REPORT OF THE 45TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 4TH AND 5TH FEBRUARY 2013 AT THE HOTEL METROPOLITAN NEW DELHI-110001

(List of Participants is at Annexure I)

INAUGURAL DELIBERATIONS

Dr. G. N. Singh, Drugs Controller General (India) and Chairman, Drugs Consultative Committee (DCC), welcomed the members and stated that the world is looking towards India for lead in drug regulatory system. The State as well as Central Drug Regulatory System is required to be strengthened to be of world class. During a recent international conference at Estonia, it was observed that the majority of countries especially non EU and non American countries are looking towards India for giving lead on various issues relating to quality control over drugs. The Parliamentary Standing Committee of the Ministry of Health and Family Welfare has also in its report recommended that both Central as well as State regulatory systems are required to be modernized. The need of the hour is to have more interaction, transparency in working and co-ordination among the drug regulatory authorities in the country and use of IT facilities for effective quality control over drugs in the country. The major agenda items for consideration of the committee are related to these issues only. Shri R.K Jain, Additional Secretary and Director General (AS&DG) and Dr. A.K Panda, Joint Secretary, Ministry of Health and Family Welfare would be addressing the gathering on issues of national importance. Other invitees include representative of Department of Animal Husbandry and Narcotics Control Bureau.

Guidelines on Recall and Rapid Alert System for Dugs (Including Biologicals & Vaccines) have been prepared by the CDSCO and have been circulated to the members for their information and perusal. These guidelines are also available on the website of CDSCO. The State Drugs Control Authorities

may go through them and follow these guidelines for the purpose of recall and rapid alert. They may offer their comments, if any, for further improvement of the guidelines before these are considered for making mandatory under the Drugs and Cosmetics Rules. Copy of the guidelines is placed at **annexure II.**

Dr. Madhur Gupta, technical officer – Pharmaceuticals, WHO country office, gave a presentation highlighting the National Regulatory Authority Assessment by WHO in December 2012, on the basis of bench marks which it has established to define international expectations for a functional vaccine regulatory system. In addition to the general framework for the system, the regulatory functions evaluated were marketing authorization and licensing; post-marketing surveillance, including for adverse events following immunization; lot release by the national regulatory authority; laboratory access; regulatory inspections of manufacturing sites and distribution channels; and authorization and monitoring of clinical trials. The review and it positively and the report of the assessment is likely to be finalized by March, 2013. The recent success is the culmination of intensive effort by the Indian NRA in collaboration with WHO to implement a roadmap (Institutional Development Plan), developed with continuous advice from WHO, to strengthen capacity for regulation of vaccines. She also played audio-visual recorded message of Dr Margaret Chan, Director General, WHO congratulating the Indian National Regulatory Authority. The DCG(I) on behalf of DCC thanked the Director General, WHO and her good offices, for the continuous technical and operational support provided by WHO for capacity building of the National Regulatory Authority of India.

Shri R.K Jain, AS&DG, stated that India is considered as pharmacy of the world because Indian drug industry has given a lead in terms of production of generic drugs. It is third largest producer of drugs by volume and drugs are exported to over two hundred countries. In vaccine production, which requires sophisticated technology, India exports vaccine to over 150 countries. The drug

regulatory system therefore has high responsibility to ensure that the drugs manufactured in the country are of standard quality. This is only possible if the drug regulatory system in the country works as a close nit system. As highlighted by Dr Madhur Gupta, the WHO team consisting of 16 representatives of different countries conducted an extensive audit from 10-14 December, 2012, in respect of the vaccine clearance procedures adopted by the National Regulatory Authority i.e. office of the Drugs Controller General India and it was satisfied that the procedures adopted by the National Regulatory Authority are stringent enough and the international community can be assured that the vaccines permitted for manufacture by the said authority in the country are of high quality and are safe and efficacious for use. CDSCO Team had worked hard to achieve this level of international acceptance. This would help in continued exports of vaccines from India for international requirements. The working of drug regulatory system is under observation at various levels. The 59th report of the Parliamentary Standing Committee and observations by the Hon'ble Supreme Court of India in a court case has emphasized that the drug regulatory system in the country, both at Central and State level need to be strengthened and modernized. The Ministry of Health and Family Welfare is ready to share the responsibilities with States for financial assistance.

He also referred to the directions given under section 33(P) to the State Government for granting permission in generic name only. If the manufacturer has a brand name registered under some other Act, he is free to use. Permissions were earlier being granted for manufacture of drugs belonging to new drug category by the State licensing Authorities in violations of the provision of the Drugs and Cosmetics Rules. The manufacturers of such drugs especially of fixed dose combinations are now required to prove the safety and efficacy within 18 months, otherwise such drugs would be discontinued for marketing. He asked the CDSCO to update the list of FDCs approved by the DCG(I) office on

its websites by 20th February 2013 for the guidance of the State Drugs Control Authorities.

He stated that the issues of strengthening of drug regulatory infrastructure, expansion of drug testing facilities in the country and interlinking of websites of the State Drug Control Organizations and creation of National Portal on Drugs stands on priority for the Central Government. State Governments should expedite submitting their plans for release of funds for strengthening of State Drug Regulatory System.

In regard to monitoring of Clinical Trials in the country, he stated that States should participate in the monitoring of clinical trials in the country. CDSCO should provide information to the concerned States about the trials permitted to be conducted in those States. CDSCO should also put details of the clinical trials on its website. The State Drug Inspectors should be associated in the inspections of sites related to clinical trials.

For creation of Data Bank he asked that the States which do not have their own websites should assign jobs to NIC or any other agency for launching the website by 28th February 2013 and States should have their own websites available by 31st March 2013. After that the phase II of interlinking the websites will be started.

For the purpose of establishing new drug testing labs he requested Dr. R.A Singh of RDTL Chandigarh, to prepare blueprint for setting up of the drug testing lab and forward to the Sates by 20th February 2013 and the States should respond by 5th of March. The proposals should be forwarded by the State Governments to the Ministry of Health and Family Welfare by 31st of March 2013.

He asked the State Drug Controllers to participate in the Pharmacovigilace Program of India. The list of medical colleges covered under the program is available on the website of the Indian Pharmacopoeia Commission. The State Drugs Controller should visit at least one site by 31st March and send their recommendations about the functioning of the center to the Central Government for consideration.

The Central Government has already initiated training of the State regulatory officers. The training would be provided in the country or abroad depending upon the requirement and program available. For this purpose the State Government should forward a panel of 10 officers for training in various fields by 31st March 2013.

He stated that the objectives cannot be achieved so long as there are no deadlines set for implementing them. He asked the members that they should ensure that the deadlines set for various projects are complied with for making a concrete move to achieve the target of setting up a world class regulatory system in the country.

The members agreed to the suggestions of AS & DG and promised to do their best to forward the proposals for strengthening of the Drugs Control Organization to the Central Government as per time lines suggested. The Central Government may also consider taking up the matter at the Secretary level or Chief Minister level for sensitizing the State Government to avail the Central Assistance for strengthening of drug control organizations as well as setting up/creation of drug testing labs. The members further desired that the Government of India may consider providing some assistance under NRHM scheme for strengthening the infrastructure in the States.

In regard to the grant / renewal of manufacturing licences in proper / generic name only, the State Drugs Controllers felt that licences of drugs

formulations in proper / generic name is feasible only in single drugs formulation. The multi drug formulations, majority of which include patent and proprietary medicines having variations in their ingredients would be difficult to licence without the trade name under which the product would be marketed.

