2 December 2020
LOD/2020/MSIA/NOUMED MIRTAZAPINE-137(1)

Deputy Director
Centre of Product & Cosmetic Evaluation, PPPK
National Pharmaceutical Regulatory Agency (NPRA)
Jln. Universiti, 46200 Petaling Jaya, Selangor.
(U/P: Puan Rosilawati)

Dear Puan Rosilawati,

Declaration of Product Labeling Requirement for Outer Carton

Product	TGA Registration No.
Noumed Mirtazapine 30mg Tablet	AUST R 308469
Noumed Mirtazapine 45mg Tablet	AUST R 308471

The For Export Only (FEO) application of the above-mentioned products is referred.

We hereby declare that the labeling requirements spelled in the Drug Registration Guidance Document (DRGD) are different from the requirement of Therapeutic Goods Administration (TGA) Australian. Both products are granted marketing authorization by TGA on 7 November 2018.

Based on the TGA product labeling requirements guidance, *Standard for Labels of Prescription and Related Medicines* (page 13 of 37, *section 9)*, as attached herewith, these are the essential information to be placed on the main label (outer carton):

(a) the name of the medicine
(b) the name(s) of all active ingredients in the medicine
(c) the quantity or proportion of all active ingredients in the medicine
(d) the name of the dosage form
(e) the quantity of the medicine

In view of this, the following information required by NPRA and in accordance to DRGD would not be available on the outer carton:
(a) manufacturing date
(b) route of administration
(c) country registration number (in Malaysia)
(d) product registration holder name and address (in Malaysia)
(e) manufacturer name and address

Both products subjected to FEO application in Malaysia are to be marketed in Australia only.
The product owner, Noumed Life Sciences Ltd (Noumed) would only adhere to product labeling requirements which are approved and imposed by TGA.
Noumed refuses to change as per NPRA's requirement since these FEO products will not be placed in Malaysia. Variation application to TGA is necessary if Noumed adopts the changes required by NPRA.

Noumed does not hold Xepa, as their assigned contract manufacturer in Malaysia any liability if these FEO products do not comply with the registered particulars granted by TGA. The liability is solely borne by Noumed Life Sciences Ltd.

Thank you.

Yours sincerely,
XEPA-SOUL PATTINSON (MALAYSIA) SDN BHD

Lee Xui Kin
Regulatory Affairs Manager

cc. Mr. Ch'ng Kien Peng, Executive Director Xepa-Soul Pattinson Malaysia

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Australian Government

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

THERAPEUTIC GOODS ORDER NO. 91

Standard for labels of prescription and related medicines

I, Harry Rothenfluh, delegate of the Minister for Health and Aged Care for the purposes of section 10 of the *Therapeutic Goods Act 1989* and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of that Act, HEREBY:

(1) DETERMINE that the matters specified in this Order constitute a standard for prescription and related medicines of the kind described in section 3 of this Order.

Dated 2 August 2016

(Signed by)

Harry Rothenfluh
Delegate of the Minister for Health and Aged Care

(c) the medicine is intended only for use in a clinical setting where self-administration will not occur; or

(d) the medicine is a starter pack.

(3) If the information required on the label on the container is obscured by intermediate packaging, then the label on the intermediate packaging must include:

(a) the name of the medicine; and

(b) the name(s) of all active ingredients in the medicine; and

(c) the quantity or proportion of all active ingredients in the medicine; and

(d) the batch number of the medicine preceded by the batch number prefix; and

(e) the expiry date of the medicine preceded by the expiry date prefix; and

(f) the name of the sponsor or distributor, or a registered trademark if it readily identifies the sponsor or distributor of the medicine.

(4) If the container is enclosed in a delivery device such that it cannot be removed, the information required on its label under subsection 8(1) must be applied on the delivery device and not the container.

(5) In addition to the requirements under this section, if the medicine comprises both a medicine in a container and an article that is not a device under the provisions of the Act but is included in the primary pack for such purposes as delivery of and/or measuring the medicine, the label on the primary pack must include a description of any such articles.

