MINUTES OF THE 86TH MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 13.04.20201 AT DGHS, NIRMAN BHAWAN, NEW DELHI (THROUGH VIDEO CONFERENCE)

PRESENT

1. Dr. Sunil Kumar, Director General of Health Services, Nirman Bhawan, New Delhi	Chairman
2. Dr. V.G. Somani Drugs Controller General (India), FDA Bhawan, New Delhi	Member Secretary
3. Shri C. Hariharan Director (I/C), Central Drugs Laboratory, Kolkata	Member
4. Dr. A. K. Tahlan Director, Central Research Institute, Kasauli, Himachal Pradesh	Member
5. Dr. Pronab Dhar IVRI, Izatnagar, UP.	Member
6. Dr. B. Suresh President, PCI	Member
7. Dr. Tapas K. Kundu Director, CDRI, Lucknow	Member
8. Shri. Pankaj Patel Chairman and Managing Director, Zydus Cadila Group, Ahmadabad	Member
9. Dr. Nilima Kshirsagar Chair in Clinical Pharmacology, ICMR, Mumbai	Member
10. Dr. R.N. Tandon Past Honorary Secretary General, IMA, New Delhi	Member
11. Prof. Dr. T.V. Narayana President , IPA, Bengaluru	Member

12. Shri. M.S Lokesh Prasad — Member
    Scientific Officer & Govt. Analyst,
    Bengaluru, Karnataka
13. Dr. Vaishali N Patel — Member
    Govt. Analyst, Food & Drugs Laboratory,
    Vadodara, Gujarat

CDSCO REPRESENTATIVES

1. Shri. A. K. Pradhan
   DDC(I), CDSCO (HQ), New Delhi
2. Shri. Sanjeev Kumar
   DDC(I), CDSCO (HQ), New Delhi
3. Shri. Balakumar Mahalingam
   Drugs Inspector, CDSCO (HQ), New Delhi
4. Shri. Shivadev D
   Drugs Inspector, CDSCO (HQ), New Delhi

President, Medical Council of India, New Delhi; Drugs Controller (I/C), Assam, Commissioner, FDA, Madhya Pradesh, elected member by MCI, elected member by PCI could not attend the meeting because of their other commitments.

Dr. V.G. Somani, DCG(I), Member-Secretary, DTAB welcomed the Board members under the supervision of new chairman Dr. Sunil Kumar, DGHS. All members were introduced to the Chairman. The Chairman then requested DCG(I) to initiate the proceedings. DCG(I) initiated the deliberation on DTAB agenda along with Action Taken Reports on previous DTAB recommendations.

AGENDA NO. 1

ACTION TAKEN REPORT (ATR) FOR 85th DTAB MEETING HELD ON 29.07.2020

The Action Taken Report (ATR) on the recommendations of DTAB in 85th meeting was approved by the Board.

During the deliberation members opined that draft of notification for each agenda may be circulated among the members before finalizing. However, DCG(I) clarified that the process of drafting the notification before sending it to the Ministry and finalizing the same are under the preview of the Ministry. Further, DGHS requested DCGI to expedite the pending agenda which are under process.

As per 85th DTAB recommendations w.r.t the safety and efficacy of FDC of Flupenthixol + Melitracen for human use, it was informed by Dr. Nilima Kshirsagar Chairperson, of the sub-committee updated the progress stating that the experts have given their opinion on the phase IV trial protocol and therefore, a meeting of the sub-committee will be conducted for finalizing the recommendations for approving the proposed phase IV clinical trial protocol.

AGENDA NO. 2

CONSIDERATION OF PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES, 1945 FOR LABELING OF DRUGS CONTAINING COMPONENTS OF NON-VEGETARIAN ORIGIN WITH A RED MARK

DTAB was apprised that, a representation had been received regarding the labeling of drugs containing components of non-vegetarian origin with a red mark.

The representation has pointed out the deliberations /recommendations of various committees including Drugs Technical Advisory Board (DTAB) and Expert committee constituted under Prof. C .K. Kokate on the matter and urged the Ministry of Health and Family Welfare, CDSCO and DTAB to:-

1. Conduct a detailed study and examine the possibility of creating a list of non-essential/non-life saving drugs for which the marking of vegetarian/non-vegetarian can be implemented without affecting public health and safety; and
2. Set up an Expert Committee to examine the feasibility of marking non-vegetarian and vegetarian drugs with a Red and Green mark respectively, after taking into account scientific evidence and availability of alternative medicines.

Earlier, DTAB in its 71st meeting held on 13.05.2016 deliberated on the proposal to incorporate a provision under the Drugs and Cosmetics Rules, 1945 for labeling of cellulose based capsule with green dot to indicate its vegetarian origin to distinguish from normally available capsule which are gelatin based. However, the members of the Board had opined

that unlike food drugs are not taken by choice but are prescribed by the doctors to save lives and marking them as vegetarian or non – vegetarian origin is not desirable.

Also, the Expert Committee constituted by the Ministry of Health and Family Welfare vide Order No. X.11015/3/2017-DR dated 20.03.2017 under the Chairmanship of Prof. C.K. Kokate in its final report submitted on 23.11.2017 to the Ministry of Health and Family Welfare had opined that the labeling of capsules with Green/Red marks to indicate its origin in case of drugs is not logical and has given the reason as follows:

> *"The drugs, unlike food, are not taken by choice of the patients, but are prescribed by the physicians. Labeling these drugs as vegetarian or non-vegetarian origin is not desirable, The contents of the capsules may also contain drugs which are not of vegetarian origin; and the labeling of drugs with Red/Green mark will lead to non-acceptance of drugs by certain sections of the patient population who are vegetarian and the same is not desirable in the interest of the patients."*

After detailed deliberation, the Board reiterated its earlier recommendations made in the 71st DTAB meeting.

AGENDA NO.3

CONSIDERATION OF PROPOSAL TO MANDATE THE REQUIREMENTS OF MEDICINE LABELS IN HINDI OR LOCAL LANGUAGES ALONG WITH ENGLISH

Board was apprised that, a representation had been received regarding the requirements of medicine labels in Hindi or local languages along with English.

It has been stated that peoples/patients who doesn't understand English are facing problems in reading & understanding the text of medicine labels, package inserts & literatures.

Further, it is requested that the labels, Package inserts & literatures should be in Hindi or local languages along with English for the ease of understanding for common people and hence to decrease the breach between the consumer and medical company.

