MINUTES OF THE 63RD DTAB MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 16TH MAY, 2013 IN THE COMMITTEE ROOM, FDA BHAVAN, KOTLA ROAD, NEW DELHI – 110002

PRESENT

1. Dr. Jagdish Prasad, Director General of Health Serivces, Nirman Bhawan, New Delhi.	Chairman
2. Dr. Sunil Gupta, Director, Central Research Institute, Kasauli, (HP) -173205	Member
3. Dr. S. D. Seth, Advisor CTRI, National Institute of Medical Statistics, ICMR, Ansaari Nagar, New Delhi-110002	Member
4. Dr. B. R. Jagashetty, Drugs Controller, Karnataka Palace Road, Banglore-560001	Member
5. Dr. B. Suresh, President, Pharmacy Council of India New Delhi	Member
6. Dr. J.A.S. Giri 815A, Road No. 41 Jublee Hills, Hyderabad-500033	Member
7. Dr. G. N. Singh, Drugs Controller General (India) FDA Bhawan, New Delhi-110002	Member Secretary

CDSCO REPRESENTATIVES

1. Shri A.K. Pradhan
   Deputy Drugs Controller (India)
   CDSCO, New Delhi

2. Shri Lalit Kishore
   Consultant, DCG(I)
   CDSCO, New Delhi

3. Dr. S.Eswara Reddy
   Deputy Drugs Controller (India)
   CDSCO, New Delhi

Dr. T.K. Chakraborty, Director, CDRI, Lucknow; Prof. K.K. Talwar, Chairman, Board of Governors, MCI, New Delhi; Dr. Dharam Prakash, Delhi; Dr. K. Chinnaswamy, Coimbatore, Dr. B.P.S. Reddy, Hyderabad, Dr. J.K. Rajvaidya, Bhopal, Shri Hariharan, Director I/C, Central Drug Laboratory, Kolkata, Dr. Dhrubajyoti Bora, Guwahati, Director IVRI, Izatnagar, (U.P), Sh. Satish Gupta, Controller Drugs & Food (J&K) and Shri Yatendra Raj Mehta, Drug Testing Laboratory, Jaipur could not attend the meeting because of their pre-occupation.

Dr. G. N. Singh, Drugs Controller General (India) and Member Secretary DTAB welcomed the Chairman and members of the Board and requested the Chairman to initiate the proceedings.

The Chairman in its opening remark stated that DTAB is an august body which takes momentous decisions after deliberations for advising the Government on technical matters. It has however, been observed that many of the members are not attending the DTAB meetings consistently. The Ministry of Health and Family Welfare may therefore be appraised of the members which are not attending the meetings in the past three or four meetings. In the case of Ex-officio members, the Government may take up the matter with the concerned organizations etc. while associations could be asked to nominate alternate members who could attend and contribute to the deliberations.

The Chairman desired that DTAB should play more pro-active role. It should review the working of regulatory agencies and recommend measures to strengthen their manpower as well as technical competence. Chairman desired that the CDSCO should

have the competence, skill and manpower matching to USFDA or such other leading regulatory agencies in the world. Its decisions should have the stamp of technical competence. The State Drug Control Authorities are also required to be trained properly so that the State Regulatory authorities are able to ensure that the drugs are manufactured in the country conforming to prescribed standards and are manufactured in compliance to the Good Manufacturing Practices norms.

Dr. G. N. Singh, member Secretary stated that the DTAB has been meeting quite regularly and has taken land mark decisions which helped the Government in making much needed changes in the Drugs and Cosmetics Rules, 1945 for regulating the quality of drugs as well as conduct of clinical trial of the country.

The Drugs Controller, Karnataka desired that in order to enthuse confidence in State Regulatory Authorities, the next meeting of the Board may be held at Bangluru, so that members are apprised of the progress made in the regulatory affairs in the Southern States.

Members agreed to the said proposal.

AGENDA NO. 1

ACTION TAKEN REPORT ON THE MATTERS ARISING OUT OF THE 61st MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 24th July, 2012, AT NEW DELHI

1. Serial No. 1 of ATR

While discussing the proposal of introduction of Schedule H1 under the Drugs and Cosmetics Rules, 1945, the Chairman desired that there should be a provision of retaining the duplicate / carbon copy of the prescription of the Medical Practitioner by the retail chemists for the sale of drugs covered under Schedule H1.