9 Information to be included on the main label

(1) Subject to the qualifications and special requirements specified in this section and section 10 of this Order, the information on the main label of the medicine must include:

(a) the name of the medicine; and

(b) the name(s) of all active ingredients in the medicine; and

(c) the quantity or proportion of all active ingredients in the medicine; and

(d) the name of the dosage form; and

(e) the quantity of the medicine; and

(f) if the medicine is:

(i) an injection or infusion - the approved route(s) of administration, such as 'intravenous', 'intramuscular', or 'subcutaneous' or other phrase, word or abbreviation denoting the approved route(s) of administration; or

(ii) contained in an ampoule but is not an injection - a statement of the approved route of administration for the medicine, such as 'inhalation', 'For oral use only' or other phrase, word or abbreviation denoting the approved route(s) of administration; and

(g) if the medicine is a solution for injection, powder for injection or concentrated solution for injection and the route of administration is only for infusion – then in addition to the requirement set out in paragraph (f), the words 'for infusion' must be displayed adjacent to the name of the dosage form

(2) The name of the medicine on the main label must be presented in a continuous, uninterrupted manner and not be broken up by additional information or background text.

(3) The name of the medicine and the name(s) of active ingredient(s) on the main label must:

(a) appear as a cohesive unit by the placing of the name and quantity of each active ingredient together on separate lines of text either

(i) immediately below the name of the medicine; or

(ii) where the trademark of the medicine might be disrupted or obscured, adjacent to the name of the medicine; and

(b) not be separated by any text or graphics, except where additional information is:

(i) required or permitted by:

(A) paragraph 11(2)(j); or

(B) subsection 11(6); or

(ii) in relation to identifying the different formulations of the medicines contained in a composite pack.

(4) All text required by this Order to be on the main label must be oriented in the same direction.

(5) Subject to subsections 9(6), 9(7), 9(8) and 9(9), the name of the active ingredient(s) and the quantity or proportion of active ingredient(s) must be displayed in a text size of not less than 3.0 millimetres.

(6) Subject to subsections 9(7) and 9(8), if there are four or more active ingredients in the medicine, the names of each active ingredient, together with its quantity or proportion, may be included on a side panel or side label or on a rear panel or rear label, displayed in a text size of not less than 2.5 millimetres.

(7) If the medicine is

(a) either

(i) for use as an intravenous infusion; or

(ii) is a haemofiltration or haemodiafiltration solution; and

(b) is supplied in a flexible bag container,

then subsections 9(3) and 9(4) do not apply to the medicine and, where there are eight or more active ingredients in the medicine, subsections 9(5) and 9(6) also do not apply to the medicine.

(8) For subsection 9(6), where a medicine is:

(a) supplied as part of either a composite pack; and
(b) there are different formulations of medicine in that composite pack;
(c) (i) the total number of active ingredient in the different formulations in the composite pack are to be counted; and
(ii) if the same active ingredient is contained in two or more formulations in the composite pack, each of those active ingredients is to be counted separately

for the purposes of determining which paragraph in subsection 9(6) applies to the composite; and

(d) the required information under subsection 9(6) must be provided separately in relation to each formulation of medicine in the composite pack.

(9) Where the name of an active ingredient included in the medicine comprises an ingredient name specified in Schedule 2 to this Order, either alone or in combination with any other descriptors, then the names of all active ingredients in the medicine, together with their quantity or proportion, must be displayed in a text size of not less than 2.5 millimetres.

(10) Subsection 9(9) does not apply:

(a) where the medicine is supplied in a small container or a very small container; or

(b) after 30 April 2023.

Note: The minimum text sizes for active ingredients on labels of small containers and very small containers are less than 2.5 millimetres and specified elsewhere in this Order.

10 Qualifications and special requirements

(1) Preparations for ophthalmic use

In addition to the requirements of sections 8 and 9 above, if a medicine is a preparation for ophthalmic use, the label on the container and on the primary pack or, where subsections 10(11) or 10(12) applies, on the primary pack, must include:

(a) the name of any antimicrobial preservative in the medicine;

(b) if the medicine, other than an ophthalmic ointment, does not contain an antimicrobial preservative - the statement 'Contains no antimicrobial preservative. Use once only and discard residue' or words to that effect;

(c) if the medicine is for multidose use - a statement to the effect that 'the medicine should not be used more than four weeks', or such shorter period as specified in the approved product details in relation to the medicine, after the container is first opened;

(d) if the medicine consists of a solid ophthalmic medicine for preparing eye drops for multidose use - a statement to the effect that the medicine when prepared should not be used more than four weeks or such shorter period as specified in