Guidance

Marketing authorisations for veterinary medicines

Guidance for the pharmaceutical industry on Marketing Authorisations for veterinary medicines in the UK.

You need a marketing authorisation (MA) to place a veterinary medicine on the market for sale and supply in the UK. However, some animal medicines do not need an MA and some products are not considered animal medicines. For more information refer to Exemption from authorisation for medicines for small pet animals and Legal controls on veterinary medicines.

If your product does require an MA you will need to apply to the VMD.

To be a Marketing Authorisation Holder (MAH) you must meet the criteria set out in Marketing Authorisation Holders, Named Distributors, and Local Representatives of veterinary medicines.

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Product types

Products are classed as either pharmaceutical or biological.

Biological products contain active substances produced or extracted from a biological source which needs, for its characterisation and determination of quality, a combination of physiochemical-biological testing together with the production process and its control.

The following are categorised as biological veterinary medicines:

- immunological veterinary medicine administered to animals to produce active or passive immunity, diagnose the state of immunity to desensitise against allergens, or produce an affect based on interaction of antigens with specific antibodies
- veterinary medicines derived from blood and plasma
- veterinary medicines falling within the scope of Part A of the Annex to Regulation No. 2309/93

Authorisation routes

There are 5 routes that can be used to get an MA in the UK, or part of:

- GB MA - National
- NI MA – National. These are only possible if same product is not already authorised or under assessment in an EU Member State
- 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 routes determine the regulation, procedures, processes and timelines used in processing an application for a new MA. Once granted, the authorisation will only be valid in the territories applied for and will be subject to applicable regulation.

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GB MA - national

A product with a GB MA has been approved for marketing in England, Wales and Scotland. These applications will be assessed against the requirements set out within the Veterinary Medicines Regulation 2013, as amended.

NI MA - national

A product with an NI MA has been approved for marketing in Northern Ireland. These applications will be assessed against the requirements set out within the EU Regulation.

Centrally authorised products

A centrally authorised product is one that has been approved by the EC for marketing in all EU member states, including Northern Ireland.

The centralised EU procedure is compulsory for some products and optional for others. Some products are not eligible for the centralised procedure.

Mutually recognised products

A mutually recognised product is one that has been approved by the EU for marketing in 2 or more EU member states. The mutual recognition EU procedure must be used when a product is already authorised in an EU member state on a national basis and the MAH wishes to obtain an MA for the same product in other EU member states and/or Northern Ireland.

The member state that has already authorised the product is known as the Reference Member State (RMS). The RMS submits their evaluation of the product to the other member states, known as Concerned Member States (CMS), and asks to have that MA mutually recognised.

If the application is successful, the CMS' National Competent Authority will issue an MA valid in their country. Please note that Northern Ireland cannot act as RMS and products must be first authorised in an EU member state.

Decentralised

The decentralised procedure (DCP) is a European authorisation route resulting in a mutually recognised product. The difference between MRP and DCP is:

- for MRP, a product must already be authorised in a member state on a national basis
- for DCP, the product is not authorised in any member state and you wish to authorise it in several or all EU member states simultaneously - but only if the centralised procedure is not mandatory, or you do not wish to use the centralised procedure (where it is optional), or the product is not eligible for the centralised procedure

You will need to ask one of the proposed member states to act as the RMS. The RMS does the initial evaluation of the product and issues a

DRAFT

draft assessment report including a list of unresolved issued. The CMS either agree with the RMS's evaluation or they ask further questions/raise objections.

If all the issues are resolved and the application is successful, each member states' National Competent Authority issues an MA valid in their country. Please note that Northern Ireland cannot act as RMS.

Legal bases

There are several legal bases upon which you can apply for an MA which reflect the type and content of the data required in support of an application.

References refer to the VMRs 2013 (Schedule 1)).

Section of VMRs 2013 (Schedule 1, Part 1)	Data requirement
Full – Part 1	Based on a full dossier using your own data or a mixture of your own data and some bibliography
Generic – Para 10	Referring to data of an already authorised product. Reference product authorisation requirements are given below.
Generic hybrids – Para 10a	Combination of referring to data of an already authorised product and your own data to support

DRAFT

Section of VMRs 2013 (Schedule 1, Part 1)	Data requirement
	differences. Reference product authorisation requirements are given below.
Bibliographic – Para 7	Also known as well-established use. Based on referring to published data
Fixed combination – Para 8	Based on active substances already used in an authorised product but not previously used in that combination. Reference product authorisation requirements are given below.
Informed consent – Para 9	Also known as copycat. Combination of referring to data of an already authorised product and your own data. Reference product authorisation requirements are given below.

DRAFT

Section of VMRs 2013 (Schedule 1, Part 1)	Data requirement
Extension	To create a new stand-alone MA from your existing MA. Reference product authorisation requirements are given below.
Exceptional MAs	Based on provisional or limited data. The data and documents required in support of these applications is provided on our Apply for a Marketing Authorisation guidance page

Unless otherwise stated, the data and documents required in support of these applications are set out in the technical annex (manual) and Volumes 6a and 6b of the European Notice to Applicants, as amended.

