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Ukraine Under Martial Law Calls For Medical Supplies As Medtechs Adjust And Respond

by Ashley Yeo

Martial law in Ukraine following the military onslaught and invasion by Russian forces has compelled the health ministry and industry to put emergency plans in place.

Ukraine's imposition of martial law in the early hours of 24 February, when Russian forces launched a military invasion of the country, has thrown normal business operations into disarray.

Decree No. 64/20 "on the imposition of martial law in Ukraine" will last for 30 days. The force majeure is having extraordinary and unavoidable effects. In a letter dated 28 February, the Ukrainian Chamber of Commerce and Industry said that implementing contracts and regulations had become impossible.

The first week of the war saw increasing loss of civilian life, local people driven from their homes in the regions under severe attack, and a growing refugee crisis. The ongoing shelling and its impact on health care infrastructure and medical supply chains compelled health minister Viktor Liashko to call for international help.

The ministry has issued a <u>list of medical supplies</u> (equipment, consumables and medicines) that the country needs to source from foreign donors. US medtech industry association <u>AdvaMed</u> is coordinating US donations, including <u>humanitarian aid</u>, from member companies. The UK <u>CBI</u> is offering itself as a conduit for aid. The EU's <u>Civil Protection Mechanism</u> members are listed on its website.

Ukraine is in strong need of medical devices as humanitarian aid, says Kyiv-based medical devices and medicines business and regulatory consultant Cratia. In particular, there is a need

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for: wound dressings; vacuum-assisted closure devices and disposables; blood stoppers; surgical instruments; sterile surgical (protective) suits; and medical backpacks. There is a huge need for pharmaceutical products.

<u>Cratia</u> is among the organizations working closely with the health ministry and volunteer organizations. It is encouraging its logistics partners to deliver products from Germany and Poland.

Contingency Moves For Health Care Products

The Ukraine minister also declared that under martial law, given the need to provide combatants and the wider population with vital health care products, the ministry will permit the importation of unregistered medicines, in foreign packaging, into Ukraine.

Further, for the duration of martial law, the ministry said it will not oppose the importation and putting into circulation of medical devices, active implantable medical devices and IVDs that are not in compliance with the respective technical regulations.

Ukraine's medical device technical regulations, Nos 753, 754 and 755, all dated October 2013, are based on the EU's medical device directives. (Also see "*Ukraine Medtech At Last Crosses From State To DoC Regulatory System*" - Medtech Insight, 14 Aug, 2017.)

The ministry will also allow the use of devices whose labels do not comply with local language requirements as set out in the of the law "on ensuring the functioning of Ukrainian as the state language."

Cratia reported on 4 March that it too had adjusted its operations. It has implemented business continuity plan measures according to ISO 22301:2012 (societal security – business continuity management systems requirements) and EU Good Pharmacovigilance Practice (GPvP) standards.

It said these measures are aimed at minimizing risks for employees and customers while maintaining critical business processes.

Cratia's staff has switched to remote working, but business head Maxim Bagreev acknowledged that the Russian air threat has led to individuals having to spend long periods in air raid shelters, basements and subway stations. With remarkable understatement, he told clients that "some delays may occur."

Regarding the conformity assessment of medical devices following the declaration of force majeure, some conformity assessment bodies have also switched to remote working to guarantee annual medtech company audits and device re-certifications, among other critical business processes.

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Cratia meanwhile reports that "spirit and unity prevails in Ukraine." As of 4 March, some UAH 7.8bn (\$290m) had been donated to a National Bank of Ukraine armed forces support fund.