Earlier, similar issue for labelling of iron tablets and polio drops distributed to the children under Government programmes with name and expiry date in Hindi along with English was deliberated in 77th meeting of Drugs Technical Advisory Board (DTAB) and the Board in its 78th meeting constituted a sub-committee to examine and give its recommendation to streamline the labeling requirements of drugs.

The sub-committee had submitted its recommendations that name of medicines shall be printed both in English and Hindi for open market, whereas Government agencies during procurement of medicines are at liberty to ask for regional language on label of drug products along with English.

However, DTAB in its 82nd meeting held on 02.04.2019 while deliberating the recommendation of the sub-committee, did not agree for making it mandatory to include drug name and expiry date in Hindi/ Regional language along with English. However, details for reasons in this regard was not captured in the minutes of the meeting of the DTAB

Board deliberated earlier recommendation of 82nd DTAB meeting and recalled the reasons for not mandating the requirements of medicine labels in Hindi or local languages along with English as below:

- ✓ Space constraint on the label of the formulations especially on small vials and multi component products.
- ✓ It is impractical to print labels in Hindi/regional languages since drug products will be manufactured in one State and the same will be distributed for sale in whole Country. Further, it will add cost and logistic burden which may be passed on to the patients and the same is not desirable.

AGENDA NO.4

COSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 FOR PLACING OF OXYTOCIN API FROM PROHIBITED LIST TO RESTRICTED LIST TO ALLOW IMPORT EXCLUSIVELY AGAINST EXPORTS

Board was apprised that, M/s Sun Pharmaceutical Industries Limited, in its representation dated 15.09.2020 stated that, it is developing Oxytocin formulation for export to the regulated market like USA and requires DMF grade of Oxytocin API. However, import of DMF grade API of Oxytocin is not possible since it has been kept in prohibited list by Director General of Foreign Trade (DGFT) as a result of G.S.R. 390 (E) dated 24.04.2018.

As per G.S.R. 390(E) dated 24.04.2018, the import of Oxytocin and its formulation in any name or manner has been prohibited in the Country in exercise of the powers conferred under Section 10A of the Drugs and Cosmetics Act, 1940. However, import of Oxytocin reference standard for the purpose of test and analysis has been exempted vide G.S.R. 52(E) dated 27.01.2020.

Therefore, the firm has requested to recommend the DGFT to shift Oxytocin API from prohibited list to restricted list.

DTAB deliberated the matter and recommended to amend the notification for allowing import of Oxytocin API to manufacture formulations only for export purpose. Further the Chairman also stated that it will give an opportunity to Indian Pharmaceutical manufacturer to export such drugs to various countries and it may also facilitate Atmanirbhar Bharat.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSALS RELATED TO THE COSMETICS RULES 2020

5.1. CONSIDERATION OF THE PROPOSAL FOR CERTAIN AMENDMENs IN THE COSMETICS RULES, 2020

Board was apprised that, MoHFW has published separate Cosmetic Rules, 2020 vide G.S.R. 763 (E) dated 15.12.2020 to regulate import and registration, manufacture for sale and distribution of Cosmetics. Various representations have been received from stake holders for consequential minor amendment in the said notification for correction etc as under:-.

A. Inclusion of provision for Cancellation and suspension of licence.−

Provisions related to the Cancellation and suspension of licence are not included in the said Cosmetics Rules, 2020. Hence it has been proposed to include the provision as below:

Cancellation and suspension of licence.−

(1) The Licensing Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under these rules or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or the rules made thereunder.

(2) A licensee whose license has been suspended or cancelled may appeal within a period of three months from the date of the order to the State Government which shall after considering the appeal, pass orders, and such orders shall be final.

B. Amendments

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
1.	**3(m)**	"Laboratory" means the Central Cosmetics Laboratory established or notified for carrying out analysis or test of cosmetics by the Central Government under rule 11;	Provision may be omitted as it is already provided in the Act and Rules under heading CDL (Central Drugs Laboratory).	As the rules are overriding the Act, which is not appropriate.
2.	**3(w)**	—Use before or "date of expiry means the date recorded on the container, label or wrapper as the date upto which the cosmetic shall retain its characteristics as per standards at proposed storage condition stated on label;	explanation proviso may be added in Rule 3(w) as below: When use before term is used it shall mean use before first day of month stated on label and date of expiry means the cosmetic will expire on the last day of the month by 24 hrs.	For clarity.
3.	**4(2)(ii)**	(ii) sale, stock, exhibit or offer for sale or distribution of all categories of cosmetics.	May be considered for deletion as the license for sale of cosmetics is exempted as per Twelfth Schedule of the Cosmetics Rules, 2020.	As for sale of cosmetics, licence is not required.
4.	**7**	**Government Analyst-** The Central Government or a State Government may appoint by notification in the Official Gazette, the Government Analyst for the purpose of these rules as provided in section 20 of the Act and rules made thereunder	**Government Analyst-** The Central Government or a State Government may appoint the Government Analyst as provided in section 20 of the Act and rules made thereunder.	Provisions as written needs re-notification, hence to rectify it, present proposal is submitted.
5.	**9**	Power, duties and functions of Inspectors specially Authorized to inspect manufacture and sale of cosmetics:- (1) subject to the instructions of the **controlling officer**, it shall be the duty of inspector appointed under section 21 of the Act by the State	Power, duties and functions of Inspectors specially Authorized to inspect manufacture and sale of cosmetics:- (1) subject to the instructions of the **controlling authority**, it shall be the duty of inspector appointed under section 21 of the	To make inline with similar provision in the Drugs and Cosmetics Rules, 1945.

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		Government, authorized to inspect the manufacture of cosmetics (1) (ii) to send a detailed report after each inspection to the **Controlling officer** indicating the conditions of the licence and provisions of the Act and rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed; (1)(vi) make such enquiries and inspections as may be necessary to detect the manufacture or **sale** of cosmetics in contravention of any provision of the Act and these rules	Act by the State Government, authorized to inspect the manufacture of cosmetics. (1) (ii) to send a detailed report after each inspection to the **controlling authority** indicating the conditions of the licence and provisions of the Act and rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed; (1)(vi) make such enquiries and inspections as may be necessary to detect the manufacture of cosmetics in contravention of any provision of the Act and these rules.	As sale of cosmetics is already exempted under Schedule 12 of the new rules, the word sale may be deleted.
6.	**11**	**Establishment and functions of the Central Cosmetics Laboratory.** (1) The Central Government may, by notification, establish Central Cosmetics Laboratory for the purpose of,- (a) to analyse or test such samples of cosmetics as may be sent to it under sub- section (2) of section 11, or under sub-section (4) of section 25 of the Act;	**Central Cosmetics Laboratory and its function.** (1) The Central drug laboratory established under the Act shall function as Central Cosmetics Laboratory for the purpose of,- (a) to analyse or test such samples of cosmetics as may be sent to it under sub-section (2) of section 11, or under sub-section (4)	Present provision in rule overrides the Act. To rectify the same it harmonized with the Act.

