MINUTES OF THE WHO WORKSHOP ON DISSEMINATION OF INFORMATION ON REGULATORY AFFAIRS, (39TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE) HELD ON 10TH DECEMBER, 2008 IN THE COMMITTEE ROOM, FDA BHAVAN, KOTLA ROAD, NEW DELHI – 110002.

(List of Participants is at Annexure I)

Inaugural Deliberations

WHO Workshop on Dissemination of information on regulatory affairs, (39th Meeting of the Drugs Consultative Committee) was held on 10th December, 2008 in the Committee Room, FDA Bhawan, Kotla Road, New Delhi-110002. Shri Debasish Panda, Joint Secretary Ministry of Health and Family Welfare also attended the meeting.

Dr. Surinder Singh, Drugs Controller General (India) and Chairman, Drugs Consultative Committee (DCC), welcomed the State Drug Controllers and thanked them for sparing time to attend this august meeting. He stated that the need of the hour is to have world class drug regulatory infrastructure in the country both at Central and State level. The world is looking towards India as major Pharmaceutical producer. Indian Pharmaceutical market accounts for 1 to 2% of global pharmaceutical market in terms of value and 8% in terms of volume. In 2007, the growth of Indian Pharma Industry was around 12%. We are manufacturing drugs worth 60 thousand crores (approx.) annually. In the field of high tech vaccines country exports vaccines worth Rs. 1500 crores (approx.) and 16 vaccines are pre qualified by WHO for purchase for global distribution under its programmes.

In the last one year or so concerted efforts at the centre has resulted in creating state of art facilities at CDSCO Hqrs. A National Regulatory Authority (NRA) assessment in respect of regulatory control over the vaccines manufactured in the country was conducted by WHO in the year 2007 and various measures to strengthen the regulatory system are still in progress. An appropriate documentation system for quality assurance for vaccines has been developed with the help of Health Canada through the good offices of WHO. The Hqrs. of CDSCO has shifted to the new spacious building, Food and Drug Bhavan, Kotla Road, New Delhi. About 46 Technical Data Associates have been recruited on temporary basis for smooth and efficient functioning of the organization. The website of CDSCO provides vital information to the industry and regulatory authorities. This is updated regularly to provide current information about the activities carried out at CDSCO. USFDA has shown keen interest in Indian regulatory system especially in the field of medical devices, clinical trial oversight & GCP, Pharmacovigilence and IT enabled services. Workshops have been conducted in CDSCO in collaboration with USFDA on clinical research and medical devices in India. More such workshops are planned in future also.

It is proposed to regulate clinical trials in the country and initiate registration of clinical research organizations to ensure that the research conducted in the country is as per international standards and is recognized all over the world. At present only ten categories of medical devices are being regulated under the Drugs and

Cosmetics Act. It is now proposed to regulate the quality of all medical devices in the country under the said Act and regulations for this purpose are being developed ensuring that these are harmonized with GHTF guidelines for introduction in the country.

The other area of concern is the prevalence of spurious drugs in the country. It is an emotive issue and a public health concern. However, no authoritative information about the extent of menace is available. In order to assess the extent of spurious drugs, a countrywide survey is being conducted by collecting about 31 thousands samples of 62 brands from different regions and stratum in the country. This would help in having a targeted approach to eliminate the ,menace of spurious drugs in the country.

The Chairman stressed that in the above scenario, it is necessary for the States to acquire new skills, strengthen their infrastructure to keep pace with the development taking place in the country. The Central Government could provide training to the regulatory officials to sharpen their skills and widen their knowledge. Capable persons could be considered for training abroad in specific fields of their operations.

Shri Debasish Panda, Joint Secretary, Ministry of Health and Family Welfare in his address to the committee stated that the world is looking towards India for health care needs both in the developing and developed countries because of production of quality drugs at affordable prices. It is emerging as major partner in the production of Pharmaceuticals in the world. State drug regulatory authorities will also have to come up to the high level regulatory set up both in terms of infrastructure and motivation to make quality control effective in the country in real terms. The present scenario of inadequate testing facilities, irregular inspections of sale and manufacturing premises and few convictions in the Court cases paints a dismal picture. The inspections of manufacturing premises are required to be done in a more professional manner to ensure that they are GMP compliant and errants are taken to task. The court cases should be pursued more vigorously for better results. The human resources are also required to be strengthened, trained and motivated to have impact on the quality of drugs manufactured in the country.

The Central Government has been able to get 62 new posts of Drug Inspectors and 10 posts of Technical Officers for CDSCO. The vacant posts of Drug Inspectors, DDC (I)s and others are being filled on priority basis. The proposal for creation of Central Drug Authority is in the Parliament. The creation of the authority would further provide powers to the regulatory authorities for effective quality control in the country. Similar efforts are required to be done at State level to convince the authorities about the essentiality of a robust drug regulatory system.

The Drugs and Cosmetics Act has been amended recently by the Parliament to enhance penalties for manufacture spurious and sub standard drugs with fine up to Rs.10 lakhs. Offences relating to adulterated and spurious drugs have been made cognizable and non bailable. Provision for speedy trials has also been provided. Concept of compounding of offences has also been introduced. It is however, necessary to draw guidelines for taking action under the new Act before it is implemented to ensure that the genuine manufacturers or sellers are not harassed.

The regulatory authorities are required to have transparency, openness and desired level of competence for bringing credibility to the system. States should also come up with their websites which should be user friendly. There should be proper data management and vital information in respect of licenses and activities of the regulatory authorities like inspection, action taken, prosecutions etc. should be stored electronically and this information should be available for sharing with other States and Central Government.

JS(DP) further stated that the Central Government would consider favourably any proposal for assistance to strengthen the infrastructure and testing facilities in the States.

After interaction with the members he suggested that following committees may be constituted to discuss the major issues before DCC for their in-depth deliberations and recommendation which would then be considered by the Central Government for further action on these matters.

1. Sub-Committee on identification, collection and exchange of data through the internet or intranet between the States or Centre and the States.
2. Sub-Committee to examine suggestions of amendments to the Drugs and Cosmetics Rules placed before DCC and suggest comprehensive proposal for the amendments.
3. Sub-Committee for preparing proposal for financial assistance required for strengthening of State Drug Control Organization to meet the challenges of present day needs for regulatory control over drugs.
4. Sub-Committee on spurious drugs with preparation of guidelines for implementation of Amendment 2008 to the Drugs and Cosmetics Act as one of the terms of reference.
5. Sub-Committee to recommend measures to enhance testing of drugs in the country by optimising the available capacities for testing and suggest mechanism for outsourcing and testing of drugs at private labs.

The list of the members of these committees and their terms of references are at **Annexure II.**

The Committee then took up the regular agenda for discussion.

CONFIRMATION OF MINUTES OF THE 38TH MEETING OF DRUGS CONSULTATIVE COMMITTEE HELD ON 4TH JUNE 2007 AT NEW DELHI.

The minutes of the 38th meeting of the Drugs Consultative Committee were confirmed and Action Taken Report approved.

The Action Taken Report is placed at **annexure III.**

AGENDA ITEMS AND RECOMMENDATIONS OF THE 39TH DRUGS CONSULTATIVE COMMITTEE

(CENTRAL AGENDA ITEMS)

AGENDA NO. (1)

TESTING OF STATUTORY DRUGS SAMPLES DRAWN BY STATE DRUGS INSPECTORS BY THE STATE DRUG TESTING LABORATORIES INSTEAD OF CENTRAL DRUG TESTING LABORATORIES

The central Drugs testing laboratories have been testing statutory samples sent by the State Drug Inspectors as Government analysts to assist the State Drug Control Organizations for testing of drugs in the country because of inadequate testing facilities available in some of States. However, it has been reported that the Central Drug Testing Laboratories are pre-occupied with the other statutory testing of drugs especially samples of new drugs and samples sent by port offices of CDSCO. The CDL, Kolkata also Acts as appellate authority for most categories of drugs. The Central labs are therefore, finding it difficult to test samples received from State Governments and issue test reports in time.

The Government of India under the Capacity Building Programme had provided assistance to the State Governments for establishing/strengthening State Drug Testing Laboratories in terms of civil infrastructure, equipments, manpower and training to the technical personnel. The aim of the project was to make State Drug Testing Laboratories self sufficient and meet the complete requirements of the respective State Governments in respect of testing of drugs. In view of this, the Central Drug Testing Laboratories were therefore, asked to request the State Governments to stop sending samples to these laboratories except in exceptional circumstances.

The office of DCG (I) has been receiving request from certain State Drug Controllers for allowing their routine samples to be tested by the Central Drug Testing Laboratories. As the testing infrastructure in most of the States has been strengthened, the spare capacity available in certain State laboratories may be utilized for testing routine statutory samples by other States wherever necessary.

DCC may kindly deliberate and develop guidelines for the purpose.

RECOMMENDATIONS

Shri N.C. Dhawan, DDG, briefed the members that the time has come when the State Drug Regulatory System should be self sufficient in respect of testing of drug samples drawn by the State Drugs Inspectors. Dependence on the Central Laboratories for testing of routine samples has to be minimized because of the pre occupation of these laboratories in testing appellate samples and other samples sent by the Central Drugs Standard Control Organization. Some of the States have developed well equipped laboratories for testing of drugs and other States should also likewise make efforts for upgrading their testing facilities. In the present circumstances the States deficient in testing facilities may take the help of such laboratories for testing samples of drugs drawn by their Drug Inspectors.

Shri Debasish Panda, Joint Secretary, Ministry of Health desired that ways and means to utilize the capacity available with the private testing labs may also be explored to enhance the testing capacity of the country so that the samples are tested in time and reports made available for quick action on the reports of drugs found not of standard quality. If required Drugs and Cosmetics Rules could be amended for the purpose and the committee may suggest specific amendments in the matter. He further suggested that the possibility of further strengthening of the State Drug Testing Laboratories, through the Central assistance, could be considered if the concrete proposals are submitted for consideration.

In view of the suggestions of the Joint Secretary, the committee decided to set up a sub-committee to look into the issue of testing of drugs in the country in broader perspective with Dr. G.N. Singh, Member Secretary, IPC, Ghaziabad as its convenor. The composition and the terms of reference of the committee are at annexure II - A.

The question of providing financial assistance to the state Drug Control Organizations for upgrading their infrastructure would be examined by another sub-committee with Shri N.C. Dhawan, Deputy Director General (Drugs) as its convenor. The composition and the terms of reference of the committee are at annexure II- D.

AGENDA NO. (2)

PHASING OUT OF ORAL SINGLE DRUG FORMULATIONS OF ARTEMISININ AND ITS DERIVATIVES FROM THE MARKET ON THE RECOMMENDATIONS OF WHO

The office of DCG (I) had earlier approved various anti malarial formulations of Artemisinin derivatives like artesunate, artemether, arteether for marketing in the country. As the drug is no longer considered as a new drug, permission for manufacture for sale of these drugs is at present being granted by the State Licensing Authorities. Artesunate and artemether have been approved both in injectable form as well as oral tablet/capsule form while arteether is approved in injectable form only. Currently many firms are manufacturing various formulations of artemisinin derivative in the country.

Various artemisinin based combination (ACT) products like artesunate + sulphadoxine – puirithamine, artemether + lumefantrine, artesunate + mefloquin have also been approved by this Directorate for marketing in the country.

WHO has recommended withdrawal of oral artemisinin based monotherapies from the market to ensure that malaria parasite does not become resistant to the drug. It recommends the use of artemisinin in combination with other effective anti-malarial as artemisinin based combination therapy (ACTs) for the treatment of uncomplicated falciparum malaria. In a high level meeting held on 13-14 October, 2008 at WHO regional office for South East Asia Region, New Delhi on anti-malarial treatment it has been recommended that the State Licensing Authorities should withdraw the manufacturing licences and export licenses for marketing oral artemisinin monotherapies in a period of 6 months i.e. by July, 2009, as finished formulations.

In view of the above recommendations and to ensure that artemisinin derivatives remain effective in the treatment of resistant malaria, the State Licensing Authorities should not grant any new manufacturing license or renew any licence for marketing oral artemisinin monotherapies and withdraw the permissions granted to manufacturers under their jurisdictions for marketing artemisinin monotherapies within a period of six months.

DCC may kindly deliberate and formulate roadmap for the implementations of the recommendation.