Dr. A.K. Panda, JS, during his address further stressed on the need of close co-operation between the Central and States Drugs Control Organizations. The issue of grant of manufacturing licenses for new drugs, especially FDCs which do not have requisite approval of the DCG(I) as required under the Drugs and Cosmetics Rules has been examined at highest level i.e., Parliamentary Standing Committee of the Ministry of Health and Family Welfare and has been adversely commented. It is a serious matter as the safety and efficacy of such drugs remain in doubt in the absence of systematic studies as required under the rules. The Central Government has given direction to the Sates under Section 33P of the Drugs and Cosmetics Act in this regard for compliance. The State Licensing Authorities should refrain from giving licenses for manufacture of such drugs without due approval of the DCG(I).

The Planning Commission has agreed for grant of assistance to the States/UTs for strengthening Food and Drug regulatory organizations in the country. New budget lines have been opened. The Central Government requires proposals for capacity building from the State Governments. The proposals may include strengthening of manpower, infrastructure and training of the officers. The persons to be nominated for training in India or abroad should be in different areas like GMP Certification, Medical Devices, Clinical Trials, Laboratory Testing, Networking or Pharmacovigilance. Central Government could provide necessary funding for such trainings.

The other area of importance is to increase the sampling of drugs to the level of one lakh samples in a year. For this purpose, State Laboratories are required to be strengthened and wherever required new labs to be established.

Drugs testing labs should be neat and clean and have proper equipment and manpower for testing of drugs. The proposal for establishing /strengthening of laboratories or purchase of equipments should be forwarded to the Central Government in one month's time. The States should have at least one lab NABL accreditation in a year.

Dr. Panda further stated that the Government is considering of introducing mobile testing vans for spot testing of quality of Drugs moving in the markets. The Drugs and Cosmetics (Amendment) Bill, 2013 having specific provision relating to Clinical Trials and Medical Devices will be introduced in the Parliament. The pharmacovigilance program is also proposed to be stepped up. By the end of 12th five year plan, 230 medical colleges are proposed to be enrolled in the program for collecting Adverse Drugs Reaction Data in the country.

Shri. R.S. Rana, JS, Department of Animal Husbandry stated that his Ministry is running various National Vaccination Programs for live stocks in the country. However, the vaccine production for the animals is not yet up to the mark and the Department is finding difficult to procure the required vaccines to run their programs effectively. He therefore requested that production of vaccines for animal use should be increased for meeting the national requirements.

Shri A. K. Yadav, Dy. Director (P&C), Narcotic Control Bureau gave a presentation in respect of statistical data to be submitted in Form P. The State Drugs Controllers stated that it was extremely difficult to collect the data from each formulation manufacturer in the State. This eventually leads to delay or non-supply of requisite information in Form P. After discussions Shri Yadav, agreed that the States will provide the data in respect of bulk drugs only and the DCG(I) office will forward the same to NCB for further collation.

AGENDA NO 1

CONSIDERATION OF THE RECOMMENDATIONS CONTAINED IN THE 59TH REPORT OF THE PARLIAMENTARY STANDING COMMITTEE OF THE MINISTRY OF HEALTH AND FAMILY WELFARE RELATING TO THE STATE / UTS DRUG REGULATORY AUTHORITIES

The Parliamentary Standing Committee of the Ministry of Health and Family Welfare in its 59th report on the functioning of CDSCO have also considered the role of State Drug Regulatory Authorities and observed that the main problem faced by the State Drug Regulatory Authorities was inadequate infrastructure, non-uniformity of enforcement among the States and lack of pro-active interaction between the State particularly, in connection with investigations relating to drug found 'Not of Standard Quality'.

The Committee recommended that given the lack of adequate resources in the States it would be unrealistic to expect them to improve the infrastructure and increase manpower without Central Assistance for strengthening drug control system. The Committee, therefore, recommends that the Ministry of Health and Family Welfare should work out a fully centrally sponsored scheme for the purpose so that the State Drug Regulatory Authorities do not continue to suffer from lack of infrastructure and manpower anymore.

The recommendations of the committee in respect of the various issues are placed below for the consideration of the committee.

A. CREATION OF DATA BANK

As regards lack of databank and accurate information, the Committee had observed that given the information technology resources currently available, developing an effective system of coordination amongst State Drug Authorities for providing quality and accurate data could have been accomplished long back had the Ministry taken any initiative towards encouraging the States to establish a system of harmonized and inter-connected databanks. Evidently, no serious

efforts seem to have been made in this regard. The Committee, however, expects that the Ministry would, at least now, play a more pro-active role in encouraging the States to employ modern information technology in the implementation of tasks assigned to them. At the same time a centralized databank (e.g. licenses issued, cancelled, list of sub-standard drugs, prosecutions etc.) may be created to which all the State Drug Authorities should be linked.

In view of the above, it has been proposed to create a database in respect of providing information about the manufacturers, their formulations, composition, MRP etc. through the website on priority basis. This Manufacturers and Formulation Database shall primarily cover the following:

1. Name and Address of all the Manufacturers approved by State Authorities (Name, License details, etc.)
2. Details of Drugs licensed for manufacturing (formulations, bulk drugs, medical devices etc.)
3. Drugs in the market (Company, Brand, formulations, strength, form, packing, MRP, etc.).
4. Details of branded pharmaceutical products along with their ingredients.

The data regarding about 85000 brands of drug formulations approved by the various state licensing authorities as obtained from the State Food & Drug Control Administration (FDCA), Gujarat has already been uploaded on the web-site of CDSCO.

Further necessary action is proposed to be taken, on priority basis, for creation of the National Portal of Drug data base.

During the 12th Five Year Plan, the Government of India envisages to put a proper e-Governance system in place which will include inter-linking of all

offices of Zonal/Sub-Zonal/Port offices/Laboratories of CDSCO and offices of State Drugs Controllers for fast communication and effective monitoring of quality of Drugs. The proposed system will include IT enabled services, National Registry, Video Conferencing facilities, archiving of all files etc.

DCC may kindly deliberate and give recommendations in respect of creation of the drug database as recommended by the Parliamentary Standing Committee as early as possible.

B. CAPACITY BUILDING OF DRUG TESTING LABORATORIES

The Parliamentary Standing Committee considered the issue of capacity building of Central as well as State Drug Testing Laboratories and recommended as under.

> "The Committee agrees that the capacity-building of the Central Drugs Testing Laboratories is the need of the hour. In this era of newer innovations coming up at rapid pace, equipping the Drug Testing Laboratories with the high-end sophisticated equipments is very essential. However, the Committee is aware that monitoring the quality of drugs is primarily the responsibility of the State Drugs Authorities, supplemented by CDSCO, which play a major role in collection of samples and testing them. Without manpower augmentation and upgradation of State Drugs Testing Laboratories, the objective of ensuring availability of quality drugs to the public cannot be realized. The Committee, therefore, recommends strengthening of both Central and State Drug Testing Laboratories."

The Ministry of Health and Family Welfare in pursuance of the above recommendations had and agreed that it would take up the matter with the Department of Expenditure about the necessity of augmenting the resources of the central labs and consider creation of more posts. The strengthening of the

States' drugs regulatory systems, including the upgradation of the State Labs would also be facilitated during the 12th Plan period.

The DCC may deliberate and forward their proposals to the Ministry of Health and Family Welfare through their State Governments for strengthening of the State Drug Testing Laboratories.

C. SUBMISSION OF REPORTS OF POST MARKETING SURVEILLANCE

As per Schedule Y, Periodic Safety Update Reports (PSURs) of new drugs are required to be submitted every six months for the first two year after approval of the drug is granted. For subsequent two years – the PSURs need to be submitted annually. PSURs are important for assessing the safety and efficacy in post marketing scenario.

The Parliamentary Standing Committee in its report had observed that there is a poor follow-up of side effects in Indian patients both by doctors and manufacturers. The objective of PSURs is to collect information about adverse effects on patients in India which would help to determine ethnic differences, if any, and result in dosage adjustment, revision of precautions and warnings, if necessary. The Committee takes strong exception to such rampant violation of the mandatory requirements.