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		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 or notify any laboratory under its control and the Director of such laboratory having facility for carrying out test and evaluation of cosmetics as Central Cosmetics Laboratory for the purposes specified in sub-rule (1): Provided that no Laboratory shall be so designated unless it has been duly accredited by the National Accreditation Body for Testing and Calibration Laboratories. (3) The Central Cosmetic Laboratory shall be headed by a Director who shall be appointed or designated by the Central Government.	of section 25 of the Act; 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 or notify any laboratory under its control and the Director of such laboratory having facility for carrying out test and evaluation of cosmetics as Central Cosmetics Laboratory for the purposes specified in sub-rule (1): Provided that no Laboratory shall be so designated unless it has been certified as GLP compliant or duly accredited by the National Accreditation Body for Testing and Calibration Laboratories. (3) The Central Cosmetic Laboratory shall be headed by a Director who shall be appointed or designated by the Central Government.	
7.	**26 (c)(ii)**	(ii) make arrangements with a laboratory approved by the Central Licensing Authority under Chapter VIII of the rules and accredited by National	(ii) make arrangements with a laboratory approved by the State Licensing Authority under Chapter VIII of the rules	As labs are approved by SLA not the CLA.

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		Accreditation Board for Testing & Calibration Laboratories (NABL) for carrying out such tests.		
8.	**26(f)**	The licensee shall keep record of the details of each batch of cosmetic manufactured by him and of the raw materials used therein as per particulars specified in the Eighth Schedule and such records shall be retained for a period of three years after the date of expiry of the batch.	The licensee shall keep record of the details of each batch of cosmetic manufactured by him and of the raw materials used therein as per particulars specified in the Eighth Schedule and such records shall be retained for a period of three years or **six** months after expiry of the batch whichever is later.	The committee agreed that manufacturer shall retain the records for a period of three years or **six** months after expiry of the batch whichever is later.
9.	**26(m) Proviso**	Provided that clauses (c) and (d) shall not apply to the manufacture of soap and the procedure for testing of raw materials and the records to be maintained by a manufacturer of soap shall be such as are approved by the Licensing Authority.	[Provided that clauses (f) and (h) shall not apply to the manufacture of soap and the procedure for testing of raw materials and the records to be maintained by a manufacturer of soap shall be such as are approved by the Licensing Authority.]	As it was earlier provided in rules.
10.	**49(1)**	Dispatch of samples for test or analysis by order of court :- (1) samples for test of analysis under sub-section (4) of section 25 of the Act shall be sent by registered post or by **courier** or delivered in person in a sealed packet, enclosed , together with a memorandum in Form Cos-20with the outer cover	Dispatch of samples for test or analysis by order of court :- (1) samples for test of analysis under sub-section (4) of section 25 of the Act shall be sent by registered post or delivered in person in a sealed packet, enclosed, together with a memorandum in Form Cos-20 with the outer	Courier needs to be deleted as per court of law Courier is not a recognized mode of sending the samples**.**

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		being addressed to the director.	cover being addressed to the director.	
11.	**53**	**Confiscation of cosmetics, implements, machinery etc.** – (1) Where any person has been convicted for contravening any of the provisions of Chapter IV of the Act or any Rule made thereunder, the stock of the cosmetics in respect of which the contravention had been made, shall be liable to confiscation. (2) Where any person has been convicted for manufacturing of any cosmetic deemed to be **misbranded under clause (a), clause (b) or clause (c) of section 17C of the Act, or adulterated cosmetic under section 17E of the Act,** or for manufacture for sale of any cosmetic without a valid licence as required under clause (c) of section 18 of the Act, any implements or machinery used in such manufacture and any receptacle, packages, or coverings in which such cosmetic is contained and the animals, vehicles, vessels or other conveyances used in carrying such cosmetics shall also be liable to confiscation.	**Confiscation of cosmetics, implements, machinery etc.** – (1) Where any person has been convicted for contravening any of the provisions of Chapter IV of the Act or any Rule made thereunder, the stock of the cosmetics in respect of which the contravention had been made, shall be liable to confiscation. (2) Where any person has been convicted for manufacturing of any cosmetic deemed to be misbranded under clause (a), clause (b) or clause (c) of section 17C of the Act, **or spurious cosmetics under Section 17D of the Act,** or adulterated cosmetic under section 17E of the Act, or for manufacture for sale of any cosmetic without a valid licence as required under clause (c) of section 18 of the Act, any implements or machinery used in such manufacture and any receptacle, packages, or coverings in which such cosmetic is contained and the animals, vehicles, vessels or other conveyances used in carrying such	No provision was made for confiscation of cosmetics if they are found to be **spurious as per Section 17D.** Hence this addition**.**

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
			cosmetics shall also be liable to confiscation.	
12.	**60**	**Validity of licence.** (1) A licence issued in Form COS- 23 shall remain valid, if the licensee deposits a licence retention fee referred in the Third Schedule before the completion of period of five years from the date of its issue, unless, it is suspended or cancelled by the State Licensing Authority. (2) The licence retention fee referred in sub-rule (1) shall be equivalent to the fee required for grant of such licence as specified in the Third Schedule. (3) If the licensee fails to pay licence retention fee on or before the due date as referred to in subrule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent of the licence fee for every month or part there of up to six months, and in the event of nonpayment of such fee, the licence shall be deemed to have been cancelled.	**Validity of Approval**. (1) **An approval** issued in Form COS- 23 shall remain valid, if the licensee deposits **the approval** retention fee referred in the Third Schedule before the completion of period of five years from the date of its issue, unless, it is suspended or cancelled by the State Licensing Authority. (2) The approval retention fee referred in sub-rule (1) shall be equivalent to the fee required for grant of such **approval** as specified in the Third Schedule. (3) If the licensee fails to pay **approval** retention fee on or before the due date as referred to in subrule (1), he shall be liable to pay approval retention fee along with a late fee calculated at the rate of two per cent of the approval fee for every month or part there of up to six months, and in the event of non-payment of such fee, the **approval** shall be deemed to have been cancelled.	Word "**licence"** may be replaced with word "**approval**" as laboratories gets approval as per rule and word licence is inconsistent.
13.	**61**	**Inspection for verification of compliance.** – The premises licensed in the	**Inspection for verification of compliance.** – The **approved premises** in	Word "**licence"** may be replaced with word "**approval**" as