RECOMMENDATIONS

Shri A.K. Pradhan, ADC (I) briefed the members that artemisinin derivatives, artesunate and artemether were approved for manufacture and marketing both in injectable form as well as tablets/capsule form and are being marked in the country by various manufacturers. In order to ensure that malaria parasite does not become resistant to the drug, WHO has recommended for the withdrawal of oral artemisinin based mono therapies from the market. It has further recommended the use of artemisinin in combination with other effective anti-malarial as artemisinin based combination therapies (ACTs) for the treatment of uncomplicated falciparum malaria.

The members after deliberations agreed that oral single drug formulations of artemisinin derivatives like artesunate and artemether should be withdrawn from the market in a phased manner and the following steps may be taken for the purpose.

(i) **No new licence should be granted for the said formulations.**

(ii) **Manufacturing licences granted earlier should be withdrawn by March 2009.**

(iii) **The formulations should be phased out from the market by July 2009.**

(iv) **DCG (I) office should issue directive to all State Drug Controllers in the matter for uniform compliance in the country.**

AGENDA NO. (3)

PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES TO REGULATE IMPORT, MANUFACTURE AND SALE OF MEDICAL DEVICES IN THE COUNTRY

(A) Control over the quality of 10 notified categories of medical devices, imported and manufactured in the country is exercised under the Drugs and Cosmetics Rules, 1945. The quality of notified medical devices imported into the country is being regulated by the CDSCO through its port offices and through the process of registration and licensing. It is however, observed that many of the devices, covered under the notification, are still being manufactured in the country without any manufacturing license in the country. As these products have been notified as drugs and their manufacture without a valid drug licence is considered as violation of the Drugs and Cosmetics Rules, 1945, it is therefore, requested that State Drug Control Authorities may take appropriate steps to ensure that these products are manufactured under a proper valid licence granted under the said rules.

(B) The medical devices are being regulated in most of countries to ensure that these are of standard quality and conform to the claims made for them and the manufacturers follow quality management systems and conformity assessment procedures for the devices marketed by them.

The Government of India has therefore, considered that it is necessary to regulate the quality of medical devices imported and marketed in the country to be brought under the purview of the Drugs and Cosmetics Act, 1940 and to harmonize the regulations related to these devices at par with the global standards. As medical devices do not have pharmacological action, like drugs, for cure, mitigation and prevention of disease but act as support systems in the intended functions, a separate set of rules for regulating their manufacture, sale and quality of the products marketed are required to be incorporated in the said rules. A detailed guidelines on the requirements for manufacture, import and sale of medical devices that are required to be incorporated in the Drugs and Cosmetics Rules are annexed.

DCC may like to deliberate on the proposed amendments and give its recommendations in the matter.

RECOMMENDATIONS

The members were briefed that the Central Government is now proposing to regulate import, manufacture and sale of all medical devices in the country. For this purpose the Drugs and Cosmetics Act is also being amended and a general scheme of the regulatory requirements which may be required to be incorporated under the Drugs and Cosmetics Rules has been circulated to the members. It is proposed to categorise the medical devices in four categories i.e. A, B, C and D depending upon the risk factor involved in the use of the devices. The regulatory control over medical devices would be under the purview of CLAA scheme. The conformity assessment procedures,

Forms for applications and licences etc. would be provided under the rules for exercising proper regulatory control over medical devices.

The members were further requested to examine the proposed guidelines and give their inputs within six weeks so that these could be incorporated in the proposed amendments to the rules for further consideration of the matter by DTAB.

It was also pointed out that certain medical devices, which are covered under the ten notified categories are still being manufactured in the country without manufacturing licence under the Drugs and Cosmetics Rules. The members were therefore, requested to take action through advertisements or manufacturers' associations to request the manufacturers of medical devices which are covered under notified categories to obtain licences under the Drugs and Cosmetics Rules, failing which stern action may be taken against such manufacturers as provided under the law.

The members agreed to take up the matter at State level to ensure that unlawful manufacture of notified medical devices is not permitted to be continued.

AGENDA NO.(4)

GRANT OF WHO GMP CERTIFICATES BY THE STATE LICENSING AUTHORITIES

WHO in its guidelines provides that WHO GMP certificates are required to be issued by the central drugs regulatory authority. It has been brought to the notice of the office of DCG (I) that certain State Licensing Authorities are issuing WHO GMP certificates for which they do not have any authority. Further it is not clear whether such certificates were issued on the basis of Joint Inspections carried out by the Central and State Drug Inspectors.

Grant of WHO GMP certificates by the State Licensing Authorities is a violation of WHO GMP norms, it is therefore, requested that such certificates if granted may be withdrawn immediately and the manufacturers asked to follow the proper procedures for obtaining WHO GMP certificates. It may be further added that use of such certificates for the purpose of advertisement and claiming the unit as WHO approved unit should also be desisted.

DCC may kindly deliberate the issue for uniform implementation.

RECOMMENDATIONS

DCG (I) brought to the notice of the members that instances have come to the notice of the Central Government that certain State Licensing Authorities are issuing WHO GMP certificates for which they do not have any authority. Such certificates are required to be issued by the Central Government after following the due procedures of Joint Inspection by the Central and State Drug Inspectors.

The Committee recommended that WHO GMP certificates should be issued only after following the due procedures as laid down by WHO.

AGENDA ITEMS FROM STATES

MAHARASHTRA

AGENDA NO.5

Certain samples are denied for analysis by Central Drug Laboratories as required under Rule 25.

The reports of Govt. analyst are challenged by parties. Under the circumstances the courts send the sample to Director, CDL, under Sec. 25(4) for analysis. It is mandatory and obligatory on the part of Director CDL to test or analyse the sample and to forward report in writing signed by Director, CDL as per provisions of Sec. 25(4) and Rule 4.

However due to lack of facility CDL has not tested following samples sent under Sec. 25(4) and the samples were returned to Hon'ble Court.

i) Lactulose solution USP/Microlac solution, B.No.L70302, Exp. 28/02/09, Micron Pharmaceuticals, Vapi, Gujarat.
Sample No.04 of 2008 in Misc. Application 107/M/2008
Metropolitan Magistrate Court 15, Mazgaon, Mumbai.

ii) Oxygen Gas, Batch No. 149; M/D – 29.5.06; Exp dt. 5 years from filling Mfgd by M/s Nobel Fire Fighting Industries, Bhyander (W), Thane (M.S.)
Sample under Misc. Application 07/M/2007
Metropolitan Magistrate Court 15, Mazgaon, Mumbai, Mumbai.

Under the circumstances, the important right of Accused is not exercised and gets affected. The Accused gets the advantage/benefit and the case may be discharged by the Magistrate.

Therefore it is necessary to get the sample tested by CDL by generating the analytical facilities.

RECOMMENDATIONS

Commissioner, FDA, Maharashtra stated that there are instances where the Central Drug Laboratory, Kolkata delayed testing of court samples also. In the two cases cited in the agenda notes, samples were returned to the Hon'ble court because the lack of facilities at CDL. In such circumstances the right of accused is not exercised and justice gets affected. The accused gets the advantage and the case may be discharged by the magistrate.

Director CDL informed that in certain cases the method of analysis has to be obtained from the manufacturer and this causes delay in testing. Large number of samples received from States puts heavy load on testing facilities at CDL and samples are not tested in time.

The Committee after deliberations recommended that as the question of enhancing the testing capacity in the country is being examined by the sub-committee at annexure II, the difficulties of State Licensing Authorities and laboratories in the matter may be considered by the sub-committee for its recommendations.

AGENDA NO.6

TO ALLOW REGISTERED PHARMACIST ONLY AS COMPETENT STAFF FOR GRANT OF WHOLESALE DRUG LICENSE

In Drugs and Cosmetics Act 1940 and Rules:-

Rule 64 – Conditions to be satisfied before licences in 20B, 21B granted (Wholesale licences)...

In First Proviso – clause (ii) – in charge of a competent person, who –

a) is a registered pharmacist, or
b) has passed the matriculation examination or its equivalent examination from a recognized Board with the four years' experience in dealing with sale of drugs, or
c) hold a degree of recognized university with one year's experience in dealing with drugs is defined. This provision was suitable when there were scarcity of pharmacist's in the country. But now a day's ample pharmacist's available and the Pharma business is taking new shape in Global business: Under such circumstances (b) & (c) are inadequate and all wholesale pharma sale should be executed by or under supervision of Registered Pharmacist only. Therefore, necessary changes are to be made in the said rules.

RECOMMENDATIONS

Commissioner, FDA, Maharashtra proposed that Rule 64 relating to the qualification of competent person for wholesale licence may be amended to allow registered pharmacist only as competent staff.

The members after deliberation opined that the agenda item has being considered earlier also and it was felt that while adequate number of pharmacists are available in urban areas there is a paucity of registered pharmacists in the interiors and far flung areas. Further such a move may prove counterproductive as it might affect the availability of drugs in these areas through proper channels.

DCC recommended that the status quo may be maintained in the matter.

AGENDA NO.7

NEED TO REGULATE THE IMPORT OF SILICONE OIL &GOT C3 F8 GAS FOR INTRAOCULAR TAMPONATE WITH OPHTHALMIC GAS INJECTION KIT AND SUCH OTHER SUBSTANCES

It has been revealed that following Silicone Oil Product & GOT C3 F8 Gas for intraocular Tamponate are being imported, sold and distributed in the market without import licence and product registration.

i)	RS - Oil 1000 Cst -	Mfg. by AL, CHI, MI, A, S.R.. 350 020 Ponte San Nicolo (PD)
ii)	_"_ 5000 Cst -	
iii)	GOT C3 F8 Gas	Italy.
iv)	Silicone Mate – 1300 Cst	Haward Instruments II. Inc. 4749 Appletree, Tuscaloosa USA AL – 35405 5747
v)	_"_ - 5000 Cst	

The literature, product, catalogue have revealed that Silicone Oil is sterile, pyrogen free medical grade pure Silicone Oil (100% Polydimethylsloxane). Silicone Oil and GOT C3 F8 Gas for intraocular Tamponade are use as long term Intraocular Tamponade in vitreoretinal surgery.

Enquiries at the Hospitals have been made and it has revealed that Silicon Oil remains 3 to 6 months and as long as 5 to 6 years in the eyes. Therefore, it's a in vivo application.

Therefore, above products fall within the definition of "Drug" as per of Sec. 3 (b)(i) of Drugs and Cosmetics Act 1940.

However while importing these products it is claimed as "Medical Device" and being imported without any Registration Certificate and Import Licence. It may also be noted that these products are not notified in official gazette as "Medical Devices". Therefore, it is necessary to take suitable action in this matter so that import and sale is regulated as per provisions of the Drugs and Cosmetics Act.

RECOMMENDATIONS

Commissioner, FDA, Maharashtra stated that Silicone Oil product & GOT C3 F8 Gas for intraocular Tamponate contain medical grade Silicone Oil and are used as long term intraocular Tamponate in vitreoretinal surgery and should therefore, be considered as a drug under section 3()b) (i) of the Drugs and Cosmetics Act.

The committee after deliberations felt that silicone oil in the above product is used as lubricant and is an inert substance forming a part of the device, it would therefore, not come under the purview of the term 'drug' as per section 3 (b) (i) of the Drugs and Cosmetics Act.

AGENDA NO.8

STANDARDS FOR MEDICAL DEVICES

Few Medical Devices are notified under Sec. 3(d) and are included under the provision of Drugs and Cosmetics Act 1940. However, no specifications other then sterility are framed. The matter needs to be expedited.

The Hon. Mumbai High Court have granted stay on the Govt. of India Notification on Medical Devices. The matter was informed to Drugs Controller General (India) Office. If may be decided as how to implement the said notification.

RECOMMENDATIONS

The question of laying down standards for medical devices has already been considered under agenda item No.3.

Legal Consultant of the Central Government informed the Committee that the status report to the Hon'ble Mumbai High court will be prepared and submitted by the legal department of CDSCO in due course.

AGENDA NO.9

GRANT OF TEST LICENSES IN FORM 29

Test licences are granted to applications to manufacture small quantities of drugs for test and analysis. However there is no clarity in law on the following aspects:

i) Whether renewal of test license can be done or not. If renewal is to be done then under which Form number the renewal is to be granted.
ii) Whether test licences for narcotics drugs should be granted which has abuse potential.
iii) Whether test licences for ban drugs should be granted if the applicant wants to generate data for products meant for export.

RECOMMENDATIONS

The Commissioner, FDA, Maharashtra stated that the format of licence to manufacture drugs for purpose of examination, test or analysis in Form – 29 require changes to make it more explicit and remove certain ambiguities.

The committee recommended that the suggestion may be examined by the amendment committee for its recommendations.

