REPORT OF THE 48TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 24TH JULY, 2015 AT NEW DELHI

(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 Hon'ble Padmashri Dr. Jagdish Prasad, Director General of Health Services and Shri Sudhanshu Pande, Joint Secretary, Ministry of Commerce. He then requested Director General Health Services to share his thoughts with the members.

Dr. Jagdish Prasad, D.G.H.S. in his address stated that the role of the Drug regulator is to be a facilitator to the industry. There should be no harassment and simultaneously no compromise on patient safety. If a particular drug is found not of standard quality but the manufacturer is found to be following Good Manufacturing Practices and its other products are of standard quality, then the licence for that particular product should be suspended and not the whole licence. Time should be provided for up-gradation of technology.

The manufacturers in the country shall have their own Research and Development facilities or get attached to the R & D facilities, so that they can properly design the manufacturing process and formulations which are consistent in quality and efficacy as per expectation of Good Manufacturing Practices under Schedule M and various other rules under the Drugs and Cosmetics Rules, 1945. This shall be meticulously checked by the regulator prior to the approval of the products.

He emphasized to provide in the rules for ensuring the bioequivalence of the medicinal products before grant of licence, for at least those, where it really makes the

difference in efficacy due to various reasons of characteristics of drug products like solubility, permeability and variability in blood levels.

It was also emphasized by him to ensure through regulation that the manufacturer or applicant submits the self attested and authenticated data or documents to the Drugs Control Authorities, so that high authenticity in the quality of data can be ensured.

He also emphasized, that the State and Centre shall follow the Standard Operative Procedures (SOPs) and checklist developed by CDSCO for inspections and shall ensure that during inspection the consistency, quality, stability of each product shall be inspected and reported, so that the inspection process and the report become a useful tool for ensuring actual quality and efficacy of the drug products.

He also stated that all regulators shall make available the data bank of manufactures and various formulation licences issued by them or regulatory actions taken by them on the website of CDSCO.

Similarly he stated that the quality of API shall be tested much more frequently at the port offices.

Shri Sudhanshu Pande, JS, Ministry of Commerce in his address stressed the importance of promotion of exports. He stated that Indian Pharmaceutical Industry has reached a level of recognition in the world market. India is exporting about 56% of its annual production. Our share in terms of value is very less as compared to the volume. It is because we mainly export generic drugs. If exports are facilitated and quality maintained, the value is bound to rise. Exports subsidize domestic research to the extent of six to eight percent and contribute to the growth of the internal market as it ploughs back the earnings from the exports to the research and development of the drugs. Countries like U.S.A. support exports by exempting many requirements of US FDA regulations for marketing the drugs in that country.

Drug regulators should associate with the inspectors from developed countries when they come to inspect Indian plants for approval for exports to those countries. This will give a vision of the requirements of the importing countries. In order to incentivize exports facilities are required to be extended to the exporters to meet requirements of the importing countries. The world pharma market is worth 1.1 trillion dollars while Indian share is only 2.5%. The regulators should therefore prioritize export related matters. There should be an interface with the exporters to built institutional memory in the departments. State regulators are required to be given exposure to the world trade so that they can have firsthand knowledge of the requirements of the importing countries. The selection may however, depend upon the share of exports from that State.

There are many areas in the world which could be explored by India for expansion of exports of pharma products. Argentina which was importing large quantity of drugs from 16 other countries excluding India has now agreed to import drugs from India after it got convinced about the quality and the prices. We must also look into the barriers created by many countries to restrict exports from India by either increasing fees extraordinarily or by putting other conditions.

Indian regulators should ensure that exports are incentivized by bringing in the system of ease of business through digitalization so that the permissions become automatic and remittances for fees are made online. Quality Management Systems as approved by leading regulators which allow reduced testing may be permitted to expedite exports.

Concerted all out efforts are required to make India an exporting hub in pharma exports.

It was put on record that DCC is greatful to the contributions of Shri Rajeev Kher, Ex-Secretary, Ministry of Commerce in promoting exports of pharma product in the world and making Indian pharma industry a proud partner of the world pharma trade.

AGENDA NO. 1

CONSIDERATION OF THE ISSUE OF CLANDESTINE EXPORT AND SALE OF MEDICINES VIA INTERNET BY CERTAIN WEB PORTALS IN THE COUNTRY IN VIOLATION OF THE PROVISIONS OF THE DRUGS AND COSMETICS ACT, 1940 AND RULES MADE THEREUNDER

Instances have come to notice that many of the website are selling medicines to national and international consumers via internet without valid prescription or sale bills in violations of the provisions of the Drugs and Cosmetics Rules, 1945. The Commissioner, FDA, Maharashtra took the initiatives and series of actions have been taken against the websites like sanpdeal, amazon and flipkart and the distributors located in different parts of Maharashtra who were involved in such clandestine activities. These kind of clandestinely operated distribution of medicines is developing at large scale in the country. Many such portals have come into existence and selling drugs illegally. There is a every likelihood that spurious or habit forming drug may be sold online by undisclosed persons as there is no specific check on the modes operandi followed by online websites. It has therefore been requested that strong laws are needed to be framed to curb such illegal sales.

The Ministry of Commerce and Industry, which was consulted by the FDA, Maharashtra also suggested that stringent action should be taken to stop this illegal practice across the country in line with the action taken by FDA, Maharashtra.

The issue of distribution of medicines by the agencies like snapdeal, amazon and flipkart through internet was considered by the DTAB in its 69th meeting held on 22.04.2015 and it gave the following recommendations.

> "The members opined that the drugs are different from the normal merchandise and the manufacture and sale of drugs is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. Sale of drugs is a licenced activity and the sale is required to be carried out at the licenced premises, under the supervision of a qualified pharmacist and in compliance to the provisions prescribed under the Drugs and Cosmetics Rules, 1945. Online sales in contravention to the provisions of the said Act and rules should not be permitted."

The matter was also considered earlier in the 47th meeting of the DCC held on 30th & 31st July, 2014 and deliberated in detail. The DCC made the following recommendations.

> "The members appreciated the initiative taken by the FDA, Maharashtra in stopping clandestine export of medicines through the internet pharmacy. The issue has become international and is being investigated by the international regulatory and law enforcement agencies as well as Interpol. The State Drug Controllers were asked to maintain a vigil in their States to ensure that such activities are not permitted in their States in the interest of the human health. It was however, felt that import of small quantities of medicines by the genuine importers for their personal use complying with the requirements of sale under the Drugs and Cosmetics Rules, 1945 should not be stopped."

The Government of India have received representation from the following associations / individuals against online sale of drugs in the country and requested for stopping the indiscriminate over the internet drug trade and suitable laws are framed to protect the people of the country.

1. All India Organization of Chemists & Druggists, Mumbai
2. The Tamilnadu Chemists & Druggist Association, Chennai
3. Indian Pharmacist Associations, Delhi
4. National President, Indian Medical Association
5. Shri Nana Patole, Member of Parliament (Lok Sabha), Mumbai
6. Karnataka Druggist and Chemists Associations, Bangalore

Government of India also received representations from the following requesting for introduction of specific provisions for online sale of drugs in the country as is available in many developed countries so that legitimate online sale is permitted in the country.

1. MediTimes, Kalyani Fresh Vegetus Pvt Ltd., Chennai
2. Netmeds, Chennai
3. At d rate Just Deliver Era Pvt Ltd., Noida
4. Optival Health Solutions
5. PM Health & Life Care Private Ltd.

Internationally US FDA permits online pharmacies but the pharmacy must be domicile with the US and registered with the DEA to dispense “control substance” and compliant to the FDA regulations. The pharmacy must comply with the States specific rules also. The list of such pharmacies is available on the State data base. Such regulated online pharmacies are required to conform to the following provisions.

1. Require a valid prescription
2. Provides physical address and telephone number in the USA.
3. Pharmacy is licensed by the state board of pharmacy in the state where it is operating.
4. Has a state licensed pharmacist to answer the questions of the consumers.
5. The pharmacy cannot dispense medications that are not approved by the FDA.

The regulatory agencies like US FDA, UK MHRA etc are however, concerned with clandestine trade by the fake or illegal pharmacies. The US FDA in partnership with other Federal and International agencies are taking actions against websites that sell potentially dangerous, unapproved prescription drugs to US consumers.

The INTERPOL has also initiated the OPERATION PANGEA for combating the sale of illegal medicines online. The Operation Pangea is an international week of action tackling the online sale of counterfeit and illegal medicines and highlighting the

dangerous of buying medicines online. The last Pangea VIII was held on 09 – 16 June, 2015 and 115 countries participated in it. A record 20.7 million fake and illicit medicines were seized. 156 persons arrested and 429 investigations launched. US FDA issued Warning Letters to Meds India Ltd and RX Partners on 08.06.2015 for unlawful sale of unapproved and misbranded products to the United States consumers over the internet in violation of Federal Food, Drug and Cosmetics Act (FD & C Act). The notice gives the details of the website covered under the letter.

In India at present there are no specific laws in respect regulating the sale of drugs over internet. Specific provisions may be required for curbing the illegal and clandestine trade of medicines through the websites while permitting legitimate online sale by the pharmacies registered for the purpose and dispensing drugs in compliance to the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder.

The DCC may consider the matter for having an integrated policy for regulating the sale of drugs via internet and suggest amendments, if any, that are required under the Drugs and Cosmetics Rules, 1945 for the purpose.

Recommendations

The issue was discussed in detail in light of the actions taken by the FDA, Maharashtra. It was however, felt that it would be difficult to deny the advent of new technologies leading to the development of E-commerce. There has to be an open minded approach to the matter. There is no denying fact that the ease of procurement of drugs through internet will drive the purchasers to look towards such sites irrespective of the fact at whether these are legal or illegal. The issue is required to be examined in detail. The *modus operandi* has however, to be within the parameters of the provisions available under the Drugs and Cosmetics Rules, 1945 and the supply chains to be maintained to preserve the quality of the drug till it reaches the consumers. The illegal sales through the internet can only be restricted if there exits an alternative provision. The DCC after deliberations constituted a sub-committee consisting of the following members to examine the issue of sale of drugs on the internet in the light of practices being followed

in the developed countries where such provisions are available for e-pharmacies, while taking care the risks and concerns related to such sales.

1. Commissioner , FDA, Maharashtra,
2. Shri Raghuraza Bhandary, Drugs Controller, Karnataka,
3. Shri H. Mahapatra,Drugs Controller, Odisha,
4. Shri Atul Kumar Nasa, Assistant Drugs Controller, Delhi
5. Shri Salim A, Veljee, Director, Food & Drugs Admin.-Goa,
6. Shri Pankaj Agarwal, State Licensing Authority, Madhya Pradesh
7. Dr. Eswara Reddy, Joint Drugs Controller, CDSCO, HQ,

AGENDA NO. 2

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 TO PRESCRIBE TIME LIMITS FOR THE GOVERNMENT LABORATORIES TO FURNISH TEST REPORTS ON THE STATUTORY SAMPLES SENT FOR TEST

The proposal for prescribing maximum time limits for testing / analysis of drug samples by the Govt. Analysts was earlier discussed in the 43rd meeting of the Drugs Consultative Committee held on 14th November, 2011. The DCC recommended that it may be difficult to prescribed time limits for testing of drug samples under the Drugs and Cosmetics Rules. However, the broad guidelines followed by CDL, Kolkata may be followed as model time lines by the Government Drug Testing Laboratories for testing drug samples as under.

HPLC testing	60 days
Normal Chemical testing	45 days
Biological products	90 days

The recommendations of the DCC were considered by the Public Accounts Committee (2012-2013) of the Ministry of Health and Family Welfare in its 84th report and the committee made the following observations in this regard.

> "The Committee are deeply concerned to note the observation of the Drug Consultative Committee (DCC) that under the Drugs and Cosmetics Rules, it may be difficult to prescribe a definite time frame for the Government Laboratories to furnish the test report. They are equally concerned to find that the time lines followed by CDL, Kolkata i.e. 60 days for HPCL testing, 45 days for Normal Chemical Testing and 90 days for Biological Products are being prescribed as model time lines, in a very casual manner, for other Government Laboratories to follow. In view of the fact that several cases of submission of test reports after a lapse of one year and administering of drugs to the patients before

obtaining the test results have been detected by the Audit, the Committee impress upon the Ministry to have a serious relook at the matter and again take up the issue with the DCC, if required by incorporating suitable Amendments in the Drugs and Cosmetic Rules, so that a definite, uniform but speedy timeline for submitting the test reports is laid down and scrupulously adhered to by all the Government Laboratories, eliminating thereby the remotest possibility of administering substandard/contentious/spurious drugs to the beneficiaries."

DCC may consider and give its recommendations for incorporating suitable Amendment in the Drugs and Cosmetic Rules, so that a definite, uniform and speedy timelines for submitting the test reports are laid down.

Recommendations

The members pointed out that during the earlier considerations, time limits could not be prescribed because of testing of drugs is different from food or other chemicals as drugs are required to be tested for all the test prescribed under the Pharmacopoeia to declare them as of standard quality or not. Biological products require certain sophisticated testing for animal testing. For Patent Proprietary medicines, method of analysis has procured from the licensing authority or the manufacturer for testing such products. Testing laboratories have also to obtain the reference standards for comparison during the testing. Apart from this laboratory receive large number of statutory samples for test and the laboratories do not have sufficient manpower, equipment, reagents and other infrastructure for completing the test and analysis in specified time limits.

The DCC however, took note of the recommendations of the Public Accounts Committee in respect of specifying the upper time limit for furnishing test reports on the statutory samples by the Government Drug Testing Laboratories and felt that it is necessary in the public interest to specify time limits for testing of statutory samples.

Commissioner, FDA, Maharashtra stated that FDA Maharashtra have about 4000 methods of analysis of patent proprietary medicines and was ready to provide access to

the concerned laboratories if specific requests are forwarded to be for providing internet access to such data.

