REPORT OF THE 46TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 12TH AND 13TH NOVEMBER, 2013 AT THE HOTEL METROPOLITAN NEW DELHI-110001

(List of Participants is at Annexure I)

INAUGURAL DELIBERATIONS

Dr. G. N. Singh, Drugs Controller General (India) and Chairman, Drugs Consultative Committee (DCC), welcomed the members and the Hon'ble Guests. He then requested Shri R. K. Jain, AS & DG, Ministry of Health and Family Welfare to initiate the proceedings and address the members.

Shri R. K. Jain, AS & DG, in his address stated that it is very essential that there is a sense of togetherness between the Central as well as State Drug Regulatory Authorities to achieve the common objective of making available quality drugs in the country. In the age of faster communications and IT facilities, the regulatory authorities should not work in isolation but act in a transparent and in harmonious manner to achieve the objective of maintaining quality of the drugs produced in the country.

The Drugs Consultative Committee is an important forum for brining harmony in exercising regulatory control under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.

The Pharma industry in the recent years has gained distinction of being one of the largest producers of drugs especially of generic drugs in the world. With the development of technical knowhow in the country, pharma industry is now manufacturing drugs which require highly sophisticated technology. India is third

largest producer of drugs in the world by volume and is exporting about its half of production to more than 200 countries. However, this large quantum of production entails a responsibility for the regulatory authorities to ensure quality, safety and efficacy of drugs manufactured in the country. Production of quality drugs should be non-negotiable area.

The Government of India in the 12th Five Year Plan has made provisions for strengthening of the Drug Regulatory infrastructure in the country both at Central and State level. New schemes have been initiated for the strengthening of manpower as well as enhancing testing facilities in the country. The State Governments are required to avail of the schemes for upgrading the drug regulatory infrastructure in their States. Training of regulatory officials is another area of importance. The Government of India has facilitated training of some of the officers belonging to the States Drug Regulatory infrastructure. State officers have been sent to foreign countries for training in respective fields. However, more exposure and up-gradation of the technical skills is required for training officers belonging to the States Drug Regulatory System. The Government of India will be sending State Drug Regulatory officers for training in the country or abroad as the case may be on regular basis.

For uniform implementation of the policies of Government of India, it is stated that the directions issued by the Central Government or the DCG(I) for uniform implementation of the provisions of the Drugs and Cosmetics Act, 1940 should be adhered to and due action taken for their implementation.

For effective monitoring of clinical trial sites, it is necessary that with State Drug Inspectors the CDSCO conduct at least inspection of one clinical trial site every month. This would not only ensure that the trial sites adhere to the provisions of Schedule Y and other regulatory provisions for conduct of clinical trials but also

helped the regulatory authorities of the States to gain necessary expertise in the field.

He desired that the State Governments may ensure that whenever, foreign agencies of European Union or USFDA visit for inspection of a manufacturing unit or a clinical trial site, a representative of the State as well as of CDSCO should be involved in the exercise.

On the request of the State Drug Controllers for appointment of a nodal officer for responding to the requests from the State Drug Control Authorities by the office of DCG(I), the AS & DG requested the DCG(I) to designate a nodal officer for monitoring the correspondence received from State Drugs Controllers. The DCG(I), in turn, nominated Shri Aseem Sahu, Deputy Drugs Controller (India), CDSCO, HQ as nodal officer for monitoring the correspondence with the States / UTs Drugs Controllers.

Dr. A. K. Panda, Joint Secretary, Ministry of Health and Family Welfare while addressing the members stated that in regard to the proposals received from the States / UTs, for strengthening of Drug Regulatory System in the States / UTs under the 12th Five Year Plan have been sent for EFC approval. Funds will be released only after these have been cleared by the Cabinet and demands justified. In respect of strengthening of Drug Testing Laboratories, he stated that the proposal should be reality based. The details of the instruments which are already available with the laboratory, their functional status and further instruments required for optimally effective testing of the samples by the laboratories should be made available.

In regard to the pharmacovigilace programme, he stated that 90 centres have been made functional in various Government Medical Colleges for capturing the adverse drug reaction data in the country. The State Drug Control representative should visit these centres to ensure that these are functioning properly. The results

of inspections may be forwarded to the DCG(I) for taking further necessary action, if any, in the matter.

He further stated that Government is considering a proposal of permitting Unbanked Directed Blood Transfusion in rural areas because of non-availability of blood in such areas. Deaths are reported at childbirth or in accidental cases in these areas because of lack of timely availability of blood. Surgeons, obstetricians and other qualified clinicians are now available in rural areas who are handicapped in saving these lives because of non-availability of blood.

The issue of fixed dose combinations considered as new drugs and licensed by the State Licensing Authorities has been discussed in the previous meeting also. The State Drugs Controllers should ensure that when a licence is granted for a product covered under the definition of new drug it should have NOC from the office of DCG(I). A time of 18 months from January, 2013 has been given for establishing the safety and efficacy of the drug formulations permitted by the State Licensing Authorities but whose safety and efficacy were not examined by the office of DCG(I) as required under the Drugs and Cosmetics Rules, 1945. The Government of India will thereafter take appropriate action for prohibiting the formulations which would be considered as not safe and efficacious for use.

He asked the State Governments to ensure that designated Courts are setup in each State / UT for the cases related to violations of the Drugs and Cosmetics Act, 1940. The States where such Courts have been established should furnish the details of the cases referred to such Courts to the office of DCG(I).

On the request of some of the State Drugs Controllers, he asked the office of DCG(I) to forward a copy of the permission to conduct clinical trial to the concerned State Government also, under whose jurisdiction the trial is to be conducted.

Dr. G. N. Singh, DCG(I) stated that he has recently visited Russia and China and shared his impressions about the regulatory systems in those countries. Even though these countries have robust Drug Regulatory infrastructure, these countries are however, looking towards India for lead in many areas. India is known as world pharmacy as it has been able to supply generic drugs at reasonable prices to most of the countries of the world. A lot is however, required to be done for establishing credibility of Indian drugs as reports of supply of not of standard quality drugs from India are reported from time to time. India has the capability of achieving a place of distinction in drug discovery and research. India has world class infrastructure and capability of clinical research. The regulatory provisions under the Drugs and Cosmetics Rules, 1945 have been strengthened in respect of monitoring of clinical trials in the country.

The State and the Central drug regulatory authorities are required to work in unison to achieve this objective. The Central Government has taken initiatives to strengthen and provide training to the State Drug Regulatory Authorities. Three workshops are being organized in early 2014 for training of personnel from the State / UT Drug Regulatory authorities.

He informed the members that the Hon'ble Union Health and Family Welfare Minister, Shri Ghulam Nabi Azad released the 7th edition of Indian Pharmacopoeia 2014, on 4th November, 2013.

He suggested that for uniform implementation of policies, zonal level meetings of the State Drug Regulatory Authorities could be convened in the respective zones to discuss matters for having uniformity in the specific regions.

He made a mention of the contributions made by Dr. B. R. Jaggashetty, Drug Controller, Karnataka and Shri D. K. Shringi, Drugs Controller, Rajasthan who have retired recently on superannuation. The Committee appreciated the contribution of

these members during deliberations on various subjects in the past. They were instrumental in helping the committee in arriving at decisions on complex issues during the deliberations. The committee desired that the Chairman may send letter of thanks to these members on behalf of the committee for their contribution to the proceedings of the Drugs Consultative Committee.

