

# MEDICINES CONTROL COUNCIL



## GUIDELINE FOR COMPLETION OF ANNUAL RETURNS FORM

This document has been prepared to serve as a recommendation to applicants wishing to complete and submit forms for annual returns and it is in line with the International Narcotics Control Board requirements and the provisions of the Medicines and Related Substances Act.

**REGISTRAR OF MEDICINES**  
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## GUIDELINES FOR COMPLETION OF THE ANNUAL RETURNS FORM

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## 1. EXPLAINING THE COLUMNS OF THE ANNUAL RETURNS FORM/ TABLES:

Before reading this page, please first refer to the two tables for narcotic and psychotropic substances on the next two pages. Descriptive notes are supplied in each column to explain the specific information required in the column.

### NOTES:

- \* Unless otherwise specified, “Quantity of substances” or “Quantity” means the total quantity of the active narcotic\psychotropic substances, expressed **as a base**, in both raw material form and contained in preparations/finished products. These preparations or finished products **do not include Schedule III preparations** (see definition of Schedule III products on page 5) of a particular narcotic substance. Schedule III preparations are not regarded as controlled substances anymore. (Calculations of the pure base content is explained in the section on statistics).
- 1. Please make sure that the figure supplied by you for stock held at 31 December 1997 (the previous year) and the stocks held at 1 January 1998 correspond.
- 2. The tables do not require all the information regarding stocks of drugs which you would normally have in a schedule 6 and 7 register, eg. Quantity of narcotic preparation manufacturer or sold locally or Quantity destroyed, etc. The tables should therefore not be seen as a register and the figures will not always “balance”. The information supplied by you will not be used for “checking up” or querying your activities. However, every figure required on the forms is to be used in further calculations and we rely on your accurate reporting. Please do not hesitate to contact us if you need more information.
- 3. Where the substance has been purchased locally as a raw material, please indicate the quantity as well as the name of the local supplier.
- 4. Where stocks are held or manufacture has been undertaken on behalf of another applicant, this fact should be indicated.

## 2. DEFINITIONS:

- 2.1. **Manufacturer:** means all processes, other than production, by which drugs may be obtained and includes refining as well as transformation of drugs into other drugs, eg. transformation of Morphine into Apomorphine. (For the purpose of the annual returns “Production” means the separation of opium, coca leaves, cannabis and cannabis resin from the plants which they are obtained).
- 2.2. **Narcotic Substances:** means any substances included in Schedule I and II of the Single Convention on Narcotic drugs, 1961. (See the attached list of substances under international control).
- 2.3. **Psychotropic Substance:** means any of the substances included in Schedule I, II, III and IV of the 1971 Convention on Psychotropic Substances. (See attached list of substances under international control).
- 2.4. **Preparations:** means a mixture, solid or liquid containing a narcotic or psychotropic substance.

## ANNUAL RETURNS FOR NARCOTIC SUBSTANCES FOR 1998

NARCOTIC SUBSTANCE (BASE)	Quantity held in stock at 1 January 1998  (Substance as a raw material and in preparations).		Quantity Imported  (Substance as a raw material and in preparations).		Quantity of raw material manufactured locally		Quantity of raw material purchased locally  (Please name local supplier)		Quantity Exported  (Substance as a raw material and in preparations)		Quantity used in the manufacture of :						Quantity held in stock at 31 December 1998	
	kg	g	kg	g	kg	g	kg	g	kg	g	kg	g	kg	g	kg	g	kg	g
name of the substance controlled internationally as a base eg: Morphine (not morphine sulphate)	See * on page 2.		See * on page 2. Only specify quantities of raw material/ products imported by yourself. Do not include imported goods purchase d from a local supplier.		This column is only for the few companies who manufactu re the chemical raw material locally				See * on page 2.		The amount of narcotic substance (raw material) transferred into a totally different narcotic substance which is controlled internationa lly. For example: Morphine transformed into Codeine.		See page 5 for definition of schedule II products. This is not Schedule 3 in terms of Act 101, but Schedule III in terms of the Internationa l Conventions		Transform ation of a narcotic substance into a chemical substance which is not controlled internation ally. For example: morphine to apomorphi ne.		See * on page 2.	