The reference standards are prepared by Indian Pharmacopoeia Commission. It was requested by the members that IPC should provide the requisite reference standard to the laboratory within 15 days on received the request.

After deliberations the DCC recommended that an upper limit of sixty days for the Government Drug Testing Laboratories for furnishing the test reports on statutory samples of drugs may be prescribed, while simultaneous efforts should be to strengthened the laboratories in terms of man power, equipments, reagents and other infrastructure to adhere to the said time lines.

AGENDA NO. 3

CONSIDERATION OF THE PROPOSAL FOR STRICT MONITORING OF USE OF DICLOFENAC INJECTION IN ANIMALS TO STOP THE DICLOFENAC POISONING IN VULTURE POPULATION CREATING ENVIRONMENT IMBALANCE THAT ALSO AFFECTS HUMAN LIFE

The use of Diclofenac in animals has been reported to be leading significant decline in the vulture population. It is alleged that diclofenac poisoning has drastically brought down vulture population in India pushing them to the brink of extinction. It creates environmental imbalance that affects human life.

The issue was earlier considered by the Government of India and the Government prohibited the manufacture, sale and distribution of diclofenac and its formulations for animal use vide Gazette notification G.S.R. 499(E) dated 4.07.2008. It was subsequently alleged that multiple dose diclofenac sodium injection in the pack size of 30 ml is being diverted for treatment of animals. The matter was accordingly again considered by DTAB and to curb the illegal use of diclofenac injection for human use in

animals, draft rules to amend rule 105 of the Drugs and Cosmetics Rules, 1945 were published vide Gazette notification G.S.R. 503(E) dated 14.07.2014 to make it mandatory that the drug for human use shall be packed in single unit dose pack only. The rules have since been finalized and the notification amending the rules is being issued by the Ministry of Health and Family Welfare.

The National Human Rights Commission (NHRC) has also taken a note of the complaint regarding the misuse of diclofenac injection in animals and have observed that even though necessary steps have been taken by the Government for prohibition of the use of the concerned drug in animals. It has however further recommended that a committee may be constituted to monitor the situation and direct the State Government to keep a watch and take steps for strict implementation of the directions.

DCC may kindly consider the matter and ensure that diclofenac injection is not used in the veterinary practice in their respective States so that the misuse of the drug is plugged to save the diminishing population of vultures in the country and to maintain the ecological balance.

Recommendations

The maintenance of ecological balance is of national importance and in this connection it is required to be ensured that the Diclofenac injection manufactured for human use is not diverted for use in animals to save vulture population. The diclofenac injection for human use is being restricted for packing in single unit dose pack only. DCC recommended that State level committees having members from the veterinary practice in the State may be constituted to educate and monitor that Diclofenac injections for human use are not diverted for use in animals.

AGENDA NO. 4

CONSIDERATION OF THE GUIDELINES FOR GRANT OF LOAN LICENCE FOR MANUFACTURE OF RECOMBINANT PRODUCTS WITH SPECIFIED TIMELINES WHILE ENSURING THAT SAFETY, EFFICACY AND QUALITY ASPECTS ARE NOT COMPROMISED

The Drugs and Cosmetics Rules, 1945 were amended vide notification G.S.R. 574(E) dated 17.07.2012 to include provision for loan licence to manufacture for sale for distribution of large volume parenterals / sera and vaccines / recombinant DNA (r-DNA) derived drugs excluding those specified under Schedule X. The r-DNA products are considered as new drugs under rule 122 E and therefore require permission from the DCG(I) office in Form 46 or Form 46A before the licence to manufacture in Form 28 DA is considered.

All biological products have to comply with the 'Post Approval Change Guidance' after approval to prove safety and efficacy. Accordingly detailed guideline was prepared for grant of loan licences for recombinant products. The office of DCG(I) had forwarded guidelines on processing of applications of loan licences of r-DNA products keeping in view of various scenarios and risk involved in the manufacture of such products on 9th June, 2015 to the State Drugs Controllers for their comments.

A copy of the guidelines is annexed for ready reference for consideration of the DCC for the purpose of finalization. These guidelines will then be submitted to the Ministry of Health and Family Welfare for its approval and implementation.

Procedure for obtaining Loan License to manufacture recombinant products:

The Drugs and Cosmetic Rules 1945 were amended vide notification GSR 574 E dated 17.7.2012 (w.e.f. 17.7.2012) to include provisions for loan license to manufacture for sale or for distribution of large volume parenteral / sera and vaccine / recombinant DNA (r-DNA) derived drugs excluding those specified under Schedule X. The Rules provide that the application can be made on Form 27DA and license will be issued on Form 28DA after the approval of Central License Approving Authority i.e. Drugs Controller

General India. The scheme is being implemented since 2012 without any issues pertaining to LVPs and in one case in vaccine. It may be mentioned that no applications were received under the scheme for blood and its products till date.

It may be mentioned that the r-DNA products are always considered as new drugs as per Rules 122E, hence the license has to have new drug permission i.e. Form 46 or 46A before consideration of license to manufacture on Form 28DA. Vaccine and r-DNA products are considered as high risk products and any change / variation in the manufacturing or testing process may have adverse impact on the quality of the final product. In view of same, all biological products have to comply with post approval change guidance after approval. In the recent past some applications of r-DNA products were received for formulation / filling activity which were considered only after generation of data including stability study data by the applicant at the loan license site. It has been represented by a manufacturer that this whole process of loan licensing is taking too much time and is one of the main impediment in growth of this sector. The firm has suggested four scenarios and ways to reduce timelines. It may be mentioned that the applicant may apply for loan license for bulk as well as formulations. There could be following scenarios

A) Applications for formulation and filling of r-DNA products	
Case 1	Applicant and the Loanee both have Form 46 and Form 28D
Case 2	Applicant has Form 46 and 28D however Loanee has only 28D
Case 3	Applicant has Form 46 and 28D however Loanee has none.
Case 4	Applicant has no form 46 and 28 D however Loanee has all.
Case 5	Neither Applicant nor Loanee has Form 46 and Form 28D
B) Applications for manufacture of r-DNA drug bulk drug (Active Pharmaceutical Ingredient).	
Case 6	Applicant has no Form 46 A and 28D however Loanee has both.
Case 7	Applicant and the loanee both have form 46A and form 28D
Case 8	Applicant has Form 46A and 28D however Loanee has only 28D
Case 9	Applicant has Form 46A and 28D however Loanee has no 28D

It is scientifically understood that the risk in preparation of bulk is far more than the filling activity hence Case 7 to 9 cannot be considered on abbreviated pathway. Only in case of bulk drug manufacturing where there is no change in site, specification and process can only be considered as abbreviated pathway for approval which is Case 6 as listed above. Similarly, as Case 5 involves development and manufacturing of r-DNA products which has to undergo preclinical and clinical studies to prove safety and efficacy, same cannot be considered on abbreviated route. Keeping these facts in mind, the whole

issue was examined in detail and the pathways applicable for consideration of loan license for r-DNA products for Cases viz **1, 2, 3, 4, and 6** are given hereunder:

Pathway along with times line for Case 1:

Applicant and the Loanee both have Form 46 and Form 28D – The applicant is using the Loanee's facility to formulate and fill r-DNA product with compliance to already approved specification and process of the product permission granted to the applicant.

S. No.	Steps	Timeline
1.	Application as per the **Annexure – A**is to be submitted to the State Licensing Authority (SLA), copy endorsed to Zonal/Sub-zonal Office of CDSCO and O/o. DCG (I). • Hard copy of duplicate application is to be submitted to the concerned Zonal/Sub-zonal Office of CDSCO • Soft copy (scanned copy) of the application is to be submitted through mail to the O/o. DCG (I).	--
2.	CDSCO officer will carry out pre-screening of the application as per **Annexure - B** at Zonal / Sub Zonal office and may seek clarification, if any.	0 to 5 working days
3.	CDSCO will initiate Joint Inspection in co-ordination with the SLA and submit inspection report to the SLA and DCG (I). • CDSCO inspection team will submit observations and recommendations on Form 35 of Drugs and Cosmetics Rules to the SLA and CLAA after completion of the inspection by Fax or e-mail. • The detailed report of the inspection may be submitted within 3 days of inspection. • The soft copy of the Joint Inspection Report to be sent to the O/o. DCG (I).	15 working days
4.	The SLA will prepare Form 28-DA in triplicate and forward the same to the O/o. DCG (I) for approval. The communication should also have relevant new drug permissions and copy of joint inspection report.	5 working days
5.	The screening of documents is carried out as per **Annx. C** at CDSCO, HQ**.** On satisfactory complianceand approval of DCG (I) two copies of licenses to be forwardedto the SLA. The forwarding letter to include following conditions to be complied by the applicant before marketing: • To produce three consistency batches and carry out comparability with	5 working days

	licensed product and confirm that product has not changed. • To commit to perform stability studies – accelerated as well as real time and compare it with licensed product at least for three months. Commit to report any significant change forthwith. • To commit to comply with post approval change guidance. • To get samples tested at NIB Noida, if required.	
6.	Issuance of license by the SLA to the applicant.	5 working days
	Total working days	35 working days
	Total days (including Saturdays and Sundays)	**49 days***

*The timelines exclude the time taken by the applicant for fulfillment of any requirement or answering query raised during the processing of application.

Pathway proposed for Case 2:

Applicant has Form 46 and 28D however Loaneehasonly Form 28D – The applicant is using the Loanee's facility to formulate and fill r-DNA product withalready approved bulk and approved specification & process as approved for the applicant.

S. No.	Steps	Timeline
1)	Application as per the **Annexure – A** is to be submitted to the State Licensing Authority (SLA), copy endorsed to Zonal/Sub-zonal Office of CDSCO and O/o. DCG (I). • Hard copy of duplicate application is to be submitted to the concerned Zonal/Sub-zonal Office of CDSCO • Soft copy (scanned copy) of the application is to be submitted through mail to the O/o. DCG (I).	--
2)	CDSCO officer will carry out pre-screening of the application as per **Annexure - B** at Zonal / Sub Zonal office and may seek clarification, if any.	0 to 5 working days
3)	CDSCO will initiate Joint Inspection in co-ordination with the SLA, Expert and submit inspection report to the SLA and DCG (I). • CDSCO inspection team will examine technology transfer and capability of loanee to manufacture and test r-DNA products and submit	15 working days

	observations and recommendations on Form 35 of Drugs and Cosmetics Rules to the SLA and CLAA after completion of the inspection by Fax or e-mail. • The detailed report of the inspection may be submitted within 3 days of inspection. • The soft copy of the Joint Inspection Report to be sent to the O/o. DCG (I).	
4)	The SLA will prepare Form 28-DA in triplicate having same permission as granted to the applicant earlier by DCG (I) on 28D and forward the same to the O/o. DCG (I) for approval. The communication should also have relevant new drug permissions and copy of joint inspection report.	5 working days
5)	The screening of documents is carried out as per **Annx. C** at CDSCO, HQ**.** On satisfactory compliance and approval of DCG (I) two copies of licenses to be forwarded to the SLA The forwarding letter to include following conditions to be complied by the applicant before marketing: • To produce three consistency batches and carry out comparability with licensed product and confirm that product has not changed. • To commit to perform stability studies – accelerated as well as real time and compare it with licensed product at least for three months. Commit to report any significant change forthwith. • To commit to comply with post approval change guidance. • To get samples tested at NIB Noida, if required.	5 working days
6)	Issuance of license by the SLA to the applicant.	5 working days
7)	Total working days	35 working days
	Total days (including Saturdays and Sundays)	**49 days***

*The timelines exclude the time taken by the applicant for fulfillment of any requirement or answering query raised during the processing of application.

<u>Pathway proposed for Case 3:</u>

Applicanthas Form 46 and 28D however Loaneehas none – The applicant is using the Loanee's facility to formulate and fill r-DNA product with using its already approved bulk and approved specification & processes. .

S. No.	Steps	Timeline
1.	• Loanee will make application on 27D for the manufacture r-DNA product as per **Annexure D**to the State Licensing Authority (SLA), copy endorsed to Zonal/Sub-zonal Office of CDSCO and O/o. DCG (I). • Hard copy of duplicate application is to be submitted to the concerned Zonal/Sub-zonal Office of CDSCO Soft copy (scanned copy) of the application is to be submitted through mail to the O/o. DCG (I).	--
2	• Applicant will make application as per the **Annexure – A**and submit it to the State Licensing Authority (SLA), copy endorsed to Zonal/Sub-zonal Office of CDSCO and O/o. DCG (I). • Hard copy of duplicate application is to be submitted to the concerned Zonal/Sub-zonal Office of CDSCO Soft copy (scanned copy) of the application is to be submitted through mail to the O/o. DCG (I).	--
3	CDSCO officer will carry out pre-screening of both the application at Zonal / Sub Zonal office and may seek clarification, if any.	0 to 5 working days
4	CDSCO will initiate Joint Inspection in co-ordination with the SLA, Expert and submit inspection report to the SLA and DCG (I). • CDSCO inspection team will examine technology transfer and capability of loanee to manufacture & test r-DNA products; segregation and area/equipment provided for grant of 28D license to loanee and 28DA to the Applicant. The team will submit observations and recommendations on Form 35 of Drugs and Cosmetics Rules for 28D as well as 28DA to the SLA and CLAA after completion of the inspection by Fax or e-mail. • The detailed reports of the inspection may be submitted within 3 days of inspection. • The soft copy of the Joint Inspection Reports to be sent to the O/o. DCG (I).	15 working days
5	The SLA will prepare Form 28D in respect of the Loanee and 28-DA in in respect of Applicant in triplicate having same permission as granted to the applicant earlier by DCG (I) on Form 28D and forward the same to the O/o. DCG (I) for approval. The communication should also have relevant new drug permissions etc. granted to the applicant and copies of joint inspection reports.	5 working days
6	The screening of documents is carried out as per **Annx. C** at CDSCO, HQ**.**	5

	On satisfactory compliance and approval of DCG (I) two copies of licenses to be forwarded to the SLA The forwarding letter to include following conditions to be complied by the applicant before marketing: • To produce three consistency batches and carry out comparability with licensed product and confirm that product has not changed. • To commit to perform stability studies – accelerated as well as real time and compare it with licensed product at least for three months. Commit to report any significant change forthwith. • To commit to comply with post approval change guidance. • To get samples tested at NIB Noida, if required.	working days
7	Issuance of license by the SLA to the Loanee and to the applicant.	5 working days
8	Total working days	35 working days
9	**Total days (including Saturdays and Sundays)**	**49 days***

*The timelines exclude the time taken by the applicant for fulfillment of any requirement or answering query raised during the processing of application.

