**LABELLING TEMPLATE**

*[Should the product to which a Labelling document refers be prequalified, the Labelling document will form Part 5 of the WHO Public Assessment Report that will be posted on the website of the WHO Prequalification Team: medicines.*

*Please also consult the prequalification guidance documents:* Annotated Labelling Template *and* Ensuring Consistency Between Product Information Documents.

*<text> signifies text to be selected or deleted as appropriate.*

*{text} refers to information to be added.]*

**PARTICULARS TO APPEAR ON THE <OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>**

**{NATURE/TYPE}**

**1. NAME OF THE MEDICINAL PRODUCT**

{(Invented) name strength pharmaceutical form}[[1]](#footnote-1)

{Active pharmaceutical ingredient(s)}

**2. STATEMENT OF ACTIVE PHARMACEUTICAL INGREDIENT(S)**

**3. LIST OF EXCIPIENTS**

**4. PHARMACEUTICAL FORM AND CONTENTS**

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the Patient Information Leaflet before use.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

|  |  |
| --- | --- |
| **FULL TERM** | **ABBREVIATION** |
| Batch number | <Batch>  <Lot>  <BN> |
| Expiry date: <mm/yyyy> | EXP <mm/yyyy> |

**9. SPECIAL STORAGE CONDITIONS**

*[For storage conditions statements see* Section Guidance for Part 5 — Labelling — of a WHO Public Assessment Report (WHOPAR).*]*

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE <APPLICANT/SUPPLIER>**

{Name and Address}

<{tel}>

<{fax}>

<{preferably functional, i.e. not personalized, email}>

**12. <WHO PREQUALIFICATION REFERENCE NUMBER>**

**13. BATCH NUMBER**

|  |  |
| --- | --- |
| **FULL TERM** | **ABBREVIATION** |
| Batch number | <Batch>  <Lot>  <BN> |
| Expiry date: <mm/yyyy> | EXP <mm/yyyy> |

**14. <ADVICE ON> GENERAL CLASSIFICATION FOR SUPPLY**

<Medicinal product subject to medical prescription.>

<Medicinal product not subject to medical prescription.>

**15. INSTRUCTIONS ON USE**

|  |
| --- |
| **MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {NATURE/TYPE}** |

**1. NAME OF THE MEDICINAL PRODUCT**

{(Invented) name strength pharmaceutical form}

{Active pharmaceutical ingredient(s)}

|  |
| --- |
| **2. NAME AND ADDRESS OF THE <APPLICANT/SUPPLIER>** |

{Name and Address}

<{tel}>

<{fax}>

<{preferably functional, i.e. not personalized, email}>

|  |
| --- |
| **3. EXPIRY DATE** |

See 4, below.

|  |
| --- |
| **4. BATCH NUMBER** |

|  |  |
| --- | --- |
| **FULL TERM** | **ABBREVIATION** |
| Batch number | <Batch>  <Lot>  <BN> |
| Expiry date: <mm/yyyy> | EXP <mm/yyyy> |

|  |
| --- |
| **5. OTHER** |

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**{NATURE/TYPE}**

**1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

{Route of administration}

**2. METHOD OF ADMINISTRATION**

**3. EXPIRY DATE**

See 4. Below.

**4. BATCH NUMBER**

|  |  |
| --- | --- |
| **FULL TERM** | **ABBREVIATION** |
| Batch number | <Batch>  <Lot>  <BN> |
| Expiry date: <mm/yyyy> | EXP <mm/yyyy> |

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

**6. OTHER**

The name and address of the supplier (i.e. the manufacturer, company or person responsible for placing the product on the market) — or a logo that unambiguously identifies the company.

**7. Directions for use, and any warnings or precautions that may be necessary**

Directions for use, and any warnings or precautions that may be necessary

1. Trade names are not prequalified by WHO. This is the national medicines regulatory authority’s responsibility. Throughout a WHOPAR the proprietary name is given as an example only. [↑](#footnote-ref-1)