REPORT OF THE 44TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 20TH JULY, 2012 IN THE COMMITTEE ROOM, FDA BHAVAN, KOTLA ROAD, NEW DELHI – 110002.

(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 thanked them for sparing their valuable time to attend the meeting. The committee has large number of agenda items for consideration and their fruitful deliberations would help in taking logical decisions. He stressed the importance of the committee which discuss various important matters relating to quality control of drugs in the country. He desired that the meeting of DCC should be attended by the head of the State Regulatory Department or its Deputy who is well versed with the subject. He then introduced Dr. V. M. Katoch, Secretary, Deptt. Of Health Research & Director General, ICMR, New Delhi and Shri Sanjay Prasad, Director, Ministry of Health and Family Welfare who would be addressing the members and apprise them the issues that have national importance.

He stated that the mission of the regulatory agencies is to safeguard the public health by ensuring that drugs available in the country are of standard quality. The CDSCO has defined its mission as to safeguard and enhanced the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices. Likewise the values have also been listed. The copies of the mission statement and values were circulated to the members for setting up their own mission and values at State level for building confidence of the public in the regulatory agencies.

Shri Sanjay Prasad, Director, Ministry of Health and Family Welfare stated that the drug regulatory frame work both at the Centre and the States is an important part of health care system. It concerns treatment of all kind of diseases and involves continuous efforts in providing quality drugs and introduction of new drugs to alleviate the sufferings of common man. Large number of Court cases and RTI applications show that there is awareness in the public about the Drugs Control Departments. The regulatory agencies are therefore required to be transparent and accountable. The Centre as well as States are required to work in tandem to ensure that there is strict control over the quality of drugs in the country. The number of samples drawn for test at present for test is not comparable to the quantum of drugs produced in the country. The Drug control machinery in the States and Union Territories is required to be strengthened. The Central Government is pursuing a scheme with the Planning Commission to strengthen the manpower and testing laboratories in the States. It has been proposed that sampling of drugs should be increased from 40,000 to 4,00,000 samples in a year in the country. The States Drugs Control Organizations are required to be strengthened both in terms of regulatory manpower and testing laboratories to achieve this objective. The State Drugs Control Organization should therefore take up the matter with their Health Departments and prepare plans for assistance from the Central Government in projects related to quality control over drugs. The other area which require attention relates to clinical trials conducted in the country. Regulatory frame work as well as requisite manpower is required to be put in place to ensure that clinical trials are conducted strictly in accordance to the provisions under the Drugs and Cosmetics Rules and are monitored from time to time.

He further stated that the Parliamentary Standing Committee of the Ministry of Health and Family Welfare has taken a serious note of the way in which the fixed dose combinations are permitted by the State Governments. In many cases the FDCs permitted by the States do not have necessary approval from the office of the Drugs Controller General (India) for their safety and efficacy as required under the rules. The Parliamentary Standing Committee has therefore recommended that new FDCs should not be permitted unless there is sufficient technical logic for permitting them in the interest of the patients.

Dr. V. M. Katoch, Secretary, Deptt. Of Health Research & Director General, ICMR, New Delhi stated that regulatory environment in the country is changing. There are lot of expectations from the drug regulatory authorities. The system which is working with the nucleus organizations at Centre as well as

State level is required to be made broad based to ensure that responsibilities are discharged more effectively. An open and transparent e-governance is essential for an efficient regulatory system. The regulatory system in the country should have the trust of the people. The infrastructure funding system of the 12th five year plan should be made use of in creating a strong infrastructure for regulatory control both at Centre and State level. Net working, creation of data base and more of interaction between the State Drug Control Organizations and the Central Government would create a creditable regulatory system for quality control over the drugs.

Dr. Madhur Gupta of WHO stressed the need to have a transparent system of conduct of clinical trials in the country especially in respect of ethical aspects. The rights of trial subjects should be taken care of during the conduct of the clinical trials. She also stated that Schedule H1 relating to antibiotics should be implemented strictly to curb the indiscriminate use of antibiotics.

The State Drugs Controllers welcomed the suggestions of Central assistance in strengthening the infrastructure of the State Drugs Regulatory system. It was however, desired that assistance should be specific to the needs of the States. Many of the States like Gujarat, Maharashtra have already taken lead in networking and e-governance and their experience should be shared by other States for implementation.

The committee appreciated the contribution of Dr. D. Roy, Deputy Drugs Controller (India), North Zone, who was retiring in September, 2012 in the regulatory frame work especially in the field of harmonization of Schedule M. Dr. Roy further desired that rules relating to competent persons to handle drugs need to be changed as large number of pharmacists are now available in the country.

The committee then took up the regular agenda for discussion.

AGENDA NO. 1

CONSIDERATION OF THE PROPOSAL OF STRENGTHENING OF DRUG REGULATORY MECHANISM AT THE CENTRE AND IN THE STATES

The Government of India, Planning Commission 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, Secretary, 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.

The group considered the issue of strengthening of drug regulatory mechanism at the Centre and in the States in detail. The Group summarized the issue and its main recommendations as under:

> "Strengthening of Drugs regulatory Mechanisms in one of the major public health interventions. This ensures that safe, efficacious and quality drugs are made available to the people. Keeping in view the recommendations of the Mashelkar Committee, it is important that the infrastructure, both physical and human resource, both at the Centre as well as in the States is substantially augmented. A more transparent and effective monitoring of Clinical Trials is required. Regulation and control of all medical devices needs to be tightened. The proposed financial outlay for these activities is Rs. 6256 cr, for the Centre and the States which includes manpower augmentation, creation and upgradation of labs, setting up of new offices of drugs regulatory control, strengthening Pharmacovigillance and creating awareness among people (care givers and receivers) regarding safe drugs both at the Centre and in the States. For providing financial and human resources support to the State, a Centrally Sponsored Scheme is proposed."

The Sub-group is of the opinion that problems in the drug regulatory system in the country are mainly in the following areas:

1. Inadequate manpower at the State and Central level.
2. Inadequate or weak drug control infrastructure at the State and Central level.
3. Inadequate testing facilities.

4. Non-uniformity of enforcement of law and regulation.
5. Lack of training to regulatory officials.
6. Lack of data base.
7. Inadequate IT services.

These problems have got further accentuated with the increasing growth of the Pharma Industry in the country while there was no parallel strengthening of the Drug Regulatory System.

For strengthening of CDSCO, the Group recommended that the Central Government should create additional posts for uniform and effective implementation of Drugs and Cosmetics Act and Rules made thereunder. CDSCO would require 1045 additional posts to regulate the pharmaceutical market in the country. For this, Rs. 45 crore is required per annum.

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, it is important to have a Centrally Sponsored Scheme to strengthen their infrastructure, both physical and human resources.

The Working group recommended for strengthening of State Drugs Regulatory Control mechanisms, Rs 3200 Crore will be required.

The report of the working group is available on the website of Planning Commission.

The question of the role of State Drug Regulatory authorities regulating the quality of drugs in the country has also been examined by the Parliamentary Standing Committee of Ministry of Health and Family Welfare in its 59th report tabled on 8th May, 2012. The Committee has noted that the shortcomings witnessed in respect of coordination with and between the States as also in implementation of applicable legislation in the State are primarily and offshoot of inadequacies in manpower and infrastructure in the States. Strengthening the

regulatory mechanism in the States will remain a far cry unless these infirmities are taken care of. The committee has therefore recommended that Ministry of Health and Family Welfare should work out a fully centrally sponsored scheme for the purpose so that the States Drugs Regulatory Authorities do not continued to suffer from lack of infrastructure and manpower any more.

A copy of the extract of the relevant portions of the recommendations of Parliamentary Standing Committee (4 Role of State Drug Regulatory Authorities, 5 Capacity building of Central and State Drug Testing laboratories) is annexed.

In the light of the above recommendations the State / UT Drug Control Authorities may take up the matter with the respective State / Union Territory health departments for strengthening of State Drugs Control Organizations.

DCC may kindly deliberate and give its recommendations.

Recommendations

The members welcomed the proposal of the Central Government for strengthening of drug regulatory infrastructure both at the Centre and State level. The module recommended by the Working Group on Drug and Food Regulations for the 12th Five Year Plan would help them in formulating the plans for upgradation of the testing facilities as well as infrastructure for regulating the quality control in the States.

Some members desired that a system of providing training to the officers of the State Drugs Control Departments in various regulatory fields would help in creating uniformity in the country for implementation of the provisions of the Drugs and Cosmetics Act and Rules made thereunder. The Chairman stated that efforts would be made to create a system for training of the drug regulatory officers of both Centre and State Governments. Some members also made a mention that the pricing under Drugs Price Control Order (DPCO) should be more realistic and broad based.

Annexure

EXTRACTS OF FIFTY-NINTH REPORT OF PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE ON THE FUNCTIONING OF CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

4. Role of the State Drug Regulatory Authorities

4.1 In reply to a query, the Ministry has informed the Committee that the condition of state drugs regulatory systems is a matter of serious concern. The Committee was informed that in order to make the State Governments appreciate their responsibilities and obligations and for strengthening their licensing and enforcement apparatus, the issue was discussed in the 39th meeting of the Drugs Consultative Committee held on 10 December, 2008 and in the Conference of the State Health Ministers and Health Secretaries held at Hyderabad from 11 to 13 January, 2011. One of the key resolutions adopted in the aforesaid Conference was that the Centre and State Governments should draw up a time-bound action plan for creation of new posts and filling up of vacant posts mainly of Drugs Inspectors and upgradation of Drugs Testing Laboratories.

4.2 The Ministry also informed the Committee that the Mashelkar Committee in 2003 had recommended one drugs inspector per 50 manufacturing units and one drugs inspector per 200 sales/distribution outlets for effective implementation of functions assigned to them. It was also informed that there were approximately 600,000 retail sales outlets and around 10,500 manufacturing units in the country, which, require just over 3,200 Drugs Inspectors. However, in reality, there were only 846 Drugs Inspectors in place against 1,349 sanctioned posts in States. Hence, the main problem faced by the States Drug Authorities was inadequate infrastructure, shortage of drugs inspectors, non-existence of data bank and accurate information, non-uniformity of enforcement among the states and lack of pro-active interaction between the States particularly, in connection with investigations relating to drugs found 'Not of Standard Quality'.

4.3 The Committee, during the visit to Bangalore, had interaction with the representatives of the State Drugs Control Department. The Committee was informed that the Department had three wings, viz., Enforcement Wing, Drugs Testing Laboratory and Education in Pharmacy. At present, the sanctioned strength of the Department was 702 out of which 408 posts were filled. The Committee was apprised of the various challenges facing it, *viz*., inadequate staff for enforcement as well as for the laboratories.

