डॉ.राजीव सिंह रघुवंशी
औषधि महानियंत्रक (भारत)
केंद्रीय औषधि मानक नियंत्रण संगठन
स्वास्थ्य एवम परिवार कल्याण मंत्रालय
भारत सरकार
एफ.डी.ए. भवन, कोटला रोड,
नई दिल्ली–110002

सत्यमेव जयते

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)
Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road
New Delhi-110002 (India)

F. No. DC-DT-13011(11)/10/2024-eoffic
E-Comp. No.: 13141

Date:
19 SEP 2024

To

All Members of DTAB

Subject: Minutes of the 91st meeting of the Drugs Technical Advisory Board (DTAB) held on 14.08.2024 through Hybrid mode.

Sir/ Madam,

91st meeting of Drugs Technical Advisory Board was held on 14.08.2024 through Hybrid mode.

The minutes of the 91st meeting of Drugs Technical Advisory Board duly approved by the Chairman, is annexed for your information please.

Yours faithfully,

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)
Member Secretary (DTAB)

Encl: Minutes of meeting

Copy to:

1. PPS to DGHS, MoHFW, Nirman Bhawan, New Delhi
2. PS to JS(R), MoHFW, Nirman Bhawan, New Delhi

MINUTES OF THE 91st MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 14.08.2024 AT 10:00 A.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. Dimple Kasana, Director, Central Research Institute, Kasauli (Attended Online)	Member
5. Dr. P Dhar, Principal Scientist, IVRI, Bareilly, U.P. (Attended Online)	Member
6. Dr. Hemant Koshia, Commissioner, FDCA, Gujarat	Member
7. Dr. Navin Sheth, Elected Member (PCI) (Attended Online)	Member
8. Dr. Jerin Jose Cherian, Scientist E, Division of Basic Medical Sciences, ICMR	Member
9. Dr. J.A. Jayalal, National President, Indian Medical Association (Attended Online)	Member
10. Smt. Pramila N. D., Chief Scientific Officer, Government Analyst, Bengaluru, Karnataka	Member

CDSCO REPRESENTATIVE

1. Smt. Annam Visala,
   Joint Drugs Controller (I), CDSCO (HQ), New Delhi

2. Shri. R. Chandrashekar,
   Joint Drugs Controller (I), CDSCO (HQ), New Delhi

3. Shri. A. K. Pradhan,
   Advisor, CDSCO (HQ), New Delhi

4. Shri. Sanjeev Kumar,
   Deputy Drugs Controller (I), CDSCO (HQ), New Delhi

5. Shri. Ashish Kumar Rai,
   Assistant Drugs Controller (I), CDSCO (HQ), New Delhi

6. Mr. Rohit Kumar,
   Drugs Inspector, CDSCO (HQ), New Delhi

7. Mrs. Meena Devi,
   Assistant Drugs Inspector, 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 the 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.

ACTION TAKEN REPORT (ATR) FOR 90th DTAB MEETING HELD ON 25.01.2024

The Board while deliberating the action taken report was apprised about the agenda 8.8 wherein it was noticed that there was a typo error in the minutes of the said agenda and therefore recommended to correct the minutes of the said agenda as under: —

From

"Matter was earlier deliberated before the DTAB in its 82nd meeting held on 02.04.2019 wherein it was proposed to amend the Drugs Rules, 1945 for incorporating a provision in Form 20G for mentioning the name of competent person-in-charge as it is mentioned in Form 20C and Form 20E.

DTAB after deliberation agreed to amend Drugs Rules, 1945 for incorporating a provision in Form 20D for mentioning the name of competent person-in-charge as it is mentioned in Form 20C and Form 20E.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and agreed for the proposal."

To:

"Matter was earlier deliberated before the DTAB in its 82nd meeting held on 02.04.2019 wherein it was proposed to amend the Drugs Rules, 1945 for incorporating a provision in **Form 20B and 21B** for mentioning the name of competent person-in-charge and **Form 20G** for mentioning the qualified person in charge.

DTAB after deliberation agreed to amend Drugs Rules, 1945 for incorporating a provision in **Form 20B and 21B** for mentioning the name of **competent person-in-charge** and **Form 20G** for mentioning the **qualified person-in-charge**.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and agreed for the proposal."

Further, the Action Taken Report (ATR) on the recommendations of DTAB in 90th meeting was approved by the Board.

AGENDA NO.1

CONSIDERATION OF CERTAIN PROPOSALS FOR RE-DELIBERATIONS

Agenda 1.1

CONSIDERATION OF THE PROPOSAL TO AMEND SUB-RULE (1) OF RULE (63) IN MEDICAL DEVICES RULES, 2017 REGARDING THE PROVISIONS FOR PERMISSION TO IMPORT OR MANUFACTURE MEDICAL DEVICE WHICH DOES NOT HAVE ITS PREDICATE DEVICE

The Board was apprised that the Rule 63 of Chapter VIII Medical Devices Rules, 2017, specifies the provisions for permission to import or manufacture medical device which does not have its predicate device.