Pathway proposed for Case 4:

Applicant has no form 46 and 28 D however Loanee has all – The applicant is using the Loanee's facility to formulate and fill r-DNA product with using its already approved bulk and approved specification & processes. .

S. No.	Steps	Timeline
1	• Applicant will make application on Form 44 to the office of DCG (I) for grant of permission on form 46 for manufacture and market of r-DNA product based on data of the Laonee. . • Applicant to submit undertaking from the Loanee that their data may be used for approval of already approved r-DNA product for grant of new drug permission which will be for grant of 28DA license for manufacture of their product only.	--

	• The data of the product for Market Authorization to be submitted in soft copy only. • Undertaking from the Applicant that the application for new drug is only for the grant of loan license so as to market r-DNA product of the Loanee as per their approved specifications and processes. That they will abide by the conditions of Post approval change and other conditions as prescribed from time to time	
	• Prescreening of application at CDSCO, HQ.	0 to 5 working days
	• Processing of application – Examination of label / package insert examinations, technology transfer agreements, marketing agreement, and approval	30 days
2	• Applicant will make application as per the **Annexure – A**and submit it to the State Licensing Authority (SLA), copy endorsed to Zonal/Sub-zonal Office of CDSCO and O/o. DCG (I). • Hard copy of duplicate application is to be submitted to the concerned Zonal/Sub-zonal Office of CDSCO Soft copy (scanned copy) of the application is to be submitted through mail to the O/o. DCG (I).	--
3	CDSCO officer will carry out pre-screening of both the application at Zonal / Sub Zonal office and may seek clarification, if any.	5 days
4	CDSCO will initiate Joint Inspection in co-ordination with the SLAand submit inspection report to the SLA and DCG (I). • CDSCO inspection team will examine label / package insert examinations, technology transfer agreements etc. and carry out inspection. The team will submit observations and recommendations on Form 35 of Drugs and Cosmetics Rules for grant of 28DA to the SLA and CLAA after completion of the inspection by Fax or e-mail. • The detailed reports of the inspection may be submitted within 3 days of inspection. • The soft copy of the Joint Inspection Reports to be sent to the O/o. DCG (I).	15 working days
5	The SLA will prepare 28-DA in in respect of Applicant in triplicate having same permission as granted to the applicant earlier by DCG (I) on Form 28D and forward the same to the O/o. DCG (I) for approval. The communication should	5 working days

	also have relevant new drug permission etc. granted to the Loaneeand copies of joint inspection report.	
6	The screening of documents is carried out as per **Annx. C** at CDSCO, HQ**.** On satisfactory compliance and approval of DCG (I) two copies of licenses to be forwarded to the SLA The forwarding letter to include following conditions to be complied • To commit to comply with post approval change guidance.	5 working days
7	Issuance of license by the SLA to the applicant.	5 working days
8	Total working days	70 working days
9	**Total days (including Saturdays and Sundays)**	**90 days***

*The timelines exclude the time taken by the applicant for fulfillment of any requirement or answering query raised during the processing of application.

<u>Pathway proposed for Case 5</u>:

Applicant has no form 46A and 28 D however Loanee has all – The applicant is using the Loanee's facility to formulate and fill r-DNA product with using its already approved bulk and approved specification & processes. .

S. No.	Steps	Timeline
1	• Applicant will make application on Form 44 to the office of DCG (I) for grant of permission on form 46A for manufacture and market of r-DNA product based on data of the Laonee. . • Applicant to submit undertaking from the Loanee that their data may be used for approval of already approved r-DNA product for grant of	--

	new drug permission which will be for grant of 28DA license for manufacture of their product only. • The data of the product for Market Authorization to be submitted in soft copy only. • Undertaking from the Applicant that the application for new drug is only for the grant of loan license so as to market r-DNA product of the Loanee as per their approved specifications and processes. That they will abide by the conditions of Post approval change and other conditions as prescribed from time to time	
	• Prescreening of application at CDSCO, HQ.	0 to 5 working days
	• Processing of application – Examination of label / package insert examinations, technology transfer agreements, marketing agreement, and approval	30 days
2	• Applicant will make application as per the **Annexure – A**and submit it to the State Licensing Authority (SLA), copy endorsed to Zonal/Sub-zonal Office of CDSCO and O/o. DCG (I). • Hard copy of duplicate application is to be submitted to the concerned Zonal/Sub-zonal Office of CDSCO Soft copy (scanned copy) of the application is to be submitted through mail to the O/o. DCG (I).	--
3	CDSCO officer will carry out pre-screening of both the application at Zonal / Sub Zonal office and may seek clarification, if any.	5 days
4	CDSCO will initiate Joint Inspection in co-ordination with the SLAand submit inspection report to the SLA and DCG (I). • CDSCO inspection team will examine label / package insert examinations, technology transfer agreements etc. and carry out inspection. The team will submit observations and recommendations on Form 35 of Drugs and Cosmetics Rules for grant of 28DA to the SLA and CLAA after completion of the inspection by Fax or e-mail. • The detailed reports of the inspection may be submitted within 3 days of inspection. • The soft copy of the Joint Inspection Reports to be sent to the O/o. DCG (I).	15 working days
5	The SLA will prepare 28-DA in in respect of Applicant in triplicate having same permission as granted to the applicant earlier by DCG (I) on Form 28D and forward the same to the O/o. DCG (I) for approval. The communication should also have relevant new drug permission etc. granted to the Loanee and	5 working days

	copies of joint inspection report.	
6	The screening of documents is carried out as per **Annx. C** at CDSCO, HQ**.** On satisfactory compliance and approval of DCG (I) two copies of licenses to be forwarded to the SLA The forwarding letter to include following conditions to be complied • To commit to comply with post approval change guidance.	5 working days
7	Issuance of license by the SLA to the applicant.	5 working days
8	Total working days	70 working days
9	**Total days (including Saturdays and Sundays)**	**90 days***

*The timelines exclude the time taken by the applicant for fulfillment of any requirement or answering query raised during the processing of application.

Annexure – A

Content of filing application for the grant of loan licensing of r-DNA products on Form 27-DA

1. Covering letter duly signed by the Director or competent person of the applicant firm giving reasons for making application under loan license provision of the Drugs and Cosmetic Rules.
2. Duly filled application form on Form 27-DA with
    - Names of the drugs applied (each item to be separately specified with strength, presentation e.g. vial, ampule, cartridge etc.
    - Names of the competent technical staff responsible for testing
    - Names of the competent technical staff responsible for manufacture.
    - A true copy of a letter from the manufacturer concerned whose manufacturing capacity is intended to be utilized. It is important to cite installed capacity and available spare capacity with justifications.
    - A true copy of the from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me / us and they will analyze every batch of finished product and maintain the registers of raw

materials, finished products and reports of analysis separately on this behalf.
    - Specimen labels, cartons of the drugs proposed to be manufactured.
3. Challan copy (proof of submission of fee)
4. Plan of premises.
5. List of equipment and machinery
6. List of Standard Operating procedures (SOPs)
7. List of standard test procedures (STPs)
8. True copy of agreement for the purpose between the parties concerned.
9. Copies of new drug permission and copies of licenses in respect of applicant and loanee.
10. Site Master File (SMF) of the manufacturing site as per Schedule M.
11. Article and Memorandum of Association of the applicant firm (current applicable)
12. Undertaking addressing variation covering followings:
    - The facility is complying to GMP
    - No change in the composition, manufacturing process or drug product specifications
    - No change in the container / closure system.
    - The application is not due to a result of unexpected events arisen during manufacture or because of stability concerns.
    - The change does not affect the sterilization procedures of the sterile product.
13. Undertaking to commit to carry out any additional requirements as prescribed by the CLAA.

Annexure – B

Checklist for screening the documents for the grant of loan licensing of r-DNA products on Form 28-DA

Name of the firm:

Date of receipt of application:

Subject: Grant/Renewal of Drugs Manufacturing Licence (28DA) recombinant products

S. No.	Name of documents	Yes	No	NA	Remarks
1.	Covering letter duly signed by the Director or competent person of the applicant firm giving reasons for making application under loan license provision of the Drugs and Cosmetic Rules.				
2.	Duly filled application form on Form 27-DA with o Names of the drugs applied (each item to be separately specified with strength, presentation e.g. vial, ampule, cartridge etc. o Names of the competent technical staff responsible for testing o Names of the competent technical staff responsible for manufacture.				
3.	o A true copy of a letter from the manufacturer concerned whose manufacturing capacity is intended to be utilized. It is important to cite installed capacity and available				

	spare capacity with justifications.				
4.	A true copy of the from the manufacturing concern that they agree to lend the services of their competent technical staff, equipment and premises for the manufacture of each item required by me / us and they will analyze every batch of finished product and maintain the registers of raw materials, finished products and reports of analysis separately on this behalf.				
5.	Specimen labels, cartons of the drugs proposed to be manufactured.				
6.	Challan copy (proof of submission of fee)				
7.	Plan of premises.				
8.	List of equipment and machinery				
9.	List of Standard Operating procedures (SOPs)				
10.	List of standard test procedures (STPs)				
11.	True copy of agreement for the purpose between the parties concerned				
12.	Copies of new drug permission and copies of licenses in respect of applicant and loanee.				
13.	Site Master File (SMF) of the manufacturing site as per Schedule M				
14.	Article and Memorandum of Association of the applicant firm (current applicable)				
15.	New Drug Permission (Form 46/46A) or PAC, if any				

16.	Undertaking addressing variation, Also				
17.	Commitment to carry out any additional requirements as prescribed by the CLAA				

Annx. c

Checklist for screening the Licenses forwarded by State Licensing Authority for the grant of loan licensing of r-DNA products on Form 28-DA at CDSCO, HQ

Name of the firm:

Date of receipt of application:

Subject: Grant/Renewal of Drugs Manufacturing Licence (28DA) for recombinant products

S. No.	Name of documents	Yes	No	NA	Remarks
1	License copies in triplicate with stamp and sign				
2	New Drug Permission (Form 46/46A) or PAC, if any				
3	Joint inspection report and recommendation letter from Zonal Head				

Annx. D

Checklist for screening the documents for Licensing of Recombinant products (28 D license)

Name of the firm:

Date of receipt of application:

Subject: Grant/Renewal of Drugs Manufacturing Licence for Vaccines/ Sera/recombinant products

S. No.	Parameter	Yes	No	NA	Remarks
1	Application from Manufacturer				
2	Site Master File (as specified in Schedule M)				
3	a. Copy of manufacturing license, if available				
	b. Form 27-D				
4	Plan of premises				
5	Constitution of the firm				
6	List of equipment and instruments				
7	List of technical staff, their qualifications, experience and approval status				
8	Quality of water and its generation at the site				
9	List of SOPs and STPs				
10	Details of HVAC system including schematic diagram used for Classified Area				
11	Washing arrangements for the components				
12	Procurement of Master Cell Bank				

13	Preparation of Cell Bank				
14	Manufacturing Process Flow Chart				
15	Certificate of Analysis				
16	Package Insert and Labels				
17	Letter from SLA				
18	Undertaking from the Company which is transferring technology to the applicant with copies of new drug and manufacturing license granted. The details of technical aspect which are to be transferred to the laonee should be specified.				
19.	The names of technical personnel from the Company which will be using loanee facility who will be responsible for activities at loanee's premises.				

Recommendations

After deliberations it was agreed that in the case of joint inspection the cases where the activity is only filling from the bulk drug, the inclusion of expert in the inspection is not necessary. However, in the cases where the activity includes both bulk and formulations, an expert should be included in the inspection. The guidelines on processing of applications for loan licences of r-DNA products in a time bound manner may be amended accordingly in this regard. The rest of the guidelines were approved by the DCC.

It was further recommended that the State Licensing Authorities should also develop similar time lines for processing such cases.

AGENDA NO. 5

CONSIDERATION OF FURNISHING OF ANNUAL STATISTICS IN RESPECT OF PRODUCTION, CONSUMPTION, IMPORT AND EXPORT OF PSYCHOTROPIC SUBSTANCES COVERED UNDER THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT, TO INCB, VIENNA

India, being a signatory to the UN Convention 1971, is required to furnish annually statistics in the prescribed format, in respect of manufacture, consumption, estimates, import and export of Psychotropic Substances and Narcotic drugs in India to the INCB Vienna. It is needless to stress that it is very important to adhere to the requirements of the Convention for the signatory countries, and non furnishing of requisite information would tarnish image of the country. Under Rule 65 of the Narcotic Drugs and Psychotropic Substances rules 1985 also, it is the statutory duty of the State Licensing Authority to consult the Drugs Controller (India) in regard to the assessed annual requirements of each Psychotropic Substances and monitor their manufacture etc. as provided under the said rules.

The following information is required to be furnished by the State Licensing Authorities for submitting to the Narcotic Control Bureau.

