MINUTES OF THE 89TH MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 10.05.2023 AT 2.30 P.M. IN RESOURCE CENTRE (445-A), DGHS, NIRMAN BHAWAN, NEW DELHI (THROUGH HYBRID MODE)

PRESENT

1.	Prof. (Dr.) Atul Goel, Director General of Health Services, Nirman Bhawan, New Delhi	Chairman
2.	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India), FDA Bhawan, New Delhi	Member
3.	Dr. Saroj Kumar Ghosh, Director (I/C), Central Drugs Laboratory, Kolkata (Attended Online)	Member
4.	Dr. P Dhar, Principal Scientist, IVRI, Bareilly, U.P. (Attended Online)	Member
5.	Dr. Montu M. Patel, President, PCI	Member
6.	Dr. Radha Rangrajan, Director, Central Drug Research Institute, Lucknow (Attended Online)	Member
7.	Dr. Sudam P Khade, Commissioner and Controller, FDA, Madhya Pradesh (Attended Online)	Member
8.	Dr. Hemant Koshia, Commissioner, FDCA, Gujarat (Attended Online)	Member
9.	Dr. Navin Sheth, Elected Member (PCI) (Attended Online)	Member
10.	Shri. Sudhir Mehta, Chairman, Torrent Pharmaceuticals (Attended Online)	Member
11.	Dr.Jerin Jose Cherian, Scientist D, Division of Basic Medical Sciences, ICMR	Member
12.	Shri. Gopal S. Magadum, Govt. Analyst, Karnataka	Member

13. Smt.J. L. Makwana, Member
    Govt. Analyst, Food & Drugs Laboratory,
    Vadodara, Gujarat (Attended Online)

CDSCO REPRESENTATIVE

1. Shri. A. K. Pradhan
   Joint Drugs Controller (I), CDSCO (HQ), New Delhi
2. Dr. Santosh Indraksh
   Assistant Drugs Controller (I), CDSCO (HQ), New Delhi

The Board meeting was conducted through hybrid mode. Dr. Rajeev Singh Raghuvanshi, DCG(I), Member-Secretary, DTAB welcomed the Chairman of the Board Prof. (Dr.) Atul Goel, DGHS and all the esteemed members participating through physical and online mode for sparing their valuable time to deliberate some important agendas. The Chairman of the Board greeted and had a brief introduction from all the members.

Thereafter, with the permission of the Chairman, DCG(I) Dr. Rajeev Singh Raghuvanshi initiated the agenda-wise proceedings of the meeting for its deliberations.

AGENDA NO. 1

ACTION TAKEN REPORT (ATR) FOR 88th DTAB MEETING HELD ON 26.09.2022

The Action Taken Report (ATR) on the recommendations of DTAB in 88th meeting was approved by the Board.

However, with respect to agenda No. 4 of 88th DTAB, the Board desired that the Chairman of the Committee should make presentation on evaluation of Fixed Dose Combinations (FDCs) related to vitamins, minerals formulations, etc. considered as irrational, before DGHS in a week's time.

AGENDA NO.2

CONSIDERATION OF THE PROPOSAL REGARDING REPRESENTATION OF P & G TO REVOKE THE BAN ON THE USE OF FIXED DOSE COMBINATION OF VITAMIN B1, B6 AND B12

A representation was received from a firm requesting to reconsider the lifting off the "prohibition of manufacture, sale or distribution of the Fixed Dose Combination (FDC) of Vitamin B1, Vitamin B6 and Vitamin B12".

The firm had submitted that as science has advanced, other levels of quantitative composition (B1, B6, B12) have been studied. MoHFW /CDSCO was requested by the firm to lift the ban of all FDC (B1, B6, B12) and open to evaluate FDC with different quantitative compositions for their specific indications. There are ample published clinical studies which support the fact that the FDC of (B1, B6, B12) has strong therapeutic rationale.

The firm also stated that many clinical studies were conducted using different quantitative levels of FDC for various indications such as Vitamin B deficiencies, neuropathy of different etiologies (diabetes, repetitive stress or trauma like in carpal tunnel syndrome,

alcohol abuse, autoimmune diseases (eq. Rheumatoid Arthritis), Chronic Inflammation and Vasculitis) and other diseases affecting the nervous system.