Shri Sudhanshu Pandey, Joint Secretary, Ministry of Commerce & Industry in his address to the members raised the issues which the Indian Pharma Industry is facing in the International arena. India produces drugs worth US $ 28 billion out of which drugs worth US $ 14 billion are exported. The generic drugs produced in the country have made inroads in both developing and developed markets of the world. Indian pharma companies are of late being targeted in many importing countries by raising barriers to protect the domestic industry. The regulatory regimes are being tightened. Indian Pharma companies are being targeted on many issues to discourage imports from India. Complaints have been received from the countries like Shri Lanka, Ghana etc. in regard to the supply of drugs which were not of standard quality. There are cases where spurious drugs manufactured in other countries have been supplied in international market as 'made in India'. The other concern is the import of cheaper Active Pharmaceutical Ingredients (APIs) from China. This is having a crippling effect on the local bulk drug industry.

The commissioner, FDA, Maharashtra in his address raised the issues which were very relevant in the context of enforcement of the provisions of the Drugs and Cosmetics Act, 1940. He stated that while the Drugs and Cosmetics Act, 1940 is well worded, the provisions are not patients centric. There are three stakeholders in the field of medicine i.e. manufacturer, trader and patient. The regulations therefore should be in favor of patient with the objective that quality medicines are produced for the benefit of the patient. India needs a better system of adverse drug reaction recording and strong pharmacovigilance system. There are problems at retail outlets also. The presence of pharmacists at the retail outlets should be non-negotiable.

The Licensing authorities should cancel the licence of the chemist if the pharmacy is being run without a pharmacist. Sale of medicines without a bill is also required to be strictly checked. Such sales lead to the introduction of spurious drugs in the sale chain. A prescription audit is one way to stop misuse of the drugs at the prescription level. There should be a visible robust system of recall of drugs reported as not of standard quality in the country. Inspection of manufacturing units is another area of concern. A uniform inspection methodology for inspection of manufacturing units to secure and protect the quality of drugs should be followed throughout the country.

It becomes the responsibility of the Indian Regulatory Authorities to ensure that position of Indian Pharma Industry is not compromised in the International market. The DGFT has introduced the system of Bar coding in all the primary and secondary packaging of the drugs to be exported, so as to keep a track of goods exported from India. The objective is to accounts for what goes out of India. He suggested that international knowledge exchange programmes should be encouraged between the regulatory authorities so that the regulators from other countries have direct interaction with the Indian Regulators and the problems faced by Indian exporters are taken care of. The Indian regulatory authorities should also participate in the International fairs organized by the Ministry of Commerce so that there is an interaction with the regulatory authorities of those countries as well as importers to facilitate export of drugs from India. The State Drug Regulatory Authorities may also appoint Public Relation Officers to facilitate export of drugs from their States.

ACTION TAKEN REPORT ON THE MATTERS ARISING OUT OF THE 45TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 4TH & 5TH FEBRUARY, 2013 AT NEW DELHI

S.NO.	Agenda No.	SUBJECT	ACTION TAKEN
1	1	Consideration of the recommendations contained In The 59th Report of the Parliamentary Standing Committee 1. Creation of Data Bank	Linking of website of the States having information in respect of their activities is being processed under the e-governance scheme and the matter would be further discussed in the meeting.
		2. Drugs Testing Laboratories	Many States have submitted proposals to the Ministry of Health and Family Welfare.
		3. PSUR Data	The manufacturers were requested to submit the PSUR data to the office of DCG(I) regularly.
		4. Deterioration of temperature sensitive drugs because of improper storage	Guidelines of Good Distribution Practices have been prepared and have been placed as agenda in the meeting.
2.	2.	Road map for strengthening of drug regulatory systems in the country under 12th Five Year Plan by the respective State / UTs Governments	States have forwarded their proposal for assistance for e-governance as well as manpower and necessary hardware and software.
3.	3.	Consideration of the proposal for a special drive of drawing samples of drugs for tests for assuring the	The States and UTs Governments were to have special drives of testing samples

		quality of medicines manufactured in the country	of drugs and ask the manufactures to submit dissolution study reports.
4.	4.	Consideration of the proposal that manufacturers marketing Fixed Dose Combinations (FDCs) falling under the definition of 'new drug' permitted for manufacture for sale in the country without due approval from office of DCG(I) to prove their safety and efficacy	The DCG(I) had written to the States on 15.01.2013 to the States to ask the manufacturers to prove the safety and efficacy of the fixed dose combinations within 18 months. Over five thousand applications have been received and arrangements are being made to examine the applications in consultation with the Expert Committees.
5.	5.	Consideration of the directions issued under section 33P of the Drugs and Cosmetics Act by the Ministry of Health and Family Welfare for grant / renewal of manufacturing licences of drug formulations in proper / generic name only	States were asked to abide by the directions issued by the Ministry of Health and Family Welfare in respect of grant of licences in generic names.
6.	6.	Consideration of the proposal to examine whether there is a need for in-acting / amending rules for restricting the number of blood banks for quality assurance on blood collection	The proposed amendment was not agreed to.
7.	7.	Consideration of the proposal to delete colour index 12150 (solvent red 1), and 20170 (resorcin brown) from schedule Q to the Drugs and Cosmetics Rules	The proposal was placed before DTAB and it recommended for the amendment in the Drugs and Cosmetics Rules.
8.	8.	Consideration of the proposal to include liquid foundation make up, cold wax-hair remover, face pack,	The proposal was placed before DTAB and it recommended for the amendment in the Drugs and

		kajal, oxidation hair dyes (emulsion type) and cream bleach under schedule s to the Drugs and Cosmetics Rules, 1940	Cosmetics Rules.
9.	9.	Rajasthan	No specific action recommended for the office of DCG(I).
10	10.	Punjab	The proposal for amendment was referred to the sub-committee.
11.	11.	Goa	Necessary clarifications were provided on the various issues. However, no specific action on behalf of Central Government was recommended.
12.	12.	Karnataka	The matters pertaining to amendment of the Drugs and Cosmetics Rules were referred to the sub-committee while in other cases clarifications were provided.
13.	13.	Himachal Pradesh	Issues relating to grant of licences for FDCs and grant of licences in generic name were already discussed in the Central items.
14.	14.	Andhra Pradesh	The recommendations for amendment of the Drugs and Cosmetics Rules were referred to the sub-committee.

AGENDA NO. 1

CONSIDERATION OF THE ISSUE OF MISUSE OF OXYTOCIN INJECTION BY THE DAIRY OWNERS TO EXTRACT MILK FROM MILCH ANIMALS AND ITS HARMFUL EFFECTS

Smt. Maneka Gandhi, MP, Lok Sabha has written to the Secretary, Ministry of Health and Family Welfare regarding the continued misuse of oxytocin injections by the dairy owners for extracting milk from milch animals and its harmful effects on the health of cows and buffaloes as well as on the consumers. Even though the drug is considered as an essential drug in medical practice for certain conditions in human as well as veterinary field, the alleged abundant availability and use of the drug, in a clandestine way is a matter of great concern for public health.

The drug oxytocin has medical use for induction and augmentation of labour, to control post partum bleeding and uterine hypo tonicity. The sale of the oxytocin injection is regulated under Schedule H of the Drugs and Cosmetics Rules, 1945 which require the drug to be dispensed on the prescription of a Registered Medical Practitioner only. Further, to avoid its bulk sale oxytocin injection is required to be packed in single unit blister pack only.

