



Ukraine Introduces Compassionate Use of Medicines

Immediately before the beginning of Russia's unprovoked invasion of Ukraine in February 2022, the Ukrainian parliament passed an important law¹ introducing the concept of the compassionate use of medicinal products (the "**Law**"). On 30 April 2022, the Law entered into force. Compassionate use programmes offer an alternative to authorised therapy options of treatment for patients with life-threatening or severe health conditions.

The Law differentiates between:

- (1) *post-trial access programmes*, providing access for clinical trial participants to investigational medicine following the completion of a clinical trial (in the interests of continuing therapy), and
- (2) *expanded access programmes*, covering the use of unauthorised medicines, authorised medicines for non-authorised indications, or medicines not envisioned in the clinical guidelines, in other compassionate use cases.

The requirements for launching compassionate use programmes are similar to launching clinical trials in Ukraine. Specifically:

- compassionate use programmes are subject to the Ministry of Health's (the "**MoH**") authorisation and approval by the ethics committee (institutional review board) of the hosting healthcare institution on the programme's ethical aspects;
- the programme cannot start before an agreement is concluded specifying the terms of its implementation between the entity that will provide medicines for the programme and the healthcare institution (or licensed individual healthcare practitioner).

The Law does not set out an exhaustive list of applicants for MoH authorisation, stating only that it can be either a business entity, organisation, or an individual. Thus doctors, investigators, sponsors, CROs, healthcare institutions, patient organisations etc. can apply for authorisation.

The **application** should contain detailed information about the medicine, a justification of its compassionate use, and information on the estimated number of patients who will participate in the programme.

Under these programmes, patients access medicines free of charge. Each patient's informed consent is a pre-condition for enrolment.

¹ [Law of Ukraine dated 15.02.2022 #2054-IX](#) "On Amendments to Certain Legislative Acts of Ukraine Concerning the Issue of Compassionate use of Medicines by Patients"

Expanded access programmes may involve:

- *patients* with a life-threatening, long-lasting or seriously debilitating illness or grave medical condition, lacking effective treatment in Ukraine or who are ineligible for clinical trials, provided the treating physician considers use of the unauthorised medicine the best option;
- *medicines* that have either been approved for use or are undergoing at least phase-II clinical trials in the USA, EEA countries, Australia, Canada, Japan, UK, Israel or Switzerland, provided there is information on safety and efficacy, sufficient to assess the benefit/risk ratio.

Post-trial access programmes can enrol trial participants with a life-threatening or severe medical condition requiring continuous treatment with the investigational medicine following the end of the clinical trial, and on evidence that the expected positive effect of taking the medicine will outweigh the underlying risks to the patients.

MoH authorisation doubles as permission to import the unauthorised medicines. The Law sets out special requirements for the labelling of such medicines.

The **authorisation procedure** and particularities of conducting compassionate use programmes will be elaborated on in subordinate legislation.

In terms of VAT, the import and supply of unauthorised medicines under compassionate use programmes will so far be taxed at the regular rate of 20%, compared to the special lower rate of 7% for authorised medicines and investigational medicinal products. While the initiators of the Law pushed for the same lower VAT rate for products in compassionate use programmes, the respective draft law (with proposed amendments to the Tax Code) is yet to reach the stage of parliamentary hearings.

If you have any questions relating to the publication, please contact us.



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