

New rules for determining drug interchangeability now in force

Russia · 04.03.2020

Available languages: [RU](#)

Amendments* to the [Federal Law on the Circulation of Medicines*](#) regarding the interchangeability of medicines came into force on 1 March 2020.

The amendments refine the concept of drug interchangeability, enabling patients to receive the least expensive drugs without affecting the quality, effectiveness and safety of their treatment.

Under the new rules, drugs will undergo an interchangeability examination and will then be grouped accordingly. The relevant information will be posted on the website of the Russian Ministry of Health and will be available to anyone. As a result, patients and healthcare professionals will be able to find out which interchangeable drugs are available for the same medical conditions.

Information on interchangeability should benefit the public procurement system by allowing state customers to see the relevant list of interchangeable drugs before deciding which drugs to purchase. This should ensure more tenders by suppliers, increased competition and ultimately lower drug prices.

The law takes into account the fact that, from a medical point of view, interchangeability is not an “absolute”. Two drugs can be interchangeable for one patient, but not for another (e.g. an adult and a child). Therefore, the concept of “relatively” interchangeable drugs will be introduced. This covers medicines whose interchangeability is determined by taking into account exceptions for certain groups of patients. In addition, the Russian government will establish special rules for determining the interchangeability of certain categories of drugs, such as combined ones.

As a whole, these changes should make the system for determining interchangeability more flexible by taking into account the characteristics of certain drug categories, drug characteristics and the features of individual groups of patients. Much will depend, however, on the specific procedure for determining interchangeability, which must still be approved by the Russian government. Equally important will be how the authorities and medical community interpret and apply the interchangeability rules.

If you have any questions on this eAlert, do not hesitate to contact CMS Russia experts [Vsevolod Tyupa](#) and [Alexey Shadrin](#) or your regular contact at CMS Russia.

* *In Russian*

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