## ANNUAL RETURNS FOR PSYCHOTROPIC SUBSTANCES FOR 1998

**Annual Returns**

PSYCHOTROPIC SUBSTANCE (BASE)	Quantity held in stock at 1 January 1998  (Substance as a raw material and in preparations).		Quantity Imported  (Substance as a raw material and in preparations).		Quantity of raw material manufactured locally		Quantity of raw material purchased locally  (Please name local supplier)		Quantity Exported  (Substance as a raw material and in preparations)		Quantity of the raw material transformed into a different chemical substance		Quantity held in stock at 31 December 1998		
	kg	g	kg	g	kg	g	kg	g	kg	g	kg	g	kg	g	
Name of the substance controlled internationally as a base eg: phendimetrazine (not phenimetrazine bitartrate)	See * on page 2.		See * on page 2. Only specify quantities of raw material/ products imported by yourself. Do not include imported goods purchased from a local supplier.		This column is only for the few compani es who manufact ure the chemical raw material locally					See * on page 2.		The amount of the psychotro pic substance transform ed into a totally different psychotro pic or into an uncontroll ed substance.		See * on page 2.	

- 2.5. **Schedule III preparations:** Schedule III of the 1961 Convention consist of list of preparations being exempted from certain international control measures. Most of these preparations contains a schedule 7 (in terms of Act 101, 1965) narcotic substance in such a low concentration that it is excluded from schedule 7 and falls in a lower schedule eg. Schedule 2 of Act 101, 1965. Take note that not all preparations excluded from Schedule 7 of Act 101, 1965 fall into schedule III of the 1961 Convention, but only those specifically listed as schedule III. (See list of substances under international control, provided). For the purpose of the annual returns, schedule III preparations are not regarded as narcotic preparations anymore and the stocks held at 31 December must not include schedule III finished products.
- 2.6. **Uncontrolled substances:** any narcotic or psychotropic substance which is not controlled internationally. In other words, any substance which is not included in the attached list of substances under the control of the Single Convention of Narcotic Drugs, 1961 and the 1971 Convention on Psychotropic Substances.

### 3. **STATISTICS AND CALCULATIONS**

#### 3.1 **Units of mass**

Full quantities of substances and preparations of such substances must be expressed in **kilograms and grams, as percentage pure anhydrous base** of the relevant substances.

Fractions of gram must be rounded off to the next higher gram. When dealing with minute quantities of raw material consisting only of a fraction of a gram, it should be rounded off to the third decimal. Example: 7.2365 kg is rounded off to 7.237 kg and the reported as 7 kg and 237 g in the two separate columns provided in the table for kilograms and grams.

#### 3.2 **Percentage pure anhydrous base content and calculations thereof:**

For the purpose of statistics, the different forms of a substance, e.g. morphine sulphate and morphine HCl, must be reduced to a common denominator, which is in most cases the equivalent in anhydrous base expressed in grams. Please refer to tables for conversion of Narcotic and Psychotropic Substances in base form into their approximate equivalent in pure anhydrous base. (Substances not listed = 100 %).

#### 3.3 **Examples of calculations of the pure anhydrous drug content:**

##### 3.3.1. **A narcotic raw material in basic form or as a salt**

Example: Calculate the pure anhydrous drug content of 20 kilograms of Codeine Phosphate B.P. with half a molecule of water of crystallization:

Refer to the tables of percentage pure anhydrous drug content for narcotics. Codeine (1/2 H<sub>2</sub>O)Phosphate contains 74 per cent pure anhydrous Codeine base.

20 kg x 74% = 14 kg 800 g Codeine = figure to be reported on the annual returns form.

##### 3.3.2. **Preparation in tablet form**

Example: A proprietary preparation contains Amfepramone (=diethylpropion) in the form of tablets,

each containing 75 milligram of Amfepramone Hydrochloride:

In terms of pure drug content this salt contains 86 per cent pure anhydrous Amfepramone base; therefore the content in anhydrous Amfepramone base of thirty tablets are:

$$30 \times 75 \text{ mg} \times 85\% \times 10^{-3} = 1,9125 \text{ grams Amfepramone} \\ = 2 \text{ grams (rounded off)}$$

### 3.3.3. Preparations in the form of ampoules

When an injectable ampoule contains a single dosage unit, its real volume exceeds its nominal volume by a percentage which may vary depending on the nominal volume and mobility of the liquid. The quantity to be reported to the Medicines Control Council must take of the real volume of the preparation and not the nominal volume. **The real volume equals nominal volume plus recommended excess volume.**

The table below indicates the standard excess volumes used for injectable preparations depending on the volume and viscosity of the preparation.