4.4 The Committee was informed that a request had been made to Karnataka Public Service Commission for recruitment of 10 Drugs Inspectors and proposal had been submitted to the Government for creation of 430 posts, which included posts of Drugs Inspectors. Besides, there was need for adequate funds for construction of infrastructure and for procurement of necessary equipment/books.

4.5 From an analysis of the above facts, the Committee concludes that shortcomings witnessed in respect of coordination with and between the States as also in implementation of applicable legislations in the States are primarily an offshoot of inadequacies in manpower and infrastructure in the States. Strengthening the regulatory mechanism in the States will remain a far cry unless these infirmities are taken care of.

4.6 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 Committee desires to be kept apprised of the initiatives taken by the Ministry in this regard.

4.7 It is a matter of grave concern that there are serious shortcomings in Centre-State coordination in the implementation of Drugs & Cosmetics Act and Rules. This, the Committee notes, is despite the Ministry's own admission that Section 33P of the Drugs and Cosmetics Act contains a provision that enables the Central Government to give such directions to any State Government as may appear to it to be necessary for implementation of any of the provisions of the Drugs and Cosmetics Act and Rules made thereunder. The Committee understands that these provisions are meant to be used sparingly. However, there have been several situations which warrant intervention through Rule 33 P. Therefore the committee hopes that in future the Ministry would not be found wanting in considering the option of using Section 33P to ensure that provisions of central drug acts are implemented uniformly in all states.

4.8 As regards lack of databank and accurate information, the Committee would like to observe 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.

5. Capacity-building of Central and State Drug Testing Laboratories

5.1 The Committee was informed that the Central Drug Testing Laboratory, Hyderabad was yet to be equipped and the other five Central Drug Testing Laboratories at Kolkata, Mumbai, Chennai, Guwahati, and Chandigarh were reasonably equipped but not fully equipped and required upgradation with the state-of-the-art facilities for testing/analyzing complex formulations and detect spurious, misbranded, sub-standard and adulterated drugs. The Ministry has indicated that upgradation of the Central Drug Testing Laboratories would require 442 additional posts and augmentation of their infrastructure on a large scale. The present drug testing capacity of the six laboratories is 8,000 samples per annum, which is targeted to be increased to 24,000 samples per annum.

5.2 As per information furnished, there are 160 Drugs Testing Laboratories in the approved private and Government sectors in various states. The State Drugs Testing Laboratories test statutory samples from the Drugs Inspectors of the respective State Drugs Control Departments.

5.3 The Ministry informed the Committee that the private Drug Testing Laboratories test the samples on behalf of manufacturers who do not have their own testing and analysis facilities as the manufacturers are required to test the final product before releasing it into the market either at their own laboratory or private approved testing laboratory. These Drug Testing Laboratories are approved and monitored/inspected by the State Drug Authorities.

5.4 The State Governments or State Drug Authorities are expected to undertake the assessment of State Drugs Testing Laboratories with respect to the compliance of Good Laboratory Practices (GLP).

5.5 It has been admitted by the Ministry that the State Drugs Testing Laboratories are not fully equipped with adequate manpower and infrastructure.

5.6 The Committee, during the visit to Chennai undertook a visit to Central Drug Testing Laboratory and State Drug Testing Laboratory. The Central Laboratory has a total sanctioned staff of 33, out of which 29 were filled up and 4 vacancies were in the

process of being filled up. The Committee was informed that this Laboratory needs a 5 storeyed building with 10,000 sq.ft., in each floor.

5.7 The Committee was informed that the Tamil Nadu Drugs Control Administration had a sanctioned strength of 337, out of which 203 were in position and 134 were vacant. The State testing laboratory was having only two HPLC systems bought more than a decade ago that had become obsolete. Hence there was a need for enhancement of facilities to keep up with the increased number of tests.

5.8 The Committee, during its visit to Chennai, also held discussions with the representatives of pharmaceutical industry. The representatives felt that there was need to provide more funds for upgradation of drug testing laboratories and more training for staff of Government Laboratory for proper analysis of samples. Other measures suggested by them included opening of 5 additional laboratories, need for more Appellant Laboratories in all zones in addition to the one located at Kolkata.

5.9 The representatives of the Ministry informed the Committee that the Government was planning upgradation of all Government Laboratories in the country and had proposed a massive investment in the Twelfth Plan proposals sent to the Planning Commission. As regards the issue of more appellate laboratories, the Ministry was examining the matter.

5.10 The Committee, during its visit to Bangalore, undertook a visit to Biocon Ltd., a pharmaceutical manufacturer. This in-house Testing Laboratory is approved by the Drug Authorities and tests samples from various plants belonging to the Biocon Group of Companies and also undertakes testing of samples upon customer request.

5.11 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.

AGENDA NO. 2

CONSIDERATION OF THE ISSUE OF MISUSE OF OXYTOCIN INJECTION

Reports had appeared from time to time in the press as well as in electronic media regarding the misuse of Oxytocin injections by the farmers to increase the size of vegetables and by the dairy owners to extract milk from cows and buffaloes. The matter was earlier also raised by the Drugs Controller, Bihar and Drug Controller, Delhi, in 40th DCC held on 29th June, 2009 and the DCC had opined that strong vigilance is required to stop its clandestine manufacture and sale. Even though the drug is considered as one of essential drug in medical practice for certain conditions in human as well as veterinary field, the alleged abundant availability and use of the drug, in a clandestine way, in growing vegetables is a matter of great concern for public health. The use of oxytocin in growing of vegetables and its harmful effects etc. on humans because of consumption of such vegetables does not come under the purview of the Drugs and Cosmetics Act, however, diversion of the drug for any unauthorized use is matter of concern for the Drug Regulatory Authorities.

The drug oxytocin has medical use for induction and augmentation of labour, to control post partum bleeding and uterine hypo tonicity and is included under Schedule H. The oxytocin injection is required to be packed in single unit blister pack only for sale and is required to be dispensed on the prescription of a Registered Medical Practitioner only. The reports of manufacture and sale of the drug in clandestine way in large quantities and its misuse by the farmers or dairy owners is a matter of great concern and is required to be checked on priority basis. The office DCG(I) had earlier written to the State Drugs Controllers to check and unearth the clandestine manufacture and sale of drug to the farmers or dairy owners in violation of the provision of the Drug and Cosmetic Rules through surveillance and raids conducted on the possible hide outs where such activities are being undertaken.

The manufacture and sale of the drug with or without a licence for such clandestine activity is an offence under the Drugs and Cosmetics Act, and the violators are required to be handled with a heavy hand. The amended penal provisions of the Drugs and Cosmetics Act, 1940 make such offences cognizable and non-bailbale. This clandestine activity of manufacture and sale of the drug to the farmers or dairy owner require constant surveillance and interstate coordination. The intelligence inputs should be passed on to the concerned State Regulatory Authorities for taking timely action. Deterrent and determined steps in

this direction will help in minimizing the use of the drug for purposes other than for which it is permitted to be marketed. Handouts and publicity in the print or electronic media about the hazards of the use of the drug by the farmers or cattle owners can go a long way in educating the public and curbing the misuse of the drug.

Recommendations

The members felt that the misuse of oxytocin is rampant in many of the States and reports of its clandestine manufacture and sale appear now and then in the press. The Drug is available as unlabelled or wrongly labeled packs. Many of the States like UP, Delhi have taken action in seizures of stocks on the basis of intelligence gathered. As the manufacture and sale of these products is through clandestine channels, it becomes difficult to stop their misuse except through continuous surveillance. After deliberations it was opined that as the bulk drug (oxytocin) is being manufactured in a few States only, the diversion of the bulk drug to the illegal channels could be curtailed to a large extent if it is ensured that the bulk drug is sold to the licensed manufacturer only.

AGENDA NO. 3

CONSIDERATION OF THE CANCELLATION OF LICENCES TO MANUFACTURE DRUG FORMULATIONS FALLING UNDER THE PURVIEW OF 'NEW DRUGS' AS DEFINED UNDER RULE 122 (E) OF THE DRUGS AND COSMETICS RULES

Rule 122 – E of the Drugs and Cosmetics Rules, 1945 provides the definition of the term new drug. The drugs falling under this category require prior approval from the Central Licensing Authority before the grant of a licence for manufacture by the State Licensing Authority. It has been observed that the State Drug Control Authorities have been granting permissions for manufacture of fixed dose combinations of drugs falling under rule 122-E in violation of the provisions of the Drugs and Cosmetics Rules. Part (c) of the rule 122-E relating to Fixed Dose Combinations is reproduced as under:

> (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.

Instances were brought to the notice of the Central Government that 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 Ministry of Health and Family Welfare had issued directions under section 33(P) of the Drugs and Cosmetics Act that the State Licensing Authorities should be instructed not to grant licences to manufacture for sale of formulations of medicines belonging to the aforesaid categories without the prior approval of the Drugs Controller General (India).

The Parliamentary Standing Committee of the Ministry of Health and Family Welfare in its 59th report presented on 8th May, 2012 has also taken note of the issue of licences of Fixed Dose Combinations by the State Licensing Authorities. It has made the following observations:

> "9.2 Unfortunately some State Drug Authorities have issued manufacturing licenses for a very large number of FDCs without prior clearance from

CDSCO. This is in violation of rules though till May 2002, there was some ambiguity on powers of the State Drug Authorities in this respect. However the end result is that many FDCs in the market have not been tested for efficacy and safety. This can put patients at risk.

9.3 To remove such unauthorized FDCs from the market, the Central Government can either issue directions under Section 33(P) to states to withdraw the licences of FDCs granted without prior DCG(I) approval or the Central Government can itself ban such FDCs under Section 26A."

"9.7 The Committee is of the view that those unauthorized FDCs that pose risk to patients and communities such as a combination of two antibacterial need to be withdrawn immediately due to danger of developing resistance that affects the entire populations.

