

CENTRE FOR SCIENCE AND ENVIRONMENT

MAIN OFFICE: 41, Tughlakabad Institutional Area, New Delhi-110 062 INDIA

Tel: +91 (011) 4061 6000, 2995 5124, 2995 6110 Fax: +91 (011) 2995 5879 Email: cse@cseindia.org Website: www.cseindia.org

BRANCH OFFICE: Core 6A, Fourth Floor, India Habitat Centre, Lodhi Road, New Delhi-110 003

Tel: +91 (011) 2464 5334, 2464 5335



LEAVES
OF
IMPORTANT
SURVIVAL
TREES
IN
INDIA —
MAHUA,
KHEJDI,
ALDER,
PALMYRA
AND
OAK

April 15, 2017

Shri Debananda Sahoo
Deputy Secretary (Drug Regulation)
Ministry of Health and Family Welfare
Room No. 301 D, Nirman Bhavan
New Delhi 110011
Email: epharmacy.drugs-mohfw@gov.in

Subject: Recommendations regarding regulation of sale of drugs in the country

Dear Shri Debananda Sahoo,

This has reference to the public notice issued by Ministry of Health and Family Welfare (MoHFW) on public consultation regarding regulation of sale of drugs in the country—dated March 16, 2017.

At the outset, we welcome the proposed initiative of the electronic platform to regulate sale of drugs, particularly in view of its usefulness in understanding antibiotic sale and consumption and helping combat antimicrobial resistance (AMR), a growing public health threat in India and worldwide. However, we have also identified certain gaps around the initiative and would like to take this opportunity to share our point of view to fill those.

We, at CSE have been working on the issue of antibiotic misuse in food-animal production sector for nearly a decade and have been advocating for a national-level online database on antibiotic sale and consumption trends (including human health and animal production sector) as surveillance of antibiotic use is a of extreme significance to effectively contain AMR. Our research on practices of antibiotic use in honey, poultry and fisheries had clearly suggested the need for regulating availability of antibiotics (including those sold in bulk and/or imported) and antibiotic-laden feed/feed pre-mix for food-animal production. Similarly, it is important to regulate disposal of unused/expired antibiotics across the drug supply chain to prevent misuse of antibiotics and spread of AMR.

While the proposed e-platform is about drugs in general, we understand that with the suggested modifications, the e-platform could be used to collect comprehensive information on antibiotic sale and use in food-animal production sector, which is potentially a huge contributor to the AMR. It is important to note that countries such as Denmark, Sweden, Netherlands and Norway have a successful history in using similar online systems to combat AMR through generating periodic information and reports on antibiotic sale and use in humans and animals. The draft Indian National Action Plan on AMR also outlines the need for registration of and data collection from manufacturers, sellers, prescribers and bulk users of antibiotics.

Founder Director
ANIL AGARWAL

EXECUTIVE BOARD

Chairperson
M.S. SWAMINATHAN

Director General
SUNITA NARAIN

Deputy Director General
CHANDRA BHUSHAN

Members
A.K. SHIVA KUMAR
B.D. DIKSHIT
BHARATI CHATURVEDI
G.N. GUPTA
JAGDEEP GUPTA
MAHESH KRISHNAMURTHY
N.C. SAXENA
N.J. Rao
WILLIAM BISSELL



CSE recommendations with reference to regulating sale and use of antibiotics in food-animal production sector in particular:

- **Besides for human health, the e-platform should collect information on antibiotic production and sales for use in animals (food-production in particular) and help segregate the data accordingly.** The said notice does not specify this. It should include or clarify (if already intended), the focus on antibiotic production and sale for animals across the supply chain (such as at the level of manufacturer/stockist/wholesaler/retailer including e-retailer) and prescriber (such as a veterinarian). Considering that a large proportion of antibiotics manufactured is believed to be used in food-animal production settings, antibiotic use surveillance data in this sector is of utmost significance to India's fight against AMR.
- **The e-platform should record data on bulk sale of antibiotics.** As of now, it focuses on manufacture and sale of antibiotic formulations. It is important to note that a significant part of antibiotic used in animal farms is bought in bulk. Even the animal feed industry using antibiotics as growth promoters in feed and feed-premixes source antibiotics in bulk. By excluding bulk antibiotic sale out of its purview, the e-platform will miss out on tracking a large portion of antibiotics in the supply chain. Given the bar-code system as the suggested tracking approach, it is important to therefore ensure that all bulk drugs are sold in pre-defined packages with bar-codes.
- **The e-platform should collect data on antibiotics imported.** India imports considerable amount of antibiotics, specifically in bulk from China. Our research had also suggested that food animal as well feed industry sources a lot of bulk imported antibiotics. It is therefore important to include it in the tracking system.
- **The e-platform should include antibiotic-laden feed and feed pre-mix.** Feed and feed pre-mix containing schedule H and H1 antibiotics must be sold under prescription, however, in view of feed and feed pre-mix not currently under the purview of regulations on Drugs and Cosmetics, it is not happening so. The said platform can help fill this gap and record information on antibiotics used in animal feed industry.
- **The scope of e-platform should be expanded to collect user and prescriber information, specifically in case of antibiotic use in animals.** As of now, the proposed platform focuses on recording information at the level of manufacturer and seller across the supply chain. Limiting antibiotic misuse in animals is also expected to be supported by understanding on trends of prescription (such as by veterinarians) and consumption (at the farm level), which provide an in-depth understanding of antibiotic use at the local level. While, collecting such information may not be directly under the purview of MoHFW, but in view of multi-ministerial/sectoral collaborated efforts required to address AMR, the MoHFW should consider expanding the scope of this e-platform. This could be done in coordination with the Ministry of Agriculture and Farmers Welfare. Besides integrated data, such a system would help in more effective and efficient data collection at the inter-sectoral level.



- **Information on disposed/unused antibiotics should also be recorded at the level other than retailer, i.e. at the level of manufacturer, stockist and wholesaler.** For example, manufacturer besides sharing information on sale, should also feed-in details around disposal of off-specified/unused bulk antibiotics. Similarly, the drug dealers across the supply chain should submit information on how the unused/unsold drugs (bulk and formulations) have been dealt with. It is important to note that drugs being hazardous in nature, the producers' responsibility are extended under the concept of EPR (extended producer's responsibility) in several countries. India too has EPR in plastic waste and e-waste sectors. While CSE has earlier recommended to the MoHFW and Central Drug Standards Control Organization (CDSCO) to bring-in EPR in the drugs sector, the current initiative provides a good opportunity to introduce and integrate it with the e-platform. As part of EPR, the drug producers' are expected to bear the responsibility and fund for the collection and safe disposal of expired/discarded medicines.
- **The e-platform should facilitate creation of a national database on antibiotic sale and consumption in humans and food-producing animals.** It would be useful to compare antibiotic consumption against antibiotic resistance trends in both humans and animals to enable suitable interventions. Annual reports on sale and consumption trends should be generated for review and feedback by stakeholders.

While the above mentioned recommendations would help this country understand antibiotic use in humans and animals and address the issue of AMR, **it is of utmost importance to note that the principle of privacy must be maintained. There should not be any provision to record and aggregate the information related to patients. All precautions should be taken that patient level consolidated data is not generated, analyzed and disseminated.**

We hope that the MoHFW gives due attention to our recommendations. If required, we would be happy to present our point of view in detail and/or respond to any queries.

With my best wishes,

Yours cordially,

Chandra Bhushan
Deputy Director General