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MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

New Delhi, 16 March, 2017

PUBLIC NOTICE

SUBJECT: PUBLIC CONSULTATION REGARDING REGULATION OF SALE OF DRUGS IN THE COUNTRY.

The Government of India has received a number of representations regarding the need for plugging the gaps in the sale of drugs including sales through online/internet. The matter has been examined in the Ministry of Health and Family Welfare and preliminary discussions have also been held with stakeholders concerned with a view to evolving ways and means of regulating sale of drugs in an efficient manner. The objective of such regulation would be to ensure availability of right drugs that meet the standards of quality to every person, in need of medicines, curbing anti-microbial resistance (AMR) and also regulating supply of medicines through online/internet to persons or other entities in outside India.

2. The Government had earlier, decided to introduce bar coding on the primary, secondary and tertiary packs of durgs/medicines. Such bar coding has since been introduced for export purposes; however, the mechanism has so far not been made mandatory for domestic sale of medicines keeping in view the concerns of MSME industry. In the absence of such track and trace mechanism, having operationalised for sales within the country, complaints continue to be received by the Government about the quality of drugs.

3. Keeping the overall context in view, the Ministry of Health and Family Welfare proposes to establish a robust e-enabled structure for regulating sale of medicines in the country and, with this in view, the following course of action is proposed:

i. An electronic platform will be developed for regulating sale of drugs in the country;

ii. The e-platform will be developed and maintained by an autonomous body under the Ministry of Health and Family Welfare.

iii. An initial grant and the minimum human resources will be provided by the Ministry of Health and Family Welfare to the identified autonomous body and expenditure incurred on this count will be met from the Consolidated Fund of India for an initial period of two years.

iv. The autonomous body will generate its own resources for meeting all its operational requirements beyond two years.

v. All manufacturers will be required to register themselves with the said portal and enter data relating to sale of drugs on the said e-platform to different distributors *i.e.* the stockists/wholesalers or otherwise with batch Number, quantity supplied and expiry date of the batch.

vi. All stockists/wholesalers or other distributors will, also be required to register themselves on the said portal and enter details of stocks received and supplied by them to further distributors or retailers.

vii. The data can be entered both through online and by using mobile phones.

viii. The pharmacies located in rural and other remote areas can upload the data either through mobile phones or through internet at least once every fortnight.

ix. No retailer/chemist/e-pharmacist outlet shall be permitted to sell any medicine/drug unless such pharmacy is registered on the e-portal.

x. The retailers *i.e* the Chemists and Druggists or e-pharmacy outlets will be required to enter all details of the

medicines/drugs received, sold, returned to the manufacturer or disposed of in any other manner.

xi. No sale by e-pharmacy shall be permitted to be carried out by any person or entity unless, it has a licenced brick and mortar facility in each of the Licencing Authority's jurisdiction.

xii. No dispensing/sale of drugs shall be permitted by any entity beyond the area for which a licence has been granted.

xiii. Medicines other than drugs included in Schedule H, H1 and X will be dispensed or made available/distributed to any person only against prescription of a registered medical practitioner. However, in case of a few identified medicines, any other person specifically authorised (such as ASHA) to distribute a particular class of medicines may do so.

xiv. The details of medicines dispensed will be entered in the e-platform and bills will be generated through the system. Such details will include prescribing doctor's Registration number (MCI or State Medical Council or the Dental Council of India) or other authorised person's identity number, the name and registration number of the dispensing chemist and the quantity supplied, etc.

xv. Details of other than the patient name and identity shall not be necessary in case of drugs not included in Schedule H, H-I or X.

xvi. The details of patient authorised person, etc. shall be kept confidential and shall not be disclosed to anyone other than the Central and State Drug Regulators or other officers authorised by the Central or State Governments. The details could, after removing the confidential information, be also made available to the Pharmacovigilance Programme of India (PvPI).

xvii. Hospitals and other clinical establishments or other authorised persons, both in the public sector and the private sector, shall be required to enter details of medicines dispensed or distributed/issued/made available to patients as also details of any adverse reaction, etc. and such data shall be kept confidential and made available only to PvPI and the regulator in the manner specified above.

xviii. At the backend, a system of audit by regulators for ensuring compliance with the Drugs and Cosmetics Act, 1940 and Rules thereunder will be developed. The audit will be facilitated through offsite analysis.

xix. The information collected may also be used by the Ministry of Health and Family Welfare, Government of India for such purposes as considered necessary in public interest.

xx. No export of anti-bacterial or any habit forming drug shall be permitted against internet orders.

xxi. Any person or entity proposing to export other medicines/drugs on the basis of internet orders shall be required to be registered with the CDSCO and details of such registration will need to be mentioned in the invoice when exporting such medicines/drugs.

xxii. An appropriate revenue model will be developed so that the organisation responsible for maintaining the portal and rendering such other assistance as may be entrusted to it, becomes self -sufficient.

xxiii. The revenue model could comprise a small transaction fee of not more than 1% of the total cost of medicines subject to a ceiling of Rs 200 per prescription, to be paid online by pharmacies/ e-pharmacies/ wholesale /retail distributions, etc., a small amount of registration fee and renewal fee as may be determined by the Government from time to time

shall also be payable by manufacturers/ pharmacies/ hospitals/ clinical establishments, etc.

xxiv. With effect from the date, the new rules come into force, it will be mandatory for all new pharmacies to register with CDSCO on payment of such fee as may be prescribed. Existing pharmacies will get a transition period of two years for registration with the online portal. Such existing pharmacies which register within first six month will be required to pay 60% of the fee prescribed for such registration.

xxv. Portability will be established with the existing softwares/e-platforms, etc. developed by NIC/other Departments of the Central Government/State Government, etc.

4. In the light of the foregoing, all stakeholders and public at large are requested to forward their suggestions/comments, etc. through e-mail to **epharmacy.drugs-mohfw@gov.in** or send hard copies to Deputy Secretary (Drug Regulation), Ministry of Health and Family Welfare, Room No. 301 D, Nirman Bhavan, New Delhi within a period of 30 days from the day of this notice *i.e.* by or before 15.04.2017. The views, comments and suggestions so received will be duly taken into account by the Government for finalising the Rules under the Drugs and Cosmetics Act, 1940.

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