**No.D.21013/47/2016**
**Central Drugs Standards Control Organization**
**Directorate General of Health Services**
**Ministry of Health & Family Welfare**

**FDA Bhavan, Kotla Road,**
**New Delhi-110002.**

Dated: 26th December, 2016

## NOTICE

Central Drugs Standard Control Organisation (CDSCO) has initiated the online licensing system to bring transparency, accountability and efficiency in the drug regulatory system. Timelines have been devised under the Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder, for disposal of different work schedules at CDSCO, a copy of which is at Annexure I. A review of the progress achieved *vis-a-vis* pendency in approval of applications relating to New Chemical entities, Global Clinical Trials and New Drugs approval during the last two years and current year, has been carried out. Findings of the review of applications for grant of CT NOC & clinical waiver are attached at Annexure II.

The stakeholders are requested to go through the review findings and give their feedback at e-mail i.d. dci@nic.in about any shortcomings/factual inaccuracies noticed in the findings i.e. if any application in respect of New Chemical entities, Global Clinical Trials and New Drugs approval is pending beyond the targetted timelines). The feedback may kindly be sent latest by 30th December, 2016.

(Arun Sharma)
Director (Admn.)

To

1. All the stakeholders.
2. PS to Secretary (HFW)/PPS to DGHS/

Annexure - I

30-05-14

CDSCO

## TIMELINES

| S. No. | Type of application | Timeline in days |
|---|---|---|
| 1. | | |
| a) | New Drug including Biological, Medical Devices/Clinical Trials/Global Clinical Trials/New Claims in consultation with NDAC/MDAC | 180 |
| b) | IND Applications in consultation with IND Committee | 180 |
| c) | Subsequent New Drugs | 120 |
| d) | Clinical Trial Protocol Amendments (If Consultation of NDAC is not required) | 60 |
| 2. | Fixed Dose Combination in consultation with NDAC | 180 |
| 3. | Import Registration of Drugs and Medical Devices | 270 |
| 4. | Endorsement of Additional Product in Registration Certificate | 120 |
| 5. | Rule 37 & Neutral Code | 60 |
| 6. | NOC for Form 29 (Biological and Medical Devices) | 60* |
| 7. | CLAA in Form 28/28-D/28-E/27-C etc. | 60 |
| 8. | Import License in Form 10 | 45 |
| 9. | Test License in Form 11 | 45 |
| 10 | Bioavailability /Bioequivalence (BA/BE) Study | 45 |
| 11. | Extension of Shelf Life for export | 45 |
| 12. | Export of Biological samples | 45** |
| 13. | Registration of Cosmetics | 90 |
| 14. | Registration of Ethics Committee | 100 |
| 15. | Post Approval Changes (major) in consultation with CDL, NDAC | 180 |
| 16. | Post Approval Changes (minor) | 90 |
| 17. | BA/BE site approval (after receipt of Joint Inspection report) | 60 |
| 18. | Written Confirmation as per EU Directives | 30 |

*If Inspection is involved, the time line is from the date of receipt of the inspection report.

**After obtaining BA/BE NOC

Note: In case of query or explanation, the time line will be from the date of receipt of the response.

30-05-14
(Dr. G.N. Singh)
Drugs Controller General (I)

To

1. JDC (I)/DDC(I)s/ADC(I)s, CDSCO HQ
2. All Zonal/Sub Zonal offices of CDSCO

Copy to: PPS to DGHS/PS to AS&DG/PS to JS (R), MoHFW

Annexure - II

## Findings of review of cases for grant of CT NOC and Clinical Trial waiver for the last three years in CDSCO

| Subject | No. of pending cases of CT NOC and Clinical Trial waiver | | |
|---|---|---|---|
| | 2013-2014 | 2014-2015 | 2015-2016 |
| Global Clinical Trial | 0 | 5 | 28 |
| New Drugs | 1 | 2 | 12 |
| Subsequent New Drugs | 2 | 2 | 9 |
| Fixed Dose Combination | 0 | 5 | 23 |
| Biological | 0 | 1 | 6 |
| Medical Device and Diagnostics | 0 | 0 | 0 |

**Note:** The delay of the above application is because of various reasons like non submission of reply by the applicant, the replies received are under review by the concerned division of CDSCO.