

Comments on the Proposed Amendments (related to e-pharmacy) to the Drugs and Cosmetic Rules, 1945, for Ministry of Health and Family Welfare (MOHFW), India

12 October 2018

Consumer Unity and Trust Society (CUTS)¹ expresses its gratitude to the Ministry of Health and Family Welfare, for inviting comments and suggestions on the Proposed Amendments to the 'Drugs and Cosmetic Rules, 1945' (The Rules) with respect to e-pharmacy.² Below are our submissions in this regards.

Preliminary comments

Parity in regulations governing Traditional and Platform-based pharmacy

Digital disruptions, which annoy incumbents, are occurring in almost all sectors, and pharmacy retail is one of them. Since such disruptions are good from consumer's perspective, care need to be taken that the policy/regulatory approach should be to protect competition (due to such disruptions) and not to protect the incumbent competitors. The approach to safeguard traditional businesses, at the cost of fair competition, could go against consumer interests. It must be noted that the Competition Commission of India has found many anti-competitive practices in the supply and distribution chain of medicines. In fact, the advent of e-pharmacy provides technological solutions to such malpractices.

The point is that the government should not, in the wake of regulating e-pharmacies, propose rules that would be more restrictive than required to meet the stated objective. *Prima facie*, the proposed regulation (vide the present draft rules), seems heavy and may tend to discourage the much needed digital disruption in pharmacy retail. (Details below under specific comments)

Need for Regulatory Impact Assessment

In light of the above, CUTS' highly recommends the MOHFW, to adopt and institutionalise undertaking Regulatory Impact Assessment (RIA)³ and Competition Impact Assessments (CIA), while framing/providing any suggestions on the policy, regulatory and/or legislative framework regarding 'The Proposed Amendments to the Drugs and Cosmetic Rules, 1945'.

It also emphasises on the need for having a consultation with a wide range of stakeholders, and also provides ample opportunity to bring up unforeseen consequences or real-life experiences for consideration while weighing and measuring the impact of any regulation or policy. Adopting such an approach will ensure the framing of optimal regulations.

¹ <http://cuts-international.org/>

² MOHFW Notification dated 28th August 2018

³ RIA is a process of systematically identifying and assessing direct and indirect impacts of regulatory proposals and existing regulations, using consistent analytical methods. It involves a participatory approach via public consultation to assess such impact, determination of costs and benefits, and selection the most appropriate regulatory alternative.

<http://cuts-ccier.org/ria/>

The adoption of RIA has also been recommended by various committees which have been highlighted in a CUTS paper⁴, a version of which was also presented to the Better Regulatory Advisory Group (BRAG) which was constituted by the Department of Industrial Policy and Promotion (DIPP).

Need for Optimal Regulation

Strengthening Digital Economy is the best way forward for achieving socio-economic and inclusive growth. This was evident from the recently concluded case study undertaken by CUTS, pertaining to eClinics in the state of Rajasthan.⁵ The purpose of highlighting the study is to stress the need for framing optimal regulations which act as an enabler and foster digital tools and technology in delivering essential services such as healthcare, to last mile consumers. The rapid evolution of disruptive technologies/innovations has altered market dynamics considerably, and must therefore be planned optimally, to maximise the benefits.

Data Localisation

Since the proposed amendment mandates ‘data localisation’, it is pertinent to highlight the contemporary debates and initial findings (CUTS has been proactively engaged in such debates) in the context of the Sri Krishna Committee report on data protection. CUTS International recently organised a roundtable on ‘Consumer Sovereignty in the times of Data Localisation’ to discuss consumer perspective on this issues. *The report is accessible [here](#).*⁶ It was found that, the ‘data localisation’ is more likely to adversely impact consumers and start-ups (which can include an e-pharmacy portal). As per the industry, civil society and consumer groups, data localisation is more likely to be counterproductive not only to the interest of the consumers, but to the whole society. The ‘cost’ seems to be outweighing any ‘benefit’ accruing from data localisation. In addition, ‘data localisation’ doesn’t seem to be the best way to safeguard privacy or add value in enhancing security.

Therefore, the proposed rules mandating ‘data localisation’ (i.e. to be kept within physical boundaries of India) need to be reviewed. It should not be imposed without conducting a thorough cost-benefit analysis.