The Committee strongly recommended that the Ministry should direct CDSCO to send a stern warning to all manufacturers of new drugs to comply with mandatory rules on PSURs or face suspension of Marketing Approval. PSURs should be submitted in CDSCO-approved format which would help track adverse effects discovered in Indian ethnic groups.

In view of the above it was decided that in case an applicant / manufacturer fails to launched the product for marketing in the country within a

period of six months from obtaining the permission / license from CDSCO, the permission / license will be treated as cancelled. The State Drugs Controllers were also accordingly requested to instruct the manufacturers that in case the applicant / manufacturer fail to launched their products within six months after getting approval from CDSCO, the permission / license from CDSCO will be treated as cancelled.

D. SPURIOUS / SUBSTANDARD DRUGS

The Parliamentary Standing Committee while considering the issue of spurious / substandard drugs made the following observations in respect of sale of drugs by the retail chemists.

> "It is known that retail chemists also stock and sell items other than drugs including chocolates, cold drinks etc. During summer these items are stored in the refrigerator while due to paucity of space temperature-sensitive medicines may be lying outside. When samples are picked up, tested and found to be sub-standard, the State Drug Authorities blame and prosecute manufacturers. Therefore the Committee recommends that specifically in the case of temperature sensitive products such as insulins, due consideration should be given to the reference samples of the same batch preserved by the manufacturers."

The State Drugs Control Authorities may take note of the observation while investigating the cases of substandard drugs.

Recommendation

The issues arising out of the recommendations of the Parliamentary Standing Committee were already deliberated in detail during the discussions with AS & DG. The committee agreed that each State / UT

should have its own website having up to date information in respect of various activities of the State like name and address of manufactures located in the State, details of the licenses granted, cases of sub-standard drugs, recall system, prosecutions launched etc.,. These websites would need to be further interlinked for easy access by the other regulatory authorities. Each State should nominate a nodal officer on its website which could be contacted by the other State Drugs Control Authorities for speedy investigations in the cases of inter-state movement of the drugs. The members however desired that Government of India may consider providing some assistance under NRHM program in terms of Computer Hardware and Data Entry Operator for setting up of and maintaining the websites.

For capacity building of testing of drugs in the country, the members agreed that each State should have its own testing laboratory. This will ensure timely testing of drugs. The members assured that they will do their best to impress upon their State Health Authorities to forward the proposals for establishing/strengthening drugs testing laboratories under the time frame suggested by AS & DG.

In regards to the submission of PSUR data in the case of marketing of new drugs, the members agreed that while granting the license for manufacture of a new drugs, the manufacturer will be requested to submit the PSUR data to the office of DCG(I) as required under the Drugs and Cosmetics Rules and in case he fails to launch the product within six months, the license granted for the purpose will be treated as cancelled.

In respect of the observations of the Parliamentary Standing Committee on deterioration of temperature sensitive drugs because of improper storage, members were of the opinion that such factors are taken into consideration during the investigations by the concerned authorities.

AGENDA NO 2

ROAD MAP FOR STRENGTHENING OF DRUG REGULATORY SYSTEMS IN THE COUNTRY UNDER 12TH FIVE YEAR PLAN BY THE RESPECTIVE STATE / UTs GOVERNMENTS

The Planning Commission had constituted a working group on Drug and Food Regulation for the formulation of the 12th Five year plan (2012-2017) under the Chairmanship of Shri K. Chandramouli, the then Secretary, Health and Family Welfare, Ministry of Health and Family Welfare. One of the terms of reference was to review the drug and food regulatory mechanism in the country to ensure providing quality, safe Drugs and wholesome food in the country.

While considering the question of strengthening of State Drug Regulatory system it was felt that major responsibilities of the States are to grant / renew the drug manufacturing licences and sale licences. They are also involved in enforcement of various provisions of Drugs and Cosmetics Act and Rules including drawing of samples for analysis, prosecutions etc. At present, States have grossly inadequate infrastructure and manpower. There is a crying need to strengthen State Drugs Control Organizations.

Considering the sensitivity of the Pharma Sector and lack of resources available with State Governments, the Working Group felt that it is important to have a Centrally Sponsored Scheme to strengthen their infrastructure, both physical and human resources.

The Working Group, therefore, recommended for strengthening of State Drugs Regulatory and Control mechanism, and for this it was estimated that Rs 3200 Crore will be required.

Further, during the meeting of the Sates Health Secretaries on 29th & 30th May, 2012 under the Chairmanship of Secretary, Ministry of Health and Family Welfare in New Delhi, the regulatory mechanism operational in the State and UTs was discussed to identify their linkages with the Central Regulatory Authorities and to identify the areas of cooperation and support. In pursuance of the decision taken, the Health Secretaries of the States and Union Territories were requested to indicate the critical gaps and year wise fund requirements for strengthening Drug Regulatory infrastructure in the respective States / UTs including requirement for construction / upgradation of laboratories, purchase of equipments and recruitments and training of personnel involved in the enforcement of Drugs and Cosmetics Act, including those working in the drug testing laboratories.

In the light of the above recommendations, it is the high time that the State / UT Drug Control Authorities take up the matter with the respective State / Union Territory Health Departments for strengthening of State Drugs Control Organizations and forward the proposals to the Government of India for its consideration.

DCC may kindly deliberate the matter.

Recommendation

The agenda item was discussed at length during the interaction with Shri R.K. Jain, AS & DG as well as Dr. A. K. Panda, JS. Members however, felt that for introduction of e-governance, the States would require computerization in a big way. Central assistance would not only be required for creating portals but also for digitalization of the existing and current documents. The Central Government may have to come out with the scheme of providing assistance in terms of manpower as well as necessary hardwares and software for the purpose.

AGENDA NO 3

CONSIDERATION OF THE PROPOSAL FOR A SPECIAL DRIVE OF DRAWING SAMPLES OF DRUGS FOR TESTS FOR ASSURING THE QUALITY OF MEDICINES MANUFACTURED IN THE COUNTRY

During the briefing of a Parliament question, the Union Minister of Health and Family Welfare had desired that a special drive may be launched to assure the public that the drugs manufactured and sold in the country are of standard quality. Efforts should be made that at least one sample of the drug of each manufacturers should be analysis to estimate the quality of drugs being sold in the country. The office of DCG(I) had accordingly asked the zonal and sub-zonal offices of CDSCO that drugs samples from the manufacturing sites located at various manufacturing hub / clusters / locations under their jurisdictions may be collected and got tested for their quality at the drug testing laboratories of the CDSCO. The Directors of the Drug Testing Laboratories were also requested to make arrangement for getting the samples drawn under the special drive, tested in a time bound manner and on priority basis. The special drive will be completed within a period of six to nine months to assess the quality of the drugs moving in the market.

It is however, felt that it would be necessary to have similar exercise undertaken simultaneously by the State Licensing Authorities also to assess the quality of drugs marketed in the country. The State Drugs Control Authorities may ask their drug inspectors to draw samples of drugs as special drive, taking care that at least one sample of the drug of each manufacturer is taken and sent for test to the Government Analyst for test and analysis. The special drive may be completed within a period of six months. The results of the samples drawn under the special drive and action taken thereon may be forwarded to the office of DCG(I) for collation of the data by the end of

September, 2013. This would help in preparing a nationwide survey of the quality of drugs manufactured in the country and for taking suitable measures to ensure that drugs available in the country are of standard quality.

DCC may kindly deliberate and give its recommendations.