Fourth proviso of said rule specifies that data on clinical investigation may not be required to be submitted where the investigational medical device is approved by regulatory authorities of either the United State of America or United Kingdom or Australia or Canada or Japan and the said device has been marketed for at least two years in that country.

During the India-EU Sub-commission on trade held on 6th June, 2018 in New Delhi, the EU side pointed out that for the regulation of new products "the new regulations stated that clinical investigation may not be required to be submitted where the investigational medical device is approved by regulatory authorities of US, UK, Australia, Canada or Japan but does not include the EU".

As per World Health Organisation (WHO) European Medicines Agency is also considered as stringent regulatory to ensure the safety, quality and performance of medical devices in the country.

Accordingly, it was proposed to include EU in the provision specified under proviso four of sub rule (1) of Rule (63) in the Medical Devices Rules, 2017 in respect of the waiver of clinical investigation.

DTAB deliberated the matter and recommended to amend the sub rule (1) of Rule (63) of Medical Devices Rules, 2017 to include the European Union (EU).

Agenda 1.2

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT IN SCHEDULE H OF DRUGS RULES TO PROVIDE EXEMPTION FROM LABELLING REQUIREMENTS FOR THE CHEMICAL CONTRACEPTIVES CENTCHROMAN AND LEVONORGESTROL MENTIONED UNDER ENTRY NO. 15 OF SCHEDULE K OF THE DRUGS RULES, 1945

The Board was apprised that the Schedule H of Drugs Rules, at the entry no. 101 and 186 specifies the drugs Centchroman and Ethinyloestradiol. Accordingly, the finished formulation of these drugs Centchroman and Ethinyloestradiol attracts the labelling requirement of clause (b) of sub-rule (1) of rule 97 of Drugs Rules. Accordingly, the label should bear the caution "Not to be sold by retail without the prescription of a Registered Medical Practitioner."

However, the drugs Levonorgestrel-0.15 mg + Ethinyloestradiol-0.03 mg and Centchroman-30 mg are exempted w.r.t. provision of sale licence under entry no. 15 of Schedule K. Which makes the requirement of prescription by RMP contradictory.

Accordingly, it was proposed to make the certain amendments under Drugs Rules, 1945 to avoid contradiction in labelling of products namely Levonorgestrel-0.15 mg + Ethinyloestradiol-0.03 mg and Centchroman-30 mg.

DTAB deliberated the matter and agreed for the dose specific amendment in Schedule H under Drugs Rules, 1945.

Agenda 1.3

CONSIDERATION OF THE PROPOSAL TO ADD PROVISIONS IN RULE 64 OF MDR, 2017 IN RESPECT OF THE WAIVER OF CLINICAL PERFORMANCE EVALUATION FOR IVDS, IN-LINE WITH WAIVER GIVEN FOR MEDICAL DEVICE UNDER RULE 63 (1) OF MEDICAL DEVICES RULES, 2017

The Board was apprised that the above said proposal was earlier re-deliberated in the 90th DTAB meeting held on 25.01.2024 and after deliberation the Board did not agree for the proposed amendment under Medical Devices Rules, 2017.

Accordingly, justification for not agreeing to the proposal was requested to be deliberated

DTAB deliberated the matter and opined that the performance of IVDs can vary significantly due to biological difference among the population, genetic and environmental factors contributing to these variations, making it crucial to assess and confirm the performance of IVDs in Indian population. Therefore, waiver of clinical performance evaluation under Rule 64 for approval of IVDs in the country was not considered by the Board.

Agenda 1.4

CONSIDERATION OF THE PROPOSAL TO PRESCRIBE THE QUALIFICATION OF MEDICAL DEVICE TESTING OFFICES AND MEDICAL DEVICE OFFICERS RESPECTIVELY UNDER MDR, 2017

The Board was apprised that the matter has been examined by CDSCO and a separate agenda has been placed before the Board at agenda no. 7. Therefore, the proposed agenda is deferred.

AGENDA NO.2

CONSIDERATION OF THE PROPOSAL FOR EXEMPTION FROM THE REQUIREMENT OF WHOLESALE LICENCE FOR LIQUID ANTISEPTIC FOR HOUSE HOLD USE AND EXEMPTION FOR THE REQUIREMENT OF RETAIL SALE LICENCE FOR HOSPITAL GRADE ANTISEPTIC UNDER SCHEDULE K OF DRUGS RULES, 1945

The Board was apprised about the agenda.