Specific Comments

S. No.	Rule	Issue / Finding	Comments/Recommendation
1	67-I(a)	“e-pharmacy” means business of distribution or sale, stock, exhibit or offer for sale of drugs through web portal or any other electronic	The definition has adequately covered entities engaged in sale, but has left it fuzzy (due to insertion of the words ‘stock, exhibit’) for other portals / websites which only display, but not

⁴ http://www.cuts-ccier.org/pdf/ViewPointPaper-Regulatory_Reforms_Needed_for_Ease_of_Doing_Business_in_India.pdf

⁵ The objective of the study was to gauge the effectiveness of technology, as an enabler of healthcare services such as eClinics, to the citizens at the last mile. It revealed that Information and Communication Technology (ICT) enabled innovative healthcare solutions, have enabled access to healthcare services to the underprivileged and underserved areas; and that ICT have the potential to accelerate the efforts moving towards achieving the objectives of Sustainable Development Goal (SDG) Number 3 of the United Nations (UN) ‘Good Health and Well-Being’.

⁶ http://www.cuts-ccier.org/Event-Round_Table_Discussion_on_Consumer_Sovereignty_in_Times_of_Data_Localisation-Sep6-2018.htm

		mode.	offer for sale any drugs. For instance, will the website of a traditional pharmacy also be covered under this definition's ambit, even if it has no option of placing orders, but displays the names and photos of prominent medicines kept in stock with him at his traditional pharmacy?
2	67-I(d)	“prescription” means an instruction from a Registered Medical Practitioner to a patient, written by hand or in any electronic mode duly signed, to dispense a drug and quantity of drug to a patient.	Reference may be drawn to the recent fining of a doctor for having illegible hand writing on prescriptions. ⁷ This issue may be rectified appropriately. What about sale of over the counter (OTC) drugs via e-pharmacy portals?
3	67J(3)	e-pharmacy registration holder shall arrange or provide the drugs, as per the prescription received from the customer	The rules, making dispensing of drugs only upon RMP prescription, seem to suggest that e-pharmacy portals cannot sell OTC drugs. This confusion need to be done away with via a proper proviso. The OTC drugs or non-prescription drugs should be allowed to be sold via e portals without RMP prescriptions.
	67P (1)	On receipt of prescription, through e-pharmacy portal, the registered pharmacist... shall verify the details of the patient, Registered Medical Practitioner...	Furthermore, it is important to maintain parity between rules governing traditional pharmacies and e-Pharmacies and not discriminate between the two. Hence, such a provision may only be enacted if applicable on traditional pharmacies as well.
4	67J(4)	The e-pharmacy registration holder shall have a facility for customer support and grievance redressal of all stakeholders which shall run not less than twelve hours for all seven days of a week.	This provision seems to put some extra burden on the e-pharmacy portals. As said earlier, it needs to be ensured that any rules applicable on e-Pharmacies, must not be in excess to those applicable to traditional pharmacies.
5	67K	Disclosure of information generated through e-pharmacy portal	Select provisions of the draft personal data protection bill 2018, with respect to sensitive personal data may be applicable and provided for, as mentioned previously.
6	67K(2)	The e-pharmacy registration holder shall be duty bound to provide such information to the Central Government or the State Government	Limitations on data sharing with the government, especially with regard to sensitive personal data as given in the draft personal data protection bill 2018 may be considered in light of such a

⁷ <https://timesofindia.indiatimes.com/city/lucknow/up-hc-fines-3-doctors-for-bad-handwriting/articleshow/66059400.cms>

