

**DEPARTMENT OF HEALTH
DEPARTEMENT VAN
GESONDHEID**
Private Bag X828
PRETORIA, 0001



**UMNYANGO WEZEMPILO
LEFAPHA LA MAPHELO**
Privaatsak X828
PRETORIA, 0001

Republic of South Africa

Republiek van Suid-Afrika

Fax : (012) 312-0051

Enquiry : Miss N Mpanza

Telephone : (012) 312-0373

Reference :

MANUFACTURER QUESTIONNAIRE

A GUIDE TO FILLING IN THE QUESTIONNAIRE

Since the distribution of the questionnaire, stakeholders have raised some questions, which have been captured below and responded to for the benefit of everyone who may be having similar queries.

A. GENERAL QUESTIONS

Question 1

Who is meant to be filling in the questionnaire?

Answer

Every Manufacturer, Wholesaler and Distributor, which is registered in terms of the Medicines, and Related Substances Act, is expected to fill in the questionnaire.

Two different questionnaires have been circulated, one for manufacturers and another for wholesalers and distributors (logistics service providers). The questionnaire was sent out to the person that is recorded as the responsible person according to the South African Pharmacy Council registration list.

Question 2

Are pharmacy buying groups or any other buying groups included in the definition of a logistics service provider?

Answer

Yes. Any group or individual that receives a logistics fee should be considered to be a logistics service provider.

Question 3.

Our company is new. There is no data for the year 2004. Should we fill in the questionnaire?

Answer

Yes. Your company should fill in the questionnaire. However your company will have to answer the question but create a row immediately below the question concerned. In the created row the time period, which is applicable, should be indicated together with an explanation to the reason for the deviation.

B. CLARITY ON SPECIFIC QUESTIONS

Question 4 - See Section 1: Company details and questions 2.3 and 2.4

What is meant by the terms patented products and innovative products?

Answer

Patented products and innovative products are used interchangeably. For the purposes of the questionnaire they refer to those products that were at some point under patent protection regardless what their patent status is presently. A product that is presently under patent protection and a product that is off patent are both included wherever the terms are mentioned.

Question 5 - See section 5: Third column

Does the question that requires the “average number of scheduled items supplied to the logistics service provider per month after April 2004” refer to:

1. The number of line items supplied or
2. The number of packs supplied

Answer

The question refers to the number of packs supplied e.g. if a manufacturer supplies only one medicine to the only logistics service provider that he pays the logistics fee to and on average 40 packs of that particular medicine have been supplied per month post 2004, the count in this case will be forty and not one. This means that 40 as a number should appear in column three of row 1. This also means that since this manufacturer only deals with one logistics service provider, only the first row of the sheet will be filled in.

For all other areas, where the question refers to the number of line items it would be clearly so indicated and where line items does not appear, the question should be read as requiring the number of packs.

It must be noted that since section 5 deals with the logistics service provider manufacturer relationship, the products referred to in this section are those that are within the ambit of the medicine pricing regulations, i.e. scheduled medicines.

In this section i.e. Section 5 a list of all companies that the manufacturer pays a logistics fee to, should be reflected.

Question 6 – See section 6

What is needed in the last two columns of section 6

Answer

The middle column requires the average number of packs of scheduled medicines distributed, that have SEP's falling in a particular category e.g. 10 to 20, in the period December 2004 – November 2005, the last column requires the average monthly value of the collective logistics fees in rands, that are associated with that particular SEP band. See example below.

ILLUSTRATION

For a company that has 4 items in the SEP range 100 to 120 and only uses one logistics service provider.

	No. Units Sold in (Dec 2004 –Nov 2005)	Man.Price	Logistics fee	SEP
Product 1	563 658	R 98.04	R1.96	R100.00
Product 2	987 326	R105.00	R2.12	R107.12
Product 3	4 256 256	R115.00	R2.30	R117.30
Product 4	2 569 801	R117.00	R2.38	R119.38

From the figures above:

- The total number of scheduled medicines supplied in the period December 2004 – November 2005 is: $=(563\ 658 + 987\ 326 + 4\ 256\ 256 + 2\ 569\ 801) = 8\ 377\ 041$
- Average number of scheduled medicines (excluding schedule zero medicines), that were distributed by your company per month to the different outlets in the period December 2004 - November 2005:

$$\frac{8\ 277\ 041}{12} = 698\ 086.75$$

- **The figure that should appear in the middle column next to the SEP range of 100 to 120 is 698 086.75 for this manufacturer**
- The total value of the logistics fee in rands, paid out by this manufacturer in the period (Dec 2004 –Nov 2005):

$$(5630658 * 1.96 + 987\ 326 * 2.12 + 4256\ 256 * 2.30 + 2\ 569\ 801 * 2.38) = 29\ 034\ 735$$

- Average value of the logistics fee attributed to the band, in the period December 2004 - November 2005

$$\frac{29\ 034\ 735}{12} = 2\ 419\ 561$$

- **The figure that should correspond with the SEP range 100 to 120 in the last column of Section 6 should be 2 419 561**

Question 7 – See Section 6

Do the SEP ranges include vat?

Answer

Yes, by definition SEP includes Vat.

Question 8 – See last column of No 4 in the logistics service provider questionnaire

I am a manufacturer but I am interested in a question that relates to the logistics service provider questionnaire. The wholesaler I know does not collect medicines from the manufacturer, instead the medicines are delivered to the wholesaler's premises, can the question be read as meaning deliver and not collect ?

Answer

Yes,

Question 9 – See Second column of Section 7 and Section 8

What does the generic name of a medicine mean?

Answer

For the purposes of the question concerned it refers to the active ingredient of the medicine.

Question 10 - See section 7 and Section 8

The last two questions are asking for the top 200 items by value and by Volume. I only have 10 items, what must I do?

Answer

If your company has less than 200 items, record only what you have. The 200 figure is a maximum and an upper limit for companies which have more than 200 items.

Should there be any queries that are not necessarily covered above, do not hesitate to contact Miss N Mpanza at the Department of Health on the contact details provided above or on mpanzm@health.gov.za