9.8 The Committee is of the view that Section 26A is adequate to deal with the problem of irrational and / or FDCs not cleared by CDSCO. There is a need to make the process of approving and banning FDCs more transparent and fair. In general, if an FDC is not approved anywhere in the world, it may not be cleared for use in India unless there is a specific disease or disorder prevalent in India, or a very specific reason backed by scientific evidence and irrefutable data applicable specifically to India that justifies the approval of a particular FDC. The Committee strongly recommends that a clear, transparent policy may be framed for approving FDCs based on scientific principles. "

The office of DCG(I) had earlier written to the State Drug Control Authorities in respect of 294 FDCs which attracted the said definition and were required to be withdrawn from the market. The matter was discussed in the earlier DCC meetings and it was decided that the State Licensing Authorities would direct the manufacturers to stop manufacturing these FDCs and to withdraw the products from the market. The manufacturer Associations however, filed the petition in the High Court of Madras and the Hon'ble Court had granted stay order in the case. The matter is subjudice.

DCC may kindly discuss the issue under the present scenario and the recommendations of the Parliamentary Standing Committee to develop mechanism / guidelines to ensure that FDCs covered under the definition of the new drug are not permitted without prior approval of the DCG(I).

Recommendations

The members stated that in the absence of clear cut guidelines in respect of FDCs, the State Licensing Authorities were granting permissions on the basis of the information available with them.

The committee after deliberations constituted a committee consisting of Drugs Controllers or their representatives from the States of Gujarat, Odisha, Himachal Pradesh, Tamil Nadu, Pondicherry, Maharashtra and Rajasthan with Shri A.K. Pradhan, Deputy Drugs Controller (India), CDSCO, HQ, Delhi as the convener. The committee shall prepare guidelines under which the States should grant licences for fixed dose combinations. The committee will also prepared the list of FDCs which have been approved by the office of DCG(I) as a new drug. It shall also recommend a cutoff date in respect of conventional FDCs which were there before the introduction of the definition of the term 'new drug'.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 122 (E) TO INCLUDE MODIFIED RELEASE FORM OF DRUG FORMULATION AS NEW DRUG

A Task Force was set up by the Ministry of Health and Family Welfare for the purpose of formulating a long term policy for strengthening the drug sector. A Sub-group under the chairmanship of Dr. V. M. Katoch, Secretary, HR, and DG, ICMR recommended in its report that the Controlled Release Formulations of the same drug are reported to be vastly different from each other with respect to their efficacy as well as toxicity. Composition as well as the process of manufacture of the carrier controlled release formulations has impact on the clinical performance of Active Pharmaceutical Ingredient in the controlled release formulation. Therefore each controlled release formulation whether a copy of a studied and approved drug or another one should be treated as a new drug and accordingly subjected to the requirement of complete studies as new drug. This practice is followed internationally. Any deviation from this norm is being observed globally as to allow sub-par performer formulations in the name of generics.

It has therefore been proposed that the explanation under rule 122 (E) of Drugs and Cosmetics Rules needs to be amended so that it cover all modified release dosage form of the drugs as new drugs along with all vaccines, recombinant DNA (r-DNA) derived drugs.

In view of the above the present entry under *Explanation* to Rule 122E,

> "(i) All vaccines and recombinant DNA (r-DNA) derived drugs shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;"

is proposed to be amended to read as

> "(i) All vaccines, recombinant DNA (r-DNA) derived drugs and all modified release form of drug formulations shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;"

DCC may kindly deliberate and give its recommendations.

Recommendations

The committee agreed to the proposed amendment. It was however, desired that the term 'modified release' may be defined under the rules for the purpose of clarity.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF RULES 71, 71B, 76 and 76A OF THE DRUGS AND COSMETICS RULES REGARDING SUBMISSION OF CHEMICAL AND PHARMACEUTICAL DATA TO THE LICENSING AUTHORITIES ALONG WITH THE APPLICATION FOR GRANT OF LICENSE.

Under the Drugs and Cosmetics Rules applications are made to the state licensing authorities (SLAs) for grant of manufacturing licenses. There is no provision which require the applicant to submit chemical / pharmaceutical data to the said authority with respect to the product applied for except for the Patent and proprietary medicines as under 71(6), 71B, 76(7) and 76A of the Drugs and Cosmetics Rules, 1945.

It may be mentioned that in the case of new drugs, an applicant while making the application for grant of permission to import and / or manufacture a new drug already approved in the country is required to submit data as per appendix 1A of schedule Y of the said rules to the office of DCG(I).

It is proposed that the SLAs should also obtained similar chemical / pharmaceutical information about the products for which the permission to manufacture for sale in the country is being sought. This will help in ensuring that the product permitted by the State Licensing Authorities has the necessary stability data generated and other relevant information about the product before the grant of permission for manufacture of the product.

In view of the above it is proposed that rules 71(6), 71B, 76(7) and 76A of the drugs and cosmetics rules may be amended to include the following information to be provided along with the application to the Licensing authority while applying for a license to manufacture drug formulation.

1. A brief description of the drug and the therapeutic class

2. Chemical and pharmaceutical information

   2.1 Chemical name, code name or number, if any; non-proprietary or generic name, if any, structure; physico-chemical properties
   2.2 Dosage form and its composition
   2.3 Test specifications
   (a) Active ingredients

(b) Inactive ingredients

2.4 Tests for identification of the active ingredients and method of its assay

2.5 Outline of the method of manufacture

2.6 Stability data

3. Marketing information

3.1 Proposed package insert / promotional literature

3.2 Draft specimen of the label and carton

4. Certificate of Analysis of the products.

5. The approval, in writing, in favour of the applicant to manufacture drug formulations falling under the purview of new drug as defined in Rule 122-E, from the licensing authority as defined in clause (b) of Rule 21.]

Note:

The above requirements will not be applicable for the renewal of the existing licenses.

DCC may kindly deliberate and give its recommendations.

Recommendations

The members agreed to the proposed amendment. The committee further recommended that method of analysis of the drugs should also be provided to the concerned Licensing Authorities so that it could be made available to the Government analyst, wherever required for testing.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 96 FOR LABELING OF VACCINES WITH SPECIFIC REFERENCE TO THE ORIGIN OF THE VACCINE

WHO during the NRA assessment at Central Drugs Standard Control Organization in respect of vaccines manufactured in the country has expressed a concern that the vaccine which are manufactured by using different source of antigen have been labeled with the same manufacturing license number without having any unique identification number which otherwise does not provide the correct information in respect of the origin of the vaccine.

As per Rule 122 E all vaccines are considered as new Drugs and any change in the source of antigen, the New Drug approval is required to be obtained from the Licensing Authority. However, there is no specific provision under Rule 96 for labeling of the vaccine with specific reference to its origin.

It is therefore proposed that Rule 96 to be amended to include a specific UID number or New Drug Approval number on the label of the vaccine as granted by the Licensing Authority.

DCC may kindly deliberate the issue and give its recommendations.

Recommendations

The committee agreed to the proposed amendment.

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL FOR GRANT OF MANUFACTURING LICENCES OF DRUG FORMULATIONS IN PROPER (GENERIC) NAME ONLY BY THE STATE LICENSING AUTHORITIES

It has been observed that at the time of the grant of the license for manufacture of a drug formulation by the State Licensing Authorities, the trade name / brand name as submitted by the manufacturer is endorsed by the licensing authority alongwith proper name of the product thereby giving legitimacy to market the drug under the brand or the trade name.

Under Drugs & Cosmetics Rules, applications in various Forms for grant / renewal of a Licence to manufacture for sale or distribution of various categories of drugs as well as various forms for grant / renewal of such licenses require that the name of drug is specified. Such Forms for application as well as grant /renewal of the Licenses do not require mentioning of any Trade Name / Brand Name. In case of drug formulation containing multiple ingredients, the licence should be granted under the name of categories of the products viz. “Multivitamin Tablets / Capsule / Syrup”, “antioxidants, multivitamins & multi minerals tablets/capsule/syrup” etc. However, the composition of such product shall mention the name of ingredients as well as its strength.

In view of above it is felt that the grant of Drugs manufacturing Licenses under a trade or brand name is not in accordance to the spirit of the legislation and therefore it is proposed that manufacturing licenses for the drug formulations should be granted in proper / generic name only.

In order to have more clarity and to ensure that license to manufacture for sale or distribution is granted only in proper name, it is proposed that following condition may be inserted in appropriate forms of applications as well as licences.

“Name of drug shall be mentioned in proper (generic) name only”

The committee may deliberate and give its recommendations in the matter.

Recommendations

The members opined that to give the name of the drug in generic name only on the licence is feasible for single ingredient drugs formulations only. The licence for products having multiple ingredients in generic names only may lead to large numbers of brands and would be difficult to implement for regulating their quality control.

AGENDA NO. 8

CONSIDERATION OF THE PROPOSAL FOR INCLUSION OF ZINC SULPHATE TABLETS UNDER SCHEDULE K OF DRUGS AND COSEMTICS RULES

Representations have been received by the office of DCG(I) from UNICEF, WHO, PATH AIIMS etc. for inclusion of Zinc Sulphate tablet under schedule-K of Drugs & Cosmetics Act and Rules.

It is claimed that numerous trial and studies have demonstrated that use of Zinc in treatment of Diarrhoea results in 16% decrease in frequency of severe diarrhoea in acute cases, 14% decrease in the number of days of diarrhoea, 25% decrease in persistent cases and 16% decrease in acute diarrhoea cases. Additionally, Zinc supplementation given for 10-14 days also lowers the incidence of diarrhoea in the following 2-3 months.

Increasing the use of Zinc tablets in childhood diarrhoea has been considered essential and easily achievable public health goal in India. Like ORS, Zinc has the possibility of making a major impact on the health of children in India.

An Expert Committee set up by the Government of India had opined in 2006 that 20mg of Zinc should be given for 10-14 days to all the children suffering from Diarrhoea. A 10mg dose of Zinc was recommended for children below 6 months of age. The committee also suggested that Zinc must be classified under regulations similar to that of ORS, so that it can be promoted together with ORS solution or other home available fluids.

In a conference organized by Clinical Development Service Agency (CDSA) and Department of Biotechnology (DBT) on August 29th, 2011, the group of experts at this meeting advocated for the inclusion of Zinc products under schedule K to ensure consistent availability and promotion of these products.

In view of the above it is proposed to include Zinc tablets of 5 mg and 10 mg under Schedule K for exemption from the sale licence.

DCC may kindly deliberate the issue and give its recommendations.

Recommendations

The committee agreed to the proposed amendment.

AGENDA FROM STATES

MADHYA PRADESH

9. Insufficient provision for renewal

As per Rule 72 of Drugs and Cosmetics Rules, 1945, the licences issued are valid for a period of 05 years from the date of issue. The licences are deemed to be valid if the licensee applied for its renewal prior to its expiry or within 06 months from the date of its expiry, until orders are passed on the application. No time limit has been specified in the Drugs and Cosmetics Rules for the renewal of licences. Thus the unit whose inspection is somehow delayed and in later course found unfit for renewal continues to work in that period also.

