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Legal & Tax
30 years anniversary

COVID-19
Legal & Tax Resource Center

PHARMA & MEDICAL SERVICES; CLINICAL TRIALS

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PHARMA & MEDICAL SERVICES; CLINICAL TRIALS	
Special Measures	Any transportation of medical devises or sanitary materials which ensure the prevention and treatment of the medical conditions associated with COVID -19, as well as the medicine provided in the National Catalog of medicine prices authorized for market purposes in Romania (i.e., CaNaMed), for the purpose of being distributed outside Romania, is prohibited. An exemption is granted to ensembles and spare parts of medical equipment produced in Romania for external beneficiaries. Other such exemptions may be granted by Order of the Health Minister. *- as per Military Ordinance no. 1 of 17 March 2020, as further amended and supplemented*
Medical devices	During the state of emergency the registration of medical devices (such as class I medical devices, in-vitro medical devices, custom made medical devices and active implantable medical devices) are exempted from registration in the national data base to the extent they are related to the prevention and treatment of conditions appeared in the context of state of emergency. Such medical devices shall be introduced on the marked by the manufacturer/ authorized representative based of statement of conformity. Also, no notification regarding the commissioning of medical devices related to the prevention and treatment of conditions appeared in the context of state of emergency shall apply. *Ministry of Health Order no 537/ 2020* During the state of emergency, out patient medical services (physical medicine and rehabilitation) and palliative care shall be provided without the medical referral. Further during such state, medical consultations, including by any remote means, shall be provided by family doctors and specialty doctors from the out patient clinics and costs shall be incurred as per the applicable provisions in the field of consultations at the medical office/ out patient clinic. *Ministry of Health Order 539/ 2020* Sportsmanship related transparency obligations are due by June 30, 202 for medicinal products and by 31 July for medical devices and sanitary materials.

	Ministry of Health Order 538/2020 **European Commission working on proposal to postpone the Medical Device Regulation application date for 1 year** The Commission announced that work on a proposal to postpone the date of application for the Medical Device Regulation (MDR) for one year is ongoing. The decision was reached with patient health and safety as a guiding principle. The Commission is working to submit this proposal in early April for the Parliament and the Council to adopt it quickly as the date of application is the end of May. This decision will relieve pressure from national authorities, notified bodies, manufacturers and other actors and will allow them to fully focus on urgent priorities related to the coronavirus crisis. *European Commission press release*
Clinical trials	Starting with March 24, 2020, no visits of persons enrolled in clinical trials may be performed except as decided by the principal investigator (in case of emergency/ any delay may affect the safety of the patient). In all cases not having an urgent nature, the National Agency for Medicines and Medical Devices of Romania (NAMMDR) recommends as follows: • re-scheduling of visits or replacing them with conference calls; • identification of solutions for at home delivery of treatment; • supervisions by remote means; • suspension of initiation of new clinical trials/ new investigation centers. *as per NAMMDR press release on measures imposed by the said authority further to Order 74527/2020*

	In the COVID-19 context, NAMMDR shall prioritize the assessment of clinical studies for medical drugs against COVID-19; depending on number of requests and the phase of the study (the prioritization is of phase III), the estimate for completion of assessment is of max 7 days. VHP procure for EU coordinated assessment is also considered and to this the assessment schedule shall be mutually agreed together with the other Member States. *as per NAMMDR press release* Also, in the field of clinical trials, the European Commission, the European Medicines Agency (EMA) and national **Head of Medicines Agencies (HMA)** have published **new recommendations for sponsors on how to manage the conduct of clinical trials** in the context of the **coronavirus disease (COVID-19) pandemic**. The guidance provides concrete information on changes and protocol deviations which may be needed in the conduct of clinical trials to deal with extraordinary situations, e.g. if trial participants need to be in self-isolation or quarantine, access to public places (including hospitals) is limited due to the risk of spreading infections, and healthcare professionals are being reallocated. This guidance includes a harmonized set of recommendations, to ensure the utmost safety of trial participants across the European Union while preserving the quality of the data generated by the trials. It also advises how these changes should be communicated to authorities. There is specific advice on the initiation of new clinical trials for treatments of COVID-19, and in particular on the need for large, multinational trial protocols. This is in line with the call issued on Thursday by EMA's human medicines committee (CHMP) for robust trial methodology in clinical trials for potential COVID-19 treatments or vaccines. The guidance was agreed by the Clinical Trials Expert Group (CTEG) of the European Commission, supported by EMA, the Clinical Trials Facilitation and Coordination Group (CTFG) of HMA and the GCP Inspectors' Working Group. It provides a harmonized approach in the conduct of trials, in order to mitigate the negative effects of the pandemic.

	The guidance text is available **here**. Global regulators map out data requirements for phase 1 COVID-19 vaccine trials Global regulators have published a report (available **here**) presenting the outcomes of a workshop on COVID-19 vaccine development that was convened under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA). The meeting report provides an overview of regulatory considerations related to COVID-19 vaccine development and data required for regulatory decision-making on two key points: • pre-clinical data required to support proceeding to first-in-human clinical trials with investigational medicinal products; and • the need to address the known theoretical risk that vaccines against COVID-19 enhance the disease prior to starting first-in-human clinical trials. All participants in the meeting acknowledged the urgency of conducting first-in-human clinical trials with COVID-19 vaccine candidates. The conclusions set out how regulatory authorities around the globe intend to strike the balance between rapid development of vaccines and the need to generate enough robust data to enable decision-making. *EMA press release*
Hospitalization	Starting with March 24, 2020, for a period of 14 days, the following are suspended: in-hospitalization for surgical interventions and other treatments and medical investigations which do not have an urgent nature and may be rescheduled, as well as the scheduled consultations/ scheduled consultations in outpatient care (irrespective in public or private). *- as per Order 74527/2020 regarding the necessary measures in view of limitation of spread of infection with SARS - Cov-2 virus at the level of public and private sanitary institutions*
Dental medicine	As of 22 March 2020, 22:00 hours, activity in dental medicine offices, except for urgent dental interventions, is temporarily suspended.

	- as per Military Ordinance no. 2 of 21 March 2020
Donations in the medical field	Measures during the COVID-19 pandemic: NAMMDR issues (within 48 h as of request) the approval for donation of medical drugs regulated by the SARS Cov 2 treatment protocol. • donations of medical drugs may also cover medical drugs holding a marketing authorization outside EEC; • validity term of medical drugs subject to donation may be lower than 8 months as of request for approval of donation, but not lower than 3 months as of the date of request; • donation of medical devices may also cover devices lacking the CE mark and those not subject to a conformity assessment (as per the EU standards) as long as the medical devices are required to prevent the infection with SARS Cov 2 / treat COVID-19.

NNDKP CONTACTS

For any questions, your contacts at NNDKP are available either by e-mail or telephone.

For the above aspects, please contact Gabriela Cacerea or Ruxandra Bologa.

Updates related to the impact of COVID-19 will be included on our website regularly, as the situation evolves.

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