Medicines Regulations	<ul style="list-style-type: none"> <li>Continued acknowledgement of specific administrative capacities acted in the EU for clusters set available by December 31, 2022 (depicted in Veterinary Medicines Directorate (VMD) Information Hub explainers)</li> <li>Many of the prerequisites starting in 2023 will be fused into the new Veterinary Medicines Regulations.</li> <li>Proposed changes to the Regulations will be dependent upon formal, public discussion in 2021, during which time Veterinary Businesses will actually want to remark (date TBC).</li> </ul>
The EU and UK Trade and Cooperation Agreement	<ul style="list-style-type: none"> <li>The EU-UK Trade and Cooperation Agreement (TCA) builds up the terms for shared acknowledgment of GMP authentications gave by NCAs for restorative items, including veterinary drugs</li> <li>In spite of the fact that clump (QC) testing isn't covered by the arrangement, the UK will singularly perceive bunch (QC) testing acted in the EU/EEA until December 31, 2022.</li> </ul>

Table 4: Key Regulations on Veterinary Products in U.K.



United Kingdom. Logical investigations directed by creature medication organisations, trailed by free administrative position assessment, guarantee that every veterinary restorative item endorsed fulfils the necessary guidelines of wellbeing, viability, and quality. This guarantees that creature drugs are ok for use, useful (compelling), and satisfy quality guidelines. These courses decide the guideline, systems, cycles, and timetables utilised in preparing an application for another MA. Once conceded, the authorisation may be substantial in the domains applied for and will be dependent upon material guideline. The dissemination class of a remarkable MA will be POM-V. An approved item in the UK will have an authorisation number went before by the symbol Vm on its item writing and marks. This shows that the item has been evaluated and endorsed for use as per the guidelines on the item writing. The initial 5 numbers are the MAH's organisation number followed by a successive item number. The main number in the item number component will be utilised to distinguish the domain. By and large, a public appraisal report (PuAR), just as the SPC, name text, and post-authorisation evaluation, will be accessible on the VMD's Product Information Database (PID) (PAA). The PAA contains a rundown of all applications finished on an item since its underlying endorsement. This segment contains data on the guideline of veterinary drugs in the European Union (EU). The European Medicines Agency (EMA) prompts and helps organisations that are exploring and creating veterinary medications. The European Medicines Agency (EMA) is accountable for leading logical appraisals of incorporated advertising authorisation applications (MAA). The European Medicines Agency (EMA) prompts drug organisations whose restorative items have been endorsed in Europe on logical and administrative issues.

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