



## Proposed measures in Germany for safeguarding supply of critical goods in the combat against COVID-19

March 25, 2020

In the wake of combatting the COVID-19 pandemic, the German Federal Government is proposing to enable further measures on federal level. The proposal includes important measures concerning supply of medical devices, diagnostics, protective gear, pharmaceuticals and narcotics, active pharmaceutical ingredients and auxiliary materials. It is relevant for manufacturers, suppliers of raw material and component parts as well as auxiliary products.

The bill - which is called *Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite* - is expected to pass in parliament today, 25 March 2020. Among other provisions, it will amend the Infection Protection Act (*Infektionsschutzgesetz - IfSG*). The Infection Protection Act is the central German law for combating infectious diseases. The purpose of the law is to prevent contagious infectious diseases among humans, to detect infections at an early stage and to prevent their further spread. The law was enacted by the German Federal Government on 1 July 2000. Against the background of Germany's federal structure, however, the German states enforce laws such as the IfSG. This results in the fact that the German Federal Government - as it has repeatedly done - can make recommendations for action on how to handle infectious diseases such as Covid-19, but these recommendations must first be implemented by the states in order to become legally binding. For this reason, the German Federal Government intends to amend the law.

The bill provides for a number of **new competences for the Federal Government in case of a national epidemic**. Provided Parliament will accept the proposal, the law grants new powers to the Federal Ministry of Health. By way of ordinance - not requiring consent of the Federal Council - the Federal Ministry of Health may, among others, order

- **Measures for procurement, storage, distribution and supply of medical devices, diagnostics, protective gear, pharmaceuticals and narcotics, active pharmaceutical ingredients and auxiliary material.** This may include reporting and notification obligations. If necessary, seizure and use of such products can be ordered. Where this amounts to dispossession, adequate provisions for compensation must be arranged for.
- **Prohibition of sale of products or other assignment of goods. This may include prohibition to fulfill contractual obligations.** Where this amounts to dispossession, adequate provisions for compensation must be arranged for.

- Provisions for supply, price setting and reimbursement.
- **Measures for continuance, conversion, opening or closure of manufacturing plants or individual facilities of companies manufacturing goods within the scope of the ordinance.** Where this amounts to dispossession, adequate provisions for compensation must be arranged for.
- **Exceptions to existing medical device regulations and the German Medicines Act (*Arzneimittelgesetz – AMG*).** The Federal Ministry of Health will have the competence to order exceptions to German and European medical device regulations and to the German Medicines Act (*Arzneimittelgesetz – AMG*) and other regulations concerning manufacturing, labelling, market authorisation, clinical trials, application and supply of such goods. That includes the possibility to establish exceptions to the conformity assessment procedure. This comes in addition to an already existing ordinance enabling exceptions from the German Medicines Act in case of disaster (*AMG-Zivilschutzausnahmereverordnung - AMGZSAV*).
- **Exceptions regarding liability for products.** The Federal Ministry of Health will have the competence to amend rules on liability for pharmaceuticals, medical devices and other goods in the scope of the bill. This comes in addition to an already existing ordinance enabling exceptions from the German Medicines Act in case of disaster.

Those new competences will presuppose an "epidemic situation of national significance". This national epidemic must be determined by the Federal Government. That means, that a decision by the Federal Minister of Health is not sufficient, but a collegial decision of the government is required.

Such an "epidemic situation of national significance" is defined as a "serious danger to public health in the entire Federal Republic". This is possible if either the World Health Organization WHO has identified a "health emergency of international significance" and the introduction of a threatening communicable disease into the Federal Republic of Germany is imminent or if the infectious disease threatens to spread in at least two Federal States.

If corresponding measures are taken and are unduly infringing rights, affected companies may seek relief before German administrative courts. Where applicable, compensation may be sought. We will monitor the further development of the planned amendments and are available to discuss any questions you may have.

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