After detailed deliberation, Board agreed for amendment at entry no. 39 of Schedule K of Drugs Rules, 1945 w.r.t. liquid antiseptic as follows.

Class of Drugs	**Extent and Conditions of Exemptions**
39. Liquid Antiseptics for household use	The provisions of Chapter IV of the Act and rules made thereunder, which require them to be covered with a sale license subject to the following conditions, namely: ─ (a) The drugs are manufactured by licensed manufacturers; (b) the drugs do not contain any substance specified in Schedule G, H, H1 or X; (c) the drugs are sold in the original unopened containers of the licensed manufacturer;
39A. Liquid Antiseptics for Hospital and other than household use	The provisions of Chapter IV of the Act and rules made thereunder, which require them to be covered with a sale license in Form 20 or Form 20A, subject to the following conditions, namely: ─ (a) The drugs are manufactured by licensed manufacturers; (b) the drugs do not contain any substance specified in Schedule G, H, H1 or X; (c) the drugs are sold in the original unopened containers of the licensed manufacturer; (d) the drugs are purchased from a licensed wholesaler or a licensed manufacturer.

AGENDA NO.3

CONSIDERATION OF THE PROPOSAL TO PROHIBIT THE MANUFACTURE FOR SALE, SALE OR DISTRIBUTION OF ALL FORMULATIONS CONTAINING FDC OF CHLORPHENIRAMINE MALEATE IP + PHENYLEPHRINE HYDROCHLORIDE FOR CHILDREN BELOW 4 YEARS OF AGE

The Board was apprised that the proposal regarding use of the FDC of Chlorpheniramine Maleate IP 2mg + Phenylephrine Hydrochloride IP 5mg drop/ml was deliberated by the SEC (Pulmonary) and after deliberation committee recommended that the FDC should not be used in children below 4 years of age and accordingly manufacture should mention warning in this regard on label and package insert.

However, various manufacturers had requested for clarification whether all formulations containing Chlorpheniramine and Phenylephrine in combinations shall be labelled or this specific strength has to be labelled.

Accordingly, the matter was re-deliberated before the SEC committee dated 04.01.2024 along with specially invited Paediatricians. After detailed deliberation, the committee recommended that all formulations of FDC of Chlorpheniramine Maleate IP + Phenylephrine Hydrochloride should not be used in children below 4 years of age and accordingly manufacturers should mention warning “FDC should not be used in children below 4 years of age" on label and package insert/promotional literature of the drug.

DTAB deliberated the matter and agreed with the recommendation of SEC that all formulations of FDC of Chlorpheniramine Maleate + Phenylephrine Hydrochloride should be prohibited for use in children below 4 years of age.

AGENDA NO.4

CONSIDERATION OF THE PROPOSAL FOR CONSIDERING PROHIBITION ON THE IMPORT & MANUFACTURE OF CHLORAMPHENICOL AND NITROFURANS DRUG FORMULATIONS FOR USE IN ALL FOOD-PRODUCING ANIMAL SYSTEM

The Board was apprised that the matter was deliberated in the 63rd meeting of DCC wherein the committee deliberated the matter and agreed with the proposal for prohibit the import, manufacture, distribution & sales of Chloramphenicol and Nitrofurans drugs for use in any food producing animal rearing system.

DTAB deliberated the matter and agreed to prohibit the import, manufacture, distribution & sales of Chloramphenicol and Nitrofurans drugs for use in any food producing animal rearing system.

AGENDA NO.5

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT IN FORM 27D, 27DA, 28D AND 28DA TO INCLUDE THE WORD "CELL OR STEM CELL DERIVED PRODUCTS, GENE THERAPEUTIC PRODUCTS OR XENOGRAFTS, ETC."

The Board was apprised that matter was deliberated in the 63rd meeting of DCC wherein it was proposed for inclusion of the words "**cell or stem cell derived products, gene therapeutic products or xenografts, etc.**" under Form 27D, 27DA and Form 28D and Form 28DA to grant manufacturing permission for Cell or Stem cell derived products, Gene therapeutic products, modified release dosage forms, and such other new drugs. After deliberation the 63rd DCC agreed with the proposed amendment.

DTAB deliberated the matter and agreed for proposed amendment under Form 27D, 27DA and Form 28D and Form 28DA of Drugs Rules, 1945 for inclusion of the words "**cell or stem cell derived products, gene therapeutic products or xenografts, etc.**"

AGENDA NO.6

CONSIDERATION OF THE PROPOSAL TO MAKE PROVISIONS IN DRUGS RULES FOR TAKING ACTION AGAINST APPLICANT FOR SUBMITTING MISLEADING OR FAKE OR FORGED/FABRICATED DOCUMENTS/ DATA TO LICENSING AUTHORITY

The Board was apprised that at present there is no provision under the Drugs Rules, 1945 to address this issue of submitting forged/ fabricated, misleading data/ document, etc. for obtaining the regulatory approvals.