The use of oxytocin injection for extracting milk from milch animals is also prohibited under the Cruelty to Animals Act, 1960. It is provided under section 11 (1)(c) that if any person wilfully and unreasonably administers any injurious drug or injurious substance to any animal or Wilfully and unreasonably causes or attempts to cause any such drug or substance to be taken by any animal, he is punishable under the Act.

In spite of the above provisions the reports of manufacture and sale of the drug in clandestine way in large quantities and its misuse by the farmers or dairy owners is a matter of great concern. The office DCG(I) had earlier also written to the State Drugs Controllers to check and unearth the clandestine manufacture and sale of drug to the

farmers or dairy owners in violation of the provision of the Drug and Cosmetic Rules through surveillance and raids conducted on the possible hide outs where such activities are being undertaken.

The manufacture and sale of the drug with or without a licence for such clandestine activity is an offence under the Drugs and Cosmetics Act, and the violators are required to be handled with a heavy hand. The amended penal provisions of the Drugs and Cosmetics Act, 1940 make such offences cognizable and non-bailbale. This clandestine activity of manufacture and sale of the drug to the farmers or dairy owner require constant surveillance and interstate coordination.

The matter was earlier considered in the 44th DCC held on 20th July, 2012 and the following recommendations were made.

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

The matter has again been brought for the consideration of the DCC as to know what measures have since been taken by the concerns State Licensing Authorities and whether more stringent actions are called for ensuring that clandestine manufacture and unauthorized diversion of the oxytocin injections does not take place to the dairy owners.

Recommendations

The members felt that the illicit manufacture of oxytocin injection for the use of extracting milk from milch animals by the dairy owners is a clandestine activity. The manufacture of the drug for dairy owners etc takes places in the regions where drug control administration is lax and then the drug is transported to other States clandestinely. It is available in unlabelled or wrongly labeled packs. Even though many of the State have taken action on the basis of intelligence gathered through surveillance. However, strong measures are required to restrict the supply of oxytocin injection for veterinary use and also ensured that diversion of the bulk drug to illegal channels is curtailed.

The DCC after deliberations recommended that the manufacture and sale of the oxytocin injections should be banned for veterinary use under section 26A of the Drugs and Cosmetics Act, 1940 along with the condition that the manufacturers of bulk drug oxytocin should supply the active pharmaceutical drug only to the manufacturers licensed for manufacture of Oxytocin formulation for human use.

AGENDA NO. 2

CONSIDERATION OF THE FINALIZATION OF GUIDELINES ON GOOD DISTRIBUTION PRACTICES FOR PHARMACEUTICAL PRODUCTS

The objective of the quality control over drugs is to ensure that the patients get quality drugs. For this purpose it is necessary to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process. Various individuals and entities are responsible for the handling, storage and distribution of the pharmaceuticals products. This includes procurement, purchasing, storage, distribution, transportation, documentation and record keeping practices. To maintained the original quality of the pharmaceutical products, adequate control over the entire chain of distribution is required to be maintained. Each activity in the distribution system is required to be carried out in accordance to the principles of Good Distribution Practices. The involvement of unauthorized entities in the distribution and sale of pharmaceutical products is a matter of concern as it leads to introduction of spurious drugs in the supply chain. It is the responsibility of all parties involved in the distribution of pharmaceutical products to ensure that the quality of pharmaceuticals products and the integrity of the distribution chain are maintained throughout the distribution process.

In view of this the CDSCO has prepared Guidelines on Good Distribution Practices for Pharmaceutical Products. The guidelines apart from giving general principles and have enumerated detailed guidelines for organization and management, personnel, quality system, warehousing, temperature controls, transportation, documentation etc. including guidelines for recalls and returns. The draft guidelines were put on the website of CDSCO. A copy of the draft guidelines is **annexed.**

Large numbers of comments have since been received from various stakeholders like chemists and druggist associations, individuals, manufacturers associations etc.

DCC may kindly consider and suggest the methodology for finalizing and approving the guidelines for the purpose of implementation.

Recommendations

The members opined that guidelines on Good Distribution Practices for Pharmaceutical products is the need of the hour as India is a vast country having major variations in temperature and climate. To ensure the quality and identity of pharmaceutical product, the criteria of the drug being tested by the manufacturer before release for sale is not sufficient and it is essential that an adequate control over the entire chain of distribution is maintained so that the quality of the drug do not deteriorate during transportation. The Guidelines prepared by the CDSCO should be finalized in consultation with the Stakeholders as well as the regulatory authorities.

The committee after deliberation constituted a committee consisting of Director General, Drugs, Andhra Pradesh and Drugs Controller, Odisha with Shri Naresh Kumar, ADC(I), CDSCO, North Zone, Ghaziabad as convener. Smt. Rubina Bose, ADC(I), HQ, New Delhi will assist the committee in providing necessary documents for consideration. The committee shall finalize the guidelines after consideration of the comments received and suggests methods for implementation of the guidelines by the State Drug Control Authorities.

AGENDA NO. 3

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

The Planning Commission in the 12th Five year plan (2012-2017) had recommended strengthening of drug regulatory system in the country. It was recommended that state drug regulatory mechanism should be strengthened. The Central Government had recommended centrally sponsored schemes to strengthen their infrastructure both physical and human resources. This includes up gradation of state drug testing laboratories and strengthening of drug control offices in the States/UT.

The approved Plan Outlay for this new Centrally Sponsored scheme during the 12th Plan is Rs. 1200 crore. The Central Share would be 75% and States' share 25%. For North-Eastern States and Special Category States, the ratio would be 90:10. The total financial outlay of the project, including states' share would be Rs.1550 crore. States' share would be Rs.325 crore and NE/Special Category states' share would be Rs.25 crore. Accordingly, the central share for states would be Rs.975 crore and for NE/Special Category states Rs.225 crore.

The matter was discussed in the 45th DCC meeting held on 04th and 05th February 2013 in the presence of Sh. R. K. Jain, AS & DG and Dr. A.K. Panda, Joint Secretary, Ministry of Health and Family Welfare. The State Drug Control authorities were requested to forward their proposals for strengthening the Drug Regulatory System in the States/UT's to the Central Government, through their respective State Governments.

Recommendations

Many of the State Drugs Controllers stated that on the basis of the discussion in the 45th meeting of the DCC held on 4th & 5th February, 2013, they have forwarded the proposals through the State Governments for strengthening the Drug Regulatory system in their States / UTs while others were actively pursuing with their State Governments to forward the proposals.

The members were informed that on the basis of the requests received by the Ministry of Health and Family Welfare has submitted a memorandum of Expenditure Finance Committee (EFC) in respect of CDSCO and new scheme of strengthening of States / UTs Drug Control Regulatory System for the estimated expenditure proposed to be incurred during the 12th Five Year Plan. The States / UTs Governments would be intimated of the outcome of the sanction in due course.

AGENDA NO. 4

CONSIDERATION OF THE CANCELLATION OF LICENCES TO MANUFACTURE DRUG FORMULATIONS FALLING UNDER THE PURVIEW OF 'NEW DRUGS' AS DEFINED UNDER RULE 122 (E) OF THE DRUGS AND COSMETICS RULES – CONSTITUTION OF A SUB-COMMITTEE TO PREPARE GUIDELINES FOR GRANT OF LICENCES FOR FIXED DOSE COMBINATIONS

The Parliamentary Standing Committee of the Ministry of Health and Family Welfare in its 59th report on the functioning of CDSCO presented on 8.05.2012 had taken note that some of the State Licensing Authorities have issued manufacturing licenses for a very large number of FDCs without prior clearance from CDSCO. This has resulted in the availability of many FDCs in the market which have not been tested for efficacy and safety. This can put patients at risk.

