MINUTES OF THE 64th MEETING OF DRUGS TECHNICAL ADVISORY BOARD (DTAB) HELD ON 19th July, 2013 IN THE CHAMBER Of DGHS, NIRMAN BHAWAN, 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. Shri C. Hariharan Director in-charge, Central Drugs Laboratory, Kolkata-700016	Member
4. Dr. B. R. Jagashetty, Drugs Controller, Karnataka Palace Road, Banglore-560001	Member
5. Sh. Satish Gupta, Controller Drugs & Food (J&K) Jammu -180002	Member
6. Dr. J.A.S. Giri 815A, Road No. 41 Jublee Hills, Hyderabad-500033	Member
7. Dr. B.P.S. Reddy, CMD, Hetero Drugs Ltd. Hyderabad	Member
8. Representative of Director Indian Veterinary Research Institute Izatnagar-243122 (U.P.)	Member

9. Dr. G. N. Singh, Member Secretary
   Drugs Controller General (India)
   FDA Bhawan, New Delhi-110002

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. Shri S.P.S.
   Deputy Drugs Controller (India)
   CDSCO, New Delhi

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

Dr. T.K. Chakraborty, Director, CDRI, Lucknow; Dr. S.C. Srivastava, MCI, New Delhi; Dr. S.D. Seth, Advisor, CTRI, ICMR, New Delhi, Dr. Dharam Prakash, Delhi; Dr. K. Chinnaswamy, Coimbatore, Dr. J.K. Rajvaidya, Bhopal, Dr. Dhrubajyoti Bora, Guwahati, and Shri Yatendra Raj Mehta, Drug Testing Laboratory, Jaipur could not attend the meeting because of their pre-occupation.

Prof. B. Suresh, President, Pharmacy Council of India, New Delhi, however, sent his comments on the agendas under consideration.

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 as the quorum was complete.

The chairman in the opening remark stated that the meeting has been convened as a special meeting with the short notice to discuss the issues related to the suspension of the drugs especially Pioglitazone and Analgin. The Secretary, Health and Family Welfare had desired in the Apex Committee meeting that the issue of suspension of the drugs Pioglitazone and Analgin should be deliberated by DTAB at the earliest and report submitted to the Government for further consideration. The members also felt that as DTAB is statutory body to advice the Government on matters relating to administration of the drugs and Cosmetics Act, it should be consulted in such matters before taking final action by the Government.

The Chairman further stated that there are certain other agendas also for the consideration of the members during the meeting.

The Chairman further stated that it is being observed that many of the members of DTAB, both ex officio and nominated, are not attending the meetings of DTAB regularly. DTAB takes momentous decisions on matters relating to the administration of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. It is therefore important that the members attend the meetings and participate fruitfully in the deliberations. He desired that in the cases where the members have not attended last three or four meetings, may be requested, in the first place, individually to attend the meetings regularly, otherwise the matter could be taken up with their associations etc. for nomination of the members which could attend regularly and take part in the deliberations. In respect of ex officio members the matter could be brought to the notice of the Ministry of Health and Family Welfare for making alternative arrangements.

The chairman further desired that as the DTAB in it deliberation take decisions on variety of subjects including safety and efficacy of the drugs introduced in the country or the continued marketing of the drugs in the country, provisions regarding clinical trials, medical devices and other matters, it is therefore necessary that the DTAB may co-opt members from the following disciplines for broad based discussions.

1. Two Pharmacologists
2. Two Oncologists
3. Two Cardiologist/Dialectologists
4. Two experts related to medical devices

These experts would be invited depending upon the agenda under consideration in the meeting.

The members agreed to the suggestion and desired that the matter may be taken up with the Ministry of Health and Family Welfare in this regard.

AGENDA NO. 1

ACTION TAKEN REPORT ON THE MATTERS ARISING OUT OF THE 63rd MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 16th May, 2013 AT NEW DELHI.

1. Agenda No. 3

The Director, CDL, Kolkata brought to the notice of the Board that the National Institute of Biologicals (NIB), Noida was recommended to be declared as Central Drugs Laboratory for testing blood products, certain enzymes and hormones, recombinant products and bio-chemical kits. The CDL, Kolkata is already testing the following products as appellate laboratory.