AGENDA NO.10

REGISTRATION ON GRANT OF MANUFACTURING LICENSES TO PSYCHOTROPIC & ABUSIVE DRUGS

Imposing restriction on grant of manufacture of certain drugs which are psychotropic & abusive is needed.

For eg: Ketamine, Buprenorphine, Ephedrine, etc.

A list of such drugs be prepared and restricted manufacturing Licences should be granted to selected manufacturers for ease of regulation.

RECOMMENDATIONS

The Commissioner, FDA, Maharashtra desired that certain restrictions may be imposed in respect of manufacture of certain psychotropic drugs which have abuse potential.

The committee was informed that DTAB has already recommended to the Central Government that manufacture of Narcotic and Psychotropic substances should be brought under the purview of CLAA scheme so that their production and use is monitored in the country. The Ministry of Health is making suitable amendments in the Drugs and Cosmetics Rules for the purpose.

The committee however, further recommended that the matter may also be referred to the Amendment Committee to suggest the type of restrictions that could be imposed on their manufacture and sale of such drugs, for restricting the abuse potential.

AGENDA NO.11

INCLUSION OF NEW FORM FOR ISSUE OF GMP CERTIFICATE FOR ALLOPATHIC DRUGS UNDER THE RULES

GMP certificate Form 26E.1 for Ayurvedic drugs is incorporated under the Rules. However, no such form for grant of GMP certificate for allopathic drugs is prescribed. In order to have uniformity in the issuance of GMP certificate for allopathic drugs it is suggested that a new form be incorporated under the Rules. Such certificate is needed by drug procurement authorities all over the country.

RECOMMENDATIONS

The Commissioner, FDA, Maharashtra proposed the inclusion of a new form for issue of GMP certificate for allopathic drugs, as has been prescribed for ayurvedic drugs under Form – 26 E.1. The committee was briefed that as the manufacturers of allopathic drugs are required to comply with the mandatory Good Manufacturing Practices as provided under Schedule M, separate GMP certificate is not required under the Rules.

GOA

AGENDA NO.12

CONSIDERATION OF THE NEED TO UPDATE THE LIST OF DRUGS CLEARED BY THE DRUGS CONTROLLER GENERAL (INDIA) INDICATING THE DOSAGE, STRENGTH OF THE FORMULATION CLEARED BY THE DRUGS CONTROLLER GENERAL (INDIA)

This Directorate received many applications for grant of licence to manufacture drug formulations which are not figuring in the approved list of 'New drugs' cleared by the office of the Drugs Controller General (India). In several instances, the approved list only indicates the date when API was cleared and there is no reference of the clearance of its formulations, dosage and strength. The manufacturer contends that some of the drugs and their formulations are already cleared by the office of the Drugs Controller General (India), and have submitted copies of permission letters clearing the formulations as new drugs. However, references of such drugs are not found in the list circulated by the Drugs Controller General (India). In these circumstances, the manufacturers face lot of inconvenience and there is undesirable delay in clearing such applications. Therefore, there is a need to consider the procedure to be adopted for ascertaining the status of drug formulations as 'New drugs'. The Drugs Consultative Committee may kindly deliberate on the issue.

RECOMMENDATIONS

The Drugs Controller, Goa stated that in the absence of an updated list of drugs cleared by DCG (I) indicating the dosage, strength of the formulation, it is difficult to process many applications for the grant of manufacturing licence permitted by DCG (I) office as new drug. Even though the website of CDSCO has certain information in respect of new drugs cleared by the office of DCG (I), it is not considered adequate to process the applications for grant of manufacturing licenses.

The office of DCG (I) agreed to update the list so as to provide dosage and strength of the formulations permitted for marketing in the country.

AGENDA NO.13

CONSIDERATION OF THE NEED TO COMMUNICATE THE SPECIFICATIONS OF NEW DRUG FORMULATION CLEARED BY THE DRUGS CONTROLLER GENERAL (INDIA) TO THE CONCERNED STATE DRUGS CONTROLLERS

It is observed by the Directorate that the manufacturers are submitting licence in Form – 46 for clearance of 'new drug' formulations, cleared by the office of the Drugs Controller General (India). However, the State Drugs Controllers are not able to verify the specifications of the products approved by the office of the Drugs Controller General (India), as the same are neither attached to the licence nor sent to the State Drugs Controller. Therefore, it becomes very difficult to control the quality of the products particularly in case of sustained release formulations, recombinant drugs or any other special products. Therefore, there is a need to adopt a methodology to overcome this problem. The Drugs Consultative Committee may please deliberate on the issue.

RECOMMENDATIONS

The Drug Controller, Goa stated that in the absence of specifications of new drug formulations cleared by the DCG (I) office, it is not possible to verify the specifications of the products permitted by DCG (I). This becomes more important in the case of sustained release formulations, recombinant drugs or other such special products.

The office of DCG (I) agreed to circulate the specifications to the State Drug Controllers at the time of first permission of the new drug.

AGENDA NO.14

CONSIDERATION OF THE QUESTION WHETHER FORMULATIONS ALREADY PERMITTED TO BE MANUFACTURED FOR EXPORT/LOCAL, REQUIRE SEPARATE ADDITIONAL PRODUCT PERMISSION FOR THE PURPOSE UNDER 'NEUTRAL CODE'

Manufacturer obtains permission to manufacture drug formulations for the purpose of export, as well as for domestic markets. These formulations are also at times applied for export under Neutral Code, whereas specifications of formulations are the same as those granted for export or domestic market under their manufacturing licence. Clarification is required whether a separate permission for each product is required for products to be exported under neutral code, or the manufacturers can be allotted a neutral code to export their products by mentioning the same Neutral Code on all their products. The Drugs Consultative Committee may deliberate.

RECOMMENDATIONS

The Drugs Controller, Goa desired to know whether permission for export under neutral code is required to be given product wise or the manufacturer can use allotted neutral code for export of the products permitted to be manufactured by them for domestic or export purposes.

DCC after deliberations agreed that neutral code can be used by the manufacturers for the export of the products permitted to be manufactured by the licensing authority.

AGENDA NO.15

CONSIDERATION OF THE NEED TO MAKE THE PROVISIONS FOR VALIDITY OF THE LICENCE TO OPERATE BLOOD BANKS, WHERE THE APPLICATIONS FOR RENEWAL OF LICENCE, ARE NOT DISPOSED

It is seen from rule 122(h) of the Drugs and Cosmetics Rules that licences issued to a blood bank in Form 28-C and Form 28-E and licences renewed in Form 28-G or Form 26-I, are valid for a period of five years from the date on which they are granted or renewed, unless the same is suspended or cancelled. However, the provision for validity of the licence pending disposal of the application for renewal of licence is not made under Rule 122(h) as it is provided for other manufacturing licences of drugs under Rules 72 and 77. As a result, if blood bank licence is not renewed before expiry of license, it will be deemed to have expired immediately

after the validity date. There is a need to make suitable provisions under the rules. The Drugs Consultative Committee may deliberate.

RECOMMENDATIONS

It was stated that under the rules for licence to operate blood banks etc. there is no provision for the licence to remain valid till such time the application for renewal of licence is disposed off. As a result, if blood bank licence is not renewed before its expiry it will expire after the validity date. It is therefore, necessary to have a suitable provision for the continuation of the licence as is the case in other licences under the rules.

The DCC recommended that the proposal may be referred to the sub-committee for suggesting suitable amendment to the rules for the purpose.

AGENDA NO.16

CONSIDERATION OF THE NEED TO CLARIFY THE APPLICABILITY OF RULE 122(E) IN RESPECT OF DIAGNOSTIC REAGENTS AND KITS

This Directorate receives many applications for grant of licence to manufacture various types of diagnostic kits like biochemical reagents, pregnancy kits, blood grouping reagents, rapid test kits for malaria, dengue, PSR and other critical diseases. However, there are only four types of diagnostic kits notified as 'drugs' under section 3(b) of the Drugs and Cosmetics Rules, viz. Blood grouping reagents, HIV, HCV and HbsAg kits. It is further clarified by the office of the Drugs Controller General (India) vide their letter No.26-9/2002-DC dated 05/12/2002, to the State Drugs Controllers that prior approval/clearance of the Drugs Controller General (India) is required in case of diagnostic kits which are categorized as 'critical kits'. However, permission for the non-critical kits can be granted by the State Drugs controllers after verification of space, facilities, personnel and documentation, etc. at the manufacturers' premises. However, in the absence of clear specific guidelines on the details of the list of critical kits cleared, the State Drugs Controllers face constraints in considering the request of diagnostic kits which are being manufactured first time in the country. In considering the provisions of Rule 122(e), there is a need to clarify whether applications for all diagnostic reagents and kits other than notified as drugs, can be considered by State Drugs Controllers. The Drugs Consultative Committee may kindly deliberate on the issue.

RECOMMENDATIONS

The Drug Controller, Goa stated that for non-critical diagnostic kits licences are granted by the State Licensing Authorities after due verification of space, facilities, personnel, documentation etc. In the absence of any specific guidelines it is not clear whether any of these diagnostic reagents or kits would fall under the category of new drugs and would require authorization from the Drugs Controller India before these are permitted for manufacture in the country.

DCC after deliberations agreed that in the case of non-critical kits the State Licensing Authorities may continue to grant the licences after due examination of the quality parameters etc.

AGENDA NO.17

CONSIDERATION OF THE NEED TO CONSIDER THE QUESTION WHETHER PERMISSION TO MANUFACTURE AYURVEDIC DRUGS CAN BE GRANTED IN THE FACILITY/SECTION APPROVED TO MANUFACTURE SIMILAR DRUG FORMULATIONS UNDER DRUGS MANUFACTURING LICENCE

Several requests have been received from the manufacturers regarding the feasibility of manufacturing ayurvedic drugs of similar dosage form in existing licensed allopathic premises, for such drug formulations and which do not pose any risk of contamination. If so, the Drugs consultative Committee may deliberate the criteria for permissibility to manufacture ayurvedic formulations in licensed premises by State Drugs Controllers.

RECOMMENDATIONS

The Drugs Controller, Goa desired to know that whether permission to manufacture ayurvedic drugs of dosage form similar to allopathic drugs could be granted in the facility approved for manufacture of allopathic drugs.

DCC after deliberations recommended that as it is specifically provided under Schedule M that no other manufacturing activity shall be undertaken in the premises licensed for modern drugs, manufacture of ayurvedic drugs in the premises licensed for modern drugs can not be permitted.

AGENDA NO.18

CONSIDERATION OF THE NEED THE PERMISSIBILITY FOR TESTING OF AYURVEDIC DRUG FORMULATIONS AND FOOD PRODUCTS IN THE DRUGS TESTING LABORATORIES APPROVED IN FORM – 37

Rule 160(B) provides for the setting up of approved testing laboratory for the analysis of ayurvedic. Siddha or unani drugs for which approval is granted under Form – 48. The Drugs Consultative Committee may deliberate whether a firm holding drugs testing approval in Form – 37, can be granted approval to test ayurvedic drugs utilizing personnel, equipments, instruments, if the spare capacity is available with approved testing laboratories. The Drugs Consultative Committee may deliberate on the issue.

RECOMMENDATIONS

The Drugs Controller, Goa desired to know whether a firm holding drug testing approval in Form – 37 for testing Drugs and Cosmetics can be granted approval to test ayurvedic drugs utilizing available personnel and equipments.

DCC recommended that there is no objection to the use of the facilities for testing of ayurvedic drugs by the approved laboratory provided the laboratory obtains additional approval in Form 48 for testing of ayurvedic, siddha and Unani drugs.

AGENDA NO.19

CONSIDERATION OF THE NEED TO CONSIDER THE ISSUE OF LICENCE TO MANUFACTURE DRUGS WITH THE CHANGED FORMULATION WITH THE SAME BRAND NAME

This Directorate receives many applications for grant of licence to manufacture drug formulations with the changed composition with the same brand name which are already existing in the market. These applications are sometimes to circumvent the provisions of the Drugs (Prices Control) Order and many times, using cheaper ingredients as cost cutting factors, etc. National Pharmaceutical Pricing Authority (NPPA) has written to the State Drugs Controllers vide their letter No. 5/35/07PI-I dated 20/9/2007 to discourage this practice and to ask the manufacturers to take prior price approval before marketing of the product with changed composition. Further, since change in APIs with same brand name may be misleading and lead to undesirable effects. There is a need to have a considered view on the matter. The Drugs Consultative Committee may kindly deliberate on this issue.