- **Annual Report Questionnaire (ARQ):** Data pertaining to the details of establishments or premises where the licit Manufacture of Psychotropic substances or their salts (Bulk Drugs only) takes place as per Form 2
- **Form P:** Annual Statistical report on substances listed in the Convention on Psychotropic Substances of 1971
- Form P and ARQ information has to be collected and submitted to NCB, which further forward the data to United Nations Office on Drugs and Crime (UNODC) and International Narcotics Control Board (INCB) as an obligation under international convention.
- Despite several reminders, the office of DCG(I) has not been able to receive data on time from many States. The details are given below:

- **Form P 2013 data:** Not received from Uttar Pradesh and Lakshadweep
- **ARQ 2013 data:** Not received from Delhi, Jammu & Kashmir, Lakshadweep, Manipur, Odisha, Uttar Pradesh, Uttarakhand
- **Form P 2014:** Data received only from Himachal Pradesh, Madhya Pradesh and Telangana. Rest of the states/UTs data have not been received for the year 2014.
- **ARQ 2014:** Data received only from Goa, Mizoram, Himachal Pradesh, Dadar and Nagar Haveli, Puducherry, Andhra Pradesh. Rest of the states/UTs data have not been received for the year 2014.

- Further, it is found that states are not responding to the query raised for the data of Form P.
- The data is not compiled by the States and the crude data, as provided by firms, have been directly forwarded to this Directorate without endorsement.

The issue was raised in the 47th meeting of the DCC held on 30th & 31st July, 2014 also and the States requested to ensure that the requisite information is provided in time so that international obligation is met in prescribed time schedule.

DCC may kindly deliberate the matter and ensure that information is provided in a time bound manner.

Recommendations

The DCC agreed that furnishing of annual statistics in respect of psychotropic substances is a National responsibility and therefore due importance should be given to the furnishing of the requisite information in time. The States which have not yet provided the requisite information should do so on priority. It was also agreed that the CDSCO may also take up the matter individually to the concerned States / UTs for obtaining the information so that international requirement is complied with in time.

AGENDA NO. 6

CONSIDERATION OF THE ISSUE OF TRAFFICKING OF CODEINE PREPARATIONS IN THE COUNTRY AS WELL AS TO THE NEIGHBORING COUNTRY LIKE BANGLADESH

At 107th session of International Narcotics Control Board (INCB) in May, 2013, INCB has taken note on information indicating the trafficking of Codeine preparations, in particular “Phensedyl”, from India to Bangladesh. Further, Nepalese authorities are also expressing concern over smuggling of Codeine Based Cough Syrups (CBCS).

On 26.08.2013, Central Bureau of Narcotics (CBN) convened a meeting at Gwalior with major codeine phosphate user pharmaceutical companies such as Pfizer, Astra, Wockardt, Abbott and others. NCB was represented by its Deputy Director General (Ops). During the meeting, the abuse and trafficking of CBCS was discussed. It was also voiced that production of CBCS in India was far more than what is required and there was a lack of transparency in the distribution system.

Reports of abuse of the codeine based cough syrups have been received from time to time. The issue was also figured during 4th DG level talks between nodal narcotics control agencies of Bangladesh and India, held in Dhaka on 22-23, March, 2015. DG, DNC, Bangladesh stated that the inflow of Phensedyl from India to Bangladesh still continuing despite of the efforts by Indian authority to restrict the same. He informed that phendesyl is getting manufactured in clandestine facilities along the Indo-Bangla border inside the Indian Territory and pushed in bulk plastic containers. The Authorities agreed to take all necessary measures to curb cross-border smuggling. The matter was referred to DCG(I) for taking appropriate action in this regard.

DCC may discuss measures to prevent abuse of CBC’s, both domestically and internationally.

Recommendations

The DCC noted that the International Narcotics Control Board (INCB) has taken note of trafficking of codeine preparations to Bangladesh from India. The members were of the view that the misuse and supply of Phensedyl on fake bills to the States bordering Bangladesh has been detected in the States of Uttar Pradesh, Telangana and many other States and cases registered for violations of the Drugs and Cosmetics Rules,

1945. It was felt that the matter required further detailed deliberations for finding remedy to such smuggling to the neighbouring countries. The DCC constituted a sub-committee consisting of following members to study the problem in detail and give its recommendations in six months time.

1. Shri H. Mahapatra, Drugs Controller, Odisha
2. Shri Devistone Swer, Assistant Drugs Controller, Meghalaya
3. Representative of Centre Bureau of Narcotics
4. Shri R. Chandrashekar, Deputy Drugs Controller (I) as convener.

The DCC further recommended that the ban of manufacture and sale of Phensedyl and preparations having similar composition may be considered by the CDSCO in view of its rampant misuse and its illegal exports to neighbouring countries.

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 PERMITTING RETAIL SALE OF MEDICINES FROM MOTOR VEHICLE

Commissioner, Food and Drug Administration, Maharashtra has written to the office of DCG(I) that they have received a proposal for seeking license to sell generic medicines through mobile van. Under rule 62C and 62D of Drugs & Cosmetics Act, 1940, license can be issued only for sale drugs by wholesales or to distribute drugs from a motor vehicle. At present there are no provisions for sale or distribution of drugs by retail from a motor vehicle. The applicant intends to reach patients in a particular area and helping easier access to generic medicines to the common man. It has been requested that necessary changes may be made under the rules to permit such social cause of making available generic medicines to the needy through motor vehicle.

The issue of permitting retail sale of medicines through mobile vans was earlier considered by the DCC in its 46th meeting held on 12th & 13th November, 2013 and it gave following recommendations.

> "The members after deliberations were of the opinion that the requirements for having an establishment for retail sale have been made for uniform application in the country. The problem of escalation of property prices is limited to metros or other similar big cities only. As such rules should not be amended to suit only a few areas. It may be difficult to keep a track of the mobile vans or take actions as per Drugs and Cosmetics Rules, 1945. The proposal was therefore not agreed to."

The DCC may again consider the proposal and give its recommendations in the matter.

Recommendations

The members did not agreed to the proposal as the issue is related only to the bigger metropolitan cities and it would be difficult to keep a track of the mobile vans or take actions as per Drugs and Cosmetics Rules, 1945.

AGENDA NO. 8

CONSIDERATION OF THE PROPOSAL FOR PRINTING OF EXPIRY DATE AND MEDICINE NAME ON EXTENDED PORTION OF THE MEDICINE STRIPES

One Shri Bulbul Shah, Kolkata has forwarded proposal that the name of the medicine and expiry date should be printed on the extended portion of the medicines stripes in the following manner.

Medicine name Exp date
Portion containing Tablets
Medicine name Exp date

It is claimed that by adopting this system the information about the name of the medicines as well as expiry date would not be lost till the last tablet is consumed. This would help in providing the vital information to the consumer while using the drug in a clear manner.

DCC may consider the proposal and recommend as to whether a mandatory provision is required to be made under the rules for the purpose or the drug manufacture associations could be requested to voluntarily adopt this extended labeling.

Recommendations

The members agreed that the proposal is in public interest and to facilitate the matter, it was decided to constitute a sub-committee consisting of the following members to deliberate the matter and give recommendations as to how to ensure that the vital information regarding medicines name and expiry date remain available to the consumer till the last tablet.

1. Shri Navneet Marwaha, Drugs Controller, Himachal Pradesh
2. Shri Salim A, Veljee, Director, Food & Drugs Admin.-Goa
3. Shri O. S. Sadhwani, Joint Commissioner (HQ), FDA, Maharashtra,
4. Members from the manufacturing associations / chemists and druggists associations may also be co-opted
5. Shri R. Chandrashekar, Deputy Drugs Controller (I) as convener.

AGENDA NO. 9

CONSIDERATION OF THE PROPOSAL FOR ENSURING THE AVAILABILITY OF INDIAN PHARMACOPOEIA AND IP REFERENCE SUBSTANCES IN THE DRUG TESTING LABORATORIES FOR TESTING OF DRUGS

The Rule 124 of the Drugs and Cosmetics Rules, 1945, provides that for the drugs included in the Indian Pharmacopoeia, the standards for identity, purity and strength shall be those as may be specified in the edition of the Indian Pharmacopoeia for the time being in force.

To ensure that the drugs conform to the prescribed standards, Indian Pharmacopoeia Commission (IPC) issues the IP Reference Substances (IPRS), which act as a finger print for identification of an article under test and its purity as prescribed in IP. IPRS are authentic specimen of drug substances, impurities, excipients, test performance calibrators, etc. and are chosen and verified on the basis of their suitability for intended use as prescribed in the Pharmacopoeia.

During the audit of NABL accredited laboratory to be empanelled for the Drug survey sample analysis of spurious and not of standard Quality (NSQ) drugs organized by NIB Noida, it was observed that many laboratories do not have the Indian Pharmacopoeia and IP Reference Substances (IPRS).

Therefore, it is necessary to ensure the availability and use of Indian Pharmacopoeia and IP Reference Substances with the manufacturing and testing laboratories by the regulatory authorities in the country. This measure is considered necessary to improve the quality of medicines as per standards in India.

DCC may kindly consider and give its recommendations in the matter.

Recommendations

The Chairman stated that the State Licensing Authorities should ensure that Indian Pharmacopoeia is available with the Drug Testing Laboratories for testing of drugs. The IP reference substances are provided by the Indian Pharmacopoeia Commission free of cost to the Government Drug Testing Laboratories and the facility should be availed of by the Laboratories. The Drug Testing Laboratories should then develop their own standards for comparison after obtaining reference standards from Indian Pharmacopoeia Commission.

AGENDA NO. 10

CONSIDERATION OF THE ISSUES RAISED BY DEPUTY DRUGS CONTROLLER (INDIA) EAST ZONE REGARDING SAMPLING OF DRUGS AND ACTION TAKEN BY THE STATE LICENSING AUTHORITIES

i) Concern regarding sampling: Some SLAs are of opinion that any investigation or sampling in the retail and / or wholesale premises is the interference in the area of jurisdiction of their work, as they are granting license for retail and / or wholesale premises. Similarly, some head of Railway Hospitals are of the opinion that Drugs Inspectors of CDSCO should obtained permission from their controlling officers in Railways before drawing samples from their premises. The matter may be brought to the notice of SLA and concerned ministry.

Recommendations

DCC agreed that the Drugs and Cosmetics Act, 1940 provides powers to the Drugs Inspectors to take samples of any drug or cosmetics within the local limits of the area for which he is appointed. The powers are for both Central and State Drug Inspectors. In case of any difficulty with the other local authorities the matter should be taken up with higher authorities for sorting out in public interest.

ii) Non-receipt of action taken by SLA in different matter like Grant of COPP, additional product for COPP etc. Drugs Inspectors of this officer are participating in inspection for grant or renewal of COPP and inspection report is accordingly being forwarded to SLA for further necessary action, but there is no communication received from SLA with regard to action taken at their end. Further, COPP for additional product is also issued by SLA for which this office is not being intimated.

Recommendations

DCC agreed that in the era of modern technology of instant communications, there should be no difficulty in maintaining better communication between the State Licensing Authorities and zonal offices. State Licensing Authorities should take in inform to the concerned Zonal office about the action taken in such cases.

AGENDA NO. 11

CONSIDERATION OF THE RECOMMENDATIONS OF NATIONAL CORE BLOOD BANK ASSESSMENT COMMITTEE CHAIRED BY DR. JAGDISH PRASAD, DIRECTOR GENERAL OF HEALTH SERVICES

A meeting of National Core Blood Bank Assessment Committee under the Chairmanship of Dr. Jagdish Prasad, DGHS was held on **26th May, 2015 at** New Delhi. During the meeting the following issues related to blood banking were discussed.

1. Bulk transfer of whole blood and components between blood banks
2. Blood storage centres
3. NOC from State Blood Transfusion Council for application for licensure to any blood bank
4. Criteria for Regional Blood Transfusion Council

The committee after discussions made the following recommendations on the above issues. Decisions taken at the meeting are placed for consideration and adoption by the DCC:

1. **Bulk transfer of whole blood and components may be allowed between blood banks where there is facility to store and monitor the same.**

It was agreed in principle, that bulk transfer of blood between blood banks shall be permitted and the following recommendations were made in this regard.

i. Transfers shall be done between licensed blood banks in any sector (Public, NGO, Private)
ii. Transfer of blood and components in bulk shall be permitted across State borders to ensure the availability at the point of need.
iii. All transfers shall be done in recommended temperature for whole blood and components for which supplier shall be responsible.
iv. Recipient blood bank should have the capacity to hold the units requested for at appropriate temperature till the time of utilization.

v. A broad based donor consent shall be incorporated in the standard donor Form to ensure that the donor agrees to his blood unit being utilized beyond the blood bank where it is donated.

vi. NBTC norms on processing charges of blood and blood components shall be followed for these instances. Recipient blood bank shall not levy any charges other than for cross matchingin addition to charges of the supplier blood bank from the patient recipient for such transferred units.

vii. The residual shelf life of blood shall be as mutually agreed between the blood banks.

viii. Only one transfer shall be allowed, and recipient blood bank cannot further transfer units obtained from another blood bank except to another blood storage centre or a patient recipient.

ix. Records of traceability shall be retained throughout the process.

x. Supplier blood bank would be responsible for all the complications except for those related to compatibility testing, which will be owned by the recipient blood bank. Recipient blood bank shall report the adverse transfusion reactions in such instances.

xi. Documents accompanying transfer shall include TTI testing report and record of transport in appropriate temperature.

xii. Standard format of request and issue formats for bulk transfers shall be developed by NBTC for uniform record maintenance.

xiii. Since by default all the approved to act as storage centers for blood and blood components, the upper limit of 2000 units annually is not applicable.

xiv. All blood banks and storage units be instructed to issue blood to all patients needing transfusion and not restricting blood issue to captive requirements of institution to which they are attached.

xv. Blood banks shall inform regarding bulk transfers to SBTC and also in case of interstate bulk transfers to NBTC.

2. Any hospital can apply to become a blood storage centre, as already permitted under the Drugs and Cosmetics Act.

Criteria for Blood Storage Centers:

Blood Storage Center:

As per the notification No GSR 909 (E) dt 20th December, 2001, issued by Ministry of Health and Family Welfare, the Drugs and Cosmetics Rules, 1945 are amended (10the Amendment). and has provided exemption from obtaining license to store, cross match and issue whole human blood I.P. and its components to the following organizations.

a) First Referral Unit.
b) Community Health Center.
c) Primary Health Center.
d) Any Hospital.