(i) Streptokinase (Natural & Recombinant)

(ii) Human Chorionic Gonadotropic

(iii) Human Menopausal Gonadotropin

The DTAB agreed that for a particular class of drugs, there should be only one appellate laboratory. As such NIB should not be declared as CDL Laboratory in respect of the products stated above. These products may continue to be tested as appellate laboratory by the Central Drugs Laboratory, Kolkata. The notification recommended earlier may be suitably amended.

2. Agenda No. 5

Dr. G.N. Singh stated that under agenda number 5, the issue of prohibiting manufacture of Diclofenac injections higher than 3 ml was considered. The DTAB had recommended for the constitution of a committee to examine the issue. He stated that the issue is not related to the ban of the drug, but restricting its pack size to 3 ml only. The multiple dose Diclofenac sodium injection in the pack size of 30 ml was alleged to be diverted for the treatment of animals, while the manufacture, sale of Diclofenac formulations for animal use are already prohibited under section 26A of the Drugs and Cosmetics Act, vide notification GSR. 499(E) dated 04.07.2008. The use of Diclofenac in animals has lead to significant decline in the vulture population. The DTAB may

therefore reconsider that the Dicolofenac injections should not be marketed for human use in multiple dose pack sizes.

The DTAB after deliberation agreed that rule 105 may suitably be amended to restrict the pack size of Diclofenac injections for human use in single unit dose pack only.

The Board there after approved the minutes of the 63rd meeting along with the changes recommended above.

AGENDA NO. 2

CONSIDERATION OF THE SUSPENSION OF MANUFACTURE FOR SALE, SALE AND DISTRIBUTION OF PIOGLITAZONE AND ALL FORMULATIONS CONTAINING PIOGLITAZONE FOR HUMAN USE IN THE COUNTRY UNDER SECTION 26A OF THE DRUGS AND COSMETICS ACT, 1940

The drug Pioglitazone hydrochloride was approved on 17.10.2000 by the office of DCG(I) as an adjunct to diet and exercise to improve glycemic control in patients with type II diabetes.

Reports raising concern about the safety of the drug Pioglitizaone had appeared in the recent past.

1. The result of an epidemiological study in France (CNAMTS: Retrospective research) showed that there was approximately 1.2 fold increase in the risk for bladder cancer in patients exposed to Pioglitazone compared to patients never exposed to Pioglitazone. The results also showed a tendency that more cumulative dose and longer duration of administration increased the risk of Bladder cancer.

2. An article was published in the Journal Diabetologia,(2012), 55: 1953-1962 in March 2012 on “Pioglitazone and risk of bladder cancer among diabetic patients in France: a population-based cohort study” (a cohort of 1.5 million diabetic patients exposed to Pioglitazone were followed between 2006 and 2009) and had concluded that Pioglitazone exposure was significantly associated with increased risk of bladder cancer.

3. In another research article published in BMJ 2012;344:e3645, May 2012 on “the use of Pioglitazone and the risk of bladder cancer in people with type 2 diabetes: nested case control study” (a cohort consisting of people with type 2 diabetes who were newly treated with oral hypoglycemic agents between 1988 to 2009), it was concluded that overall, use of Pioglitazone was associated with an increased rate of bladder cancer. It was also concluded that the rate of bladder cancer increased as a function of duration of use and in those with a cumulative dosage greater than a certain quantity.

The use of the drug was under review in many countries and some of the countries have taken regulatory actions as under:

1. The regulatory authority of France (AFSSAPS) decided on June 9th, 2011 suspended the use of the medicines containing pioglitazone, based on an opinion from French Marketing Authorization Committee and the French National Pharmacovigilance Committee (Commission National de Pharmacovigilance).

2. Germany's Federal Institute for Drugs and Medical Devices (BFARM) has allowed the use of the drug in the existing patients only and the matter is under study.

3. US FDA also reviewed the use of pioglitazone drug and have issued safety information on 15.6.2011 that healthcare professionals should:
    - Not use pioglitazone in patients with active bladder cancer.

- Use pioglitazone with caution in patients with prior history of bladder cancer. The benefits of blood sugar control with pioglitazone should be weighed against the unknown risk for cancer recurrence.

4. European Medical Agency (EMA) on 21.7.2011 recommended new contraindications and warnings for pioglitazone to reduce small increased risk of Bladder cancer and the drug is under review.