RECOMMENDATIONS

The Drugs Controller, Goa stated that certain manufacturers apply for grant of licence to manufacture drug formulations with changed composition but retaining the same brand. This practice is a specially followed to circumvent the provisions of Drugs (Price Control) order.

DCC after deliberations agreed that the change of formulation without changing the brand name is not only misleading but may also result in undesirable effects as the consumer would take the formulation assuming it as having the earlier composition. The practice is therefore, required to be discouraged and the members should ensure that the same brand should not be permitted to be retained if the composition of the formulation has been changed.

AGENDA NO.20

CONSIDERATION OF THE NEED TO CONSIDER PERMISSIBILITY OF GRANT OF LICENCE TO MANUFACTURE DRUGS FOR EXPORT ON THE BASIS OF N.O.C. ISSUED BY THE DRUGS CONTROLLER GENERAL (INDIA) TO ONE MANUFACTURER, ONLY IN CASE OF PRODUCTS OTHER THAN BANNED FOR MARKETING IN THIS COUNTRY

The Drugs Controller General (India) is issuing N.O.C. for many drug formulations for the purpose of export, in consideration of the rationality of the formulations and on the basis of the export order submitted by the manufacturers, though the same are not cleared for marketing in the country. This Directorate receives applications for permission to manufacture identical formulations for export by other manufacturers. Since the rationality of the combinations is decided by the Drugs Controller General (India0 for such formulations, there is a need to consider whether once N.O.C. for export is granted by the Drugs Controller General (India), applications of other manufacturers can be considered for the grant of permission if the formulations are identical and are meant for export. The Drugs Consultative Committee may kindly deliberate on the subject.

RECOMMENDATIONS

The Drugs Controller, Goa stated that licences for manufacture of drugs for export, in respect of formulations not otherwise permitted to be manufactured in the country, are granted on the basis of permission granted by DCG (I) office. He desired to know whether other manufacturers could be granted licence to manufacture similar formulations for export as permission for the formulation has already been granted by the office of DCG (I) to one manufacturer.

DCC after deliberations agreed that such permissions should be granted only after the NOC has been granted by the DCG (I) office in the specific cases.

AGENDA NO.21

CONSIDERATION OF THE QUESTION FOR PERMISSIBILITY OF THE USE OF COLOURS OTHER THAN SPECIFIED IN RULE 127 IN DRUG FORMULATIONS FOR EXPORT

This Directorate receives many applications for drug formulations with colours which are not permitted under Rule 127. However, their products are registered with other regulatory authorities in the foreign countries. Whether permission can be granted to manufacture products with such colours for the purpose of export, if the documentary evidence is produced that proposed colour is permitted to be used in the importing country. The Drugs Consultative Committee may kindly deliberate on the issue.

RECOMMENDATIONS

The Drugs Controller, Goa desired to know whether the use of colours other than those specified in Rule 127 could be permitted in drug formulations meant for export provided the documentary evidence is produced by the manufacturer that the colour is permitted in the importing country.

DCC recommended that in the case of exports, colours permitted in the importing country could be permitted in the manufacture of the formulations meant for export to that country.

AGENDA NO.22

CONSIDERATION OF THE NEED TO CONSIDER THE CONDITIONS FOR GRANTING TEST LICENSE FOR CLINICAL TRIALS

This Directorate receives applications to grant test license to manufacture drugs for clinical trials on the basis of the permission granted by Drugs Controller General (India) to conduct clinical trials. Since the quantity of drugs and size of clinical trials may be large, there is a need to consider conditions to be incorporated in the test licence in Form 29, in respect of facility for manufacturing and product specifications and to mention the name of institutions where such clinical trials are authorized to be conducted. The Drugs Consultative Committee may deliberate on the matter.

RECOMMENATIONS

The Drugs Controller, Goa suggested that the licence in Form – 29 to manufacture drugs for the purpose of examination, test or analysis is needed to be amended so that certain information like facility for manufacturing, products specifications and name of the institutions where clinical trials are to be conducted should also be included so that these vital particulars are available to the State Licensing Authorities.

DCC recommended that the proposal may be considered by the sub-committee for amendments and suggest whether any change in present provision is required or not.

AGENDA NO.23

CONSIDERATION OF THE QUESTION WHETHER APPLICATIONS TO MANUFACTURE IDENTICAL DRUG FORMULATIONS PERMITTED TO BE IMPORTED FOR USE IN THE COUNTRY AND HAVING BEEN FOR FOUR YEARS, CAN BE PERMITTED FOR DOMESTIC PURPOSES

This Directorate has received an application to grant permission to manufacture drug formulation which is permitted for import for marketing in the country more than four years back. There is a need for clarification whether such drug formulation can be permitted by State Drugs Controllers for manufacture in the country for local use. The Drugs Consultative Committee may kindly deliberate on the matter.

RECOMMENDATIONS

The Drugs Controller, Goa desired to know whether drug formulations which is permitted for import for marketing in the country more than four year ago could also be considered for grant of manufacturing licence by the State Licensing Authorities while, its manufacture in the country had started at a later date.

DCC recommended that permission could be granted for manufacture of new drug formulation after four years of its approval in the country irrespective of the fact whether it was permitted to be imported or manufactured for marketing in the country.

KARNATAKA

AGENDA NO.24

AMENDMENT TO RULE 65(10)

Rule 65(10) to be amendment such that the definition of prescription shall be applied to all the rules given under various parts in Drugs & Cosmetics Rules & not only to sub rule 9 of Rule 65.

RECOMMENDATIONS

The Drugs Controller, Karnataka stated that Rule 65 (10) need to be amended in order to ensure that the definition of term 'prescription' is applicable in general and not limited to Rule 9 only.

DCC recommended that the proposal may be considered by the sub-committee for amendments and suggest suitable amendment for the purpose.

AGENDA NO.25

NOTE PORTION GIVING DISCRETIONARY POWERS TO LICENSING AUTHORITIES IN "SCH.M"

Earlier "Sch.M" covered requirements of machinery, equipments, premises for few categories of drugs and the Licensing Authority was given discretionary powers in "Note" portion at the end of "Sch.M" to examine the adequacy or other wise of factory premises, spares, plant, machinery etc. or other requisites and to grant product permission other than those categories not covered under "Sch.M".

In the amended "Sch.M" too, all the categories of dosage forms are not covered i.e. Diagnostic kits & discretionary power is also not given.

In view of this, discretionary powers by way of "Note" portion may be incorporated once again at the end of "Sch.M".

RECOMMENDATIONS

The Drugs Controller, Karnataka stated that "Note" portion at the end of "Schedule M" in the earlier version provided discretionary powers to the licensing authorities to examine the adequacy of requirements of the categories not specifically covered under the Schedule. He desired that these powers may be incorporated under the revised Schedule M also, so that adequacy of requirements could be considered on case to case basis in such categories.

The committee was briefed that Schedule M was revised to ensure that Good Manufacturing Practices are followed by the drug manufacturers to ensure the quality of drugs manufactured by them. Specific exemptions wherever considered essential were provided. A general discretionary power would dilute the spirit of Good Manufacturing Practices.

In view of the above, the proposal was not accepted by DCC.

AGENDA NO.26

MANUFACTURE OF NEUTRACEUTICALS , COSMETICS, AYURVEDIC ETC., IN THE LICENSED PREMISES

As per a present “Sch.M”, in the note portion it has been mentioned as “the manufacturing premises shall be used exclusively for production of drugs & no other manufacturing activity shall be undertaken therein”.

In view of this whether the licensee can manufacture the above products in the licensed premises.

RECOMMENDATIONS

The agenda has already been discussed under the agenda item no.17 of Drugs Controller, Goa.

AGENDA NO.27

BLOOD STORAGE CENTER

Approval is granted for Blood storage center as per the provision of Sch.K of D & C Rules. No fees is prescribed for the grant/renewal of approval for Blood storage center. It is suggested to prescribe fees for grant/renewal of Blood storage center.

Further at present there is no provision to take departmental action such as suspension/withdrawal of approval against defaulting Blood storage centers. Hence provision may be made to take departmental action in D & C Rules.

RECOMMENDATIONS

The Drugs Controller, Karnataka pointed out that in the case of blood storage centres, approval is granted under the provision of Schedule K which provides exemptions from a licence to operate blood bank. There is no provision to take department action against defaulting centres under the conditions of exemption.

DCC recommended that the proposal may be considered by the sub-committee for amendments and suggest suitable amendment for the purpose.

AGENDA NO.28

ISSUE OF DUPLICATE LICENSE/APPROVAL – PROVISIONS TO BE MADE-

There is no provision in Drugs & Cosmetics Act, 1940 and Rules thereunder to issue Duplicate licence/approval for the following-

a) Licence in Form 29
b) Approval in Form 37
c) Issue of duplicate permission letters for the product list

It is suggested that necessary amendments may be made in Drugs & Cosmetics Act, 1940 and Rules thereunder for issue of Duplicate licence/approval.

RECOMMENDATIONS

The Drugs Controller, Karnataka stated that there is no provision for issue of duplicate licence/approval for licences in Form – 29, Form – 37 and product lists of manufacturing licences. A provision under the rules should be provided for issue of duplicate licences/approval in these cases also.

DCC recommended that the proposal may be considered by the sub-committee for amendments and suggest suitable provisions that could be incorporated.

AGENDA NO.29

WHETHER "HERNIA MESH" IS "DRUG"

"Hernia Mesh" is available in the market made up of Polymers. Whether "Hernia Mesh" is a "Drug" at present.

RECOMMENDATIONS

The Drugs Controller, Karnataka desired to know whether "Hernia Mesh" could be considered as a drug.

The committee opined that the product is a medical device and is not considered as a drug.

AGENDA NO.30

PRODUCT DECLARED AS NOT OF STANDARD QUALITY BY CDL AFTER CHALLENGING THE TEST REPORT. WHETHER PROSECUTION IS MANDATORY

If the product has been declared as Not of standards Quality and after the Challenge of the test report, the sample is sent to CDL through court after filing the miscellaneous application either by the Drugs Inspector or by the challenger. If this sample is also declared as Not of standard Quality, whether prosecution is mandatory irrespective whether it is declared as Not of standard Quality with respect to Description, Uniformity of Weight, etc.

Whether 27th DCC Guidelines can be considered in such situation.

RECOMMENDATIONS

The Drugs Controller, Karnataka desired to know that in the case of a drug declared as not of standard quality by the CDL after challenging the test report, whether it is mandatory to launch a prosecution irrespective of the fact that the defect is of minor or major nature.

DCC after deliberations opined that in such cases where prosecution is not mandatory, action can be taken by the licensing authority depending upon the nature of the defect.

AGENDA NO.31

STANDARDS FOR THE MEDICAL DEVICES

Govt. of India vide notification no S.O. 1468 (E) dated 6-10-05 notified 10 medical devices as “Drug”. More than 2 and half years are over after notifying these medical devices as “Drug”. However standards for the same have not been published. Unless standards are published these Medical Devices can not be declared as Not of Standard Quality. Hence it is suggested that the issue may be discussed in the forthcoming DCC meeting.

RECOMMENDATIONS

The agenda has already been discussed under the agenda item no.3.

AGENDA NO.32

THE FOLLOWING DRUGS HAVE BEEN INCLUDED IN SCH G AND SCH H

A) Chlorpheniramine maleate
B) Insulin, all types in Sch G and Human Insulin in Sch H.

Whether the manufacturer is required to comply with the labelling provisions as per rule 97 in respect of both Sch G and Sch H. (As per present provisions both are required).

RECOMMENDATIONS

The Drugs Controller, Karnataka desired to know that in the case of drugs included both in schedule G and H these are required to comply labelling provisions for both the Schedules.

The committee opined that as per provision of Rule 97 both warnings are required to be printed on the label in such cases.

AGENDA NO.33

EXEMPTION GIVEN IN SCH K (SL NO. I.E. COSMETICS)

As per Sch. K Sl no. 16, it is stated that “ The provisions of Chapter IV of the Act and the Rules made thereunder, which require them to be covered by a license for sale provided that the Cosmetics sold, if of Indian origin, are manufactured by licensed manufacturers. That means if the cosmetics is of Indian origin, then sales license is not required. If it is imported, whether license is required.

RECOMMENDATIONS

The Drugs Controller, Karnataka desired to know as to whether a sale licence is required to sell imported cosmetics in view of entry no. 16 under Schedule K which specifically provides that no sale licence is required for cosmetics manufactured in the country.

