REPORT OF THE 42ND MEETING OF DRUGS CONSULTATIVE COMMITTEE ON 15TH FEBRUARY, 2011 AT 2:30 PM AT FDA BHAWAN, KOTLA ROAD, NEW DELHI TO DISCUSS CERTAIN ISSUES RELATING TO ENFORCEMENT OF DRUGS AND COSMETICS ACT AND RULES

DCG(I) welcome the members and thanked them for making it possible to attend the meeting in a short notice time.

He informed the member that the Union Minister of Health has taken up the matter with the State Health Secretaries in meeting held in January, 2011 for strengthening of the Drug Regulatory infrastructure in the States /UTs.

He then initiated the discussion on agenda items. Copies of the Gazette Notification GSR 82(E) dated 10th February, 2011 prohibiting manufacture, sale and distribution of certain drugs was circulated to the members.

AGENDA NO. 1

PROHIBITION OF MANUFACTURE, SALE AND DISTRIBUTION OF NIMESULIDE FOR USE IN CHILDREN BELOW 12 YEARS OF AGE, CISAPRIDE, PHENYPROPANOLAMINE, HUMAN PLACENTAL EXTRACT, SIBUTRAMIN AND R-SIBUTRAMIN AND ROSIGLITAZONE

The Drugs Technical Advisory Board in its 58th meeting held on 9th November, 2009 constituted a sub-committee (Expert Committee) to examine the issues relating to safety and efficacy of certain drugs formulations which have been discarded or banned in other countries but are continued to be marketed in the country.

The expert committee had its deliberations in the meetings held on 5th May, 2010, 8th November, 2010 and 27th January, 2011. The committee in its meeting held on 8th November, 2010 recommended prohibition under section 26A of the Drugs and Cosmetics Act in respect of the following drugs.

1. **Nimesulide formulations for use in children below 12 years of age.**
2. **Cisapride and its formulations**
3. **Phenylpropanolamine and its formulations**
4. **Human Placental Extract and its formulations**

Representations were received by the Ministry of Health and FW in respect of Nimesulide and Human Placental Extract. The committee therefore considered the presentations made before it by representatives of M/s. Panacea Biotech. and M/s. Dr.

Reddy's Labs. in respect of continued use of Nimesulide in children below 12 years of age, in its meeting held on 27th January, 2011. Keeping in view the fact that the drug is contraindicated in children below 12 years of age in EU; information provided by M/s. Reddy's lab that they have withdrawn the Nimesulide suspension drug in India & Russia; and no additional concrete substantial evidence for its safety aspects in children presented by M/s. Panacea; the committee reiterated its earlier recommendation.

The sub-committee also considered the presentation of M/s. Albert David Ltd. in respect of use of Human Placental Extract and felt that the firm has not generated data as requested by the office of DCG(I) in its directions dated 3rd March, 1989. The sub-committee reiterated its earlier recommendation in this case also.

The continued marketing of Sibutramine and R-Sibutramine formulations for human use as adjunctive therapy for management of obesity including weight loss was examined by an expert committee set up for the purpose separately as European medicines agency had recommended suspension of marketing authorization of sibutramine across the European Union on 21.01.10 due to increased risk of cardiovascular events such as heart attack and strokes. On 25th October, 2010, the originator of the drug M/s. Abbott stopped the marketing and distribution of the drug in India. Various other regulatory authorities including those in Europe, USA, Canada & Australia had either suspended or withdrawn the marketing authorization of the drug formulations in October, 2010.

A separate Expert Committee was setup to examine the marketing of Sibutramine and R-Sibutramine in the country. The Expert Committee recommended prohibition of manufacture, sale and distribution of these drugs under the section 26A of the Drugs and Cosmetics Act, 1940 in the country.

In view of the above the Ministry of Health and Family Welfare has now issued a Notification on 10th February, 2011 for banning of the following drug formulations under section 26A of the Drugs and Cosmetics Act, 1940.

1. **Nimesulide formulations for use in children below 12 years of age.**
2. **Cisapride and its formulations**
3. **Phenypropanolamine and its formulations**
4. **Human Placental Extract and its formulations**
5. **Sibutramine and its formulations**
6. **R-Sibutramine and its formulations**

It may be added that **Rosiglitazone has already been prohibited for manufacture, sale and distribution in the country vide GSR 910(E) dated 12.11.2010** with immediate effect.

The State Drug Controllers may therefore, ensure that licenses for manufacture of these Drug formulations granted in their States/UTs are cancelled with immediate effect and the chemists and Druggists associations are requested to ensure that these drug formulations are not offered for sale by the chemists and remaining stocks are returned to the manufacturers with immediate effect.

RECOMMENDATIONS

The member agreed to the proposed ban and for speedy withdrawal of drug formulations containing these drugs from the market. In the case of Nimesulide formulations for use in children below 12 years of age, it was agreed that pediatric preparations like syrups and 50mg tablets stands prohibited under the present notification and need to be withdrawn immediately.

The members however, requested that as the notification becomes valid on the date on which it is signed and it takes some time before it reaches the States Drug Control Organizations for implementation, a time limit of at least one month may be given in the notification for its implementation especially in respect of prohibition of sale of drugs for smooth withdrawal of the drug from the market.

The members further desired that the Government may give extensive publicity about the banned drugs, its side effects and reasons for banning for creating awareness in the public.

