



**APPLICATION TO VARY A MARKETING AUTHORISATION:  
Variations requiring assessment (VRA)**

An incomplete application form may delay the application process.

Further guidance about this application type is available on [GOV.UK](https://www.gov.uk)

**Please note the following:**

1. The list of VRAs is available [here](#).
2. You can't include a variation not requiring assessment (VNRA) in an application involving variations requiring assessment (VRA). If you wish to apply for a VNRA, please use the VNRA application form.
3. An application for a VRA may include one or more changes to one or more products. The products must be held by the same MA holder.
4. If you are submitting an unforeseen variation (as explained in the guidance on [GOV.UK](https://www.gov.uk)), please ensure you have spoken to the VMD prior to submission to agree how the proposed change should be applied for. Not doing so may lead to your application being refused at validation.
5. If you are applying for a VRA that was previously known as an 'extension' (categories include I.I.1.a) – f), I.II.1.a) – e), and I.III.1.a)) that will be incorporated into an existing MA, please use this form. For a new standalone MA please use the 'new MA' electronic application form, available on the [VMDS](#).

## SECTION 1 - PRODUCT(S) TO BE VARIED

Authorisation Number	Product Name

Please add extra rows, if needed

## SECTION 2 – VARIATION PROCEDURE

- Single**
- One change to one product or product range
- Group**
- One change to several products or product ranges
  - Several changes to one product or product range
  - Several changes to several products or product ranges

## SECTION 3 – LABELLING, PACKAGE LEAFLET AND SPCs

If your variation affects the QRD (labelling and packaging leaflet text) and / or SPC, please provide revised versions, in editable Word format, with your application. DO NOT provide mock-ups until requested to do so, which will be once the application has been assessed.

Does your application affect the labelling, package leaflet, and / or SPC? Yes  No

## SECTION 4 – COMMENTS

Is there anything else you would like to tell us?

## SECTION 5 - APPLICATION CONTACT INFORMATION

### 5.1 Name and address of MAH:

MAH Name:

MAH Address:


### 5.2 Details of application contact:

Name:

Telephone No.

Email Address:

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The application contact must be registered as part of the company account in the Veterinary Medicines Digital Service ([VMDS](#))

### 5.3 Purchase order number (if applicable):

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### 5.4 Invoice email address:

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If you have already provided these details to the VMD's finance team, you may leave this field blank.

## SECTION 6 - DECLARATION

By ticking the 'agree' box, I confirm that the information provided in support of this application is correct at time of submission and all requirements have been fulfilled.

I understand that if any information provided in this application is later found to be false or incorrect, the Secretary of State may suspend or revoke the authorisation

**AGREE**

*Note – not ticking this box will lead to your application being refused at validation.*

**ANNEX 1 – DETAILS OF CHANGES APPLIED FOR**

Please complete the table below.

- If the fields are not big enough for you to provide all the necessary information, please add annexes to this form and ensure they are correctly referenced in the table below.

Category	Variation Reason	Timetable: Reduced (R), Standard (S) or Extended (E)	Present	Proposed

**Unforeseen variations**

For unclassified 'z' categories, i.e. Other Variation, please confirm if you have spoken to the VMD about the proposed change prior to submission.

**Justification**

PRECISE SCOPE AND BACKGROUND FOR CHANGE(S) - Include a description and background of the proposed change(s).