Dr. V. Mohan, Madras Diabetes Research Foundation in his letter dated 30.1.2013 addressed to the Ministry of Health and Family Welfare also raised concerns regarding risk of bladder cancer. He mentioned that a group of Diabetologists from India including him in the "Journal of the Association of Physicians in India" Vol.60, Dec 2012 issue, have reported 8 cases of bladder cancer associated with Pioglitazone use from different geographical locations in India such as Salem, Belgaum, Hyderabad and Mumbai.

In view of the above, the manufacture for sale, sale and distribution of Pioglitazone and all formulations containing Pioglitazone for human use was suspended under Section 26A of the Drugs and Cosmetics Act, 1940 vide Gazette notification G.S.R. 379(E) dated 18.06.2013.

The issue of suspension of the drug was considered by the Apex Committee, of the Ministry of Health and Family Welfare, under the Chairmanship of Secretary, Health and Family Welfare and it recommended that the matter may be referred to the DTAB for its expert opinion along with the opinion of the medical specialist from various medical colleges and institutes.

Prof. B. Suresh in his written comments have stated that the implication of withdrawal of Pioglitazone may result in reversal of beneficial effects already experienced by them and will result in the option of using injectable insulin thereby defeating patient compliance due to inconvenience. Pioglitazone is the only drug that

refers reverse insulin resistance. While the report stating the implications of bladder cancer cannot be overlooked, the need for having detailed pharmacovigliance data for arriving at such a conclusion cannot be overemphasized here. However, on the basis of present findings as done by US FDA, the safety announcement can be incorporated on the medication package as well as directions to the prescribers and the patients highlighting the concern.

The Chairman stated that a meeting of the Expert Committee consisting of medical experts was held on 11.07.2013 to examine the safety of Pioglitazone formulations reported to be prohibited or restricted in other countries. The committee after detail deliberations had recommended that the suspension or manufacture and sale of Pioglitazone and formulations containing Pioglitazone should be revoked immediately. The drug should be allowed to be marketed with the following conditions as stipulated by MHRA.

1. The drug should not be used as first line of therapy for diabetes.
2. The manufacturer should clearly mention following box warning in bold red.

   Advice for healthcare professionals:

   - Patients with active bladder cancer or with a history of bladder cancer, and those with uninvestigated haematuria, should not receive pioglitazone
   - Prescribers should review the safety and efficacy of pioglitazone in individuals after 3–6 months of treatment to ensure that only patients who are deriving benefit continue to be treated. Pioglitazone should be stopped in patients who do not respond adequately to treatment (eg, reduction in glycosylated haemoglobin, HbA1c)
   - Before starting pioglitazone, the following known risk factors for development of bladder cancer should be assessed in individuals: age; current or past history of smoking; exposure to some occupational or chemotherapy agents such as cyclophosphamide; or previous irradiation of the pelvic region
   - Use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age. Elderly patients should start on the lowest possible dose and

be regularly monitored because of the risks of bladder cancer and heart failure associated with pioglitazone.

The minutes of the Expert Committee meeting were circulated among the members. Copy of the minutes is annexed.

The members agreed to the recommendations of the expert committee and the Board recommended that the suspension should be revoked immediately. The drug should be allowed to be marketed subject to condition that the manufacturers shall mention in their package insert and promotional literature of the drug the conditions as recommended by the Expert Committee. The DTAB further recommended that the drug should be put under focussed pharmacovigilace programme and the adverse reactions reported by the Healthcare professionals should be examined for taking any further action in the matter. The Board also recommended that the issue of safety of the drug may be again reviewed after three years.

The members further, stated that decision for banning / suspending the use any drug in the country should be based on the scientific evidence including safety of the drug, disease prevalence and overall risk benefit ratio. The members felt that DTAB should be consulted before taking any decision to suspend / ban any drug in the country. It was further added that as and when such decision is taken, a reasonable time period may be given for phasing out of the drug from the market.