Generics

You may apply for a generic MA by referring to the safety and efficacy aspects of a data package submitted in support of an already authorised veterinary medicine, which is referred to as the reference product.

The reference product must be authorised in accordance with either Part 1 of Schedule 1 and Paragraphs 7, 8 and 9 of the Veterinary Medicines Regulation and must be authorised in:

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- the UK for a GB-National MA
- the EU for a NI-National MA
- the EU for mutually recognised and decentralised procedures with NI as CMS

You cannot use a product authorised in accordance with Paragraph 10 of the VMRs, an exceptional MA or a Biological (including Immunological) veterinary medicine as a reference product.

In addition to a full quality data package, you would need to provide an environmental risk assessment for the product and a user risk assessment. The type of user risk assessment provided depends on the degree of similarity between the generic and reference products.

For generics of injectable products, the submission of injection site residues data is necessary, unless a biowaiver exempts the need for residues studies.

You must demonstrate that the generic product is bioequivalent to the reference product, unless an exemption from demonstrating bioequivalence applies. The reference product must have been authorised for at least 10 years, or part of the Global Marketing Authorisation where 10 years has lapsed from original authorisation, before the generic product can be placed on the market.

For applications for generic products, which are based on reference products authorised after October 2005 but before [xxx], the application can be submitted after 8 years of authorisation, but the generic product cannot be marketed until the 10-year data protection period has expired.

In some cases, the data protection period for the reference product may be extended to 13 years. For products indicated for the treatment of bees and fish the protection period of the reference product is automatically 13 years.

For products authorised after [xxx], the periods of data protection are:

18 years in the case of products authorised for bees

14 years in the case of products authorised for cattle, sheep (for meat production), pigs, chickens, dogs and cats (major species) and where

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the product contains an active substance which is an antimicrobial which has not been an active substance in a veterinary medicinal product previously subject to a marketing authorisation in Great Britain

10 years in the case of a veterinary medicinal product authorised for cattle, sheep (for meat production), pigs, chickens, dogs and cats (major species);

14 years for a veterinary medicinal product authorised for all other species.

The Summary of Product Characteristics (SPC) of the generic product should be essentially similar to the SPC of the reference product.

The legal distribution category (LDC) of the generic product must be the same as that of the reference product. A change to the LDC cannot be processed as part of the MA application but you can submit a variation application to change the LDC after the MA has been issued.

The global marketing authorisation concept applies when a veterinary medicinal product has been granted an initial authorisation. Then, any subsequent authorisations issued to that Marketing Authorisation Holder for products containing the same active substance, for example additional species, strengths, pharmaceutical forms, administration routes, and presentations, as well as any variations and extensions, shall be considered as belonging to the same global marketing authorisation. This means that for practical purposes the start of the data protection period is the date at which the initial authorisation is granted.

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Generic-hybrids

A hybrid MA follows the same principles as those for generic applications, but such applications are required:

- if you are not able to demonstrate bioequivalence to the reference product through bioavailability studies
- where bioequivalence can be demonstrated to the reference product, but you want to make changes to the active

substance(s), the therapeutic indications, strength or pharmaceutical form, withdrawal period, or to the route of administration.

In practical terms this means that the applicant can cite a reference product but needs to provide bridging data to account for the differences between the proposed product and the reference product. However, it is not possible for an applicant to submit a hybrid application that deletes or adds an active substance to that of the reference product cited.

Example of a Generic-hybrid MA: The reference product is indicated for use in cats and dogs and is administered orally. You want your product to include cats and dogs but want an injectable product. You refer to the reference product to cover some of the safety and efficacy data requirements but produce your own data to support the change in the route of administration.

Bibliographic

A bibliographic MA is based on an application where all parts of the data dossier are addressed using published data. This type of MA may also be referred to as an MA based on well-established use. You must demonstrate the active substance has been used for at least 10 years in the target species for the indications applied for.

It is not possible to apply for a bibliographic MA for a biological (including immunological) veterinary medicine.

Fixed combination

An application for a product containing active substances already used in an authorised product, but not previously used in that combination in an authorised product. In this case, you don’t need to provide safety and efficacy data for the individual active substances.

Informed consent (copycats)

One of the most common types of MA. Copycat is an informal term used to describe an MA authorised based on informed consent.

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For these applications you cross-refer to specific parts of the data package for an already authorised product, which is referred to as the parent product. A full Part I of the dossier must be submitted, along with the VMDS requirements, where these are not already included. Also, if applicable, a Letter of Access from parent holder; for Pharmaceutical products only, a copy of the Finished Product Specification (FPS) in the prosed product name, a statement regarding residual solvents and the European tables of materials of human and animal origin.

The parent product must be authorised in accordance with Part 1 of Schedule 1 or Paragraphs 7 and 8 of the Veterinary Medicines Regulation and must be authorised in:

- GB for a GB MA
- NI for a NI MA national or as part of an EU procedure

You cannot use a product authorised in accordance with Paragraphs 9 and 10 of the VMRs, or an exceptional MA as a parent product.