Further, it was informed by the firm that products with different level of FDC of neurotropic vitamins (B1, B6, B12) are marketed for more than 50 years worldwide and are well established and extensively used in clinical practice, available mainly Over The Counter (OTC) but also on prescription depending on vitamin strengths and application route by several marketing authorization holders.

The firm has also received approval from Hungary, Czech Republic and Indonesia with same formulation and same indication.

The Board was apprised that the FDC of Vitamin B1, Vitamin B6 and Vitamin B12 was banned in India *vide* Gazette notification no. G.S.R. 702(E), dated October 14, 1999 *w.e.f.*01.01.2001 on the basis that the said FDC did not have therapeutic value claimed or purported to be claimed for it.

DTAB deliberated the matter and opined that the justification and documents are not adequate for revocation of prohibition of manufacture, sale or distribution of the Fixed Dose Combination (FDC) of Vitamin B1, Vitamin B6 and Vitamin B12 and therefore the Board did not agree for the revocation.

AGENDA NO.3

CONSIDERATION OF AGENDA ON USE OF INDUCED PLURIPOTENT STEM CELL (iPSC) ADDITIONAL TESTING METHODS OTHER THAN ANIMAL TESTING ETC. TO INVESTIGATE THE SAFETY AND EFFICACY OF A NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Board was apprised that representation was received from the stakeholder involved in Research & Development requesting suitable changes in Rules, enabling adoption of iPSC and related technologies.

The US House of representatives had passed the FDA Modernization Act as a rider to a larger package of FDA related reforms.

The FDA Modernization Act, 2.0, a law passed on 29.12.2022 allows drugs to progress to human studies if they have been tested on any of the following models:

1. Cell-based assay
2. Organ chips and microphysiological systems
3. Sophisticated computer modelling
4. Other human biology-based test methods
5. Animal test

Considering the matter, the New drugs and Clinical Trials Rules,2019 was amended by MoHFW through Gazette Notification published vide G.S.R. 175(E) dated 9th March, 2023, allowing additional testing methods other than animal testing etc. to investigate the safety and efficacy of a new drug or investigational new drug.

DTAB deliberated and ratified the amendment published vide G.S.R. 175(E) dated 9th March, 2023.

AGENDA NO.4

CONSIDERATION OF PROPOSAL FOR BAN ON THE VET DRUGS KETOPROFEN AND ACECLOFENAC FOR TREATMENT OF LIVESTOCK ANIMAL TO CONSERVE VULTURE

The Board was apprised that representation was received requesting for ban on veterinary drugs Ketoprofen and Aceclofenac for treatment of livestock animals to conserve vultures.

In the representation, it was mentioned that Ketoprofen and Aceclofenac in cattle is equally toxic as Diclofenac and can kill vultures. Study showed that the Aceclofenac was rapidly metabolised into Diclofenac and Ketoprofen is toxic to *Gyps* vultures.

The same matter was referred to Department of Animal Husbandry and Dairying (DAHD), Ministry of Agriculture & Farmer's Welfare for expert opinion. The matter was examined by DAHD in consultation with the subject experts and it was recommended to impose ban on the veterinary drugs "Ketoprofen and Aceclofenac" for treatment of livestock animal to conserve vulture.

DTAB deliberated the matter and agreed to prohibit the manufacture, sale and distribution of the drugs (i) Ketoprofen and its formulations and (ii) Aceclofenac and its formulations for animal use.

Further, the Board also opined that the issue should be proactively examined and a list of all such drugs which affect the animal health or environment should be prepared for taking further appropriate action in the matter and accordingly recommended to constitute a sub-committee to examine the matter in details and submit its report to the Board.

AGENDA NO.5

CONSIDERATION OF AGENDA ON AMENDMENT IN RULE 18 AND 19 OF MEDICAL DEVICES RULES, 2017, TO EMPOWER STATES/UTs TO NOTIFY CENTRAL MEDICAL DEVICES TESTING LABORATORY (CMDTL) AND MEDICAL DEVICE TESTING OFFICER (MDTO)

The Board was apprised that several proposals were received from various State Licensing Authorities requesting the Central Government to notify Central Medical Devices Testing Laboratory, to test the sample taken by Medical Devices Officers of their State/UT.

Further, they had also requested the Central Government to notify their State Laboratories to test Medical Devices.