AGENDA NO. 3

CONSIDERATION OF THE SUSPENSION OF MANUFACTURE FOR SALE, SALE AND DISTRIBUTION OF ANALGIN AND FORMULATIONS CONTAINING ANALGIN FOR HUMAN USE IN THE COUNTRY UNDER SECTION 26A OF THE DRUGS AND COSMETICS ACT, 1940

The members were briefed that analgin is indicated as an analgesic and antipyretic drug. The drug has remained under review from time to time because of the heightened risk of agranulocytosis a medical condition that involves a lowered white blood cell count, weakening the immune system's ability to fight diseases. The incidents of fatal anaphylactic shocks have also been a major concern with the use of the drug.

The continued marketing of analgin was considered by the DTAB in its meeting held on 16.01.1995 and it recommended the use of Analgin may be restricted for severe pain or pain due to tumour only and also for bringing down temperature in refractory cases when other antipyretics fail to do so. The Fixed Dose Combination (FDC) of Analgin with any other drug was, however, prohibited under Section 26A of the Drugs and Cosmetics Act, 1940 by the Ministry of Health and Family Welfare, vide Gazette notifications G.S.R. 63(E), Dt.13.09.1995 and G.S.R. 405 (E), Dt.3.6.1999 on the recommendations of the DTAB.

The use of the drug was under review in many countries and some of the countries have taken regulatory actions as under:

1. In the year 1965, the Department of Health, Australia had prohibited the importation of Analgin.
2. In July 1976, Norway had withdrawn Analgin from the market.
3. On 27th June, 1977 the US FDA had withdrawn Analgin from the market and prohibited its manufacture for export on the basis of reports of agranulocytosis.

4. In September, 2000, products containing Analgin were withdrawn from Ireland.
5. In April 1979, preparations containing Analgin were banned for systemic use due to the potential risk of fatal agranulocytosis in Denmark.
6. In the year 1980, Saudi Arabia prohibited all preparations containing Analgin due to reports of several anaphylactic shocks.
7. On 9th June, 1981, pharmaceutical preparations containing Analgin were banned United Arab Emirates.
8. In June, 1982, Bangladesh banned oral drops and tablet forms containing Analgin due to high incidence of adverse effect and availability of safer alternatives.
9. In January, 1987, all products containing Analgin were withdrawn in Malaysia.
10. In the year 1988, all combination products containing Analgin were withdrawn in Pakistan.
11. In Sep1989, Ghana, in Jan1992, Sri Lanka,in Jul 1997 Nepal, in1998, Syria, Yemen and Zimbabwe,in May, 2000, Morocco, in Sep 2000, Lithuania, Armenia and Bahrain also withdrew the drug Analgin due to adverse reactions viz. agranulocytosis and anaphylactic shock.

The Parliamentary Standing Committee of Ministry of Health and Family Welfare in its 59th report desired that CDSCO should be directed to reexamine the rationality of continued marketing of Analgin.

The matter was accordingly considered by DTAB in its 61st meeting held on 24th July 2012. The Board after deliberations recommended that the continued marketing of the drug may be examined by an expert committee in the context of present day knowledge while manufacturers of Analgin may be directed to market the product giving the full indications approved earlier by DTAB as under:

"Severe pain or pain due to tumor and also for bringing down the temperature in refractory cases when other antipyretics fail to do so."

The Board further recommended that the use of all analgesics with special reference to Analgin should be placed under focused Pharmacovigilance under Pharmacovigilance Programme of India (PvPI). The safety data so collected should be properly analyzed to take further suitable action on use of the drug.

The continued marketing of Analgin was also referred to NDAC for examination in light of further recommendation by the Parliamentary Standing Committee in its 66th report.

The NDAC (Analgesics) examined the issue and noted that there is no adequate data on Indian population in support of either ban of the drug or to 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 suspension and the firm should be asked to generate adequate data in Indian scenario to consider the matter further.

In view of the above, the Ministry of Health and Family Welfare suspended the manufacture for sale, sale and distribution of analgin and all formulations containing analgin for human use under Section 26A of the Drugs and Cosmetics Act, 1940 vide Gazette notification G.S.R. 378(E) dated 18.06.2013.

The matter was deliberated in the 63rd DTAB meeting held on 16.05.2013. The members were of the view that the drug is being marketed in some European countries and there are no adequate reports of adverse effects of the drug which may warrant prohibition of the drug in the country at present juncture.

The issue of suspension of the drug in the country was considered by the Apex Committee, of the Ministry of Health and Family Welfare, under the Chairmanship of

Secretary, Health and Family Welfare and it recommended that the matter may be referred to the DTAB for its expert opinion.