Apart from the product name, the product's authorisation number and, possibly, the MAH and pharmacovigilance systems, all the details of the proposed copycat are identical to the parent.

For a product to be authorised based on informed consent, the MAH for the parent product must give the VMD permission to refer to the data submitted in support of the parent product.

If the MAH of the parent product is different from the applicant, a formal letter of access from the parent MAH is required to be submitted as part of the application package submitted in support of the copycat. If the applicant is the MAH of the parent a formal letter of access is not required.

A parent MAH has a responsibility to notify a copycat holder when changes have been made to the parent MA. The parent MAH should provide the copycat holder with at least the categories used for the variation(s) and, ideally, the application number in order to apply for the same changes.

Extension

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An extension is a type of variation to one of your existing MAs to create a new stand-alone MA (new extension) or to change an MA (variation extension).

You must state in your application which you are applying for.

A new extension will be dealt with as a new MA application using the same procedures and timescales. A new MA is granted at the end of the procedure.

Exceptional MAs

An exceptional MA may be granted where no fully authorised product is available in the UK to prevent or treat a particular condition, following submission of a reduced data package where specific data is not available. However, you must demonstrate that the benefits of the availability of the product on the market (immediate availability in the case of a provisional MA) outweigh any potential risks.

There are 2 types of exceptional MA:

- Provisional - a provisional MA (PMA), these are normally granted to help address an urgent situation, such as a new disease. PMAs are intended to exist in the short term whilst you generate data to support a full MA
- Limited – a limited MA (LMA), a product for a limited market intended to help fill an existing therapeutic gap but where the product is not expected to be sold in vast quantities; therefore, it is unrealistic to expect you to generate full data packages and incur those costs.

A limited market is defined as a market for one of the following types of veterinary medicine:

(a) a veterinary medicine for the treatment or prevention of diseases that occur infrequently or in limited geographical areas;

(b) a veterinary medicine for an animal species other than cattle, sheep for meat production, pigs, chickens, dogs or cats;

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For Northern Ireland, eligibility for classification as a Limited Marketing Authorisation should be confirmed with the European Medicines Agency.

An Exceptional MA is reassessed on an annual basis without the need for you to submit an application or any supporting data.

This reassessment will examine all relevant data available to the VMD to confirm that the benefit:risk balance remains favourable; if not, the MA may be suspended or expired.

There is no fee to reassess an Exceptional MA.

If a formal renewal is required, this will be specified as a condition on the initial authorisation. The timing of the renewal and the supporting data to be supplied will also be specified. In these cases, a renewal fee will apply.

Distribution Categories

Distribution Categories, sometimes called Legal Categories, relate to the retail supply of the authorised product. For example, a product classified as Prescription Only Medicine - Veterinarian (POM-V) may only be supplied by a veterinary surgeon or a pharmacist and must be supplied in accordance with a prescription from a veterinary surgeon.

Further information about Distribution Categories refer to the guidance for retailers.

The distribution category of an exceptional MA will be POM-V. It is possible to apply for a change in distribution category for PMAs from POM-V to POM-VPS if the product:

- has been on the market for at least 12 months with a high volume of sales
- only makes preventative claims
- has a good record in terms of adverse events (AE) and Suspected Lack of Efficacy (SLE)

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Product authorisation numbers

An authorised product in the UK will have an authorisation number preceded by the symbol Vm on its product literature and labels. This shows that the product has been assessed and approved for use in accordance with the instructions on the product literature.

The first 5 numbers are the MAH's company number followed by a sequential product number. The first number of the product number element will be used as a territory identification number. These are:

- 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

Central authorisations issued by the European Commission (EC) are valid in Northern Ireland, and will have an EU MA number.

Post authorisation steps

Variations

To make any changes to your MA you must submit a variation application to the VMD.

Refer to Apply to change a marketing authorisation for an animal medicine.

Note - Exceptional MAs are subject to the same variation procedures as other types of MA.

Referrals

We have the authority and procedures in the UK for reviewing products and requesting changes and for taking action as a result of Pharmacovigilance data, should new data/evidence come to light.

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NI MAs and existing MAs valid UK wide authorised through EU procedures remain subject to EU Referral procedures.

UK Public Assessment Reports (UKPARs)

In most cases a public assessment report (PuAR) will be available on the VMD's Product Information Database (PID) along with the SPC, label text and a post authorisation assessment (PAA). The PAA lists all applications completed on a product since initial authorisation.

Please note that for some products originally authorised under an EU procedure and converted to a Great Britain and/or Northern Ireland authorisation on 1 January 2021, a UK Public Assessment Report (UKPAR) may not be immediately available. We will endeavour to populate this information over time.

For exceptional MAs and copycats only the SPC and PAA will be available.

For mutually recognised products the PuAR will be available from the member state that acted as the RMS for the procedure.

For centrally authorised products, the SPC, PuAR and PAA will be available on the EMA website.

How to apply

See Apply for a Marketing Authorisation for Veterinary Medicine.

Contact us

Email: postmaster@vmd.gov.uk

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