A new procedure for importing medical devices in the context of their marketing authorisation comes into force in Russia

Russia · 29.12.2020

Available languages: RU

On 1 January 2021, a new procedure* will come into force in Russia for the import of medical devices in the context of their marketing authorisation.

While the new rules do not introduce fundamental changes to import procedures of medical devices, they should eliminate the ambiguities of the current procedure and simplify the process.

In particular, in the new procedure:

- the scope of application is specified;
- an electronic application form and import permit have been established;
- the amount of information provided in the application for a permit has been expanded; and
- the period of validity of the import permit has been increased.

The new procedure was adopted within the framework of the "regulatory guillotine" and is aimed at improving the process of obtaining permission to import medical devices in the context of their marketing authorisation. Market participants need to pay attention to these new rules and take them into account when applying for import after 1 January 2021.

Scope of application

Similar to the current procedure, the new rules establish the procedure for the receipt of an import permit for medical devices in the context of their marketing authorisation.

At the same time, the new rules specify that they apply not only to cases of importation for the initial process of marketing authorisation, but also, if necessary, to make changes to the registration dossier.

The new rules also emphasise that if the place of manufacture of a medical device is outside the Russian Federation, then obtaining a permit is mandatory, even if the manufacturer is registered in Russia.

In addition, to simplify the authorisation process for software, there is no need to obtain a permit for software that is considered a medical device.

Electronic form

Unlike the current rules, the new procedure provides for interactions in electronic form between applicants and the authorised body.

An application for the issue of an import permit must be signed with an enhanced qualified e-signature and submitted through the portal of public services ("*gosuslugi*"). In case of a positive decision, the permit will be posted in the applicant's personal account in the portal of public services and in the Roszdravnadzor register.

This innovation should simplify interaction with Roszdravnadzor, but each applicant will need an electronic signature to submit documents.

Content of the application

The new procedure imposes more requirements on the content of an application for an import permit. Now, among other things, the application must contain information confirming the accreditation of organisations hired to conduct toxicological, technical, clinical research and testing.

Permit validity period

The new rules increase the validity period of the import permit: instead of six months, the permit will be valid for one year, which will allow applicants more flexibility to structure the state-registration process of products imported into Russia.

For more information on this eAlert, please contact CMS Russia experts Vsevolod Tyupa, **Alexey Shadrin** or your regular contact at CMS Russia.

** In Russian*

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