The committee opined that Schedule K provide exemptions from the provisions of Chapter IV of the Act related to manufacture and sale of drugs in the country. As there is no provision for sale licence for sale of cosmetics in the country, no sale licence is required for sale of imported cosmetics also.

AGENDA NO.34

PRESENT STATUS OF FIXED DOSE COMBINATIONS:

In view of the stay order granted by the Hon. Madras High Court, whether permission to manufacture FDCs included in the list forwarded by DCG (I) can be granted or not. (Knowingly that these FDCs are irrational)

RECOMMENDATIONS

The Drugs Controller, Karnataka desired to know about the present status of licensing of Fixed Dose Combinations in light of stay granted by the Hon'ble High Court of Madras.

The committee was informed that the matter is under consideration of DTAB and further action in the matter would be taken on the recommendations of the DTAB.

AGENDA NO.35

REQUEST TO NOTIFY GOVT. ANALYSTS IN CIPL, GHAZIABAD, CDTL, MUMBAI AS GOVT. ANALYSTS FOR THE STATE OF KARNATAKA. (WHEN SAMPLE WAS SENT TO CIPL, GHAZIABAD, THEY HAVE NOT ISSUED TEST REPORT IN FORM 13).

RECOMMENDATIONS

Agenda item has already been discussed under agenda item No.1.

AGENDA NO.36

PERMISSION TO MANUFACTURE THE FORMULATIONS CONTAINING THE COLOURS OTHER THAN PRESCRIBED IN RULE 127 FOR EXPORT

Some of the manufacturers of formulations submit applications for permission to manufacture formulations containing colour other than prescribed in Rule 127 for Export purpose. (i.e. Allura Red is one of the colour which is not included in Rule 127 of D & C rules). Can permission be granted for such formulations if the said colour is not prohibited in buying country.

RECOMMENDATIONS

Agenda item has already been discussed under agenda item No.21 (Goa).

AGENDA NO.37

CLARIFICATION REGARDING MENTIONING THE PROPER NAME OF THE DRUG

As per Rule 96(1)(i)(A) the manufacturer is required to mention the proper name of the drug on the label. In case of Vitamin with Minerals formulations, it may contain more than 10-15 ingredients. If it is not mentioned it amounts to be "Misbranded Drug" within the meaning of Section 17 of D&C Act, 1940. It is difficult for the manufacturer to mention the proper name of the drug. In such cases if the manufacturer writes as "Vitamins with Minerals" will it serve the purpose.

RECOMMENDATIONS

The Drugs Controller, Karnataka stated that formulations of vitamins with minerals some time contain 10 to 15 ingredients and it is difficult to mention all the ingredients on the label. In such cases whether labelling with "vitamins with minerals" will serve the purpose.

The DCC opined that as per requirement of the rule 96 all the ingredients are required to be mentioned on the label.

AGENDA NO.38

CORRECTION IN SECTION 27-A(I) OF D&C ACT

Definition of Spurious Cosmetics is given in Section 17d whereas in penal clause in Section it has been mentioned as Section 17C instead of Section 17D which is required to be corrected.

RECOMMENDATIONS

The Drugs Controller, Karnataka proposed a correction in section 27A of the Drugs and Cosmetics Act.

DCC was informed that section 27A has already been amended through the Drugs and Cosmetics (Amendment) Act, 2008.

AGENDA NO.39

AMENDMENT TO SECTION 31

Mere stocking of Banned drug is not an offence. Whenever the firm is stocking banned drugs provision may be made to confiscate and destroy the same. Hence Section 31 may be amended to incorporate for confiscation of Banned drugs.

RECOMMENDATIONS

The Drugs Controller, Karnataka desired to have a provision under section 31 to incorporate for confiscation of banned drugs.

DCC recommended that the proposal may be forwarded to Ministry of Health for its consideration.

AGENDA NO.40

AMENDMENT TO RULE 58 AND 58A

Drug or Cosmetics can be confiscated under Section 31 of D & C Act. The confiscation of Drugs, Machinery etc is stipulated under rule 58 and disposal of Drug is given under rule 58 A. However both these rules do not speak about the cosmetics. Hence provision may be made in these rules to incorporate the word 'Cosmetics' otherwise after conviction of the accused or not of standard Quality Cosmetics cannot be disposed of.

RECOMMENDATIONS

The Drugs Controller, Karnataka proposed that rule 58 and 58A deals with a confiscation of drugs. However, these are not applicable to cosmetics. The word cosmetics may therefore be incorporated for the purpose of taking action in case of 'cosmetics' found not of standard quality.

DCC recommended that the proposal may be considered by the sub-committee for amendments and suggest suitable amendment to the rules.

AGENDA NO.41

AMENDMENT TO RULE(2)

As per this rule the wholesaler is required to preserve the carbon copies of Cash or Credit memos for a period of three years from the date of sale of drug. Since "Sch.P" stipulates the date of expiry as 60months (for those product which are included in Sch.P), a suitable amendment may be incorporated in this rule to preserve the records for 60 months from the date of sale of drugs.

RECOMMENDATIONS

The Drugs Controller, Karnataka proposed that rule 65 (5) (2) may be amended for so that the records are preserved for sixty months from the date of the sale of the drug.

DCC recommended that the proposal may be considered by the sub-committee for amendments and suggest suitable amendment to the rules.

AGENDA NO.42

WHAT IS THE MEANING OF THE WORD "CONDITIONS" IN SECTION 18C

Section 18 C reads as follows' manufacture for sale....., except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter.

Rule 65 reads as follows-Conditions of licences – Licences in (Forms 20, 20A...) shall be subject to the conditions stated therein and to the following general conditions-

I am of the opinion that the word "and in accordance with the conditions of," has to be deleted from Section 18(e) otherwise the licensee who violates any of the

conditions mentioned in the conditions of licence of the conditions given in Rule 65 will be violating Section 18 (c) also.

RECOMMENDATIONS

The Drugs Controller, Karnataka proposed that section 18 (e) may be amended to delete the words "and in accordance in the condition of".

DCC after deliberations agreed that there is no necessity to delete the provision under section 18(e).

GUJARAT

AGENDA NO.43

The Educational Qualification & Experience is not laid down under the Drugs & Cosmetics Act, 1940 for newly included Medical Devices, rDNA products etc. As long as the suitable amendment is not brought into force, the department policy may be laid down to stream line certain specialized products like cardiac stent, cardiac valve, orthopaedic implants, intra ocular lenses etc.

RECOMMENDATIONS

The Commissioner, FDCA, Gujarat stated that qualification and experience of competent technical staff for medical devices are required to be laid down under the rules.

DCC recommended that the proposal may be considered by the committee for medical devices for suggesting suitable amendments.

AGENDA NO.44

In case of Schedule K entry No. 5B is related to the approval of Blood Storage Centre, whereas the qualification of Blood Bank technician carries option. An experienced laboratory technician is also to be considered. However the qualification of experienced laboratory technician is not given. Therefore, it may be decided whether experienced laboratory technician should be under graduate, graduate, post graduate or diploma holder from any discipline.

RECOMMENDATIONS

The Commissioner, FDCA, Gujarat desired that minimum qualification of the experienced laboratory technician should also be prescribed under entry .5B of Schedule K.

DCC recommended that the proposal may be considered by the sub-committee for amendments for its recommendations.

AGENDA NO.45

The Rule 162-A provides the qualification for State Drugs Licensing Authority for licensing of Ayurved, Siddha and Unani Drugs. The qualification prescribed for the same includes in addition to other B. Pharm (Ayurvedic Drugs is being carries bout by Food & Drugs Control Administration in addition to Allopathic Drugs. The qualification of B.Pharm (Allopathic) should also be inserted as an appropriate for consideration for State Drugs Licensing Authority for licensing of Ayurved, Siddha and Unani Drugs.

The manufacturing, testing machineries, equipments etc. used for manufacturing of Ayurved Drugs are nearly same for Allopathic Drugs. The Allopathic System requires high degree of techniques, up gradation and sophisticated approach for smooth and effective working. Under such circumstances the qualification of B. Pharm (Allopathic) should also be viewed with due regards. In view of this necessary amendment may also be made under the Act. Moreover the syllabus of B.Pharm (Allopathic) includes Pharmacognosy as one of the subjects of graduate level and principal subject at post graduate level. The subject Pharmacognosy deals totally with herbal drugs, it's identification standardization and therapeutic effect. This way the officer with the qualification of B. Pharm Allopathic are not lagging behind at all, with the qualification of B.Pharm, Ayurvedic.

RECOMMENDATIONS

The Commissioner, FDCA, Gujarat stated that Rule 162A relating to qualification for licensing authority for ayurveda, Siddha and Unani drugs is required to be amended.

The committee felt that as the matter pertains to the Indian system of medicine, the matter may be placed before the Ayurvedic, Siddha and Unani Drugs Consultative Committee for its consideration.

TAMIL NADU

AGENDA NO. 46

DELETION OF CERTAIN WORDS IN THE CONDITION OF LICENCE IN FORM 20 B AND 21 B

In G.SR. 812 (E) dt. 14.11.1994 the words "or charity or voluntary subscription" was omitted in serial No.5A of Schedule K Hence Drugs supplied by a hospital or dispensary maintained or supported by Government or local body alone are exempted from taking out a sale licence under chapter IV of the Act.

However, in condition of licence in form 20 B serial no:2 (ii) (b) and in form 21 B serial No.4(ii) (b) the words a hospital still there and this will permit the whole seller to supply Drugs other than Government Hospital also. Hence, the word "a hospital" may be deleted or changed as "a hospital or dispensary maintained or supported by Government or local body"

RECOMMENDATIONS

The Drugs Controller, Tamilnadu stated that the word hospital may be deleted from the conditions of Form 20B and Form 21B so that wholesalers are not permitted to sell drugs directly to the hospitals other than Government hospitals. Some of the members were of the view that this may result in difficulty of procuring medicines by the private hospitals at reasonable prices. DCC however, recommended that the proposal may be considered by the sub-committee for amendments for its recommendations.

AGENDA NO. 47

DELETION OF CERTAIN WORDING IN THE FORM 24A AND 27A

In form 24A Serial No. 3(b) and in form 27A serial No. 3(b) It is given as "..... they will analyze every batch of finished products and maintain the registers of raw materials, finished products and reports of analysis separately on this behalf" whereas in Rule 74-B (3) (Condition of licence in form 25 – A) and Rule 78 – A (3) (condition of licence in form 28-A) it is given as "The licensee shall test each batch or lot of the raw materials used by the manufacturer of the products and also each batch of the final products and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule "U" since the rule clearly states who has to maintain the records it is suggested in the form 24 A and form 27 A " the words_____ Maintain the registers of raw materials, finished products and reports of analysis....." may be deleted.

RECOMMENDATIONS

The Drugs Controller, Tamilnadu further suggested that Form 24A and Form 27 A pertaining to grant or renewal of loan licences need to be amended in respect of maintaining records of analysis of finished products.
DCC recommended that the proposal may be considered by the sub-committee for amendments for its recommendations.

AGENDA NO.48

IN FORM 32 A IN CONDITION OF LICENCE ADDITION OF ONE MORE CLAUSE

In form 32A only 3 conditions are there. In other form of licence in condition of licence itself it is given as under "The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the licence, where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change taken place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution.

Hence, for uniform in all licences, this condition may be inserted as condition No.4 in the licence in form 32A

RECOMMENDATIONS

The Drugs Controller, Tamilnadu desired that conditions of licence of Form 32 A relating to loan licence to manufacture cosmetics need to be amended.

DCC recommended that the proposal may be considered by the sub-committee for amendments for its recommendations.

AGENDA NO.49

INCLUSION OF OTHER PHARMACOPOEIAS LIKE B.P. AND USP IN RULE 122-E DEFINITION OF NEW DRUGS

In Rule 122E Explanation (ii) it is given as "a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopeia whichever is earlier"

Since now our nation has become one of a biggest exporter of Drugs and Pharmaceuticals and to promote the export after the words Indian Pharmacopeia "British Pharmacopoeia", USP or other Pharmacopoeias" may be inserted.

RECOMMENDATIONS

The Drugs Controller, Tamil Nadu desired that the drugs included in Pharmacopoeias like B.P., U.S.P should also be exempted like drugs included in the IP from the purview of new drugs. For this purpose explanation to Rule 122 E may be amended.

DCC after deliberations agreed that only drugs included in the Indian Pharmacopeia are exempted from approval as new drugs while drugs included other Pharmacopoeias would remain new drugs as these would have not been used in the country to any significant extent.