AGENDA NO. 2

GRANT OF LICENSE OF DRUGS FALLING UNDER THE CATEGORY OF NEW DRUGS WITHOUT PERMISSION FROM DCG(I)

Instances have been brought to the notice of the Central Government that Licensing Authorities of many States/Uts have granted licenses for manufacture of drug formulations which fall under the definition of 'New Drugs' as defined under rule 122 (E) of the Drugs and Cosmetics Rules, 1945. The drugs falling under this category require prior approval from the Office of Drugs Controller General (India) (DCGI) before grant of licence for its manufacture by the State Licensing Authorities.

Part (c) of the rule 122-E, includes Fixed Dose Combinations as defined below:

> "(c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination proposed to be changed, with certain claims, viz., indications dosage, dosage form (including sustained release dosage form) and route of administration.

The licensing authorities of many States and Union Territories have been granting licenses for manufacture of drug formulations falling in the above category without the prior approval of the Central Licensing Authority i.e. Drugs Controller General (India) in violation of the said provision of the Drugs and Cosmetics Rules.

The Parliamentary Standing Committee has shown concern about the licensing of such formulations without following the due procedure laid down under the Drugs and Cosmetics Rules.

The State Drugs Controllers are therefore, requested to direct the licensing authorities under their jurisdictions not to grant licenses for manufacture or for sale of formulations belonging to the categories of 'new drugs' as defined under Rule 122 E, except in accordance with the procedure laid down under the said rules i.e. with prior approval of the Drugs Controller (India). Violations of these rules would be viewed sternly and the Government of India would be constrained to take up the matter with the State Governments to address the issue of deliberate violations of laid procedures by the licensing authorities.

RECOMMENDATIONS

The members were of the view that in order to avoid varied interpretation by different licensing authorities, a subcommittee may be constituted for preparing Standard Operative Procedures for issue of product licenses by the State Licensing Authorities. The committee may consist of the following members:

1. **Shri H.G. Koshia, Commissioner, FDCA, Gujarat**
2. **Shri A.K. Pradhan, Assistant Drug Contoller (I), CDSCO, HQ**
3. **Mr. Shinde, Technical Officer, FDA, Maharashtra**

Dr. G.N. Singh, Secretary IPC informed the committee that as New Drugs are being tested for their specifications at IPC laboratory. Indian Pharmacopeia Commission (IPC) is maintaining specifications for new drugs and the State Licensing Authorities are free to ask for specifications of any new drug permitted to be marketed by the office of DCG(I).

AGENDA NO. 3

PROMOTION OF GENERIC DRUGS

Parliamentary Standing Committee on Health & Family Welfare in its 45th Report has given recommendations on the "Issues Relating to Availability of Generic, Generic-branded and Branded Medicines, their Formulation and Therapeutic Efficacy and Effectiveness". The committee has given number of suggestions to ensure that only generic drugs are purchased by the Government procurement authorities. This would result in huge savings on drug expenditure and enable rational use of drugs in the country. The recommendations of the committee were forwarded to the State Drugs Controllers by the office of DCG(I) vide letter 15-49/2010-DC, dated 19.11.2010.

The committee has cited examples of experiments done in certain States which could be replicated in other States for making drugs available at affordable prices.

"(a) Chittorgarh district for making affordable medicines available to patients through Low Cost Drug Shops selling generic medicines by involving Government Co-operative Medical Stores procurement of generic medicines through open tender which resulted in sharp fall in the treatment costs.

(b) Bihar where every medical college, district hospital and PHC has a shop selling generic medicines at less than 50 per cent of the MRP and yet Bihar Government is earning 45 per cent revenue on the project.

(c) Tamil Nadu which follows the system of finalizing list of Essential Drugs based on National List of Essential Medicines (NLEM) and purchases only generics, ensuring adequate funds and human resources for supply of drugs from its warehouses to various points of health care delivery associated with testing drugs for quality, supplying drugs only in strips and blister packing, making proper arrangements for storage of drugs in modern warehouses, etc. This resulted in huge savings on drug expenditure and enabled rational use of drugs."

The committee has also noted that in its bid to bring down healthcare costs the Union Ministry of Health and Family Welfare has issued directions to doctors in the Central Government-run hospitals to prescribe only generic drugs as far as possible and not branded drugs. In order to eliminate middlemen (C&F agents, distributors, wholesalers, retailers) the Committee recommended that the Governments, both at the Centre and the States procure generic drugs in bulk from manufacturers and dispenses them directly to patients, through its health centers.

The State procurement agencies may follow the above policy and ensure that they procure, as far as possible generic drugs in bulk from the manufacturers and dispense them directly to the patients at health centers.

It has also been recommended that sale outlets like Jan Aushadhi stores should be opened by the State Government down to district level to help the people to procure life saving medicines at affordable prices.

It is therefore requested that the State Drugs Controllers may take action on the recommendations of the committee to promote the use of generics drugs in the country.

It may be further added that in the 41st meeting of DCC the proposal to promote generic drugs in the country was also considered and it was recommended that the State Drug Controllers may grant licences for marketing of single drug formulation in generic name only to promote availability of generic drugs at affordable prices in the country.

