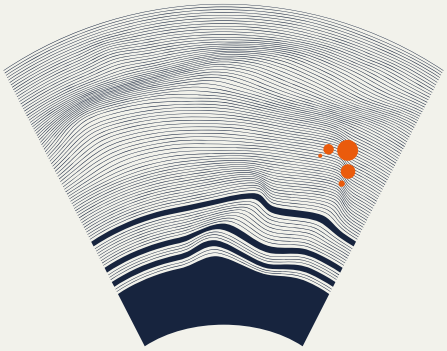

Noerr

Healthcare

/ Selected healthcare measures in CEE

30 April 2020

Governments across Central and Eastern Europe (CEE) have introduced various measures to cope with and mitigate potential adverse consequences of the coronavirus situation. The healthcare and life sciences sectors are playing a crucial role and facing the most dynamic developments during the current state of emergency.

This short overview summarises healthcare measures taken in the region. Due to the ever-changing regulatory situation, we will update this overview regularly as required.

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Czech Republic

Export ban: The Government has introduced measures imposing restrictions on the export and sale of respirators with FFP3 filters that apply to certain Czech manufacturing companies, as well as obligations to report export of certain drugs and medicines to the State Institute for Drug Control. There are also limitations on prescriptions of the medication Plaquenil.

State aid: State aid is provided for hospitals in the form of monetary aid and provision of personal protection equipment (PPE).

Reporting: Medical facilities are obliged to immediately report changes in their ICU capacity and changes in the number of available doctors and other healthcare workers.

Telemedicine: No official regulation of telemedicine is in place. Some examinations are currently being performed via telephone, which are intended to be covered by health insurance.

Switching to new lines of business: Some private laboratories are in the process of procuring a licence to do Covid-19 testing. Customs authorities are helping manufacturers of ethanol for disinfections to register a licence. Companies that are manufacturing PPE, e.g. using 3D printing/copper or silver plating of face masks, are closely co-operating with the State and with universities or other research facilities. A new topic related to the business side of matters currently being discussed is acquisitions of human tissue manipulation companies.

Employment matters: In the Czech Republic, a shortage of medical staff is being closely monitored. The Government has ordered certain medical students (usually medical students who would otherwise not perform mandatory work) and social sciences students to do lower-risk work and is also deploying volunteers in Czech regions. Hospitals have adopted internal regulations for special remuneration for overworked employees for mandated extra shifts. They are also allowing the possibility of doctors from third countries to work in Czech hospitals without an approbation exam. While the outbreak is on-going, Czech employers are not required to have periodic medical examinations of their employees performed.

Hungary

Export ban: The export of certain pharmaceutical products is currently prohibited in order to ensure a continued supply of such products in Hungary. The scope of this prohibition has been determined on the basis of the effects of the pharmaceutical products.

Switching to new lines of business: New measures have been introduced by the Hungarian Government that facilitate the use, prescription and approval of pharmaceutical products. Even using and applying for approval of the pharmaceutical products before authorization have become easier subject to the following terms: (i) the product must have been tested in a phase I clinical trial (instead of phase II), (ii) use may also be requested by healthcare providers (not only by doctors), and (iii) the consent of the manufacturer of the pharmaceutical products is not required for such use.

In addition to the foregoing, the criteria for producing biocidal products have been eased, i.e. alcohol as a necessary active substance may be purchased from any source, provided that the manufacturer ensures compliance with the applicable quality standards.

Telemedicine: The Hungarian Government has relaxed the requirements for prescribing pharmaceutical products using e-prescription. Pharmaceutical products are also permitted to be provided without confirmation of an e-prescription if the person receiving the product reports the patient's social security number and his/her own identification data. E-prescriptions may be issued in case of remote medical consultation.

Interactions with healthcare professionals (HCPs): Despite the restrictions on movement introduced by the Hungarian Government, healthcare services are available and may be used. However, organized and targeted screening tests have been postponed, and only emergency treatment may be provided in the context of dental primary care. The Hungarian Government has also introduced an option to use e-prescriptions and remote medical consultation in line with the rules of social distancing.

The Minister of Human Capacities recommends against any interaction with patients by healthcare professionals over 65 years of age.

Giving a helping hand: Healthcare workers will receive a one-time payment of HUF 500,000 (approx. EUR 1,500). Public transport is also free of charge for healthcare workers in Budapest and on interurban routes.

Employment matters: During the state of emergency declared by the Hungarian Government, medical students or other students participating in any healthcare education on a full-time basis aged over 18 may be required to perform any duties related to the healthcare crisis due to the pandemic. Healthcare workers are only permitted to leave the country with special permission from the Minister of Human Capacities.

Poland

Export ban: Polish authorities have significantly increased the number of medical products which cannot be exported from Poland, even to other EU Member States. Although the list was created in 2015 in order to prevent medical shortages due to parallel export driven by low pricing of medical products, in recent weeks, the authorities have added almost 1,000 products (including protective equipment, antiviral medicines and antimalarials) to this list. Many institutions (especially hospitals) are allowed to purchase needed materials or products outside the limitations of the Polish Public Procurement Law, which implements the EU directives on public procurement.