The DCC in its 44th meeting while considering the recommendations of the Parliamentary Standing Committee constituted a sub-committee of representatives of various State Drugs Controllers with Shri A. K. Pradhan, Deputy Drugs Controllers, India, CDSCO, HQ, as the convener to prepare guidelines for grant of license for FDCs. In the meanwhile, in light of the observations made by the Hon'ble Parliamentary Standing Committee in its 59th Reports on the functioning of Central Drugs Standard Control Organization (CDSCO), the Ministry of Health and Family Welfare constituted an Expert Committee to prepare Policy Guidelines for Approval of Fixed Dose Combinations (FDCs) in India under the Chairmanship of Prof. C.K. Kokate. The committee has submitted its report which is already available on the website of the CDSCO.

As per the Action Taken Report of the Ministry of Health on the observations of the Parliamentary Standing Committee, the DCG (I) would request all States/UT Drug Controllers to ask the concerned manufactures in their State to prove the safety and efficacy of such FDCs before the office of DCG (I) within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country.

In view of above, the DCG (I) vide no.4-01/2013-DC (Misc. 13-PSC) dated 15.0.1.2013 has requested all State/UT Drug Controllers to ask the concerned manufacturers in their State to prove the safety and efficacy of such FDC as mentioned above before the office of DCG (I) within a period of 18 months, failing which such FDC will be considered for being prohibited for manufacture and marketing in the country.

In view of the above it is felt that no useful purpose would be served by preparing another set of guidelines by the sub-committee of DCC for the purpose.

Recommendations

The members agreed that in view of the report of the committee constituted under the Chairmanship of Prof. Kokate for Policy Guidelines for approval of fixed dose combinations in India for taking action in the matter and other related decisions as mentioned above, no useful purpose would be served by preparing another set of guidelines for the same purpose by the sub-committee of DCC with Shri A. K. Pradhan, Deputy Drugs Controller (India) as the convener.

AGENDA NO. 5

CONSIDERATION OF THE ISSUES RELATING TO GRANT OF COPP CERTIFICATES BY STATE LICENSING AUTHORITIES

A. THE PRACTICES OF GRANTING EXTENSION TO COPP CERTIFICATES FOR ONE YEAR (TWO TIMES FOR SIX MONTHS)

It has been observed that after joint inspection for COPP certificates as per WHO TRS, the COPP certificates after inspection are issued by the State Licensing Authority for a period of two years. After completion of two years the manufacturing firms apply for extension of COPP certificates for further six months (2 times). In certain cases the applicant applies without submitting the application to the office of CDSCO or the application for inspection is submitted near to expiry of second extension.

The provision of extension was made only in such cases where delay occurred during the scrutiny of documents or inspection delay due to paucity of CDSCO Inspectors for inspection.

It is proposed that the firm may be advised to submit the application one month before the expiry of COPP certificates to have on time inspection. The extension by State Licensing Authority should only be given in exigencies under intimation to Zonal/Sub-Zonal Offices of CDSCO.

B. THE PRACTICES OF APPLYING FOR INCLUSION OF ADDITIONAL PRODUCTS IN THE COPP DIRECTLY TO THE STATE LICENSING AUTHORITY

It has been observed that after joint inspection for COPP as per WHO TRS, the COPPs as inspected are issued by the State Licensing Authority and list of which is also attached along with inspection report. Afterwards the firm applies for COPP of additional products directly to State Licensing Authority and COPP issued by State Licensing Authority without intimation to Zonal/Sub-Zonal offices of CDSCO.

It is proposed that the COPP certificate for additional products should only be granted after the recommendation from Zonal / Sub-Zonal offices of CDSCO.

The DCC may deliberate and give its recommendations in the matter

Recommendations

The committee was informed that the staff strength of CDSCO is being continuously increased and the number of drug inspectors in each zone has been increased and as such there is no reason that zonal offices would not be in a position to conduct joint inspections regularly. As a principle the joint inspections should not be bypassed.

A. The members agreed that in the cases of grant of extension of COPP certificates the applicant is required to make application for issue of WHO-GMP COPP well before the expiry of validity (i.e. 2 months) of certificates and joint inspection shall be carried out for issue/ reissue of WHO-GMP-COPP certificates. However, in cases where application for reissue of COPP is already made in time by applicant (with all the data) and where CDSCO has not been able to organize the inspection along with State Licensing Authority (SLA) within 28 days after the receipt of the complete application, then the extension may be granted to the applicant by the SLA for reasons of delay to be recorded in writing.

B. For issue of COPP for additional product the following guidelines shall be followed.

    i. The application for inclusion of additional products shall be made simultaneously to both State Licensing Authorities and concerned zonal/sub-zonal office of CDSCO.

    ii. The application shall be accompanied by the list of applied additional products, product license copy, product summary sheet (as per the Proforma given below) and Stability data of three batches accelerated/ real time with condition(temperature and relative humidity) and process validation data.

    iii. Technical scrutiny of the application shall be done by CDSCO as per Guidance Document for Functions and Responsibilities of Zonal, Sub-Zonal and Port

Offices of CDSCO available on the website of CDSCO. The recommendations (of issuance or rejection or query) on application shall be forwarded to the applicant and State Licensing Authority within 21 days.

iv. In case no recommendation (about issuance or rejection or query) is not forwarded by CDSCO to the applicant and the State Licensing Authority (SLA) within 21 days, the SLA may conduct technical scrutiny of the application for appropriateness and decide on the issuance of the COPP and forward its decision to the manufacturer along with intimation to CDSCO indicating the reasons of grant of COPP in the particular case.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL TO AMEND SCHEDULE D OF THE DRUGS AND COSMETICS RULES, 1945 TO EXCLUDE DRUGS IMPORTED FOR FURTHER PURIFICATION WITHOUT FOLLOWING THE PROCESS OF REGISTRATION AND IMPORT LICENCE

It is reported in various forums that many importers are importing Bulk Drug or Active Pharmaceutical Ingredients as Crude Drug or (Feed Grade) etc. for further purification. Such crude and feed grade drugs are nothing but impure or not of standard quality drugs imported from unregistered, non-GMP sources.

This type of drugs "which are produced at unregistered, non-GMP sources", if imported by means of bypassing registration procedure under misleading names like Crude & Feed Grade and then by minor purification are sold for use in drug formulations cannot be considered safe for use and can put patient at risk.

This fact is already recognized by CDSCO and the Guidance Document for Zonal & Port Offices (already on the website of CDSCO) on Page No. 403 states that *"The import of drug under dual use for purification or rendering it sterile will not be considered under dual use".*

As per all International guidelines (i.e. ICH, WHO, MHRA guidelines) drug molecules after N-1 step shall be prepared in GMP, therefore, it is very important for patient safety, that completely formed Drug molecules imported for further purification purposes shall not be exempted from provisions of Chapter III (specially registration requirement).

In view of the above in Schedule D under item no. 1 relating to substances not intended for medicinal use. It is proposed that under “extent and condition of exemption” the following clause may be inserted

“the exemption *excludes drugs imported for further purification only”.*

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

Recommendations

The members agreed that the exemption provided under Schedule D should not be used for bypassing registration procedure and import of crude and feed grade drugs which could be sold as drugs after minor purification etc. The DCC therefore recommended that

Schedule D may be suitably amended to exclude drugs imported as non-drug items for purely purification and marketing as drugs.