Recommendation

The members agreed to the proposal of having a special drive of drawing of samples of drugs from manufacturers to assess the quality of drugs being marketed in the country. It was also agreed that at the time of approval for marketing a new drug, the bioavailability of the product would also be taken into consideration. The manufacturers would be asked to submit dissolution study reports to ensure that drugs manufactured by them have high degree of bioavailability.

AGENDA NO 4

CONSIDERATION OF THE PROPOSAL THAT MANUFACTURERS MARKETING FIXED DOSE COMBINATIONS (FDCs) FALLING UNDER THE DEFINITION OF 'NEW DRUG' PERMITTED FOR MANUFACTURE FOR SALE IN THE COUNTRY WITHOUT DUE APPROVAL FROM OFFICE OF DCG(I) TO PROVE THEIR SAFETY AND EFFICACY

The grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs), which fall under the definition of the term 'new drug' in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India), had been raised in many forums from time to time. The Parliamentary Standing Committee of the Ministry of Health and Family Welfare in its 59th report on the functioning of CDSCO have also observed that the some of the State Licensing Authorities have issued manufacturing licenses for a very large number of FDCs without prior clearance from CDSCO. This has resulted in the availability of many FDCs in the market which have not been tested for efficacy and safety. This can put patients at risk.

The Ministry of Health and Family Welfare had issued repeated statutory directions under Section 33P to the State Governments to instruct their respective drug licensing authorities to refrain from granting licenses for manufacture of new drugs and FDCs covered under the definition of the term 'new drug' without due approval of the Drugs Controller General (India). The last such direction was issued vide letter No. X11011/1/2011-DFQC dated 1st October, 2012 wherein the State / UT Governments were directed to instruct their respective Drug Licensing Authorities to abide by the provisions prescribed under the Drugs and Cosmetics Rules for grant of manufacturing licenses for drugs falling under the definition of the term 'new drug' and not to grant licenses for manufacture for sale or for distribution or for export of such new drugs except in

accordance with the procedures laid down under the said rules i.e. without prior approval of the Drugs Controller General (India). A copy of the letter is at **annexure III.**

In the case of 294 FDCs which were required to be withdrawn as these were licensed without approval of DCG(I) a stay was granted by the Hon'ble High Court of Madras, Chennai, which is still pending. Action in respect of the aforesaid 294 FDCs will be taken after the outcome of the court case.

In respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authorities before 1st October, 2012, without the permission of DCG(I), it has been decided that the concerned manufacturers are required to obtain necessary approval as a new drugs from the office of DCG(I) for such FDCs within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country.

As regards new FDCs, if any, licensed by the State Licensing Authorities after 1st October, 2012 without approval of DCG(I), the same will also be considered for being prohibited for manufacturing and marketing in the country.

The concerned manufacturers in your State may therefore be asked to obtain necessary approval from the office of DCG(I) for marketing of the product along with the requites data to prove the safety and efficacy of the FDCs mentioned above within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country.

Recommendation

The issue of fixing a dead line for the fixed dose combinations was deliberated in detail. The Drugs Controller, Rajasthan brought to the notice of the committee that in the matter of Social Jurist Vs. Union of India

(C.W.P. No. 8335/02), the Hon'ble High Court of Delhi while considering the FDCs of Nimesulide directed that all products permitted prior to 1st May, 2002 may be permitted to continue. The members however, felt that this verdict was limited to Nimesulide combinations only and as such cannot be considered as applicable for all fixed dose combinations. It was further, observed that all recommendation of the Parliamentary Standing Committee also does not specify any cut off date for the purpose of ensuring the safety and efficacy of the FDCs permitted without due approval of the Drugs Controller General India.

After deliberations it was agreed that state licensing authority will write to all the concerned manufacturers to prove the safety & efficacy of fixed dose combinations within 18 months which are licensed after 21st September 1988 but are not approved by DCG (I). It was however, reaffirmed that no new FDC shall be licence without prior permission of DCG (I). Whichever FDCs are already existing/licenced by the state licensing authorities can only be allowed till 18 months from the date of directions in this regard with the condition that their safety and efficacy shall be proved by 14 July 2014.

The recommendations of the DCC may be communicated to the Ministry of Health and Family Welfare also.

AGENDA NO 5

CONSIDERATION OF THE DIRECTIONS ISSUED UNDER SECTION 33P OF THE DRUGS AND COSMETICS ACT BY THE MINISTRY OF HEALTH AND FAMILY WELFARE FOR GRANT / RENEWAL OF MANUFACTURING LICENCES OF DRUG FORMULATIONS IN PROPER / GENERIC NAME ONLY

The Ministry of Health and Family Welfare had issued directions under Section 33P of the Drugs And Cosmetics Act by the Ministry of Health and Family Welfare to the Principle / Health Secretaries of all State / UTs vide letter No. X11011/1/2011-DFQC, dated 1st October, 2012 to instruct their licensing authorities to grant / renew manufacturing licences of drug formulations in proper / generic name only. The following clarifications were further provided by the Central Government in this regard vide letter dated 8th November, 2012.

1. This direction is applicable only for the manufacturing license issued by the drug licensing authorities under the provisions of the Drugs and Cosmetics Act, 1940

2. This direction does not apply to the various types of certificates, namely, COPP, GMP Certificates, Free Sale Certificates, etc required for the purpose of export of drugs, as these are not issued under the Drugs and Cosmetics Act, 1940. The exports have to comply with the regulatory requirements of the importing countries which require such certificates.

3. This direction is not applicable to grant / renewal of license for import of drugs.

4. This direction is not applicable to grant / renewal of license for manufacture and import of medical devices.

Copies of the directions issued in this regards are at **annexure IV.**

DCC may kindly deliberate and give its recommendations.

Recommendation

The agenda was deliberated in detail for the purpose of having uniform procedure for implementation of the directions issued by the Central Government in this regard. It was agreed by the members that the following procedures may be followed.

1. **Manufactures having registration of brand name under any other law applicable may be permitted to use the brand / trade name, either for export or for domestic purposes.**

2. **There are many products existing in the country under brand / trade names which are endorsed in the licences by the Drug Regulatory Authority. It was opined that 18 months time may be given for existing licencees for obtaining the permission / NOC from trade mark registration department or any other competent Authority. The changes in the licneces would be made in a phased manner.**

3. **The involvement of Drug Regulatory Authority in endorsing the brand/trade name in the licence was considered necessary for maintaining control & traceability of drugs to ensure the quality of product moving in the market & also to have check on spurious drugs as per present definition in Drugs and Cosmetics Act.**

The recommendations of the committee may be forwarded to the Government of India for further consideration and review of the directions issued in this regards.

AGENDA NO 6

CONSIDERATION OF THE PROPOSAL TO EXAMINE WHETHER THERE IS A NEED FOR INACTING / AMENDING RULES FOR RESTRICTING THE NUMBER OF BLOOD BANKS FOR QUALITY ASSURANCE ON BLOOD COLLECTION

The Ministry of Health and Family Welfare during a meeting held on 5.11.2012 under the Chairmanship of Shri Anshu Prakash, Joint Secretary, on the subject of quality assurance of blood collection, it was discussed whether there was a need of inacting / amending rules for restricting the numbers of blood banks for quality assurance on blood collection. In this connection the office of DCG(I) was asked to provide the information on the following issues:

(a) Statutory changes required to restrict the number of blood banks.
(b) Upscaling the basic criteria for setting up of blood banks.
(c) Minimum floor level of units required for a BB and a storage centre
(d) Methodology to set up several blood storage units / satellite centres under one mother blood banks.

As the blood banks are licenced by the State Licensing Authorities, the DCC may deliberate and give its recommendations on the issues raised.