AGENDA NO.50

CERTAIN CORRECTION IN RULE 85-D

In Rule 85D form of licence to manufacture Homeopathic Medicines, it is given as “Licence for manufacture Homeopathic medicines, licence to manufacture potencies preparation from back potencies by Pharmacies who are already licensed to sell Homeopathic medicine by retail shall be granted in form 25C”.

This in turn means that only person holding retail licence to sell Homeopathic drugs in form 20C alone is eligible for getting licence in form 25-C whereas Schedule M-I specifically gives the area, machineries etc., for grant of licence in 25C. Hence it is suggested to delete the word “is a licence” and to add the word “and” after the wording licence for manufacturer of Homeopathic medicine.

RECOMMENDATIONS

The Drugs Controller, Tamilnadu stated that Rule 85 D is required to be amended as the present wording permits only retail sellers to manufacture potentised preparation from back potencies.

DCC recommended that the proposal may be considered by the sub-committee for amendments for its recommendations.

AGENDA NO.51

INTERSTATE MOVEMENT OF HOMEOPATHIC DRUGS CONTAINING MORE THAN 12% V/V ALCOHOL

In Rule 106B one more provision to be included to curb the illegal movement and misuse of Homeopathic drugs containing more than 12% v/v alcohol.

It came to light that certain Homeopathic drug manufacturers are supplying their products to the dealers situated in other state and those dealers are not maintaining any records of purchase and keeping the drug so imported in some unauthorized place and selling illegally. To prevent this in Rule 106B itself the provision of the manufacturer/dealer who supplies Drugs containing more than 12% v/v alcohol to other state shall intimate the same to the their licensing authority as well as to the State Licensing authority wherein the drug is sold/supplied.

RECOMMENDATIONS

The Drugs Controller, Tamil Nadu desired that Rule 106B may be further amended to curb illegal movement and misuse of homeopathic drugs containing more than 12% v/v alcohol.

DCC recommended that the proposal may be considered by the sub-committee for amendments for its recommendations.

DELHI

AGENDA NO.52

AMENDMENT OF CLAUSE 5 B OF SCHEDULE K TO THE DRUGS & COSMETICS RULES 1945 WITH REGARDS TO BLOOD STORAGE CENTRE:-

In the meeting of the 35 Drugs Consultative Committee held on 29th & 30th April, 2004 some proposals made by the Drugs Control Department Delhi relating to blood storage centre were discussed (Agenda item No.65). It was recommended by the DCC that since the provision at that time was a new one it was necessary that actual working of the storage centres might be assessed before incorporating any amendment to this provision. In the intervening period a number of blood storage centers have come up in Delhi and applications for renewal of approval of some these storage centres have also been received.

While processing the application for grant or renewal of approval of blood storage centres some difficulties have been observed based on which the following suggestions are made.

(i) Provision for payment of inspection fee of Rs.1500/- along with application of grant or renewal of approval of blood storage centre may be incorporated.
(ii) Suitable provisions may be made in the rules for taking action against a blood storage centre for any contravention of condition of approval.
(iii) Since all the licences under Drugs & Cosmetics Rules are issued for a period of 5 years from the date of grant of licence approval for blood storage centres or its renewal may also be made for a period of 5 years.
(iv) At present there is no format provided under DCGI guidelines for renewal of approval of blood storage centres. A suitable format may be devised for the same.

RECOMMENDATIONS

The Drugs Controller, Delhi suggested that clause 5B of Schedule K relating to Blood Storage Centres may be amended so as to have provision for payment of inspection fee of Rs.1500 and provision for action against the centre for violation of condition.

DCC recommended that the proposal may be considered by the sub-committee for amendments along with the proposal of Drugs Controller, Karnataka at agenda no.27 for giving its recommendations in the matter.

AGENDA NO.53

CLARIFICATIONS REGARDING PAYMENT OF FEES FOR PERMISSION TO MANUFACTURE ADDITIONAL ITEMS OF HOMOEOPATHIC MEDICINES:-

Rule 85(B) (5) of the Drugs and Cosmetics Rules, 1995 provides that applications for licence to manufacture additional items of homeopathic medicines shall be made to the licensing authority and such applications shall be accompanied by a fee Rs.50/- for each additional item.

Necessary clarification is required in the matter whether different potencies of the same medicine like 1k, 3x, 6x, 30, 200, 1000 etc constitute one time or more than one item.

RECOMMEDATIONS

The Drugs Controller, Delhi desired to know that in the case of permission to manufacture additional items of homeopathic medicines different potencies of same medicine will constitute one item or more than one item.

The DCC after deliberations recommended that different potencies of same homeopathic medicine should be considered as one item for the purpose of licensing of the homeopathic medicines.

RAJASTHAN

AGENDA NO.54

Mandatory provision be incorporated in Drugs & Cosmetics Rules to test drug samples by Govt. analysts in time frame

Testing of drugs samples often takes very long time & in some cases the test reports are received even after expiry date. If such sample is declared adulterated/spurious, the manufacturers gets the benefit as he is debarred of his right to challenge the test reports. Therefore, maximum time limit be prescribed for testing/analysis of drug samples by the Govt. analysts as in case of Prevention of Food Adulteration Act, where 40 days are prescribed under Rule 7 to the public analyst for analysis of Food samples.

RECOMMENDATIONS

The Drugs Controller, Rajasthan proposed that a mandatory provision may be incorporated under the rules prescribing maximum time limit for testing of drug samples by the Government analysts. He stated that similar provision exists under PFA Act for analysis of food samples by Public Analyst.

DCC felt that it may be difficult to prescribe time limits in case of drugs as testing procedures sometimes take time for analysis because of biological testing and a repeat test would require more time for analysis. However, the sub -committee on testing of drugs may consider the proposal and give its recommendations.

AGENDA NO.55

Government analyst should also write Date of Manufacture and Date of Expiry in the test reports:

It has been observed that some Govt. analysts including Central Drug Laboratories Kolkata do not mention date of manufacture and date of expiry in the test reports. In case of any drug batch number, date of manufacture, and date of

expiry are three important ingredients which constitute distinct identification of the drugs & therefore these should be mentioned on the report.

RECOMMENDATIONS

The Drugs Controller, Rajasthan stated that some Government analysts do not mention date of manufacture and date of expiry in the test report. The Government analysts may be asked to mention these particulars in the test report.

DCC recommended that the date of manufacture and date of expiry should be mentioned in the test report by the Government analyst. The State Drug Control Authorities may take up with the State laboratories to mention these particulars. The Central laboratories would also be instructed to comply with this requirement.

AGENDA NO.56

DURATION OF TRAINING AT CENTRAL DRUGS LABORATORY, KOLKATA BE REDUCED

Central Drugs Laboratory, Kolkata is organizing two months training programme for the officers working in Govt. Analyst Laboratories in the country. This duration is really to long & the experience of the trained officers at Kolkata is, that it can be very well reduced to one month. D.C.C. may consider this proposal after approval of Director, C.D.L. Kolkata, so that more officers can be trained.

RECOMMENDATIONS

The Drugs Controller, Rajasthan desired that the duration of training programmes for analysts at Central Drug Laboratory, Kolkata may be reduced to three weeks to one month from two months, so as to ensure that more officers are trained during the period.

The Director, CDL, Kolkata agreed to device programme with the duration of three weeks to one month and would intimate the States accordingly.

AGENDA NO.57

SHARING OF INFORMATION BY CENTRAL GOVT. ABOUT IMPORT LICENSES WITH STATE DRUG AUTHORITIES

Officers of C.D.S.C.O in the country are granting Import Licence for drugs to various manufacturers and drugs dealers in the country but this information is not shared with State Drug Authorities by Central Govt.

Any Importer of drugs should first obtain wholesale/retail drugs licence and the State Drugs Authority should also have knowledge of the importing dealers in there state. If some strict action is taken against such dealers, it can be informed to Central Govt. by State Licensing Authority therefore the information should be shared with the States.

RECOMMENDATIONS

The Drugs Controller, Rajasthan proposed that information about the activities of the Centre in respect of import licences issued and the regulatory action taken by different States against the dealers or manufacturers should be shared with the States.

The committee was informed that CDSCO has its websites www.cdsco.nic.in which provides information in respect of various activities carried out by the office of the Drugs Controller General (India) and is updated regularly. States Drug Control Authorities can likewise launch their websites also to provide essential information for the benefit of other States as well as public.

AGENDA NO.58

ESTABLISHMENT OF CLINICAL TRIAL CENTERS IN STATE BY CENTRAL GOVT

Drug Controller General of India New Delhi is granting permission to undertake Clinical Trials under Schedule Y of Drugs & Cosmetics Rules 1945 but the information regarding such permission to various clinical Centre in the state is not shared with State Licensing Authorities. This, sometimes puts State Govt. in to a great dilemma when such information are called by Human Right Commission or under Right to information Act.

It is therefore, suggested that the Central Govt. while granting the permissions for the clinical trials, should also inform the State Licensing Authority in this matter.

RECOMMENDATIONS

The Drugs Controller, Rajasthan stated that the information in regard to the permission to various clinical trial centres to conduct clinical trials is not shared with the State Licensing Authorities under whose jurisdiction the trial is being conducted.

The office of DCG (I) informed the committee that it is difficult to share the information on centres conducting clinical trial with State Licensing Authorities as multicentric clinical trials are conducted in many sites located in different States and sponsor/CRO frequently add or replace sites due to administrative or other reasons. Currently applicants are being advised to register their clinical trials at ICMR web based clinical trial registry at www.ctri.in where all details about the ongoing clinical trials are available.

Annexure I

List of the participants of DCC Meeting held on 10th December 2008 under the Chairmanship of Dr. Surinder Singh, Drugs Controller General (India)

A. List of the participants from State Drugs control Organizations

S.NO	NAME & DESIGNATION OF THE PARTICIPANTS
1	R.Rangarao-Director Drugs Control Administration, Drugs Control Bhavan, Vengalarao Nagar, Hyderabad-18 , Andhra Pradesh
2	C.V.Subba Rao, State Drugs Controller, Vikash Bhawan, IVth Floor, Bihar, Patna-800015.
3	Sunil Chaudhary, Drugs Control Officer,Government multispeciality Hospital Sector-16, Chandigarh
4	S.Babu, Dy. Drugs Controller.Food & Drugs Admn, Raipur, Chhattisgarh
5	M.M.Molasana, Senior Drug Inspector, O/o Controller Food & Drugs Admn,Raipur , Chhattisgarh
6	Dr. Ajay Kumar Singla ,Drugs Control Department, Govt. of NCT of Delhi, F-17, Karkardooma, Shahdara, Delhi -110032.
7	P.K.Jaggi, ADC, Drugs Control Department, Govt. of NCT of Delhi, F-17, Karkardooma, Shahdara, Delhi -110032.
8	S.Murali Krishna, Commissioner of FDCA, O/o, FDCA, Block No. 8, Old Secretariat, Gandhi Nagar, Gujarat
9	Pramod K.Jain, Director of Food & Drug Administration, Old IPHB Building, Attinho Panaji, Goa.
10	R.M.Sharma, State Drugs Controller, Government Dispensary, Sector-20, Panchkula, Haryana
11	Navneet-Marwaha, Asstt, Drugs Controller, Sai Road, Baddi District, Solan , Himachal Pradesh
12	Madan Mohan Prasad, State Drugs Controller cum Chief Licensing Authority, Nankum, Ranchi, Jharkhand
13	Dr. B.R. Jagashetty, Drugs Control, Karnataka State Drugs Control Department, Palace Road, Bangalore, Karnataka
14	M.P.George, Drugs Controller, Kerala Red Cross Road, Thiruvananthapuram, Kerala
15	Shri Khamatkar, IAS, Commissioner, FDA, Maharastha
16	Sh. K.B.Shende, Technical Officer, FDA, Maharastha

