Legislation limbo on e-pharmacies in India

In the era of digitalization and electronic empowerment, every person has a freedom to procure what they want with a click of the button. Medicines are no exception. Evolution of e-pharmacies seems to be a logical progression of medicine and technology. However, there is a need to have an in-depth analysis of its functioning and possible medico-legal issues that might prop-up.

India is fast emerging as an e-commerce powerhouse. Online purchases have moved from the realm of the selected few who were thought to be technologically savvy to every Indian on the street. From online recharges to large scale purchases, the marketplace has moved from physical brick and mortar stores to the desktop and now to mobile. E-pharmacies have a few benefits to offer to consumers but have prompted re-examination of a few issues related to ethical, legal and safety of medicines when dispensed online[1]. In general, public access to medicines has been strictly governed ensuring judicious use of safe and effective medicines by consumers and healthcare professionals[2].

An e-pharmacy is just like any other pharmacy but sells pharmaceutical preparations, both prescription-only and over-the-counter medicines through online, delivering medicines to the consumers' doorsteps. According to an article published in a newspaper, there are two types of e-pharmacies operating in India at the moment. First, the e-pharmacy partners with brick and mortar pharmacies to deliver the medicines to home. Second, the e-pharmacy directly delivers the medicines[3]. There exist three categories of e-pharmacies, namely, organized, unorganized and illegal. In the organized sector, pharmacists in the e-pharmacies take orders through internet and dispense medicines to end user. A thorough check on prescription is warranted in the organized e-pharmacies while in the unorganized and illegal, this arrangement is done away with[4].

Pharmacies at large in India are governed majorly by Drug and Cosmetics Act 1940 and Rules 1945. A few related Acts pertaining to sale of medicines are Pharmacy Act 1948, Drugs and Magic Remedies Act and Indian Medical Act 1956. However, there are no guidelines regulating online sale of medicines in India. It is evident that archaic laws pertaining to sale of medicines are insufficient to govern e-pharmacies.

Provisions related to sale of medicines are mentioned in The Drugs and Cosmetics Rules 1945. According to Subsection 1 of Section 42 of Pharmacy Act 1948, '….no person other than a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner.' However, e-pharmacies have exploited loopholes in the existing laws to sell medicines online. Some have taken the route of claiming to be only delivery service providers also known as aggregator sites. This means they come under the category of intermediaries as per the Information Technology Act 2000. It may be assumed that Sections 4 and 5 of the IT Act, 2000 in conjunction with Rule 65 of the Drugs and Cosmetic Rule, 1945 satisfy the legality if the prescriptions are handwritten and electronically sent[5]. Pharmacy Practice Regulations 2015 formulated by Pharmacy Council of India has a mention of electronic prescription in its guidelines. Hence, pharmacists can accept an electronic prescription as well, but the contention is whether the electronic prescription can also be valid to sell medicines online. The Medical Council of India has tried to streamline the prescription methodology of allopathic doctors in India and provided guidelines while prescribing. Prescription should include doctor's name, work/clinic address, state/medical council registration details along with the name/s of the drug/s, potency, dosage and duration for which the drugs are to be supplied[6]. Overall, ambiguity exists in the prevailing Acts and demands a separate Act or at least guidelines to govern e-pharmacies.

In the developed countries due to commercial growth and capitalism, e-pharmacies have emerged some time back and are well regulated. US, Australia, Canada, UK among others permit e-pharmacies, governed by their respective drug regulatory authorities and other agencies. In US, the National Association of Boards of Pharmacy provides Verified Pharmacy Program that promote safe pharmacy practices. However, in majority of the countries their respective drug regulatory authority governs e-pharmacies.

