F. No. D.21013/76/2017-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation

New Delhi, dated the 27th June, 2017

NOTICE

Subject: **Streamingthe Regulatoryprocedures by Relaxing and Modifying the existing provisions of the Drugs and Cosmetics Rules, 1945 – regarding.**

In compliance to the directions of the Government to reduce the layers/steps for providing prompt services to the stakeholders, the CDSCO has initiated various measures in the last few years to streamline the regulatory proceduresby relaxing, rationalizing and modifyingthe existing provisions of the Drugs and Cosmetics Rules, 1945.This has resulted in accelerating the regulatory approvals/clearances without compromising the safety, quality and performance of medical products.

Some of the important Notifications/stepstaken are appended below:

- **G.S.R. 103(E**), Dated 2nd February, 2017: Small quantity of drugs with residual shelf life of one year or more, received through donation by charitable hospitals for the purpose of treatment of patients may be imported, provided that these drugs are given free of cost to the patients.
- **G.S.R. 80(E)**, Dated 1st February, 2017:Provision for obtaining licence for sale is exempted for homeopathic medicines with certain conditions.
- **G.S.R. 76 (E)**, Dated 31st January, 2017: Provision for obtaining licence for sale is exempted for homeopathic medicines with certain conditions.
- **G.S.R. 56(E)**, Dated 19th January, 2017: PPM level of Mercury is reduced for import of cosmetics applicable in area under eye.
- **G.S.R. 43(E)**, Dated 17th January, 2017: To ease the importer for obtaining import licence, undertaking in form 9 is exempted.
- **G.S.R.1041(E)**, Dated 4th November, 2016: Animal toxicology study is replaced with non-animal toxicity study test as an alternative test.
- **S.O. 2612(E)**, Dated 4th August, 2016: The import of human biological samples by the Indian diagnostic laboratories/Indian Clinical Research Centres for lab analysis/R & D testing or export of these materials to foreign laboratories should be permitted by Customs authorities at the port of entry/exit without prior approvals (import licence/export permit) from any other Government agency

- **G.S.R. 313(E)**, Dated 16th March, 2016: NOC/permission from DCGI is simplified vide G.S.R. 313(E) for conducting clinical trials for new indication, new dosage form etc. For academic research institutes.
- **G.S.R. 648 (E)**, Dated 20th August, 2015: Licence validity provision for Merger & Acquisitions firms. Licensing requirements for 100% EOU units waived off for manufacturing LVPs for export purpose only.
- **G.S.R. 611 (E)**, Dated 31st July, 2015: Audio-Visual (AV) recording of Informed Consent Process (ICP) is now mandatory only for vulnerable subject in clinical trials of New Chemical Entity (NCE)/New Molecular Entity (NME) and anti-HIV and anti-Leprosy drugs.
- **G.S.R. 289(E)**, Dated 15th April, 2015: Prohibition of advertisements of drugs covered under Schedule H, Schedule H1 and Schedule X.
- **G.S.R. 224(E)**, Dated 25th March, 2015: Rules for timelines of 21 working days is in place to issue or deny the permission of NDPS substances for the purpose of export or import.
- **G.S.R. 107(E)**, Dated 18th February, 2015: The word "in Form 20C" omitted in Schedule K (for exemption of Licence) at serial no. 35 for classes of drugs for Homeopathic hair oils have been active ingredients up to 3X potency only.
- **G.S.R. 701(E)**, Dated 29th September, 2014: Prohibition of use of Polyethylene Terephthalate in liquid oral formulations for primary packaging of drug formulations.
- **G.S.R. 570(E)**, Dated 7th August, 2014: Generic name for the single active ingredient drug formulations.
- **G.S.R. 498(E)**, Dated 11th July, 2014: Prohibition of the manufacture for sale, sale and distribution of the Flupenthixol and Melitracen (FDC) for human use.
- **G.S.R. 328(E)**, Dated 3rd April , 2017: Transfer facility of blood and its components are in place to facilitate the blood distribution to the needy patients. Blood donation camps can be organized by a private/voluntary or charitable hospital licenced blood banks.
- **G.S.R. 327(E)**, Dated 3rd April, 2017: The applicants are facilitated by introducing G.S.R. 327(E) dated 03-04-2017 as they can submit the result of bioequivalence study along with the application for grant of a licence of oral dosage form of drugs specified under category II and category IV of the biopharmaceutical classification system.
- **G.S.R.302(E),** Dated 30th March, 2017: Proper name of the drug be printed or written in a conspicuous manner which shall be in the same font but at least two font size larger than the brand name or the trade name.
- **G.S.R. 78(E),** Dated 31st January, 2017: Regulation for manufacturing for sale and distribution or sell or import of medical devices are in place to facilitate public domain and stakeholders.
- **G.S.R. 44(E),** Dated 17th January, 2017: Certain enzymes, hormones, and bacterial & viral vaccines are introduced in the list of items to carry out test or analysis as a function of CDL under rule 3.
- **G.S.R. 1179(E),** Dated 28th December, 2016 : Those who have qualification and experience of a competent person prior to the coming into force of the Drugs and

