

Track Changes

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April 2020

COVID-19 Logbook: Romanian Legal Updates – Day 17 – 2nd April: Healthcare/Employment

Developments related to COVID-19 are occurring rapidly. Wolf Theiss will continue to distribute regular Client Alerts via email and publish up-to-date analysis on our website. A list of daily updated resources can be found here: <https://www.wolftheiss.com/covid19/>

The State measures aimed at limiting the effects of the pandemic continue with a relaxation of the regulatory authorization process of the medical devices used in the prevention and treatment of COVID-19 disease, in an attempt to cover the uprising demand.

The social measures are complemented with financial aid granted to families with a low level of income, to support the use of baby-sitting services and ensure work continuity, given the difficulties of combining childcare and job responsibilities.

For today's newsletter we shall analyze the measures adopted by the following:

- Law no. 35/2020 ("**Law 35/2020**") on granting financial aid to families for payment of the services offered by a babysitter.
- Ministry of Health ("**MS**") Order no. 537/2020 for amending the MS Order no. 1.009/2016 regarding the registration of medical devices in the national database.

HEALTHCARE

MEDICAL DEVICES

- Time to market of the medical devices aimed at preventing and treating the illnesses related to the Covid-19 epidemic is essential given the scarcity of such products at national level. The Ministry of Health has decided to relax the registration rules for such products in view of boosting production and covering the uprising internal demand. Thus, on the duration of the state of emergency **the medical devices which previously required the registration to ANMDM prior to placement on the market, may now be marketed** by the manufacturer or the authorized representative of the manufacturer established in Romania **based solely on their declaration of conformity.** .

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- Similarly, the medical devices, for which the first use in Romania was conditioned by a notification made by the manufacturer to ANMDM, are now exempted from such formality.
 - **the medical devices will no longer require a notification to ANMDM for the start-up procedure** (in Romanian: *punere în funcțiune*)

The measures are in line with the government priorities to increase domestic production and imports volumes by removing the time consuming regulatory barriers and potentially, encouraging new market entry and manufacturers' reconversion.

EMPLOYMENT

- **Persons who have pre-school children**, whose incomes are up to RON **3,500 per family member** per month can benefit from the financial aid for the payment of the services offered by a babysitter.
- The financial aid, having a value between RON 250 and RON 710, is granted for each child, **depending on the level of net monthly income per family member**.
- In order to benefit from the financial aid, among other **conditions**, the applicants must obtain income in various capacities, such as based on an individual employment contract, as freelancers or licensing of intellectual property rights.

Does your business need support in implementing a work from home policy? We are pleased to offer our online collaboration platform WT Space to support you during the current COVID-19 pandemic.

WT Space is a fully customizable, secure collaboration platform that requires no additional hardware or software. Whether you need to collaborate on documents, manage project tasks or communicate more efficiently, WT Space can help bring your team together. Please let us know if you have questions or wish to discuss pricing. space@wolftheiss.com

About WOLF THEISS

Wolf Theiss is one of the leading law firms in Central, Eastern and Southeastern Europe (CEE/SEE). We have built our reputation on a combination of unrivalled local knowledge and strong international capability. We opened our first office in Vienna over 60 years ago. Our team now brings together over 340 lawyers from a diverse range of backgrounds, working in offices in 13 countries throughout the CEE/SEE region.

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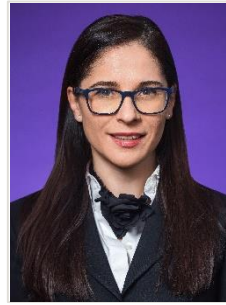
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