Recommendations

The members were of the opinion that because of the shortage of man power in most of the States, the Drugs Control Authorities are unable to renew the licenses in time. This being an administrative matter and the States are required to renew the licenses within reasonable time. The DCC therefore did not agree to specify time limit for renewal of licenses.

10. Non-discrimination in major and minor offences

Drugs and Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945, make no discrimination in major and minor offence. Thus, the decision of taking administrative action or launching prosecution is left on the discretion of Drugs Controller or Drugs Inspector who remain under external pressure. Although it is a fact that major / minor offences have been categories in guidelines by D.C.C. and this Administration is following these guidelines.

Recommendations

As the subject matter was raised by many State Drugs Controllers, the DCC decided to set up a committee consisting of the Drugs Controllers Maharashtra, Rajasthan, Odisha and with Dr. D. Roy, Deputy Drugs Controller, North Zone as the convener to examine the matter afresh in the context of amended provisions of the Drugs and Cosmetics Act, 1940 and prepare guidelines for the purpose. The committee may give its report within one month of the constitution of the committee. On the suggestion or some of the members it was agreed that the committee will also examine and recommend changes, if any, in respect of provisions for Blood Bank licensing.

11. Lack of provision for sampling without tendering / offering payment

As per the present provision, Drugs Inspector shall draw the samples only after payment of the cost of the drugs. The fund allotted for the purpose, are generally insufficient and thus, the provisions of the Drugs and Cosmetics Rules pose a hindrance in drawing sufficient number of samples for test / analysis.

Recommendations

DCC was of the opinion that samples for test are required to be drawn after tendering the payment of the cost of the drug. It is for the States Governments to make appropriate financial provisions for drawing of more number of samples by the Drug Inspectors.

12. Lack of time limit for launching prosecution

No time limit has been defined in the Drugs and Cosmetics Act, 1940 for launching prosecution in the court by the Administration and thus delay is observed in taking action against the offenders.

Recommendations

The members opined that the prosecutions are launched by the Drugs Inspectors after necessary investigations at the place where the sample was drawn and also where the drug was manufactured. This exercise in most of the cases is of interstate nature and time consuming. As such it may not be feasible to prescribe time limits for launching of prosecutions.

13. Lack of time limit for testing of drugs samples

No time limit has been fixed for testing of drugs samples and thus Not of Standard Quality / Spurious drugs are being sold in the market.

Recommendations

The issue was discussed in the earlier meeting also. DCC recommended that the following general guidelines could be followed by the testing laboratories subject to the availability of method of analysis.

1. **Pharmaceuticals products non HPLC – 45 days**
2. **Pharmaceuticals products with HPLC – 90 days**

In regard to the availability of the reference standards the members were informed that Indian Pharmacopoeia Commission will be able to provide reference standards to the Government testing laboratories in about six months time.

ODISHA

14. Contractual Manufacturing

Keeping in view of the existing provisions laid down under rule 69A regarding grant of Loan Licenses, permission by different licensing authorities to encourage contractual Mfg. System appears to be not legal in absence of proper rule in the following aspects:-

I. **Loss of Govt. Revenue for Rs. 7200/- per licence:** if a brand name owner intends to manufacture the product on contractual basis with a valid licensee, the Licensee has to deposit an additional fee of Rs. 300/- only to the concerned Licensing Authority to get the approval in the body of the respective licenses (Form -25 & 28). If the applicant apply for a loan licence for that product as a loan licensee with the licensed Manufacturer, whose manufacturing facilities to be availed by him, he has to deposit a license fees of Rs. 7500/- for each license.

II. **Loss of Govt. Revenue of Rs. 50,000/- for each F.D.C:-** If a licensed manufacturer has been permitted to manufacturer any F.D.C. by paying fees of Rs. 50,000/- then any person can approach him on contractual basis to manufacture the said F.D.C. with different brand name by paying fees of Rs. 300/- only as additional item in the existing license.

III. Allowing on contractual manufacturing of FDC (New Drug) it is observed that one manufacturer is manufacturing a F.D.S. with different brand name on contractual basis for more than one firm. By doing so, the same F.D.C. is available in the market with different brand name with different MRP having same Mfg. Licence No. having one manufacturing address.

Recommendations

The issue was raised by many of the State Drugs Controllers. The committee felt that the issue of contractual manufacturing requires indepth examination. The present practice is not only leading to loss of revenue to the Government but also permit a manufacturer to manufacture different brands of the same product while there are no specific provision under the rules in this regard. The committee therefore constituted a sub-committee consisting of Drugs Controllers of Odisha, Uttar Pradesh and Maharashtra and with Dr. V.G. Somani, Deputy Drugs Controller, CDSCO, HQ as convener to examine the matter in detail and give recommendations for changes, if any, under the Drugs and Cosmetics Rules, 1945. The committee may give its recommendations in three months time.

15. Fixed Dose Combination

I. Name of Manufacturer with the details of F.D.C. approved with date of approval maye circulated to all State Licensing Authority.

II. Labeling provisions for new drug should be incorporated in rule 96 instead of in Form 46 because:- [A F.D.C. is considered as New Drug for 4 yrs from the date of its first approval or its inclusion in the I.P. whichever is earlier. In case of F.D.C. (injectable form) there should not be a **Red vertical line**as per the labeling provision under rule **96(xi)**. But the F-46 covers the same in spite of the period of validity after four years. Most the manufacturer are putting the **Red Vertical Line** on the label of the New Drug (in injectable form) even after four years.]

Recommendations

i. The issue was discussed under agenda No. 3.

ii. The members did not agree to the proposed changes in rule 96.

16. Repacking licence for combi-pack of water for Injection/Syringes with Injection

The manufacturers of Sterile Injectable preparations in powder form/Lyophillized form are invariably marketing their product in combipack alongwith Sterile Water for injection and/or Disposable syringes alongwith the Injections. On verification, it is observed that Sterile Water for Injection and Syringes are manufactured by other companies whose name and address, Mfg. licence No. Mfg. Date, Exp. Date etc. are different as that of the manufacturer of combipack.

The combipack having such different in Batch No., Mfg. Date, Exp. Date, name & address of the manufacturer are sold under single brand name. In such cases the concerned Licensing Authority many insist such manufacturer to have a **Repacking Mfg. Licence** to repack such drugs in combipack to be sold in one brand name in one pack.

Recommendations

The committee felt that as the labeling and packing of water for injection and syringes are kept intact, it may not be necessary to insist upon for repacking licence to repack such drugs in a combi-pack.

UTTAR PRADESH

17. Manufacture of drugs under a loan licence or contract

1. The Rules 69-A, 70-A, 71-B, 73-A, 73-AA, 75-A, 76-A, 78-A, of the Drugs and Cosmetics Rules, 1945 prescribe provisions for grant of Loan Licences. As per an explanatory note to Rule 69-A a loan licence means, licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by a licencsee in Form 25.

   As per labels of pharmaceutical products being marketed throughout the country it can be observed that there are two type of loan licensees:

   (1) Companies / firms which are having their own duly licensed manufacturing facilities are still getting their products manufactured on loan licences on manufacturing facilities of other pharmaceutical companies / firms.

   (2) Companies / firms / private persons who are not having any manufacturing facilities, are getting their products manufactured on loan licences on manufacturing facilities of other pharmaceutical Companies / firms.

   Discussion / Clarification Desired:

   Do such Companies / firms, which are having their own licensed manufacturing facilities, could be granted loan licences in view of the explanatory note as mentioned above.

   Further, discussion / explanation is desired in respect of indiscriminate permission being granted for manufacture of pharmaceutical products by the licensed manufacturers on behalf of persons / firms / Companies on contractual basis without grant of loan licence as prescribed under the Drugs and Cosmetics Rules. Could such contract manufacturing be allowed circumventing the prescribed loan licensing provisions of the Drugs and Cosmetics Rule, 1945 which also leads to revenue losses to the State Governments in terms of licence loan licece fees.

It is not out of place to mention here that in a Writ Petition (Public interest Litigation) no. 4423 (M/B) / 2011 ‘ Anil Kumar Bajpai Versus Union of India and

others' the matter related to the above mentioned contract manufacturing without having loan licence has been raised.

Recommendations

The matter was discussed under item number 14.

18. Marketing of vitamin preparations as food supplements

2. A fairly large no. of non pharmaceutical manufacturers have been manufacturing and selling products containing Vitamins in quantities which fall either into Prophylactic category or Therapeutic category as specified under Schedule 'V' to the Drugs and Cosmetics Rules, 1945 but such products are being indiscriminately licenced under Food Safety and Standards Act, 2006 as Dietary Supplements / Nutritional Supplements / Nutraceuticals. Many such products carry inserts wherein medicinal claims are also being made.

Discussion / clarification Desired:

Could such products be licensed under Food Safety and standard Act, 2006 in view of the following:

(A) The Section 22 of the Food Safety & Standards Act, 2006 envisages as hereunder "Save as otherwise provided under this Act and regulations made there under, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this befalf.

Explanations- For the purpose of this Section,-

(1) "foods for special dietary uses or functional foods or nutraceuticals or health supplement" means:

(a) Foods which are specially proposed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such

ordinary food exist, and may contain one or more of the following ingredients, namely:-

(i) Plants or botanicals or their parts in the form of powder, concentrate or extract in water, ethyl alcohol or hydro alcoholic extract, single or in combination;

(ii) minerals or vitamins or proteins or metals or their compounds or amino acids in amounts not exceeding the Recommended Daily Allowance for Indians) or enzymes (within permissible limits);

(iii) substances from animal origin;

(iv) a dietary substance for use by human beings to supplement the diet by increasing the total dietary intake;

(b) (i) a product that is labeled as a "Food for special dietary uses or functional foods or nutraceuticals or health supplements or similar such foods" which is not represented for use as a conventional food and whereby such products may be formulated in the form of powders, granules, tablets, capsules, liquids, jelly and other dosage forms but not parenterals, and are meant for oral administration;

(ii) **such product does not include a drug as defined in clause (b)** and ayurevedic, sidha and unani drugs as defined in clauses (a) and (h) of **section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made thereunder;**

(iii) **does not claim to cure or mitigate any specific disease, disorder or condition (**except for certain health benefit or such promotion claims as may be permitted by the regulations made under this Act;

(v)does not include a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and rules made thereunder and substances listed in Schedule E and E1 of the Drugs and Cosmetics Rules, 1945.