S.NO	NAME & DESIGNATION OF THE PARTICIPANTS
17	Dr. W.Motilal Singh, Medical Directorate, Director, Health Services, (Drugs Controller) Govt. of Manipur , Imphal, Manipur
18	Devistone Swer, Asstt. Drugs Controller (SLA),C/o Directorate of Health Services, Lower Lachummiera, Meghalaya, Shillong-1
19	Alok Shrivastava, Joint Controller, C/o Controller Food and Drugs Administration, idgah hills, Bhopal,Madhya Pradesh
20	D.M.Chincholikar, Sr. Drug Inspector, Licensing Authority, C/o Controller Food and Drugs Administration, idgah hills, Bhopal,Madhya Pradesh
21	Bhag Singh, Drugs Controller,DHS Office, Sector 34-A, Pariwar Kalayan Bhawan, Chandigarh, Punjab
22	G.Deenadayalan, Assistant Commissioner, Food & Drugs Administration, Ist Floor Govt. Hospital Building, Murungapakkam, Puducherry
23	D.K.Shringi Drug Controller, Swasthya Bhawan, Tilak Marg, Jaipur, Rajasthan
24	P.N.Saraswat Drug Controller, Swasthya Bhawan, Tilak Marg, Jaipur, Rajasthan
25	C.N.Sharma, Chief Drugs Inspector cum Licensing Authority, Drugs & Cosmetics cell Deptt of Health Care, Human Services & Family Welfare convey-ground-Dara-Gaon Tadung , Sikkim
26	K.Sundaraswamy, Director of Drugs Controller, The Directorate of Drugs Control, 238, 261, Anna Salai, Teynampet, Chennai-6, Tamilnadu
27	M.K.Pal, Dy. Drugs Controller, P.N.Office Complex, P.O.Kunjaban, Agartala-799006, Tripura
28	A.K.Jain, Asstt. Drugs Controller, Meerut Division, C/o Additional Director, Medical Health & Food Meerut Division, Meerut, UP
29	Ashok Gupta, Controller Drugs & Food , Patoli Mangotran Jammu (J & K)
30	Dr. Sajal Kumar Roy Choudhary Director, Direcotrate Drugs Controller Govt of West Bengal, P-16, India Exchange Place Extension, C/T Building, 5th Floor, Kolkata , West Bengal

B. <u>Ministry of Health</u>

S.NO	NAME & DESIGNATION OF THE PARTICIPANTS
31	Sh. Debashish Panda, Jt. Seceartry, Ministry of Health and Family welfare

C. Central Drug Testing Laboratories

S.NO	NAME & DESIGNATION OF THE PARTICIPANTS
33	P.K Guha, Director, Central Drugs Laboratory , Kolkata, West Bengal
34	G.N Singh, Director Indian Pharmacopiel Commision, CIPL .sector 23, Raj Nagar , Ghaziabad
35	Dr. Gopa Ghosh, Director, CDTL , Mumbai
36	Dr. P. K Gagoi, Director, RDTL Guwahati , Assam
37	Murgan, Technical Officer, CDSCO, FDA Bhawan, New Delhi

D. Zonal Officers

S.NO	NAME & DESIGNATION OF THE PARTICIPANTS
38	M. Mitra, Deputy Drug Controller – Incharge –CDSCO (East Zone)
39	Dr. D. Roy, Deputy Drug Controller – Incharge –CDSCO (South Zone)
40	Dr. A. Ramakrishna, DDC I/C , CDSCO North Zone, Ghaziabad

E. CDSCO Hqrs.

S.NO	NAME & DESIGNATION OF THE PARTICIPANTS
41	A.B. Ramteke, Jt. Drug Controller (India) – CDSCO, FDA Bhawan, New Delhi
42	N.C Dhawan, D.D.G – CDSCO, FDA Bhawan, New Delhi
43	Lalit Kishore, Consultant, CDSCO, FDA Bhawan, New Delhi
44	S. P Shani, Asstt. Drug Controller (India) – CDSCO, FDA Bhawan, New Delhi
45	Janak Raj, Asstt. Drug Controller (India) – CDSCO, FDA Bhawan, New Delhi
46	A.K Pradhan, Asstt. Drug Controller (India) – CDSCO, FDA Bhawan, New Delhi
47	Manjula Chandra, Asstt. Drug Controller (India) – CDSCO, FDA Bhawan, New Delhi
48	Lucas .L Kamsuan, Dy. Director Admin, CDSCO, FDA Bhawan, New Delhi

S.NO	NAME & DESIGNATION OF THE PARTICIPANTS
49	R. K Rishi, Pharmacologist, CDSCO, FDA Bhawan, New Delhi
50	A.K. Khanna, Technical Officer, CDSCO, FDA Bhawan, New Delhi
51	Ravi Kant, Technical Officer, CDSCO, FDA Bhawan, New Delhi
52	S.N Basu, Technical Officer, CDSCO, FDA Bhawan, New Delhi
53	Kavita Sharma, Technical Officer, CDSCO, FDA Bhawan, New Delhi
54	Assem Sahu, Technical Officer, CDSCO, FDA Bhawan, New Delhi
55	Dr. I.S. Hura, Technical Officer, CDSCO, FDA Bhawan, New Delhi
56	Sunil Kulshrestha, Technical Officer, CDSCO, FDA Bhawan, New Delhi
57	Gaurav Kumar, Technical Officer, CDSCO, FDA Bhawan, New Delhi
58	Anita Vegas, STA, CDSCO, FDA Bhawan, New Delhi
59	Sudha Jose, STA, CDSCO, FDA Bhawan, New Delhi
60	Pratyush Kumar, Technical Consultant, CDSCO, FDA Bhawan, New Delhi
61	Kaushiki Mukherjee, TDA, CDSCO, FDA Bhawan, New Delhi
62	Rahul Vij, TDA, CDSCO, FDA Bhawan, New Delhi
63	Kashi Shankar, TDA, CDSCO, FDA Bhawan, New Delhi

Annexure-II-A

No.X-19013/1/2008 - D
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/o DCG (I))

FDA Bhawan, Kotla Road,
New Delhi.
Dated: the 24th December, 2008

OFFICE MEMORANDUM

Subject: Constitution of a Sub-Committee to recommend measures to enhance testing of drugs in the country by optimising the available capacities for testing and suggest mechanism for outsourcing and testing of drugs at private labs – regarding.

The 39th meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 10th December, 2008 to discuss the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and rules made thereunder in the country. During the course of the meeting the issue of testing of statutory samples by the Government Drug Testing Laboratories was considered. Shri Debasish Panda, Joint Secretary to the Government of India, who addressed the meeting suggested that the DCC may form a sub-committee to deliberate in depth the issue of testing of drugs in the country with a view to enhance testing of drugs in the country by optimising the available capacities for testing statutory and other samples and suggest mechanism for outsourcing and testing of drugs at private labs. The DCC accepted the suggestion and decided to set-up a sub-committee to look into all these issues and give its recommendations.

Composition of sub-committee

1. Dr. G.N.Singh (Director IPC Ghaziabad (UP) - Convener
2. Sh P. K.Guha (Director CDL Kolkata (WB) - Member
3. Sh. M.P.George (Drugs Controller Kerala) - - do --
4. Sh M k Paul (Dy. Drugs Controller Tripura) -- do --
5. Dr. Subba Rao (Drugs Controller Bihar) - - do --
6. Sh D. K Shringi (Drugs Controller Rajasthan) - - do --
7. Govt Analyst, Nominated by Commissioner FDA, Maharastra - - do –

Terms of Reference:

1. Turnaround time for testing of drug samples.
2. Testing capacity of each laboratory of the state or centre and the testing loads with them.
3. Preparation of standard operating procedures for testing of drug samples.
4. Mechanism of outsourcing & inclusion of private testing laboratories which are NABL accreditation.
5. Corresponding amendments to the Drugs & Cosmetics Act & rules a required for the purpose of testing of samples at private labs and creation of statutory drug testing laboratories in the States.
6. Any other issues raised by the members.

The Committee will give report in two months.

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

To
The Members of Committee

Annexure-II-B

No.X-19013/1/2008 - D
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/o DCG (I))

FDA Bhawan, Kotla Road,
New Delhi.
Dated: the 24th December, 2008

OFFICE MEMORANDUM

Subject: Constitution of the Sub-Committee on identification, collection and exchange of data through the internet or intranet between the States or Centre or the States -– regarding.

The 39th meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 10th December, 2008 to discuss the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and rules made thereunder in the country. During the course of the meeting the issue of non-availability of various kinds of data from one State to another or between Centre and the States was discussed. The DCC after deliberations recommended for setting up of the following sub-committee to suggest ways and means for data management and its exchange between the States.

Composition of sub-committee for data management

1. Shri A.K. Kukrety, Assistant Drugs Controller (India), Delhi. -Convener
2. Shri, B.R. Jaga Shetty (Drugs Controller ,Karnataka) - Member
3. Sh. M.P.George (Drugs Controller Kerala) - Member
4. Shri. Murlikrishana (Commissioner, FDCA,Gujarat) - Member
5. Shri. R. Rangarao (Director, Drugs Control Administration, A.P.) - Member

Terms of Reference:

1. Identify the data required for exchange between States or State/Centre
2. Creation of data bank in respect of manufacturers licensed and their products and related information.
3. Online filing of application and grant of approval.
4. Any other matter raised by the member related to e-governance.

The Committee will give report in two months.

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

To

The Members of Committee

Annexure-II-C

No.X-19013/1/2008 - D
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/o DCG (I))

FDA Bhawan, Kotla Road,
New Delhi.
Dated: the 24th December, 2008

OFFICE MEMORANDUM

Subject: Constitution of the Sub-Committee to examine suggestions of amendments to the Drugs and Cosmetics Rules placed before DCC and suggest comprehensive proposal for the amendments -– regarding.

The 39th meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 10th December, 2008 to discuss the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and rules made thereunder in the country. Various proposals for the amendment of the Drugs and Cosmetics Rules were suggested by the members. It was decided in the DCC meeting that these proposals shall be examined by a sub-committee and comprehensive draft proposal for the amendment of the Drugs and Cosmetics Rules suggested for further consideration.

Subcommittee for Amendments to Drugs & Cosmetics Acts & Rules

1. Shri. R. Rangarao (Director, Drugs Control Administration, A.P.) - Convener
2. Dr. Ajay Kumar Singla (Drugs Controller, NCT of Delhi) -Member
3. Shri. Deen Dayalan (Asstt. Commissioner,Pudducherry) - - do –
4. Sh. M.P.George (Drugs Controller Kerala) - - do --
5. Shri. M.Mitra (DDC (I) Incharge, CDSCO, E.Z.) - - do --

Terms of Reference:

1. To examine various proposals for amendments to the Drugs and Cosmetics Rules referred to it by the committee.

The Committee will give report in two months.

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

To

The Members of Committee

Annexure-II-D

No.X-19013/1/2008 - D
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/o DCG (I)

FDA Bhawan, Kotla Road,
New Delhi.
Dated: the 24th December, 2008

OFFICE MEMORANDUM

Subject: Constitution of a Sub-Committee for preparing proposal for financial assistance required for strengthening of State Drug Control Organization to meet the challenges of present day needs for regulatory control over drugs -– regarding.

The 39th meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 10th December, 2008 to discuss the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and rules made thereunder in the country. The members requested that the Central Government may provide financial assistance to the State Drug Control Organizations for upgrading their infrastructure for effective regulatory control in the country. Shri Debasish Panda, Joint Secretary to the Government of India, Ministry of Health and FW, who addressed the members suggested that the DCC may recommend concrete financial proposal for the areas where Central assistance could be provided. After discussions, DCC constituted the following subcommittee for preparing financial proposal for strengthening of State Drug Control Organization and their testing laboratories.

Subcommittee for preparing financial proposal for strengthening of State Drug Control Organization

1. Shri. N.C. Dhawan, Dy. Director General (Drugs) -Convener
2. Shri. K. Sundharaswami (Director, Drug Control, Tamilnadu) - Member
3. Shri. R. Rangarao (Director, Drugs Control Administration, A.P.) -- do--
4. Shri. Navneet Marwahe (Asstt. Drugs Controller, H.P.) - - do –
5. Shri. A.K. Jain(Asstt. Drugs Controller, Meerut Division) - - do --
6. Dr. Subba Rao (Drugs Controller Bihar) - - do --
7. Shri C.N. Sharma (Drugs Controller, Sikkim) - - do --
8. Shri Pramod (Director, FDA, Goa) - - do --

Terms of Reference:

1. To identify the areas where the Central assistance could be provided to State Drug Control Organization.
2. Preparation of financial proposal for infrastructural development and testing facilities in the State Drug Control Departments.

The Committee will give report in two months.

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

To
The Members of Committee

Annexure-II-E

No.X-19013/1/2008 - D
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/o DCG (I)

FDA Bhawan, Kotla Road,
New Delhi.
Dated: the 24th December, 2008

OFFICE MEMORANDUM

Subject: Constitution of the Sub-Committee on spurious drugs -– regarding.

