FORM II: Request for use of medicinal products without a marketing authorization asrequested by specific prescribers within the Government Health Services

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)*	**Source** *(Verified Supplier)*
Quantity Requested *(Number of Packs)*	**Period Requested** *(Duration of Contract)*

Reason for Request

- □ *Product manufactured as unlicensed (special)*
- □ *Product only available from outside the EU*
- □ *Others (specify)*

Name & Signature *Date*

Section B: *To be filled in by the Central Procurement & Supplies Officer Qualified Person (QPPV)*

Marketing Authorization Holder	**Country of Registration**
□ *Unlicensed (Specify Manufacturer)*	□ *Unlicensed (Specify Country of Source)*

Name & Signature *Date*

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

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

Indication/s for Use

Name, Registration Number & Signature *Date*

FORM II: Request for use of medicinal products without a marketing authorization asrequested by specific prescribers within the Government Health Services

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 for the use of medicinal products without a marketing authorization as requested by specific prescribers, 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 (where extended approval is required)*

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*

[1] *Guidelines for the use of medicinal products without a marketing authorization as requested by specific prescribers.*