THE HCFI ROUND TABLE ON HEALTH AND WELLNESS: BUILDING CONSENSUS

Minutes of the Second Meeting, held 17th MAY 2019 at 4 pm, at the
at the PHD Chambers of Commerce and Industry, PHD House,
SIRI FORT INSTITUTIONAL AREA, AUGUST KRANTI MARG,
NEW DELHI 110016

The 2nd Meeting of HCFI Round Table Committee on Health and Wellness: Building Consensus, convened on 17th May, 2019, under the Chairmanship of Dr. KK Aggarwal, Padma Shri Awardee and was attended by following:

1. Dr. KK Aggarwal, Padma Shri Awardee
2. Ms. Meenakshi Datta Ghosh
3. Mr. Bejon Kumar Misra
4. Mr. Anil Khaitan
5. Mr. B. R. Sikri (Also representing Mr R.C. Juneja)
6. Dr. KK Kalra
7. Ms. Balbir Verma
8. Dr. Girshar Gyani
9. Dr. NV Kamat
10. Dr. (Major) Prachi Garg
11. Ms. Ira Gupta, Advocate
12. Mr. Saurabh Aggarwal

Dr. KK Aggarwal welcomed in Committee, members of HCFI Round Table and all participants present. He stated that this HCFI Round Table on Health and Wellness: Building Consensus, is an initiative of the Heart Care Foundation of India, a registered charitable trust. The mission of this Round Table is to consistently keep building consensus in respect of health issues, in public interest, and in consultation with eminent stakeholders of the society, on diverse aspects of governance, policy and program.

Dr. KK Aggarwal stated that ab initio, it would help if we can take a view for instance, that this Round Table should meet perhaps on the third Friday of every month, in order to deliberate health related governance, policy and programme. With an eye on public interest, the Round Table would invite suggestions from diverse stakeholders for examination and deliberation.

Dr. KK Aggarwal placed on record that the Founding Members of the HCFI Round Table are Dr K K Aggarwal, Mr. Bejon Misra, Mr. Praful D Sheth, Mr. Anil Khaitan, Ms. Meenakshi Datta Ghosh, Dr N K Ganguly and Mr. R C Juneja. The Round Table would co-invite Persons of Eminence from time to time, to participate in this Forum.

Dr. KK Aggarwal invited all members present to introduce themselves, and thereafter, opened the meeting for discussions.

ITEM NO. 1

CONFIRMATION OF THE MINUTES OF THE LAST MEETING

The Minutes of the meeting held at IIC on 19th April, 2019, were confirmed by Shri Bejon Misra and seconded by Sh Anil Khaitan.

ITEM NO. 2

ATR ON THE MINUTES OF THE LAST MEETING

A second meeting of the HCFI Round Table was scheduled on 17th May, 2019 at the PHD Chambers, Siri Fort Institutional Area, New Delhi.

ITEM NO. 3

REGRETS RECEIVED FROM THOSE UNABLE TO ATTEND

Dr S Y Quraishi, Mr Alok Mehta, Mr Amod Kanth, Dr N K Ganguly, Dr Narottam Puri, Mr Nikhil Rohatgi, Mr Dr A K Dhariwal, Dr Ganesh Mani, Mr R C Juneja, Mr P D Sheth, Mr Rakesh Mehta.

ITEM NO. 4

INDUCTION OF NEW MEMBERS

Dr PP Sharma and Sh. Rajiv Nath were nominated by Members of the HCFI Round Table.

ITEM NO. 5

INTERPRETATION OF CLAUSE 23 IN SCHEDULE K, of THE DRUGS AND COSMETICS ACT AND RULES

Clause 23 in Schedule K, of the Drugs and Cosmetics Act, 1940 is fraught with ambiguity. This Round Table will identify these ambiguities, to determine how these should be addressed and resolved. This would impact health governance positively.

Towards this end, several questions have been identified below, along with the relevant legal provisions:

Question I: *Under any / all of the national or the state health programs does the government envisage empowering, enabling and allowing health-care providers to dispense, prescribe, distribute, and supply drugs and medicines, as per defined standard treatment protocols?*

Relevant Legal Provisions of the Drugs and Cosmetics Act and Rules:

1. 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

2. Clause 23 of Schedule K of Drugs and Cosmetic Act and Rules states that:

"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.

