Guidance

Marketing Authorisation Holders, Named Distributors and Local Representatives of veterinary medicines

Who in the pharmaceutical industry can be a Marketing Authorisation Holder, named distributor or local representative and how to make changes to these.

The term Marketing Authorisation Holder includes holders of Veterinary Homeopathic Registrations (VHR) and veterinary medicines include veterinary homeopathic remedies.

Marketing Authorisation Holders

A veterinary medicine may not be placed on the UK market unless it is subject of a Marketing Authorisation (MA) valid in the UK. The applicant will need to demonstrate that it can meet the obligations of a Marketing Authorisation Holder (MAH) during the application process and before an MA is granted.

The MAH can be a natural person, limited company, or other body such as a partnership or charity.

The holder of the MA is responsible for the marketing of the product. The designation of a representative, such as a named distributor or local representative, does not relieve the MAH of their legal responsibility.

MAH location

For Centralised MAs, the MAH must be located in the EU for these products to be on the NI market.

For mutually recognised MAs (in NI), or national MAs (in GB or NI), the MAH must be located in either the UK or a country which the VMD has determined to have equivalent regulatory standards to the UK. This currently includes countries within the European Economic Area (EEA), given the similarity between the two regulatory regimes. The UK will

consider the equivalence of the regulatory standards of other countries on a case-by-case basis.

Proof of establishment

When applying to be an MAH for the first time, as part of your MA application you must provide:

Person	As a person wishing to be an MAH you must be a resident in GB, NI or the EU and provide proof of residency.
Limited Company	As a Limited Company you must be registered with Companies' House (or EU equivalent) and must have a physical address. PO Boxes are not acceptable. The company personnel, such as Director or Secretary, do not have to be based at the registered office and can live anywhere.
Other bodies	As a charity you must provide proof that you are registered as such with an address in GB, NI or the EU. We will accept a letter on headed paper showing the address and registered charity number (or EU equivalent) as proof of establishment. For partnerships and other bodies, you must have a registered office in GB, NI or the EU.

Company Numbers

An MAH will be given a unique 5-digit company number, which forms the first part of a product's authorisation number. The authorisation number will be preceded with a Vm for veterinary medicines or Vh for registered veterinary homoeopathic remedies and will appear on the product's labels.

Company numbers are issued by the Medicines and Healthcare products Regulatory Agency (MHRA), who keep and maintain the register of company numbers for MAHs of human and veterinary medicines.

Changes to MAH details

Once your MA is authorised, you may wish to change the details of an MAH, such as your name and address, or transfer the MA from one company to another (change to legal entity).

To change the name and / or address of an existing MAH you will need to submit a national VRNA (Variation Not Requiring Assessment), (category A.1(a)).

Changing the legal entity of the MAH is a VRA (Variation Requiring Assessment – Reduced, (category U.I.z.a) dealt with on a national basis. A change in legal entity will result in a change to the 'company number', which forms part of a product's Vm number.

When submitting a change of legal entity variation, you must provide:

- confirmation that no other aspect of the dossier has changed
- evidence that a variation to replace or change an existing Summary of the Pharmacovigilance System Master File (PSMF) has been submitted, or an explanation as to why no variation is necessary
- formal letters of transfer from the current and proposed MAH
- proof of establishment of the company – unless they already hold MAs for veterinary medicines

See Variations to MAs or VHRs and Submission of applications to an animal medicines for further guidance.

Distributors and named distributors

A distributor is authorised to be in possession of and supply veterinary medicines wholesale. They can only supply the products to which their authorisation relates and can only supply to another person who is entitled to supply that product either wholesale or retail.

You can only be a distributor if you are the holder of either:

- a marketing authorisation (MA)
- a manufacturing authorisation (ManA)
- a wholesale dealer's authorisation (WDA)

An MAH may wholesale supply products for which they hold the MA without the need for a WDA; however, they must still comply with Good Distribution Practice (GDP).

Named distributor

The MAH can designate a named distributor as part of a product's MA. This means that their name and address can appear on the labels instead of the MAH name and address, for example 'distributed by …' instead of 'Marketing Authorisation Holder …' A named distributor may also have its own branding.

