REPUBLIC OF CROATIA
MINISTRY OF HEALTH

Independent Sector for Health Inspections
Section for Pharmaceutical Inspection
CLASS: 530-01/19-11/16
REG. NO.: 534-08-2/1-19-06
Zagreb, June 28th 2019

Croatian Medicines Verification Organisation
attn. Morana Dostal, Executive Director
morana.dostal@hopal.hr

Croatian Chamber of Pharmacists
attn. Ana Soldo, President of the Chamber
asoldo2209@gmail.com

SUBJECT: Proposal to extend the alert management period of the Croatian Medicines Verification System (CMVS) during System's initial operation phase

- *reply, to be delivered*

Dear Madam/Sir,

On 08 February 2019 the Ministry of Health issued a decision regarding alert management during the initial operational phase of the Croatian Medicines Verification System (from 09 February until 30 June 2019) to facilitate uninterrupted work of pharmacies and regular supply of medicines to patients. Given that the Croatian Act on Implementation of the Commission Delegated Regulation (EU) 2016/161 dated October 2nd 2015 in connection to the amended Directive 2001/83/EC of the European Parliament and of the Council for establishing detailed rules for the safety features appearing on the packaging of medicinal products for human use has not yet come into force, and in accordance with the HOPAL's memorandum from 13 June 2019 proposing extension of the initial operation period of the System, and due to the fact that even after 30 June 2019 there will be many "false" alerts regarding potentially falsified medicines generated in the System because of lack/insufficiency of the data in the System, we agree to send information to the public and hospital pharmacies that the initial operation phase of the System is extended until 31 December 2019.

Pursuant to the Commission Delegated Regulation (EU) 2016/161 from 09 February 2019 pharmacies shall verify the safety features and decommission the unique identifiers; when an alert is triggered in the System, the pharmacy will supply the medicine to the patient in accordance with its own operating procedures, unless potentially falsified medicine is identified. HOPAL will inspect the cause of alerts and ensure urgent investigation of all potential incidents of falsification flagged in the System pursuant to Article 37 item (d) of the Commission Delegated Regulation (EU) 2016/161.

Respectfully,

MINISTER
Milan Kujundžić, MD, PhD, Prof.

Attachment:
-as in text
To be delivered:

1. Titled recipient
2. Archive, here

To be informed:

1. Agency for Medicinal Products and Medical Devices of Croatia, suzana.ostarcevic@halmed.hr
2. Croatian Employers' Association, barbara.majcen@pliva.com