The 39th meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 10th December, 2008 to discuss the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and rules made thereunder in the country. The Chairman briefed the members that one of the major issue is the reports of availability of spurious drugs in the country. CDSCO is conducting an all India survey to assess the extent of availability of spurious drugs in the country by drawing samples from different regions and different strata in the country. The States are required to play pro-active role in assessing the extent of spurious drugs. The DCC after deliberations constituted a sub-committee which will not only co-ordinate with the CDSCO in conducting the survey but also suggest ways and means for co-ordinating between the States and the efforts for combating the menace of spurious drugs in the country.

Subcommittee on Tackling the Spurious Drugs

1.	Dr. D. Roy (Dy. Drugs Controller (South Zone), Chennai	-Convener
2.	Shri D.K. Shringi (Drug Controller, Rajasthan)	- Member
3.	Shri. M.M. Prasah(Drugs Controller , jharkhand)	- - do --
4.	Shri, B.R. Jaga Shetty (Drugs Controller ,Karnataka)	-- do --
5.	Shri. Alok Shrivastva (Jt. Drugs Controller, M.P.)	- - do --
6.	Shri Devistno Swer (Asstt. Drugs Controller , Meghalaya)	- - do –
7.	Shri. Deen Dayalan (Asstt. Commissioner,Pudducherry)	- - do –
8.	Government analyst Representative nominated by FDCA, Gujarat	- - do

Terms of Reference:

1. To help CDSCO in drawing up of samples for conduct of study of spurious drugs in the country.
2. device guidelines in the light of strict penalties under the Drugs and Cosmetics Act passed by the Parliament
3. device guidelines for co-ordinating with others State licensing authorities for speedy investigations of cases of spurious drugs.
4. Device guidelines for dissemination of information of serious violations of Drugs and Cosmetics Act to other States and Public.
   The Committee will give report in three months.

The Committee will give report in two months.

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

To

The Members of Committee

ANNEXURE III

ACTION TAKEN REPORT ON THE MATTERS ARISING OUT OF THE 38TH MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 4TH JUNE, 2007 AT NEW DELHI.

S.NO.	Agenda No.	SUBJECT	ACTION TAKEN
1	1	CREATION OF A NEW SCHEDULE-H(1) AND CORRESPONDING CHANGES IN THE RULES UNDER THE DRUGS AND COSMETICS RULES FOR SPECIAL PRODUCTS WHICH ARE REQUIRED TO BE SOLD UNDER SPECIFIED CONDITIONS i.e. DICLOFENAC AND SPECIFYING CONDITIONS FOR SALE OF SUCH PRODUCTS.	DTAB constituted a sub committee to examine the matter. Recommendations of the committee for introduction of new schedule will be considered by the DTAB in its next meeting. The manufacture, sale and distribution of Diclofenac and its formulations has been prohibited for animal use under section 26A vide gazette notification GSR 499 (E) dated 4.7.08
2	2	INCLUSION OF PSYCHOTROPIC SUBSTANCES UNDER THE LIST OF THE PRODUCTS TO BE LICENSED BY THE CENTRAL LICENSING APPROVING AUTHORITY (CLAA) AND DEVISING A SYSTEM FOR COLLECTING INFORMATION OF ANNUAL CONSUMPTION OF THESE DRUGS IN THE COUNTRY FOR SUBMISSION TO INCB, VIENNA AS INTERNATIONAL OBLIGATION.	DTAB agreed to the proposal and the Drugs and Cosmetics Rules for the purpose are being amended by the MOH.
3	3	PROPOSAL FOR CONSIDERATION OF GUIDELINES FOR RECALL AND DESTRUCTION OF DRUGS WHICH ARE DECLARED TO BE NOT OF STANDARD QUALITY.	Guidelines for recall and destruction of drugs were prepared by the office of DCG(I).
4	4	PROPOSAL TO CONSIDER LABELLING OF HOMEOPATHIC MEDICINES IMPORTED INTO THE COUNTRY TO GIVE THE NAME OF THE IMPORTER ON THE LABEL –REG.	Draft rules to amend rule 106A were published by MOH vide GSR 593 (E) dated 13.8.08. The amendment is in the process of finalization.
5	5	AMENDMENT OF RULE-94 OF THE DRUGS AND COSMETICS RULES FOR PROVIDING	Draft rules to amend rule 94 were published by MOH.

S.NO.	Agenda No.	SUBJECT	ACTION TAKEN
		EXEMPTION FROM CERTAIN LABELING REQUIREMENTS FOR LABEL AND PACKAGES OF DRUGS MEANT FOR EXPORT ONLY.	
6	6	CONSIDERATION OF PROPOSAL FOR AMENDMENT OF DRUGS AND COSMETICS RULES IN RESPECT OF LABELLING CLAIMS ON COSMETICS INCLUDING BABY COSMETIC PRODUCTS.	DTAB desired that the matter may be re-examined by DCC and comprehensive amendments suggested for further consideration.
7	7	CONSIDERATION OF THE PROPOSAL TO INCLUDE UMBILICAL CORD BLOOD STEM CELLS IN THE EXISTING REGULATORY REQUIREMENTS OF BLOOD BANKS AND SPECIFY REQUIREMENTS FOR COLLECTION, PROCESSING etc.-REG.	DTAB agreed to the proposal and the Drugs and Cosmetics Rules for the purpose are being amended by the MOH.
8	8	PROPOSAL TO CONSIDER AMENDMENT OF ENTRY NO. 14 OF THE GAZETTE NOTIFICATION GSR 578 (E) DATED 23.7.83 REGARDING BAN ON FDC OF CORTICOSTEROIDS WITH ANY OTHER DRUG FOR INTERNAL USE.	DTAB recommended the proposal. Amendment to entry number 14 of list of banned drugs is being processed by MOH.
9	9	FIXED DOSE COMBINATION FORMULATION CONTAINING THE ANTI-TB FIXED DOSE COMBINATION OF RIFAMPICIN 200MG + ISONIAZID 300MG + PIPERAZINE EXTRACT 10MG.	DTAB recommended the proposal. Amendment to entry number 29 of list of banned drugs is being processed by MOH.
10	10	FIXED DOSE COMBINATION FORMULATION CONTAINING THE ANTIHISTAMINE LEVOCETIRIZINE WITH THE LEUKOTRIENE RECEPTOR ANTAGONIST MONTELUKAST.	Entry No. 36 of the list of banned drugs has been amended vide notification GSR 290 (E) dated 16.4.08 by the MOH.

S.NO.	Agenda No.	SUBJECT	ACTION TAKEN
11	11	TO IDENTIFY LABORATORIES WHICH COULD BE NOTIFIED AS GOVERNMENT ANALYST FOR TESTING OF MEDICAL DEVICES ESPECIALLY FOR TESTING THEIR BIOCOMPATIBILITY, STERILITY ETC.	No information received from Maharashtra or Karnataka. However, a separate agenda for medical devices is at agenda No.(3).
12	12	MANUFACTURE OF RECOMBINANT DNA (r-DNA) DERIVED DRUGS i.e. BIOTECH DRUGS AND VACCINES TO BE CONSIDERED AS NEW DRUGS AND THE MANUFACTURING LICENCE FOR EACH MANUFACTURE WOULD BE GRANTED AFTER THE NOC AS A NEW DRUG FROM THE DRUGS CONTROLLER GENERAL (INDIA).	DTAB agreed to the proposal and the Drugs and Cosmetics Rules for the purpose are being amended by the MOH.
13	13	GRANT OF SCHEDULE-K EXEMPTION FOR HOMEOPATHIC PRODUCTS LIKE HAIR OILS (ASHWINI HAIR OIL).	DTAB agreed to the proposal and the Drugs and Cosmetics Rules for the purpose are being amended by the MOH.
14	S-1	GRANTING PERMISSION FOR MARKETING BY STATE DRUGS CONTROLLERS FOR FIXED DOSE COMBINATIONS CONSIDERED AS NEW DRUGS UNDER RULE 122B.	DTAB constituted an expert committee to review the safety issues and the report of the committee will be considered by DTAB in its next meeting.
15	S-2	PROPOSAL FROM THE DRUGS CONTROLLER, KARNATAKA TO AMEND THE DEFINITION OF “RETAIL SALE” UNDER THE DRUGS AND COSMETICS RULES.	The DTAB deferred the agenda.
16	S-3	PROPOSAL FROM THE DRUGS CONTROLLER, TAMIL NADU TOAMEND SCHEDULE-M TO PROVIDE FOR RELAXATION FOR CONDITIONS OF MANUFACTURES IN RESPECT OF MANUFACTURERS OF SURGICAL BANDAGES.	No action was recommended.

S.NO.	Agenda No.	SUBJECT	ACTION TAKEN
17	S-4	CONSIDERATION OF THE PROPOSAL TO AMEND RULE-49-A AND 50-A CONCERNING QUALIFICATION OF A LICENSING AUTHORITY AND CONTROLLING AUTHORITY.	The proposal was withdrawn as it was not considered desirable at present juncture to limit the statutory qualifications of the licensing or controlling authority.

F.No. 22-1/2007-DC

From:

The Drugs Controller General (India)

Directorate General of Health Services,

Nirman Bhawan, New Delhi

Dt.

To,

All the members of DTAB.

Sub: Minutes of 55th Meeting of the Drugs Technical Advisory Board held on 6th July, 2007 at Nirman Bhawan, New Delhi.

Sir,

A copy of the minutes of the 55th Meeting of the Drugs Technical Advisory Board held on 6th July, 2007 duly approved by the Chairman is annexed, for your information and perusal please. Your comments in the matter, if any, may be sent to this Directorate before (13th August, 2007).at Nirman Bhawan, New Delhi.

Yours faithfully,

(Dr. M. Venkateswarlu)
Drugs Controller General (India)
Member Secretary
Drugs Technical Advisory Board

Encl- Copy of the minutes

AGENDA NO. (2)

PHASING OUT OF ORAL SINGLE DRUG FORMULATIONS OF ARTEMISININ AND ITS DERIVATIVES FROM THE MARKET ON THE RECOMMENDATIONS OF WHO

The office of DCG (I) had earlier approved various anti malarial formulations of Artemisinin derivatives like artesunate, artemether, arteether for marketing in the country. As the drug is no longer considered as a new drug, permission for manufacture for sale of these drugs is at present being granted by the State Licensing Authorities. Artesunate and artemether have been approved both in injectable form as well as oral tablet/capsule form while arteether is approved in injectable form only. Currently many firms are manufacturing various formulations of artemisinin derivative in the country.

Various artemisinin based combination (ACT) products like artesunate + sulphadoxine – puirithamine, artemether + lumefantrine , artesunate + mefloquin have also been approved by this Directorate for marketing in the country.

WHO has recommended withdrawal of oral artemisinin based monotherapies from the market to ensure that malaria parasite does not become resistant to the drug. It recommends the use of artemisinin in combination with other effective anti-malarial as artemisinin based combination therapy (ACTs) for the treatment of uncomplicated falciparum malaria. In a high level meeting held on 13-14 October, 2008 at WHO regional office for South East Asia Region, New Delhi on anti-malarial treatment it has been recommended that the State Licensing Authorities should withdraw the manufacturing licences and export licenses for marketing oral artemisinin monotherapies in a period of 6 months i.e. by July, 2009, as finished formulations.

In view of the above recommendations and to ensure that artemisinin derivatives remain effective in the treatment of resistant malaria, the State Licensing Authorities should not grant any new manufacturing license or renew any licence for marketing oral artemisinin monotherapies and withdraw the permissions granted to manufacturers under their jurisdictions for marketing artemisinin monotherapies within a period of six months.

DCC may kindly deliberate and formulate roadmap for the implementations of the recommendation.

RECOMMENDATIONS

Shri A.K. Pradhan, ADC (I) briefed the members that artemisinin derivatives, artesunate and artemether were approved for manufacture and marketing both in injectable form as well as tablets/capsule form and are being marked in the country by various manufacturers. In order to ensure that malaria parasite does not become resistant to the drug, WHO has recommended for the withdrawal of oral artemisinin based mono therapies from the market. It has further recommended the use of artemisinin in combination with other effective anti-malarial as artemisinin based combination therapies (ACTs) for the treatment of uncomplicated falciparum malaria.

The members after deliberations agreed that oral single drug formulations of artemisinin derivatives like artesunate and artemether should be withdrawn from the market in a phased manner and the following steps may be taken for the purpose.

(v) No new licence should be granted for the said formulations.
(vi) Manufacturing licences granted earlier should be withdrawn by March 2009.
(vii) The formulations should be phased out from the market by July 2009.
(viii) DCG (I) office should issue directive to all State Drug Controllers in the matter for uniform compliance in the country.