Accordingly, it was proposed that provision may be incorporated under the Drug Rules, 1945 for taking action against applicant for submitting misleading, or fake, or fabricated documents/ data to the licensing authority.

DTAB deliberated the matter and recommended that in such cases, the applicant may be debarred for submitting forged/ fabricated, misleading data/ document, etc. to licensing authority in addition to suspension/ cancellation of the product as applicable.

AGENDA NO.7

CONSIDERATION OF PROPOSAL TO AMEND RULE 44 OF DRUG RULES, 1945 TO INCLUDE THE REQUIRED QUALIFICATION FOR MEDICAL DEVICE TESTING OFFICER SO AS TO DESIGNATE OTHER GOVERNMENT LABS SUCH AS ENGINEERING, TEXTILE, ETC. TO MEDICAL DEVICE TESTING LABORATORY UNDER RULE 19 OF MDR, 2017

The Board was apprised that in order to strengthen the testing facility of Medical Devices & In-vitro Diagnostic devices in the country, government has approached various institution based on their area of scope for designation of Medical Device Testing Laboratory so that Medical Devices & In-vitro Diagnostic devices available in the market may be tested with respect to Safety & performance by these labs.

Various government institute requesting for designation of Medical Device Testing Laboratory. These labs are having facility to test various types of medical equipment's, In-vitro Diagnostic devices, medical devices etc., and these test involves electrical, electrical communications, biocompatibility and physical test are carried out by professionals from Engineering and science background;

However, the qualification of technical competence staff of these institutions is not included in the existing qualification of government analyst under Rule 44 of Drugs Rule, 1945.

Therefore, it is proposed to amend the rule 44 of Drugs Rules, 1945.

DTAB deliberated the matter and agreed for amendment under provisions of Drugs Rules, 1945 in line with the qualification prescribed for Medical Devices Officers.

AGENDA NO.8

CONSIDERATION OF PROPOSAL TO AMEND RULE 19H AND 19J OF CHAPTER IIIB OF MEDICAL DEVICE RULES, 2017 TO INCLUDE THE QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR CLASS A (NON-STERILE AND NON-MEASURING) MEDICAL DEVICE

The Board was apprised that the Medical Devices Rules, 2017 under Chapter IIIB specify the provisions for exemption of license to manufacture & import of the Class A (Non-Sterile and Non-Measuring) medical devices for marketing in the country. Though, the manufacturer or importer may obtain registration number by submitting the requisite information prescribed under sub-rule (2) of Rule 19H & sub-rule (2) of 19J of Medical Devices Rules, 2017 respectively.

It is observed that the scope for conformance of Quality Management System for manufacturing of such medical devices is not included in the above said rules. Quality Management System is utmost important for manufacturing of medical devices to ensure that the product meets relevant standards & Essential principles applicable for medical devices and the firm shall adhere with the Quality Management System of Fifth schedule of Medical Device Rules, 2017.

So that the safety & performance of medical devices will be ensured, hence the undertaking stating that the manufacturing facility has complied the Quality Management System as prescribed in the Fifth schedule of Medical Device Rules, 2017 may be included in the said rules.

Accordingly, it was proposed that to amend rule 19H and 19J of chapter IIIB of Medical Device Rules, 2017 to include the Quality Management System requirements for class A (non-sterile and non-measuring) medical device.

DTAB deliberated the matter and agreed for the proposed amendment under Medical Devices Rules, 2017.

AGENDA NO.9

CONSIDERATION OF PROPOSAL TO AMEND RULE 26 AND RULE 38 OF MEDICAL DEVICE RULES, 2017 REGARDING THE INTIMATION OF ANY REPORTABLE EVENTS OF MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTIC MEDICAL DEVICES TO THE LICENSING AUTHORITY

The Board was apprised that the manufacturer or importer of medical devices has the mechanism (**Quality Risk Management**) to ensure the quality and safety of medical devices in India. The Government of India has established the **Materiovigilance Programme of India (MvPI)** for reporting of Serious Adverse Events (SAE).

However, the reporting of reportable events is not clearly prescribed in the Medical Device Rules, 2017 and there is no mandatory requirement of reporting of reportable events by the licence holder.

Therefore, it is proposed to amend the Rule 3, Rule 26, Rule 38 and Rule 65 of MDR, 2017 to include the provisions for intimation of any reportable events of Medical Devices including In-Vitro Diagnostic Medical Devices.

DTAB deliberated the matter and opined that the proposal needs to be revisited to ensure that there is no overlapping or ambiguity.

