

LEGAL UPDATE

# Medicinal Products as Humanitarian Aid to Ukraine

On Tuesday, 22 March 2022, the Parliament adopted the Act on certain measures in connection with the situation in Ukraine, which includes an amendment to the Act on Medicinal Products. This amendment allows the supply of medicinal products, including reimbursed products, to international humanitarian organisations, and their subsequent export from Slovakia.

Until now, humanitarian aid to Ukraine in the form of medicinal products has been restrained by the lack of authorisation of humanitarian organisations to handle medicinal products, and the inability of wholesale distributors to supply medicinal products to such organisations. Products included in the list of reimbursed medicinal products are also subject to export restrictions.

The legislation is currently awaiting signature by the President, and will enter into force on the day of its publication in the collection of laws, which may occur in the next few days. Below, we are presenting the details.

## New powers of the Ministry of Health

The Ministry of Health has been given the new power to render, during a crisis situation, a decision, by which it may, in the necessary extent and time:

- permit an international humanitarian organisation to procure medicinal products for human use from wholesale distributors, to store these medicinal products, and to supply them for the purpose of humanitarian aid;
- permit the export of medicinal products for human use included in the list of reimbursed medicinal products for the purpose of humanitarian aid;
- permit the export of human plasma for the purpose of humanitarian aid.

An exemption from the general rule under which only the persons holding the respective authorisation may handle medicinal products is being introduced. It will depend on the decision of the Ministry of Health whether this exceptional regime will apply to all or only some medicinal products, whether it will apply only to enumerated humanitarian organisations or to any organisations meeting certain criteria, and whether exports will be possible only to Ukraine or also to other countries. It also remains to be seen whether and how will the Ministry of Health address good distribution practice requirements, in particular cold chain, in handling of medicinal products by humanitarian organisations.

## Supply of medicinal products by wholesale distributors

The amendment to the Act on Medicinal Products extends the scope of entities to which wholesale distributors may supply medicinal products for human use, including those listed in the list of reimbursed medicinal products, to international humanitarian organisations, if the Ministry of Health permits so. Wholesale distributors will be therefore able to supply medicinal products to humanitarian organisations, however, only after the Ministry of Health gives its permission, and under the conditions to be determined by the ministry.

## Exemption from export restrictions for reimbursed medicinal products

According to the Act Medicinal Products, medicinal products included in the list of reimbursed medicinal products may be exported from Slovakia only by the manufacturer who manufactured the exported products, the marketing authorisation holder, or a wholesale distributor acting based on a written power of attorney from the marketing authorisation holder.

The amendment introduces an exemption under which the provisions restricting export of reimbursed medicinal products will not apply to export of reimbursed medicinal products by international humanitarian organisations for the purpose of humanitarian aid, if such export has been permitted by the Ministry of Health. Exports will still not be possible by the wholesale distributors directly, but only by humanitarian organisations to which the wholesalers supply the products.

## Export of human plasma

If the Ministry of Health permits export of human plasma for the purpose of humanitarian aid, the provisions of the Act on Medicinal Products requiring an applicant for a permit to export human plasma or a holder of such a permit:

- to procure documentation proving that the exported human plasma will be industrially processed by an authorised person;
- to take measures to ensure traceability of the exported human plasma and medicinal products manufactured from the exported human plasma; and
- to provide information on exported human plasma to the Ministry of Health upon request,

will not apply to such export.

## Disposal of State property

The amendment also simplifies the disposal of State property during the state of emergency declared in connection with mass influx of foreigners to the territory of the Slovak Republic caused by the armed conflict in Ukraine, which is necessary for provision of humanitarian aid, in particular medicinal products for human use, medical devices, or dietetic food, including its sale or donation abroad to mitigate the negative consequences of the armed conflict or to provide healthcare.

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This legal update has been prepared on 24 March 2022 solely for the purpose of general information and shall not be considered a legal advice. The information above is not comprehensive and the legal update only briefly outlines the respective legislative changes. In case you are interested in further information on the above legislative changes, do not hesitate to approach our pharmaceutical law experts:

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