Switching to new lines of business: Poland adheres to the EU recommendations concerning PPE, medical devices and disinfectants used during pandemic and the regulatory requirements that they must meet. No new relief measures to place them on the market have been introduced. Many state-owned companies have switched the scope of their typical activity and commenced production of disinfectants or other products of which there is a shortage.

Claw-back tax: The Polish Government has not introduced any new claw-back mechanism in the healthcare system. This means that the claw-back payment for medicines and medical devices reimbursed from public funds remains at the same statutory level that was established before Covid-19. Nevertheless, as it is based on the actual volume of prescription products dispensed to patients, we cannot rule out a significant reimbursement increase with respect to certain groups of products (i.e. antivirals).

Transfer of Value (ToV) reporting under Transparency Regulations: There are no statutory 'sunshine' regulations in Poland. However, most innovative companies are members of INFARMA (Polish EFPIA's organisation), and all its members must submit disclosure declarations concerning any 'transfer of value'.

Telemedicine: The Ministry of Health has opened an online consultation platform for patients who believe they might be infected with Covid-19. It requests that they remain at home rather than visit a stationary clinic. It is possible to obtain a prescription for prescription medicinal products online.

Interactions with HCPs: Representatives of companies that supply the healthcare sector are not allowed to have face-to-face meetings with HCPs pursuant to a non-binding recommendation of the Main Sanitary Inspectorate, according to which most medical company representatives are not allowed to enter state-run hospitals or clinics. All conferences, workshops and medical events have been cancelled due to the strict ban on any gatherings.

Giving a helping hand: Charitable donations to state-run hospitals and clinics are allowed on the same basis as they were before the Covid-19 crisis (donations to individual HCPs are strictly forbidden).

Employment matters: It is forbidden to organize any gatherings, meetings or events for more than two people. This restriction does not apply to meetings with relatives.

Workplaces are exempted from this rule. However, employers must provide their employees with additional safety measures, i.e. employees must use gloves or have access to liquid disinfectants, and there must be a distance of 1.5 meters between workplaces. If an employer is not able to ensure this distance (1.5 m) for objective reasons, e.g. because a production line does not allow it, it has the right to deviate from this principle, but only if it provides its employees with personal protective equipment.

Other relief efforts: The Polish Government has introduced measures, predominantly in the form of loans, to form an overall package aimed at ensuring that medium-sized and small undertakings have sufficient liquidity. A programme called 'Shield' is open to all sectors and applies to the entire territory of Poland.

Romania

Export ban: The export of medicines included in the Protocol for SARS-CoV-2-virus Treatment, as approved by the Ministry of Heath's order no. 487/2020, as well as medicines under increased risk of shortage for chronic pathological conditions in the context of the SARS-CoV-2 pandemic (an exhaustive list is set forth by Ministry of Health order no. 672/23 April 2020) is banned for a period of six months. A few exemptions apply, i.e. medical equipment systems and components manufactured in Romania for non-domestic customers as well as drugs that are produced in Romania.

The procedure for requisitioning goods and services needed in the public interest has been simplified and can be used during the state of emergency, currently declared until 16 May 2020.

Switching to new lines of business: A simplified authorization procedure has been enacted in order to certify the production of PPE and biocides. The Ministry of National Defence and the National Institute for Medical-Military Development Research, "Cantacuzino", handle these expedited formalities.

More than 80 companies were authorized to produce biocides as of the beginning of April, and other major state-owned companies have been retooled and are currently contributing to efforts to ensure that Roma-

nia's PPE stocks are not depleted. Private automotive and textile entities have successfully implemented new lines of business to supply the current demand of first-line hospital units.

Claw-back tax: The percentage of the claw-back tax to be paid by producers for medicines subject to reimbursement related to Q1 of 2020 has been capped (i.e. the value of "p" is capped at 27.65% of the value for Q4 of 2019).

ToV reporting under Transparency Regulations: The original deadline of 31 March 2020 for submitting data pertaining to ToV made available to HCP and healthcare organizations (HCO) in 2019 to the National Agency for Medicines and Medical Devices has been postponed to 31 July 2020.

Telemedicine: The practice of telemedicine, which was forbidden until recently, has been approved during the state of emergency, and medical consultations may be performed remotely by both primary care and specialist physicians using any means of communication. There is a limit of a maximum of eight consultations per hour.

"Off-label" prescribing has been approved for Covid-19 patients as long as such treatment is approved by the internal committee of the healthcare unit.

Medical staff capabilities: In order to supplement the personnel directly involved in activities aimed at preventing and fighting the Covid-19 pandemic, for a limited duration of six months, hospitals may hire medical and auxiliary staff who have not completed any admission exams or testing.