Recommendation

The members after deliberations felt that India is a vast country and requirements vary geographically as well as population wise. It is important to maintain the availability of blood in far flung areas. It was therefore considered that it was not desirable to restrict the number of blood banks in the country at present or make any changes in the minimum floor level of units required for a blood bank or storage centres.

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

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.

Dr. (Mrs.) Vijay Malik, Sc 'F' & Head (PCD) of Bureau of Indian Standard has written to the office of DCG(I) that during the Cosmetic Sectional Committee PCD 19 meeting held on 12th May, 2011 at Western Regional Office of BIS, Mumbai, it was decided to delete the following three colorants from IS:4707 (Part I) – 2001 as these have been banned in developed countries based on latest research findings:

Colour Index Number 12150, 20170 and 27290

BIS has therefore requested that the above mentioned colours may also be deleted from Schedule 'Q' of Drugs and Cosmetics Rules 1945.

It is however, observed that Colour Index No. 12150 (Solvent Red 1), 20170 (Resorcin Brown) are included in the Schedule Q of Drugs and Cosmetics Rules while the colour at colour index number 27290 does not figure in Schedule Q. It has therefore have been proposed to delete the entries relating to colour index numbers 12150, 20170 in Schedule Q of the Drugs and Cosmetics Rules.

DCC may kindly deliberate and give its recommendations.

Recommendation

The DCC agreed for the proposed deletion of color index 12150 (Solvent Red 1) and 20170 (Resorcin Brown) from Schedule Q to the Drugs and Cosmetics Rules as recommended by BIS.

AGENDA NO 8

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

Schedule S of the Drugs and Cosmetics Rules lays down the standards for the cosmetics included in the Schedule, in the finished form which shall conform to the Indian Standard specifications laid down from time to time by the Bureau of Indian Standards. At present there are 29 cosmetics under Schedule S. The cosmetic 'Sindoor IS:14649:1999' as item no. 30 is being processed for inclusion under Schedule S on the basis of recommendations of DCC in 41st meeting held on 28th October, 2010. The amendment is being processed by the Ministry of Health and Family Welfare.

The BIS has now recommended that the following cosmetics may also be included under Schedule S along with their standards for exercising regulatory control over their quality.

- 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

Further, Dr. (Mrs.) Vijay Malik, Sc 'F' & Head (PCD) of Bureau of Indian Standard has also informed that besides these, an important standard on Herbal Cosmetics (IS 15735:2006-Herbal Cosmetics-General Guidelines) has also been

published which can be used by Regulators for monitoring of herbal cosmetics in the country.

BIS has also stated that a standard for monitoring the quality of all cosmetics products and raw materials viz 'IS 14648:2011 – 'Microbiological Examination of Cosmetics and Cosmetics Raw Materials – Method of Test' has also been developed. This standard has been aligned with International Standards on the subject. BIS has recommended that this may also be considered for adoption under the Drugs and Cosmetics Rules.

DCC may kindly deliberate and give its recommendations.

Recommendation

The DCC agreed for the inclusion of the following cosmetics under Schedule S to the Drugs and Cosmetics Rules along with their standards for the purpose of regulating their quality under the Drugs and Cosmetics Rules.

- **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**

AGENDA FROM STATES

RAJASTHAN

1. To avoid misuse and to have monitoring and control on the production of Drugs containing Narcotics and Psychotropic substances, it is proposed that all the Raw materials either imported or manufactured in India which are NDPS Act covered under should only be supplied / sold to the licensed manufacturers in the country, so that the suppliers of such drugs can be tracked and misuse of these drugs could be checked in a better way.

Recommendation

The members felt that major misuse of Narcotic and Psychotropic drugs is of the formulations manufactured under a valid licence but sold clandestinely. Regulating the sale of imported / manufactured raw material of such drugs may not be much help.

2. It has been observed that sometimes the samples send to the Apex Laboratory (i.e. CDL Kolkata) by the court for retesting are tested even after its expiry date whereas in some cases the samples are returned back with the remarks that sample cannot be tested after its expiry date as it will not be of much use. There exists a disparity, therefore it is proposed that uniform policy in such matter may be adopted by the Apex Laboratory.

Recommendation

The Director, CDL, Kolkata stated that care is taken to test the code samples within the expiry date, if received prior to its expiry.

3. The ministry of Health and Family Welfare, Government of India has issued directions under section 33(P) of Drugs and Cosmetics Act to grant / renew

manufacturing license of dugs formulation in proper / generic name only. This is likely to create lot of confusion as the manufacturers have been permitted to use any brand name as per their choice as per another letter of ministry dt. 21.12.2012.

It is therefore proposed that the manufacturers having registration for a brand name from the proper authority under law in the country may only be permitted products with brand name so that the likely confusion in future could be avoided.

As regards the fixed dose combination, as per the Delhi High Court's decision in the matter of Social Jurist v/s Union of India in writ petition 8335/2002 and c.m. 1119/2002 all the products permitted prior to 1-05-2002 in fixed dose combinations may be permitted and thereafter such combination may be treated as new drugs as per the court order.

Recommendation

The member agreed that the manufacturers having registration of the brand name under any other law applicable may be permitted to use the brand name of the drug.

In regard to fixing a dead line for the fixed dose combinations that all products permitted prior to 1st May, 2002 may be permitted to continue on the basis of the decision of the Delhi High Court in the matter of Social Jurist Vs. Union of India, the members felt that this verdict was limited to Nimesulide combinations only and as such cannot be considered as applicable for all fixed dose combinations. It was further, observed that the recommendation of the Parliamentary Standing Committee does not specify any cutoff date for the purpose of ensuring the safety and efficacy of the FDCs permitted without due approval of the Drugs Controller General India.

4. Permission for clinical trials on new Drugs are granted by Drugs Controller General (India) as per schedule Y of Drugs and Cosmetics Act & GCP guidelines. States have not been assigned any responsibility to look in to this activity. It is therefore proposed that CDSCO should depute Drugs Inspector in the state to monitor the activities at the sites of all the principal investigators to ensure compliance of said provisions.

Recommendation

The matter was already discussed during the deliberations with AS & DG.

PUNJAB

1. Procedure for the disposal of Drugs seized in Form 16 in which prosecutions are not launched but action under rule 66(1) of the Drugs and Cosmetics Rules, 1945 have been taken.

The Drugs Inspector seize drugs for various contraventions of the provisions of Drugs & Cosmetics Act 1940 and Rules 1945 under section 22(c) of the Drugs and Cosmetics Act 1940 in Form 16 and custody orders are taken from the Judicial Magistrates under section 23(5)(b) of the Drugs & Cosmetics Act 1940. As per section 23(5)(b), the orders of seizure can be revoked by the Drugs Inspector, if the defect regarding contravention is remedied by the possessor. Sub-section 23(5)(c) of this Act is reproduce as below:-

> 23(5)(c):- "Without prejudice to the institution of any prosecution, if the alleged contraventions be such that the defect may be remedied by the possessor of the drug, he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause."

Drugs and Cosmetics Rules 1945 and generally action is initiated under Rule 66(1) of the Drugs and Cosmetics Act 1940 and Rules 1945. The drugs licences of the firms are suspended or cancelled in these cases and prosecutions are not launched. There is no procedure mentioned in the Drugs and Cosmetics Rules 1945 for the disposal of seized drugs after action under Rule 66(1) of the Drugs and Cosmetics Rules 1945. The seized drugs remain in the custody of Drugs Inspector and usually get expired.

In case of court cases, the drugs etc are liable to be confiscated on the conviction of the accused under Rule 58 of the Drugs and Cosmetics Rules 1945 and the procedure for disposal of confiscated drugs has been prescribed in under Rule 58-A of the Drugs and Cosmetics Rules 1945. Most of the times, the seized

drugs get expired during trial and are liable for destruction after the orders of the court.