AGENDA NO.10

CONSIDERATION OF PROPOSAL TO AMEND RULE 36 (4) OF MDR, 2017 WITH RESPECT TO REQUIREMENTS OF CLINICAL INVESTIGATION OF MEDICAL DEVICES WHICH ARE NOT APPROVED BY STRINGENT REGULATORY AUTHORITY AND ALSO THE RULE 3 (L) WITH RESPECT TO DEFINITION OF CLINICAL INVESTIGATION OF MEDICAL DEVICE RULES, 2017

The Board was apprised that the rule 3 (l) of Medical Devices Rules, 2017 specifies the definition of Clinical investigation as *"clinical investigation" means the systematic study of an investigational medical device in or on human participants to assess its safety, performance or effectiveness*

So as per the above definition, the clinical investigation is only applicable for investigational medical devices.

However, the Chapter VII of MDR, 2017 prescribed the provisions to conduct the clinical investigation of the investigational medical devices to establish safety & efficacy of medical devices in Indian population. It is to mention that, Chapter VII of MDR, 2017 is not applicable for devices having predicate device approved in India.

The objective for conducting clinical investigation for the devices, which has predicate devices approved in India that are not approved by the Stringent Regulatory Authority provided that there are no adequate clinical evidences is provided by the applicant, is to ensure the additional safety & efficacy / performance in Indian population before marketing it in to the country.

However, in case the applicant has submitted adequate / required clinical investigation data, may not be required to submit the additional safety, quality and performance data in Indian population.

Therefore, it is proposed to suitably amend the rule 3 (l) and sub-rules (4) of rule 36 under MDR, 2017.

DTAB deliberated the matter and opined that the proposal needs to be revisited comprehensively on overall perspective in light of the existing provisions of MDR, 2017.

AGENDA NO.11

CONSIDERATION OF THE PROPOSAL TO AMEND THE MARGINAL HEADING IN RULE 19 OF MEDICAL DEVICES RULES, 2017

The Board was apprised that the sub-rule (ze) of rule 3 of MDR, 2017 specifies that *"medical devices testing laboratory" means any institute, organisation registered under sub-rule (3) of rule 83 for carrying out testing or evaluation of any medical device on behalf of a licencee for manufacture for sale;*

Therefore, in order to distinguish government medical device testing laboratory from the private medical device testing laboratory. It is proposed to amend the marginal heading of **Rule 19** of MDR-2017 as under:

From

"Medical Device Testing Laboratories";

To

"Government Medical Device Testing Laboratories"

DTAB deliberated the matter and agreed with the proposed amendment of marginal heading of rule 19 of Medical Devices Rules, 2017.

AGENDA NO.12

CONSIDERATION OF PROPOSAL TO AMEND RULE 59 (3) (I), SEVENTH SCHEDULE (1) (III), TABLE-2 (III) OF MEDICAL DEVICE RULES, 2017 TO REPLACE THE WORDS "SCHEDULE Y" WITH THE WORDS "NEW DRUGS AND CLINICAL TRIALS RULES, 2019"

The Board was apprised that New Drugs & Clinical Trials Rules was notified in 2019 vide G.S.R.227 (E) dated 19.03.2019 which replaced the requirements specified in Schedule Y for conducting clinical trial of new drugs for human use.

The Medical Devices Rules were published in the year of 2017 before publishing the ND&CT Rules. Thus it has all the references to Schedule Y only and not of NDCT Rules.

Accordingly, it is proposed to replace the word "Schedule Y" in the Medical Device Rules to amended with New Drugs and Clinical Trials Rules, 2019.

DTAB deliberated the matter and opined that there could be medical devices for veterinary use and further the proposal may have wider implication and need to be reviewed in detail by a sub-committee in light of the consequential changes requires in other rules namely Drugs Rules, etc.

AGENDA NO.13

CONSIDERATION OF THE PROPOSAL FOR INCLUSION OF ALL ANTIBIOTICS IN THE DEFINITION OF "NEW DRUG'' IN NEW DRUGS AND CLINICAL TRIAL RULES, 2019

The Board was apprised that Antimicrobial Resistance (AMR) has been recognised as a serious and growing threat to the public health Globally. The problem of Antimicrobial Resistance (AMR) has been highlighted as a global health priority in multiple high-level flora ranging from the UNGA, G7 to G20.

In view of above, it was proposed to include all antibiotics in the definition of "new drug'' in New Drugs and Clinical Trial Rules, 2019.

DTAB deliberated the matter and observed that the G20 declaration sated for tackling the issue of antimicrobial resistance. Antimicrobial resistance can be caused by due to misuse of antibiotic, antiviral, antifungal, etc. and accordingly recommended that the matter may be deliberated in the DCC initially.