(4) "proprietary and novel food" means an article of food for which standards have not been specified but is not unsafe.

However, many of the Vitamin products being manufactured and marketed under licence granted under Food Safety and Standards Act, 2006 contain vitamins in quantities much higher than the daily allowable quantities in gross violation of Section 22(1)(a)(ii) of the F.S.S. Act 2006 and are according to Schedule 'V' of the Drugs and Cosmetics Rules, 1945.

(B) The item no. 1 of the Schedule 'K' of the Drugs and Cosmetics Rules, 1945 provides exemption from all provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and Rules to the drugs falling under clause [b][i] of Section 3 of the Drugs and Cosmetics Act which are not intended for medicinal use and such products are conspicuously labeled with the words 'NOT FOR MEDICINAL USE'.

Many of the vitamin products which are being manufactured on FSSA licence fall under one or more of the following categories:-

(i) They contain vitamins in quantities which is as per Schedule V of the Drugs and Cosmetics Rules but they are labeled with the words 'NOT FOR MEDICINAL USE';

(ii) They contain vitamins in quantities which is as per Schedule V of the Drugs and Cosmetics Rules but they are not labeled with the words 'NOT FOR MEDICINAL USE';

(iii) They have inserts with or without medicinal claims.

(C) The vitamin products which are manufactured and marketed under Drug Licences and Dietary supplements / Nutritional supplement / Nutraceuticals which are manufactured and marketed under licence granted under Food Safety and Standard Act, 2006 and both having similar vitamins composition but having huge difference in M.R.P.

Such price difference clearly indicates that such dietary supplements / nutritional supplements / Nutraceuticals are intentionally manufactured and marketed using licences under FSS Act to escape the provisions of Drugs Prices Control Order which otherwise has to be complied with if such products are manufactured under Drug Licences.

This is to bring to your kind notice that in the Writ Petition (Public Interest Litigation) no. 4423 (M/B) / 2011 "Anil Kumar Bajpai Versus Union of India and others' this matter of dietary supplements being manufactured on Food Licence and not on drug licences has also been raised.

Recommendations

The Drugs Controller Karnataka informed that Food Safety and Standard Authority of India (FSSAI) has asked the State Food Authorities to withdraw the permissions granted for vitamin preparations to be marketed as food supplements. The members opined that formulations of vitamins and minerals should be considered as drugs if they fall within the purview of Schedule V of the Drugs and Cosmetics Rules. The committee after deliberations recommended that item 1 of Schedule K may be amended to ensure that the drugs substances manufactured for non-medicinal use should be with the permission of the concerned Licensing Authority under the Drugs and Cosmetics Rules.

19. Sale of Homeopathic medicines

Rule 106-B was incorporated vide notification no. GSR 108(E) dated 22.02.1994 which envisages as hereunder:

> "No homoeopathic medicine containing more than 12% alcohol v/d (Ethyl alcohol) shall be packed and sold in the packing or bottles of more than 20 millilitres, except that it may be sold to hospitals / dispensaries in packing or bottles of not more than 100 millilitres."

It is clear from the above provision that homeopathic medicine manufacturers can manufacture and pack medicines containing more than 12% alcohol v/v in packing less than 30 ml and also in packing of up to 100 ml for sale to hospital or dispensaries.

The licences on Form 20-C are granted under Rule 67-C of the Rule for retail sale of homeopathic medicines. The condition no. 4 printed on the said licence on Form 20-C authorizes the sale of Homeopathic medicines made from one earlier potency up to a quantity of 30 ml at a time.

Te Sub Rule(5) of Rule 67-G of the Rules envisages as hereunder:

> "The licensee in Form 20-C shall maintain records of purchase and sale of Homeopathic medicines containing alcohol. No records of sale in respect of Homeopathic potentised preparations in containers of 30 ml or lower capacity and in respect of mother tinctures made up in quantities up to 60 ml need be maintained."

The licences on Form 20-D are granted under Rule 67-C of Rules for wholesale of homeopathic medicines. The condition no. 3 printed on licence on form 20-D envisages as hereunder:-

"No sale of any drug shall be made to a person not holding the requisite licence to sell, stock or exibit for sale or distribute the drug. Provided that this conditions shall not apply to the sale of any drug to (a) an authority purchasing on behalf of Government, or (b) a hospital, medical, educational or research institution or a Homeopathic medical practitioner for the purpose of supply to his patients."

Thus, a wholesaler having licence on Form 20-D is authorized to sell homeopathic medicine to Hospitals and is a channel between manufacturer and hospitals.

A wholesaler is also a channel between manufacturer and retailer of homeopathic medicines.

Discussion / clarification Desired:

A discussion / clarification, therefore, is desirable in view of provisions of Rule 106-B of the Drugs and Cosmetics Rules, 1945 whether manufactures of homeopathic medicines can sell medicines containing more than 12% v/v alcohol in packing of upto 100 ml to retailers having licence of Form 20-C considering them as dispensaries who are authorized as per condition of said licence to potentise the preparation and dispense and to wholesalers having licence on Form 20-D who act as channel between manufacturer and hospitals.

Recommendations

The committee recommended that status quo may be maintained in the case of homeopathic drugs as the provisions of rule 106B are sub-judice.

20. Advertisement of Homeopathic drugs

3. Rule 106 of the Drugs and Cosmetics Rules, 1945 envisages as hereunder:

(1) No drugs may purport or claim to prevent or cure or may convey to the intending user thereof any idea that it may prevent or cure, one or more diseases or ailments specified in Schedule 'J'.

The Schedule 'J' to the Drugs and Cosmetics Rules, 1945 enlists the diseases or ailments which a drug may not purport to prevent or cure or make claims to prevent or cure.

Under Schedule 'J' words Rule 106 is printed inside brackets. The Rule 106 is covered under Part IX of the Drugs and Cosmetics Rules, 1945 which covers Rules 94 to 106 pertaining to labeling and Packing of Drugs other than Homeopathic medicines. For labeling and packing of Homeopathic medicines Rules 106-A and 106-B are prescribed under a separate Part i.e. Part IX-A of the Drugs and Cosmetics Rules.

Discussion / Clarification Desired:

In view of the above a discussion / clarification is desired whether restrictions of Schedule 'J' is also applicable on Homeopathic medicines or not.

Recommendations

The members were of the opinion that Schedule J is applicable to the drugs belonging to the modern system of medicines only and not for homeopathic medicines. The definition of the term 'drugs' under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, however, includes all medicines for internal or external use of human beings or animals and as such the advertisements of homeopathic drugs for the diseases, disorders or conditions specified in the Schedule to this Act are prohibited.

RAJASTHAN

21. **Manufacture & sale of Banned Tobacco containing Tooth Paste / Gum Paste in the name of creamy snuff:** Ban/prohibition under sec 26-A / 33-EED of Drugs & Cosmetics Act, 1940.

Government of India banned manufacture and sale of tooth paste/ tooth powder in Cosmetics and Ayurvedic drugs containing Tobacco under Section 26-A and Sec. 33-EED under Drugs & Cosmetics Act, 1940 vide Gazette Notification no. GSR(444)E and GSR(443)E dated April 30, 1992 respectively. The Drugs Consultative Committee in its meeting held in July, 1978 had resolved that "Gudakku" being used as Tooth Paste & Dental Tooth Powder containing tobacco is a cosmetic and was thus prohibited, where as "Creamy Snuff" can neither be considered as a "drug" nor as a "Cosmetic" and therefore it was decided not to exercise control over this item under this Act. The matter was again taken in DCC meeting held on 6th / 7th July, 1994, which was raised by the Drugs Controller, Goa but earlier decision was adhered to.

Rajasthan had again brought this issue as an agenda item in 41st DCC meeting held on 28th October, 2010 but due to lack of time only Central agenda items were discussed and it could not be taken up therefore it is again submitted for examination by the DCC.

Two products namely "IPCO creamy snuff" of Asha Industries, Nadiad and Dentobac Creamy Snuff of Parag Perfumes, Sihor (Gujarat) are popularly marketed throughout the country which contain 35 to 40% of tobacco & it claims its use by way of rubbing on gums with help of tooth brush or finger.

Dictionary meaning of Snuff is "Powdered Tobacco which people take by breathing it quickly through their nose" but this fine powder of tobacco cannot have any added ingredients like clove mint, salt, black pepper etc., because these substances will increase irritation in nose and therefore cannot be inhaled. The manufacturers of creamy snuff are mixing so many other ingredients with tobacco powder to make it semisolid which cannot be inhaled. It is actually used for rubbing on gums as toothpowder or tooth paste, as claimed.

Sample of Dentobac creamy snuff was drawn for Analysis. The Test Report was challenged by the manufacturer and it was sent for re-testing to the Director, Central Drug Laboratory, Kolkata by Chief Judicial Magistrate, Udaipur (Rajasthan). The Director, CDL have issued a report on Form 2, in which he has categorically mentioned that the sample product is to be used for rubbing on

teeth or gums therefore it is covered in the definition of cosmetics under section 3(aaa) of Drugs and Cosmetics Act, 1940 (copy of the test report enclosed).

It is therefore proposed to review DCC earlier recommendation and to consider all products, which contains tobacco and are likely to be used as tooth paste or tooth powder including Creamy Snuff / Gul / Manjan etc as Cosmetics.

Recommendations

The Drugs Controller, Rajasthan stated that tobacco containing preparations in the name of Creamy Snuff / Gul / Manjan etc are being used as toothpowder and toothpaste. These products attract the definition of the term 'cosmetics' under the Drugs and Cosmetics Act. The Gazette notification GSR 444(E) dated 30.04.1994 issued under Section 26A of the Drugs and Cosmetics Act prohibits the manufacture and sale of all cosmetics licenced as toothpastes / toothpowders containing tobacco. Snuff as per the dictionary meaning is "to inhale something through nose". The creamy snuff marketed in the form of toothpastes or toothpowder cannot be used for inhalation, it can only be used as toothpastes / toothpowders. The Director, Central Drug Laboratory Kolkata in its report No. 2-1/2012-SS / CC-188/596 dated 24.04.2012 on Form – 2 have reported that Dentobac Creamy Snuff is intended to be used for rubbing on teeth and gums, therefore it is Covered in the definition of "Cosmetics" under Sec-3 (aaa) of Drugs and Cosmetics Act, 1940.

The DCC after deliberations agreed that toothpastes / toothpowders are covered under the definition of the term 'cosmetics' and if a product is marketed as a toothpaste for rubbing on teeth then it should be considered within the definition of the term 'cosmetics' under the Drugs and Cosmetics Act and manufacture and sale of such products containing tobacco is prohibited under Section 26-A of the said Act.