Ambiguity: In Clause 23 of SCHEDULE K in the Drugs and Cosmetics Act, 1940, (i) the word "supply" appears to be synonymous with the words `dispense', `prescribe', and `distribute'. (ii) Have any of the above health workers been

already authorised to " supply" drugs and medicines under national government health programs?

Question II:

Has Clause 23 of Schedule K been applied to any government (national or state) health program? Under central government and state government run national health programs, are health-care providers and health care workers authorized to prescribe and dispense drugs? Is any such authorization limited to supplying and distributing drugs in keeping with the standard treatment protocols? Example, under the national TB programme, is a nurse authorised, in the absence of doctors, to prescribe and administer anti-vomit medication to a TB patient? Which drugs and medicines has the ASHA worker been authorised to dispense? To what extent is the ANM authorised to handle/perform child-birth? Is the ASHA or the ANM permitted to give Injection Gentamycin to a neonate suspected of sepsis, or Injection Methargin to a PPH patient before transferring her to a higher,better equipped healthcare facility? Are malaria workers allowed to dispense anti malaria drugs to a patient with chills and rigors?

3. Under Medical Council of India 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.

Question III:

Is it unethical for a physician to prescribe or supply drugs, remedies or appliances as long as there is no exploitation of the patient?. Drugs prescribed by a physician or brought from the market for a patient should explicitly state the proprietary formulae as well as generic name of the drug.

Question IV:

Is there consensus within the Round Table on whether the word `supplied' applies as follows: (i) Malaria workers are allowed to dispense anti malaria drugs to a patient with

chills and rigors; (ii) Asha workers or an ANM are permitted to give Inj Gentamycin to a neonate suspected of sepsis or Inj Methargin to a PPH patient before transferring to a higher center; (iii) ANMs are allowed to supply contraception.

4. **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 and Rules requires no license to sell or prescribe.

Question V:

Can these non-schedule drugs be incorporated into ongoing (and future) central government and state government healthcare programs, and further, can these be administered by health-care providers.

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5. **Essential Commodities Act:** The said Act was established to ensure the delivery of certain commodities or products, the supply of which if obstructed owing to hoarding or black marketing, would affect the normal life of the people.

Question VI: *The HCFI Round Table observed that typically, national and state health programs address pandemics, infectious diseases, and other potential significant conditions of ill-health. Example, absence of hundred percent coverage of immunization for measles if not appropriately handled, could endanger the lives of healthy members of society. Should the HCFI Round Table recommend that in such situations, and in keeping with Section 3 of the Essential Commodities Act, government should invoke The Essential Commodities Act on a case to case basis for maintaining and/or increasing the supplies and availability of drugs and medicines. Should the HCFI RT further recommend that in the event of a national /state health emergency, these powers should be invoked to direct universal use of standard treatment protocols. Third, over and above the national and state health programs, government can identify diseases of national importance, and incorporate these and their respective treatment protocols, under Essential Commodities Act, within the ambit of Schedule K.*

Item 5: **Deliberation in the Round Table**

The fact that the word ' supplied' in Clause 23 of Schedule K of the Drugs and Cosmetic Act is used synonymously with the word 'dispensed', 'prescribed', 'distributed', needs to be addressed.

One, the word "supplied" in Clause 23 of Schedule K of the Drugs and Cosmetics Act and Rules must be rigorously defined.
Two, should the scope of the expressions `supply' or `supplied' be limited only to giving and distributing (as in condoms, for contraception)?
Three, in actual practice, has the scope of the expressions `supply' or `supplied' been extended to include for instance, administering a drug (as in giving injections, etc)? In that event, which health worker has been / should be specifically empowered to carry out this function of administering the drug.
Four, in actual practice, has the scope of the expressions `supply' or `supplied' been extended to include dispensing and prescribing, as well?

It is for consideration if the HCFI Round Table should file an RTI application with the Office of Drug Controller General of India, Union Ministry of Health and Family Welfare, seeking specific information on the following:

1. Precise meaning of the words "supply" and "supplied", as used in Clause 23 of Schedule K of the Drugs and Cosmetics Act and Rules. If the scope of the words "supply" and "supplied" are being routinely extended to also include the functions of "dispensing" or "prescribing", then this fact ought to be specified, and the respective rights and duties of the health worker so authorised need to be clearly defined.

