

HCFI Round Table on Health and Wellness on the Interpretation of the Word “Supplied By” in Clause 23 of Schedule K of Drugs and Cosmetics Act/Rules

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Consensus Sutra: ‘Supplied’ to be read as ‘dispensed or distributed’ in Clause 23 in Schedule K of the Drugs and Cosmetics Act & Rules.

The Drugs and Cosmetics Act & Rules regulate the import, manufacture and distribution of the drugs in the country. Some drugs have been mentioned in Schedule E1, G, H, H1, X of the Drugs and Cosmetics Rules, 1945, which cannot be sold or purchased without proper license; they are commonly known as Scheduled Drugs. All Scheduled Drugs cannot be purchased by anybody without prescription of the registered medical practitioner. The various provisions relating to licence, sale, manufacture, etc., of the Scheduled Drugs are enumerated in Chapter IV of the Drugs and Cosmetics Rules, 1945.

However, there is an exception to the above i.e., Rule 123 of the Drugs and Cosmetics Rules, 1945 which provides that the provisions of Chapter IV of the Drugs and Cosmetics Rules, 1945 are not applicable to drugs mentioned in Schedule K to the extent specified in Schedule K of the Drugs and Cosmetics Rules, 1945.

In Schedule K of the Drugs and Cosmetics Rules, 1945 there is one Clause 23 as per which Drugs **supplied** by Multipurpose Workers attached to Primary Health Centres/Sub-Centres, Community Health Volunteers under the Rural Health Scheme, Nurses, Auxiliary Nurse, Midwives and Lady Health Visitors attached to Urban Family Welfare Centres/Primary Health Centres/Sub-Centres and Anganwadi Workers are exempted from the provisions of Chapter IV of the Act and the Rules there under which require them to be covered by a sale licence, **provided the drugs are supplied under the Health or Family Welfare Programme of the Central or State Government.**

Time and again there has been lot of debate as to the interpretation of Clause 23 of Schedule K of the

Drugs and Cosmetics Rules, 1945 as the word used in Clause 23 is ‘Supplied’ as firstly the multipurpose workers cannot supply any drugs as they are not registered medical practitioner and secondly, if they are supplying the drugs, then the patient has to pay relevant prevailing tax on the price of the drugs.

So, to understand the interpretation of the word “Supplied” in Clause 23 of the Schedule K of the Drugs and Cosmetics Act & Rules, Heart Care Foundation of India (HCFI) Round Table on Health and Wellness: Building Consensus discussed this issue in its Round Table meeting. After numerous discussions and deliberations, HCFI Round Table on Health and Wellness came out with its consensus statement, which is reproduced hereunder:

⇒ **The HCFI Round Table on Health and Wellness: Building Consensus** was held on 21st June 2019 at 4 pm, at the PHD Chambers of Commerce and Industry, PHD House, Siri Fort Institutional Area, August Kranti Marg, New Delhi - 110016 on the subject **“Interpretation of the word ‘supplied by’ in Clause 23 in Schedule K of the Drugs and Cosmetics Act & Rules”.**

The following consensus was made:

⇒ Under the Clause 23 in Schedule K, of the Drugs and Cosmetics Act, 1940, the health care workers have been empowered to give malaria drugs (by Malaria workers); gentamicin and methergine (by Asha workers), etc.

WHAT IS CLAUSE 23?

“Drugs **supplied** by Multipurpose Workers attached to Primary Health Centres/Sub-Centres: (i) Community

Health Volunteers under the Rural Health Scheme; (ii) Nurses, Auxiliary Nurse, Midwives and Lady Health Visitors attached to Urban Family Welfare Centres/Primary Health Centres/Sub-Centres and (iii) Anganwadi Workers.

Exemptions: The provisions of Chapter IV of the Act and the Rules there under which require them to be covered by a sale licence, **provided the drugs are supplied under the Health or Family Welfare Programme of the Central or State Government.**

WHAT WAS THE CONSENSUS?

"In Clause 23 of Schedule K in the Drugs and Cosmetics Act, 1940, (i) the word 'supplied' should be read as synonymous with 'dispensed' and/or 'distributed'."

BASIS OF INTERPRETATION

- Rule 123 of Drugs and Cosmetics Rules, 1945: "The drugs **specified in Schedule K** shall be exempted from the provisions of Chapter IV of the Act and the Rules made there under, to the extent and subject to the conditions specified in that schedule."
- Under Medical Council of India Code of Ethics Regulations Clause 6.3: *"Running an open shop (Dispensing of Drugs and Appliances by Physicians):*

A physician should not run an open shop for sale of medicine or for dispensing prescriptions prescribed by doctors other than himself or for sale of medical or surgical appliances. (The word dispensing here is synonymous with prescribing and dispensing).

- Clause 3.7.1 of the Indian Medical Council (Professional Conduct, Etiquettes and Ethics) Regulations, 2002 provides that: 3.7.1 "A physician shall clearly display his fees and other charges on the board of his chamber and/or the hospitals he is visiting. The **prescription should also make clear if the Physician himself dispensed any medicine. (The word dispensed here is synonymous with supplied).**
- **Non-Schedule Drugs** i.e., drugs other than drugs mentioned in Schedule H, H1, X (for Modern Systems of Medicine), and Schedule E for (Indian Systems of Medicine), of the Drugs and Cosmetics Act & Rules requires **no licence to sell or prescribe.**
- **Essential Commodities Act, 1955:** Any State Government has the powers to control production, supply, distribution of essential commodities including **drugs as specified** in Clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940.

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