AGENDA NO.14

CONSIDERATION OF THE PROPOSAL TO AMEND THE CONDITIONS OF LICENSE - 3(II)(C) UNDER FORM 20B, FORM 20BB, AND 4(II)(C) UNDER FORM 21B, FORM 21BB OF DRUGS RULES, 1945

The Board was apprised that the proposal was deliberated in the 64th DCC meeting wherein it was informed to the committee that antimicrobials may also be used in other industries such as food, beverages and other non-medicinals, where the sale and use of antimicrobials in non-pharma industries lead to Antimicrobial Resistance (AMR). AMR has been recognised as a serious and growing threat to the public health Globally.

In this connection, it was proposed to amend the conditions at serial no. 3 (II) (C) under Form 20B, Form 20BB, and 4 (II) (C) under form 21B, form 21BB of Drugs Rules, 1945 to tackle Antimicrobial Resistance (AMR).

DCC after deliberating the proposal opined to amend the above said conditions under Drug Rules 1945, to include the word 'except Antimicrobials'.

DTAB deliberated the matter and agreed with the recommendation of the 64th Drugs Consultative Committee.

AGENDA NO.15

CONSIDERATION OF THE PROPOSAL FOR PROVIDING SUITABLE PROVISIONS UNDER DRUGS RULES, 1945 FOR INCLUDING WARNING/ CAUTION IN BLUE COLOR (STRIP, BOX, ETC.) ON LABEL OF ANTIMICROBIALS

The Board was apprised that Antimicrobial Resistance (AMR) has been recognised as a serious and growing threat to the public health Globally.

Accordingly, it was proposed for addition of Blue strip/ Box for providing AMR warning on the label of the antimicrobial products, for keeping special focus on antimicrobials, which may lead to reduction in Antimicrobial Resistance (AMR). The proposal was also deliberated in the 64th DCC meeting.

DTAB deliberated the matter and agreed to suitably amend the labelling requirements under Drugs Rules, 1945 for addressing the issue of AMR. Further, Board also recommend to take necessary step for awareness of the public.

AGENDA NO.16

CONSIDERATION OF THE PROPOSAL FOR WAIVER OF TOXICITY STUDIES FOR INTRAVENOUS INFUSIONS AND INJECTABLES UNDER SECOND SCHEDULE NDCT RULES, 2019

The Board was apprised that the sub-rule 4.2 of rule 4 under Table 2 of Second Schedule of New Drugs & Clinical Trials Rules, 2019 specifies that the applicant shall submit the sub-acute animal toxicity study data for intravenous infusions and injection to the Central Licensing Authority.

In order to reduce the animal usage and minimize sacrifices during drug testing procedures. It is proposed to waive off toxicity studies for intravenous infusions and injectables, by proving the qualitative and quantitative composition similarity with the reference listed drug which has previously been approved in the country or in other countries.

Accordingly, it was proposed to delete sub-para 4.2 of para 4 under Table 2 of Second Schedule of NDCT Rules, 2019 i.e. sub-acute animal toxicity studies for intravenous infusions and injectables.

DTAB noted that Table 2 of Second Schedule pertains to grant of permission to import or manufacture a new drug already approved in the country. The Board further noted that sub-acute animal toxicity studies are not required in such formulations in case the qualitative and quantitative composition similarity with the reference listed drug is stablished.

AGENDA NO.17

CONSIDERATION OF THE PROPOSAL OF CERTAIN AMENDMENTS W.R.T. PERIODIC SAFETY UPDATE REPORT UNDER FIFTH SCHEDULE OF NDCT RULES, 2019

The Board was apprised that the NDCT Rules, 2019 under Fifth Schedule as well as Drugs Rules, 1945 under Schedule M prescribes that the applicant/ licensee shall have a

Pharmacovigilance system in place for collecting, processing and forwarding the report to the licensing authority for information on adverse drug reactions emerging from the use of the drug imported or manufactured or marketed by the applicant in the country.

Therefore, the following amendment are proposed in NDCT Rules, 2019.

1. The words "**Pharmacovigilance System Master File (PSMF)"** shall be inserted under the appendix of Fifth Schedule of NDCT Rules, 2019 which is as under:

   Appendix: The appendix includes the copy of marketing authorisation in India, copy of prescribing information, line listings with narrative of Individual Case Safety Reports (ICSR), **Pharmacovigilance System Master File (PSMF).**

2. In the sub-clause (iii) of clause (c) of sub-rule (5) of rule 1 under Fifth Schedule of NDCT Rules, 2019 the words "**For subsequent two years – the periodic safety update reports need to be submitted annually.**" Shall be substituted by the words "**For subsequent years – the periodic safety update reports need to be submitted annually till the drug product is marketed.**".

DTAB deliberated the matter and agreed w.r.t. amendment proposed above at point no. 1. As regard to point no.2, Board recommended to constitute a sub-committee in the matter.