2. A listing of all government programmes in which this Clause 23 of Schedule K has been applied?
3. A listing of all government programmes wherein health workers are being allowed to dispense drugs and medicines? Have these health workers been specifically authorised?
4. Are government employed health workers authorised to prescribe and dispense drugs?

ITEM NO. 6

UTILISING THE SKILLS and TRAINING of TECHNICIAN and/or PARAMEDIC TRAINED BY A DOCTOR

Question: Can technicians and/or paramedics, trained by doctors and registered medical practitioners be treated at par with the qualified technician?

Relevant Legal Provisions

Clause 7.10 of the Indian Medical Council (Professional Conduct, Etiquettes and Ethics) Regulation, 2002 provides that:

A registered medical practitioner shall not issue certificates of efficiency in modern medicine to an unqualified or non-medical person.

(Note: The foregoing does not restrict the proper training and instruction of bonafide students, midwives, dispensers, surgical attendants, or skilled mechanical and technical assistants and therapy assistants under the personal supervision of physicians.)

Deliberation in Round Table :

The present situation is restrictive. Should this Round Table recommend to the Medical Council of India (MCI) that a policy change is in order?

ITEM 7

CAN A DOCTOR DISPENSE DRUGS, APPLIANCES, DIETARY PRODUCTS AND CHARGE FOR IT?

Relevant Legal Provisions

1. 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.

2. Clause 6.3 of the Indian Medical Council (Professional Conduct, Etiquettes and Ethics) Regulations, 2002 provides that:
   Running an open shop (Dispensing of Drugs and Appliances by Physicians): - A physician should not run an open shop for sale of medicine for dispensing

prescriptions prescribed by doctors other than himself or for sale of medical or surgical appliances. It is not unethical for a physician to prescribe or supply drugs, remedies or appliances as long as there is no exploitation of the patient. Drugs prescribed by a physician or brought from the market for a patient should explicitly state the proprietary formulae as well as generic name of the drug.

3. <u>Clause 5 of the Schedule K of the Drugs and Cosmetics Rules Schedule K:</u>

Drugs supplied by a registered medical practitioner to his own patient or any drug specified in Schedule C supplied by a registered medical practitioner at the request of another such practitioner if it is specially prepared with reference to the condition and for the use of an individual patient provided the registered medical practitioner is not a) keeping an open shop or b) selling across the counter or c) engaged in the importation, manufacture, distribution or sale of drugs in India to a degree which render him liable to the provisions of Chapter IV of the Act and the rules thereunder are exempted under all the provisions of Chapter IV of the Act and the Rules made thereunder, subject to the following conditions:

(1)The drugs shall be purchased only from a dealer or a manufacturer licensed under these rules and records of such purchases showing the names and quantities of such drugs together with their batch numbers and the names and addresses of the manufacturers shall be maintained. Such records shall be open to inspection by an Inspector appointed under the Act, who may, if necessary, make inquiries about purchases of the drugs and may also take samples for test.

(2) In the case of medicine containing a substance specified in 1 [Schedule G, H or X] the following additional conditions shall be complied with]:

(a) the medicine shall be labeled with the name and address of the registered medical practitioner by whom it is supplied;

(b) if the medicine is for external application, it shall be labeled with the words 2 “For external use only” or if it is for internal use with the dose;

(c) the name of the medicine or ingredients of the preparation and the quantities thereof, the dose prescribed, the name of the patient and the date of supply and the name of the

person who gave the prescription shall be entered at the time of supply in register to be maintained for the purpose;

(d) the entry in the register shall be given a number and that number shall be entered on the label of the container;

(e) the register and the prescription, if any, on which the medicines are issued shall be preserved for not less than two years from the date of the last entry in the register or the date of the prescription, as the case may be.

(3)The drug will be stored under proper storage conditions as directed on the label.

(4) No drug shall be supplied or dispensed after the date of expiration of potency recorded on its container, label or wrapper or n its container, label or wrapper or in violation of any statement or direction recorded on such container, label or wrapper.