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		manner specified in these rules shall be inspected jointly by Inspector appointed by the Central Government and State Government to verify compliance with the conditions of licence and provisions of the Act and these rules at least once in three years based on risk based approach.	the manner specified in these rules shall be inspected jointly by Inspector appointed by the Central Government and State Government to verify compliance with the conditions of **approval** and provisions of the Act and these rules at least once in three years based on risk based approach.	laboratories gets approval as per rule and word licence is inconsistent.
14.	**62(e)**	The approved institution shall from time to time report to the State Licensing Authority any changes in the person-in-charge of testing of cosmetics or in the expert staff responsible for testing and any material alteration in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the State Licensing Authority before grant or renewal of approval.	The approved institution shall from time to time report to the State Licensing Authority any changes in the person-in-charge of testing of cosmetics or in the expert staff responsible for testing and any material alteration in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the State Licensing Authority before grant **or end of retention period of approval.**	In Rule 62 (e) at the end it is mentioned as "----grant or renewal of approval" but the use of word "renewal" is not right, instead it would have been "---grant or end of retention period of approval", as there is no system of renewal, but there is a system of retention of licence.
15.	**63.**	**Withdrawal and suspension of approval.**– (1) The State Licensing Authority may, after giving the approved laboratory an opportunity to show cause why such an order should not be passed, by an order in writing, stating the reasons therefore, withdraw an approval	**Withdrawal and suspension of approval.** – (1) The State Licensing Authority may, after giving the approved laboratory an opportunity to show cause why such an order should not be passed, by an order in	The words "**Chapter,"** may be considered in place of word "Part", as there are no "Parts" in rules, but there are only "Chapters".

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		granted under this Part or suspend it for such period as considered appropriate either wholly or in respect of some of the categories of cosmetics to which it relates, if in his opinion, the approved institution has failed to comply with any of the conditions of the approval or with any provisions of the Act or Rules made thereunder.	writing, stating the reasons therefore, withdraw an approval granted under this **Chapter** or suspend it for such period as considered appropriate either wholly or in respect of some of the categories of cosmetics to which it relates, if in his opinion, the approved institution has failed to comply with any of the conditions of the approval or with any provisions of the Act or Rules made thereunder.	
16.	**69.**	**Debarment of applicant.**– (1) Whoever himself or, any other person on his behalf, or applicant submits misleading, or fake, or fabricated documents, may, be debarred by Licensing Authority for such period as deemed appropriate in the facts and circumstances of the case after giving an opportunity to show cause as to why such an order should not be made. (2) Where an applicant is aggrieved by an order made by the Central Licensing Authority under sub-rule (1), such applicant may, within thirty days from the receipt of the order, make an appeal to the Central Government or the State Government, as the case may be, and the Central	**Debarment of applicant.** – (1) Whoever himself or, any other person on his behalf, or applicant submits misleading, or fake, or fabricated documents, may, be debarred by Licensing Authority for such period as deemed appropriate in the facts and circumstances of the case after giving an opportunity to show cause as to why such an order should not be made. (2) Where an applicant is aggrieved by an order made by the **Licensing Authority** under sub-rule. (1), such applicant may, within thirty days from the receipt of the order, make an appeal to the	The said clause is applicable for central and state licensing authorities, but state licensing authority was missing, therefore to bring consistency with clause (1) of Rule 4 word "Central Licensing Authority" replaced by "Licensing Authority".

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		Government or the State Government, may, after such enquiry as it considers necessary, and after affording an opportunity of being heard, pass such orders in relation thereto as considered appropriate.	Central Government or the State Government, as the case may be, and the Central Government or the State Government, may, after such enquiry as it considers necessary, and after affording an opportunity of being heard, pass such orders in relation thereto as considered appropriate.	
17.	**First Schedule (Clause 6)**	In case of any violation of Drugs and Cosmetics Act, 1940 and Rules thereunder, the authorised agent shall continue to be responsible even after withdraw of this **Power of Attorney** for the cosmetics imported in India.	In case of any violation of Drugs and Cosmetics Act, 1940 and Rules thereunder, the authorised agent shall continue to be responsible even after withdraw of this **authorization** for the cosmetics imported in India.	To make similar provision in line with the Drugs and Cosmetics Rules, 1945.
18.	**Twelfth Schedule (Clause 2)**	**Hair Fixers**, namely mucilaginous preparations containing gums, used by men for fixing beard.	Clause 2 to be omitted from D&C rules, 1945	The provision is already covered by the new rules. Therefore same may be deleted from D&C rules, 1945
19	**34(10)**	**Manner of Labelling:-** in case, the cosmetics is meant for export then the labels on packages or container of cosmetics shall meet the specific requirements of law of the country to which the cosmetics is to be exported, but the following particulars shall appear in a conspicuous manner on the label of the inner most pack of the cosmetics in	**Manner of Labelling:-** "In case, the cosmetics is meant for export then the labels on packages or container of cosmetics shall meet the specific requirements of law of the country to which the cosmetics is to be exported. Provided that where a cosmetic is required by the consignee to be not	To make the provisions as per earlier Rules, & to make labelling provisions as per the requirements of importing county to facilitate export

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		which the cosmetics is packed and every other outer covering in which the container is packed:- (a)name of the cosmetics; (b)the distinctive batch number or lot number or serial number preceded by the word Lot No. or Lot or Batch No. or B. No. or Serial No. or B; (c)use before or date of expiry, if any; (d) the name and address of manufacturer and address of actual premises where the cosmetics has been manufactured; (e) licence number preceded by letters Licence No. or Lic. No.; (f) internationally recognised symbols in lieu of text, wherever required: Provided that where a cosmetic is required by the consignee to be not labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the State Licensing Authority".	labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the state Licensing Authority."	

Board was also apprised that the proposed amendments as above were deliberated in 59th DCC meeting held on 02.03.2021 and 60th (special) meeting held on 07.04.2021 and the DCC agreed to the proposed amendments.