Medical students (at least in their 4th year) and junior doctors are being recruited by university medical centres and may be asked to work, depending on the evolution of the pandemic and the needs of the medical infrastructure.

Medical staff currently in retirement may be called upon to help ensure that some responsibilities of the healthcare system are covered. However, no legislation has been issued on this topic at this stage.

For the moment, medical staff capacity seems to be sufficient, but additional measures are being contemplated for implementation if the outbreak worsens.

Giving a helping hand: The procedure on sponsorship and donation has been simplified in order for medical facilities to receive immediate help from private entities and non-governmental organisations (NGOs).

Medicines, medical devices, vaccines and other specialized healthcare materials may be given to hospitals without any formal contract other than an authorization issued by the National Agency for Medicines and Medical Devices; PPEs and disinfectants may be provided without any formalities, regardless of their value.

Direct financial support may be provided based on sponsorship agreements. Under certain conditions, the sponsorship may also constitute a tax break, as the sponsor is permitted to deduct the equivalent of the sponsorship amount from its taxable income as long as this amount does not exceed 5% of such taxable income.

Financial impact: On 15 April 2020, the Romanian Government approved the first budget rectification in response to Covid-19 crisis. The budget deficit has increased to 6.7% of GDP.

The Healthcare Ministry was allocated an additional amount of RON 3.8 billion (EUR 775 million), and the expenses on social securities have been increased by over RON 6 billion (EUR 1.2 billion) and are to be used to cover the technical unemployment costs ensured by the State during the coronavirus lockdown and for other healthcare expenses.

The European Commission has approved a RON 16 billion (EUR 3.3 billion) Romanian scheme to support small and medium-sized enterprises in the context of the coronavirus outbreak. The scheme was approved

under the State aid Temporary Framework adopted by the Commission on 19 March 2020, as amended on 3 April 2020.

Other relief efforts: Several organizational and economic measures have been implemented in order to enhance domestic production and make full use of national companies and resources. Production of medicines used in the treatment of Covid-19 patients (e.g. paracetamol and novocalmin) at national level has been resumed. Romanian military researchers have developed an isolated gurney to safely transport people infected with the new coronavirus. It has been successfully tested and is currently in production. The first Romanian ventilator is currently in its trial period.

Slovakia

Export ban: The Government has introduced measures to prohibit the export of registered medicinal products for human use, medical devices and in vitro diagnostic medical devices intended for the Slovak market.

Switching to new lines of business: A shorter registration period for human medicinal products used in the treatment of Covid-19 disease has been enacted. The State Institute for Drug Control provides information within 24 hours (during business days) on whether an accelerated registration process is applicable. For medicinal products that are registered in the EU, the approval period is a maximum of seven days (otherwise 30 days). Legislation on a shorter approval period for clinical trials with Covid-19 patients has also been passed. The process must be co-ordinated directly with the State Institute for Drug Control. Clinical trials are being carried out in accordance with the Guidance on the Management of Clinical Trials during the Covid-19 (Coronavirus) Crisis issued by the State Institute for Drug Control, which is regularly updated to conform to a measure promulgated by the European Medicines Agency (EMA) of the same name.

Telemedicine: E-health is being strongly supported by issuing e-prescriptions, pre-examination of patients over the telephone and an increase in hygiene standards in ambulances.

Medical Devices Regulation (MDR) and its enactment throughout CEE

The European Parliament has decided to postpone the application of the Medical Devices Regulation by one year, i.e. **until 26 May 2021**.

Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions, was published in the EU Official Journal on 24 April 2020. It provides that Member States are to continue to adhere to currently applicable national rules implementing the Directive on active implantable medical devices and the Directive on medical devices. The present amendment also postpones the date of repeal of the existing directives but will not have any impact on the date of application of the In Vitro Diagnostics Medical Devices Regulation, which becomes applicable from 26 May 2022. It must be stressed that derogation from the applicability of the MDR is not limited to medical devices, such as medical gloves, surgical masks, equipment for intensive care or other medical equipment which plays a crucial role in the context of the Covid-19 outbreak but **applies to all kinds of medical devices and other MDR provisions**.

Regulation (EU) 2017/745 also empowers the Commission and national competent authorities, in response to a justified request, to authorize the placing on the market of medical devices for which the relevant conformity assessment procedures have not been carried out, but the use of which is in the interest of protecting health, or in the interest of public health or patient safety. Taking into account the Covid-19 outbreak and the associated public health crisis, the Commission has the power to adopt Union-wide derogations in response to national derogations in order to address potential Union-wide shortages of vitally important medical devices in an effective manner. Therefore, the relevant provision of Regulation (EU) 2017/745 is already applicable and the corresponding provisions of Directives 90/385/EEC and 93/42/EEC have been repealed.

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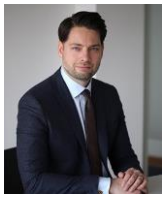

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