The Chairman further suggested that the Pharmacovigilance committees of the medical colleges should also monitor the use of antibiotics in the respective hospitals along with their routine function of Adverse Drugs Reaction monitoring.

2. Serial No. 5 of ATR

While discussing the question of continued marketing of the drug analgin, the members were of the opinion that the criteria of banning a drug should not be solely on the basis of its prohibition in certain countries but also on the basis of its safety, efficacy and context of its usages permitted in the country.

The drug analgin is presently indicated to be used only for severe pain or pain due to tumor and also for bringing down the temperature in refractory cases when other anti-pyrtics fail to do so. The drug has also been put under focused pharmacovigilance programme to capture incidences of Adverse Drugs Reactions with the drug.

The New Drugs Advisory Committee (Neurology and Psychiatry), which has examined the issue of continued marketing of analgin in the country, has recommended that there is no adequate data on Indian population in support of either ban of the drug or allow the continued marketing of the drug in the country. However,, considering the issues related to the safety aspect of the drug and regulatory actions in many other countries and the fact that alternate analgesics are available, committee recommended that the marketing of the drug in the country should be put under the suspension and the firm should be asked to generate adequate data in Indian scenario to consider the matter further.

The DTAB, however, opined that the drug is being marketed in some European countries and there are no adequate reports of adverse effect of the drug which may warrant prohibition of the drug in the country at present juncture.

AGENDA NO. 2

CONSIDERATION OF THE CONCERNS RAISED BY VARIOUS STAKEHOLDERS IN RESPECT OF THE PROVISIONS INTRODUCED UNDER THE DRUGS AND COSMETICS RULES VIDE GAZETTE NOTIFICATION GSR 53(E), DATED 30.01.2013 RELATING TO GRANT OF COMPENSATION IN CASE OF INJURY OR DEATH DURING THE CLINICAL TRIAL AND THE PROCEDURES FOR REVIEW OF THE SERIOUS ADVERSE EVENTS

The Chairman briefed the members that the Drugs and Cosmetics Rules, 1945 were amended by the Ministry of Health and Family Welfare vide Gazette Notification G.S.R. 53(E), dated 30.01.2013. Under this notification, a new rule 122 DAB has been introduced for the grant of compensation in the case of injury or death during the clinical trial and an APPENDIX XII has been added in Schedule Y prescribing the procedures for examination of the cases of Serious Adverse Events and compensations to be paid in the cases of clinical trial related injury or death during the clinical trial. This is a land mark amendment which has provided a regulatory support for the protection of the rights of clinical trial subjects.

The Government of India have, however, received representations from many stakeholders like Dr. Swati Piramal, Vice Chair person, Piramal Enterprises Limited, Indian Society for Clinical Research, Dr. Ajay Kumar, MP, Lok Sabha, FICCI, Drugs manufacturers associations, Individual Drug Manufacturers, Medical Professionals especially those involved in clinical research on certain provisions of the notification like free medical management in case of injury, compensation time lines, financial compensation in the case of failure of investigational product to provide intended therapeutic effect or use of placebo in a placebo control trial etc. It has been stated that the notification is not in line with the international guidelines and is likely to have cascading effect on the future of clinical trials in India. It has been requested that certain provisions in the notification require clarification or modification for the continuation of the clinical research in the country.

Under the directions of the Hon'ble Supreme Court of India during the hearing of a Court case (Swasthya Adhikar Munch Vs. Union of India), the Ministry of Health and Family Welfare had constituted two committees for supervising the clinical trials on new chemicals entities. The Technical Committee is headed by the Director General of Health Services and the Apex Committee for overall supervision is headed by the Secretary, Ministry of Health and Family Welfare. The Technical Committee in its meeting on 27.02.2013 deliberated the various clauses of the notification and opined that the certain provisions of the notification need modifications.

The Technical Committee felt that the issue of providing free medical management to the subject in case of any injury irrespective of whether it is related to clinical trial or not is required be suitably amended to ensure that medical management is provided in the case of injury due to clinical trial related activities only. Further, the clause relating to financial compensation in the case of injury or death due to failure of investigational product to provide intended therapeutic effect need be deleted. Similarly in the case of Placebo controlled trial, the eligibility for compensation should be in the case of injury or death due to use of Placebo in a placebo controlled trial if standard care is denied. Further the timeline requirements for submitting of SAEs report after due analysis by the sponsor / investigator should be harmonious to the international practice of fourteen calendar days instead of ten days as prescribed. The committee had further recommended that in the case of investigator initiated institutional trials, the department of health research should maintained a corpus funds to compensate subjects who suffer injury or death during such institutional clinical trials.