DTAB deliberated the matter and agreed to the recommendations of 59th & 60th DCC and recommended to amend the Cosmetic Rules, 2020 accordingly.

5.2. CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS & COSMETICS RULES, 1945 FOR MANDATING INDICATION OF RED/BROWN OR GREEN DOT ON EVERY PACKAGE OF SOAPS, SHAMPOOS, TOOTHPASTES AND OTHER COSMETICS AND TOILETRIES FOR NON-VEGETARIAN OR VEGETARIAN ORIGIN

Board was apprised that, the DTAB in its 79th meeting held on 16.05.2018 agreed to the proposal for mandating the indication of green or red /brown dot on every package of soaps, shampoos, tooth paste & other cosmetics & toiletries for vegetarian/non-vegetarian respectively in the Drugs and Cosmetics Rules. The Board also suggested taking opinion from stakeholders and public before taking action in the matter.

Accordingly, a draft notification foramending Rule 148 of Drugs & Cosmetics Rules, 1945 was prepared for consideration of the Ministry. In the mean time, separate Rules, named as the Cosmetic Rules 2020 for regulation of import and manufacture of Cosmetics have been published vide GSR 763(E) dated 15.12.2020. The proposal for mandating the indication of green or red /brown dot on every package of soaps, shampoos, tooth paste & other cosmetics & toiletries for vegetarian/non-vegetarian respectively under Rule 34 of the Cosmetics Rules, 2020 may be deliberated in light of the Cosmetics Rules 2020.

Board after detailed deliberation emphasized that there is no clarity and system to certify vegetarian and Non-vegetarian ingredients in the Country. Hence, the Board did not agree for mandating the indication of green or red /brown dot on every package of Cosmetics, as it may complicate the regulation and add regulatory burden on stakeholders. Board also opined that, it can be voluntary and left to the company's own decision and accordingly, advisory may be issued for labeling red/brown or green dot on packages of soaps, shampoos, toothpastes and other cosmetics and toiletries for non-vegetarian or vegetarian origin.

AGENDA NO.6

CONSIDERATION OF THE RECOMMENDATION OF THE PROF. KOKATE COMMITTEE ON PENDING 17+ 49 FDCs OUT OF 294 FDCs AND 3 FDCs REFERRED BY HON'BLE HIGH COURT OF MAHARASHTRA, NAGPUR BENCH.

Board was apprised that, the Office of Drugs Controller General (India) received complaints from Consumer Associations in year 2007 regarding Fixed Dose Combinations (FDCs) not approved by DCG(I) but marketed in the country. As a part of follow up action of complaints, the office of DCG(I) prepared a list of 294 FDCs and directions were issued to all State/UT Drugs Controllers to withdraw these 294 FDCs which were licensed without

approval of DCG(I). The manufacturers association however, got stay from the Hon'ble High Court of Madras in respect of directions issued in the matter.

The matter was then placed in DTAB in the 56th meeting dated 16.01.2008. A Sub-Committee was constituted by DTAB to examine these FDCs. Accordingly, the Sub-Committee examined these FDC'S and submitted its report to the DTAB.

In this report of 294 FDCs;

(a) For, 17 FDCs it was reported that data provided by the manufacturer was considered inadequate to prove its rationality, safety & efficacy.

(b) With regard to 49 FDCs it was reported that further data generation in terms of safety and efficacy by conducting clinical trial/PMS study.

It has been approved by the Ministry that all pending issues (17+49) with respect to 294 FDCs may also be dealt by the by Prof. Kokate Committee and once Prof. Kokate Committee submits its report, it may be placed before DTAB for further necessary action.

Further, with respect to 3 FDCs i.e. 1. Cefadroxil + Clavulanic acid 2. Cefixime + Cloxacillin 3. Cefixime + Cloxacillin + Lactobacillus, in view of direction of Hon'ble High Court of Maharashtra, Nagpur Bench, 84th DTAB held on 27.08.2019 has also proposed that this may also be required to refer to Prof. Kokate Committee, which is already examining such similar FDCs.

In summary, all the pending issues of (17+49 FDCs/out of 294 FDCs) and 3 FDCs referred by Hon'ble High Court of Maharashtra, Nagpur Bench were required to be examined by the Prof. Kokate Committee.

Accordingly, Prof. Kokate Committee examined these 17+49+3 FDCs and categorized them into following categories (a) 33 FDCs considered as rational (b) 20FDCs require further data generation (c)16 FDCs considered as irrational. The irrational combinations are proposed, not to be allowed for their continued manufacturing and marketing in the country.

Board examined the Expert Committee report of Prof. Kokate dated 12.03.2021 and in principle agreed to the recommendations of the Prof. Kokate Committee and recommended that the sub-committee under Dr. Nilima Kshirsagar should quickly look at the 33 rational FDCs and 20 FDCs which needs further deliberations, to see if there are any inconsistencies and revert back to the Chairman of DTAB. However, the sub-committee shall examine the 16 irrational FDCs in details as per the earlier procedures.

AGENDA No.7

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT IN THE DEFINITION OF 'NEW DRUG' UNDER NEW DRUGS AND CLINICAL TRIAL RULES 2019 FOR REPLACING THE TERMINOLOGY "STEM CELL DERIVED PRODUCTS" WITH "CELLS OR STEM CELLS DERIVED PRODUCT"

DTAB was apprised that New Drugs and Clinical Trials Rules, 2019, were published vide G.S.R. 227 (E) dated 19.03.2019. The definition of "New Drugs" prescribed under these rules also includes "stem cell derived products".

In order to provide clarification on "stem cell derived product", the matter was discussed in the DTAB. Based on the recommendation of the 84th DTAB in its meeting held on 27.08.2019 and 85th DTAB held on 29.07.2020, the Central Government vide letter no X-11026/21/20107-DRS dated 09.02.2021 has issued directions under 33(P) to all Principal/Health Secretaries of states & UTs for issuance of clarification on stem cell derived product under New Drugs and Clinical Trial Rules, 2019.

The said direction also clarifies that cell based products are covered in the rules as per criteria mentioned in the letter.

The term "cell derived product", however, is missing in the definition of the New Drug, which only includes "stem cell derived products".

It is also pertinent to mention here that during various discussions; it has been proposed to consider for regulating the **cells or Stem cells derived product** instead of only **stem cell derived products** that will be appropriate terminology to regulate such products. Otherwise cell derived products are not getting clearly covered under the stated terminology i.e. "Stem cell derived products".