Nominal Volume (Labelled Size)	Recommended Excess Volume:	
	For Mobile liquids	For Viscous liquids
0.5 ml	0.10 ml	0.12 ml
1.0 ml	0.10 ml	0.15 ml
2.0 ml	0.15 ml	0.25 ml
5.0 ml	0.30 ml	0.50 ml
10.0 ml	0.50 ml	0.70 ml
20.0 ml	0.60 ml	0.90 ml
30.0 ml	0.80 ml	1.20 ml
50.0 ml or more	2%	3%

(a)Example: Calculate: 10 000 ampoules of Pethidine hydrochloride 50mg per 1ml. The nominal volume is 1,0 ml and therefore real volume is 1,10 ml. This salt of Pethidine contains the equivalent of 87 per cent pure anhydrous base (refer to conversion tables):

$$\text{The contents in anhydrous Pethidine base of ten thousand ampoules is:} \\ 10\,000 \times 1,1 \times 50 \text{ mg} \times 87\% \times 10^{-3} \text{ (mg to g)} = 478,5 \text{ grams Pethidine} \\ = 479 \text{ grams Pethidine (rounded off)}$$

(b)10 000 Pethidine hydrochloride ampoules containing 100 mg per 2 ml (nominal volume):

$$10\,000 \times 2,15 \text{ (real volume)} \times 50 \text{ mg (mg/ml)} \times 87\% \times 10^{-3}$$

= 935 grams Pethidine base (rounded off)

### 3.3.4. Opium preparations

#### **A. Preparations made direct from opium:**

Opium preparations (including “medicinal opium”), extracts and tinctures of opium, must not be expressed in terms of the opium base, but in terms of **opium containing 10% morphine**.

Therefore an amount of opium preparations, extracts or tinctures, containing 1kg of morphine base is equivalent to 10 kg of opium; in other words the morphine content preparations, extracts and tinctures should be multiplied by 10 in order to calculate the amount of opium with a 10% morphine content.

EXAMPLE: 25 kg Extract of Opium for tincture B.P., containing 11,8% anhydrous morphine:

-to calculate the morphine content:  $25 \text{ kg} \times 11,8 \% = 2,95 \text{ kg morphine}$

-convert to Opium with a 10% morphine content:  $2.95 \text{ kg} \times 10$

$= 29,5 \text{ kg Opium, } 10 \% \text{ morphine content}$

Therefore 25 kg Extract of Opium (11,8 morphine content) =

29.5 kg Opium (10% morphine content), to be reported on the forms.

**B. Preparations which are not made from opium itself, but are obtained by a mixture of opium alkaloids** (as is the case of example with omnopon and papaveretum) they should be considered as morphine and expressed as such. In other words Total Extracts of Opium must be given in their morphine equivalent, which is 50%. A quantity of 1 kg of Omnopon is equivalent to 500 grams of morphine.

Example: calculate the base drug in: 100 x 1ml ampoules of Total Extract of Opium (e.g. Omnopon, Pantopon and Papaveretum) 20mg/ml. Each ampoule has a nominal volume of 1,0 ml and a real volume of 1,1 ml:

In terms of pure drug content it contains 50 per cent anhydrous Morphine base.

The contents in anhydrous Morphine of one hundred ampoules is:

$100 \times 1,1 \times 20 \text{ mg} \times 50\% \times 10^{-3}$

$= 11 \text{ grams Morphine}$

## 4. COMMON ERRORS FOUND ON THE COMPLETED FORMS:

It might be helpful to draw your attention to the most common errors found in the annual returns forms of previous years:

1. Substances, preparations, etc. are not expressed in terms of the pure anhydrous base content.
2. Stocks held at 1 January do not correspond to stocks held at 31 December of the preceding year as reported on the annual returns the year before.
3. Quantities of imported substances purchased locally are indicated as imports. Only the actual importer himself should indicate this.
4. Preparations defined as schedule III products are regarded as controlled substances.
5. Forms not returned by 28 February.