

# Russia finally adopts off-label drug use requirements

On 27 October 2023, the government adopted [Resolution](#)\* No. 1799, approving new requirements for the off-label use of drugs, i.e. administration of drugs under indications that are not specified in their instructions for use.

The Regulation will come into force on 1 September 2024. Off-label drug use can be included in the standards of medical care for children as well as clinical recommendations if the relevant drug is registered in Russia and meets at least one of two criteria:

- The effectiveness and safety of off-label drug use are confirmed by data from scientific research and/or descriptions of clinical cases published in scientific publications listed in the Russian Science Citation Index, international academic databases Scopus or Web of Science;
- An indication of the effectiveness and safety of off-label drug use is supported by recommendations adopted by international professional organisations.

In the initial version the rules required the drugs to be of higher effectiveness or safety compared to drugs used on-label, as well as confirmation of drug's effectiveness and safety through clinical trials. Thus, the final wording has been significantly relaxed.

The idea of including off-label use in the standards of medical care for children and clinical recommendations was already reflected in the legislation. The lack of requirements for the drugs to be used off-label was the final obstacle to implementing this idea.

These amendments should increase the number of off-label prescriptions and make the relevant drugs more popular on the Russian market.

\* *In Russian*

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