DCC in its 59th meeting held on 02.03.2021 deliberated this matter and agreed to replace the terminology **"stem cell derived products"** in the definition of "New Drugs" published under New Drugs and Clinical Trials Rules 2019 with **"Cells or Stem cells derived product"**

In view of above, it is now proposed to replace terminology **"stem cell derived products"** in the definition of "New Drugs" published under New Drugs and Clinical Trials Rules 2019 with **"Cells or Stem cells derived product"**.

DTAB deliberated the matter and recommended to amend the definition of "New Drugs" published under New Drugs and Clinical Trial Rules 2019 for replacing the terminology **"stem cell derived products" with "cells or stem cells derived product"**

AGENDA No.8

CONSIDERATION OF THE PROPOSAL FOR ISSUANCE OF CORRIGENDUM IN RESPECT OF THE NEW DRUGS AND CLINICAL TRIALS RULES, 2019

DTAB was apprised the representation forwarded by Department of Health Research (DHR), that New Drugs and Clinical Trials Rules, 2019 has been notified by the Ministry of Health and Family Welfare vide G.S.R. 227(E) dated 19.03.2019 wherein Chapter IV deals with Ethics Committees (ECs) for Biomedical and Health Research.

As per Rule 17(1) of the said Rules, such EC shall be required to register with the authority designated by the Department of Health Research (DHR). Accordingly, "National Ethics Committee Registry for Biomedical Research" (NECRBHR) has been set up at DHR to conduct, online, the entire process for registration of such ECs.

It was noted that the Form CT-03 contains some apparent inconsistencies,- attributable, perhaps to typing /printing errors. Statements, depicting these errors, suggested replacements with justification as proposed by DHR are listed below:

Line	As shown in the Form CT-03 published in the Gazette	May be replace with	Remarks
3rd line	… the Regulation of New Drugs ……	……the ~~**Regulation of**~~ New Drugs ……..	The words '*Regulation of*' do not appear to make any sense here, and appear to be by way of printing error It may be mentioned that in Form CT 02 applicable to CDSCO, this has been correctly given
At the place of signature	'Central Licensing Authority'	'Designated Registration Authority'	As per Rule 3 The Drugs Controller, India appointed by the Central Government in the MoHFW shall be the Central Licencing Authority for the purpose of these rules. And this Authority is for ethics committees in relation to clinical trial studies, New drugs etc, only and not granting registration of ECs for

			medical and health research. EC registration for biomedical and health research is to be done by the authority designated for the purpose by DHR

Board was also apprised that the above amendments were deliberated in the 59th DCC meeting held on 02.03.2021 and the DCC agreed for the proposed amendments.

DTAB deliberated the matter and agreed to the recommendations of the 59th DCC and recommended to amend the New Drugs and Clinical Trials Rules, 2019 accordingly.

AGENDA NO.9

PROPOSALS RELATED TO MEDICAL DEVICES RULES, 2017

9.1 CONSIDERATION OF THE PROPOSAL TO REGULATE SALE AND DISTRIBUTION OF REGULATED MEDICAL DEVICES BY SYSTEM OF REGISTRATION OF PREMISES AND SELLER OR DISTRIBUTOR, INVOLVED IN IT.

DTAB was apprised about the representations received from various Associations/ stakeholders for exemption of Drugs Sale Licence for all imported Medical Equipments (Instruments/ Equipments/ Apparatus/ appliances), provided the importer/ stockist / retailer of Medical Devices make a registration of such premises where Medical Devices are stocked for sale and distributed.

DCC in its 59th meeting held on 02.03.2021 deliberated the matter and agreed in principle. Further, it was noted by the Committee that most of medical devices which are recently taken for regulation in phase wise manner are sold & distributed by distributors (shop-owners) directly to the hospitals or doctors and in-vitro diagnostics (IVDs) and related diagnostic machinery are sold or distributed directly to the pathological laboratories. Very few medical devices or in-vitro diagnostics, which are directly used by consumers, are sold to the consumers and usually prescription is not involved for such purchases by consumers.

Accordingly, there are inherent differences between the sale and distribution of drugs and medical devices as the drugs are usually sold or distributed by wholesalers to retailers and by retailers to the patients/consumers on the basis of prescription while

medical devices are sold and distributed mainly to hospitals/doctors or pathological laboratories.

Therefore, looking at above aspects and international practices, Committee recommended to regulate the sale of medical devices in a different manner than the drugs by creating a system of registration of the premises and person involved in the business of sale or distribution of medical devices to maintain the traceability, security and integrity of supply chain of medical devices.

Committee observed that the sale and distribution of regulated medical devices, which fall under the definition of 3(b)(iv) of "drug" is as such permissible under present rule which can also be allowed to be continued in addition to maintain continuity of already existing system.

Further, Committee had recommended to constitute a sub-committee under the chairmanship of Dr. S. Eswara Reddy, JDC(I),CDSCO to examine the subject matter. The sub-committee examined the matter and submitted its report in 60th(special) DCC meeting held on 07.04.2021.

60th DCC (special) deliberated the sub-committee report in detail including the proposed draft Rules as prepared by the sub-committee and accepted the report of the sub-committee with the suggestion to reframe the provision with respect to appeal [proposed Rule 87(D)(2)] as under :-

" A registration certificate holder whose registration has been suspended or cancelled by State Licensing Authority under sub Rule (1) an appeal to the State Government or Authority designated by the State Government".

DTAB examined the recommendations made by the sub-Committee and 60th DCC .

Board after detailed deliberations agreed to amend provisions of sale of Medical Devices prescribed under Rule 87 of Medical Devices Rules, 2017 as per the recommendations made by the sub-committee and the 60th DCC

9.2 CONSIDERATION OF THE PROPOSAL TO ADD THE COUNTRY UNITED KINGDOM TO THE LIST OF THE COUNTRIES IN SUB-RULE (3) OF RULE 36 OF THE MEDICAL DEVICES RULES, 2017 TO RECOGNIZE THE FREE SALE CERTIFICATE ISSUED BY THE NATIONAL REGULATORY AUTHORITY OF UK ALONG WITH THE COUNTRIES

NAMELY, AUSTRALIA, CANADA, JAPAN, EUROPEAN UNION COUNTRIES, OR THE UNITED STATES OF AMERICA IN SUB-RULE (3) OF RULE 36 OF THE MEDICAL DEVICES RULES, 2017

Board was apprised that United Kingdom has requested to add UK to the list of the countries in sub-rule (3) of Rule 36 of the Medical Devices Rules, 2017 to recognize the Free Sale Certificate issued by the National Regulatory Authority of UK along with the countries namely, Australia, Canada, Japan, European Union Countries, or the United States of America in sub-rule (3) of Rule 36 of the Medical Devices Rules, 2017 for granting an import licence under sub-rule (1) of Rule 36 of the Medical Devices Rules, 2017 to applicants without further clinical investigation of the products.