22. Time limit of 60 days may be prescribed for test / analysis of drugs by Government Analyst under Drugs & Cosmetics Act / Rules

It is again submitted that very purpose of sending a drug sample for testing to Govt. Analyst & getting its report close to its expiry date is defeated as stocks in market are consumed and in many cases the manufacturers are deprived of their right to challenge the test report within 28 days & to get the sample retested from Director, CDL, Kolkata. Hon'ble Supreme Court and High Courts have held that if the

manufacturer challenges the findings of Govt. Analyst, then the sample must be sent for retesting otherwise the manufacturer gets the benefit and he is acquitted by the courts. Therefore it is found that a time limit of 60 days for testing a drug samples should be fixed under the rules rather than as recommendation.

Recommendations

The matter was already discussed under item number 13.

23. Whether Private Hospitals, Nursing Homes etc. require to take sale licences for keeping the drugs for making them available to the indoor patients

The agenda item was discussed in 43th DCC meeting and the decision was to be taken after perusal of court judgment of Kerala High Court. Drugs Controller, Kerala must have made available the copy of judgment to Drugs Controller General (India) & therefore the matter may now be decided.

Recommendations

The members informed the house that in many of the States private hospitals and nursing homes are required to take sale licence for storing the drugs for indoor patients.

24. Testing of patent & proprietary medicines

It has been observed that when a sample of patent & proprietary medicines is taken for test / analysis as per the provisions of the Drugs and Cosmetics Act, 1940 & sent for analysis to the Government Analyst, more of the Government Laboratories demand test protocols & in some cases ask for reference standards. Testing procedure & reference standard is to be provided by the manufacturer of the drug but it has been observed in some cases the manufacturer intentionally delay in supplying the test protocols / reference standard to avoid timely testing. The delay in testing ultimately benefits the manufacturer because after expiry the Apex laboratory will not accept the sample for retesting. The report of state laboratory on form 13 can be challenged u / s 24 of the Drugs and Cosmetics Act by the manufacturer thus report of Government Analyst is not a conclusive report as per the Act, if it is challenged.

The prevailing provisions are as follows:-

Rule 46 (*Explanation)*

(3) for patent or proprietary medicines containing pharmacopoeial drugs for which the official test or analysis or methods of assays are modified and applied, a description of the actual tests or, as the case may be, analysis or methods of assays so applied is given in the report;

(4) for patent or proprietary medicines for which no pharmacopoeial test or methods of analysis are available or can be applied but for which tests or methods of analysis given in standard books or journals are followed, a description of such tests or methods of analysis applied together with the reference to the relevant book or journals from which the test or methods or analysis have been adopted, is given in the report;

(5) For those drugs for which methods of test are not available and have been evolved by the Government Analyst, a description of tests applied is given in the report.

Provisions should be made that laboratory may call for test protocols / reference standard directly from the manufacturer or the concern inspector who has drawn the sample may ask for test protocols / reference standard from the manufacturer. The manufacturer may be bound to supply the required test protocols / reference standard within the stipulated period.

Recommendations

The DCC recommended that in case manufacturer does not sent the method of analysis for patent & proprietary medicines, the Government Analyst is free to test the sample as per method available to him in the standard books or journals.

25. Prescribing time limit for taking final action on the test reports of not of standard quality

It is observed that the state licensing authorities are not taking final action on the drugs declared not of standard quality by the Government Analyst report issued on form 13 as per the provisions of the Drugs and Cosmetics Act 1940. It is therefore suggested that all the state licensing authorities should take final action on the reports declared as not of standard quality within six months of the

receipt of test report & should intimate to the concern state Drugs Controller if the sample is drawn & tested in the other state.

Recommendations

The issue was discussed under item number 12.

26. Publication of updated Drugs and Cosmetics Act and Rules by the Government of India

Publication of 'Drugs & Cosmetics Act 1940 '& Rules by Government Press has not been done since last so many years. The need of publication is felt as many major amendments have been done in the Act in last few years & Government Publication is the only authentic book admissible in the courts otherwise so many notifications of the amendments are required to produced in the courts. To overcome these day today problems of collecting old notification the publication of this Act by the Government Press is required so that amended Drugs and Cosmetics Act 1940 & Rules, 1945 can make available to the courts or / other legal persons. Recently Government of India has published the Pharmacopoeia of India & national formulary is in process of publication. The Act should also be published by the concern department.

Recommendations

The Chairman agreed that efforts would be made to publish an updated edition of the Drugs and Cosmetics Act and Rules.

27. Number of loan licences

The numbers of loan licences and contract manufacturing that can be permitted to a manufacturer licenced under the provisions of Drugs & Cosmetics Act 1940 & Rules, thereunder.

Recommendations

The DCC recommended that the number of loan licenses that could be permitted to a manufacturer depends upon the installed capacity of the manufacturer. Many of the State Drugs Controllers however, stated that they follow the practice of limiting 10 loan licenses to a manufacturer in general.

PUNJAB

28. Categorization of thermolabile and thermostable drugs for taking action regarding samples declared not of standard quality in Assay

In the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act 2008, the guidelines are issued by the DCG(I) office, New Delhi for taking action on the samples of drugs declared "Not of Standard" quality. As per guidelines, if the active ingredients contents of drugs are below 70% for the thermoliable drug and below 5% of the permitted limits for the thermostable drugs are categorized as grossly sub standard drugs. In most of the drugs formulations including biological and non-biological formulations, the storage conditions mentioned by the manufacturer on the labels are to be stored in cool place which means temperature below 25 °C. In schedule P of the Drugs and Cosmetics Rules, 1945, for most of the antibiotic and Vitamins formulations no specific storage condition are prescribed and these are to be stored under normal room temperature. In schedule P, no storage conditions are prescribed for enzyme preparations. Enzyme are also not listed in Schedule C and C1 and thus are non-biological drugs. The drugs for example Vaccine, Sera and Insuline Injection etc. which required storage in cold place i.e. temperature below 8 °C Are highly thermoliable drugs. As per guidelines, the weapon for persecution should be used sparingly and judiciously.

The Drugs Consultative Committee should decide which categories of drugs are to be taken as thermoliable or thermostable specifically.

Recommendations

The DCC recommended that categorization of thermolabile and thermistable drugs should also be examined by the committee set up for making guidelines for taking action on drugs declared as not of standard quality under item number 10.

29. Proposal for amendment of Rule 65(9) (b) of the Drugs and Cosmetics Rules, 1945 to better regulate the wholesale of drugs which are misused as intoxicants and other potent drugs

The following categories of narcotic drugs formulations are widely misused as intoxicants in many states:

a. Drugs containing Dextroproposyphene salts in capsules & tablets

b. Drugs containing Codeine salts in cough syrups / tablets

c. Drugs containing Diphenoxylate salt in tablest etc.

All these three salts are narcotic drugs under the NDPS Act 1985 but their drugs formulations coming in the market are not covered in the definition of narcotic drugs as the contents of these salts per dose are less than limits as mentioned at para 35, 58 and 87 in notification No. S.O 826(E) dated 14.11.1985 issued under sub clause (b) of Clause (xi) of section 2 of the NDPS Act, 1985 by Central Government. The drug addicts take larger doses of these drugs for intoxication purpose. Similarly, drugs formulations containing many psychotropic substances are also misused for intoxication. Similarly, many other potent drugs e.g. Anabolic steroids, sex hormones, Sildenafil etc. are misused without prescription of doctors.

As per Drugs and Cosmetics Rules, 1945, these drugs are Schedule H drugs and in retail sale can be sold on prescription. The prescription sale of many of these drugs is very less than actual volume of sales.

The drugs are sold by the drugs manufacturers to be distributors and wholesalers in large quantities, who further sell to wholesalers and retailer. As per Rule 65(9) (b) of the Drugs and Cosmetics Rules, 1945 for selling such drugs to doctors and nursing homes etc. written order is required from concerned doctors. **The written orders of drugs licensee whether retailer or wholesalers, is not required for conducting sale of these drugs to drugs licensee.** It has been observed that large qualities of these drugs are shown as sold by the wholesalers to the other wholesalers or retailer. For example bills are issued in the name of some drugs licensee firm but the supplies are done to some other persons as no signed written order is required to issue bills to drugs licensee. These drugs formulations which are sold on fictitious bills is main cause of availability of such drugs / medicines in the market who even are sold to unlicensed persons. Many cases are detected where wholesalers in their sale records show sales to the other drugs licencee, but when those drugs licencee are asked to show the further sale records of these drugs, they deny the purchase of the drugs. These drugs available freely from many wholesalers without any restrictions Easy availability of all types of drugs in wholesales is main cause of misuse of drugs.

To control the illegal sale of these drugs, the following amendment in the provisions of Drugs and Cosmetics Rules, 1945, is suggested:

Proposal for amendment in rule 65(9) (b) of Drugs and Cosmetics Rules, 1945:-

Provisions under rule 65(9) (b) of Drugs and Cosmetics Rules, 1945, are already exit for sale / supply of schedule G, H & X to the Hospitals, nursing homes, regd. Medical practitioners etc. against written signed order. To better regulate the wholesale of these drugs provisions 65(9) (b) may also be amended, so, that such drugs should be supplied to drugs licensee also against written orders.

So, if the proposed amendment is done, it will be a big step to control the illegal and unethical sale of these drugs and will be in the interest of national health.

Recommendations

The DCC after deliberations agreed for the amendment of rule 65(9) (b) so that the drugs are supplied to the Drug Licensees also by the wholesalers against the written orders.

30. Proposal to ban drug formulations containing Diphenoxylate salt and its preparations under section 26A of Drugs and Cosmetics Act, 1940

Diphenoxylate is a narcotic drug under the NDPS Act 1985 as per serial no 58 of Govt of India Gazette notification No. S.O. 826(E) dated 14.11.1985 issued under sub-clause (b) of Clause (xi) of section 2 of the NDPS Act, 1985, by Central Government. This drug in combination with atropine is coming in drugs formulations as antidairroeal which is least being used for therapeutic purpose. There is hardly any prescription of Diphenoxylate and atropine combination drug and more effective drug Loperamide is prescribed by the doctors for this purpose. The drug formulations containing diphenoxylate are widely misused as intoxicants as contain narcotic drug in the formulation. Some addicts take even hundred tablets of this drug at one time and even some drugs manufacturers are packing hundered tablets pouch / bottle packing of this drug though it is a Schedule H drug and cab be sold in retail on the prescription of a registered medical practitioner. Previously Dovers Powders I.P. and Dover Powder tablets I.P. were banned by the Central Government under Section 26A of the Drugs and Cosmetics Act, 1940 vide notification No. GSR 111(E) dated 22.02.1994 and GSR 612(E) dated 09.08.1994 for the similar reasons.