Keeping in view the availability of blood and blood components to the places where it becomes difficult to get the blood on emergency or to maintain the full-fledged blood bank.

The Blood and /or its components shall be procured by the above centres from following categories of blood bank (hereafter referred to as the mother blood bank and shall be used for captive consumption only.

a) Government Blood Bank.
b) Indian Red Cross Society Blood Bank.
c) Regional Blood Transfusion centers.

However, the criteria's for Regional Blood Transfusion Centers are not clearly defined in the Drugs and cosmetic Rules 1945.

Further, to address geographical constraints and ensure easy accessibility of blood and blood components to the community following amendment may be made to the aforesaid notification No. GSR 909 (E) dt 20th December, 2001.

The word "Captive"consumtion and ceiling of " 2000" unit storage capacity in Schedule K after serial 5B (2) deleted. The Blood Storage center would then be permitted to supply blood and blood components to nearby nursing homes and hospitals in the region.

Note: The State Blood Transfusion Council should abide with aforesaid criteria while designating Licensed and registered (with SBTC) Blood Bank as Regional Blood Transfusion Center. Secondly, any application received with the SBTC for designating Blood Bank as RBTC should be approved or rejected (if criteria's are not fulfilled) within a period of 30 days from the receipt of the application at SBTC office. If the application is not processed within the stipulated time the application stands considered and blood bank stands designated.

3. NACO/NBTC to clearly define RBTC and revise the criteria as those blood banks already possessing a NOC from State Blood Transfusion Councils and collecting at least 2000 blood units per annum and following quality norms.

Criteria for Designating BB as RBTC:

i. The blood bank should be licensed and preferably provide round the clock service.
ii. The blood bank should have minimum collection of 2000 per annum with voluntary contribution nearing to 90%. (The criteria for minimum collection may be relaxed in rural, tribal, hilly region, desert, island and Armed Forces).
iii. The Blood bank should have component separation facility. Alternately, blood bank should provide undertaking to establish component separation facility within 2 years' time frame.
iv. The blood bank should have adequate facilities to store and transport blood and blood components at required temperature.
v. The blood bank should have minimum TTI screening by Elisa facility for at least 80% collected units for and should be practicing tube method for blood grouping and cross matching. (The criteria for minimum collection may be relaxed in rural, tribal, hilly region, desert, island and Armed Forces).
vi. The blood bank should be capable of periodic training to staff attached with Blood Storage center for blood grouping, cross matching, storage, identifying hemolysis and record keeping
vii. All equipment's in the blood bank should be under AMC/CMC and calibrated at the time of applying for RBTC Status and subsequent renewal every year as mandated under Drugs and Cosmetics Act.
viii. All records books should be available with the blood bank as stipulated in the D&C Act 1940 and Rules 1945 there upon.

ix. The blood bank should have computer and trained staff to maintain database of donor, blood and products and inventory of demand and supplies made on daily basis.

x. The blood bank must update its stock status of blood availability group wise online on the NACO/NBTC website

Note : The RBTC Status accorded will be initially for a period of 2 years only. However would be renewed based on the performance and fulfillment of all aforesaid conditions for a further period of five years and at five years intervals thereafter.

4. NOC from the SBTC should be a pre-requisite for application for licence to any blood bank other than government or IRCS *(Hospitals should also be exempted for NOC from SBTC*).

"Rule 122 G (ii) (2) " Application for grant or renewal of a license for operation of blood bank or processing of human blood components shall be made by blood bank run by Government, Red Cross Society, Hospital, Charitable trust or voluntary organization approved by a State/Union territory Blood Transfusion Council."

Thus it is pertinent that NOC for establishment of New blood bank or renewal of license of blood bank run by voluntary or charitable trust organization needs to be provided by State Blood Transfusion Council.

However the Criteria's for accepting and approving application for new blood bank or renewal of license are not defined in the Drugs and Cosmetics Rule 1945.

Therefore to bring about clarity and uniformity regarding the criteria for accepting and approving application are quoted below.

A. NOC for New Blood Bank:

i. A registered voluntary or charitable trust , which is registered in the territory of Union of India or Union Territory, as the case may be under any such law which is at the time of enforcement of this rule in force.

ii. The aforesaid organization must be at least 2 years old and should not be a family society or trust.

iii. The objectives mentioned in the Memorandum of Organisation must include the activities related to health care delivery system or blood transfusion services.
iv. The activities undertaken by the organization must showcase social accountability and is reflected in the annual Audited Statement of accounts of last two year. (ie before the submission of application).
v. The organization should submit undertaking to ensure annual blood collection more than 2000 units per year with nearing 90% contribution from Voluntary blood donor, preferably collected from outdoor blood donation camps.
vi. The organization should submit undertaking to appoint MSW and Counsellor with the blood bank for arranging VBD camps and conduct Pre and Post donation counselling respectively.
vii. The organization should submit undertaking to establish blood component separation facility of its own or a storage facility for components within a period of 2 years from receiving license to operate blood bank.
viii. The organization should submit undertaking to abide with the guidelines of SBTC/NBTC issued from time to time, including the guidelines for processing charges for blood and blood components. .

Note :

1. The Organisation should submit undertaking on the letter head expressing willingness to abide with aforesaid conditions.

2. The SBTC should process the application within 30 days from the date of its receipt in the office, failing which NOC shall be deemed granted to the organization.

B. NOC for Renewal of Blood Bank License:

i. A registered voluntary or charitable trust , which is registered in the territory of Union of India or Union Territory, as the case may be under any such law which is at the time of enforcement of this rule in force.
ii. The aforesaid organization must be atleast 2 years old and should not be a family society or trust.
iii. The objectives mentioned in the Memorandum of Organisation must include the activities related to health care delivery system or blood transfusion services.
iv. The activities undertaken by the organization must showcase social accountability and is reflected in the annual Audited Statement of accounts of last two year. (ie before the submission of application).

v. The organization should submit photocopy of license and application two months before the expiry of validity period of license.

vi. The organization should submit Annual blood collection report wherein the total blood collection (Jan- Dec) is shown with voluntary contribution to total collection along with numbers of blood donation camps conducted. (The annual blood collection should be more than 2000 units per year with nearing 90% contribution from Voluntary blood donor, preferably collected from outdoor blood donation camps. The condition may be relaxed for rural, tribal, hilly region, desert, island and Arm Forces)

vii. The organization should submit the proof and details of appointment of MSW and Counselor with the blood bank for arranging VBD camps and conduct Pre and Post donation counseling respectively along with training certificate.

viii. The organization should submit Annual report indicating blood component separation facility has been established either of its own or a storage facility, wherein the components were sourced from RBTC approved by SBTC.

ix. The organization should submit details of processing charges collected by the blood bank after 12 the February 2014. The SBTC should verify, if charges collected are subsidized or at par with guidelines issued by NBTC.

Note :

1. The Organisation should submit undertaking on the letter head expressing willingness to abide with aforesaid conditions.

2. The SBTC should process the application within 30 days from the date of its receipt in the office, failing which NOC shall be deemed granted to the organization.

5. All blood banks upon receipt of license must register with the respective State Blood Transfusion Councils.

6. **Blood Donation camps may be conducted by all government, IRCS and blood banks possessing No Objection Certificate from the SBTC, including hospital based corporate blood banks.**

DCC may consider and give its recommendations in the matter for uniform implementation of the recommendations of the committee.

Recommendations

The DCC agreed that there is a need for increased the availability of the blood to the patients in the country. The recommendations of the National Core Blood Bank Assessment Committee in respect of transfer of blood components between the blood banks, blood storage centers, requirement of NOC from State Blood Transfusion Councils and Regional Blood Transfusion Council were accepted. It was agreed that the recommendations of the committee on these issues should be followed by the States Drugs Control Authorities. The Chairman however suggested that any further proposal arising out of these recommendations may be forwarded to the CDSCO for further considerations within one month.

AGENDA NO. 12

CONSIDERATION OF THE RECOMMENDATIONS OF THE SCIENTIFIC BODY OF INDIAN PHARMACOPOEIA COMMISSION FOR DELETION OF EXEMPTION UNDER SCHEDULE K FOR RADIOPHARMACEUTICALS

Radiopharmaceuticals are radioactive agents used for diagnosis of certain medical problems or to treat certain diseases. These are used in tracer quantities in the field of nuclear medicines as radioactive tracers. These drugs have short half lives. They may be administered to the patients in several different ways for example orally or by injection or placed inside the body.

Schedule K of the Drugs and Cosmetics Rules, 1945 under serial number 20 provides exemption from the provisions of the Chapter IV of the Act and rules made thereunder relating to manufacture and sale of radiopharmaceuticals.

Radiopharmaceuticals have been incorporated in the seventh edition of Indian Pharmacopoeia for the quality control of Radiopharmaceuticals after exhaustive consultations with the IP expert sub-group of Radiopharmaceuticals. Nineteen monographs and one general chapter have been included in IP-2014 for the first time. Later ten more monographs have been included in the Addendum 2015 of IP-2014.

In the 30th meeting of Scientific Body of IPC, held on 11th April, 2015 at FDA Bhawan, New Delhi, it was decided that there is a need to amend the clause of the Schedule K, exempting all Radiopharmaceuticals from Chapter IV of the Drugs & Cosmetics Act, 1940.

DCC may consider and give its recommendations in the matter.

Recommendations

The DCC recommended that to consider the issue of Radiopharmaceuticals and their regulations under the Drugs and Cosmetics Rules, 1945, a sub-committee may be constituted under Shri A. K. Pradhan, Deputy Drugs Controller (I), North Zone, CDSCO along with subject experts nominated by the Chairman.

AGENDA NO. 13

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 124-A RELATING TO STANDARDS FOR VETERINARY DRUGS AND ENTRY NUMBER 2 OF SCHEDULE II OF THE DRUGS AND COSMETICS ACT, 1940

1. Amendment of Rule 124-A

Under the Drugs and Cosmetics Rules, 1945 standards for veterinary drugs have been prescribed under Rule 124-A as under:

> **"124-A. Standards for veterinary drugs.-** For drugs intended for veterinary use, the standards shall be those given in the current edition for the time being in force of the British Pharmacopoeia Veterinary."

The Indian Pharmacopoeia (IP) 2014 has included under it a separate volume for veterinary drugs. The standards for identity, purity and strength for veterinary drugs included in the Indian Pharmacopoeia are required to be those as may be specified in the Indian Pharmacopoeia.

In view of this it is proposed to omit rule 124-A of the Drugs and Cosmetics Rules, 1945 as the rule 124 includes all drugs included in the IP and separate provisions for veterinary drugs is no longer required.

2. Amendment of Entry No. 2 of Schedule II of the Drugs and Cosmetics Act, 1940

Schedule II of the Drugs and Cosmetics Act, 1940 prescribe standards to be complied with for drugs in the country. Entry No. 2 provides standards for the biological products for human use or for veterinary use as under.

"2	Substances commonly known as vaccines, sera, toxins, toxoids, antitoxins and antigens and biological products of like nature, for human use or for veterinary use.	The standards maintained at the International Laboratory for Biological Standards, Stantans Serum Institute, Copenhagen, and at the Central Veterinary Laboratory, Weybridge, Surrey, U.K., and such other laboratories recognized by the World Health Organization from time to time, and such further standards of strength, quality, and purity, as may be prescribed. "

As the standards for these biological products are now included in the IP, the relevance of the entry is required to be examined in the present context which was introduced in 1984 through a Gazette notification G.S.R. 299(E) dated 23.01.1984.

DCC may kindly deliberate and give its opinion in the matter.

Recommendations

The DCC after deliberations agreed that rule 124-A may be omitted under the Drugs and Cosmetics Rules, 1945 in view of inclusion of such drugs under the Indian Pharmacopoeia 2014.

AGENDA NO. 14

RECOMMENDATIONS OF SUB-COMMITTEE OF DRUG TECHNICAL ADVISORY BOARD AS PER DIRECTIONS OF THE HON'BLE HIGH COURT OF PATNA FOR CLASSIFICATION OF THE VITAMIN PRODUCTS UNDER DRUGS AND COSMETICS ACT, 1940 OR AS FOOD UNDER THE PREVENTION OF FOOD ADULTERATION ACT

The Hon'ble High Court of Patna while hearing one of the petition on the vitamin products has directed DGHS to take a fresh look into the matter by directing the experts to analyse the ingredients of each drug to know the effect of such drugs on human body and to conclude whether the product would fall under the classification of Drugs & Cosmetics Act 1940 or as food under the PFA Act.

The Court while hearing a review petition in the matter, in its order dated 22.08.2014 directed that the matter can be referred back to the expert committee of the Drug Technical Advisory Board as provided under the Drugs and Cosmetics Act, 1940 and also under the provisions of the Prevention of Food Adulteration Act, 1954 for analyzing the component of ingredients of each products and its effect on the human body if consumed as a food and come to the conclusion whether the products would fall under the classification of the Drugs and Cosmetics Act, 1940 or under the Prevention of Food Adulteration Act as Food.

The DTAB in its 68th meeting constituted a sub-committee having medical experts to examine the matter as directed by the Hon'ble High Court.

The sub-committee examined the issue and following consensus was emerged for the classification of these products.

1. Ingredients which are covered under the range as prescribed under schedule "V" of the Drugs and Cosmetics Rules for Tablets, capsules, granules are classified as drug, while those powders like Farex, Oats and Cereal fortified vitamins are exempted from the provisions of chapter IV under schedule K of Drugs and Cosmetics Rules.

2. Ingredients which fall below the range as prescribed under schedule "V" shall be classified as food. However if there is a claim for treatment,

mitigation or prevention of any diseases or disorder then it will be classified as drug.

3. Fortified powders which are supposedly exempted under schedule K and for Special Medicinal Products (SMP) to be used as substitute for food shall not be considered as food if the label of the product indicates name of disease.

