

*Government Notice No. 49 of 2023*

**THE CONSUMER PROTECTION  
(PRICE AND SUPPLIES CONTROL) ACT**

**Regulations made by the Minister under section 35 of the  
Consumer Protection (Price and Supplies Control) Act**

1. These regulations may be cited as the Consumer Protection (Pharmaceutical Products) (Maximum Mark-Up) Regulations 2023.

2. In these regulations –

“Act” means the Consumer Protection (Price and Supplies Control) Act;

“bill of entry” means a declaration, written or electronic, made by or on behalf of an importer under the Customs Act;

“classified pharmaceutical product” means a class of pharmaceutical product specified in the First Schedule;

“import” has the same meaning as in the Customs Act;

“importer”, in relation to a pharmaceutical product at the time of import, includes –

- (a) the owner of the pharmaceutical product or his agent; or
- (b) any other person who has in his possession, or is beneficially interested in, the pharmaceutical product;

“non-classified pharmaceutical product” does not include any class of pharmaceutical product specified in the First Schedule;

“pharmaceutical product” has the same meaning as in the Pharmacy Act;

“return” means a return in the form set out in the Second Schedule;

“simple drug” means such medicine or drug, the retail sale of which is authorised in any place other than in a pharmacy, as specified in the Pharmacy Act;

“type”, in relation to a pharmaceutical product, includes –

- (a) the make, brand and grade; and
- (b) where the pharmaceutical product is canned, tinned, packed or bottled, its can, tin, package or bottle, of any kind, weight or volume;

“wholesaler”, in relation to a pharmaceutical product, means a person who purchases, for the purpose of resale to a retailer, the pharmaceutical product from an importer or a manufacturer.

**3.** (1) Every importer or manufacturer of a pharmaceutical product shall, before selling or supplying the pharmaceutical product, submit to the Minister not later than 10 working days from the date of passing of the first bill of entry inwards of the pharmaceutical product, electronically through the Price Fixing Information System or, in exceptional or unforeseen circumstances, in such manner as the Permanent Secretary may determine –

- (a) a return in respect of the pharmaceutical product; and
- (b) such other particulars or documents as the Minister may require.

(2) No person shall, in respect of a consignment of a pharmaceutical product, sell or supply the pharmaceutical product unless he has submitted the return specified in paragraph (1).

(3) Every manufacturer of any pharmaceutical product shall, before selling or supplying the pharmaceutical product, submit to the Minister –

- (a) certified copies of audited final accounts for the preceding financial year and, where the accounts of the preceding financial year have not yet been audited, a return of the cost of production duly certified by an auditor pending the submission of audited final accounts; and
- (b) such other information as the Minister may require.

4. (1) The Minister shall determine the maximum mark-up applicable to any pharmaceutical product.

(2) The maximum mark-up as the Minister may determine under paragraph (1), in respect of non-classified pharmaceutical products shall, in accordance with the second column of the Third Schedule, be the percentage of the cost price which may be added to the cost price of the pharmaceutical product.

(3) The maximum mark-up for a classified pharmaceutical product shall, in accordance with the Fourth Schedule, be the percentage of the cost price which may be added to the cost price of the pharmaceutical product.

5. (1) Where an importer, a manufacturer or a wholesaler of pharmaceutical products sells any pharmaceutical product, he shall forthwith –

- (a) draw up the bill of sale in his book of sales;
- (b) sign the bill of sale drawn up under paragraph (a); and
- (c) issue the original of the bill of sale to the retailer.

(2) No retailer shall take delivery of any pharmaceutical product from an importer or wholesaler of the pharmaceutical

product unless the importer or the wholesaler, as the case may be, issues to him a bill of sale under paragraph (1).

6. (1) The cost price of a pharmaceutical product shall be determined in accordance with the exchange rate of the convertible currency at the time the importer effects payment.

(2) The importer shall, in respect of an imported pharmaceutical product, record the details specified in the form set out in the Fifth Schedule.

(3) The record referred to in paragraph (2) shall be available for inspection by the authorised officer.

(4) The importer shall keep the record for a period of at least 7 years.

7. (1) Every importer shall, prior to selling or supplying a pharmaceutical product, affix a label to every pack, packet or container of the product, indicating –

- (a) the name of the importer; and
- (b) the maximum retail price at which the product is to be dispensed, exposed, offered for sale or sold.