Cosmetics (Amendment) Rules, 2016, shall continue to be considered as a competent person for the said purposes."

- **G.S.R. 640 (E),** Dated 29th June, 2016: Rules under "Schedule M-III for quality management system –for notified medical devices and In-Vitro diagnostics introduced.
- **G.S.R. 897(E),** Dated 21st September, 2016:CoPP is to be provided along with application for obtaining RC as per European or USA guidelines etc. or Information and undertaking required to be submitted under schedule D(I) and D(II) by manufacturer with the application for registration certificate.
- **S.O. 705(E) To 1048 (E),** Dated 10th March, 2016: Irrational fixed dose combinations, prohibited from manufacture, sale and distribution (matter is subjudice).
- **G.S.R. 287 (E),** Dated 8th March, 2016: Mandatory provision for New Drug permission holders to have pharmacovigilance system in their organisation.
- **S.O. 237 (E),** Dated 25th January, 2016: Inclusion of Ablation device in the definition of drug in section-3.
- **G.S.R. 918(E),** Dated 30th November, 2015: New regulation for Phytopharmaceutical drug is introduced.
- **G.S.R. 826(E),** Dated 30th October, 2015: Definitions of Clinical trial, GCT, IND, NCE introduced.
- **G.S.R. 558(E).** Dated 17th July, 2015: Diclofenac inj. For human use shall be in single unit dose pack only (To avoid misuse for veterinary).
- **G.S.R. 203(E),** Dated 18th March, 2015: Omission in Schedule Q and new addition in Schedule S for patient safety.
- **S.O. 873(E),** Dated 30th March, 2015: Additional branches of Bank of Baroda are added for submission of Fees to facilitate filing of various applications to CDSCO.
- **S.O. 376 (E**) Dated 5th February, 2016: Addition of Mephedrone in the list of psychotropic substances.
- **GSR 68 (E),** Dated 3rd February, 2015: (i) In rule 71, 71-B, 76, 76A- applicant shall submit evidence and data justifying that the drugs are stable for proposed shelf life under recommended storage conditions as per Appendix IX of Schedule Y. (ii) In the Drugs & Cosmetics Rules in Schedule D, in the Table, against item 1, under the column "Class of drugs", for the existing entries, the following entries shall be substituted, namely:-"Substances not intended for medicinal use excluding those intended to be used as drugs after further purification or rendering them sterile."
- **GSR 38 (E),** Dated 16th January 2015: Procedure for disposal of Psychotropic substances and controlled substances.
- **GSR 908 (E),** Dated 22nd December, 2014: Functions of CDL under rule 3 for classes of drugs listed in said notification.
- **GSR 889(E),** Dated 12nd December, 2014: Rules pertains and relates to areas like criteria for deciding the relatedness of the SAEs to clinical trials and payment of compensation were amended.
- **G.S.R. 503(E),** Dated 14th July, 2014: Diclofenac inj. For human use shall be in single unit dose pack only and Post approval change for vaccine or biological product as a new drug.

- **G.S.R. 502(E),** Dated 14th July, 2014: Definition under rule 122E of further defined and elaborated labelling requirements under rule 96 additional information to be provided
- Certified Quality Management System is introduced at CDSCO(HQ) and zonal offices to have transparency and accountability.
- E-governance for online submission and processing of various applications at CDSCO HQ has been introduced.
- Time for review process for application is reduces from 9 months to 4 months.
- Reduction in timelines for issuance of licence on Form 10/ Test licence from 45 days to 10 days.

Feedback fromthe stakeholders on other issues which fall under the jurisdiction of drug regulatory regime are invited by 31st July, 2017 to streamline the regulatory processfurther.

Office of Drug Controller General (India)

To

1. All State Drug Controllers.
2. All Drugs/Pharma Manufacturing Associations/Stakeholders
3. Website of CDSCO.