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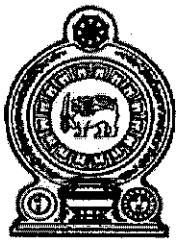

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தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

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எனது இல
My No.
NMRA/P4/L02
/2019

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உமது இல
Your No.

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திகதி
Date
12/09/2019

To All Marketing Authorization Holders of Medicines

Implementation of the recommendations of the National Language Commission regarding labelling of Medicines

I wish to highlight you the following recommendations made by the Chairman, National Language Commission by letter No. OLC/C/177(a) dated 19.10.2012.

1. All information and advices labelled on medicines that can be brought from pharmacies and other sales outlets without a prescription or without the supervision of a pharmacist should be in accordance with the national language policy.
2. With regard to prescription only medicines, information that a patient should be compulsorily aware of such as the name, directives for use, dose, important side effects, storage instructions, date of expiry etc. should be in accordance with the national language policy.

Point 1, above is already implemented for schedule I drugs as a patient information leaflet in both Sinhala and Tamil languages. On the directive of the Supreme Court related to case No. SC (FR) 102/2016, meetings of all relevant stakeholders were convened to explore the ways of implementing the national language policy for medicines classified under other schedules. Based on discussions that took place at these meetings, the National Medicines Regulatory Authority (NMRA) has decided to implement the following:

1. With effect from 1st January 2020, the generic name of the finished product should be labelled in Sinhala and Tamil languages on all medicines.

   As some foreign manufacturers might find it not viable to have a customised label specifically to Sri Lanka due to lesser volume marketed in Sri Lanka, the NMRA would allow the respective marketing authorization holders to paste a sticker depicting the same information on the label. The sticker shall not cover essential information such as the batch number, date of expiry, storage recommendations and any precautionary statements.

2. Also, marketing authorization holders would be required to insert a patient information leaflet. This requirement would be implemented step by step and NMRA has selected the following medicines in the initial step:
   a) Metformin
   b) Atorvastatin
   c) Losartan potassium
   d) Ciprofloxacin (oral dosage forms only)
   e) Co-amoxiclav (oral dosage forms only)

NMRA would publish the content for the patient information leaflet for each of above medicine and the date of implementation would be announced in due course.

Dr. Kamal Jayasinghe
Director General/Chief Executive Officer
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Copies: 1. President/Sri Lanka Chamber of Pharmaceutical Industry
2. President/Sri Lanka Pharmaceutical Manufacturers Association
3. President/Small Scale Pharmaceutical Industries Ltd