Accordingly, the Board deliberated the safety issue of use of analgin in the country and opined that the drug is used as analgesic for short period as and when necessary. It is not indicated for long term use. There are no adequate reports of agranulocytosis at present associated with the use of the drug which may warrant suspension / prohibition of the drug in the country. The suspension notification issued should be revoked and the drug should be allowed to be marketed for severe pain or pain due to tumor only and also for bringing down temperature in refractory cases when other antipyretics fail to do so. The manufacturers should clearly mention the above indication clearly in their package insert and promotional literature.

AGENDA NO. 4

CONSIDERATION OF A QUERY RAISED BY ANTI CORRUPTION BUREAU, JAIPUR REGARDING THE INTERPRETATION AS TO WHETHER BECOSULE AND BECOSULE Z CAPSULES CONTAINING VITAMIN B1, VITAMIN B6, VITAMIN B12 AND OTHER VITAMINS / MINERALS ARE COVERED UNDER THE NOTIFICATION G.S.R. 702(E) DATED 14.10.1999 PROHIBITING THE MANUFACTURE AND SALE OF FDC OF VITAMIN B1, VITAMIN B6, VITAMIN B12 FOR HUMAN USE

The Chairman briefed the members that a reference has been received by the Ministry of Health and Family Welfare from Central Vigilance Commission (CVC) regarding a complaint alleging that the Becosule and Becosule Z which contains Vitamin B1, Vitamin B6, Vitamin B12 and other vitamins/minerals are covered under the Notification No. GSR 702(E) dated 14.10.1999 as issued by the Government of India under section 26A of the Drugs and Cosmetics Act, 1940, whereas DCG(I) has issued clarification that

Becosule and Becosule Z which contains Vitamin B1, Vitamin B6, Vitamin B12 and other vitamins/minerals are not covered under the ban Notification. Under this notification FDC of vitamin B-I, vitamin B-6 and vitamin B-12 was prohibited by the Government of India through a Gazette Notification GSR 702(E) dated October 14, 1999 for the reason that the FDC did not have the therapeutic value claimed or purported to be claimed for it. In the complaint it has been stated that the office of DCG(I) has issued a clarification to the Drugs Controller, Rajasthan that Becosule and Becosule Z which contains Vitamin B1, Vitamin B6, Vitamin B12 and other vitamins/minerals are not covered under the said notification.

The DTAB deliberated the matter in detail. The Board was informed by the members that the FDC of vitamin B-I, vitamin B-6 and vitamin B-12 was earlier manufactured and marketed in the oral as well as injections form for indication like neuropathy. The said FDC of vitamin B-I, vitamin B-6 and vitamin B-12 was prohibited under Section 26A of the Drugs and Cosmetics Act, 1940 as it did not have therapeutic value claimed or purported to be claimed for it. The notification had come into effect from 1st January, 2001. The Board was further informed that a clarification was issued by the then DCG(I) in January 2000 itself vide letter number 18-7/99-DC that the above notification prohibits the manufacture, sale or distribution of combination of Vitamin B-I, Vitamin B6 and Vitamin B12 only and does not cover other multivitamin preparations having B-Complex drugs of vitamins. The manufacturers associations were requested to give wide publicity to the contents of the notification. The vitamin B-I, vitamin B-6 and vitamin B-12 are the ingredients of many multi-vitamin preparations marketed in the country.

The Board after deliberations opined that as per the notification FDC of vitamin B-I, vitamin B-6 and vitamin B-12 only is prohibited in the country. Fixed dose combination of vitamin B-I, vitamin B-6, vitamin B-12 and other ingredient(s) do not fall under the said notification.

AGENDA NO. 5

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 stated that the final report of the expert committee under the Chairmanship of Dr. Y. K. Gupta, Prof. & HOD, Department of Pharmacology, AIIMS, New Delhi is awaited. The matter may therefore be deferred for consideration in the next meeting.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 122A AND RULE 122B OF THE DRUGS AND COSMETICS RULES FOR MAKING PROVISIONS FOR OBTAINING APPROVAL BY THE SPONSOR / MANUFACTURER FOR MAKING POST APPROVAL CHANGES IN BIOLOGICAL PRODUCTS

Dr. G. N. Singh briefed the members that during the assessment of the National Regulatory Authority of India (CDSCO) by WHO from 11 to 14 December, 2012, it was observed by the WHO team that provisions in respect of Post Approval Variations in the manufacturing process etc. is not specifically provided under the Drugs and Cosmetics Rules. WHO team therefore, recommended that specific provisions in respect of Post Approval Changes should be incorporated under the Drugs and Cosmetics Rules.

