**Form III**

**Request for the use of an unlicensed medicinal product**

**by a Hospital / Clinic in the private practice**

All sections must be filled before the request is submitted.
Information is processed in accordance with the provisions of the Data Protection Act.

**Section A:** ***To be filled by Medical Director in charge of Hospital / Clinic***

| Medicinal product | Dosage form | Strength |
|---|---|---|
| | | |
| Dosage regimen | Duration of treatment | |
| | | |
| Indications for use | Reasons for requesting the medicinal product | |
| | | |
| Hospital Department utilizing medicine | Estimated Number of Patients | |
| | | |
| Wholesale dealer supplying medicine | | |
| | | |
| Authorized Prescribers (Names and Registration Numbers) | | |
| | | |

I declare that:

- The above mentioned information is correct
- There is no therapeutically equivalent licensed product to the medicine requested authorized or licensed in Malta
- I am fully knowledgeable that the medicine requested is unlicensed in Malta
- I am fully knowledgeable that the medicine requested is a 'specials' manufacture product *(delete if not applicable)*
- Full responsibility for the use of the unlicensed medicinal product is undertaken by all authorized prescribers
- All authorized prescribers have been informed of the unlicensed status of the medicinal product and their responsibilities

**Signature of Medical Director:** **Date:**

**Name of Medical Director, Registration Number and Rubber stamp:**

Requests are to be submitted to:
Pharmaceutical Unit
Office of Director General, Public Health Regulation
203 Rue d'Argens, Gzira, GZR 1368

**Section B:** ***To be filled in by the responsible person of the wholesale dealer***

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|---|
| I am aware of the obligations, as per 'Guidelines for the supply of medicinal products for human use through processes which are not covered by legislation (unlicensed products)' – DH Circular 270/06 and abide by this. |
| **Marketing Authorisation Holder and Country:**<br><br>**Source and Country:**<br><br>**Name and Signature:** **Date:** |

**Section C:** ***To be filled in by the pharmacist***

| |
|---|
| The above request for the use of an unlicensed medicinal product at _____Hospital/Clinic is being referred for approval. I am aware of the obligations as per 'Guidelines for the supply of medicinal products for human use through processes which are not covered by legislation (unlicensed products)' – DH Circular 270/06 and abide by this. |
| **Name and Signature:** **Pharmacy Council Registration Number:**<br><br>**Pharmacy name and location:** **Date:** |

**Section D:** ***To be filled in by the Pharmaceutical Unit, Office of Director General, Public Health Regulation***

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| **Recommendations:** |
| |
| **Signature:** **Date:** |

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

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|---|
| I authorize Dr. _____ to use the above mentioned medicine for a period of _____, quantity _____, for the department of_____.<br>The approved quantity is to be supplied by _____and dispensed by _____ from _____. |
| **Signature:** **Date:** |

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