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL OF MAKING A PROVISION UNDER THE DRUGS AND COSMETICS RULES FOR PERMITTING RETAILS SALE OF MEDICINES ESPECIALLY GENERIC MEDICINES THROUGH MOBILE VANS

Shri Anil Desai, Member Rajya Sabha had written to the officer of DCG(I) to examine the feasibility of permitting retail sale of medicines through mobile vans so that the medicines could be made available to the needy patients in view of the sky rocketing prices of real estate.

The Commissioner, FDA, Maharashtra had also written to the office of DCG(I) that the escalating property prices in metros like Mumbai, it is becoming increasingly un-remunerative to open new drug dispensing retail outlets as the capital costs of such premises does not support the business module for sale of drugs. It was therefore suggested that drug dispensing may be permitted through mobile vans of appropriate sizes and these may be operated as “Mobile Drugs Dispensing Outlets” with certain stipulation like restriction of number of mobile vehicles in a geographical locality. Initially it may be permitted to sale generic drugs and subsequently extended to branded medicines at an appropriate time.

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

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.

AGENDA NO. 8

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES, 1945 TO MAKE A PROVISION OF UNBANKED DIRECTED BLOOD TRANSFUSION IN RURAL AREAS FOR EMERGENCY AND NEEDY PATIENTS

The Ministry of Health and Family Welfare received a representation from the Association of Rural Surgeons of India, Maharashtra for making a provision under the Drugs and Cosmetics Rules, 1945 for "Unbanked Directed Blood Transfusion" in rural areas because of the non-availability of blood in such areas. The scarcity of blood banks in rural areas and non-availability of safe stored blood in a reasonable time at affordable price results in loss of life due to the delays in the rural areas. Surgeons, obstetricians and other qualified clinicians now available in nodal villages are handicapped due to non-availability of blood. The association has therefore requested that the Drugs and Cosmetics Rules should be amended for making it convenient arrangement of blood transfusion for emergency and needy patients in rural areas who have no facility of blood banks. The blood for transfusion can either be made available through services of blood banks or can be taken from a donor after doing all the test and directly given to the patient without banking or storing. It is requested that the exemption granted to Armed forces medical services in Border areas, small mid-zonal hospitals including peripheral hospitals from the provision of taking blood bank licence subject to certain conditions may be extended to the rural areas also.

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

Recommendations

A power point presentation was made on the proposal to apprise the members. The Association of Rural Surgeon of India claimed that WHO guidelines specified that there is 31% deficit in the demand for blood at the National level while in rural and backward areas it is more than 80%. In view of this the Associations have requested that rural areas and small towns without blood banks should be permitted Unbanked Direct Transfusion of whole human blood. The facility will be under qualified physician and trained medical lab technician and under the supervision of designated licensed blood bank closest to the

facility. For this purpose exemption would be required to be provided under Schedule K of the Drugs and Cosmetics Rules, 1945 for permitting transfusion of blood in such centres which have adequate infrastructure facilities for collection testing and cross matching of blood.

The members after deliberations agreed that there is poor accessibility of blood in rural or remote areas. Certain exemptions as provided under Schedule K for Armed Forces Medical Services in Border areas could be extended to such centres provided it is consistent with the National Blood Policy and the centres are properly equipped to ensure safe blood transfusion in emergency cases and have facilities for testing and cross matching of blood. The exemption provided should simultaneously take care that there is no scope of misuse and the blood is collected for transfusion only.

AGENDA NO. 9

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES, 1945 TO MAKE PROVISIONS FOR PROVIDING EVIDENCE AND DATA ABOUT THE STABILITY OF THE DRUG PRODUCTS BY THE MANUFACTURERS

Conditions to be prescribed for "Stability of Products"

1. Since there is no requirement as a condition of license of proving that drugs are stable under recommended conditions of storage for other than Patent & Proprietary Medicine in Drugs & Cosmetics rules it can lead to unstable products being licensed in the country. As it is serious lacuna, it is very important to put it in rules. Therefore, it is proposed that in condition of license (s) to manufacture drugs it shall be clearly written "in rule 71, 71-B in rule 76 etc." that ----------" The applicant shall, while applying for license to manufacture drugs, furnish to the Licensing Authority evidence and data justifying that the drugs are stable for proposed shelf life under the condition of storage recommended. The data shall be generated as per Appendix IX of Schedule Y".

2. Secondly, as the long term stability conditions for India as published in WHO TRS 937 guidelines are as per Zone IV b i.e. 30ºC at 70% RH or 30ºC at 75 ± 5% RH, it is imperative to correct it in Appendix IX of Schedule Y, where long term conditions is mentioned as 30ºC ± 2ºC / 65% RH ± 5% RH for 12 months (which is not Indian Climatic Condition). Therefore, it is proposed that --------- In the Schedule Y, Appendix IX, Long Term Stability Conditions shall be prescribed as **;**

30ºC ± 2 / 70% RH OR **30ºC ± 2/ 75 ± 5% RH for 12 months instead of**

30ºC ± 2ºC / 65% RH ± 5% RH for 12 months

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

Recommendations

The members agreed that it is necessary that evidence and data of the stability of the drug products proposed to be manufactured by the licensee are required to be submitted to the regulatory authorities so as to ensure the stability of the drug formulations liceced in the country by the State Licensing Authorities. The DCC after deliberation agreed to the proposed amendments to the Drugs and Cosmetics Rules, 1945.

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AGENDA FROM STATES

ANDHRA PRADESH

1. **Specific prohibitory provisions in Section 18 and corresponding penal provisions in Section 27 of the Act are required for approved Drug Testing Laboratories**

There is no penal section provided in the Act for taking legal action against Approved Testing Laboratories in instances where these labs holding licenses under Form – 37 are found violating conditions laid down under Part XVI-A / condition laid down under the approval.

Rule Position: At present the approved laboratories licensed under Form 37 have to comply the conditions laid down under Rule 155-E of Drugs and Cosmetics Rules, 1945. The withdrawal or suspension of the approvals can be done by the approving authority as per Rule 155-K but not legal action against the laboratories, is feasible due to lack of penal section.

Amendment required: The prohibitory section under Drugs and Cosmetics Act i.e. Section 18 does not speak about the prohibition of illegal activity by approved laboratories licensed under Form-37. Hence Section 18 may be suitably amended to bring the activity of the approved institutions under the ambit of Section 18 of Drugs and Cosmetics Act 1940.

Recommendations

The Chairman informed the members that the Drugs and Cosmetics (Amendment) Bill, 2013 has already been introduced in the Rajya Sabha and has been referred to the Parliamentary Standing Committee of the Ministry of Health

and Family Welfare. The proposed amendment, if required, may be forwarded by the State Government to the Parliamentary Standing Committee for its consideration.

2. Specifying storage conditions (temperature range) on the labels of the drugs for better understanding to the consumers / dealers.

Though the conditions of the storage of a drug is of vital importance for preserving the potency of the drug throughout its storage conditions, there is no enabling provision in the Drugs and Cosmetics Rules 1945, prescribing the manner of labelling of the drug **with storage conditions indicating the specific temperature / range of temperature for the drugs not listed in Schedule P.** Because of this position, different manufacturers are labelling the same drug in different ways as " store below 25^0C " , " store in cool place ", " store under normal room temperature " etc. **Further these conditions are not conspicuously** printed on the label so as to clearly visible to the consumer / dealer who wants to comply the storage conditions at their end. And moreover in many times and in many places the temperature is above 25^0 C. The terms like "normal room temperature ", " general conditions " are not defined. The normal room temperature varies from place to place, season to season and there is a lot of variation in temperatures.