4. Ingredients which are within Recommended Daily Allowance (RDA) levels but fall under the range as prescribed under schedule V Drugs and Cosmetics Rules shall be classified under drug as it is already mentioned in the rules.

5. Products containing ingredients which are neither covered under Schedule V nor fall within RDA, these can be classified as unapprovable products under Drugs and Cosmetics Rules unless otherwise specifically permitted by the Licensing Authorities of drugs based on major purpose of item (like food/drug).

6. The Committee also opined that both the authorities shall implement the enforcement on the product standards as per the principles given above (for withdrawing or approving the products). It was also generally accepted by the Committee that the Fixed Dose Combinations of Vitamins and Minerals etc. which are given in schedule “V”, shall be considered as generally safe as was opined in various expert Committees on the subject. Whenever there is additional ingredients, than those given in schedule V, including some of herbal ingredients, a separate and conscious view has to be taken about safety and efficacy of drug.
7. Committee also observed that there are no pure chemical vitamins in Ayush product; therefore, any product containing herbal ingredients shall be dealt by food or drug authority based on above principles.

The report of the sub-committee will be placed before the DTAB for its consideration in its next meeting schedule to be held on 18.08.2015.

The matter is brought to the notice of DCC as the licences are granted by the State Licensing Authorities for such products.

Recommendations

The members were informed that the Drugs Technical Advisory Board had constituted a committee to examine the classification of the vitamin products as food or drugs as per Directions of the Hon'ble High Court of Patna. The recommendations of the sub-committee will be placed before the DTAB for its consideration in its next meeting. The members were requested to take note of the recommendations of the sub-committee for guidance in the matter.

AGENDA NO. 15

CONSIDERATION OF VARIOUS RECOMMENDATIONS OF THE DEPARTMENT OF COMMERCE ON THE REGULATION OF MEDICAL DEVICES

The Ministry of Commerce has forwarded the following recommendations after consultation with the CDSCO for compliance by the State Licensing Authorities in respect of Medical Devices.

1. Extension of validity period of Free Sales Certificate from 2 years at present to 5 years or till the expiry of the manufacturing licence of the product. (for 'drug' items notified for medical devices)

2. Waiving of the condition of obtaining NOC from the port officer of CDSCO to facilitate faster clearance of Medical Devices export shipments at ports on the account that goods meant for export should not be regulated by the country of export.

3. Waiver of requirements of brand approvals for lunch of products in the domestics and overseas market even if the manufacturer is holding license for generic products. The process of obtaining approval is time consuming due to which importers prefer to go to China, Malaysia to get their products manufactured.

   If a manufacturer does not want approval of brand, the licence may be issued in generic name only. In case of any medical device which is licenced in generic name but exported with both generic as well as brand name, the port officer may not raise any objection.

   Recommendations

   The DCC agreed in principal that the exports are required to be promoted. The specific recommendations may be examined by the office of DCG(I) for making necessary changes in the rules or to provide discretionary powers to DCG(I) in granting exemptions in the matter of manufacture for export.

MAHARSHTRA

1. THE MATTER OF CLANDESTINE EXPORT OF MEDICINES THROUGH CLANDESTINELY OPERATED WEBSITES WAS DISCUSSED IN 47TH DCC MEETING

Food and Drug Administration, Maharashtra State has taken an initiative and series of actions has been initiated against distributors located in different parts of Maharashtra who were involved in such clandestine activity.

Letters were written to various authorities regarding actions taken by the Food and Drug Administration, Maharashtra State to stop clandestine export of medicines known as internet pharmacy. This clandestine export of medicine is not only a threat to well being of patients but it could also become an issue regarding mainstream export worth approx. Rs.80,000 crores from India.

Some cases were filed in Hon. High Court, Mumbai by the distributors who were the part of this clandestine operation. However, Hon. High Court, Mumbai has refused stay in this matter.

This matter was also informed to the Joint Secretary, Ministry of Commerce and Industry, Government of India to initiate the appropriate action in this matter. The Ministry of Commerce and Industry has also taken a same view as that of Food and Drug Administration, Maharashtra State and have felt that such clandestine export of drugs has huge potential to damage the credibility by Indian Pharma exports for which department of Commerce and Industry has been harping about strong measures to be taken by regulatory regime of the country. The Ministry of Commerce and Industry has also suggested that a stringent action should be taken to stop this illegal practice all across the country in the line with the Food and Drug Administration, Maharashtra State and to evolve an action plan to counter such sales including suspension of manufacturing licence.

The proactive measures taken by the Food and Drug Administration, Maharashtra State in this matter have yielded outstanding results.

It is also pertinent to note that USFDA and UKMHRA have also initiated the action to protect consumers from dangerous medicines sold by illegal online pharmacies. The actions are initiated in partnership with international regulatory and law

enforcement agencies and Interpol. Over 100 countries were involved in the Interpol operations with several policing organizations conducting raids on addresses linked to online pharmacies and this operation is named as “Operation Pangea” held in May’2014.

Organized, sophisticated criminals and rogue pharmacies are unfortunately using the internet to defraud innocent consumers. To protect the rights and health of the consumers it is suggested that, the necessary steps should be initiated to become the part of operation “Pangea” and also initiate the similar action, even Government officials involved in the matter may also be questioned by the international agency.

The same illegal and clandestine operations may also be carried out not only in Maharashtra but many other cities of the country. In view of the action taken by FDA, Maharashtra and the orders passed by the Hon’ble High Court , appropriate measures are required for unified action by all the authorities under different Acts in India to control this illegal export of drugs, which violates Drugs and Cosmetics Act and other Acts.

Recommendations of 47th DCC Meeting

Matter was discussed in detail. The members appreciated the initiative taken by the FDA, Maharashtra in stopping clandestine export of medicines through the internet pharmacy. The issue has become international and is being investigated by the international regulatory and law enforcement agencies as well as Interpol. The State Drug Controllers were asked to maintain a vigil in their States to ensure that such activities are not permitted in their States in the interest of the human health. It was however, felt that import of small quantities of medicines by the genuine importers for their personal use complying with the requirements of sale under the Drugs and Cosmetics Rules, 1945 should not be stopped.

Recently FDA, Maharashtra also raided the premises of online shopping websites like Snapdeal, Amazon and Flipcart which were distributing medicines to National and International consumers without a valid prescription and sale bills. It was also brought to notice that, FDA, Maharashtra ordered closure of Chemist On-line in website which was selling drugs online.

This is observed that, these kinds of clandestinely operated distribution of medicines are developing at large scale in the country.

There is every likely hood that spurious medicines may be sold online by undisclosed persons as there is no specific check in modus followed by online shopping website.

Since there are no strict provisions in this aspects, enforcement agencies observed reluctance and abstractions of many Government agencies to co-operate in this type of distribution network.

FDA, Maharashtra requests DCC to discuss this matter for the suggestions to Government of India to amend the specific Rules in this regards or formulate the uniform policies as early as possible to curb this clandestine business which will adversely affect the human health.

The agenda was already discussed under agenda No. 1 of Central agenda.

2. NICOTINE PREPARATIONS COMING UP IN THE FORM OF E-CIGARETTES

Nicotine preparation manufactured and sold in form of E-Cigarettes is not approved by Drugs Controller General India, New Delhi. As per Rule 122 (E) of Drugs and Cosmetics Act 1940, for a New drug prior approval of Drugs Controller General India is required. Only Nicotine (as Polarcrilex) gums 2 mg and 4 mg and Nicotine transdermal therapeutic patches are approved as drugs by Drugs Controller General India.

Considering the rampant sale of E-Cigarettes containing lethal quantity of Nicotine and its health hazards this Food and Drug Administration, Maharashtra State has appealed to all the citizens of Maharashtra State to stop the sale or use of E-Cigarettes containing Nicotine.

This Administration is in the opinion that, since the formulation of the drugs i.e. Nicotine is changed which is in the form of liquid vaporizer, the E-Cigarettes containing Nicotine shall be consider as a NEW DRUG and needs a prior approval of Licensing Authority as mentioned in Rule 21. The liquid containing Nicotine which used in the e-cigarettes shall be only approved by Food and Drug Administration.

As various verbal issues are coming up from the media and citizens regarding this form of E-Cigarettes and control of Administration over it. FDA, Maharashtra requests DCC to discuss this matter for the suggestions to Government of India to issue a guideline in this regards and to include the E-Cigarettes containing 2mg and more than 2mg of Nicotine in a New Drug category with a therapeutic significance as Nicotine replacement therapy.

Recommendations

E-cigarettes are not covered under the definition of the term 'drug' and therefore do not come under the purview of Drugs and Cosmetics Act, 1940. E-cigarettes therefore cannot be regulated under the provisions of the said Act.

3. SALE OF NICOTINE (NICOTINE REPLACEMENT THERAPY) NEEDS TO BE REGULATED STRICTLY

Nicotine 2mg and 4mg Gums & Lozenges are used as Nicotine replacement therapy drugs. Nicotine 2mg Gums & Lozenges pose several health hazards of varying severity, as they are sold as OVER THE COUNTER (OTC) drugs without any medical supervision. It is likely that many addicts may use it to counter their withdrawal symptoms when they cannot access cigarettes. It is observed that, its rising unsupervised usage poses several health hazards and serious threat to the society.

Considering the above serious facts it becomes necessary to include the said drug 'Nicotine' in Schedule H of Drugs and Cosmetics Act 1940.

Recommendations

Nicotine 2mg and 4mg Gums & Lozenges are permitted under the Drugs and Cosmetics Rules, 1945 as replacement therapy. The issue of their continued use may be examined by the Government of India in consultation with the Experts in the light of rising unsupervised usages leading to health hazards.

4. A UNIFORM INSPECTION METHODOLOGY OF MANUFACTURING UNITS

There is a provision of inspection of every manufacturing unit by the drugs inspector to monitor the condition of licenses as per the provisions laid down in Schedule M, M I, M II, M III., however the varying level of competence of the regulatory official, absence of uniform inspection methodology and training resulted in to ineffective and superficial inspections of manufacturing units.

It is also observed that when international agencies inspect the manufacturing units in this country, serious noncompliance and GMP violations are observed.

A uniform inspection methodology for inspections of manufacturing units to secure and protect the quality of the drugs, cosmetics and medical devices manufactured in the country does not exist, to assure the implementation of law for the benefit of patients and the citizens of this country.

Recommendations

The guidelines for uniform inspection methodology of manufacturing units are available with the CDSCO. Copies of these guidelines will be circulated by the CDSCO (HQ) for the purpose of implementation to the State Drugs Control Authorities.

5. DRUGS & MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENT) ACT.

Today, cures of questionable efficacy and gadgets of unknown values are being peddled through not just the print, but also television and the Internet. There is a proliferation of such advertisements that exploit the vulnerability of those suffering from certain diseases or an inferiority complex regarding their physical stature or looks.

The Drugs and Magic Remedies (Objectionable Advertisements) Act is specifically meant to tackle such false and misleading claims, but it is totally outdated and inadequate to deal with the present-day situation — it has no provision to tackle television and Internet advertisements.

With the toothless provisions of this Act state regulatory authorities are completely failed to achieve a expected objectives of this Act and may times demanded appropriate amendments in this Act. The failure in the enforcements causes immense loss of patients due to self medication.

FDA, Maharashtra understood the hazardous effect of self medications through misleading advertisements in print and electronic media and started enforcing this Act with the letter and spirit to achieve the objectives of this Act

Recommendations

The members were informed that the proposal for amendment of the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 is already under consideration of the Government of India and a committee constituted by the Ministry of Health and Family Welfare is considering the matter.

6. NOTIFICATION OF CERTAIN MEDICAL DEVICES AS 'DRUG' UNDER THE DRUGS (PRICE CONTROL) ORDER, 2013.

Various medical devices are used for the treatments/surgeries of ailments in human beings. Government of India has already notified certain medical devices as drugs on 6th of Oct. 2005 and bought control over their manufacture and sale. Up till now, manufacture and sale of more than 10 such devices are being regulated under Drugs and Cosmetics Act.

During study of such devices it was found that some medical devices are used as a replacement to the important body parts such as hip joints, knee joints etc. Some other are used in the treatment of disease or disorders such as pace makers, annuloplasty rings, neural coils etc. These non notified devices are of equal importance to the medical fraternity and to the patient. The quality of such devices is of utmost importance because they are implanted inside the body and they remain inside throughout the life of the patient. Hence these devices need to be brought under the purview o Drugs and Cosmetics Act.

A further study was carried out by this Administration for their pricing and distribution trends. It has also emerged during study that some of the devices are life saving. It is observed that these devices are exorbitantly priced. It was revealed in the study manufacturer prints Maximum Retails price on the Medical Devices, this is done at the behest of importer. The importer arbitrarily fixes the MRP in case of the imported Medical devices in the country. Wholesalers and hospitals earn huge margins, which are minimum 2 times more than those prescribed in the Drugs (Price Control) Order, 2013 for Schedule drugs. Many of these devices are imported and marketed by subsidiaries of foreign multinationals. A very few indigenously manufactured Medical devices are available at low cost. Surgeons prefer imported Medical devices over indigenous one. The cost of imported Medical devices are exorbitant and most of the patient may not afford such high cost, thus making treatment with imported Medical devices/implants unaffordable.

In current scenario, MRP of Medical devices is not monitored and controlled as they are out of purview of the Drugs (Price Control) Order, 2013. The term Medical Device is not included in the definition of 'Drugs' under the Drugs (Price Control) Order, 2013.

It is therefore requested to take necessary steps to notify these devices as 'Drugs' under Drugs and Cosmetics Act and also fix the maximum retail price.

Use of devices in medical fraternity is ongoing requirement and is also changing fast due to technological innovations. Each device needs a detail study to find out the functions it carries inside the human body and hence its possible use as drug in human body. It's a huge area. It opens a new chapter in the field of drugs and requires dedicated and independent study. Hence it is requested to kindly get such study conducted and involve more such devices as drugs and accordingly control their maximum retail prices.

