

Ljubljana, 29.11.2019

## Dear stakeholders, partners, colleagues

Medicines verification institute Slovenia (ZAPAZ) has been an engaged and proactive member of EU FMD community from the early stages of the EMVS project. We did our best to support our stakeholders on the national and European level - to help our End users in establishing stable and reliable connections to the NMVS, to support MAHs with information on on-boarding and data upload and to ensure our NCA's access to required information for supervisory activities.

Since February 9<sup>th</sup>, when Stabilisation period was introduced in Slovenia, we worked closely with End-Users and their software providers to reduce number of unnecessary alerts as much as possible and I am proud and thankful to everyone who contributed and helped us reaching such low alert rates in last weeks.

During last few months we are also focused on establishing supporting processes and platforms that will be essential in the every-day operational phase, when all stakeholders will need to prosecute their legal commitment to its full extent.

Our stabilisation period has now come to an end. Therefore, I would like to provide you with some valuable information on the following pages, that should help us continuing strong and trustful relationship and cooperation.

Sincerely,

Mitja Pirman  
Managing Director  
Medicines Verification Institute Slovenia



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## State of the NMVS

### National system

Slovenia established NMVS with Solidsoft Reply as the blueprint system provider. We were the first EU country to establish connection to the EU Hub in beginning of April 2018. We are following agreed validation procedures in close cooperation with other SSR countries and whole EMVS community since the first release. Our production NBS version will provide most of requested NCA reports by end of this year.

### Connected End users, onboarded MAHs

There are 341 pharmacies, 21 wholesalers and 28 healthcare institutions connected to NMVS system in Slovenia.

We have signed cooperation arrangements with over 200 MAHs, which upload serialization data in the Slovenian system. All our contractual partners will receive annexes to the cooperation agreement by end of 2019 where annual fee reduction information will be enclosed.

## National legislation and applicable fines

Slovenian Government has published [national legislation](#), which prescribes sanctions and fees for non-compliance with Delegated regulation 2016/161.

Article 23 exceptions defined in the legislation allow Slovenian wholesalers to decommission medicines before supplying to:

- Armed forces and police,
- Veterinarian organizations,
- Educational institutions,
- Social welfare institutions,
- Other medical institutions for supplying of vaccines.

Legal FMD compliance inspection body is the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP).

Penalty fine for non-compliance with any particular clause of delegated regulation range between 8.000 and 120.000 € for legal entity.

## End of stabilisation period

Slovenian Ministry of Health and the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) [announced](#), that **stabilisation period ends on December 1<sup>st</sup> 2019**.

Due to the end of the stabilization period, pharmacists at pharmacies will no longer be able to dispense medicines to patients in an event of alerts of any type.

## Alert handling

### Alert handling guidance

Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) and Medicines Verification Institute Slovenia (ZAPAZ) in association with Slovene Chamber of Pharmacies prepared guidance document to provide the system users and software suppliers with additional information and recommendations regarding the management of responses and alerts. The guidance document is based on the current system design and may be upgraded with further development of the system and practical user experience.

[English version of the document is available here.](#)

### Collaboration platform for our stakeholders

ZAPAZ uses **NMVS Alerts** portal as the central collaboration platform for exchanging necessary information with all stakeholders, that need to be involved within individual alert investigation.

Portal displays updated overview on alert information to all stakeholders and provides options for submitting feedback and marking related activities:

- ZAPAZ can identify most-likely root cause and initiate appropriate investigation request;
- End user can mark potential technical or procedural issues and provide other valuable information;
- MAH can initiate pack photo or pack return request, mark investigation actions, conclusions and treat alerts on a Batch level;
- All events and responses are logged with timestamp.

Alert investigation details on the portal are also accessible to Slovenian NCA (JAZMP).

### Alert investigation - response times

Stakeholders in Slovenia have agreed, that alert investigation activities should be concluded **within 24h or latest until the end of the next workday**, as this is also the time limit for medicines to remain in the pharmacy quarantine. After that packs will be returned to the wholesaler.

Therefore, we propose, that all stakeholders submit feedback with alert investigation information and conclusions through the NMVS Alerts portal, as this is the fastest possible communication exchange channel, available 24/7. Every marked activity or investigation status update is **instantly** available to all involved stakeholders. This way we are already resolving substantial number of alerts within 4 hours.

ZAPAZ keeps track on stakeholder response times and reports to NCA all unresponsive cases.

## ZAPAZ - contact details and working hours

### Company name:

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EN: Medicines verification institute Slovenia

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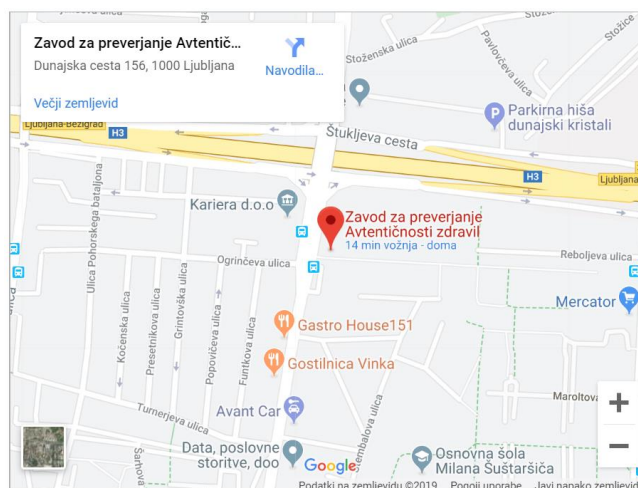
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### Business hours

We operate within standard business hours, Monday to Friday, between 8:00 and 16:00 CET.

### Our team

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