The MAH is responsible for the marketing of the product and the designation of a representative, either named distributor or local representative, does not relieve the MAH of their legal responsibility.

If the ManA or WDA documentation is provided in support of including a named distributor, the name and address on the ManA or WDA documentation must be the same as the proposed named distributor in the application.

There can be more than one named distributor on an MA. The details of the product, including its name and Vm number, remain the same regardless of who is distributing the product. The only difference on the labels will be the name and address of the named distributor and, possibly, the package branding in which it is distributed in.

Details of named distributors will appear in an MA's memorandum document, which forms part of the authorisation documentation. If you don't provide us with the name and address of a proposed named distributor with an application for a new MA, it will be assumed that the MAH is the distributor. In this case, we will state 'Same as MAH' on the memorandum document.

Changes to named distributor details

To add, remove or change distributor details, you will need to submit a VRA (category U.I.z.b) which will be dealt with on a national basis regardless of whether the MA is mutually recognised (where NI is a CMS) or nationally authorised in NI and GB.

If the MAH is also the distributor, and the MAH details change, you do not need to submit a separate variation to change the distributor; however, if the distributor is no longer going to be the same as the MAH, you must state this in your application.

When submitting a change of distributor variation, you must provide:

- confirmation that no other aspect of the dossier has changed
- evidence that a variation to replace or change an existing detailed description of the pharmacovigilance system (DDPS) has been submitted, or an explanation as to why no variation is necessary
- a copy of the WDA or ManA documentation

See Variations to MAs or VHRs and Submission of applications to an animal medicines for further guidance.

Local Representatives

Local representatives and named distributors perform different roles, although a single company may perform both roles for a specific MA.

If the name and address of your MAH or a named distributor is based outside of the UK, we strongly encourage you to also include the details of a local representative. This is not a legislative requirement, but it is VMD policy and good practice to include a UK contact on the labels, so that users are able to contact someone easily to discuss any problems or concerns with the product.

The local representative may be indicated by name, postal address, telephone number and email address only. The details included on the packaging will appear in an MA's memorandum document, which forms part of the authorisation documentation.

If local representative details are not included in an application for a new MA it will be assumed that this is not required.

Changes to local representative details

To add or remove a local representative, or change the details of an existing local representative, you need to submit a VRNA (category C.10.a).

Please note, a local representative cannot be introduced or amended under VRA G.I.18.z.

See Variations to MAs or VHRs and Submission of applications to an animal medicines for further guidance.

Company mergers and acquisitions

The merging of companies can result in changes to the MAH details but can also include many other areas, such as batch release site, manufacturing sites, DDPS.

You will need to submit a change of legal entity variation for each MA affected and you can group changes, but you need to bear in mind:

- a change in legal entity will mean a new Vm number; the new number will be annotated onto the product's mock-ups and SPC during the variation procedure
- a change in batch release site may affect the mock-ups; however, you do not need to submit mock-ups for this change (see Variation applications)
- a change in batch release site, manufacturing site or DDPS will be dealt with on an EU basis for mutually recognised products (where NI is a CMS), so you cannot group these changes with change of legal entity or distributor which are dealt with on a national basis
- the standard period for implementing packaging changes is 6 months from the variation approval date. This means that products QP released from the implementation date must reflect the agreed changes.
- an MAH does not need a WDA to wholesale supply their own products, so the new company must be the named MAH, or have a WDA that covers that type of product, to be able to wholesale supply the product

Remember, you do not need to submit a change to the distributor if it is changing as a result of a change to the MAH.

Variation applications

See Variations to MAs or VHRs and Submission of applications to an animal medicines for further guidance.

SPCs, QRD and Mock-Ups

You do not need to submit revised Summary of Product Characteristics, QRD text or mock-ups for administrative national procedure changes. We

will annotate the agreed changes onto the latest authorised versions held on file and issue them back to you at the end of the procedure.

However, if you intend to make other changes to the mock-ups, you will need to submit mock-ups for assessment under a VRA G.I.15.z.

If you are unsure if any of the other proposed mock up changes require a variation, please email notification@vmd.gov.uk.

See the SPC and Product Literature page for more details.

Timetable

Details about timetables can be found on the Timetables for national applications page.