RECOMMENDATIONS

DCG(I) briefed the members that the State Drugs Controllers, even though not directly involved in procurement of drugs, may suggest the State Health Authorities that only generic drugs are purchased by the State procurement agencies. This would result in huge savings. Certain States like Bihar, Tamil Nadu

and Rajasthan have taken a lead in making affordable medicines available to the patients as generic medicines.

The State Drugs Controllers of Karnataka and Andhra Pradesh informed that they are not only procuring only generic drugs for distribution at Government Dispensaries and Hospitals but also promoting sale of generic drugs through select retail and whole sale outlets. By and large other States like Haryana, West Bengal, Maharashtra, Goa, Gujarat, Orissa, Himachal Pradesh, Tamil Nadu, Punjab, Chhattisgarh, Uttrakhand and Jharkhand echoed similar sentiment.

The committee however suggested that to further strengthen the movement of propagating and sustaining generic drugs in the medical stores, the following measures could be taken.

1. **Creating awareness amongst doctors on the advantages to the patient/consumers, in prescribing generic drugs and to bring about a change in their prescribing habits.**
2. **Reduction of license fee for generic drug stores. The present licence fee is Rs. 1,500/-.**
3. **A proper definition of generic drugs may be introduced as distinct from pharmacopeial drugs.**
4. **Finance Ministry may be requested to provide excise duty exemptions for manufacture of pharmacopeial drugs as was prevalent in earlier years.**
5. **NPPA may be asked to issue ceiling prices in the case of common widely used drugs.**
6. **Suitable amendment may be made in Drugs and Cosmetics Rules that all single ingredients drugs should be marketed as generic drugs except new drugs.**

Dr. G.N. Singh informed the committee that National Formulary of India (NFI) has been updated and forwarded to the State Drugs Controllers for their guidance. It contains a list of generic formulations and has been created for the use of prescribers.

AGENDA NO. 4

GRANT OF PRODUCT PERMISSION OF DIFFERENT DRUGS WITH SIMILAR BRAND NAME

Instances have come to the notice of the Central Government that certain licensing authorities while granting the licenses for manufacture under brand names have granted permission for manufacturer of different drugs with similar brand name. One of such brand name "**AZ**" is marketed with different ingredients as given below:

a. Cetirizine, manufactured by M/s Sienna Formulations Pvt. Limited, Vadodara, Gujarat.
b. Albendazole, manufactured by M/s. Cure Quick Pharma, Karnal, Haryana.
c. Azithromycin, manufactured by M/s. Eugenics, Lucknow, Uttar Pradesh.

It is understood that some formulations of Alprazolam are also marketed as **AZ** brand.

Keeping in view the seriousness of matter and confusion it may create at consumer end the State Drug Controllers were requested to withdraw permission of AZ brand on top priority and to change it to other suitable brand names vide letter No. 12-01/10DC (Pt. RSQ.), dated 7th February, 2011.

It is therefore requested that the State Licensing Authorities may take extra caution while granting approval of the products for marketing under the brand names to ensure that similar brand name are not granted to different drug formulations. If there are other similar cases of brand names for different drugs, they may also be withdrawn from the market in public interest to avoid any confusion at the end of consumers.

RECOMMENDATIONS

The members stated that the difficulty arises as no Central Directory is available to cross check the brands available in the market. They are however, taking an undertaking from the manufacturers while granting the licenses that the brand name would be cancelled in case it is found to be similar to another existing brand. It was suggested that a National Data Bank may be created to provide information about the licenses granted by different State Licensing Authorities along with brand names for the guidance of the licensing authorities.

AGENDA NO. 5

GRANT OF SAME BRAND NAME EVEN AFTER CHANGE IN ACTIVE INGREDIENT

The proposal that same brand name should not be permitted to be retained while issuing of licences to manufacture drugs with changed formulations was considered in the 39th as well as 41st meeting of the DCC. Dr. S.M. Jharwal, Director, NPPA in 41st meeting had emphasized that the manufacturers should not be permitted to retain the brand name while changing the composition of the formulation for circumventing the DPCO and charging much higher price for the product claiming that it does not fall under DPCO.

It is therefore, again stressed that the State Licensing Authorities may ensure that the manufacturers are not permitted to retain the same brand name if the active ingredient are changed.

RECOMMENDATIONS

The members agreed to the suggestions and stated that they are not permitting to retain the same brand name if the active ingredients are changed.

AGENDA NO. 6

AUDIT OF STATE DRUG TESTING LABORATORIES

The State Drug Testing Laboratories test statutory samples of drugs send by Drugs Inspectors and the test reports are issued in the specified formats (i.e. Form 13). Legal actions are initiated on the basis of these reports against the manufacturers and dealers by the concerned authorities. The State Drugs Laboratories are therefore, required to be GLP compliant to ensure that testing is done as per prescribed standards.

The Parliamentary Standing Committee has raised its concern that no assessment of the State Drug Testing Laboratories have been carried out to ensure that the testing in these laboratories is as per prescribed standards.

The test reports issued by the State Drug Testing Laboratories should be in accordance to the prescribed procedures and state of art testing. The State Governments should ensure that these laboratories conform to the Good Laboratory Practices as prescribed under the Drugs and Cosmetics Rules and should be audited from time to time to ensure that proper procedures are followed in testing of drugs. These laboratories could also be made NABL accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL), and are audited from time to time to ensure that the conform to the highest standards. The Central Drug Testing Laboratories like the Central Drug Testing Laboratory, Chennai, Central Drug Laboratory, Kolkata and RDTL, Guwahati have already obtained NABL accreditation.