- As per sub-rule (1) of Rule 18 of Medical Devices Rules, 2017*, the Central Government may designate a Government Analyst appointed under Section 20 of the Drugs & Cosmetics Act, 1940, as Medical Device Testing Officer.*

- As per Rule 19 of the MDR, 2017, *the Central Government may by notification establish Central Medical Devices Testing Laboratory, for the purpose of testing and evaluation of Medical Devices or to carry out any other function as may be specified assigned to it.*

The Board was informed that Central Government has notified six Central laboratories under Medical Devices Rules, 2017 where the testing of medical devices is taking place.

In view of the above, MoHFW has published draft rules *vide* Notification No. G.S.R. 157(E) dated 1st March, 2023 in the official gazette.

DTAB deliberated and agreed for the amendment in Rule 18 and 19 of MDR, 2017, to empower States/UTs to notify Medical Devices Testing Laboratory and Medical Device Testing Officer.

AGENDA NO.6

CONSIDERATION OF THE AGENDA FOR GUIDING THE WAY FORWARD ON CERTAIN ISSUES /SUGGESTIONS ON MEDICAL DEVICE REGULATIONS IN INDIA REGARDING INCLUSION OF EXEMPTION FOR REQUIREMENT OF IMPORT LICENCE

The Board was apprised that the hospitals like AIIMS, PGIMER, MEDANTA, DGFAMS are importing medical devices directly from Original Equipment Manufacturer (OEM) for the consumption/ use at their institutes only. However, as per implementation of S.O.775(E) dated 08.02.2019, S.O. 4672(E) dated 27.12.2019 and GSR 102(E) dated 11.02.2020, there is requirement of import license to import the medical devices in line with provisions of Medical Devices Rules, 2017.

Presently, there is no specific provision in the MDR, 2017 for import of such equipments directly by the hospitals. Therefore, it was proposed to make a provision in Eighth Schedule of MDR, 2017 for an exemption from the provisions of Chapter V of the said rules, for import of medical devices directly by the hospitals on behalf of the authorized agent, which require them to be covered by a license for import provided that the Central Licensing Authority, subject to the following conditions:

1. The manufacturer and medical devices are registered in Form MD-15 by the authorized agent.
2. A letter of authorization issued by the authorized agent to such hospitals shall be submitted to Port Office of CDSCO, at the time of import, for import of such quantity of medical devices.
3. The authorized agent shall be responsible for the safety, quality and performance for such medical devices imported.

DTAB deliberated the matter and recommended that consultation with the stakeholders including the hospitals or institutes like AIIMS, PGIMER, MEDANTA, and DGFAMS who are involved in such activities and Advisor (Cost), MoHFW should be held to understand the issue that the practices being followed by the hospitals for procurement of such devices for further action in the matter.

AGENDA NO.7

CONSIDERATION OF AGENDA TO RECOGNIZE SITRA'S TESTING LABS AS NODAL CENTRAL MEDICAL DEVICES TESTING LAB

The Board was apprised that representation was received from South India Textile Research Association (SITRA), Coimbatore, Tamil Nadu a not-for-profit research organisation actively involved in carrying out R&D on conventional and technical textiles, requesting the Central Government to recognize their lab as "Central Medical Device Testing Laboratory" for testing of Bio-protective coveralls, surgical/medical facemasks, surgical gowns, surgical drapes etc.

During Covid-19 pandemic SITRA was approved by Ministry of Textile and accepted by MoHFW to Test and certify Personal Protective Equipments (PPE) and coveralls to be used by frontline healthcare workers.

SITRA is empanelled by BIS under Group 2 category for testing medical textiles such as coveralls, facemasks, surgical gowns, surgical drapes etc. The lab is accredited by NABL as per ISO/IEC 17025:2017 and is being used by the textile industry.

Further, the Board was informed that currently there is no Central Medical Devices Testing Laboratory which is having facility for testing of medical textiles such as coveralls, facemasks, surgical gowns, surgical drapes etc.

As per rule 19 of Medical Devices Rules, 2017, the Central Government may, by notification, establish Central Medical Devices Testing Laboratory for the purpose of,—

(a) testing and evaluation of medical devices; or
(b) functioning as an appellate laboratory; or
(c) to carry out any other function as may be specifically assigned to it.

(2) Without prejudice to sub-rule (1), the Central Government may also designate any laboratory having facility for carrying out test and evaluation of medical devices as central medical devices testing laboratory for the purposes specified in sub-rule (1) Provided that no medical devices testing laboratory, shall be so designated unless it has been duly accredited by the National Accreditation Body for Testing and Calibration Laboratories.