(2) No retailer or wholesaler shall take delivery of a pharmaceutical product unless the price label referred to in paragraph (1) is affixed thereupon.

(3) No retailer or wholesaler shall sell any free sample of a pharmaceutical product.

(4) No person shall, without the approval of the Minister, alter, erase, obliterate, remove, or tamper with, the price label affixed pursuant to paragraph (1).

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- 8.** Any person who –
- (a) for the purposes of, or in connection with, these regulations –
    - (i) furnishes any information or produces any document which he knows or ought to have known to be false or misleading in any material particular;
    - (ii) makes or causes to be made, or without reasonable excuse has in his possession, any writing which so closely resembles a document as to be likely to deceive;
    - (iii) fraudulently alters a document;
    - (iv) with intent to deceive, produces or makes use of a document which is false or misleading in any material particular or has been fraudulently altered; or
    - (v) delivers, produces, furnishes, sends or otherwise makes use of, for the purpose of determining the price of any goods, any document which is false or misleading in any material particular or which has been fraudulently altered; or
  - (b) otherwise contravenes these regulations,

shall commit an offence and shall, on conviction, be liable to a fine not exceeding 100,000 rupees and to imprisonment for a term not exceeding 3 years.

- 9.** These regulations shall come into operation on 12 May 2023.

Made by the Minister on 27 April 2023.

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**FIRST SCHEDULE**

[Regulation 2]

**CLASSIFIED PHARMACEUTICAL PRODUCTS****CLASSES**

1. Anti-acid
  2. Anti-cancer
  3. Anti-diabetic
  4. Anti-hypertensive
  5. Biological
  6. Cardiovascular
  7. Inhaler
  8. Vaccine
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**SECOND SCHEDULE**

[Regulation 2]

**PART I – RETURN**

Name of importer .....

National Identity Card no.....

Address .....

Trade name .....

Contact details .....

Telephone no. .... Mobile no. ....

Fax no. .... Email address .....

Business Registration no. ....

Value Added Tax Registration no. (VAT no.) (if any).....

Pharmaceutical product .....

Brand name .....

Category .....

Manufacturer/name of laboratory .....

European Article Number (EAN) .....

Country of origin .....

Invoice no. ....

Invoice date .....

CIF value as per invoice .....

Free On Board (FOB) .....

Insurance .....

Freight .....

Rate of exchange (as per Bill of Entry) .....

Quantity invoiced and landed .....

Date of importation (passing of first entry inwards) .....

Bill of Entry no. ....

Stock from previous consignments – .....

(a) in bonded warehouses .....

(b) on trading premises .....

### PART II – INVOICE

	<b>To be filled by applicant (Rs)</b>	<b>For office use (Rs)</b>
C.I.F. value		
Customs duty		
Cost price		
Conversion ratio		
Cost Price CIF/FOB		

I/We, .....

*(name of signatory)*

of .....

*(address)*

importer/authorised agent of the importer\* of the pharmaceutical product mentioned above do hereby certify that –



- (a) all the particulars given above are true and correct; and
- (b) no arrangement or understanding affecting the purchase price of the pharmaceutical product specified in this return has been or will be made or entered into between the importer and the exporter or by anyone on behalf of either of them by way of discount, commission, rebate, compensation, or in any other manner, other than as fully shown on the invoice and as follows –
  - (i) no application for refund of duty has been made; and
  - (ii) the Ministry of Commerce and Consumer Protection will be notified accordingly if such application is made and refund of duty obtained.

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Name	Signature
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Date

*\*Delete as appropriate.*

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**THIRD SCHEDULE**

[Regulation 4(2)]

**MAXIMUM MARK UP FOR NON-CLASSIFIED  
PHARMACEUTICAL PRODUCTS**

	<b>Maximum mark-up (%)</b>
Non-classified pharmaceutical products	30

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**FOURTH SCHEDULE**

[Regulation 4(3)]

**MAXIMUM MARK UP FOR CLASSIFIED  
PHARMACEUTICAL PRODUCTS**

<b>Import costs range (Rs)</b>	<b>Mark-up (%)</b>
Not exceeding 500	35
Exceeding 500 but not exceeding 5,000	32
Exceeding 5,000 but not exceeding 15,000	29
Exceeding 15,000 but not exceeding 40,000	26
Exceeding 40,000	26

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