Therefore it is suggested that, the definition of 'Drug' in the Drugs (Price Control) Order, 2013 may be included and should be similar to that of Section 3(b) of the Drugs and Cosmetics Act, 1940. It is also suggested that, 'Medical Devices' may be included in Schedule I of the Drugs (Price Control) Order, 2013 in order to monitor and control their prices. The prices of Medical Devices may be fixed according to methodology prescribed in the Drugs (Price Control) Order, 2013.

Recommendations

The issue pertains to the pricing of medical devices. The DCC however, recommended that the matter may be brought to the notice of the Department of Pharmaceuticals / NPPA.

7. INCLUSION OF MEDICAL DEVICES IN THE LIST OF ESSENTIAL MEDICINE.

The major concern of the society is the prices of the various medical devices; many are the out of reach of a common people because of the un-affordability. However Central Government has not seriously shown any concern in this regard to include the various costly indigenous and imported medical devices under the purview of DPCO.

It is suggested that all the costly and un-affordable medical devices shall be included in the list of essential medicine and controlled under DPCO.

Recommendations

The DCC recommended that the proposal may be taken into consideration by the Central Government when the list of essential medicines is again revised.

8. INCORPORATION OF DRUGS CLASSIFIED AS NARCOTICS DRUGS AND PSYCHOTROPIC SUBSTANCES IN SCHEDULE X OF DRUGS AND COSMETICS ACT 1940 AND RULES THEREUNDER.

The drugs covered under Narcotic drugs in Narcotic drugs and Psychotropic Substances Act, 1985 are included in Schedule H of the Drugs and Cosmetics Act 1940 and Rules thereunder at Sr.No. 132 Codeine and Sr.No. 346 Narcotic drugs listed in Narcotic drugs and Psychotropic Substances Act, 1985. The drugs covered under Psychotropic Substances are covered under Schedule H of the Drugs and Cosmetics Act 1940 and Rules there under individually like Sr.No.108 Chlorpromazine, Sr.No. 120 Clobazam, etc.

The list of 16 drugs included in Schedule X of Drugs and Cosmetics Act 1940 are all drugs covered under Psychotropic Substances in Narcotic drugs and Psychotropic Substances Act, 1985.

The regulations for Narcotic drugs are more severe than that for Psychotropic Substances under the NDPS Act. The Central Government vide notification No.S.O.826(E) dated 14.11.1985 has declared the list of Narcotic drugs and preparations to be considered to be manufactured drugs. At Sr.No. 35 Codeine is stated. This entry has exemption for preparations compounded with one or more other ingredients and containing more than 100mg of the drug/per dosage unit and with a concentration of NMT 2.5% undivided preparation and which have been established in therapeutic practice are not to considered as manufactured narcotic drug. Hence, these preparations are also as per Rule 97(c) not to be labeled with suffix NRx but rather to be labeled as Rx as per Rule 96(b) of and Cosmetics Act 1940 and Rules there under.

For the criteria of manufacturing of bulk drugs of Narcotic drugs and Psychotropic substances, considering the high vulnerability of misuse and illicit trafficking the manufacturing of Narcotic bulk drugs is restricted only to government factories whereas that for Psychotropic substances is allowed to non-government manufacturers.

The regulations impart a stringent control over products covered under Schedule X with respect to those covered under Schedule H for purchase, stocking, distribution and sale criteria. This directly implies a more rigid accountability in the supply chain of drugs covered under Schedule X with a focus to prevent and control abuse of the products.

In the present Scenario it is observed that there is rapid rise in R & D resulting in emergence of more new drugs and their formulations. This

has resulted in categorizing these drugs in various Schedules of Drugs and Cosmetics Act 1940 and rules thereunder. The observations of these inclusions indicate that though the inclusion in Schedule H has drastically increased, on the contrary those included in Schedule X has reduced due to some omissions.

Since these products are covered under Schedule H of the Drugs and Cosmetics Act except the 17 covered under Schedule X, the effective monitoring of these products due to numerous constraints and the enforcement of rules are very difficult, if not impossible. Further, this enforcement of rules in the law has lead to more manufacturers marketing their products containing Narcotic drugs or Psychotropic substances leading to more flow and availability of the products in the market magnifying the extent of misuse and abuse of products containing Narcotic drugs or Psychotropic substances.

With reference to correspondence from Drugs Controller (General) India vide letter DDC(I)/Misc/General/62/2011/618 dated 22.12.2011 under the subject of 'Urgent need for barring/restricting the sale of sedative drugs which are being used by criminals for drugging passengers in Indian Railways.' Had enclosure of Director General RPF. In the letter of Director General RPF emphasis has been laid on directing druggist/chemist to sell these drugs only on production of authorized prescription besides maintaining records of the doctors and details of purchases. This can be most effectively achieved by inclusion of all these products in Schedule X of the Drugs and Cosmetics Act 1940 and Rules.

Considering the parameters under Narcotic drugs or Psychotropic substances Act 1985 for more stringent control on the movement of Narcotic drugs and then on Psychotropic substances this administration strongly urges that the following matter be considered seriously and urgently:

1. Inclusion of Codeine in Schedule X of the Drugs and Cosmetics Act 1940 and Rules there under
2. Inclusion of all other Narcotic drugs listed in Narcotic drugs and Psychotropic substances Act 1985 in Schedule X of the Drugs and Cosmetics Act 1940 and Rules there under.
3. Inclusion of all other Psychotropic substances listed in Narcotic drugs and Psychotropic substances Act 1985 in Schedule X of the Drugs and Cosmetics Act 1940 and Rules there under.

It is urged that due consideration to the matter is given in National and International interest for curbing the menace.

Recommendations

The issue of misuse of codeine preparations was already discussed under agenda no. 6 of Central agenda. DCC however, did not agree for inclusion of all Narcotics Drugs and Psychotropic Substances under Schedule X of the Drugs and Cosmetics Rules, 1945.

9. INCLUSION OF DRUG - ETIZOLAM IN SCHEDULE H / H1.

It is observed that various manufacturers of a said drug Etizolam, specify different warnings on their product package.

The therapeutic use of the said drug Etizolam is Antidepressant. Presently the said drug is not covered under 'Schedule H/H1' of Drugs and Cosmetic Act.

Considering the therapeutic effect of the said drug, its overdose may lead to severe health hazard to patient. So, it becomes necessary to include the said drug 'Etizolam' in Schedule H/H1 of Drugs and Cosmetics Act 1940. This will also bring uniformity in claims specified on packaging of the said drug.

Recommendations

The DCC agreed that sale of the drug need to be regulated and recommended that the matter may be placed before DTAB for further consideration.

10. IMMUNOTHERAPY FOR TREATMENT OF REPEATED MISCARRIAGES.

The human body rejects anything that is foreign to it through its immunological system. For example, in case of a kidney transplant, you require a kidney from a blood-related donor. If there is no tissue matching, the body rejects it. In case of a pregnancy, 50% of the baby is from the father, which is totally foreign to the body of the mother immunologically. Naturally, it should be rejected. But certain immunological mechanisms protect the pregnancy from rejection. These mechanisms are disturbed in some women, resulting in an immunological reaction against pregnancy, leading to a miscarriage. This can be prevented by giving immunotherapy.

Immunotherapy involves collection of 300 ml of blood from the husband & separation of the lymphocytes (a special type of white blood cell concerned with

immunological functions) in the Laboratory and injecting them into the wife before conception. This induces certain changes in the wife which help to prevent miscarriages in subsequent pregnancies or leading to conception.

A multicentre study was done at eight centres all over the world in 1992. After the study was completed, immunotherapy was started in HN Hospital. So far, 402 couples were treated with this therapy and obtained excellent (91% success- take home baby rate) results.

This therapy is practiced in Denmark, China, Japan, Canada and many other countries with the approval of the Government body.

On this process Medical practitioners are using another person's blood to isolate the immunocytes which subsequently injected into the patients. This involves the transfusion of blood product and hence this administration is in the opinion to bring this process under the purview of Drugs and Cosmetics Act and the provisions as that of stem cells transfusion shall be applied to theses process.

Recommendations

The DCC agreed that the agenda need to be deliberated by the Government of India in consultation with the Experts. The Chairman stated that the issue will be taken up in the Technical Committee under the Chairmanship of DGHS for its expert opinion. ICMR will also be consulted in the matter as to whether any intervention is required.

GOA

11. Consideration of the question whether the register prescribed to be maintained by the drugs retailers for recording the particulars of the supply of drugs specified in Schedule H-1 can be permitted to be maintained as a part of the computerized software generated cash /credit memos;

By and large, all across the country, the drugs retailers as well as wholesalers have introduced a computerized software system of generating the cash / credit memos for the supply of drugs dispensed by them on the prescription of a Registered Medical Practitioner; Recently Government of India vide notification dated 30/08/2013 has amended the Drugs & Cosmetics Rules 1945 in respect of Rule 65(3)(1)(h), wherein the drugs specified in Schedule H-1 shall be recorded in a separate register at the time of supply, giving the name and address of the prescriber, name of the patient, name of the drug and the quantity supplied; since all these particulars otherwise are also available on the cash /credit memos issued for the purpose and as the provisions of the Drugs & Cosmetics Rules 1945 under Rule 65(3)(2) also provides the option to maintain the cash / credit memo instead of the Prescription Register book for schedule H drugs, recording the same particulars again in a separate register for Schedule H-1 drugs are repetitive and the drugs retailers face severe difficulties and challenge for the register maintenance, specially during peak rush hours for their compliances; it is also the request of the drugs retailers that the software manager / designers are also in position to modify their existing software features to provide a system to generate a special report on the lines of the particulars sought in the separate register, at the end of the day's business and which report duly signed by the Retailers can be produced before any inspection verification by the Drugs Inspector;

Committee may therefore like to deliberate on the matter to consider whether such an arrangement for compliance of the law can be permitted, in lieu of the current usage of computerization technology in the drugs sales activities;

Recommendations

The DCC agreed that the use of electronic media in the day to day activities is increasing day by day and if the records are maintained electronically, for the purpose of compliance to the provisions relating to Schedule H1 drugs, hard copies of the data as required for Schedule H1 should be pasted in the register and duly authenticated by the registered pharmacist.

12. Consideration of the question to incorporate and include drugs and their formulations containing Lorazepam, Clonazepam and similar psychotropic drugs under the list of Schedule H-1 drugs;

The Government of India vide notification dated 30/08/2013 has amended the Drugs & Cosmetics Rules 1945 regarding introduction of a new Schedule H-1 and have inserted 46 drugs substances and their formulations in the said Schedule; however, it is seen that drugs namely **Lorazepam, Clonazepam** which re also psychotropic substances and which are likely to be mis-used are not included in the said Schedule H-1 drugs list;

Committee may therefore like to deliberate on the matter to consider the inclusion of said drugs substances and recommend the same to DTAB for their consideration and examination;

Recommendations

The DCC agreed that sale of these drugs need to be regulated and recommended that the matter may be placed before DTAB for further consideration.

13. Consideration of the question whether drugs sales licenses for operating an exclusive Pharmacy for the purpose of compounding of drugs other than the conventional / traditional NFI listed drugs, can be permitted under the provisions of the Drugs & Cosmetics Rules 1945;

It is observed that in larger States of Karnataka, Maharashtra there are trendsof several compounding pharmacies being operated which are exclusively engaged in the compounding of drugs, which are other than the traditional / conventional NFI listed drugs through such compounding pharmacies and such Pharmacies in the States of Karnataka / Maharashtra have been issued a drugs retail sale licenses in Form 20 and 21 with their due compliance to the requirements of Schedule N of the Drugs &Cosmetics Rules 1945; to cite a name of few such Compounding Pharmacies are **M/s Belle Sante Pharma** (Belle Sante Diagnostic & Therapeutic Institute, Bangalore; **M/s Avi Pharma, Malad, Mumbai**;

These compounding pharmacies compound and dispense drugs by compounding / formulating such drugs at the said compounding pharmacies on the

prescription of doctors in the dosage forms of tablets, capsules, creams, etc, which drugs are namely**Steroid** (Estradiol Micronized, Hydrocortisone, Pregnenolone);**nutrition OTC drugs** (alpha Lipoic acid, Ascorbic acid, Melatonin, Minoxidil, Pyridoxine Hydrochoride,etc); **pain management drugs** (Acyclovir, Ibuprofen, Ketoprofen,, Piroxicam, Tramadolol, etc); **dermatology drugs** (fluconazole, Glycolic acid, Retinoic, Hydroquinone, Zinc Oxide, Tamoxifen, Amphotericin B, etc); the detail list of drugs which are compounded at such compounding pharmacies as obtained from their respective websites is annexed herewith for ready reference;www.bellesante.in; www.avipharma.com;

Although these drugs, as mentioned above, are freshly formulated at their licensed premises, on the basis of the prescription of the medical practitioners, but it is not known what are the safety, efficacy, purity norms adopted or followed by such compounding pharmacies, as there is no scope available of any additional sample portion of the drugs to check for its quality parameters in terms of its bio-availability, stability of such products, etc;

Several companies of overseas origin have now approached the FDA-Goa Administration for such compounding pharmacies drug licenses in the State, on the strength of those that are being granted and operated in Karnataka, Maharashtra States on Form 20 and 21 of the Drugs & Cosmetics Rules 1945 in terms of Schedule N compliances;

In the light of the above, Committee may like to deliberate and advise on the operation of such compounding pharmacies across the country and the various safe guards that the State Licensing Authorities needs to exercise whilst permitting such compounding pharmacies;

Recommendations

It was recommended that a pharmacy may compound drugs as per directions of physician for dispensing to a specific patient only. However, any misuse or violation of the Drugs and Cosmetics Rules, 1945 has to be investigated separately.