RT Members may kindly forward their views on the following:

1. A registered doctor may prescribe or supply drugs, remedies or appliances as long as the supply is transparent and does not include exploitation of the patient. [Here, we need to define "exploitation of the patient"].
2. It is not unethical to charge appropriately for supply under the prevalent income tax laws. The term "Remedies" includes plans, courses, counseling, diet products, life-style choices.

ITEM NO. 8

REGULATION OF VAPING PRODUCTS

(Electronic Nicotine Delivery Systems)

Question: 1

Should the vaping products be banned or should they be permitted and regulated?

Relevant legal Provisions:

Preamble of the Cigarettes and Other Tobacco Products Act states that:

"An Act to prohibit the advertisement of, and to provide for the regulation of trade and commerce in, and production, supply and distribution of, cigarettes and other tobacco products and for matters connected therewith or incidental thereto.

AND WHEREAS, it is expedient to prohibit the consumption of cigarettes and other tobacco products which are injurious to health with a view to achieving improvement of public health in general as enjoined by article 47 of the Constitution"

Article 47 of the Constitution of India, 1950 :

Article 47 of The Constitution of India is one of the Directive Principles which directs the State to raise the level of nutrition and the standard of living and to improve public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of intoxicating drinks and drugs which are injurious to health."

RT Members may kindly forward their views on the following:

1. The Preamble of COPTPA read along with Article 47 of the Constitution of India, does indicate that it may be more appropriate at this stage, to regulate Vaping Products under a separate jurisdiction.
2. Members of the Round Table may kindly contribute their time and expertise to develop the contours of a draft Regulation, for deliberation in the next meeting.

ITEM NO. 9

NOTIFICATION OF DISEASES:

Dengue, TB, and other diseases needs to be notified at the level of suspicion and not only at the stage of confirmation.

Discussion:

Notifiable diseases are diseases of public importance and require notification in the event of actual as well as suspected cases.

Once notified, (i) the onus is on the state or the central government to immediately put in place some systems whereby diagnosis is confirmed, after which treatment must commence. (ii) Further, the onus is also on government to ensure that all steps are being simultaneously taken to arrest further spread of the disease, within the community.

What is the change in policy and practice being proposed? Beyond dengue, what are the other restrictive practices and policy currently in place?

Dengue: The government should not insist of confirmatory test like ELISA in dengue. The onus of confirmatory test should be on the government and not the patient.

Should the Round Table make specific recommendation in this respect. Please share feed-back, so that we can build consensus.

ITEM NO. 10

AYUSHMAN ONLY HOSPITALS/ OPDs

RT Opinion: The Round Table will prepare a draft for feasibility of an Ayushman Hospital, i.e. a 100 bedded hospital with 80% occupancy and 300 daily OPD attendance . The draft will examine if this would be at all viable, given the prevailing Ayushman Rates. What additional steps may need to be taken to make this viable.

ITEM NO. 11

TOPICS SUGGESTED BY RT MEMBERS:

Following are the topics which are suggested by Members of the Round Table, for examination and building consensus:

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1. Advertisement of sub-standard and spurious products
2. Abolition of NPPA i.e. pricing policy of drugs in India
3. Guidelines and SOPS in Clinical Establishment Act
4. How to bill if the doctor dispenses the drugs to his own patient?

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5. Is GST applicable on doctor if he dispenses the drugs to his own patients?

ITEM NO.12

REMAINING ITEMS / TOPICS OF THE AGENDA OF MEETING

Following items / topics of the agenda of the 2nd Meeting of Round Table were not discussed and considered due to paucity of time and the same will be discussed in next meeting:

i. Why export and national units for drug manufacture differ in quality?
ii. WHO advice on screen time for children under five?

ITEM NO. 13

THIRD (3RD) MEETING OF ROUND TABLE : The third (3rd) Meeting of Round Table has been discussed and decided to be held on 21st June, 2019 i.e. the 3rd Friday of June, 2019 at MOHTA room, PHD Chambers of Commerce and Industry, PHD House, 4/2, Siri Institutional Area, August Kranti Marg, New Delhi – 110016 at 4pm to 6pm.

VOTE OF THANKS: The meeting ended with Vote of Thanks.