REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

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Letter to manufacturers of medical devices

With the transition from the medical device directives to the Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) the last years can be described with some uncertainty and pressure on all parties to achieve the required goals in transitioning to the new requirements. Understandably, the requirements in the regulations have demanded a lot of effort from the manufacturers in transitioning their devices.

Among other challenges there has also been changes to the language requirements that are expected to be fulfilled for each member state. Ultimately, the manufacturer is responsible for their device as well as for the information that is supplied with it. It is easily understandable how the manufacturers, when faced with stricter regulation, demanding timelines and language requirements that are member state specific, would prioritize their marketing activities based on the projected market size of the EU member states.

However, we want to call on manufacturers to still consider the smaller member states in their planning and move at a timely pace to market their MDR/IVDR devices there also. To facilitate this, we would like to outline the acceptable regulatory ways to achieve compliance with Estonian language requirements to hopefully alleviate some concerns that manufacturers might have.

The Estonian language requirements for medical devices are laid out in the Estonian Medical Devices Act (MDA) § 16, that states the following:
(3) The manufacturer, relying on risk analysis, ascertains the information necessary for the safe use of a device for the intended purpose, and the information related with a medical device placed on the market, made available on the market, distributed and put into service in Estonia must be presented:
1) in the Estonian language and in an appropriate manner if the medical device is intended for the use of ***lay users****;*
2) in the Estonian or English language and in an appropriate manner if the medical device is intended only for the use of ***professional users****;*
3) in the language understandable to a specific user and in an appropriate manner in case of a ***custom-made medical device****.*
(4) Differently from the provisions of subsection 3 of this section, the remaining information related with a medical device may be presented in another language of a Member State of the European Union or the European Economic Area that is understandable to potential users.

For devices intended for the professional user, information provided in English only is acceptable

As stated in the Estonian MDA, the information necessary for the safe use of a device for the intended purpose can be presented in the Estonian or English language. Another national act, the Language Act does give the professional user the right to receive information from the trader about the product or service features and terms and conditions of use in Estonian. It is understandable that for devices that are sold in large quantities to multiple users it would be impractical to establish clarity on the part of each professional user. However, for devices sold rarely to select locations we strongly encourage manufacturers to make full use of the flexibility that the Estonian MDA provides. The local distributors are well able to support and facilitate any necessary communication between parties.

For cases where the professional user does require the information in Estonian language, the same approach could be utilized as for the devices intended for the lay user.

For devices intended for the lay user, only information in Estonian is acceptable

However, we encourage manufacturers to also consider the few options of how this could be achieved and to not underestimate the ability of a local distributor to carry out necessary activities.

The first option is for the manufacturer to fully translate and label the device as required by the law to market it in Estonia. This however, seems sometimes to be the lengthiest option as it depends on the resources and timelines of the manufacturer.

The second option is to make use of the local Estonian partners. According to MDR/IVDR article 16 other economic operators might perform repackaging/relabelling activities, which include translating the information provided with the device. The EU regulations lay down some strict conditions for these activities - the actor must establish a suitable quality management system and submit to the competent authority a certificate issued by a notified body attesting that the quality management system complies with relevant requirements. The actor also has to include the information on the activity as well as on themselves with the information. Also, 28 days prior to making the relabelled or repackaged device available on the market the distributor or importer has to notify the manufacturer as well as the competent authority. These are by no means quick actions and might cause considerable delay in marketing devices as well. This letter aims to strongly empathize that according to the MDCG guideline 2021-26, these requirements (in MDR/IVDR article 16(2), (3) and (4)) do not apply to operators subcontracted by the manufacturer (that may also qualify as importers or distributors), who also carry out relabelling and/or repackaging activities on behalf and under the control of the manufacturer. Taken together, this means that good cooperation between manufacturers and local distributors could allow the easiest way to market devices in Estonia.

The third option is to let the local distributors fulfil all the requirements set out in the MDR/IVDR article 16. We strongly urge the manufacturers to not exclude Estonia from their list of countries that they supply their devices to if there is an actor willing to fulfil all relevant requirements.

The goal of the Estonian competent authority on medical devices is to work alongside the industry and users to achieve the best possible supply of safe and effective devices in Estonia so that our patients are given the same quality care as the larger member states.

We particularly want to invite manufacturers to make full use of the ability of local distributors to facilitate any necessary communication and activities to ensure regulatory compliance. This applies in all activities – from communication with the local competent authority to establishing contact with local health care providers.

With any concerns regarding local regulatory compliance, we invite all manufacturers to consult the competent authority on medical devices in Estonia directly by contacting the department of medical devices at State Agency of Medicines at mso@ravimiamet.ee.