MINUTES OF THE MEETING WITH STAKEHOLDERS OF IN-VITRO DIAGNOSTIC DEVICES INDUSTRY (MEMBERS of FICCI, CII & ADMI) HELD ON 07/08/2012 AT CDSCO, FDA BHAVAN, KOTLA ROAD, NEW DELHI-110002

Present :

Officers of CDSCO

1. Dr. G.N.Singh

   Drugs Controller General (India), CSCO, New Delhi.

2. Dr. S.Eswara.Reddy,

   Deputy Drugs Controller (India), CDSCO, New Delhi.

3. Mr. Sella Senthil M- Drugs Inspector, CDSCO Delhi.
4. Mr. S.N. Saini- Drugs Inspector, CDSCO Delhi.
5. Mr. K.K. Bhardwaj-Drugs Inspector, CDSCO Delhi.

Invitees

1. Federation of Indian Chambers of Commerce and Industry (FICCI)

I. Mr. Ganu Shekher-GM RA- Johnson & Johnson
II. Mr. Sushant Kinra- VP Siemens
III. Mr. Sheshan Sunder-Head RA-Beckman Coulter
IV. Mr. Imran Parvez-Head RA, Siemens
V. Ms. Sushmita Roy Chowdhury - Head RA, Roche Diagnostics India Pvt. Ltd
VI. Mr. Gaurav Mendiratta-FICCI
VII. Mr. Tanmoy Bose- Joint Director-FICCI

2. Confederation of Indian Industry (CII)

I. Mrs. Rekha Khanna- MD, BioMerieux India
II. Mr. Santosh Rane –Head RA- Abbott Diagnostics
III. Mr. Ramesh Pandey- Head RA-Biorad Lab
IV. Mr. Bivash chakrabarty-Head RA BioMerieux India
V. Mrs. Elizabeth Jose- Executive officer-CII

3. Association of Diagnostics Manufacturers of India (ADMI)

I. Mr. Nintal Patel-Secretary, Reckon Diagnostics –ADMI
II. Mr. Dinesh Parmar-Vital diagnostics, Joint Secretary-ADMI

The meeting was chaired by Dr. G.N.Singh, Drugs Controller General (India).

Dr. G.N.Singh welcomed the participants. He stated that the objective of the meeting was to examine and resolve the current issues of IVD Industry. He also informed to all invitees that Dr. S.Eswara.Reddy, elevated to Deputy Drugs Controller (India). Dr. G.N.Singh welcomed all global IVD Industry to take initiation to setup their manufacturing facilities in the country as the country has huge potential of human resources and technology. Further Dr. G.N.Singh also requested all stakeholders to give their suggestions to achieve the mission and vision of the CDSCO to ensure quality, Safety and Performance of the In-Vitro Diagnostic Devises.

Dr. S.Eswara.Reddy , Deputy Drugs Controller (India) gave brief presentation on functioning of Diagnostic division which includes:

- Activities of Diagnostics Division,
- Workload Statistics,
- Current Manpower
- Major Initiatives/Achievements of Diagnostics Division
- Overseas inspection of Diagnostics manufacturers located in China in Year 2012
- Road Map for the year 2012-2017

All the members appreciated the progress, performances and Initiatives of Diagnostics Division for uniform, effective and timely approvals.

After the deliberation in the meeting and discussion with stakeholders (members of FICCI, CII and ADMI) following points emerged:

1. It is decided that the submission of Performance Evaluation Reports (PER) of Notified Diagnostic Devices may be exempted at the time of submission of application for Re-registration of the manufacturing site and the products. However, PER should be submitted by the applicant with in three month from the date of submission of the application. This exemption may be considered for the applications submitted for Re-registration before 31st December 2012.

Further it is also decided that this exemption is not applicable for the fresh registration application.

2. It is decided that for grant (Re-issue) of import licence for cancer markers, an application may be accepted along with one batch Performance Evaluation Report with a condition that the applicant should submit legal undertaking along with the application stating that the Performance Evaluation Reports of remaining two batches will be submitted to the licensing authority before sale or distribution of the products.
3. It is informed to the members that as recommended by Internal standing committee of CDSCO all kits intended for identification / screening / diagnosis / monitoring of hepatitis B virus are regulated as notified diagnostic devices under Drugs and Cosmetics Act and Rules.
4. It is informed to the members that no exemption will be granted for the import of Diagnostic kits / reagents having less than sixty per cent residual shelf-life period as on the date of import. However, in exceptional cases the licensing authority may allow the import of such kits as per Rule 31 of Drugs and Cosmetics Rules.
5. It was suggested by the members that the office of DCGI may design / prepare guidance documents for regulation of In – Vitro diagnostic devices / reagents for grant of manufacturing licences by State Licensing Authority for the uniform interpretation and implementation of regulations.
6. The industry members also requested attention of CDSCO to the constraints and bottlenecks faced in testing of Closed Systems IVD products at National Institute of Biological, Noida. It was conveyed that for specific operational issues related to NIB, Noida , industry members may request the Director NIB to examine the issues. For cases where Closed System/Testing facilities are not available in NIB,Noida, CDSCO may consider approval of alternate laboratories like CMC Vellore, NIV Pune, AIIMS, Nizam Institute of Medial Sciences (NIMS) or other Govt. institutes of national repute for testing purposes of Notified In Vitro Diagnostic Devices on case to case basis.
7. It was clarified to members by CDSCO that Rule 37 requirements is not applicable for cases where the reagents are imported in bulk packs under Form 10 license mentioning Bulk or the use of product in manufacturing .

However, in such cases, the exemption is only applicable if the applicant holds the valid manufacturing license for the finished product.

8. CDSCO also clarified that for products which are not marketed in country of origin, applicant may furnish Free Sale Certificate from any country issued by National Regulatory Authority of the country for grant of Form-10 for Non-Notified diagnostic devices.
9. Members of FICCI, CII and ADMI requested the CDSCO to conduct such meetings / interaction with industry stakeholders in future also

The meeting ended with the vote of thanks to the chair.

DI (SS)

DDC(ER)

DCG (I) 21-09-12