Recommendation

The committee recommended that the proposal may be examined by the sub-committee examining the proposals for amendment of the Drugs and Cosmetics Rules.

GOA

1. **Consideration of question on the sue of Reference Standard which are not available in the question Pharmacopeia but available in other countries Pharmacopeias**

   It is observed that several times the Reference Standard which are mentioned in Indian Pharmacopeia for the analysis of various API's are not available with the Indian Pharmacopeia commission and that such Reference Standard mentioned in the other Pharmacopeia are available. For example, for Prednisoleone I.P., under test for "Related Substances", Reference Standard of Prednisolone RS and Hydrocortisone RS are required; However during inspection of one site pharmaceutical factory in Goa, the firm had used Reference Standard of BP and the reasons disclosed was that the above reference standard of IP were not available. Clarification is sought whether in case of non availability of such Reference Standards of Indian Pharmacopeia Commission could the same be procured from other Pharmacopeias for undertaking analysis of APIs.

   Recommendation

   The members recommended that the clarification may be obtained from the Indian Pharmacopoeia Commission for having a uniform policy in the matter.

2. **Consideration of the question whether manufacturers engaged in manufacturing of drug Pharmaceutical coating in-active materials required to be covered under drug manufacturing licence under Drugs and Cosmetics Rules, 1945.**

   The Directorate has a unit of M/s Colorcon Asian Pvt. Ltd, which is engaged in the manufacture of various drug formulations in active colours and coating materials and at present this Dirctroate has covered them under a drug

manufacturing licence under the provision of Drugs and Cosmetics Rules. The objective of covering them under such a drug licence is for the sole purpose that the coating materials used in the formulation of drugs products, although they may be inert inactive additives, the said material plays a crucial and critical role in overall stability of drug formulation. The said manufacturer now contests that being inactive pharmaceutical ingredients they are not required to obtain or be covered under a drug manufacturing licence under the Drugs and Cosmetics Rule and hence clarification is sought on the status of such activities in the light of the provision of Drugs and Cosmetics Act and Rules, and overall concept involved in the product formulation stability.

Recommendation

The DCC recommended that the colors used in the drug formulations are covered under the definition of the term 'drug' which include all substances intended for use as component of a drug, irrespective of the fact that whether these are active or inactive ingredients.

3. **Consideration of the question whether Drugs Pharmaceutical formulation unit can be permitted to outsource their product stability studies to any other location or agencies.**

Under the provisions of the Schedule M to the Drugs and Cosmetics Rules, 1945 every drug formulation manufacturer in its attempt to ensure the quality, purity and efficacy of the product are required to undertake stability studies both at accelerated temperature studies and real time basis. Although the overseas regulations such as ICH, MHRA, USFDA etc. guidelines do not stipulate any condition for the conduct of such stability studies at their own product manufacturing locations but permit them for outsourcing the same outside their product manufacturing location and it is observed that several pharmaceutical companies have now adopted a practice of outsourcing their work of undertaking stability studies to external agencies, although records are

being maintained at their site of manufacturing for drugs for verification. Such external agencies include separate site sought whether such stability study data generated from outside external sources or agencies can be taken permitted for accepting the compliance of the Schedule M of the Drugs and Cosmetics Rules.

Recommendation

The members agreed that the Pharmaceuticals manufacturers, if considered necessary could be permitted to outsource their products stability studies to external agencies provided proper records are being maintained at the site of manufacturing for verification.

4. **Consideration of the question whether paste / creams / granules manufactured by an applicant in one State can be permitted to undertake filling / packing in the unit of the same applicant in another State.**

This Directorate have come across several instance where the drug manufacturer located in the State have requested specific permission to permit them to undertake filling / packing of their drug formulation which are being manufactured in bulk form at the different site location either in the same State or outside the State and bring the said bulk for filling and packing at their other site location in the same State or outside the State. The reason cited for such practice are mostly on account of saturation in their manufacturing capacity or labour related issues and hence clarification is sought whether such activities can be permitted and if so what necessary are required to be stipulated besides maintenance of records in the larger of product safety and quality.

Recommendation

The Committee opined that the filling and packing of drugs should be carried out at the site where bulk form of the drug as paste, cream or granules has been manufactured to ensure the quality of the formulation.

5. **Consideration of the question whether medical devices like Stents can be permitted to be manufactured at the licensed disposable syringes manufacturing unit having sterile facilities.**

This Directorate has been receiving constant inquiry from a lot of medical devices manufacturer requesting for the manufacturing of sensitive critical medical devices like stents in a unit which is already being licensed and having facility for the manufacture of sterile disposable syringes and whether such stents medical devices products could be permitted in the said section.

Recommendation

The committee did not agree to the manufacture of medical devices like stunts in the same section where other devices like disposable syringes are being manufactured.

6. **Consideration of the question as regards to combipack that is combination of two dosage forms manufactured at different site location brought at one location and assembled as combination packing at one of the location .**

With the advent of the large export of the drug from State, the manufacturers have come this Directorate informing that their overseas buyers are requesting permission for combination pack of the same drug formulation i.e. tablet manufactured at one site location and the same drug ointment formulation manufactured at another location brought for packing at either one of the above location and packed as combination pack. As you are aware that since such product are being manufactured at different site location and obliviously under different drug licence and if s the same can be assembled at any of the location as a combination packing. Clarification is sought whether primarily in the first place whether such combination pack can be permitted and if so what are the precautions to be adopted for labeling of such products in the light of Rule 96 and 97 of the Drugs and Cosmetics Rules.

Recommendation

The members were of the opinion that for a combi pack having a combination of two dosage forms manufactured at different sites, each drug in the combipack is required to be labeled separately as required under rule 96. The combipack may give information in respect of both the drugs on its label for the information of the consumers.

7. **Consideration of the question of incorporating candidates possessing a degree in Biotechnology as one of the qualification for consideration as expert technical Staff for the manufacturing and testing of Biotechnological Formulation.**

At present under the provision of Drugs and Cosmetics Rules, person possessing degree in pharmacy or pharmaceutical chemistry or degree in science or microbiology or biochemistry, etc are being consideration as adequate for approval as competent expert staff for manufacturing and testing of drug formulation. But recently with the advent of several biotechnology and recombinant technology product, there is a need to amend the Drugs and Cosmetics Rules, 1945 to incorporate and allow candidates possessing a degree in …….

Recommendations

The members were the opinion that the term 'degree in science' covers the qualification of biotechnology and as such no amendment is required.

8. **Consideration of question whether the drugs manufacturers can be provided with an alternative neutral code numbering pattern of their choice.**

This Directorate has received a request from one M/s Tulip diagnostic (P) Ltd. Goa engaged in the manufacturing and distribution of various medical diagnostic reagents/kits of in-vitro nature and undertakes exports in huge volumes and turn over. The said firm while exporting their products licensed as 'drugs' under neutral code labeling are allotted the neutral code as approved by the office of Drugs Controller General (India) under provisions of Rule 94 of the Drugs and Cosmetics rules, wherein each States are allotted specific abbreviation, followed by the words "DRUGS" and the firms drugs manufacturing license nos. According for all Goa related drugs manufacturers the neutral code allotted is GO/DRUGS/_____;

The said firm has now made a representation both to the Office of Drugs Controller General(India) as well as Goa State Drugs Controller, citing a reference of minutes of meeting convened by Drugs Controller General(India) on 15/12/2008 with Members of Association of Diagnostic Manufacturers of India (ADMI), wherein at the penultimate para 11 of the said minutes , it was recorded that "**Drugs Controller General(India) clarified that neutral code is approved by his office under the provision of Rule 94 of Drugs Rules and a manufacturer can get a neutral code of his choice".** Copy enclosed of the said minutes which was circulated by Asst. Drugs Controller(I), vide letter No. 29/Misc/4/2008-DC dated 20/01/2009.

