

## NON-INTERVENTIONAL STUDY APPLICATION FORM

## MEDICINES CONTROL AGENCY

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\*Write N/A if an item is not applicable

Section 1: Study identification	
Study title	
Observation Plan, date, and version <sup>1</sup>	
Study identification, where applicable	
Purpose of the study	

1 Any translation of the observation plan should be assigned the same date and version as those in the original document

Section 2: Identification of the Responsible Person		
Name of the responsible person		
Name of the organisation, if applicable		
Address		
Telephone number		
E-mail		
Website (if applicable)		
Qualification (Medical doctor, other)		
Status	Commercial Non-commercial	
Persons the responsible person has delegated functions to <sup>2</sup>		
Name of the organisation		
Name of the person		
Function		
Professional Address		
Telephone number		
E-mail		
Website (if applicable)		

2 Repeat as necessary

Section 3: Details of location <sup>3</sup>	
Name of location	
Physical address	
Contact person including telephone and email	
Name(s) of the medical doctor (s)	
MDCG Registration number(s)	

3 Repeat as necessary

Section 4: Information on the Products under observation <sup>4</sup>	
Name of the product	
Marketing Authorisation Holder	
Manufacturer	
Marketing Authorisation Number	
ATC code(s) of medicine	
Pharmaceutical form of medicine	
Strength	
Dosage Regimen	
Route of administration/application	
Name of each active substance of medicine (INN)	
<ul> <li>Is the medicine (if applicable)?</li> <li>Immunological product (vaccine, allergen, immune serum)</li> <li>Plasma derived product</li> <li>Recombinant product</li> <li>Radiopharmaceutical product</li> <li>Herbal medicinal product</li> <li>Other, specify</li> </ul>	
Is the related product (if applicable)? <ul> <li>Medical device</li> <li>Cosmetic</li> <li>Homeopathic medicine</li> </ul> Other, specify	
Date of publication of the product information	

4 Present this information for each product to be under observation

Section 5: Information on the patients	
Medical condition or disease <sup>5</sup> the product is prescribed for	
Number of patients	

5 Present this information for each product to be under observation

Section 6: Study duration	
Total duration of the study	
Start date	
End date	

## **DECLARATION BY THE APPLICANT**

I, the undersigned have submitted all requested and required documentation, and have disclosed all information that may influence the approval of this application.

I, hereby declare that all information contained therein, or referenced by, this application is complete and accurate and is not false or misleading.

Signature of the Responsible Person

Name	Signature	Date

## **OFFICIAL USE**

Date received:	Application fee:
Comments	