The State Drugs Controllers may therefore take steps to ensure that the Government Drug Testing Labs comply with the requirements of Good Laboratory Practices as prescribed under Schedule L-I of the Drugs and Cosmetics Rules and are audited time to time. Efforts should also be made for accreditation of these laboratories by the National Accreditation Board for Testing and Calibration Laboratories (NABL).

RECOMMENDATIONS

The members agreed that the State Laboratories may be audited to ensure that they conform to the Good Laboratory Practices.

Dr. G.N. Singh stated that IPC will be ready to take the lead in auditing the state Drug Testing Laboratories and also facilitated NABL accreditation of these laboratories.

The committee after deliberation agreed that teams may be formed from the concerned zonal offices, Central Drugs Testing Laboratories labs in the area, in consultation with IPC for auditing the laboratories in an expeditious manner.

It was also agreed that a turnaround time for testing labs may also be prescribed (say 60 days) for getting test reports in time for taking action in the cases reported as not of standard quality.

AGENDA NO. 7

NON-COOPERATION BETWEEN THE STATES IN PROVIDING INFORMATION IN RESPECT OF MANUFACTURERS LOCATED UNDER THEIR JURISDICTION

The State Licensing Authority under whose jurisdiction the statutory sample of a drug manufactured in another State is declared as not of standard quality is required to obtain necessary details about the constitution of the manufacturing firm from the licensing authorities of the State under which the manufacturer is located. It has however, been observed that there is lack of cooperation and coordination amongst the State Drug Controllers in providing information in respect of manufacturers located under their jurisdiction. The delay in obtaining the vital information results in long delays or non action for the want of requisition information to launch prosecution in the Court of law.

The Parliamentary Standing Committee of the Ministry of Health and Family Welfare has taken is serious view of the lack of cooperation amongst the State Drug Controllers.

For an effective drug control and speedy investigations in the cases of drugs declared as not of standard quality it is important that the States should developed a system of cooperation and coordination. The State Drug Control Organization may put on their websites or at any other place, the nodal officer along with his phone number who could be contacted to obtain such information.

It is therefore requested that the State Drug Controller may deliberate and discuss the factors responsible for such a position and the remedial measures which could be taken to have an effective cooperation among the State Drugs Controllers.

RECOMMENDATIONS

The members were of the opinion that the problems of delay in getting cooperation from other States for taking action on samples declared as not of standard quality exists for various reasons like non availability of the concerned officers or of the manufacturer for having information about the constitution of the firm and other relevant information.

It was therefore recommended that the States may nominate the contact officer along with the phone number etc. who could be contacted for such information. The zonal offices of CDSCO can play a proactive role in assisting the State Drug Control Authorities for obtaining the requisite information. Certain States however, inform that they are using provisions of Indian Penal Code through the Courts where other State Government officers refuse to cooperate to provide necessary information.

AGENDA NO. 8

GRANT OF LOAN LICENCE FOR MANUFACTURE OF NOTIFIED MEDICAL DEVICES

The manufacturing licences for the manufacturers Medical Devices notified as drugs under the Drugs and Cosmetics Act are granted in Form 28 by the State Licensing Authorities and the licence is then forwarded to the Central Licence Approving Authority i.e. DCG(I) for approval under CLAA scheme. Loan Licence to manufacture such medical devices is issued by the State Licensing Authorities in Form 28A.

Office of DCG(I) is receiving applications, forwarded by the State Licensing Authorities, for grant of loan licences in the case of medical devices falling under CLAA scheme for approval by DCG(I). It is however observed that Form 28A do not have the provision of counter signature by the Central Licence Approving Authority. In view of this the office of DCG(I) is unable to process these applications.

DCC may kindly deliberate and suggests a system under which such licences could be approved by the Central Licence Approving Authority.

RECOMMENDATIONS

The members agreed that at present Form 28A does not have the provision of counter signature by CLAA. The Drugs and Cosmetics Rules may therefore be amended to make a provision for loan licenses for Medical Devices.

AGENDA NO. 9

(Additional agenda items)

CONSIDERATION OF THE PROPOSAL OF NETWORKING OF SALE OF DRUGS IN THE COUNTRY AND USE OF MODERN TECHNOLOGY TO PREVENT AVAILABILITY OF COUNTERFEIT/SPURIOUS DRUGS IN THE COUNTRY

DCG(I) briefed the members that in the 41st meeting of DCC held on 28th October, 2010, a committee was constituted in view of the directions of the Hon'ble High Court of Allahabad for computerization of drug trade in the country, to have an in depth study to evolve a National strategy for networking of transactions of sale of drugs from manufacturer to retail chemist. The subcommittee had its meeting on 19th January, 2011, and discussed various methodologies which could be adopted for tracking and tracing of drugs marketed in the country. The committee recommended the following technologies which could be used for identifying the product:

1. 2D Bar-coding

Bar coding of all labels on primary, secondary ad shipper cartons can have all details of the product. A product can be identified by a bar-code which will have the details of the product including its batch number, date of manufacture, date of expiry, name of manufacturer etc. Anyone with a suitable bar-code reader will be able to get the data from the barcode. Barcode data if linked to a website can give details of the movement of a drug from the manufacturer to a retailer. This will help in easy traceability and recall if required.