In the light of the above and the apprehension put forth by the concerned manufacturer that the existing neutral code that is allotted by State Drugs Controller can be clearly traced to the country of origin and hence their concern for request neutral code of their choice.

Recommendations

The committee was of the opinion that neutral code numbering pattern on the choice of the manufacturer should not be permitted.

KARNATAKA

1. **Amendment to Rule 143:** As per Rule 85 of D&C Rules, 1945 licensing Authority is having powers to issue Stop Production Order in respect of manufacture of drugs. However such type of provision is not included under Rule 143(Licensing Authority is having powers to suspend/cancel the cosmetics license only). Hence necessary amendment may be made under Rule 143 for issue of Stop Production Order.

   Recommendations

   The committee agreed to the proposed amendment in principle, the members however desired that the proposal may be examined by the sub-committee for suitably wording the amendment.

2. **Clarification regarding the manufacture of drugs having anticancer properties:** There are certain products such as Azathioprine, Cyclophosphamide, and Methotrexate etc. which are categorized as Cytotoxic drugs. These drugs are also used as anti-rheumatic drugs. As per Sch M of D&C Rules separate area is required for the manufacture of anti-cancer (Cytotoxic drugs). When the manufacturer apply for the permission to manufacture these drugs as anti-rheumatic drugs, whether separate area is required for the permission to manufacture these drugs or not to be clarified.

Recommendations

The committee agreed that as per Schedule M, separate area is required for the manufacture of cytotoxic drugs. The anti-rheumatic drug would therefore cannot be permitted to be manufactured under the same premises.

3. **Amendment to Rule 51:** There is no specific provision prescribed under the existing Rules for the Drugs Inspector to draw samples for test & Analysis from the retail shops, therefore, Rule 51 may be amended. When Drugs and Cosmetics Rules were framed in 1945, Indian Government was mainly dependent on the drugs which were imported. Therefore, it might have been prescribed to procure and send such imported drugs for test or analysis, However, in the present situation India is producing drugs worth about Rs.1, 00, 000 crores , out of which Rs. 52, 000 crores drugs are meant for domestic market and Rs. 48, 000 crores are meant for Export. Since there is no explicit provision to draw the samples of Drugs of Indian Origin. Hence, it is felt necessary to amend Rule 51 by incorporating specific provision.

Recommendations

The committee agreed to the proposed amendment in principle, the members however desired that the proposal may be examined by the sub-committee for suitably wording the amendment.

4. **Drugs manufactured for Export purpose are found in Domestic market:** This department has found on various occasion that certain drugs manufactured for export purpose have found in domestic market. What is the action to be taken in this regard

Recommendations

The committee opined that if a drug has been exclusively manufactured for export and have found way to the domestic market.

5. **Clarification regarding Bromazepam**: As per proviso of Rule 65(1) of the Narcotics Drugs and Psychotropic Substances Act, 1985, the State Licensing Authority is empowered to grant permission to manufacture Psychotropic Substances mentioned in Sch III attached to the Narcotics Drugs and Psychotropic Substances Rules for the purpose of Export only.

One of the Psychotropic substances in the list is Bromazepam. One of the manufacturers in Karnataka was permitted to manufacture the said product for Export purpose destination wise and quantity wise 4 years back based on NOC issued by your good office and thereafter the said manufacturer has been permitted to manufacture the said product on different occasions for export purpose destination wise and quantity wise.

Since first permission has been granted 4 years back, it is considered that it is no more a 'new Drug". In view of this whether blanket permission can be granted to the said manufacturer for the permission to manufacture Bromazepam for export purpose only.

Recommendation

The DCC recommended that as the drug Bromazepam is covered under the Narcotic drugs and Psychotropic substances Act, the present practice may continue.

6. **In-operative sales licenses** for a certain period-cancellation procedure should be prescribed: Few applicants apply for the grant of fresh wholesale license. Once the licenses are granted they do not operate. Whenever these units are visited for inspections these are found closed. In such cases what is the action to be taken.

Recommendation

The DCC recommended that such licences which have become non-operative may be considered for cancellation.

7. **Rule 65(7)** to be amended to increase the period of retention of documents, registers etc., for a period from 2 years to 5 years in line with the provision for maintaining manufacturing records

Recommendation

The proposal may be considered by the sub-committee for amendments to suggest suitable amendments under the rules.

8. **Rule 74 and 78** are to be suitably amended w.r.t retaining the control samples for a duration of 5 years from the date of manufacturing or 3 months from the date of expiry, whichever is later (since the manufacturing records are required to be maintained for a period of 5 years from the date of manufacturing, it is appropriate to make it mandatory that the corresponding control samples are also retained for the said duration.)

Recommendation

The proposal may be considered by the sub-committee for amendments to suggest suitable amendments under the rules.

9. **Sale and Distribution of cosmetics** needs to be regulated in line with drugs in order to control menace of spurious: At present there is no provision under the Drugs and Cosmetics for issuing of sales license for cosmetics. Rules have been amended for the purpose of registration of imported cosmetics. The object of Drugs and Cosmetics Act is to prevent substandard in Drugs and Cosmetics. Hence amendment may be made for issue of sales license for cosmetics in line with Drugs.

Recommendation

The DCC opined that in the absence of adequate manpower and logistics, it may not be to desirable to initiate sale licences for cosmetics in line with drugs.

10. **Fixing of Fees for Blood Storage Centre:** At present no prescribed application Form, fees, prescribed license form is given in Drugs and Cosmetics Rules for Blood Storage Centre. Hence, necessary amendments may be made in the Drugs and Cosmetics Rules.

Recommendation

The proposal may be considered by the sub-committee for amendments to suggest suitable amendments under the rules.

HIMACHAL PRADESH

1. The list of the FDCs approved by the DCG(I) since 1971 is not complete and needs to be updated as this list is to be consulted by the State Licensing Authorities at the time of approval of additional products. It is proposed that matter may be deliberated and a positive list of FDC's approved by DCG(I) may be uploaded on the site of CDSCO. It is further requested that a cut of date for FDC's to be considered as new drugs may be informed to avoid any confusion at the time of grant of product license by the State Licensing Authorities.

Recommendation

The issue was deliberated during inaugural deliberations and the States are required to comply with the directions of the Central Government.

2. As per directions issued under section 33(P) regarding grant of Licenses in Generic/ proper name only and subsequent clarification dated 21.12.2012 it may be clarified whether manufacturer can use one brand name for the Generic Product approved or he can use many brand names for the Generic drug approved, as this office is receiving lot of quarries in this regard.

Recommendation

The issue was deliberated during inaugural deliberations and the States are required to comply with the directions of the Central Government.

3. All the State Drugs Controllers are using different formats / letters for the approval of additional products; it is proposed that uniform format may be devised in this meeting so that there is uniformity throughout the country in this regard.

Recommendation

The members did not agree to the proposal. However, the sub-committee for amendments may look into the suggestion for its recommendation.

4. In the list of new drugs since 1988 there are many drugs which are approved as basic drugs only. There are many formulations of these drugs available in market. Matter may be deliberated to avoid any confusion at the time of grant of product license for different kind of formulations by the State Licensing Authorities.

Recommendation

The issue was deliberated during inaugural deliberations and the States are required to comply with the directions of the Central Government.

ANDHRA PRADESH

1. **Agenda Item:** Rule 89 mandates for the manufacture of drugs for the purpose of test or analysis only in such cases where the manufacturer doesn't hold any license in Form 25 or 28 which is serious ambiguity wherein it may allow the firms to manufacture the drugs if they fall under various other Forms of manufacturing licenses under the Act.

