FORM I: Request for the Use of an Unlicensed Medicinal Product on a Named Patient Basis

Section A: *To be filled in by the Central Procurement & Supplies Officer responsible for Procuring the Product*

Active Ingredient *(Generic Name)*	**Strength & Dosage Form**
Proprietary Product *(Brand Name)*	**Product Code** *(SAGE number)*
Order Reference *(CPSU File Number)*	**Period Requested** *(Duration of Expiry)*

Reason for Request

- □ *Manufactured outside the European Union*
- □ *Manufactured in the European Union as unlicensed (special).*
- □ *Manufactured for export to third countries and not licensed in the European Union.*
- □ *Other (specify)*

Name & Signature *Date*

Section B: *To be filled in by the Central Procurement & Supplies Officer responsible for Regulatory Affairs*

Marketing Authorization Holder	**Country of Registration**
□ *Unlicensed (Specify Manufacturer)*	□ *Unlicensed (Specify Country of Source)*
Source *(Verified Supplier)*	**Authorised Prescriber** *(Formulary Status)*

Name & Signature *Date*

Section C: *To be filled in by Head of Department / Prescriber*

Hospital Department	**Patient Name & ID Number** *(where applicable)*

Indications for Use

Name, Registration Number & Signature *Date*

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Section D: *To be filled by the Pharmaceutical Unit of the Licensing Authority*

□ *The above mentioned product is being recommended for use by the department listed in Section C.*

Further Recommendations:

Name & Signature *Date*

Section E: *To be filled by the Licensing Authority*

The above mentioned product is approved for use by the department / entity listed in Section C for a period of:

_____*until -*_____

This approval is subject to the terms and conditions of use listed in the relative Guidelines (DH Circular xxx/xx), the Medicines Act and relative legislation, provided that any reports on relevant safety issues submitted during this period shall warrant re-evaluation of this approval, and subject further to the conditions listed hereunder.

Further Conditions:

Superintendent of Public Health *Date*

Section F: *To be filled by the Licensing Authority*

The above approval is extended for use by the department / entity listed in Section C for a period of:

_____*until -*_____

Superintendent of Public Health *Date*