However information on 2D Bar-code could be copied and require the assistance of barcode reader to get the information.

2. Unique Identifier Code

Unique randomly generated numeric code (UID) on each label will be able to identify the product and this number when forwarded by an SMS to a mobile number can provide the sender with the details of the product.

To make these technologies mandatory under the law Rule 96 need to be amended as voluntary implementation may not be effective. In view of this Rule 96 may be amended as under:

After Rule 96 (xii) the following can be inserted:

(xiii) every drugs manufactured in India shall bear on its primary label Unique Identifier Code that shall be used for anyone to verify the drug through a system of SMS by mobile phone.

(xix) every drug shall bear on its primary, secondary and any other label a 2D bar-code for identification.

The members agreed to the above proposal of amendment of Rule 96.

Regarding networking of sales, the members recommended that manufacturers associations especially in small scale sector and chemists associations may be consulted for evolving a methodology which can be easily followed by the manufacturers and dealers in various part of country.

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ANNEXURE I

List of the participants of 42nd Drugs Consultative Committee meeting held on 15.02.2011 under the Chairmanship of Dr. Surinder Singh, Drugs Controller General (India)

A. List of participants from State Drugs Control Organizations

S. no.	Name & Designation of the participants
1.	Sh. Satish Gupta, Drugs Controller, Jammu and Kashmir, Jammutavi- 180001 (J&K)
2.	Sh. Shiv Narayan Sahu, Drugs Controller, Bihar Vikas Bhawan, Bailey Road, Patan-800001 (BIHAR)
3.	Dr. S.S. Ghonkrokta, Drugs Controller Delhi, Govt. of National Capital Territory of Delhi, F-17, Karkardooma, Dte. of Health Services Building, (Near Karkardooma Court), Shahadara, Delhi
4.	Sh. P. K. Jaggi, Asstt. Drug controller, Delhi Govt. of National Capital Territory of Delhi, F-17, Karkardooma, Dte. of Health Services Building, (Near Karkardooma Court), Shahadara, Delhi
5.	Sh. H. G. Koshia, Commissioner, FDCA Gujarat, Food and Drugs Control Administration, Ist Floor, Block No.-8, Dr. Jivraj Mehta Bhawan, Gandhi Nagar-382010 (GUJARAT)
6.	Sh. Salim A. Veljee, Drugs Controller, Goa, Dte. of Food & Drugs Administration, Old G.M.C. Building, Panaji, GOA.
7.	Sh. R.M.Sharma, Drugs Controller, Haryana Dte. General of Health Services, Civil Dispensary, Sector 20, Punchkula (HARYANA)
8.	Sh. Navneet Marwaha, Assistant Drugs Controller, Himachal Pradesh Health & F.W. Deptt., SDA Complex, Kasumpati, Shimla-17009 (HIMACHAL PRADESH)
9.	Sh. A. L. Arya, Deputy Drugs Controller, Uttar Pradesh Swasthya Bhawan, Lucknow-6, (UTTAR PRADESH)
10.	Dr. B. R. Jagashetty, Drugs Controller Karnataka, Drugs Control Department, Next to Carlton House, Palace Road, Banglore
11.	Mr. M. Khalid Ahmed Khan, Assistant Drugs Controller, Karnataka, Drugs Control Department, Next to Carlton House, Palace Road, Banglore
12.	Sh. C.S. Satheesh Kumar, Drugs Controller & Licensing Authority, Kerala, Public Health Laboratory Campus, Red Cross Road, Thiruvananthapuram, KERALA

13.	Sh. P. R. Uttarwar, Commissioner, FDA. Maharashtra Food and Drugs Administration, Mumbai, MAHARASHTRA
14.	Sh. K.B. Shende, Technical Officer, FDA. Maharashtra Food and Drugs Administration, Mumbai, MAHARASHTRA
15.	Sh. Devistone Swer, Assistant Drugs Controller Meghalaya Director of Health Services, Meghalaya, Shillong
16.	Sh. Shobhit Koshta, Controlling and Licensing Authority Madhya Pradesh, Food & Drugs Adm. Idgah Hills, Bhopal (MADHYA PRADESH).
17.	Sh. Bhag Singh, Drugs Controller, Punjab Sector 34-A, Chandigharh (PUNJAB)
18.	Sh. A.S.Das, Drugs Controller, Orissa New Nandan Kanan Road, Bhubneshwar (ORISSA)
19.	Sh. D. K. Shringi, Drugs Controller, Rajasthan, Medical and Health Services (FW), Swasthya Bhawan, Tilak Marg, Jaipur, RAJASTHAN
20.	Sh. M. Bhaskaran, Drugs Controller Tamil Nadu, 359, Anna Salai, Tynapet, Chennai.
21.	Sh. Sunil Kumar Choudhay, Licensing Authority, Chandigharh (UT) CHANDIGHARH
22.	Sh. G. Thyemge, Assistant Drugs Controller, Arunachal Pradesh Dte. Of Health Services, Naharlagun-791110 (ARUNACHAL PRADESH)
23.	Sh. Deepak Kumar, Drug Inspector, Uttarakhand Directorate of Medical Health Uttarakhand, Dehradun, UTTARAKHAND
24.	Dr. Sajal Kumar Roychoudhary, Drugs Controller, West Bengal, Directorate of Drugs Control, K.I.T. Building, 5th Floor,P-16, India Exchange Place Extension, Kolkata
25.	Sh. C.N. Sharma, Chief Drugs Inspector, Sikkim, Department of Health and Family Welfare, Gangtok-737101, SIKKIM
26.	Dr. S. Ibomcha Singh, Director of Health Services, Manipur Medical & Health Services, Lamphlept, Imphal-7795004
27.	Sh. Rajkumaran, Drugs Controller, Puducherry 99-A, Mission Street, Puducherry-605011, PUDUCHERRY
28.	Sh. Avijit Roy, Deputy Director, Andaman and Nicobar Islands Port Blair-744104, ANDAMAN AND NICOBAR ISLANDS
29.	S.Babu, Dy. Drugs Controller, Food & Drugs Admn, Raipur, Chhattisgarh