Medical Devices Rules, 2017 was notified by Ministry of Health & Family Welfare on 31.01.2017 and the same was implemented with effect from 01.01.2018. As per sub-rule (3) of Rule 36 of Medical Device Rules, 2017 "Where, a free sale certificate has already been issued in respect of any medical device by the national regulatory authority or other competent authority of any of the countries namely, Australia, Canada, Japan, European Union Countries, or the United States of America, a licence shall be granted under sub-rule (1) to the applicant without carrying out clinical investigation."

Under sub rule (3) of Rule 36 of Medical Device Rules, 2017, Free Sale Certificate issued by the National Regulatory Authority or other competent authorities of European Union Countries were already recognized and UK was part of the EU at that point of time. Hence, Free Sale Certificate issued by the National Regulatory Authority of UK was also accepted for considering the marketing approval. In the current scenario, as UK is being separated from the EU, the request of UK may be considered for appropriate action/ amendment in the Medical Device Rules, 2017 as per the procedures for amendment in the rules, prescribed under the Drugs and Cosmetics Act, 1940.

DTAB deliberated the matter and agreed to amend the sub rule (3) of Rule 36 of the Medical Devices Rules, 2017 to include the country "United Kingdom" along with existing countries specified in the said Rules.

AGENDA No.10

CONSIDERATION OF THE PROPOSAL FOR THE FORMS (LICENSES) SPECIFIED IN SCHEDULE A OF D&C RULES FOR REDUCING THE REGULATORY COMPLIANCE BURDEN (ONLINE PAYMENT / SELF CERTIFICATION / DIGITALISATION)

DTAB was apprised about the exercise on rationalizing/simplifying and minimizing regulatory compliance burden on businesses in order to improving cost and ease of doing business in the India in a strategic manner being made by the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, as Nodal Ministry for this exercise.

DPIIT has requested all Ministries and departments to prepare a plan of action and roadmap for reducing and rationalizing the overall compliance burden:

a. By examining Acts and compliances which are out dated in order to remove redundant laws and compliances.
b. To do business process reengineering to reduce, rationalize and simplify the multitude of Acts, Rules and Administrative orders.
c. To digitize all processes so as to do away with all physical submission of papers.

Further, DPIIT has requested to identify their respective area of compliance and focus on executing the identified points to reduce the compliance burden within the timeline of 31st March, 2021(Phase-I) in case of Rules and Regulations and within the timeline of 15th August, 2021 (Phase-II) in case of compliances related to the Act.

Accordingly, CDSCO and Ministry of Health and Family Welfare has identified following compliances for reducing compliance burden;

1. No. of compliances proposed to become less burdensome before 31st March 2021;

   i. Auto renewals with online payment –06 compliances
   ii. Licences/approval kept on self-certification (Risk –based classification)- 01 compliance.
   iii. To be digitized- 10 compliances.

2. No. of compliances proposed to become less burdensome before 15th August, 2021;

   i. Laws identified for decriminalization-02 compliances.
   ii. Any other- 01 compliances.

Also, DPIIT has forwarded a data received from Team Lease, a Third Party which has identified 1132 compliances related to Drugs and Cosmetics Rules, 1945; Medical Devices Rules, 2017 and New Drugs and Clinical Trials Rules, 2019 as burdensome, which are categorized as follows;

- Rules or regulations based-3 compliances
- Rule based and reviewable-399 compliances
- Procedural Guidelines-730 compliances

CDSCO and MoHFW after comprehensive review of these 1132 compliances have identified 8 compliances as redundant, which are required to be removed from the Rules.

CDSCO has also convened consultation meetings with Drugs Manufacturers Associations, Chemists and Druggists Associations and Consumer Associations on this matter for their views.

Board was also apprised that the above amendments were deliberated in 59th DCC meeting held on 02.03.2021 and the DCC agreed to the proposed amendments.

DTAB deliberated the matter and agreed to the recommendations of the 59th DCC and recommended to reduce above compliances burden by amending Rules under the Drugs and Cosmetics Act 1940.

AGENDA NO. 11

CONSIDERATION OF THE REVISED RECOMMENDATIONS OF THE SUB-COMMITTEE CONSTITUTED BY THE DRUGS CONSULTATIVE COMMITTEE (DCC) FOR CLARIFICATION ON EXEMPTION OF DETTOL ANTISEPTIC LIQUID (CLOROXYLENOL, TERPINEOL AND ALCOHOL) AS ANTISEPTIC LIKE THAT OF DISINFECTANT IN THE COUNTRY UNDER SCHEDULE K (RULE 123) OF DRUGS AND COSMETICS RULES 1945 AND IDENTIFY SUCH SIMILAR TYPE OF PRODUCTS.

Board was apprised that DCC in its 55th meeting held on 31.01.2019 & 01.02.2019 has constituted a sub-committee for clarification on exemption of Dettol antiseptic liquid (cloroxylenol, terpineol and alcohol) as antiseptic and disinfectant in the country under Schedule K (Rule 123) of Drugs and Cosmetics Rules 1945 and identify such similar type of products and give its recommendations.

The sub-committee was constituted vide Office Memorandum vide X-19013/04/2018-DC(1) dated 20.02.2019 & 05.03.2019, under the Chairmanship of Shri. N.K. Ahooja, State Drugs Controller, Haryana. As per the terms of reference, the Sub-committee in its meeting held on 26.07.2019 invited the representatives from (1) M/s. Reckitt Benckiser (Manufacturer of Dettol antiseptic liquid) (2) M/s. ITC Limited (Manufacturer of Savlon antiseptic liquid), both leading manufacturers for antiseptic liquids to offer their views.

The Sub-committee presented revised recommendations on the exemption of liquid antiseptics form the requirements of sale license. The committee expressed that the access to liquid antiseptics should not be restricted from licensed premises but should be permitted to sold at all shops especially during the current COVID pandemic. The committee recommended that the D&C rules may be amended as proposed by the sub-committee subject to the conditions mentioned in the report.