The Independent Expert Committee constituted to examine the report of the Serious Adverse Events of death also recommended that timelines for the examination of Serious Adverse Events and payment of compensations to be followed by Investigator, Ethics Committee, Sponsor and DCG(I) should also be required to extended so that cases are properly examined.

The Apex Committee headed by the Secretary, Ministry of Health and Family Welfare desired that the above concerns may be placed before DTAB for its consideration and further recommendations in the matter.

The DTAB deliberated on the issues raised in the representations and gave the following recommendations.

(1) Free medical management

As per the clause (1) of rule 122 DAB, in the case of an injury occurring to the clinical trial subject, he or she shall be given free medical management as long as required.

The members agreed to the suggestion of the technical committee that medical management should be provided in case the injury is due to clinical trial related activities only, as the free medical management may create undue influence for patient to enroll in a clinical trial.

The DTAB therefore recommended that the clause may be amended to read as under

'In the case of clinical trial related injury to a subject occurring during the clinical trial, he or she shall be given free medical management as long as required'.

(2) **Financial compensation in case of an injur**y

In the clause (2) of rule 122 DAB, it has been provided that in case the injury occurring to the trial subject is related to the clinical trial, he or she shall also receive financial compensation as per order of the licensing authority defined under rule 21(b). The financial compensation will be over and above any expenses incurred on the medical management of the subject.

The DTAB recommended that a qualifying clause may be further added in the sub-rule that 'in case there is no permanent injury, the quantum of compensation shall commensurate with the inconvenience, loss of wages, transportation.'.

(3) Responsibility of payment of financial compensation

DTAB recommended that no changes required in the clause (4) relating to responsibility of payment of financial compensation by the sponsor.

(4) **Entitlement for financial compensation**

Sub-rule (5) of rule 122 DAB provides the causes when injury and death would be considered as clinical trial related injury or death and entitlement for financial compensation.

(i) Clause (c) relating to providing financial compensation in the case of injury or death due to failure of investigational product to provide intended therapeutic effect may be deleted as there is always a possibility that the investigational product may fail to provide intended therapeutic effect and the trial is conducted with the objective of assessing the therapeutic effect of the drug along with safety.

(ii) In the clause (d) relating to the use of placebo in a placebo-controlled trial, DTAB agreed to the suggestion of the Technical Committee that in certain cases placebo controlled trial is necessary to evaluate the efficacy of the investigational drug. Lack of therapeutic effect of placebo is explained to the subject during the consent process and the said clause may be further modified to read as under.

"Use of placebo in a placebo-controlled trial if the standard care is denied.".

(iii) In the case of clause (b) relating to the liability of sponsor to pay compensation for injury or death due to violation of approved protocol, scientific misconduct and negligence by the investigator, the Board did not agree to the concerns raised in the representations and did not recommend any change in the clause as investigator are indentified and are under contract of the sponsor for conduct of the study.

(iv) Similarly in the case of clause (e) relating to compensation for injury or death due to adverse effect due to concomitant medication excluding standard care, necessitated as part of approved protocol, DTAB did not agreed to any change in the clause as concomitant medication excluding standard care is administered to the subject because of requirement of the protocol.

(5) The requirement of sponsor and investigator to report Serious Adverse Events of death to the Chairman of the Expert Committee constituted by the Licensing Authority under APPENDIX XII may be deleted wherever it occurs in the notification. The report will be forwarded to the expert committee, so constituted, by the office of DCG(I).

(6) DTAB deliberated the concerns raised in respect of timelines to be followed by various agencies in reporting of the serious adverse events as well as recommendations by the Expert Committees and the decisions taken by the office of DCG(I) and recommended as under:

(i) The concern on requirement of investigator to report serious adverse events to the licensing authority and others within 24 hours of their occurrence was not agreed to by the DTAB and it did not recommend any change in this regard.

(ii) The requirements of sponsor and investigator to report the Serious Adverse Events after due analysis in 10 days may be changed to **14 days**, as per International practice.

(iii) The timelines to be followed by the Ethics Committees to forward the reports of Serious Adverse Events after due analysis along with their

opinion on quantum of compensation (in case of related deaths), within 21 day may be changes to **30 days**.