			<p>provision.</p> <p>However, anonymised data may be shared with the government and other relevant stakeholders (such as research institutes) for appropriate purposes. For instance, such data may be useful in drafting policy on rational prescription of drugs.</p> <p>Reference may also be made to section 21(a) of the draft personal data protection bill 2018, which allows for processing health data ‘to respond to any medical emergency involving a threat to the life or a severe threat to the health of the data principal’.</p> <p>In addition, the consumers may be allowed to have the ‘right to data portability’ from one e-pharmacy portal to another. The relevant provision in the draft personal data protection bill 2018 may be considered on this account. While digital disruption is good for consumers, there are inherent tendency of “winner takes all” syndrome that can go against consumers. Data portability could be a tool in the hands of consumers to prevent occurring of such a situation.</p>
7	67K(3)	<p>Provided, that in no case the data generated or mirrored through e-pharmacy portal shall be sent or stored, by any means, outside the India.</p>	<p>Section 41(3)(a) of the draft personal data protection bill becomes important in this regard, which allows for health data to be transferred outside the country ‘to a particular person or entity engaged in the provision of health services or emergency services where such transfer is strictly necessary for prompt action’.</p> <p>Other grounds for opposing data localisation as mentioned above, may also be considered.</p>
8	67M(2)	<p>The details of patient shall be kept confidential and shall not be disclosed to any person other than the Central Government or the State Government concerned, as</p>	<p>Recommendation given above pertaining to rule 67(K)(2) may be referred here as well.</p> <p>Furthermore, our survey⁸ revealed that consumers were not willing to share</p>

⁸ CUTS had commissioned a user perception survey pertaining to data privacy and user welfare in India. The objective of the survey was to gauge perception and experience of users with respect to privacy, purpose of data collection, usage of data collected, strategies for data protection, data breach, among others, in relation to data collected by online and

		the case may be.	their data pertaining to their medical history with the government. 65% of the respondents felt that they were not sharing their health data with the government, and 64% of the respondents were not comfortable in sharing this data with the government.
9	67M(6)(iv)	The e-pharmacy shall mention the following details on its e-pharmacy portal - details of the logistic service provider.	This may not be practical in implementation by the registration holder due to the many and changing logistic partners. An Industry perspective may need to be taken on such issues, in order to make the rule making process more consultative and avoid heavy cost of compliance.
10	67P(3)	The details of the drugs dispensed including the patient details shall be maintained on the e-pharmacy portal.	It remains to be clarified as to for how long will such patient details need to be maintained on the e-Pharmacy portal, and who all will have access to such accumulated data, and what measures will need to be taken to secure this sensitive personal information.
11	67P(4)	In case of e-prescription, the prescription shall be uploaded on the e-pharmacy portal and shall be kept in record by the dispenser.	

About CUTS

In its 34 years of existence, CUTS has come a long way from being a grassroots consumer-centric organisation based in Jaipur, to opening overseas resource centres in Hanoi⁹, Nairobi¹⁰, Lusaka¹¹, Accra¹², Geneva¹³ and most recently in Washington DC¹⁴. It continues to remain an independent, non-partisan and non-profit economic policy think tank, while opening various programme centres, namely: Centre for International Trade, Economics & Environment (CITEE)¹⁵; Centre for Consumer Action, Research & Training (CART)¹⁶; Centre for Human Development (CHD)¹⁷; and Centre for Competition, Investment & Economic Regulation (CCIER)¹⁸. It has been working towards enhancing the regulatory environment through evidence-backed policy and governance related interventions across various sectors and national boundaries. For further details regarding CUTS, please visit: <http://cuts-international.org/pdf/About-CUTS-2018.pdf>

offline service providers, as well as the government. A total of 2400 respondents (10 percent of whom were non-internet users) were interviewed across six states (one from each region – north, south, east, west, central and northeast) of the country. The sample was distributed between urban, peri-urban and rural areas, with adequate representation of respondents with different education levels, occupations, genders and age groups. In this context, few key findings from the survey have been incorporated in our submissions.

⁹ <http://cuts-hrc.org/en/>

¹⁰ <http://www.cuts-international.org/ARC/Nairobi/>

¹¹ <http://www.cuts-international.org/ARC/Lusaka/>

¹² <http://www.cuts-international.org/ARC/Accra/>

¹³ <http://www.cuts-geneva.org/>

¹⁴ <http://www.cuts-wdc.org/>

¹⁵ <http://www.cuts-citee.org/>

¹⁶ <http://www.cuts-international.org/CART/>

¹⁷ <http://www.cuts-international.org/CHD/>

¹⁸ <http://www.cuts-ccier.org/>

Being a consumer-oriented organisation, CUTS has observed a few critical issues in the Rules. These have been discussed in subsequent sections, along with a few recommendations to solve them.

We look forward to assisting the Ministry of Health and Family Welfare on the issue.

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