DTAB deliberated the matter and agreed in principle for the notification of SITRA for testing of medical textiles under the Medical Devices Rules, 2017. However, prior to that, the laboratory should be inspected by CDSCO to assess the facilities available in the laboratory.

AGENDA NO.8

CONSIDERATION OF PROPOSAL TO RESTRICT THE AVAILABILITY AND USAGE OF BANNED ANTIBIOTICS IN FOOD PRODUCING ANIMALS, INCLUDING SHRIMPS

The Board was apprised that the Antimicrobial Resistance (AMR) is an increasingly serious threat to public health. The Ministry of Health and Family Welfare in consultation with various stakeholders developed National Action Plan on AMR (NAP-AMR), which was

officially released on 19.04.2017. The details of the action taken/planned for implementation of the interventions/activities on the points pertaining to CDSCO were shared with NAP-AMR Secretariat, NCDC, MoHFW.

Further, it was informed to the Board that concerns had been raised by Marine Products Export Development Authority (MPEDA), Ministry of Commerce and Industry about the availability of many pharmacologically active substances including antibiotics that are already banned for use in aquaculture. This use of banned antibiotics & other drugs are causing menace in the form of AMR. The results of National Residual Control Plan (NRCP) for aquaculture analysis showed that the banned antibiotics are detected in shrimp samples indicating the usage of those compounds which leads to rising trend of rejections of shrimp export consignments in EU. The authority has requested to take measures that will restrict availability and usage of banned antibiotics in food producing animals, including shrimps.

According to Gazette Notification No.1-100/SP(PAR)-Notification/Enf/FSSAI/2014 dated 20.07.2018 issued by FSSAI, MoH&FW, various antibiotics and veterinary drugs including Nitrofurans such as Furaltadone, Furazolidone, Nitrofurantoin, Nitrofurazone and Chloramphenicol are not permitted to be used at any stage of processing of meat and meat products, poultry and eggs, sea foods including shrimps, prawns or any variety of fish and fishery products. The Extraneous Maximum Residue Limit of 0.001 mg/kg will be applicable except for Chloramphenicol for which it shall be 0.0003 mg/kg.

DTAB deliberated the matter and recommended that a stakeholders' consultation including Food Safety and Standards Authority of India (FSSAI), Department of Animal husbandry and Dairying (DAHD), Department of Fisheries and Ministry of Agriculture & Farmers Welfare, Marine Products Export Development Authority (MPEDA) should be held for developing strategy and for taking further action in the matter.

The Board also recommended that the matter should also be deliberated in the DCC for ensuring proper implementation of the provisions of the Drugs and Cosmetics Act and Rules thereunder so that the antibiotics are not diverted for illegal use in food producing animals, aquaculture including shrimps.

AGENDA NO.9

CONSIDERATION OF THE PROPOSAL TO AMEND ENTRY NO.33 OF SCHEDULE K TO INCLUDE NICOTINE ORALLY DISINTEGRATING STRIPS ALONG WITH NICOTINE GUMS AND LOZENGES FOR EXEMPTION FROM THE PROVISION OF SALE LICENSE

The Board was apprised that the DTAB in its 81st meeting held on 29.11.2018 deliberated the said agenda and agreed to amend the entry No. 33 in Schedule K for providing exemption for all nicotine oral formulations containing 2 mg of nicotine. Accordingly draft notification was forwarded to Ministry for consideration.

Subsequently, the matter was referred by Ministry to Tobacco Control Division (TCD) for opinion on the draft proposal to amend entry no.33 of Schedule K to include nicotine orally disintegrating strips along with nicotine gums and lozenges.

As per the existing provision under Schedule K (Entry No.33) of Drugs Rules, 1945, Nicotine gum and lozenges containing unto 2mg of nicotine are exempted from sale license and prescription of RMP for retail sale. Earlier this provision was incorporated in Schedule K based on recommendation of ICMR.

The TCD has examined and stated that some of NRTs (Nicotine Replacement Therapy) (Nicotine gums, lozenges and patches) are currently available "Over The Counter". The proposed amendment envisages that all Nicotine Replacement Therapies (NRTs) be made available through OTC sales, whereas, such a step may lead to increased access to NRTs for prospective quitters, the same also poses the risks such as:

- The NRTs may be used by addicts for nicotine substitution in forced periods of abstinence, rather than as NRTs for quitting tobacco.
- India has prohibited the e-Cigarettes and like devices by bringing a separate legislation i.e. The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019 but does not include any product licensed under the D&C Act, 1940.
- With any relaxation, e-Cigarette industry might innovate and bring products.