   Amendment required: Rule 89 may suitably be amended to remove the Form 25 and 28 which will then over all such drugs which are not licensed by the manufacturer and still proposes to manufacture for the purpose of examination, test or analysis.

   Recommendation

   The committee recommended that the proposal may be examined by the sub-committee examining the proposals for amendment of the Drugs and Cosmetics Rules.

2. **Agenda Item:** In order to facilitate the effective recall of drugs and check the unethical movement of drugs within their own state and interstate movement of drugs there needs to be two different licenses for wholesale dealing of drugs.

   Rule Position: At present the licenses granted in Form – 20 B and Form 21B are meant for the sale of drugs by wholesale throughout the country.

   Amendment required: The license Form for wholesale dealing within the state and the license Form for wholesale dealing interstate may be prescribed separately for facilitating effective check on the movement of drugs.

   Recommendation

   The committee after deliberations did not agree to the propose amendment as it would create multiplicity of licenses and would be difficult to monitor.

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ANNEXURE I

List of the participants of 45th Drugs Consultative Committee meeting held on 4th & 5th February 2013 at New Delhi under the Chairmanship of Dr. G. N. Singh, Drugs Controller General (India)

A. LIST OF PARTICIPANTS FROM STATE DRUGS CONTROL ORGANIZATIONS

S. No.	NAME AND ADDRESS OF THE PARTICIPANTS
1	Shri B. L. Meena, Director General, Drugs and Copyrights, Andhra Pradesh, Vengalrao Nagar, Hyderabad – 500 038
2	Shri Meduri Kodandaram, Director, D.C.A., Andhra Pradesh, Drugs Control Bhawan, Vengalrao Nagar, Hyderabad – 500 038
3	Shri G. Tayeng, Assistant Drugs Controller, Arunachal Pradesh Directorate of Health Service, Naharlagun, AP-791 111
4	Shri Hemant Kumar Sinha, Drugs Controller, Bihar, Department of Health, Vikas Bhawan, Patna, Bihar
5	Shri Atul Kumar Nasa, Dy. Drugs Controller, Delhi, F-17, Karkardooma, Delhi 110 032
6	Dr. G. L. Singal, Drugs Controller, Govt. of Haryana, Govt. Dispensary, Sector – 20, Panchkula, Haryana – 139 109
7	Shri Navneet Marwaha, Drugs Controller, Himachal Pradesh Sai Road Baddi, Disstt. Solan-173205
8	Shri Satish Kumar Gupta, Controller Drug and Food Organisation, Jammu & Kashmir, Patoli Mangotrian, Jammu.
9	Dr. B. R. Jagashetty, Drugs Controller, Karnataka, Palae Road, Bangalore – 560 001, Karnataka
10	Shri Salim A, Veljee, Director, Food & Drugs Admin.-Goa, Old IPHB Complex, Altinho, Panaji, Goa-403001
11	Shri P. Hari Prasad, Drug Controller (I/c), Kerala, Red Cross Road, Thiruvananthapuram- 695 035
12	Shri D.M. Chincholkar, State Licensing Authority, Madhya Pradesh Idgah Hills, Bhopal (M.P.)- 462 001

13	Shri Shobhit Kosta, Dy. Drugs Controller, FDA, Madhya Pradesh, Idgah Hills, Bhopal, Madhya Pradesh
14	Shri Omprakash S. Sadhwani, Joint Commissioner (HQ), FDA, Maharashtra, Opposite RBI, Bandra Kurla Complex, Bandra East, Mumbai –400 051
15	Dr. Asem Bijoy Singh, Director, Manipur, Directorate of Health Services, Imphal –West.
16	Dr. I. L. Sharma, Add. Director, Drugs & Cosmetic Cell, Dept. of HC & FW, Govt. of Sikkim, Convay Ground, Tadong, Gangtok
17	Shri Lal Sawma, Dy. Drugs controller, Dte. Of Health Services, Dinthar Veng, Aizwol, Mizoram – 796 001
18	Shri H. Mahapatra, Drugs Controller, Odisha, Dte of Drugs Control,Nandankanan Road, Bhuvneswara – 751 017
19	Shri Ajay Singla, State Drug Controlling Authority, Punjab, Directorate of Health & Family Welfare, Pariwar Kalyan Bhawan, Sector – 34A, Chandigarh – 22
20	Shri D.K. Shringi, Drug Controller, Rajasthan, Swasthaya Bhawan, Tilak Marg, Jaipur – 302 015
21	Shri G. Selvaraj, Director Drugs Control (I/c), Tamil Nadu, DMS Campus, Anna Salai, Chennai – 600 006
22	Dr. S. C. Sharma, Drugs Controlling and Licensing Authority, Uttrakhand, Dte. of Medical Health, Sahashtra Dhara Road, Dehradun
23	Dr. C. M. Ghosh, Director Drugs Control, West Bengal, P-16, KIT Building, India Exchange Place Extension, Kolkatta – 700 073
24	Shri Sunil Chaudhary, Drug Control Officer, Chandigarh, GMSH, Sector -34, Chandigarh
25	Shri D.D. Agrawal, I.A.S., Office of Food and Drugs Administration, Madhya Pradesh

B. INVITEES

26	Shri R. K. Jain, AS & DG, Ministry of Health and Family Welfare, New Delhi
27	Shri A. k. Panda, Joint Secretary, Ministry of Health and Family Welfare, New Delhi
28	Dr. Madhur Gupta, Technical Officer – Pharmaceuticals, WHO Country office, New Delhi
29	Shri R. S. Rana, Joint Secretary, Dept. of Animal Husbandry, Ministry of Agriculture, New Delhi
30	Dr. S. K. Dutta, Assistant Commissioner, Dept. of Animal Husbandry, New Delhi
31	Dr. Mrs. Vijay Malik, Sc.(F) & Head PCD, Bureau of Indian Standards, New Delhi
32	Mrs. Nisha Busa, Bureau of Indian Standards, New Delhi
33	Shri A.Kk. Yadav, Deputy Director General, Narcotics Control Bureau, New Delhi
34	Shri Bhanu Pratap, Narcotics Control Bureau, New Delhi

C. DRUG TESTING LABORATORIES

35	Shri C. Hariharan, Director I/C, Central Drugs Laboratory, 3, Kyd Street, Kolkata 700016
36	Mrs. M. M. Patel (Technical), Central Drugs Testing Laboratory, Zonal FDA Bhawan, Belasis Rd, Mumbai-400008
37	Dr. R. A. Singh, Regional Drug Testing Laboratory, Sector 39-C, Chandigarh-160036
38	Dr. N. Nurugesan, Director, Central Drug Testing Laboratory, Chennai

D. ZONAL OFFICES OF CDSCO

39	Dr. V. G. Somani, DDC(I), CDSCO West Zone, Mumbai
40	Shri P. B. N. Prasad, DDC(I), South Zone, Chennai
41	Shri A.C.S. Rao, DDC(I), Hyderabad
42	Shri S. Manivannan, DDC (I), Bangaluru
43	Shri B. Kumar, ADC(I), Sub Zone, Chandigarh
44	Shri Soumen Mukhopadyay, DDC(I) I/C, East Zone, Kolkata
45	Dr. A. Ramkishan, ADC(I), Ahmedabad, Air Cargo Complex, Airport, Ahmedabad-380 003
46	Shri B. K. Samantary, ADC (I), CDSCO, Jammu

E. CDSCO HQRS

47	Dr. G. N. Singh, Drugs Controller General (India), CDSCO, FDA Bhawan, New Delhi
48	Dr. K. Bangarurajan, DDC(I), CDSCO, FDA Bhawan, New Delhi
49	Shri A. K. Pradhan, DDC(I), CDSCO, FDA Bhawan, New Delhi
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