<u>Rule Position:</u> The **Rule 96(1)(vii)** reads that the drugs specified in **Schedule P** and their preparations including combinations with other drugs shall bear on their labels, the date of manufacture and the date of expiry of potency and the period between the date of manufacture and the date of expiry shall not exceed that laid down in the said schedule **under the conditions of storages specified therein**. Schedule P of the Drugs and Cosmetics Rules 1945 prescribed the storage conditions for certain drugs only in terms of cool place (between 10^0 and 25^0 C), cold place (not exceeding 8^0 C) and at normal room temperature. The

Indian Pharmacopeia, is a book of standards for drugs also mentioned storage conditions in some monographs only. But the manner of mentioning of storage conditions with specific temperature / range on the label of the drugs is not prescribed.

Amendment required: The Rule 96 of the Drugs and Cosmetics Rules 1945 is to be amended directing the manufacturer to print the storage conditions on the label with specific temperature / range in bold red letters to enable the consumer to understand the storage conditions properly. The general terms like " normal room temperature ", " general conditions ", " cool " and " cold " are to be avoided on the label. The Schedule P may be amended accordingly in a more specific manner.

Recommendations

The members agreed in principle that the storage conditions should be given on the label with the specific temperature range in bold letters for the benefit of the consumers. The DCC recommended that as the storage conditions are prescribed in Schedule P as well as Indian Pharmacopoeia. The India Pharmacopoeia Commission may be requested to examine the issues raised and give its recommendations in respect of providing storage conditions with specific temperature / range on the label and the amendments wherever required under the Drugs and Cosmetics Rules, 1945.

3. Approval of Fixed Dose Combinations for veterinary drugs

In view of the lack of comprehensive and consolidated list of approved FDCs for veterinary drugs, it is becoming very difficult for the state licensing authorities in approving the veterinary FDCs. The state licensing authorities are unable to assess the new drug status of the veterinary FDCs under these circumstances.

Rule Position: The Rule 122-E of the Drugs and Cosmetics Rules 1945 defines new drug under clause C of the Rule 122 E, a fixed doze combination of two or more drugs individually approved earlier for certain claims which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in already marketed combinations is proposed to be changed with certain claims fall under new drug category. It is applicable for both human and veterinary FDCs.

Clarification required: Clarification from DCG(I) is sought for approving veterinary FDCs by the state licensing authorities throughout the country.

Recommendations

Manufacturing licences for sale of fixed dose combinations which fall under the definition of the term 'new drug' can be granted provided the applicant has the approval in writing from the DCG (I) in favour of the applicant to manufacture the drug formulation.

In view of the above the State Licensing Authorities are required to direct the concern manufacturers to make an application to the office of DCG(I) for NOC to market the 'new drug' along with necessary technical data to prove its safety and efficacy.

4. **Transport offices and their godowns (railway parcel offices and their godowns) shall be brought under specific set of prohibitory provisions and corresponding penal provisions in the Act.**

There are no rules or guidelines in Drugs and Cosmetics Rules 1945 to be followed by transport agencies who are engaged in transport of drugs. Drugs remain stocked for longer time in transport agencies are not being stored properly thereby losing their potency. Many a time the spurious drugs, physician samples, drugs without proper documents which are seized from the transport

agencies and the investigation could not be proceeded further because of lack of details of the persons who booked and dealt with such drugs.

Rule Position: There is no rule or section in the Drugs and Cosmetics Act 1940 and Rules 1945 to monitor the activities of transport agencies who deal with the transport of drugs.

Amendment required: The Drugs and Cosmetics Rules 1945 is to be amended to incorporate a special rule to register or license the transport agencies by prescribing certain conditions of license to store the drugs properly during transport / stocking and to register the details of the persons who are booking the drugs for transport or persons who are dealing with the drugs through transport.

Recommendations

The members agreed that guidelines are needed to regulate the transportation of the drugs as not only the drugs are transported like ordinary commodities to the different regions having diverse climatic conditions, but also stored improperly by the transport agencies. Even proper documentation is not maintained by the transporting agencies. The DCC after deliberations decided to constitute a sub-committee to prepare guidelines and suggest amendment if any required under the Drugs and Cosmetics Rules, 1945 for regulating the transportation of drugs in the country. The committee shall consist of Director General, Drugs, Andhra Pradesh; Commissioner, FDCA, Gujarat; Drugs Controller, Himachal Pradesh; Drugs Controller, Odisha and Drugs Controller, Goa. Shri K. Bangarurajan, DDC(I), CDSCO, HQ, New Delhi will be the convener. The committee will submit its report within three months.

5. **Marketing of the drug products displaying the name of the firm as 'marketed by' or 'in associations with' in addition to the name of the manufacturer.**

Many market labels of the drugs products display the name of the firm as marketed by, in association with etc. in addition to the name of original manufacturer. This is misleading the consumer in regard to the name of the actual manufacturer of the products.

Rule Position: The labeling provisions laid down under Rule 96 and Rule 97 of Drugs and Cosmetics Rules does not expressly prohibit the labeling of drugs with the name of marketer along with the original manufacturer.

Amendment required: The Rule 96 may be suitably amended by prohibiting the labeling of drugs with the name of any manufacturer / marketer / promoter other than the original manufacturer of the product.

Recommendations

The members agreed that the names of the firm marketing a product sometime gives the impression that the product has been manufactured by the firm whose name appear in bold letters on the label, while it is not actually manufactured by the such firm. The DCC agreed in principle and recommended that a provision may be made in the rules that the label of the drug formulation should not contain any other information except what is required under the Drugs and Cosmetics Act and Rules or is required to be given in compliance to any other Act in force.

6. **Mentioning the batch number, expiry date and the name of the manufacturer on the cash / credit memo for all drugs**

The mention of batch No., Expiry date and name of the manufacturer is not mandatory for other than Schedule C, C1 and H drugs in the cash or credit memos issued for the sale of such drugs. Whereas the same details are to be

mentioned in cash or credit memos issued for the sale of Schedule C and H drugs as per Rule 65(3)(1) & 65(4)(1) of Drugs and Cosmetics Rules. Such discrimination is causing difficulty during the investigation of cases related to serious adverse reactions caused by the consumption of other than Schedule C and H drugs.

Rule Position: The Rule 65(3)(1)(f) & 65(4)(1)(e) direct the retailer to mention the name of manufacturer of the drugs, Batch No. and date of expiry of potency in a cash or credit memo issued against the name of drug supplied on prescription or without prescription as the case may be regarding the drugs of Schedule C and H drugs.

Amendment required: The Rules 65(3)(1) and 65(4)(1) under the Drugs and Cosmetics Rules 1945 may be suitably amended for mentioning the details of the name of manufacturer of the drugs, Batch No. and date of expiry of potency in a cash or credit memo issued against the sale of any type of drug whether it is on prescription or without prescription.

Recommendations

The DCC agreed that necessary amendments may be made under the Rules so that the details of the name of the manufacture, batch number and date of expiry is mentioned on the cash / credit memo for all drugs.