B. Ministry Of Health & Family Welfare

30.	Dr. A. K. Panda, Joint Secretary, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi

A. Invitees

31.	Dr. S. M. Jharwal, Director National Pharmaceutical Pricing Authority (NPPA), Jai Singh Road, New Delhi.
32.	Dr. Madhur Gupta, WHO, New Delhi
33.	Dr. A. Gunasekar, National Professional Officer WHO Country Office for India, New Delhi
34.	Dr. Y. K. Sharma, DDG, National Informatics Centre (NIC), CGO Complex, Lodi Road, New Delhi-110003
35.	Dr. Kashi Nath, DDG, National Informatics Centre (NIC), CGO Complex, Lodi Road, New Delhi-110003
36.	Sh. V.V. Ringe, National Informatics Centre (NIC), CGO Complex, Lodi Road, New Delhi-110003

D. Drug Testing Laboratories

37.	Dr. P.K. Guha, Director, Central Drugs Laboratory, 3, Kyd Street, Kolkata
38.	Dr. G.N. Singh, Secretary-cum-Scientific Director, Indian Pharmacopeia Commission, Raj Nagar, Sector -23, Ghaziabad 201002 (U.P)
39.	Sh. K.K. Singh, Head Publications, Indian Pharmacopeia Commission, Raj Nagar, Sector -23, Ghaziabad 201002 (U.P)

E. Zonal Offices of CDSCO

40.	Dr. D.Roy, DDC (I), I/c, CDSCO, North Zone, Ghaziabad
41.	Dr. R. Ramakrishna DDC (I) I/c, CDSCO, West Zone, Mumbai
42.	Ms. Rubina Bose, ADC(I), CDSCO, East Zone, Kolkatta
43.	Ms. Shanthy Gunasekaran, DDC(I), I/c, CDSCO, South Zone, Chennai
44.	Sh. A.C.S. Rao, ADC(I),CDSCO, Sub-Zone, Hyderabad
45.	Dr. A. Ramkishan, ADC(I), CDSCO, Sub-Zone, Ahmadabad

CDSCO, Hqrs

46.	Sh. A. B. Ramteke, DDC(I), FDA Bhawan, New Delhi
47.	Sh. M. Mitra, DDC (I), CDSCO, FDA Bhawan, New Delhi
48.	Dr. S.Eswara Reddy, ADC (I), CDSCO, FDA Bhawan, New Delhi
49.	Sh. Lalit Kishore, Technical Consultant, CDSCO, FDA Bhawan, New Delhi
50.	Sh. Rishi Kant Singh, Legal Consultant, CDSCO, FDA Bhawan, New Delhi
51.	Sh. A.K.Pradhan, ADC (I), CDSCO, FDA Bhawan, New Delhi
52.	Sh. Arvind Kukrety, ADC (I), CDSCO, FDA Bhawan, New Delhi
53.	Sh. Naresh Sharma, Drugs Inspector, CDSCO, FDA Bhawan, New Delhi
54.	Sh. Sushant Sharma Drugs Inspector, CDSCO, FDA Bhawan, New Delhi
55.	Sh. A. K. Khanna, Technical Officer, CDSCO, FDA Bhawan, New Delhi
56.	Sh. S.N. Basu Technical Officer, CDSCO, FDA Bhawan, New Delhi
57.	Sh. Aseem Sahu, Technical Officer, CDSCO, FDA Bhawan, New Delhi
58.	Sh. Jayant GangaKhedkar, Technical Officer, CDSCO, FDA Bhawan, New Delhi
59.	Sh. Nitin Kalra, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
60.	Miss Kavnit Kaur, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
61.	Sh. Varun Arya, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
62.	Miss Kamna, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi

63.	Sh. Abhinav Shrivasatava, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
64.	Sh. Kshitiz Saini, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
65.	Miss Prabhjot Kaur Deol, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
66.	Sh. Rahul Malhotra, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
67.	Miss Sakshi Nautiyal, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi

No.X-19013/2/2011-D
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/o DCG (I))

FDA Bhawan, Kotla Road,
New Delhi.
Dated: the 21st February, 2011

OFFICE MEMORANDUM

Subject: Constitution of a Sub-Committee of the Drugs Consultative Committee for preparing standard operative procedures for issue of product licenses by the State Licensing Authorities–reg.