(iv) The time lines for Independent Expert Committee to examine the Serious Adverse Events of death and to recommend to the DCG(I) about the cause of the death and quantum of compensation (in case of clinical trial related death) within 30 days may be changed to **60 days**.

(v) The timelines for Licensing Authority i.e. Drugs Controller General (India) to determine the cause of the injury or death and decide the quantum of compensation to be paid may be amended to read as **two months after receiving the report of the Expert Committee**.

(vi) As regards to the requirement of sponsor or his representative to pay compensation within 30 days of receiving the order from DCG(I), the DTAB did not agree for any changes.

(vii) The requirements of investigator to report all serious and unexpected adverse events whereas the sponsor is required to report all serious adverse events should be harmonized to make provision that both investigator and sponsor are required to report all serious adverse events.

AGENDA NO. 3

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 3A OF THE DRUGS AND COSMETICS RULES DECLARING NATIONAL INSTITUTE OF BIOLOGICALS, NOIDA AS THE CENTRAL DRUG LABORATORY FOR TESTING BLOOD PRODUCTS, CERTAIN ENZYMES AND HORMONES, RECOMBINANT PRODUCTS, BIOCHEMICAL KITS

The member Secretary briefed the members that National Institute of Biologicals, Noida has the expertise to test many of the biological products for their quality. It was earlier declared as Central Drugs Laboratory for testing of Blood Grouping reagents and diagnostic kits for HIV, Hepatitis B Surface Antigen and Hepatitis C virus. In order to utilize the capacity of the laboratory for testing more biological products for their quality, an inspection of the laboratory was conducted along with the experts and the inspecting

team recommended that the laboratory could be declared as Central Drug Laboratory in respect of the following products also.

(1) Blood Products

(i) Human Albumin,

(ii) Human Normal Immunoglobulin (IM&IV)

(iii) Human Coagulation Factor VIII,

(iv) Human Coagulation Factor IX

(v) Plasma Protein Fractionation,

(vi) Fibrin Sealant Kit,

(vii) Anti Inhibitor Coagulation complex

(2) Enzymes and Hormones

(i) Streptokinase (Natural & Recombinant)

(ii) Human Chorionic Gonadotropic

(iii) Human Menopausal Gonadotropin

(3) Recombinant Products

(i) Recombinant Insulin and Insulin analogues

(ii) r- erythropoietin (EPO)

(iii) r-Granulocyte Colony Stimulating Factor (G-CSF)

(4) Biochemical Kit

(i) Glucose Test Strips

(ii) Fully automated analyser based glucose reagents

In view of the above it was proposed to declare the laboratory as Central Drug Laboratory in respect of the above drugs also. The clause (8) of rule 3A is therefore required to be amended as under:

"(8) the function of the Laboratory in respect of the following kits or class of drugs shall carried out at National Institute of Biologicals, Noida and the functions of the Director in respect of the said drugs or class of drugs shall be exercised by the Director of the said institute.

(1) Blood grouping reagents

(2) Diagnostic kits for human immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus

(3) Blood Products
- (i) Human Albumin,
- (ii) Human Normal Immunoglobulin (IM&IV)
- (iii) Human Coagulation Factor VIII,
- (iv) Human Coagulation Factor IX
- (v) Plasma Protein Fractionation,
- (vi) Fibrin Sealant Kit,
- (vii) Anti Inhibitor Coagulation complex

(4) Enzymes and Hormones
- (i) Streptokinase (Natural & Recombinant)
- (ii) Human Chorionic Gonadotropic
- (iii) Human Menopausal Gonadotropin

(5) Recombinant Products
- (i) Recombinant Insulin and Insulin analogues
- (ii) r- erythropoietin (EPO)
- (iii) r-Granulocyte Colony Stimulating Factor (G-CSF)

(6) Biochemical Kit
- (i) Glucose Test Strips
- (ii) Fully automated analyser based glucose reagents."

Members after deliberations agreed to the proposed amendment.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL FOR CONSTITUTION OF A SUB-COMMITTEE OF DTAB ON HOMEOPATHIC MEDICINES TO DELIBERATE TECHNICAL MATTER RELATING TO HOMEOPATHY AND GIVE ITS RECOMMENDATIONS TO DTAB FOR FURTHER CONSIDERATION.