The authority responsible for drafting the new policy on the e-pharmacies, the Drugs Controller General of India (DCGI) had engaged in discussions with some of the stakeholders. Industry body was said to be appointed as nodal agency by DCGI for consolidating the e-pharmacy guidelines with views from Organisation of Pharmaceutical Producers of India, All India Chemists and Druggists Association, Chemists and Druggists Associations across India, Indian Medical Association among others. A meeting was convened by the industry lobby, the Federation of Indian Chambers of Commerce and Industry, for formulating new guidelines for operating e-pharmacies. About 8.5 lakh chemists across the nation went on a day strike by closing down their shutters on 14 October 2015 upon call from the All India Organization of Chemists and Druggists. This protest was against illegal online sale of medicines and issues pertaining to e-pharmacies. They also expressed that they would lose their livelihood if e-pharmacies goes unregulated[8,9]. According to an article in one of the newspapers, pharmaceutical industry in India is worth Rs 85,000 crores with a double digit growth year-on-year. The value of online pharmaceutical retail might reach 4–5% of the total value, reaching 5000 crore rupees in 5 years[10]. With such a large amount of money at stake, it is even more important that there are proper checks and balances in place.

Updates on e-pharmacy are emerging on a day-to-day basis in the recent times. On 13 December 2018, Delhi High court sent notice to Central Drugs Standard Control Organization (CDSCO) to ban online sale of medicines by e-pharmacies. This action by the court is the result of case filed by South Chemists and Distributors Association against e-pharmacies[11]. On the other hand, the Drug Technical Advisory Board has approved the draft regulations pertaining to e-pharmacies proposed by Union Health Ministry[12]. The draft rules facilitate accessibility to genuine medicines from online portals. However, such intended portals/e-pharmacies are to be registered. Registration is mandatory if one purports to sell medicines online. Applications may be sent online in the prescribed form (Form 18AA) with

prescribed fee to get licence to sell medicines online. Such licence issued will be valid for three years. Online sales of tranquilisers, narcotic drugs, psychotropic substances and all habit forming medicines are banned. Premises of e-pharmacies is said to be inspected on a regular basis by a team of officers either from CDSCO or state licensing authorities, stated the draft. Moreover, registered e-pharmacies have to comply with provisions of Information Technology Act. Madras High Court on 17 December 2018 imposed a blanket ban on sale of medicines through e-pharmacies until the Central Government notifies rules on e-pharmacies[13].

In the light of draft regulations on e-pharmacies, physicians, pharmacists and consumers should be trained alike on various aspects of functioning of e-pharmacies. There should be a strict vigilance with officers from both central and state licensing authorities visiting the premises of e-pharmacies to check authenticity of medicines sold and their storage conditions. Moreover, misuse and duplication of electronic prescriptions should be strictly monitored through available technologies. The CDSCO should play a pivotal role in governing e-pharmacies and should address the issues raised by Chemists and Druggists Associations.

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Genetic modification technology

The article by Datta *et al.*[1] (henceforth referred to as 17 authors) states that it deals with negative perceptions of genetic modification technology in general, as also discussed in a recent review by Kesavan and Swaminathan[2] (henceforth PCK–MSS paper). The latter publication provides concrete data and valid scientific references for most of the important statements, hence their criticisms are unfounded and invalid.

With reference to *Bt* and herbicide-tolerant crops, the 17 authors' paper does not provide either data or valid references to make claims about their biosafety. There is no food security without a solid foundation of food safety, and in particular for GMOs. In this regard, the United Nations Food and Agriculture Organization's (FAO) definition of *food security* is as follows: Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life. Therefore, *Bt* brinjal was rightly not released for commercialization. *Bt* toxins were once considered to cause damage only to insect species having alkaline guts. It was therefore assumed that *Bt* toxins are safe for mammals, including humans. This is no longer true as has been explained in the PCK–MSS paper. The currently known mechanism of action of *Bt* toxins can certainly damage the intestines of humans and other mammals. This has been demonstrated in laboratory animals. The 17 authors' paper states that datasets on livestock from publicly available sources starting from 1983 and representing over 100 billion animals did not reveal unfavourable or perturbed trends in livestock health and productivity after introduction of GM crops. This is an untenable statement in view of the fact these billions of animals are not allowed to live their full lifespan and reproduce, since they are marked for slaughter for meat consumption within a few months of their birth. It is essential that real food safety assessment of genetically engineered foods must be tested over long periods of time, including descendants and their further descendants. It is well recognized that toxicity/cancer is chronic, not acute and requires long-term, multigenerational testing. Therefore, the reference cited by the 17 author's paper with respect to billions of animals is invalid.

The PCK–MSS paper has made reference to the biosafety dossiers of *Bt* brinjal. There was resistance despite a