The 42nd meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 15th February, 2011 to discuss the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and rules made thereunder in the country. During the course of the meeting it was recommended to constitute a subcommittee for preparing standard operative procedures for issue of product licenses by the State Licensing Authorities.
The DCC after deliberations constituted the following sub-committee for the purpose.

Composition of sub-committee

1. Shri H.G. Koshia, Commissioner, FDCA, Gujarat
2. Shri A.K. Pradhan, Assistant Drug Contoller (I), CDSCO, HQ
3. Mr. Shinde, Technical Officer, FDA, Maharashtra

Terms of Reference:

1. Preparation of Standard Operative Procedures for issue of product licenses by the State Licensing Authorities especially in respect of grant of licenses for new drugs and fixed dose combination.
2. Documentations required for proper verification of the application.
3. The committee will give its report in three months.

(Dr. Surinder Singh)
Drugs Controller General (India)

To

The Members of Committee

Central Drugs Standard Control Organization

Dr. Surinder Singh
DRUGS CONTROLLER GENERAL (INDIA)

Directorate General of Health Services
Tele – 011-23236965
Fax - 011 -23236973
Email: - surindersingh_n@yahoo.co.in
Web: WWW.cdsco.nic.in
FDA Bhawan, Kotla Road, New Delhi –110002.

F.No. X-19013/1/2011-D

Dated: 9th March, 2011

To,

All State Drugs Controllers

Sub: Report of the 42nd Meeting of the Drugs Consultative Committee held on 15th February, 2011, at FDA Bhawan, Kotla Road, New Delhi-110002 - reg.

Sir,

42nd meeting of the Drugs Consultative Committee was held on 15th February, 2011, at FDA Bhawan, Kotla Road, New Delhi – 110002.

The Report of the 42nd meeting of the Drugs Consultative Committee held on 15th February, 2011, containing agenda and minutes of the meeting, duly approved by the Chairman is annexed herewith for your information and taking further necessary action, wherever required.

Yours faithfully,

Encl. Copy of the minutes

(Dr. Surinder Singh)
Drugs Controller General (India)

Copy forwarded for information and necessary action to

Zonal offices/Sub-zonal offices

Draft Letter

OFFICE MEMORANDUM

Subject: Constitution of an Expert Committee under the directions of the High Court of Delhi to examine the issues related to the safety and efficacy of Human Placental Extract-reg.

A notification issued by the Central Government under Section 26-A of the Drugs and Cosmetics Act, 1940 to prohibit certain drugs including Human Placental Extract vide Gazette Notification GSR 82(E) dated 10.02.2011 on the recommendations of an Expert Committee set up by Drugs Technical Advisory Board (DTAB) has been challenged by M/s. Albert David Ltd., the manufacturer of the drug in the High Court of Delhi. The Court in its interim order has agreed to the suggestion of the Government that a larger committee consisting of the following members may examine the issues related to safety, efficacy etc. in respect of Human Placental Extract.

Composition of the Expert Committee

1. Dr. Y.K. Gupta
   HOD Department of Pharmacology
   AIIMS, New Delhi

2. Dr. Ajay Kumar
   Patna, Rep. of Indian Medical Association

3. Dr. S.K. Sharma
   HOD, Department of Medicine
   AIIMS, New Delhi

4. Dr. Vijay Kumar
   ICMR, New Delhi

5. Prof. M.C. Sharma
   Director, IVRI, Izatnagar

6. Dr. P.P. Kotwal
   Prof. & Head Dept. of Orthopaedics
   AIIMS, New Delhi

7. Dr. Lakhbir Dhaliwal, Prof. & Head
   Department of Obstetrics and Gynaecology
   Post Graduate Institute of Medical Education and Research,
   Chandigarh

8. Dr. B.N. Chakravarty
   Institute of Reproductive Medicine
   Kolkata

9. Dr. V.K. Tiwari
   Prof., Department of Burns
   Safdarjung Hospital, New Delhi

Terms of Reference:

1. The committee in its first meeting (within 10 days) will collate material which it would seek to rely upon and delineate the areas of concern qua the petitioners i.e. M/s. Albert David Ltd.
2. M/s. Albert David Ltd. Will file its response and the material in support of its stands within a week there after.
3. The Committee will examine the complete material filed by the petitioners.
4. The committee will also give a hearing to the petitioners.
5. The committee will Endeavour to complete and submit a report of its finding alongwith reasons before 15.05.2011.
6. The TA/DA will be paid as per Government of India rules.

Under Secretary to the Government of India

To

The Members of Expert Committee

Copy forwarded to:

DCG(I)

File No. 14-5/2011-DC
Directorate General of Health Services
Central Drugs Standard Control Organisation
O/o Drugs Controller General (India)

Subject: Constitution of an Expert Committee under the directions of the High Court of Delhi to examine the issues related to the safety and efficacy of Human Placental Extract-reg.

A notification issued by the Central Government under Section 26-A of the Drugs and Cosmetics Act, 1940 to prohibit certain drugs including Human Placental Extract vide Gazette Notification GSR 82(E) dated 10.02.2011 on the recommendations of an Expert Committee set up by Drugs Technical Advisory Board (DTAB) has been challenged by M/s. Albert David Ltd., the manufacturer of the drug in the High Court of Delhi. The Court in its interim order has agreed to the suggestion of the Government that a larger committee consisting of nine members may examine the issues related to safety, efficacy etc. in respect of Human Placental Extract.

