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2024 No. 37

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Essential services in the health sector

Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities lays down obligations on Member States to take specific measures aimed at ensuring that services which are essential for the maintenance of vital societal functions or economic activities are provided in an unobstructed manner in the internal market, in particular obligations to identify critical entities and to support critical entities in meeting the obligations imposed on them.

According to this Directive (Art. 5), the Commission may establish a non-exhaustive list of essential services to which the competent authorities shall have recourse in order to carry out a risk assessment, taking into account relevant natural and man-made risks, including those of a cross-sectoral or cross-border nature, accidents, natural disasters, public health emergencies and hybrid or other antagonistic threats, including terrorist offences.

On the basis of this provision, the Commission has adopted this list of essential services by means of a delegated regulation published in the Official Journal of the European Union on 30 October 2023[1]: Commission Delegated Regulation (EU) 2023/2450 of 25 July supplementing Directive (EU) 2022/2557 of the European Parliament and of the Council by establishing a list of essential services.

This list includes essential services in the health sector, which are as follows:

i) provision of healthcare services (healthcare providers);

ii) analyses performed by a European Union reference laboratory (EU reference laboratories);

iii) research and development of medicinal products (entities carrying out research and development activities of medicinal products);

iv) manufacturing of basic pharmaceutical products and of basic pharmaceutical preparations (entities manufacturing basic pharmaceutical products and pharmaceutical preparations);

v) manufacturing of medical devices considered as critical during a public health emergency (entities manufacturing medical devices);

vi) distribution of medicinal products (entities holding a distribution authorisation).

[1] ***Link***

Judgments, rulings and decisions

European Union

Restrictions on the free movement of Union citizens on public health grounds

The Court of Justice - in its judgment of 5 December 2023, C-128/22, ECLI:EU:C:2023:951 - has dealt with restrictions on the free movement of EU citizens on public health grounds.

Thus, the Court has held that Directive 2004/38/EC on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States does not preclude "legislation of general application of a Member State which, on public health grounds connected with combating the COVID-19 pandemic, (i) prohibits Union citizens and their family members, whatever their nationality, from engaging in non-essential travel from that Member State to other Member States classified by it as high-risk zones on the basis of the restrictive health measures or the epidemiological situation in those other Member States, and (ii) requires Union citizens who are not nationals of that Member State to undergo screening tests and to observe quarantine when entering the territory of that Member State from one of those other Member States, provided that that national legislation complies with all the conditions and safeguards referred to in Articles 30 to 32 of that directive, the fundamental rights and principles enshrined in the Charter of Fundamental Rights of the European Union, in particular the principle of the prohibition of discrimination and the principle of proportionality".

Nor, according to the Court of Justice, does Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code) preclude legislation of a Member State which, on public health grounds connected with combating the COVID-19 pandemic, prohibits, under the control of the competent authorities and on pain of a penalty, the crossing of the internal borders of that Member State in order to engage in non-essential travel from or to States in the Schengen area classified as high-risk zones, "provided that those control measures fall within the exercise of police powers" which is not to have an effect equivalent to border checks or that, where those measures constitute border controls at internal borders, that Member State has complied with the conditions referred to in Articles 25 to 28 of that code for the temporary reintroduction of such controls, given that the threat posed by such a pandemic corresponds to a serious threat to public policy or internal security.

Personal data processing in the context of a medical service connected to health insurance

1. Among the cases in which the General Data Protection Regulation (Regulation 2016/679) lawfully permits the processing of personal data of a medical nature are those scenarios in which the processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or

treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional (Art. 9(2)(h)).

In these cases, it is also necessary that the data be "processed by or under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies or by another person also subject to an obligation of secrecy under Union or Member State law or rules established by national competent bodies" (Art. 9(3)).

2. The Court of Justice - in its recent judgment of 21 December 2023 (C-667/21, ECLI:EU:C:2023:1022) - has interpreted this provision of the General Data Protection Regulation.

   In particular, the Court examines whether the said exception applies only where the medical service processing the personal data is an entity other than the employer of the data subject to whom the health-related data relate, or whether, on the other hand, the processing of medical data by the employer itself is also permissible. That question is referred for a preliminary ruling by reason of a German body governed by public law that issues medical reports on the incapacity for work of persons insured with compulsory health insurance companies *(Krankenkassen)*, a body which issues such reports even in respect of its own employees.

   The Court holds that the exception in question applies to situations in which a medical supervisory body processes data relating to the health of one of its employees, not as an employer but as a medical service, for the purpose of assessing that employee's capacity to work.

Harm caused by provisional measures concerning supplementary protection certificates for medicinal products

The Court of Justice, in its judgment of 11 January 2024 (Mylan, C-473/22, ECLI:EU:C:2024:8), has analysed whether liability for damage resulting from provisional measures which were subsequently lifted is strict or fault(-based) liability.

This judgment was handed down in the context of proceedings for infringement of a supplementary protection certificate for medicinal products in Finland, which led to the adoption of provisional measures against the defendant, which were subsequently lifted as a result of the invalidity of the supplementary certificate. In those circumstances, what is at issue in the national proceedings is whether the Finnish legislation providing for the fault basis of the liability of the applicant for provisional measures adopted and subsequently lifted complies with Directive 2004/48/EC on the enforcement of intellectual property rights.

The Court of Justice held that Directive 2004/48/EC does not regulate the form of the liability in question, strict or fault-based, but rather leaves the Member States free on this point. Nonetheless, the Court does stress that whatever the liability system, national courts must be able to take into account all the circumstances of the case before them, including the conduct of all the parties.

Moreover, the Court also considers that a strict liability system in which the national courts are able to take into account all the circumstances of the case, including whether the defendant played a part in the occurrence of the harm, is a system that complies with the obligations of

Article 3 of the Directive, according to which the measures, procedures and remedies established to ensure the enforcement of intellectual property rights must be "effective, proportionate and dissuasive and shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse".

Parallel trade in plant protection products and labelling

According to the Court of Justice - Judgment of 7 December 2023, C-830/21, *Syngenta Agro GmbH* - Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products is to be interpreted as meaning that an importer introducing a plant protection product in a Member State, on the basis of a parallel trade permit, "may, on the packaging of that product, replace the name and address of the holder of the authorisation in the Member State of origin with its own name and address", and, moreover, "is obliged to display, on the packaging of that product, the batch number of the formulation concerned initially allocated by the manufacturer".

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