The Member Secretary briefed the members that DTAB had earlier constituted a sub-committee on Homoeopathic Medicines to deliberate technical matters relating to homoeopathic medicines and give its recommendations to the DTAB for its consideration. The committee is constituted by the Department of AYUSH, Ministry of Health & Family Welfare which looks after the issues relating to homoeopathy. The proposal for reconstitution of this sub-committee was earlier considered by the DTAB in its 59th meeting held on 24th June 2011. The members then desired that the sub-committee should be more broad based having experts from diverse fields related to homoeopathy for induct deliberations.

Joint Secretary, Department of AYUSH has now forwarded the proposal of reconstitution of the sub-committee of DTAB on Homeopathic medicines with the following members.

1. Chairman : Director General, Central Council for Research in Homoeopathy.
2. Official members:
   - i. Member Secretary: Deputy Advisor / Joint Advisor Homeopathy
   - ii. Member: Deputy Drugs Controller General (India)
   - iii. Member Director, Homoeopathic Pharmacopoeia Laboratory, Ghaziabad
   - iv. Member: Deputy Secretary, or above level officer of Department of AYUSH
3. Non-official Members:
   - i. Member: Drug Analyst from Maharashtra Drug Testing Laboratory as Drug Analyst
   - ii. Member: Dr. Indira Balachandran, Centre for Medicinal Plants Research, Arya Vaidyasala, Kottakal (Kerala), as Pharmacognosist.
   - iii. Member: Shri Vijay Kumar Kapoor, Dean, Faculty of Pharmacy and Allied, Punjab Technical University, Jalandhar
   - iv. Member: Representative of Homeopathy Pharmacopeia Committee

v.	Member:	Managing Director, Kerala State Co-Operative Homeopathic Pharmacy, Kerala as representative of Drug Industry.
vi.	Member:	Chairman of Association of Homeopathy Drug Manufacturers
vii.	Member:	Head of Department of Materia Madica, National Institute of Homeopathy, Kolkata
viii.	Member:	Dr. V.K. Gupta, C-3/29, Rajouri Garden, New Delhi-110027, as Homeopathy practitioner

The members of deliberations agreed to the constitution of the said sub-committee on homoeopathic medicines It however recommended that one or two State Drugs Controllers having experience in enforcing the provisions of the Drugs & Cosmetics Rules relating to homoeopathic medicines may also be inducted in the committee for providing inputs in respect of implementation of the provisions of the Drugs & Cosmetics Rules, 1945 for homoeopathic medicines in the States. It was further recommended that the tenure of the committee shall be of two years.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL TO PROHIBIT MANUFACTURE FOR SALE, SALE AND DISTRIBUTION OF DICLOFENAC INJECTION IN DOSES HIGHER THAN 3 ML UNDER THE SECTION 26A OF THE DRUGS AND COSMETICS ACT, 1940 TO PREVENT DECLINE IN VULTURE POPULATION

The Member Secretary briefed the members that the green Indian States Trust, New Delhi wrote to the Ministry of Health and Family Welfare for preventing Diclofenac caused vulture decline in India and have requested for additional steps to prevent the misuse of Diclofenac Sodium injection in animals. It was alleged that multiple dose of Diclofenac Sodium Injection in the pack-size of 30ml is misused in the treatment of animals because of the lower cost of the treatment even though alternative treatment in the firm of meloxicam is available for animal use. It was therefore recommended that the manufacture, sale and distribution of all packs higher than 3ml of Diclofenac Sodium Injection may be prohibited to save the vulture population.

The members felt that banning of multi dose injections alone may not provide a long term solution to the problem of declining vulture population. The DTAB after deliberations decided that a sub-committee consisting of the following members may be constituted to examine the issues related to the use of Diclofenac Sodium Injection and decline in vulture population:

1. Dr. S.D. Seth, Advisor CTRI, National Institute of Medical Statistics, ICMR, New Delhi.
2. Dr. Y.K.Gupta, Professor & Head, Department of Pharmacology, AIIMS, New Delhi.
3. Dr. N.K. Gupta, Director Professor, Department of medicine, Maulana Azad Medical College, New Delhi

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL TO INCLUDE LIQUID FOUNDATION MAKE UP, COLD WAX-HAIR REMOVER, FACE PACK, KAJAL, OXIDATION HAIR DYES (EMULSION TYPE) AND CREAM BLEACH UNDER SCHEDULE S TO THE DRUGS AND COSMETICS RULES, 1940

