KERALA STATE DRUGS CONTROL ENFORCEMENT OFFICERS ASSOCIATION
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To Date: 11/10/2018

Under Secretary (Drugs)
Ministry of Health and Family Welfare, Government of India
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Email:drugsdiv-mohfw@nic.in

Sir,

Sub: The Gazette of India: Extraordinary-objections and suggestions-submitting of-reg.

Ref: Notification No.G.S.R.817(E) dated 28/08/2018 of Ministry of Health and Family Welfare, Government of India.

It is my pleasure to introduce Kerala State Drugs Control Enforcement Officers Association (KSDCEOA), the only association representing all the enforcement officers in the Drugs Control Department, Government of Kerala. The association is affiliated to All India Drugs Control Officers' Confederation.

We submit the following facts for your kind perusal in the event of publication of the draft notification referred above.

Without any prejudice to the proposed amendment, we would like to convey the message that we welcome the concept of e-pharmacy in our country and no doubt, it will be a milestone in the pharma business with its projected appealing benefits. But at the same time, we strongly oppose some of the provisions in the referred draft notification since it lacks clarity in the legal framework and shows disruptions in the usual work flow of pharmacy.

It may noted that many amendments have been introduced by Government of India time to time in Drugs and Cosmetics Act, 1940 (herein after referred as the Act) to tackle and control the public health issues such as antibiotic resistance, eradication of tuberculosis, prevention of misuse of habit forming drugs etc. in our country. The ultimate aim for implementing Schedule H1 in the Act on 1st March 2014 vide Gazette Notification No.G.S.R.588(E) dated 30/08/2013

was also the same reasons as mentioned above. On 16 March 2018, another Notification F.No.Z-28015/2/2012-TB was published by Ministry of Health and Family Welfare in order to detect the TB patients in the country and even made a provision to institute legal action against the chemists, if the Anti TB drugs are sold unreported to the Health Authority in the prescribed Performa. Subsequently, sale of anti-TB drugs were strictly made under control vide above notification and the patients are highly monitored by tracking the details recoded in Schedule H1 register maintained in the medical shops. But, when we go through the recently published e-pharmacy notification, we can see that importance of most of the above national policies have already been forgotten by the authority and shown hurry to publish the draft without putting paramount importance. We can clearly see that rules for e-pharmacy were framed with a vision of e-commerce only, rather than giving importance to any national policies or the ill impacts that causes to public health in future.

Our objections and suggestions are briefed below for your kind consideration.

1. As per Rule 67I (a), e-pharmacy means “business of distribution or sale, stock, exhibit or offer for sale of drugs through web portal or any electronic mode”. The provision for selling through “any electronic mode” as mentioned under Rule 67 I(a) is not clear and cannot be entertained as such. Hence we proposed to make amendments comprehensive enough to facilitate the validation of prescription by the Registered Pharmacist.

The definition of prescription given under Rule 67-I(d) should be elaborated on par with Rule 65(10) of the Act. The “Date” of prescription is very much required so as to avoid the possibility of repeated sales on the same prescription. Since there is no word “dispense” in the act, it is better to avoid the term and incorporate the words like sale/supply only. The name and address of the person for whose treatment it is given must also be mandatory in the prescription. It is suggested that each prescriptions be registered in the software by the prescriber and specific code number may assigned to it. Any further processing of the prescription should be based on this code number so that partial dispensing will be possible if stocks are insufficient in the particular e-pharmacy. Provisions for dispensing the same prescription for certain number of times if so decided by the prescriber should also be included.

Since the Part VIB (read with Rule I(a)) is not restricted to the sale of allopathic drugs only, we understand that the drugs for veterinary purposes and homoeopathic medicines also come under the preview of e-pharmacy. It may note that the registered pharmacist is not

competent for handling prescription of homoeopathic medicines. Hence it is suggested that the definition of both e-pharmacy (Rule 67I(a)) and prescription (Rule 67-I(d)) may be modified accordingly.

Similarly, 67I(e) is contrary to definition for the retail sale under Rule 2(f) of the Act. As per Rule 2(f), a retail sale means "other than a sale by way of wholesale dealing". Hence we suggest that the definition for "sale by way of e-pharmacy" may be modified accordingly so as to prevent the purposes for resale of drugs from any end points of e-pharmacy.

2. From the Rule 67J(3), we understand that the registration holder can arrange medicines upon receipt of orders through e-pharmacy portal. But we strongly oppose the system of arranging medicines by e-pharmacy. We doubt that this provision may open a channel for delivery of drugs that are purchased out of the track and without proper records and distributed by non-complying the storage directions. Hence we propose that all e-pharmacy must be licensed for retail sale with Drugs Licenses in Form 20 and 21 as per Drugs and Cosmetics Act, 1940 from the concerned State Drugs Control Department so that the purchase and sale of drugs can clearly be monitored by the state officials. The Rule 67I(a) and the application in Form 18AA are also not exempt the e-pharmacy from Section 18(c) of the Act as it is meant for the purposes of distribute and sell, stock or exhibit or offer for sale drugs through e-pharmacy.

The minimum time for supply of drugs to the patient concerned shall also be mentioned in the Rule.

3. Provisions of Chapter IV of the Act is enforced by the State Drugs Control Departments in all States vide Gazette Notifications of the concerned States. Since e-pharmacy is a mode of sale of drugs, we opine that the power of issuing Registration to e-pharmacies may be delegated to the Licensing Authorities in the States concerned. It may help to do ease of business for the stakeholders in our country.