AGENDA NO.18

CONSIDERATION OF THE PROPOSAL FOR CERTAIN AMENDMENT UNDER DRUGS RULES, 1945 PERTAINS TO IMPORT AND REGISTRATION

The Board was apprised about the details in this regard.

DTAB deliberated the matter and opined that the proposal needs to be revisited comprehensively and deferred the proposal.

AGENDA NO.19

CONSIDERATION OF THE PROPOSAL TO OMIT THE REQUIREMENTS OF GRANTING OF PROVISIONAL CERTIFICATE FOR REGISTRATION OF ETHICS COMMITTEE UNDER RULE 17 OF CHAPTER IV F NDCT RULES, 2019

The Board was apprised that Ethics Registry in Department of Health Research (DHR) issues provisional and final certificate in CT-03 format to each ethics committee who apply for Naitik portal for EC registration.

Both certificates are issued after review of applications, which is valid for two and five years consecutively. It may be seen that now a system is in place in DHR for review, scrutinize the documents of all ethics committees, and review at both provisional and final stages of registration leads to duplication of efforts and resources which can be removed and only final certificate can be issued to ECs directly.

Accordingly, it was proposed to delete the sub-rule (3) of 17 and the sub-rule (4) of rule 17 may be modified as "On receipt of application in Form CT-01 under sub-rule (1), the

authority designated under sub-rule (1) shall scrutinise the documents and information furnished with the application, and if satisfied that the requirements of these rules have been complied with, grant final registration to Ethics Committee in Form CT-03; or if not satisfied, reject the application, for reasons to be recorded in writing".

DTAB deliberated the matter and agreed with the proposed amendment under ND&CT Rules, 2019.

AGENDA NO.20

CONSIDERATION OF THE PROPOSAL TO INCORPORATE PROVISION FOR INCLUSION OF FEE WHICH SHALL BE CHARGEABLE IN RESPECT OF APPLICATION FOR REGISTRATION/ RE-REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL, BIOAVAILABILITY AND BIOEQUIVALENCE STUDY

The Board was apprised that the fee payable for Registration and Re-registration of Ethics Committee is not mentioned in the NDCT Rules, 2019.

Therefore, it is proposed to made suitable provision for inclusion of fee which shall be chargeable as per Sixth Schedule, Fee payable for licence, permission and registration certificate as per Sixth Schedule of New Drugs and Clinical Trial Rules, 2019.

vide S.No. 42, "Any other application which is not specified above in INR 50,000" may be made in respect of application for Registration/Re-registration of Independent Ethics Committee relating to Clinical trial, Bioavailability and bioequivalence study.

Institutional Ethics Committee of Government Institutes may be exempted.

DTAB deliberated the matter and did not agree with the proposed amendment under ND&CT Rules, 2019 as ethics committee discharge its duty to ensure rights, safety and wellbeing of the trial participants and it is not like as business entity. However, the Board recommended for inspection of Ethics Committee(s) alongwith experts under rules.

AGENDA NO.21

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 64 OF THE DRUGS RULES, 1945 IN RESPECT OF QUALIFICATION OF THE COMPETENT PERSON

The Board was apprised that rule 64 of the Drugs Rules, 1945 specifies the conditions to be satisfied before a licence in Form 20, 20-B, 20-F, 20-G, 21 or 21-B is granted or renewed.

The second proviso to sub-rule (2) of rule 64 specifies the requirements of the area and the qualification of the competent person for grant of licence in 20-B and 21-B.

In this connection, it was proposed that the qualification of the competent person should be with pharmacy background only i.e. D. Pharmacy/ B. Pharmacy/ M. Pharmacy/ Pharm D/ Registered Pharmacist for grant of Wholesale Licence(s) on Form(s) 20B/ 21B/ 20G. Other qualifications like matriculation examination or its equivalent examination from a recognised board with 04 years' experience in dealing with sale of drugs or degree of a recognised university with one year experience in dealing of drugs should be deleted.

DTAB in its 70th meeting held on 18.08.2015 deliberated the matter and after deliberation recommended that the clause (b) and (c) of the second proviso of above sub-rule may be deleted. A protection clause may also be provided that the academic qualification shall not apply to the persons already registered prior to the date of final notification.

As per the recommendation of DTAB, a draft notification was published vide G.S.R 1179(E) dated 28.12.2016 for amendment of rule 64.

A large number of issues were raised due to which the said draft notification couldn't be finalized and there was a concern about its desirability and accessibility.

After examination of the stakeholders comments, Ministry recommended has requested to furnish the comments/ inputs in the matter.

DTAB deliberated the matter and again recommended for the finalization of the Draft G.S.R 1179(E) dated 28.12.2016 for amendment of rule 64 to strengthens the supply chain for ensuring the quality, safety and efficacy of drugs.