The guidance document for the use of industry had been put on the website of CDSCO for submission of clinical trial applications for evaluating safety and efficacy and processing of applications for clinical trial or for permission for marketing as new drug.

The said document provides guidelines for making applications for Post Approval changes in biological products also in respect of their quality, safety and efficacy. These guidelines provide that the office of DCG(I) is required to be intimated in respect of

changes that have a substantial potential to have an adverse effect on the identity, strength, quality, purity or potency of a biological product that have already received an approval to market the product.

A similar provision is provided in the case of Registration Certificates to be issued for import of drugs into India in Form 41 under the conditions appended to the Form as under:

> "in such cases, where there shall be any major change / modification in manufacturing, or in processing or in testing or in documentation, as the case may be, at the discretion of the Licensing Authority, the manufactured or his authorized agent in India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fees as specified in clause (ii) of sub-rule (3) of rule 24A".

The Post approval changes in respect of indications, dosage, dosage form and route of administrations are already covered under the definition of new drugs under rule 122E.

It was proposed to amend rule 122A and rule 122B relating to application for permission to import new drug and application for approval to manufacture new drug respectively by inserting the following clause as applicable in both the rules in the following manner:

> "subsequent to grant of permission for import / manufacture of vaccine or biological product as a new drug, changes in manufacturing process, manufacturing facility, site of manufacture, batch size, shelf life, presentation or any other change which might affect its identity, strength, quality, purity shall be submitted to the licensing authority as defined in clause (b) of rule 21, duly supported by technical data for the purpose of approval. The fee to accompany such an application shall be fifthteen thousand rupees".

The DTAB after deliberations agreed to the proposed amendment.

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL TO AMEND THE NOTIFICATION S.O. 1468(E) DATED 6.10.2005 ISSUED BY THE MINISTRY OF HEALTH AND FAMILY WELFARE REGARDING THE INCLUSION OF CERTAIN MEDICAL DEVICES UNDER THE DRUGS AND COSMETICS

Dr. G. N. Singh, briefed the members that ten medical devices are being regulated as 'drugs' under the Drugs and Cosmetics Act, 1940 through the Gazette notification S.O. 1468 dated 6.10.2005 issued by the Ministry of Health and Family Welfare in consultation with the DTAB which mentioned that only sterile devices are covered under the notification. Another notification G.S.R. 627(E) dated 7.10.2005 was also issued in this regard for these devices to be licenced for manufacture, for sale or distribution by the Central Licence Approving Authority appointed by the Central Government. The notification 1468 (E) dated 6.10.2005 mention that only sterile devices are covered under the notification while notification G.S.R. 627(E) date 7.10.2005 covers all medical devices as drugs irrespective of the fact that these are sterile or non-sterile.

On the basis of the recommendations of an Expert Committee on Medical Devices that if the end use of the notified medical devices is as a sterile product, it will fall within the ambit of the notification, the office of DCG(I) was licensing the import and manufacture of non-sterile medical devices also. However, because of anomaly in the two notifications some of the importers and manufacturers of non-sterile orthopedic implant have gone to the Court stating that the notification S.O. 1468(E) dated 6.10.2005 do not cover non-sterile implants and hence non-sterile implants are not covered under the provisions of the Drugs and Cosmetics Act, 1940.

In order to ensure that the medical devices covered under said notification are uniformly regulated as both sterile and non-sterile under the Drugs and Cosmetics Act, 1940, the word 'sterile' in the notification S.O. 1468 (E) dated 6.10.2005 was proposed to be deleted.

The DTAB agreed to the proposed amendment in the notification so that the ambiguity in the two notifications is removed. DTAB further desired that specific rules / Schedule specifying the requirements for approval, registration and licensing of medical devices notified as drugs may be incorporated under the rules through necessary amendments for regulating their quality, safety and effectiveness of these devices.

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