Minutes of the Expert Committee meeting to examine and recommend changes/ measures to simplify forms/ format (to be filled up by the applicants) and reduce their numbers on 04.11.14 at 10:00 A.M. At 1ST floor, FDA bhawan, CDSCO (HQ) New Delhi

Present:

1. Dr.G.N.Singh,
   DCG(I)
2. Dr. B. R. Jagashetty,
   Retd. Drugs Controller,
   Karnataka
3. Shri Uttarwar,
   Retd. Joint Commissioner,
   FDA, Maharashtra
4. Shri D. K Shringi,
   Retd. Drugs Controller, Rajasthan
5. Shri P.K Jaggi,
   Retd. Deputy Drugs Controller, Delhi
6. Mr. R. Chandrashekar
   Deputy Drugs Controller (I)
   CDSCO (HQ)
7. Dr. Suresh Menon,
   Representative of OPPI
8. Dr. KiranMarthak,
   Representative of IDMA
9. Mr. Rajiv Nath,
   Representative of AIMED
10. Mr. KuldeepWakhloo,
    Representative of FICCI
11. Mr. Sudhesh Kumar,
    Representative of CIPI

DCG (I) welcomed the members and in his address briefed the members about the desire of the Hon'ble Prime Minister on the need of administrative reforms. Accordingly, this Committee was constituted to review the existing processes/procedures/forms/licenses etc., used not only by the CDSCO but as

well as the States and Drugs Control Laboratories. He indicated that the Committee should study the practices followed by international agencies like WHO and also in countries like Singapore and adopt the best practices to the needs of the country. He also stated that the objective of the Committee should also be the uniform implementation throughout the country.

R. Chandrashekar, DDC (I) welcomed the members to the first meeting of the Task force. He apprised the Committee that a public Notice was also issued seeking suggestions/comments/inputs from all the stakeholders in this regard which would be placed before Committee for consideration. He also brought to the notice of the members the timelines prescribed in the Order for accomplishing its assigned job.

Thereafter, the members gave their brief introduction.

The members expressed their views on the pathway to be adopted for simplification.

Sh. D.K.Shringi opening the discussion stated that there is necessity to simplify the forms. He also observed that though forms prescribed are uniform throughout the country procedures differ from State to State. Hence, guidelines have to be issued by the Central Government for uniform implementation throughout the country.

Dr. B.R.Jagashetty in his remarks briefed the Committee about his experience on the implementation of Information Technology in the State of Karnataka and emphasized the need for accountability. He further stated that the forms should be so devised that they are amenable for online submissions. He proposed that an IT Expert and Drugs Controllers of States with Pharma clusters should be invited to the future meetings of the Committee.

Sh. P.R.Uttarwar in his remarks stated that there is no second opinion on simplification but the Committee should also delete unnecessary forms.

Sh. P.K.Jaggi in his remarks agreed that the forms should be simplified and suggested that international practices should also be kept in view in this process.

Dr.Suresh Menon in his remarks stated that the existing forms should be summarily reviewed, merged or modified wherever necessary and should not hesitate recommend from deleting forms which are redundant.

Sh. Rajiv Nath in his remarks stated that the forms should be made concise, process should be simplified in such a manner so that it reduces processing time, minimizes file movement and should enable uniform implementation across the country.

The industry representatives have requested time to deliberate forms 9, 10, 43 and 44 with their members and agreed to submit their comments in the next meeting.

The Committee opined that the Drugs Controllers of Gujarat and Himachal Pradesh, representatives of Cosmetic importers, All India Organisation of Chemists and Druggists and an IT expert should be invited in the next meeting.

The Committee then deliberated the forms pertaining to the CDSCO and recommended as under:

1. The Committee observed that there are separate forms and licenses prescribed for different categories of drugs viz., Sch C & C1, other than Sch C & C1and Sch X for Import, Manufacturing, sale or distribution and there is no discernable benefit with such a system. Hence, the Committee recommended for making a single unified application form and single unified license in all such cases.
2. Accordingly, the Committee recommended for merging of the application forms 8, 8-A and their corresponding license forms 10 and 10-A and devise a new unified forms 8-U and 10-U.

3. The Committee opined that the permission/approval for the import/manufacture of a new drug and new bulk drug substance viz., 45, 45-A, 46, 46-A can be merged and recommended for a single unified form 45-U.
4. The Committee opined that legal opinion should be taken on the issue of numbering of the unified form/license

The meeting ended with vote of thanks by the convener to all the members attended.

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