ADDITIONAL AGENDA NO. 1

CONSIDERATION OF PROPOSAL TO AMEND RULE 20 AND RULE 23 OF MEDICAL DEVICE RULES, 2017 TO INCLUDE THE VARIOUS TIMELINE FOR GRANT OF MANUFACTURING LICENSE

PART-A

The Board was apprised that the license for manufacturing of Class A and Class B medical devices is controlled by State Licensing Authority under Rule 20 of said rules. The timeline for scrutiny of applications, auditing of manufacturing site with respect to compliance of Quality Management System (QMS) as per Fifth Schedule is prescribed under the Rule.

However, the specific timeline for audit to be carried out and compliance verification of non-conformance reported in previous inspection is not mentioned in the rule which resulting in delay in QMS inspection and compliance verification by the registered notified body in case of Class A and Class B medical devices.

Therefore, it was proposed that following amendments may be incorporated under rule 20 of Medical Devices Rules, 2017:

1. **In sub-rule (5) of Rule 20 of MDR, 2017, the following may be substituted.**

The State Licensing Authority shall, after scrutiny of documents and on being satisfied that the requirements of these rules have been complied with, grant a licence to manufacture Class B medical devices in Form MD-5 or loan licence in Form MD-6, as the case may be, or if not satisfied, reject the application for reasons to be recorded in writing, within forty-five days from the date, the application is made under sub-rule (1).

Provided that where deficiencies that can be rectified, are pointed out by the State Licensing Authority within the stipulated period, the period referred to in sub-rule (5) shall reckon from the date these deficiencies have been removed.

5(A) The State Licensing Authority shall cause an Audit of the manufacturing site by registered notified body under rule 13.

2. Clause (i) of sub-rule (6) of Rule 20 of MDR, 2017, the following shall be substituted.

The State Licensing Authority shall ensure that the audit of the site is carried by the registered Notified Body in the manner specified in the Third Schedule within a period of forty-five days from the date of assignment of applications to notified body.

(i)(a) In case of non-conformance of Quality Management System requirements as observed during the Audit by the registered notified body, the compliance verification shall be carried out within twenty days from the date of receipt of compliance report from manufacturer.

3. Clause (ii) of sub-rule (6) of Rule 20 of MDR, 2017, the following shall be substituted.

(ii) the Notified Body shall furnish its report to the State Licensing Authority within fifteen days of the completion of audit;

PART-B

The Board was also apprised that the license for manufacturing of Class C and Class D medical devices is controlled by Central Licensing Authority under Rule 21 of said rules. The timeline for scrutiny of applications, inspection of manufacturing site with respect to compliance of Quality Management System (QMS) as per Fifth Schedule is prescribed under the Rule.

However, the specific timeline for inspection to be carried out is not prescribed.

Therefore, it was proposed to amend the sub-rule (1) of rule 23 of Medical Devices Rules, 2017 as under:

From

(1) Before grant of licence to manufacture for sale or for distribution in respect of Class C or D medical device, the manufacturing site shall be inspected within a period of sixty days from the date of application by a team comprising not less than two Medical Device Officers which may include any officer senior to the Medical Device Officer with or without an expert, or a Notified Body referred to in sub-rule (4) of rule 13:

To

(1) Before grant of licence to manufacture for sale or for distribution in respect of Class C or D medical device, the manufacturing site shall be inspected within a period of sixty days after scrutiny application as referred to in sub-rule (4) & (7) of rule 21 by a team comprising not less than two Medical Device Officers which may include any officer senior to the Medical Device Officer with or without an expert, or a Notified Body referred to in sub-rule (4) of rule 13:

DTAB deliberated the matter and agreed for the proposed amendment **to** include the various timeline for grant of manufacturing license.

ADDITIONAL AGENDA NO. 2

CONSIDERATION OF PROPOSAL FOR TRACK & TRACE MECHANISM FOR ONCOLOGY PRODUCTS BY PROVIDING QUICK RESPONSE & BAR CODE

The Board was apprised that in New Delhi where unscrupulous criminals in collusion with hospital pharmacies were found refilling empty vials of expensive anti-cancer medicines with counterfeit drugs. These fake drugs were then mixed with genuine stocks and sold to unsuspecting cancer patients and putting their life at risk.

These anti-cancer drugs must be issued under strict directives to implement mandatory QR codes and rigorous track and trace mechanisms on every vial and strip of medication that are marketed in India.

Accordingly, it was proposed that Schedule H2 of Drugs Rules, 1945 may be amended to include All Anticancer Medicines to have mandatory provision to print or affix Bar Code or Quick Response Code in its labels.

DTAB deliberated the matter and agreed for the proposed amendment to include all Anticancer Medicines under Schedule H2 of Drugs Rules, 1945.

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