Drugs Consultative Committee should consider to ban immediately narcotic drug Diphenoxylate formulations under section 26A of the Drugs and Cosmetics Act 1940. It will save the addicts from ill effects of this drug, which is least being used for therapeutic purpose and is in the interest of the nation.

Recommendations

The members agreed that the formulations of Diphenoxylate are commonly misused by the drug addicts and therefore should be prohibited under Section 26A of the Drugs and Cosmetics Act. The matter may be further examined by DTAB for making necessary recommendations to the Government of India.

31. Inclusion of Buprenorpine under Schedule H or X

Buprenorpine is psychotropic substance listed at Sr. No. 92 in the Schedule of the Narcotic Drugs and Psychotropic Substance Act 1985 but is not listed in the schedule H or X of the Drugs and Cosmetics Rules, 1945. This drug is also highly misused as intoxicant. Most of the other psychotropic substance are in the list of schedule H drugs. Thus, Buprenorphine should also be included and listed in schedule H or Schedule X. Drugs Consutlative Committee should decide for inclusion of this drug in Schedule H or Schedule X of the Drugs and Cosmetics Rules, 1945.

Recommendations

The DCC agreed that stricter controls are required for the sale of Buprenorpine which is covered under the Schedule of the Narcotic Drugs and Psychotropic Substance Act 1985. The matter may be further examined by DTAB for its inclusion under Schedule H or Schedule X of the Drugs and Cosmetics Rules.

GUJARAT

32. Restriction on Sale of M.T.P. Medicine

It is felt that, many illegal abortions are being done in the country by unauthorized doctors. This has also created imbalance in male – female child birth ratio and female child birth rate is decreased compared to male child. In this regard, it was suggested in a meeting of Gujarat State Drug Advisory Board that:

- MTP medicines be dispensed by qualified medical practitioner who is eligible for MTP procedures as per MTP act 1971.
- No chemist can sell MTP medicine.
- Direct advertisement of such product should be stopped.

It is therefore suggested that the M.T.P. Medicines mainly Mifeprestol and Mesopreston should be sold to only medical practitioner who is eligible for MTP procedure are per MTP act 1971 and Obstetrician and Gynecologist and no chemist should sell these medicines by way of retail.

Hence, it is suggested that, these medicines should be labeled as “Not for Retail sale” and “To be supplied to Obstetrician and Gynecologist and Doctor authorized for MTP procedure as per MTP act 1971”.

Recommendations

The DCC agreed that the M.T.P. medicines namely Mifeprestol and Mesopreston should be sold to only medical practitioner who is eligible for MTP procedure are per MTP act 1971 and Obstetrician and Gynecologist. The drug should not be sold by the retail chemists and it should be labeled as “Not for Retail sale” and “To be supplied to Obstetrician and Gynecologist and Doctor authorized for MTP procedure as per MTP act 1971”.

ANDHRA PRADESH

33. In view of the emergence of contract research institutions and testing facilities for manufacture of drugs for test or analysis, there need to be filling of gaps in the licensing process under Form – 29, like prescribing fees for inspection, defining test / analysis, clarification on whether BA / BE studies fall under the said definition, if compliance of schedule M by the licencee for drugs meant for clinical studies, meaning of small quantity of drugs under Form – 29

Rule Position: The licence to manufacture the drugs for the purpose of examination, test or analysis is prescribed under Drugs and Cosmetics Rules, 1945 in Form – 29, vide Rule 89.

Amendment required: Before grant of licence in Form – 29 the process of inspection with inspection fees may be prescribed under the Rules. The requirements for grant of licence in Form – 29 for manufacturing of drus for clinical trial / BA & BE studies may require to be comply with the provisions of schedule M. The terms test, analysis, examination may be defined under the Rules. Whether the licence includes the BA / BE Studies is to be clarified. The term small quantity of drugs may be clarified for exemption of taking licence in Form – 29.

Recommendations

The DCC agreed in principle that the scope, the conditions and fees etc. for license in Form 29 should be enhanced. The validity period of such a licence may also be increased to three years against the present period of one year. The detailed proposal for specific amendments in the rules may be submitted in next meeting of DCC.

HARYANA

34. Test License on Form – 29

i) Test license on Form – 29 can be issued by SLA, but it does not speak about number of items to be allowed under the license. Nothing has been spelled about additional item / fee of item etc. Now a days, many Research and Development Centres are applying for test license by depositing Rs. 250/- as license fee accompanying list of about 100 items or more. Kindly discuss if such large number of items may be allowed in such cases.

ii) 2nd part is renewal of the test license. Presently, there are no provisions under the Act for its renewal.

Recommendations

The matter was already discussed under item number 33.

35. Compounding of offences: Section – 32-B

Recently the amendment Act, 2008 provides for compounding of offences under newly inserted section 32-B of the Act, but the Rules about the compounding as provided under section 32-B have not been notified so far, for the amount / sum to be credited to the Government.

Recommendations

The Chairman agreed that an agenda for making rules for compounding of offences as provided under Section 32B will be taken up for consideration in the next meeting.

36. Utilization of all components of blood

It has been observed that the blood banks engaged as manufacture of blood components face problem regarding proper utilization of all the components. Sometimes platelets are in demand, but the other components i.e. packed RBC, plasma etc. are not utilized / are not in demand. Consequently, the unutilized / un-demanded part of the blood remain unused and expired. Can such unutilized components be allowed to transfer to other needy blood banks in Govt. / Pvt.

Sector to ensure proper utilization and minimal discard / wastage of this precious human tissue.

Recommendations

The DCC after deliberations recommended that the issue was deliberated in detail. Blood can be distributed to the patients only. A Blood Bank may inform the other Blood Banks about the availability of particular component of the blood in that Blood Bank, so that the patients could approach that Blood Bank for obtaining the component.

37. FDC of Ofloxacin

OFLOXACIN suspension and FDC of Ofloxacin with other drugs in suspension form are available in the market in plenty isnpite of the fact that it is in the rejected list of FDC issued by DCG(I). Some of SLA's might be approving such formulations. Steps to ensure uniformity are required in this context.

Recommendations

The DCC recommended that FDC of Ofloxacin with other drugs in suspension should be withdrawn from the market as these have not been approved for marketing in the country by the office of DCG(I).

38. Renewal of licensed blood bank, which are stand-alone or voluntary organization / charitable trust not recognized by SBTC.

Whether blood banks which were licensed prior to 21.12.2005 (before GSR 733(E) dt. 21.12.2005) and were stand alone or run by charitable trust or voluntary organization not approved by State / Union Blood Transfusion Council are required to get approval from SBTC while applying for renewal after 21.12.2005

Recommendations

Some of the members were of the opinion that Blood Banks run by registered voluntary or charitable organizations recognized by State / Union Territory Transfusion Councils (STBC) are also considered as recognized Blood Banks. The rule 122G (2) however, requires that application for grant or renewal of a licence of operation of Blood Bank or processing of human blood components shall be made by the Blood Bank run by charitable trust or voluntary organization approved by a State / Union Territory Transfusion Council only.

39. Microbiological analysis for sterile manufacturer Orthopedic implants

Orthopedic implants have been notified as a “drug” and the firms engaged in mfg. of such products require DML. Most of them do not have any facilities of microbiological analysis and undertake to outsource such testing. For manufacture of sterile orthopedic implants, whether microbiological analysis can be allowed to outsourced.

Recommendations

The DCC recommended that Microbiological testing is required in the case of manufacture of sterile Orthopedic implants.

40. Manufacture for sale Homeopathic Medicines

Rule 85-B(5) provide for fee of Rs. 50 for approval of additional item by license holders . While as per Rules 85-B(2), there is no limit for the items to be approved at the time of grant of license. Thus an applicant can have as many items as he wants by depositing just Rs. 250.00 while a license holder is required to pay Rs. 50.00 per item as additional items. It appears that, there is some ambiguity in the Rules, which needs to be looked into.

Recommendations

The DCC recommended that proposal to increase the fees for licences of Homeopathic drugs may also be considered along with the comprehensive proposal for enhancement of fees under the Drugs and Cosmetics Rules.

MAHARASHTRA

41. **INCLUSION OF Drug FORMULATIONS containing Narcotic drug or psychotropic drugs under SCHEDULE X The strict provisions applicable to Schedule X drugs will enable to curb the misuse of these drugs**

    The various drug formulations containing Codeine and ketamine are abused. Narcotic drugs or psychotropic drugs are habit forming and hence abuse of these drugs in rampant. In the large interest of the society it is felt necessary to include these drugs under Schedule X.

Recommendations

The DCC did not agree to the inclusion of codeine and ketamine under Schedule X as this would affect the availability of these drugs to the legitimate patients.

42. **INCLUSION OF EPHEDRINE, PSEUDOEPHEDRINE IN SCHEDULE X**

    Ephedrine, Pseudoephedrine is not included in any of the Schedules under the Act. This administration has detected various cases of misuse of Pseudoephedrine.

    Hence with a view to regulate the same Pseudoephedrine, ephedrine should be included under Schedule X of the Rules.

    Recommendations

    The DCC did not agree to the inclusion of these drugs under Schedule X as this would affect their availability to the legitimate patients.

43. **CANCELLATION AND SUSPENSION OF LICENCES UNDER RULE 66** In Rule 66 of the D&C Act licensing authority is empowered to cancel or suspend the licenses as per the prescribed procedure. Vide this Rule amendment is suggested that, "**the directives given by licensing authority to the license in writing issued in interest of public health should be followed by the license."**
    Many times license indulges n sale of drugs in absence of pharmacist, Non disclosure of source of purchase etc. It takes time to take the action as per present prescribed procedure and hence the licensee is continued to violate the provisions of the Act considering the time period required for this action.

Recommendations

The DCC agreed that the provision may be brought at par with the rule 85 in respect of manufacturing licences. The subcommittee constituted earlier for recommending amendments to the Drugs and Cosmetics Rules may deliberate the matter and give its recommendations in this regard.