The Member Secretary briefed the members that Schedule S of the Drugs and Cosmetics Rules lays down the standards for the cosmetics included in the Schedule, the standard for cosmetics are prepared by the Bureau of Indian Standards. The cosmetics covered under the Schedule are required to conform these specifications. At present there are 29 cosmetics under Schedule S. Draft rules for inclusion of 'Sindoor IS:14649:1999' as item no. 30 has been published by the Ministry of Health and Family Welfare vide G.S.R. 43(E) dated 24.01.2013 for comments for the purpose of finalization on the recommendations of DTAB in 60th meeting held on 10th October, 2011.

The BIS has now recommended that suitable standards have been prepared for the following cosmetics only for inclusion under Schedule S.

- IS 14318:1996 – Liquid foundation make up
- IS 15152:2002 – Cold Wax-Hair remover
- IS 15153:2002 – Face pack
- IS 15154:2002 – Kajal
- IS 15205:2005 –Oxidation Hair Dyes (Emulsion type) (First revision)
- IS 15608:2005– Cream Bleach

The matter was considered in the 45th meeting of the Drugs Consultative Committee held on 4th & 5th February, 2013 and it recommended that Schedule S to the Drugs and Cosmetics Rules may be amended to include the said cosmetics along with the their standards for the purpose of regulating their quality under the Drugs and Cosmetics Rules, 1945.

The DTAB after deliberations agreed to the proposed amendment in Schedule S of the Drugs & Cosmetics Rules.

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL TO DELETE COLOUR INDEX 12150 (SOLVENT RED 1), AND 20170 (RESORCIN BROWN) FROM SCHEDULE Q TO THE DRUGS AND COSMETICS RULES

The Member Secretary briefed the members that Schedule Q of the Drugs and Cosmetics Rules lays down the list of Dyes, Colours and Pigments permitted to be used in Cosmetics and Soaps as given under IS:4707 (Part I) – 1988 as amended by the Bureau of Indian Standards.

BIS had informed to the office of DCG(I) that the **Colour Index Number 12150, 20170 and 27290** may be deleted from Schedule 'Q' of Drugs and Cosmetics Rules, 1945 as these have been banned in developed countries based on latest research findings. It is however, observed that Colour Index No. 27290 does not figure in Schedule Q.

It was therefore proposed to delete the entries relating to colour index numbers 12150, 20170 in Schedule Q of the Drugs and Cosmetics Rules.

The matter was also considered in the 45th meeting of the Drugs Consultative Committee held on 4th & 5th February, 2013 and it agreed for the proposed deletion.

The DTAB after deliberations agreed to the proposed amendment.

AGENDA -8

CONSIDERATION OF THE REPRESENTATION OF HIM JAGRITI, UTTARANCHAL WELFARE SOCIETY AGAINSTS PACKAGING OF PHARMACEUTICAL PRODUCTS IN PET / PLASTIC BOTTLES DUE TO PUBLIC HEALTH AND ENVIRONMENTAL HAZARD

The chairman brought to the notice of the members that HIM JAGRITI, Uttaranchal Welfare Society, Dehradun has forwarded a representation to the Government of India suggesting complete ban on usages of PET bottles (both coloured and uncoloured) as primary packaging material in pharmaceutical liquid orals, suspensions and dry syrups as it has severe adverse effects on human health due to the presence of endocrine disruptors. Medical and pharmaceutical products, whether consumed orally by or injected into human beings, should not be made available to the public / consumer in a health threatening packaging. It has been stated that pharmaceutical liquid orals which were earlier packed in glass bottles are now being packed in Polyethylene Terephthalate (PET) bottles. Most of the cough syrups, antacids, vitamins etc. are packed in coloured (Amber) PET bottles. In PET bottles leaching take place under varying storage temperature conditions and the age of packaging. The PET / plastic bottles are composed of rigid plastic and are referred because of their light weight and shatter resistant quality. Studies have revealed that leaching of plastic leached to contamination of stored product with the chemicals released by its packaging which may be even carcinogenic.

The DTAB after deliberations decided that an Expert Committee may be constituted by the Chairman for examination and generation of scientific opinion on the issues raised in the representation before the matter is further deliberated in detail by the DTAB.

The meeting ended with the vote of thanks to the chair.

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