APPLICATION FORM

concerning assessment of medical technologies in support of proposal for inclusion of new INNs, reimbursable INNs with extension of indication, generics with INNs not reimbursable in the List, biosimilars whose INNs are not reimbursable in the list and fixed-dose combinations in the List of International Non-proprietary Names of medicinal products as provided to insurants, irrespective of personal contribution, based on medical prescription, in the health insurance system frame, as well as of International Non-proprietary Names of medicinal products granted in national health insurance programs

1. Medicinal product identification data

Individual applications are submitted for each strength and pharmaceutical form of the medicinal product for human use.

Trade name:

International Non-Proprietary Name:

ATC Code:

MA released on:

Patent expiry date:

2. Pharmaceutical form, strength, administration route and package size

Pharmaceutical form:

Strength*:*

Administration route:

3. Data on medicinal product price

Retail price per package:

Retail price per therapeutic unit:

4. Marketing Authorisation Holder

Name of the company:

Contact person:

Address:

City:

Country:

Telephone number:

Fax number:

E-mail:

5. Medicinal product type

☐ **New INN**

☐ **Known INN with new therapeutic indication**

☐ **Associations of two or several INNs**

☐ **Biosimilar medicinal product with INN not in the List**

☐ **Generic medicinal product with INN not in the List**

6. Section of the List for which inclusion is proposed

☐ **Sub-list A**

☐ **Sub-list B**

☐ **Sub-list C**

- ☐ **Section C1**
- ☐ **Section C2**
- ☐ **Section C3**

7. Therapeutic indication

Therapeutic indication:

Minimum Daily Dose:

Maximum Daily Dose:

Average Daily Dose (DDD):

Average therapy duration (according to SmPC)

8. Data on assessment of medical technologies
(please provide for reports in France, Great Britain and Germany only)

9. Data on reimbursement in EU Member States (please consider all EU Member States)

Country:

Compensation (yes/no):

Level of compensation:

Condition for prescribing (restrictions included) (yes/no):

Prescription protocol:

I hereby declare that all details of the information provided in this application are accurate and complete.

At the same time, I fully understand that, for verification and conformation of declarations herein, the National Agency for Medicines and Medical Devices is entitled to request any corroborating documents.

It is also my understanding that, should this application be non-compliant with actual facts, I shall be liable for breach of criminal law provisions relating to misrepresentation.

10. Signature of the Applicant, stamp and date

Signature of the Applicant and stamp

Date ..../........./............