In view of the above, TCD division has proposed to take necessary action to place all formulations of nicotinic containing upto 2 mg or 4 mg under the concerned schedule so that their supply is restricted and available only on the prescription of authorized medical practitioners, and not as Over The Counters (OTCs) preparation.

DTAB deliberated the matter and recommended that ICMR should be requested to give comments/ inputs for taking further action in the matter.

AGENDA NO.10

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 43A TO NOTIFY GANGAVARAM PORT FOR IMPORT AND EXPORT OF DRUGS

The Board was apprised that the Department of Health & Family Welfare published a draft Gazette notification vide G.S.R. 158(E) dated 01.03.2023 for notifying Gangavaram Port for Import and Export of Drugs under Drugs Rules, 1945 to elicit public comments.

DTAB deliberated the matter and agreed for notifying the Gangavaram Port for Import and Export of Drugs under Drugs Rules, 1945.

AGENDA NO.11

CONSIDERATION OF THE PROPOSAL TO AMEND MEDICAL DEVICES RULES 2017 TO EXEMPT CLASS A MEDICAL DEVICES FROM LICENSING REGIME

The Board was apprised that representation was received from M/s Ostwal Rehabilitation Aid Ind on behalf of Micro Level firms, registered under MSME regarding the subject cited above. It was stated that most of the firms are so small that they are using only one or two sewing machines, run by family members. Recently, there have been change in rules and Class A category of products were coming under regulation which are LOW RISK,

NON TOXIC, NON HAZARDOUS and Non Invasive posing minimal or no risk to human body. However, by bringing such low risk products under drug regulation not only these micro level firms would be overburdened with regulation rather there was high cost involved, which would be absolute burden on these micro level firms, which were giving employment to many poor people as well as house hold women. These micro level firms would close down.

M/s AIMED has requested to consider waiver of ISO 13485 certification for low risk Non Sterile Non Measuring Class A Medical Devices (other than IVD reagents/kits).

M/s Non-sterile surgical instruments Industry has requested that all non-sterile surgical instruments should be classified in Class A and that all non-sterile surgical instruments and other Class A and B products should be regulated by the ISO certification only.

In light of the above representation, the International practices for Regulation of Class A medical devices in terms of its process, details for registration and compliance requirement were examined for various countries viz; Japan, USA, Australia, Singapore, Korea, Canada and EU.

It was observed that for Class A Medical Devices (Non-sterile, Non Measuring) most of the regulators allow self-certification and registration of manufacturer/importer by way of notification/registration of the establishment (Manufacturing site/Importing site).

Considering the matter on overall perspective, the Department of Health & Family Welfare had published a Gazette notification vide G.S.R. 777(E) dated 14.10.2022 to amend Medical Devices Rules, 2017 for exempting Class A medical devices from licensing regime by providing following exemptions :

(1) Class A Medical Device (Non-sterile and/or non measuring) may be exempted from licensing, by giving provision of exemption under Eight schedule of MDR, 2017, subject to the condition that the manufacturer shall make registration of such devices, as per Chapter IIIB of these rules.

(2) Chapter III B is proposed to be inserted for Registration of Class A (Non-sterile and/or non measuring medical devices, under which

- The Manufacturer of Class A Medical Device (Non-sterile and/or non measuring) shall register the site and products
- The Importer/Indian agent of Class A Medical Device (Non-sterile and/or non measuring) shall register the foreign manufacturing site and products.

DTAB deliberated the matter and ratified the G.S.R. 777(E) dated 14.10.2022 for exempting the Class A medical devices from licensing regime. However, the Board recommended that all measure should be taken to ensure that such devices follow the prescribed quality standard to ensure their quality.

AGENDA NO.12

CONSIDERATION OF THE PROPOSAL TO AMEND NEW DRUGS AND CLINICAL TRIALS RULES, 2019 WITH RESPECT TO USE OF UNAPPROVED NEW DRUGS

The Board was apprised that the Central Government had published a draft notification vide G.S.R. 354 (E) dated 05.06.2020 to include the provisions relating to the compassionate use of unapproved new drugs under the New Drugs and Clinical Trial Rules, 2019.