4. How long the cash/credit memos are to be preserved in the e-pharmacy premises has not been specified under Rule 67M. Also, the name, address and Register Number of RMP should be included in the cash/credit memos. Return policy of drugs specified under Rule 67M(6)(v) is also

not seen detailed with the procedure of inverse logistics and responsibility is also not made to assure quality of returned drugs.

The drugs covered under NDPS, tranquilizers and drugs specified under Schedule X are exempted from e-pharmacy. But we draw your kind notice to the fact that nowhere the term "tranquilizer" is defined under the Drugs and Cosmetics Act and Rules, 1940. Hence we propose that a new schedule listing the names of tranquilizers may be incorporated in the Act.

Also, what will be the fate of Schedule H, H1 and other drugs requiring cold storage facility? The Rule 65 (3)(1)(h) directs the licensees to maintain register for the sale of Schedule H1 drugs in order to track the prescriptions and monitor the sale of such drugs, whereas e-pharmacy forget all such restrictions to be followed during the sale of schedule H1 drugs.

5. Since the premises of e-pharmacy situated under State Jurisdiction and the process of selling and supplies of drugs are effected from each local areas of the State concerned, the duty of conducting periodic inspection at the e-pharmacy premises shall also be delegated to the State Drugs Control Officials. By doing so, it will make easy to detect any offences happen through e-pharmacy at any time and enables to enforce the rules properly in the country. Hence we propose that the Rule 67-O shall be modified accordingly to delegate the power to the State Drugs Control Officials for conducting periodic inspections.

6. Proposed Rule P states that the e-pharmacy registration holder shall dispense or make arrangement for supply of drugs from any retail or wholesale licensed premises under the Drugs and Cosmetics Act and Rules made there under. It may noted that sale to any patient will be effected only with the original prescription of a RMP, which cannot not be made possible in the case of e-pharmacy if the drugs are arranged from any licensed retail outlet. Also, the drugs cannot be arranged by the registration holder to his customers from a wholesaler through e-pharmacy since it is contrary to the definition of Rule 2(g) of the Act. Wholesaler are authorized to supply drugs as per the conditions of licenses only and retail drugs license numbers are to be recorded on sales bills also. To solve this problem, we propose that all e-pharmacy should be licensed with retail drugs licenses under Drugs and Cosmetics Act and Rules. One other benefit is that it enables the existing retail outlets with Form 20 and 21 drugs licenses to change over to e-pharmacy set up, if they wish to do so.

7. Rule 67Q says that the validity of registration of e-pharmacy is for three years only. Also Rule 67R says that the e-pharmacy registration will be renewed upon remitting required fee with application in Form 21AA. But we point out the error that the said notification is missing the statutory form/ renewal certificate for the renewal of registration certificate. The late fee is also not prescribed.

But at the same time we opine that there is no need for e-pharmacy renewal in this hi-tech era. We can adopt the concept of retaining validity of registration certificate in Form 21AA upon receipt of required fee remitted by the registration holder through online before its expiry. It may note that the same procedure was already come in to force in the country after amending the Act vide Gazette Notification No. G.S.R. 1337 (E) dated 27/10/2017 for offline pharmacies.

8. Under Rule 67 T(3), the word "Provisio to sub-rule(2) of rule 67 P" mentioned is found to be an error; and we think the same may be corrected as "Provisio to sub-rule(2) of rule 67 T". We suggest that the power for suspension and cancellation may be delegated to the State Drugs Control Authorities.

The Rule 67 T (3) refers to cancellation of e-pharmacy registration by two or more states. As per the draft notification, States are not authorized for such cancellation.

9. Under Section 22(1)(ii), an inspector appointed under this Act, whether it is Central or State Government, has the power to inspect any premises wherein the drug is being sold, or stocked or exhibited or offered for sale or distributed. Also they have given the power to enter, search and conduct seizure at any place, if detected any offences or violations of provisions of the Act. Hence we suggest that the Rule 67U may be modified accordingly so that it may help the State Drugs Control Officers vigil always and to inspect e-pharmacies at any time instead of the event of suspicion only as proposed under Rule 67U. It helps to prevent any chances for occurrence of other violations like substitutions, overpricing, sale of expiry medicines, sale of banned drugs etc. through e-pharmacy during their routine inspections.

10. The fee of Rs.50,000/- fixed in the proposed rule will become a stump block before the beginners of e-pharmacy and no doubt, it will be an unimaginable dream for common man in our country. Hence it may be reduced to an affordable fee.

In this context, we the Kerala State Drugs Control Enforcement Officers Association strongly oppose the gray areas in the referred draft notification published by the Central Government. When we go through the notification, we feel that the enforcement authorities of respective states get sidelined and Central Government Authority dominates over in crucial decisions and effective enforcements. Since Drugs and Cosmetics Act is 78 year old statute which got refined through series of amendments for safeguarding the public health, any changes should be performed with utmost care and perfection. We are ready to represent the matter before any authority, if given an opportunity to highlight the imperfections in the draft rules and our suggestions for refinement. Hence, Kerala State Drugs Control Enforcement Officers Association humbly requests you to consider our views favorably and appropriate measures may be taken in this regard.

Thanking you,

Yours faithfully,

Sd/-

NISHITH M.C (Mob:09895532615)

(General Secretary, KSDCEOA)

Sd/-

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