44. VALIDITY FOR TEST LICENCES IN FORM 29 Validity period of Test License (Form 29) may be increased from existing 1 year to 2 years It is necessary to prescribe a Form for Renewal of Form 29

Presently as per Rule 91 of the said Act, the license in **Form 29** of the said Act, the license in Form 29 is granted for the **validity period of One Year.** Generally the products which are developed are having shelf life of 2-3 yrs.(for formulation) & generally 5yrs for API's. Stability is to be monitored for at least 2-4 years after manufacturing the formulation.

Rule 91 also prescribes that the Test Licence may be renewed for a period of one year. Howeve Form for renewal is not prescribed.

Recommendations

The matter was discussed under item number 33.

45. REVISION OF SCHEDULE P

Schedule P of the Rules lays down the storage condition and life period for various drugs. **However this list needs to be reviewed to include drugs like meropenem, imipenem, feropenem, moxifloxacin, vancomycin, cefipime, cefpirone ceftazidime, cefuroxime etc.**

Recommendations

The DCC agreed that the Schedule P may be revised to include new drugs which have been permitted to be marketed in the country in consultation with the experts.

46. Form 15 At present at the time of prohibiting stock of drug to the inspector issuing Form 15 is having the maximum limit of 20 days. This limit of issuing Form 15 may be increase for at least 60 days. Hence appropriate

amendment may be suggested under Section 22(C)(III)for increasing this limit or to amendment may be made to take undertaking in case of licensee for a particular period certain prescribed form.

Many times the inspector while discharging the duties prohibits the stock of drugs for various reasons. Such as for doubt of quality for non-production of purchase records etc. or stock of drug without license. At the time of such incidences the inspector draws the sample which takes the period of at least 30 to 60 days from the laboratory. Hence he has to visit twice or thrice for prohibiting the stock further considering the various duties interested on the inspector the suggested limit will be of appropriate nature.

Recommendations

DCC agreed that the limit of issuing Form 15 may be increased from 15 days to 40 days and the committee examining different amendments to the Drugs and Cosmetics Rules may deliberate the matter and give its recommendations in this regard.

ANNEXURE I

List of the participants of 44th Drugs Consultative Committee meeting held on 20th July, 2012 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 R. P. Thakur, Director General, 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 C. N. Bhattachirjee, Dy. Drugs Controller, Assam, Hengrabari, Guwahati – 781036
5	Shri Shiv Narayan Sahu, State Drugs Controller, Department of Health, Vikas Bhawan, Patna, Bihar
6	Shri P.K. Jaggi, Assistant Drugs Controller, Delhi, F-17, Karkardooma, Delhi 110 032
7	Dr. H. G. Koshia, Commissioner FDCA, Gujarat, Block No. 8, Dr. J. M./ Bhavan, Gandhi Nagar, Gujarat – 382010
8	Dr. G. L. Singal, Drugs Controller, Govt. of Haryana, Govt. Dispensary, Sector – 20, Panchkula, Haryana – 139 109
9	Shri Navneet Marwaha, Drugs Controller, Himachal Pradesh Sai Road Baddi, Disstt. Solan-173205
10	Shri Satish Gupta, Controller Drug and Food Organisation, Patoli Mangotrian, Jammu.

11	Shri S. K. Mukhopadhyay, Director of Drugs Control, Jharkhand RCH Campus, Namkum, Ranchi, Jharkhand
12	Dr. B. R. Jagashetty, Drugs Controller, Karnataka, Palae Road, Bangalore – 560 001, Karnataka
13	Dr. S. K. Paul, Director of Health Services, Port Blair, Andman & Nicobar
14	Shri C.S Satheesh Kumar, Drug Controller, Kerala, Red Cross Road, Thiruvananthapuram- 695 035
15	Shri D.M. Chincholkar, State Licensing Authority, Madhya Pradesh Idgah Hills, Bhopal (M.P.)- 462 001
16	Shri P.R. Uttarwar, Joint Commissioner, FDA, Maharashtra, Opposite RBI, Bandra Kurla Complex, Bandra East, Mumbai –400 051
17	Shri S. K Dabhade, Assistant Commissioner, FDA, Maharashtra Bandra Kurla Complex, Bandra (E), Mumbai – 400 051
18	Shri N. Rimot Kumar, Drug Inspector, Manipur, Directorate of Health Services, Imphal –West.
19	Dr. R.F. Zauva, Drugs Controller, Mizoram, Dte. Of Health Services, Dinthar Veng, Aizwol, Mizoram – 796 001
20	Shri Lal Sawma, Dy. Drugs controller, Dte. Of Health Services, Dinthar Veng, Aizwol, Mizoram – 796 001
21	Shri R. F. Lotha, Addl. Drugs Controller, Nagaland Directorate of Health & Family Welfare, Kohima- 797001.
22	Shri H. Mahapatra, Drugs Controller, Odisha Dte of Drugs Control,Nandankanan Road, Bhuvneswara – 751 017
23	Shri Ajay Singla, Drug Controller, Punjab, Directorate of Health & Family Welfare, Pariwar Kalyan Bhawan, Sector – 34A, Chandigarh – 22
24	Shri D.K. Shringi, Drug Controller, Rajasthan Swasthaya Bhawan, Tilak Marg, Jaipur – 302 015

25	Shri G. Selvaraj, Director Drugs Control, Tamil Nadu, DMS Campus, Anna Salai, Chennai – 600 006
26	Shri M. Dhilip Kumar, Senior Drug Inspector, Tamil Nadu DMS Campus, Anna Salai, Chennai – 600 006
27	Shri A.K. Malhotra, Assistant Commissioner Drug, Uttar Pradesh 9, Jagat, Narayan Road, Lucknow
28	Shri Devistone Swer, Drugs Controller, Health Complex red hills road laitumkrah, Meghalaya, Shilong-793003
29	Dr. S. C. Sharma, Drugs Controller, Uttrakhand, Dte. of Medical Health, Sahashtra Dhara Road, Dehradun
30	Dr. C. M. Ghosh, Director Drugs Control, West Bengal, P-16, KIT Building, India Exchange Place Extension, Kolkatta – 700 073
31	Shri Sunil Chaudhary, Drug Control Officer, Chandigarh GMSH, Sector -16, Chandigarh

B. <u>Invitees</u>

32	Dr. V. M. Katoch, Secretary, Deptt. Of Health Research & Director General, ICMR, New Delhi
33	Shri Sanjay Prasad, Director, Ministry of Health and Family Welfare, New Delhi
34	Dr. Madhur Gupta, WHO representative, New Delhi

C. <u>Drug Testing Laboratories</u>

35	Dr. M.F.A. Beg, Director, I /C Central Drugs Laboratory, 3, Kyd Street, Kolkata
36	Dr. N. Murugesan, Director, Central Drug Testing Laboratory, 37, Naval Hospital Road, Periamet, Campus G.M.S.D., Chennai – 600 003.

D. Zonal Offices of CDSCO

37	Dr. D. Roy, DDC(I), North Zone, Ghaziabad
38	Shri P. B. N. Prasad, DDC(I), South Zone, Chennai
39	Shri A.C.S. Rao, DDC(I), Hyderabad
40	Shri B. Kumar, ADC(I), Sub Zone, Chandigarh
41	Dr. A. Ramkishan, ADC(I), Ahmedabad, Air Cargo Complex, Airport, Ahmedabad-380 003
42	Shri Soumen Mukhopadyay, DDC(I) I/C, East Zone, Kolkata

E. CDSCO Hqrs

43	Dr. V. G. Somani, DDC(I), CDSCO, FDA Bhawan, New Delhi
44	Dr. K. Bangarurajan, DDC(I), CDSCO, FDA Bhawan, New Delhi
45	Shri A. K. Pradhan, DDC(I), CDSCO, FDA Bhawan, New Delhi
46	Shri Satyapal Shani, DDC(I), CDSCO, FDA Bhawan, New Delhi
47	Shri S. Manivannan, DDC(I), CDSCO, FDA Bhawan, New Delhi
48	Shri Lalit Kishore, Consultant, CDSCO, FDA Bhawan, New Delhi
49	Shri Rishikant Singh, Legal Consultant, CDSCO, FDA Bhawan, New Delhi
50	Mrs. Swati Srivastava, ADC(I), CDSCO, FDA Bhawan, New Delhi
51	Dr. S. Eswara Reddy, ADC(I), CDSCO, FDA Bhawan, New Delhi
52	Shri Sanjeev Kumar, ADC(I), CDSCO, FDA Bhawan, New Delhi
53	Shri Arvind Kukretty, ADC(I), CDSCO, FDA Bhawan, New Delhi
54	Smt. Robina Bose, ADC(I), CDSCO, FDA Bhawan, New Delhi
55	Shri A. Senkthir , ADC(I), CDSCO, FDA Bhawan, New Delhi
56	Shri Naresh Sharma, Drugs Inspector, CDSCO, FDA Bhawan, New Delhi
57	Shri Shushant Sarkar, Drugs Inspector, CDSCO, FDA Bhawan, New Delhi
58	Shri N.K. Jayasenthil, Drugs Inspector, CDSCO, FDA Bhawan, New Delhi
59	Dr. Ravi Kant Sharma, Technical Officer, CDSCO, FDA Bhawan, New Delhi

60	Shri Aseem Sahu, Technical Officer, CDSCO, FDA Bhawan, New Delhi
61	Shri Sunil Kumar, Technical Officer, CDSCO, FDA Bhawan, New Delhi
62	Shri Gaurav Kumar, Technical Officer, CDSCO, FDA Bhawan, New Delhi
63	Shri Kashish Kr Rajguru, TDA, CDSCO, FDA Bhawan, New Delhi
64	Mrs. Prabjyot Kaur, TDA, CDSCO, FDA Bhawan, New Delhi
65	Mrs. Pragya Thakur, TDA, CDSCO, FDA Bhawan, New Delhi
66	Mrs. Amita Nawani, TDA, CDSCO, FDA Bhawan, New Delhi
67	Mrs. Priya Sharma, TDA, CDSCO, FDA Bhawan, New Delhi
68	Mr. Diwakar Sharma, TDA, CDSCO, FDA Bhawan, New Delhi
69	Ms Deepali Chaku, TDA, CDSCO, FDA Bhawan, New Delhi
70	Mr. Vijay Pal Bhati, TDA, CDSCO, FDA Bhawan, New Delhi
71	Mr. Nekib Chaudhary, TDA, CDSCO, FDA Bhawan, New Delhi
72	Ms Sana Noori, TDA, CDSCO, FDA Bhawan, New Delhi
73	Mr. Firdose Ahmed, TDA, CDSCO, FDA Bhawan, New Delhi

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