Recommendations of the Sub-committee:

The Sub-Committee has examined the issue in detail and had made the following recommendations: -

i) Antiseptics in general are extensively used during post disaster prevention and spread of infection, environmental and social hygiene to prevent disease outbreak, rural maternal health to address infection after child birth. They are also used amongst all age group and amongst all population in different regions, rural and urban areas. They are also recommended by WHO for in prevention and treatment of maternal peripartum infections.

It is necessary to make antiseptics accessible to the entire population. Restricting sale of antiseptics from only licensed premises denies access and availability to rural and remote areas. Further, the safety of the available antiseptics does not raise any concern.

ii) After careful consideration of the representation of the firms, M/s Reckitt Benckiser and M/s ITC, related judgments, the Sub-Committee recommends that all antiseptic formulations for external use including Dettol and savlon, may be exempted from being covered under a sale license.

iii) Antiseptics should continue to be manufactured under valid licence and there should not be any requirement of licence for its sale as is the case of disinfectant which also does not need sale license.

iv) Accordingly, the Schedule K may be amended by inserting the category of Antiseptics under Sl.No.12.

1. The report of the Sub-committee has been presented in the Drugs Consultative Committee in its 58th meeting held on 14.07.2020. After deliberation the DCC observed that there are numerous such products in the market which the sub-committee did not evaluate due to its specific mandate on three products only. Hence DCC suggested that the scope of the sub-committee shall be revised and broadened to relook the matter for examination all the available liquid antiseptic solutions in the market.

2. Accordingly, the sub-committee examined the products available in the market, the details are available in the annexure to this report. The marketed Liquid

antiseptics contain Cetrimide, Chlorhexidine or Chloroxylenol as active ingredients.

3. The Sub-Committee has examined the issue in detail and had made the following recommendations: -

i) The sub-committee has taken into consideration the concerns of the DCC to prevent misuse/abuse of the product if exempted from the requirement of sale license.

ii) Enhancing the accessibility of Liquid Antiseptics to remote locations and places which are deprived of the presence of retail medical shops is necessary, especially during pandemics and epidemics .

iii) Safety of the ingredients of the currently available antiseptics does not raise any concern.

iv) In view of the above, the sub-committee recommends that the retail sale of the Liquid Antiseptics may be exempted from the requirement of sale license. Accordingly, Schedule K may be amended by inserting the following at appropriate position:

Class of Drugs	**Extent and Conditions of Exemption**
Liquid Antiseptics for household use	The provisions of Chapter IV of the Act and rules thereunder, which require them to be covered with a sale license in Form 20 or Form 20A subject to the following conditions:- (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

Board was also apprised that the above proposed amendments were deliberated in the 59th DCC meeting held on 02.03.2021 and the DCC agreed for the amendments.

DTAB after deliberation in the matter to the recommendations of the 59th DCC and recommended to amend the Schedule K of the Drugs Rules, 1945 as per the recommendations made by the sub-committee.

AGENDA NO. 12

CONSIDERATION OF THE PROPOSAL TO INCLUDE DRUG 'ACITRETIN' IN THE SCHEDULE H OF THE DRUGS RULES, 1945

DTAB was apprised that a representation had been received on 06.02.2021 wherein it had been requested for inclusion of the drug 'Acitretin' in the Schedule H of Drugs and Cosmetics Rules 1945.

It has been stated that the drug Acitretin is not included in any Schedule of the Drugs & Cosmetics Rules 1945, which requires prescription from the RMP. Hence, the drug 'Acitretin' possesses the status of non-prescription and over the counter drugs (OTC) in India.

Acitretin is one of the systemic retinoids used in medicine particularly in dermatological diseases and has serious side effect profile particularly pregnancy related (teratogenic drug).

In this regard, it is to inform that CDSCO had approved Acitretin for sever psoriasis in adults (excluding female of child bearing potentials) on 09.09.2005 with the condition that the label of the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning;

"*acitretin should be prescribed by Dermatologists knowledgeable in systemic use of retinoid"*

DTAB deliberated the matter and agreed to include the drug " Acitretin" in the Schedule H of the Drugs Rules, 1945.

ADDITONAL AGENDA S-1

ISSUE OF BAR CODING/QR CODING-CONSIDERATION OF THE PROPOSAL FOR INTRODUCTION OF TRACE AND TRACK FOR MOST POPULAR OR TOP 300 PHARMACEUTICAL BRANDS AVAILABLE IN INDIAN MARKET BY THE MANUFACTURERS

Boards was apprised that the issue of bar coding/QR coding on packaging of drugs has been under discussion for quite some times now. MoHFW as nodal Ministry may implement the bar coding/QR coding system on packaging to ensure the quality safety and efficacy of drugs through trace and track mechanism.

In this regard draft rules for this purpose were earlier published for comments vide G.S.R. 449 (E) dated 03.06.2015. These rules could not be finalized as many of the pharmaceutical companies showed their inability to introduce this sophisticated technology

in their manufacturing processes. It is however observed that some of the pharmaceutical companies have already introduced bar coding system in some of the brands.

Further, it was proposed to sensitize the major drug manufacturers who have introduced bar coding systems in their manufacture to share their experience in respect of their top 300 pharmaceutical brands for which such system was introduced through the manufacturers associations. This would facilitate in introduction of barcoding system for trace and track.

The DTAB in its 79th meeting held on 16.05.2018 deliberated the matter and agreed for introduction of trace and track mechanism for major 300 pharmaceuticals brands on voluntary basis. The Board informed that an order may be issued by DCG (I) to all the concerned to this effect.

Subsequently, Ministry of Health and Family Welfare, has published draft notification vide G.S.R. 567 (E) on 08.08.2019 mandating QR code for APIs only based on the recommendations of 82nd DTAB. A number of objections have been received from the Industry, which are being examined.

In view of above, in order to introduce QR code in phase wise manner, in present context, it is proposed that trace and track mechanism by QR coding system on packaging may be implemented initially for the top 300 brands through amendment in the Drugs Rules, 1945 and the earlier draft notification issued in this regard vide G.S.R. 449 (E) dated 03.06.2015 may be withdrawn.

DTAB deliberated the matter but partially and could not deliberate the agenda completely and deferred for examining it separately in its early next meeting.

The meeting ended with a vote of thanks to the Chair.

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