The list of the members is placed at **'F/A'.**

The list of the members submitted by ASG was also agreed to by the Hon'ble Court. The Court has given a time bound programme for the Enlarged Expert Committee to examine the issues and give its recommendations. A copy of the interim directions of the Hon'ble Court is placed at **'F/B'.**

It is requested that the Ministry of Health may kindly see and issue appropriate orders for constitution of the committee on priority basis. As per order dated 06.04.2011, the Committee is required to be constituted within **three days** of the order.

A draft of the order is placed at **'F/C'.**

(Dr. Surinder Singh)
Drugs Controller General (India)
07-04-2011

US(D)

F.No. 14-5/2011-DC
Directorate of General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi
(O/o DCG (I)

To,

The Members of the Expert Committee

Subject:- Constitution of an Expert Committee under the directions of the High Court of Delhi to examine the issues related to the safety and efficacy of Human Placental Extract-reg.

Sir,

The Ministry of Health and Family Welfare has constituted a committee, as per directions of the Hon'ble High Court of Delhi to examine the issues related to the safety and efficacy of Human Placental Extract. A copy of the order issued by the Ministry of Health and Family Welfare is enclosed.

It would be observed that you have been selected as a member of Expert Committee to examine the issues related to the safety and efficacy of Human Placental Extract.

The background of the constitution of the committee is as under:

A notification was issued by the Central Government under Section 26-A of the Drugs and Cosmetics Act, 1940 to prohibit certain drugs including Human Placental Extract vide Gazette Notification GSR 82(E) dated 10.02.2011 (copy enclosed) on the recommendations of an Expert Committee set up by Drugs Technical Advisory Board (DTAB). The Notification has been challenged by M/s. Albert David Ltd., the manufacturer of the drug in the High Court of Delhi. The Court in its order dated 06.04.2011 has agreed to the suggestion of the Government that a larger committee consisting of nine members may examine the issues related to safety, efficacy etc. in respect of Human Placental Extract and give its report in a time bound manner.

The Court had desired that the committee in its first meeting will collate material which it would seek to rely upon and delineate the areas of concern of the petitioners i.e. M/s. Albert David Ltd.

In view of the above the first meeting is Schedule to be held on ----- at -----.

You are requested to kindly make it convenient to attend the meeting.

Confirm your participation through fax or phone at 23236973/23236975.

Yours faithfully,

Drugs Controller (India)

No.X-19013/2/2011-D
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/o DCG (I))

FDA Bhawan, Kotla Road,
New Delhi.
Dated: the 21st February, 2011

OFFICE MEMORANDUM

Subject: Constitution of a Sub-Committee of the Drugs Consultative Committee for preparing standard operative procedures for issue of product licenses by the State Licensing Authorities–reg.

The 42nd meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 15th February, 2011 to discuss the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and rules made thereunder in the country. During the course of the meeting it was recommended to constitute a subcommittee for preparing standard operative procedures for issue of product licenses by the State Licensing Authorities.
The DCC after deliberations constituted the following sub-committee for the purpose.

Composition of sub-committee

4. Shri H.G. Koshia, Commissioner, FDCA, Gujarat
5. Shri A.K. Pradhan, Assistant Drug Contoller (I), CDSCO, HQ
6. Mr. Shinde, Technical Officer, FDA, Maharashtra

Terms of Reference:

4. Preparation of Standard Operative Procedures for issue of product licenses by the State Licensing Authorities especially in respect of grant of licenses for new drugs and fixed dose combination.
5. Documentations required for proper verification of the application.
6. The committee will give its report in three months.

(Dr. Surinder Singh)
Drugs Controller General (India)

To

The Members of Committee

No. 12-1/subcommittee/2011-DC
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/o DCG (I))

FDA Bhawan, Kotla Road,
New Delhi.
Dated: the 4th November, 2011

To,

1. Shri H.G. Koshia, Commissioner, FDCA, Gujarat
2. Mr. K.B. Shinde, Technical Officer, FDA, Maharashtra

Subject: Meeting of the Sub-Committee of the Drugs Consultative Committee for preparing standard operative procedures for issue of product licenses by the State Licensing Authorities–reg.

The 42nd meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 15th February, 2011. During the course of the meeting a subcommittee was constituted with the following members for preparing standard operative procedures for issue of product licenses by the State Licensing Authorities vide letter no. X-19013/2/2011-D dated 21st February, 2011.

1. Shri H.G. Koshia, Commissioner, FDCA, Gujarat
2. Shri A.K. Pradhan, Deputy Drug Controller (I), CDSCO, HQ
3. Shri K.B. Shinde, Technical Officer, FDA, Maharashtra

The meeting of the Sub-committee is proposed to be held on 11.11.2011 at 11:00 AM in the office of Shri. H.G.Koshia Commissioner, Food and Drug Control Admn., Gujarat,Block-8, Dr. Jivraj Mehta Bhavan,1st Floor, Gandhi Nagar-382010.

You are requested to make it convenient to attend the meeting on the said date at the venue stated above.

Kindly confirm your participation.

Yours faithfully,

(A.K. Pradhan)
Deputy Drugs Controller (India)