Minutes

Date 30.03.2016

Meeting to understand the issues and grievances of the stakeholders

---

- An interactive meeting of stakeholders with DCG (I) to understand their issues and grievances was held on 30.03.2016 at 02:30PM at FDA Bhawan, Kotla Road, New Delhi.
- Representatives of various industry associations viz. OPPI, IDMA, CII, FICCI, ADMI, AIMED, ASSOCHAM, ISCO, CIPI, IBHA, FOPE, PHD etc. attended the meeting.

Following issues were deliberated:

- **Banning of FDCs:**
  DCG(I) mentioned that the matter is sub-judice hence beyond the scope for discussion at this particular time. However, the members expressed their concern and requested DCG(I) to communicate to higher officials of the Ministry and if feasible organize a meeting of the important members of the industry associations with the Ministry officials.

  [DCGI –in one week time]

- **Clinical Trials:**
  The Clinical Trials concern on issues like restriction of three trials per investigators, Trials to be conducted minimum in 50 beds Hospitals, Audio-Visual recording during Inform Consent Process (ICP), delay in conduct of Technical / Apex committee meetings. The participants further requested to compile amendments in "Schedule Y" and uploaded on the website of CDSCO.

  DCG(I) informed that it would be addressed within few weeks time as it has been cleared from the highest level of the Ministry of Health and Family Welfare. It would be put under the public domain after informing the revision to the Hon'ble Supreme Court through affidavit.

  [DDC (AKP) –in two weeks time]

- **Medical Devices:**
  The issues related to Medical Devices, and IVD's regarding notification of Schedule M-III, Drugs & Cosmetics Amendment Bill etc. have been raised. It was informed that notification of Schedule M-III will be published shortly by the central Government.

  It was also decided to convene a separate meeting with medical device and IVD manufacturers in 3rd week of April, 2016.

  [JDC (ER) –in 15 days]

- **Cosmetics:**
  The issue regarding the guidelines for approval of cosmetics post implementation of banning of testing of cosmetics on animals was raised and it was informed that the draft guideline will be deliberated with the stakeholders.

  [DDC (SD) –in 3 months time]

  It was agreed to have regular meetings with the stakeholders and points suggested in the meeting would be addressed in a time bound manner.

  [DDC (AS)]

  It was also reiterated that all efforts would be made for enabling ease of doing business and "Make in India" by our deep penetration in market of other countries by achieving zero quality defect in products and services by bringing ease in regulatory procedures and current science based regulatory requirements.

  [DCGI]

The meeting ended with vote of thanks to chair and other participatory members.

*****