GOA

1. **Consideration of the question of Role of State LA in clinical trials, clarification is needed as regards the exact role of State enforcements in monitoring of Clinical Trial**

The circular no. 14-33/2010-DC/DFQA(Pt) dated: 23/05/2012 from Government of India; ministry of Health and family Welfare; states, that, the State Drugs Controller under the State Health Departments shall constitute a cell under a nodal officer-in charge whose particulars and contact number would be made available to the office of DCG(I); for quick exchange of inspection.

Same point was also included in the Agenda Note for discussion during the meeting of Secretary Health and Family Welfare with the Chief Secretary/ Health Secretary of the State / UT on 13th August 2013 at Nirmana Bhavan to discuss all facts and aspects concerning the legal frame work for strengthening the regulation of clinical trials and other incidental matters;

Further Rule 122 DAC; inserted under notification no. GSR 63(E) dated: 01/02/2013; at sub rule (g) it is stated, that, the premises of Sponsor including their employees subsidiary and branches their agents contractors and sub-contractor and clinical trial sites shall be open to inspection by the Officers authorized by the Central Drugs Standard Organisation, who may be accompanied by an Officer of the State Drugs Control Authority concerned. Other than as stated above, the exact role of State Drugs Controller in monitoring the clinical trials is not specified.

A guideline in this respect may be issued.

Recommendations

The role of State Licensing Authorities had already been discussed in the meeting of the Chief Secretaries / Health Secretaries of the States Governments and administration of the Union Territories with the Secretary, Health and Family Welfare, Ministry of Health and Family Welfare on 13.08.2013. The Drugs and Cosmetics Rules, 1945 were amended vide G.S.R. 63(E) dated 1st February, 2013 introducing rule 122DAC relating to permission to conduct clinical trials.

Under the rule it was provided that Investigator, Sponsor including his representatives shall be open to inspection by the officers authorised by CDSCO who may be accompanied by an officer of the State Drug Control Authority concerned. During the meeting of Chief Secretaries / Health Secretaries of States with the Secretary (HFW), the issue of making compulsory participation of the State Drug Inspectors in clinical trial inspection by amending the word 'may' to 'shall' in the above said provision of rule 122DAC was raised.

The matter was deliberated in the DCC meeting and the members were of the view that the present provision is adequate and the amendment of the word 'may' to 'shall' in the provision is not considered necessary in the present circumstances.

2. Clarification required whether the drugs manufactured for export market with other than I.P. specifications; but, which are official in I.P. can be used for local market

Many times a request is received stating that, the products manufactured for export market; which are official in I.P.; but were manufactured with other than I.P. specifications; are to be diverted to local market; due to cancellation of export order.

Clarification is required, whether such request can be considered.

The situation to be considered will be

a) When the product has already left the factory.
b) When the product has not left the premises. If the party prepares the SOP for such an activity; files a deviation; and prepares to re –labels the product as per I.P. for domestic market.

Then, can the request be considered.

Recommendations

The DCC recommended that the issues related to permitting marketing of the drugs manufactured for export are required to be examined on case to case

basis. The licensing Authority shall, however, ensure that drugs marketed in the country comply with the provision of the Drugs and Cosmetics Rules, 1945 in respect of the sale of drugs in the market.

3. Consideration of question of permitting FDC formulations of paracetamol containing 500mg per tablets, which are being sold as OTC products for indication which are other than pain medication prescription based products:

The office of DCG(I) vide their letter dated 23/09/2011 address to all State Drugs Controllers and also subsequent clarification issued vide letter dated: 04/04/2012; wherein it is clarified by your office that the restriction of limiting of contents of paracetamol to 325mg is applicable to prescription products only.

It is seen that the IDMA organization had filed a representation before your Office seeking further clarification on the above limitation of paracetamol as applicable to others paracetamol products indications, including other than combination for pain medication products. There are several products available in market which are sold as OTC products as mentioned below; and which are meant for indication other than pain medication prescription based products.

1) <u>DCOLD TABLETS</u>
Composition:

Each uncoated tablets contains:

Paracetamol I.P.	…..500mg
Caffein Anhydrous I.P.	….32mg
Phenylephrine HCl I.P.	….10mg

2) <u>VICKS ACTION 500</u>
Composition:

Each uncoated tablets contains:

Paracetamol I.P.	…..500mg
Phenylephrine HCl I.P.	….10mg
Caffein Anhydrous I.P.	….32mg

3) CROCIN COLD & FLU MAX

Composition:

Each uncoated tablets contains:

Paracetamol I.P.	…..500mg
Caffein Anhydrous I.P.	….32mg
Phenylephrine HCl I.P.	….10mg

In the light of the above clarification issued vis-a-vis the OTC products being manufactured and marketed across the country as mentioned above and which are containing Paracetamol as 500mg per tablets, it is requested to kindly advise whether such formulations for similar action as mentioned above, which are OTC products can be permitted to the manufacturer in the strength of 500mgs.

The question that needs to be clarify , whether such OTC products having indications other than pain medication based products can be permitted to contain Paracetamol 500mg instead of 325mg as stated in DCG(I) s circular.

Recommendations

It was informed that DCG (I) has already issued clarification that lowering of the Paracetamol content to 325 mg is applicable to the combination of the Paracetamol with other analgesic/anti-inflammatory drugs.

HIMACHAL PRADESH

1. **Tracking of the movement of raw materials used in the manufacture of drugs**

   To stop the misuse of the drug formulations, it is necessary that there should be provision for tracking of the movement of the raw materials used in the manufacture of the drugs, maintenance of manufacturing records as well as sale records

   Recommendations

   The DCC agreed that to check the misuse of the drug formulations it is necessary to prepare guidelines for tracking the movement of raw materials used in the manufacture of drugs. The DCC after deliberations constituted a sub-committee to prepare the guidelines for tracking the movement of raw materials used in the manufacture of drugs. The members of the committee were Drugs Controller, Himachal Pradesh; Drugs Controller, Odisha; Drugs Controller, Punjab and Director Food and Drug Administration, Goa. 3. The committee will submit its report within three months.

2. **Manufacture, distribution and sale of phenylpropolamine and its preparations in the light of the stay by Hon' ble Madras High Court may be clarified so that further action is taken accordingly.**

   Recommendations

   The members were informed that the Government of India had filed a petition in the Hon’ble High Court of Madras for the vacation of the stay. The matter is subjudice.

ODISHA

1. **Amendment in condition of licences / loan licences to manufacture / repack for sale of drugs / cosmetics / to operate blood bank for processing of whole human blood and / or preparation for sale or distribution of its components or approval for carrying out tests on drugs / cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture of drugs / cosmetics:**

   Condition 2 of licences in Form 25, 25A, 25B, 25C, 32, 32A and condition 3 of licences / approval in Form 25F, 28, 28A, 28B, 28C, 28D, 37 may be suitably amended as followed-

   For forms other than 37: Any change in the competent technical staff named in the licence / appointment of additional technical staff shall be reported to the Licensing Authority within seven days of such change / appointment.

   For Form 37: Any change in the analytical staff or in the person-in-charge of the testing / appointment of additional analytical staff shall be reported to the Approving Authority within seven days of such change / appointment.

   Recommendations

   The DCC after deliberations agreed that the clause relating to change in the competent staff under the conditions of the licence may be amended to qualify that the change shall be reported to the Licensing Authority within seven days of such change or appointment.

