Common Application Form

APPLICATION FOR A NEW MARKETING AUTHORISATION FOR PHARMACEUTICAL AND BIOLOGICAL/IMMUNOLOGICAL PRODUCTS

A separate application form is required for each strength and/or pharmaceutical dosage form. Different pack sizes of the same product can be included on the same form.

SECTION 1 - PRODUCT NAME(s)

1.1. Proposed trade name of product

1.2. International Non-Proprietary Name (Generic Name)

SECTION 2 – APPLICATION DETAILS

2.1 Product Type

Please select either pharmaceutical OR Biological/Immunological

☐ Pharmaceutical

☐ Biological/Immunological - A VMP sourced from a biological source or a vaccine.

2.2 Type of Drug Substance

Please select only one

☐ Newly marketed Product with New Drug Substance

☐ Newly marketed Product with New Combination of Drugs Substances

☐ Newly marketed Product with Existing Drug Substance

☐ Re-evaluation of an Existing Product

SECTION 3 – PRODUCT DETAILS

3.1 Formulation *(provide the full formulation details)*

	Name of the substance	**Concentration in the final product**	**Description of Function** *(example, active substance, attenuated virus, adjuvant, excipient)*
1			

2			

Please add extra rows, if required.

3.2 Therapeutic Subgroup Classification (example, inactivated viral vaccine, diuretic drug)

3.3 Dosage Form (example, solution for injection)

3.4 Visual appearance including colour (example, clear, light yellow oily solution)

3.5 Target Species and Route(s) of Administration

	Target Species	**Route of Administration**	**Food-producing?** *(tick as appropriate)*
1			Yes ☐ No ☐
2			Yes ☐ No ☐

Please add extra rows, if required.

3.6 Do all active substances have the appropriate MRLs set in the species and for the route of administration(s) for which they are indicated? For example, from Codex, EU or other.

YES ☐ NO ☐

If no, please tell us what you are doing to obtain the appropriate MRL(s):

3.7 Pack type details

Please provide information of all pack types including their container and closures.

	Pack Size *(example, 100 ml)*	**Container** *(example HDPE bottle)*	**Closure** *(example, polyethylene screw-cap)*
1			
2			

Please add extra rows, if required.

3.8 Proposed shelf-life

SECTION 4 – CONTACT INFORMATION

4.1 Details of the proposed Marketing Authorisation Holder (MAH) contact:

Company Name:	
Company Address:	
Telephone No.	

4.2 Name, address and contact details of the proposed finished product manufacturer(s):

If the proposed named manufacturer is the same as the proposed MAH, simply enter 'same as MAH' in the field below.

	Name, address and telephone number	**Brief description of functions performed** *(e.g. bulk manufacturing, batch release, primary or secondary packaging)*
1		
2		

Please add extra rows, if required.

SECTION 5 – REGULATORY STATUS

5.1 Regulatory Status in Country of Origin

Provide the regulatory status in the country of manufacture and the authorisation number/reference.

5.2 Regulatory Status in Other Territories

Regulatory status of the proposed product in other countries globally, including successful or pending, rejected, withdrawn, suspended or revoked applications.

Country/Region with successful authorisations

Please add extra rows, if required.

Country/Region where applications are pending

Please add extra rows, if required.

Country/Region where applications/authorisations have been rejected, withdrawn, suspended or revoked

Please add extra rows, if required.

SECTION 6 - DECLARATION

Contact details of the person responsible for the application:

A legal representative of the applying company to take full responsibility for the application on behalf of the MAH and is answerable to the authority.

Name:	
Address (including country):	
Telephone No.	

Email Address:	

Position and Affiliation:	

I confirm that the information provided in support of this application is correct at time of submission.

I understand that if any information provided in this application is later found to be false or incorrect, the authorisation may be suspended or revoked

SIGNATURE:	
DATE:	

Note – not signing this box will lead to your application being rejected at validation.