After considering the objections/ suggestions received from various stakeholders for finalization of draft notification G.S.R. 354 (E) dated 05.06.2020, it was opined to revisit the draft notification in line with existing rules for import and manufacture of unapproved new drug instead of framing new rules for compassionate use of unapproved drugs.

On the recommendations of the Committee constituted under the Chairmanship of Director General, ICMR, the draft rules amending existing provision under NDCT Rules have been proposed.

DTAB deliberated the matter and agreed to the proposed draft rules for amending NDCTR, 2019 on recommendations of ICMR committee.

AGENDA NO.13

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT IN DEFINITION OF PHYTOPHARMACEUTICAL DRUG UNDER NDCTR, 2019

The Board was apprised that a representation was received requesting following amendments to the existing definition of Phytopharmaceutical drug --

"Phytopharmaceutical drug includes purified and standard fraction of an extract of a medicinal plant or its part, assessed adequately by defined chemical marker(s) or biological methods of evaluation that demonstrate batch wise similarity, for internal or external use of human beings or animals for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include administration by parenteral route as specified in Rule 2.

The details of the representation were placed before the Board for consideration.

DTAB deliberated the matter and opined that the existing definition of Phytopharmaceutical drug including minimum four bio-active or phytochemical compounds of an extract of a medicinal plant or its part, assessed qualitatively and quantitatively are important for ensuring batch to batch consistency of such product.

Hence, the Board did not agree to the proposed amendment of existing definition of Phytopharmaceutical drug in NDCTR, 2019.

AGENDA NO.14

CONSIDERATION OF THE PROPOSAL FOR EXEMPTING FROM REQUIREMENTS OF PRESCRIPTION FOR SALE OF APPROVED DRUG "DRIED IVY LEAF EXTRACT COUGH SYRUP" UNDER SCHEDULE K OF DRUGS RULES, 1945

The Board was apprised about the representation received from M/s USV Private Limited, wherein firm requested for marketing of approved drug "Dried Ivy Leaf Extract Cough Syrup" under Schedule K (See Rule 123) of Drugs and Cosmetics Rules, 1945 and requested exemption from the "WARNING: *"To be sold by retail on the prescription of a RMP only"*

Details of the proposal and recommendation of SEC were placed before the Board for consideration.

DTAB deliberated the matter and recommended that a sub-committee should be constituted to examine the proposal and also to examine the requirement of RMP for sale of various cough syrups in the country.

AGENDA NO.15

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT IN SCHEDULE P1 OF DRUGS RULES, 1945 (GLYCERYL TRINITRATE SPANSULES)

The Board was apprised about the representation received regarding the requirement of 25' pack in the Schedule P1 [Rule 109] should be revisited and to be changed to 30' for all the Nitroglycerin timed release solid oral dosage forms (tablets and capsules) to avoid possible non-compliance to this life saving drug.

Further, it was informed to the Board that, all the strengths of Nitroglycerin solid oral dosage forms are available in even number of tablets / capsules pack and generally in pack of 30's or 60's to cover dosage of 15 or 30 days respectively considering the b.i.d dose. The Schedule P1 [Rule 109] requirement is very specific to the "Glyceryl Trinitrate Spansules (Long Acting)" hence not applied for other dosage forms (tablets) and sold in India in even number of unit packs and mostly 30's pack to cover 15 days dose. Within a pack of 25' one capsule is always left in the pack and there is risk of missing dose on 13th day by patient and high probability of dose noncompliance as there is only one capsule left in the bottle.

The Board was also apprised that as per the Rule 105, unless specified otherwise in Schedule P1, the pack sizes for Tablets/Capsules where the number of Tablets/ Capsules is above 10, shall contain multiples of 5.

DTAB deliberated the matter and agreed to the proposal for deleting the provisions from Schedule P1 of Drugs Rules, 1945 with respect to Glyceryl Trinitrate spansules.

The Board also recommended that the existing provision should be amended to provide that, for the pack size of Tablets/ Capsules where the number is above 10, the pack sizes of Tablets/ Capsules shall contain multiples of 5 or 7, considering the recommended dosage duration of the therapy.

AGENDA NO. 16

CONSIDERATION OF CERTAIN PROPOSALS FOR RE-DELIBERATIONS

The Board deferred the agenda and agreed to take up these agenda in the next meeting of DTAB to be held at the earliest.

End of the Document