14. **Consideration of the question whether the dispatch of finished products goods under quarantine status, awaiting final microbiological / document review clearance, to their own warehouse / go-downs / depots within the State, can be permitted for domestic market as well as for the drugs meant for exports for the reasons of fulfilling the commercial time bound commitments and reduce the transportation time**;

This Directorate have been receiving constant representations from the local based pharma units to permit them to dispatch their finished products under quarantine, awaiting final microbiological testing / document review clearance to their respective go-downs / warehouses / depots within the State and such consignments are then finally released for its actual destination from these warehouses / go-downs / depots, only upon receipt of the final clearance from the Quality Assurance;

Further, for 100% export oriented units, whether the exporting units can be permitted to store their final finished goods under quarantine at an outer warehouse within the State, until final Quality Assurance clearance is obtained, prior to the final release and shipment of the goods;

Committee may like to deliberate and advise whether such practices requested by pharma companies can be permitted, despite assurances provided for all the safe guards / other SOP's in the matter;

Recommendations

The DCC after deliberations agreed that for the purpose of promotion of exports such facilities may be extended to the 100% export oriented units.

15. **Consideration of the question whether 'reduced testing of incoming material' can be permitted to the manufacturers, who manufacture the drug products only for the exports**;

As per the provisions of the Drugs & Cosmetics Rules 1945 with specific reference to Schedule M, Part I, all raw materials and packaging materials to be used in the products are to be sampled, tested and released by the Quality Control Department;

It is come to the notice during the inspection carried by the officials of this Directorate that certain units, who manufacture drug products, exclusively for exports, adopt a concept of '**reduced testing'**, whereby all the consignments of the API as well as the batches of finished products are not subjected to complete analysis;

Such firms represent that relying only on the testing of small sample quantity has its own limitations and hence Current GMP of various other countries like USA, UK, European countries, Australia, etc give more emphasis on building assurance in quality of materials by adopting systems like vendor qualifications, control on transportation, verification of certificate of Analysis from the manufacturer, etc; the firms further represent that in line with the above, they implement a robust vendor

qualification program and other control system at all their sites / locations; after placing the robust system in place, which is always available for verification, the Regulatory authorities of various countries where they export drugs allow the materials to be released based on the review of their certificate of analysis and carrying out limited tests by drug product manufactures;

Committee may like to deliberate on the above concepts adopted by almost all the exporting units who claim that their overseas regulatory agencies do not show any reservation to these practices, provided safe guards system are put in place and available for verification, but which are in contrary to the Indian law and advise whether such practices can be permitted for the purpose, exclusively for exports;

Recommendations

The matter is already under consideration of the DTAB for making necessary amendment in the rules.

16. Consideration of the question whether the API's can be permitted to be used in the manufacture of finished products based on the 're-test date' of the API's and expiry date of which is less than the proposed expiry date of the finished product;

Para 10.9 of Part I of Schedule M under the Drugs and Cosmetics Rules , under the heading of "Raw Materials" specifies that 'it shall be ensured, that shelf life of the formulation product shall not exceed that of the active raw material used';

It is observed that several export oriented units are using the raw materials which are having very short expiry date in the manufacturing of finished formulations, based on the re-test of the API's, which is a clear violation of the requirements of Schedule M; the export oriented units represent that Schedule M is a only GMP guide, which requires the shelf life of the finished product should be less than or equal to the API shelf life; it represents that all international GMP guidelines do not have such requirements but these International guidelines stipulates that the shelf life of the product shall be given on the stability study for the products;

Committee may like to deliberate the above matter on the lines of the above submission and advise the correct practice to be adopted, especially when such products are being exported and need to adhere to the international requirements too;

Recommendations

The matter needs to be examined in consultation with the experts and the international practices being followed in this regard for the purpose of amendment of the rules and specifying safe guards to ensure that the finished products so manufactured retained their potency for the shelf life of the formulation.

17. Consideration of the question whether the raw materials and finished products can be permitted to comply to in-house specifications, inspite of their being official in the Pharmacopoeia;

As per Section 16 of the Drugs & Cosmetics Act, 1940, 'Standards of Quality' specifies that a drug should comply to the standard set out in Second Schedule and the Second Schedule specifies that the drug, other than that patent and proprietary drug should comply to the requirement specified under Indian Pharmacopoeia or any other Pharmacopoeia, in which the drug substance is official;

It is observed that some manufacturers register their product with the importing country under in-house specification and they continue to test the same under in-house specification, even if the said drug substance has become official in Indian Pharmacopoeia or any other Pharmacopoeia;

Committee may like to deliberate on the above and provide advice on the manner in which such cases should be dealt;

Recommendations

The DCC agreed that the drugs meant for exports are required to comply with the specifications of the importing countries, the standards prescribe in Indian Pharmacopoeia need not to be insisted upon.

18. Consideration of the question whether status labels on the raw materials can be replaced by electronic form by way of bar code on the container;

Under Section 10 and 13 of the Schedule M, there is a need to affix coloured status labels on '**under test**', '**approved**' and '**rejected**' materials; and under such section, there is no provision to maintain electronic form of records;

The export oriented units as well as the local based units represent that to bring about better control over the operation and to reduce errors in manual mode of operations, electronic management system is now being employed widely across all areas of the pharmaceutical operations including the material management and supply chain management; the status of material is controlled through ERP systems like SAP which ensures 100% status of each material without recourse to manual maintenance of status labeling; such a system is validated and is reliable, scalable and ensures complete traceability of materials throughout its life cycle;

In some units, the status is controlled through bar code labels affixed on the containers of raw materials and finished products; the status is always available on-line at any given point of time through scanning the bar code on the container; the identity of material with respect to material name, material code and lot number as well as status of the materials as quarantine, released or rejected is readily traceable by verification of bar code using a scanner; this eliminates need for pasting multiple labels on the containers as and when the status of the material is changing; this also eliminates inherent possibility of error due to manual maintenance of status labels on the containers;

Committee may like to deliberate whether the use of electronic mode for the status movement of the raw materials as adopted by the industry can be permitted in contrary to the one prescribed under Schedule M of the Drugs & Cosmetics Rules 1945;

Recommendations

The electronic mode or bar coding is now progressively being used. If the bar codes signify the status labels as required under Schedule M, these may be accepted.

19. Consideration of the question regarding the maintenance of 'Residual sample retention' by the Laboratories under Schedule L-1;

Clause 16a of the Schedule L-1 to the Drugs & Cosmetics Rules specifies to retain the residual sample in proper storage condition for a period of one year after the final report; this clause does not specify its applicability to the type of the laboratories;

Laboratories which are attached or are a part of the drugs manufacturing units as well as the contract approved testing laboratories are also in the purview of this clause applicability; however, as per the provisions of the Schedule M, every manufacturing units are required to maintain reference reserve samples for all the materials going in the market along with their RM and PM and these samples are maintained beyond their stipulated shelf life and therefore since Schedule M already regulates this concept, it is repetitive in contradiction with Schedule l-! requirement to retain for a period of one year from the date of the final report;

It is understood that this Clause 16a would be more applicable for the Approved Testing Laboratories rather than those attached to the manufacturing units and if that be so, then there is a need to clarify this clause 16a applicability;

Committee may like to deliberate on the above and advise suitably for its clarity and implementation;

Recommendations

It is the manufacturer who is required to maintained reference samples beyond their stipulated shelf life. The laboratories involved in the testing of drugs are required only to comply with the provisions of storing the residual samples for a period of one year after the final report.

20. Consideration of the question as regards to the issue of NOC for exports of drugs for country and quantity specific

It is need of the industry that they find it very cumbersome and time consuming to approach every time to apply to the respective CDSCO zonal office for grant of NOC for the exports of certain drugs formulations, which NOC's are country specific and quantity specific and as a result, the industry has to approach the respective zonal offices for the repetitive exports orders, which renders loss of time and delay in the export consignment;

It is the request of the industry to grant one time NOC which is not quantity specific or country specific to tackle the above eventuality;

Committee may like to deliberate and take suitable decision on the matter in the larger interest of the Industry and exports needs of the country, which generates foreign exchange for the country;

Recommendations

NOCs for export of drugs which are prohibited for marketing in the country are only required to be issued country specific and quantity specific. In other cases for repetitive export orders office of DCG(I) may review the guidelines in consultation with the Ministry of Health and Family Welfare.

21. **Consideration of the question whether the requirement of height of the Pharmacy or Dispensing Chemist of 2.5 metres as stipulated in Schedule N of the Drugs & Cosmetics Rules 1945 should be strictly insisted whilst grant of retail sale drugs licenses**;

Recommendations

The DCC recommended that height of 2.5 meters should be uniformly applied for as requirement for pharmacy or dispensing chemist.

DELHI

22. Amendment of the Rule 64 of the Drugs & Cosmetics Rules, 1945 – Competent Person – Regarding:

The qualification of the competent person should be with pharmacy background only i.e D. Pharmacy/ B. Pharmacy/ M. Pharmacy/ Pharm D/ Registered Pharmacist for grant of Wholesale Licence(s) on Form(s) 20B/ 21B/ 20G.

Other qualifications like matriculation examination or its equivalent examination from a recognised board with 04 years experience in dealing with sale of drugs or degree of a recognised university with one year experience in dealing of drugs should be deleted.

Recommendations

The DCC recommended that the following provisions under rule 64 in regard to the competent person may be deleted.

"(b) has passed the matriculation examination or its equivalent examination from a recognised Board with the four years' experience in dealing with sale of drugs"

23. Change of Heading on Form 28C:

The blood and its components are given by the blood bank to a patient either after receiving replacement donations or after receiving *voluntary* donation. There is no provision for the sale of blood and / or its components. Moreover, there is ban on donation of blood by professional donors.

However the title of Form 28C reads as "**Licence to operate a blood bank for collection, storage and processing of whole human blood and/or its components for sale or distribution**".

*Therefore it is suggested that the word '**sale'** should be deleted from the said title of Form 28C*.

Recommendations

The DCC did not agree to the proposed recommendation as certain charges are levied by the Blood Bank at the time of release of blood.

HIMACHAL PRADESH

24. The issue of FDC's may be decided at the earliest. It is requested that if a FDC is refused to any manufacturer, then it should not be allowed to be manufactured by any manufacturer in India. DCGI office should ensure that the orders regarding grant of new FDC's by States is implemented uniformly in all the States as due to this huge business of manufacturing States is shifting to other States.

Recommendations

The question of grant of Fixed Dose Combinations by the State Licensing Authorities without the due permissions from the office of Drugs Controller General (India) has been examined by a committee under the Chairmanship of Prof. C. K. Kokate, constituted by the Government of India. It has submitted its report and its recommendations are being examined. The list of the drugs found rational or irrational will be published by the Government of India for guidance of the State Drugs Control Authorities.

MADHYA PRADESH

25. On receipt of Test Report from the Government Analyst, action such as Product permission suspension or prosecution permission against the manufacturer should not be initiated by FDA, without receiving the investigation report.

Recommendations

For taking action in the cases of the products declared as not of standard quality, procedures prescribed under the rules and the guidelines earlier approved by the DCC may be followed.

26. The Test Report pertaining to NSQ LVPs failing in particulate matter should also be studied on whether it describes the type of particle and also particulate count as per pharmacopoeia or not?

Recommendations

As the standards of LVPs are prescribed under the Indian Pharmacopoeia, the Government Analyst will test the particulate matter count as per IP only.

27. Product permission:- If product is approved for manufacturer in I.P. or B.P. or U.S.P. then it should be approved for manufacture by Licensing Authority from the State without sending application to Delhi.

Recommendations

The term new drug is already defined under the Drugs and Cosmetics Rules, 1945. The inclusion of a drug in IP or BP or USP is not considered as criteria for grant of licence by the State Licensing Authority, if the product is considered a new drug.

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(Extracts of the minutes of the 48th DCC meeting held on 24.07.2015)

AGENDA NO. 3

CONSIDERATION OF THE PROPOSAL FOR STRICT MONITORING OF USE OF DICLOFENAC INJECTION IN ANIMALS TO STOP THE DICLOFENAC POISONING IN VULTURE POPULATION CREATING ENVIRONMENT IMBALANCE THAT ALSO AFFECTS HUMAN LIFE

The use of Diclofenac in animals has been reported to be leading significant decline in the vulture population. It is alleged that diclofenac poisoning has drastically brought down vulture population in India pushing them to the brink of extinction. It creates environmental imbalance that affects human life.

The issue was earlier considered by the Government of India and the Government prohibited the manufacture, sale and distribution of diclofenac and its formulations for animal use vide Gazette notification G.S.R. 499(E) dated 4.07.2008. It was subsequently alleged that multiple dose diclofenac sodium injection in the pack size of 30 ml is being diverted for treatment of animals. The matter was accordingly again considered by DTAB and to curb the illegal use of diclofenac injection for human use in animals, draft rules to amend rule 105 of the Drugs and Cosmetics Rules, 1945 were published vide Gazette notification G.S.R. 503(E) dated 14.07.2014 to make it mandatory that the drug for human use shall be packed in single unit dose pack only. The rules have since been finalized and the notification amending the rules is being issued by the Ministry of Health and Family Welfare.

The National Human Rights Commission (NHRC) has also taken a note of the complaint regarding the misuse of diclofenac injection in animals and have observed that even though necessary steps have been taken by the Government for prohibition of the use of the concerned drug in animals. It has however further recommended that a committee may be constituted to monitor the situation and direct the State Government to keep a watch and take steps for strict implementation of the directions.

DCC may kindly consider the matter and ensure that diclofenac injection is not used in the veterinary practice in their respective States so that the misuse of the drug is plugged to save the diminishing population of vultures in the country and to maintain the ecological balance.

Recommendations

The maintenance of ecological balance is of national importance and in this connection it is required to be ensured that the Diclofenac injection manufactured for human use is not diverted for use in animals to save vulture population. The diclofenac injection for human use is being restricted for packing in single unit dose pack only. DCC recommended that State level committees having members from the veterinary practice in the State may be constituted to educate and monitor that Diclofenac injections for human use are not diverted for use in animals.