**ANNOTATED 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.

A separate text for outer and inner packaging labelling should be completed per strength and per pharmaceutical form. Different pack-sizes of the same strength can be presented in one document.

Text which will not appear in the final printed material is to be presented as shaded text.

The leaflet must be readable for the patient. The European Commission’s Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use is a useful reference document.

Where the same text for outer and inner packaging labelling is used, this should be clearly indicated in the heading and in {nature/type}. Text which is identical for different presentations should be provided only once; e.g. text of inner vial label where such vial is part of different pack-sizes.

On the printed outer packaging labelling, an empty space should be provided for the prescribed dose.

Please also consult the prequalification guidance document: 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} *[as it appears in the Summary of Product Characteristics under Section 1. See prequalification guidance:* Summary of Product Characteristics Template *and* Annotated Summary of Product Characteristics Template*.]*

{Active substance(s)}

[The reference to the active substance should correspond to the strength expressed in the name. For example:

(invented) name 60 mg capsules

toremifene (since 60 mg corresponds to toremifene, even if the active substance is actually present as toremifene citrate)

(invented) name 60 mg tablets

diltiazem hydrochloride (since 60 mg corresponds to the hydrochloride salt).]

[For mock-ups and specimens, this information may be presented on different lines of text or in different font sizes if necessary, provided that the appearance of the name is as an integrated item. For example:

(invented) name Z mg/ml solution for injection.]

[The international non-proprietary name (INN) of the active substance(s) shall be included, or, in absence of INN name, the common names should be used.

In addition, the different strengths of fixed-combination products should be presented separated by a “/”. The names of the active substances should be presented separated by a “/” and in the same order relating to the strength. For example:

(invented) name 150 mg/12.5 mg tablets irbesartan/hydrochlorothiazide.]

**2. STATEMENT OF ACTIVE SUBSTANCES**

[Expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight. Where the active substance is present as a salt, this should be clearly indicated. E.g. for the examples given above: “60 mg toremifene (as citrate)” or “toremifene citrate equivalent to 60 mg toremifene”; “60 mg diltiazem hydrochloride”.]

**3. LIST OF EXCIPIENTS**

[Express qualitatively those excipients known to have a recognized action or effect and included in the European Medicines Agency’s (EMA) guideline on Excipients in the Label and Package Leaflet of Medicinal Products for Human Use. However, if the medicinal product is a parenteral, a topical or an eye preparation or if used for inhalation, all excipients must be stated.

Additional excipients information (e.g. warnings) should be presented under this section and not under Section 7.]

**4. PHARMACEUTICAL FORM AND CONTENTS**

[Pharmaceutical form according to the full Standard Terms database of the European Directorate for the Quality of Medicines (EDQM). Contents by weight, by volume or by number of doses or number of units of administration of the medicinal product (i.e. pack size, including a reference to any ancillary items included in the pack such as needles, swabs, etc.). In case of a combined labelling text covering different pack-sizes of the same strength, each pack-size should be listed on a separate line in grey shading. For example:

28 tablets

56 tablets

100 tablets.]

**5. METHOD AND ROUTES OF ADMINISTRATION**

[Method of administration: directions for proper use of the medicinal product, e.g. “Do not swallow”, “Do not chew”, “Shake well before use”. In all cases, and especially if full details cannot be included on the outer packaging itself, a reference to the package leaflet must be made.]

Read the package leaflet before use.

[Route of administration according to the Standard terms database of EDQM.]

**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 WARNINGS IF NECESSARY**

**8. EXPIRY DATE**

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

[The expiry date printed on medicinal products stating only month and year should be taken to mean the last day of that month. Expiry dates should be expressed with the month and given as two digits, or at least three characters, and the year as four digits. E.g.: February 2007, Feb 2007, 02-2007.]

[Where applicable, shelf life after reconstitution, dilution or after first opening the container. Please refer to EMA’s Guidance on Maximum Shelf Life for Sterile Products for Human Use after First Opening or Following Reconstitution. If, however, the maximum in-use shelf life for the reconstituted product varies, depending on how, or with what, it is reconstituted, a statement on the label, such as “read the leaflet for the shelf life of the reconstituted product”, should be included.]

**9. SPECIAL STORAGE CONDITIONS**

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

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

[E.g. radiopharmaceuticals, cytostatics.]

[A reference to any appropriate collection system in place should be included in the ‘Blue Box’ on the outer packaging.]

**11. NAME AND ADDRESS OF APPLICANT/SUPPLIER**

[Including town, postal code (if available) and country name of the Applicant in the language of the text (Telephone, fax numbers or email addresses may be included (but excluding websites and emails that link to websites). Local representatives of the Applicant, if mentioned in the leaflet, may be included in the ‘Blue Box’ on the outer packaging.]

{Name and address}

<{tel}>

<{fax}>

<{email}>

**12. <WHO PREQUALIFICATION REFERENCE NUMBER> <APPLICANT/SUPPLIER>**

{………… }

**13. BATCH NUMBER**

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

**14. GENERAL CLASSIFICATION FOR SUPPLY**

<Medicinal product subject to medical prescription.>

<Medicinal product not subject to medical prescription.>

**15. INSTRUCTIONS ON USE**

[Only for medicinal products **not subject** to medical prescription only, include:

* *Indication(s).*
* *Dosage recommendations, contraindication(s) and warnings. If full details cannot be printed a reference to the package leaflet should be made, e.g. “Read the package leaflet before use”.*
* *General warnings and overdose warnings are not routinely required, but for certain medicinal products such warnings may be added.]*

**16. INFORMATION IN BRAILLE**

[Information that will appear in Braille on the printed outer packaging material should be mentioned here in normal text format (See also EMA’s Guidance concerning the Braille requirements for labelling and the package leaflet.)

**minimum particular to appear on blisters or strips {NATURE/TYPE}**

**1. NAME OF THE MEDICINAL PRODUCT**

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

*[Active substance – see guidance in section 1 of the outer packaging.]*

*[Pharmaceutical form short terms according to the current version of EDQM’s* Standard Terms *database may be used if space is limited if consistently used in all language versions.]*

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

{Name} [Full/short name of the Applicant/Supplier.]

**3. EXPIRY DATE**

See 4, below.

**4. BATCH NUMBER**

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

**4. OTHER**

[Space permitting, any other information necessary for the correct use and administration of the product can be included here, e.g. calendar days.]

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}**

[Small immediate packaging units are defined as containers sized up to and including 10 ml. On a case-by- case basis the minimum particulars could also be considered for other containers where it is not be feasible to include all the information. Such exceptional cases have to be justified, discussed and agreed with the competent authority/EMA.]

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

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

{Route of administration}

*[Pharmaceutical form short terms according to the current version of EDQM’s* Standard Terms *database may be used if space is limited, if consistently used in all language versions.] [If different labels apply to different constituents of the pharmaceutical form, the pharmaceutical form in the name on the specific label should refer only to the constituent concerned (e.g. separate label for powder vial and solvent ampoule).]*

**2. METHOD OF ADMINISTRATION**

[Method of administration: directions for proper use of the medicinal product, e.g. “Do not swallow”, “Do not chew”, “Shake well before use”. If full details cannot be included on the immediate packaging itself, a reference to the package leaflet should be made, e.g. “Read the package leaflet before use”.]

**3. EXPIRY DATE**

[Where applicable, shelf life after reconstitution, dilution or after first opening the container. Please refer to EMA’s Note for Guidance on Maximum Shelf Life for Sterile Products for Human Use after First Opening or Following Reconstitution.]

**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**

[Space permitting, any other information necessary for the correct use and administration of the product can be included here, e.g. storage conditions.]