2. **Licence Fee for number of items of Homoeopathic Medicines for manufacture for sale of may be specified under Rule 85B:**

   The fee structure for a specific number of items of Homoeopathic medicines to be manufactured for sale (as specified to be 10 items for allopathy medicines) may be specified for Homoeopathic Mother Tinctures, Homoeopathic Potentised

Preparations. Further, Homoeopathic Medicines may also be categorized for Patent and Proprietory preparations for oral use, Patent and Proprietory preparatios for external use, Biochemic Tablets, Eye Drops etc. and licence fee may also be fixed for such category Homoeopathic medicines **(As per Para 3 of Schedule M-I).**

Recommendations

The Department of the AYUSH, Ministry of Health and Family Welfare is the nodal authority for making recommendations in respect of Homeopathic medicines under the Drugs and Cosmetics Rules, 1945. The proposal will be forwarded by the office of DCG(I) to the said department for their consideration.

3. **Amendment in conditions of licences to be incorporated in the body of Form 20-B, 21-B, 20-G:**

A time of one month may be fixed for reporting of change in Competent Person for wholesalers and the conditions which are reflected on the body of licences may be accordingly amended as follows.

> "The licensee shall report to the Licensing Authority any change in the Competent Person within one month of such change."

Recommendations

The DCC recommended for the Necessary amendment as suggested.

4. **Conditions to be satisfied before a licence in Form 20B, 20G and 21B.** The educational qualification to act as a Competent Person may be fixed to be a Registered Pharmacist only. Other qualification / experience may not be considered (Rule 64).

Recommendations

The proposal required wider consultation with the stakeholders.

5. **Signature of registered pharmacist may be incorporated on the cash / credit memo and steps may be taken for necessary amendment in Rule 65(4) (3)(i).**

   Recommendations

   The DCC recommended for the Necessary amendment as suggested.

6. **The Amendment in the condition 3(ii)(b), 4(ii)(b) and 5(b) of licence in Form 20B, 21B, and 20G respectively towards supply of drugs to hospitals & others as follows:**

   "a hospital / clinic run by R.M.P. / Nursing home (registered under clinical Establishment Act & rules thereunder), educational & Research institution against a valid written order signed by the R.M.P. / Head of the Department of educational / Research Institution."

   Recommendations

   The DCC recommended for the Necessary amendment as suggested.

PUNJAB

1. **Rule 122-G(2) of the Drugs and Cosmetics Rules, 1945 which requires the approval of State Blood Transfusion Council Blood situated inside the Charitable Hospitals.**

As per rule 122-G(2) application for grant or renewal of a license for operation of Blood bank or processing of human Blood Components shall be made by the Blood Banks rub by the government, Indian Red Cross Society, hospital, Charitable trust or voluntary organizations approved by the State or Union Territory Blood transfusion council only.

So, the blood bank run by charitable trust or voluntary organization approved by State Blood Transfusion Council can apply for the blood bank license and clarification in this regard was sent by DCG(I) office vide letter f No. CLA/B&BP/Misc/06/2012-D dated 28.06.2013 to NBTC New Delhi.

The Blood Banks run by the Government, Indian Red Cross Society and hospitals does not require the approval of State Blood Transfusion Council. From this rule, it is not clear that whether blood banks run by charitable trust or voluntary organization situate inside the charitable trust or voluntary organization situated inside the charitable trust or voluntary organization hospitals require the approval of State Blood Transfusion Council or not. DCC should decide that whether approval of State Blood Transfusion Council is required or not for the blood banks run by the charitable trust or voluntary organization inside their hospitals.

Recommendations

The members were informed that application for grant of licence to operate Blood Bank attached to a hospital do not require to submit the approval of the State Blood Transfusion Council.

2. Guidelines for taking action on Samples of Drugs Declared Spurious or not of Standard Quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008.

Under category B (Grossly Sub-standard drugs) the defect regarding tablets and capsules failing in disintegration test and dissolution test are mentioned in category B for which prosecution is recommended. Sometimes the samples fail for minor variations in the time of disintegration test and dissolution test. In the previous guidelines approved in 1993, theses defects were mentioned except for marginal variations to be viewed on case to case basis.

Drugs consultative committee should decide that whether the samples failing with marginal variations in the disintegration test and dissolution test requires prosecution or administrative action under rule 85(2) of the Drugs and Cosmetics Rules, 1945.

Recommendations

The members opined that the issue will be considered while revising the present guidelines for taking action on Samples of Drugs Declared Spurious or not of Standard Quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008.

HARYANA

1. **Status of Dextroproxyphene and its formulations put under form 15 (Non disposal) after notification dated 23.05.2013.**

   Recommendations

   The members were informed that the suspension of the Dextroproxyphene and its formulations suspended under Section 26A of the Drugs and Cosmetics Act, 1940 is being reviewed by the DTAB to examine the safety issues involved and likely risks to human being with their use. The recommendation of the DTAB would in turn will be forwarded to the Ministry of Health and Family Welfare for further consideration.

2. **There is no from provided for grant of loan license for medical devices (CLAA items) having provision for CLAA signature The form for grant of loan license for LVP having provision of CLAA signature has been added by RECENT amendment in the drug rules, similar amendment for medical devices (CLAA items) needed.**

   Recommendations

   The members were informed that the Drugs and Cosmetics (Amendment) Bill, 2013 has been introduced in the Parliament. It has a separate chapter for regulation of medical devices. The detailed provisions would be incorporated under the rules in accordance to the amendments made in the Act by the Parliament. However, specific issue of loan licence for medical devices would be examined in consultation with experts for making necessary changes in the rules.

3. **Presently test license on form 29 is issued for manufacture of drugs for test, analysis, and examination purposes (not for conducting bioequivalence**

studies / clinical trials). Whether the license on form 29 can be allowed for manufacturing of bio batches of medicines for performance of bioequivalence studies in their facilities. In our views these plants must be GMP / Schedule M certified for manufacturing of drugs for bio batches.

Recommendations

Biological drugs like vaccines and r-DNA products are considered as new drugs under rule 122E and require permission from the office of DCG(I) for their manufacture. The manufacturing facilities are required to be GMP compliance for manufacture of the biological drugs proposed to be manufactured in the facility.

4. **Requirement of fresh approval from State Blood Transfusion Council in cases of existing licensed blood banks undergoing change in premises / change in constitution.**

   Recommendations

   It was clarified that fresh application would be required in such cases.

5. **Suspension / cancellation of drug licence of licensed firms found violating various provisions of Drug Rules for CLAA items by CLAA. Cases are referred by the o/o DCG(I) for suspension / cancellation of such licensee for CLAA items to the SLA after joint inspection. It would be appropriate if PUNITIVE action is taken against CLAA licensee for the detected violations by CLAA instead of SLA.**

   Recommendations

   Under the Drugs and Cosmetics Rules, 1945 even in the case of CLAA items, the State licensing Authority after being satisfied that the applicant is in a position to fulfill the requirements laid down in the rules forward the duly completed licence to

the Central Licence Approving Authority. In view of this it is appropriate that punitive action is taken by the State Licensing Authority.

6. **Whether the products manufactured by licensed firm under any brand name(s) is legal after seeking permission under generic name.**

   Recommendations

   The issue was discussed in detail in the last DCC meeting held on 4th & 5th February, 2013.

7. **Whether firm licensed to manufacture products under brand names prior to 01.10.2012 can manufacture all its approved branded formulation under generic names without seeking fresh approvals from appropriate authorities.**

   Recommendations

   The manufacturer would be required to seek approval from the concerned authority.