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Substances of Human origin (SoHo): the EU Parliament approved a new Regulation

On 24 April 2024, The EU Parliament approved a Regulation concerning Substances of Human origin (so called SoHo).

Through this Regulation, the European Union aims to establish high standards of quality and safety for SoHo and activities related to such substances, ensuring a high level of protection for human health (in particular for SoHo donors, SoHo recipients and offspring from medically assisted reproduction).

The Regulation will repeal the directives that regulate this subject (and will re-define quality and safety standards concerning SoHo, including reproductive cells and embryos) and will be directly applicable across EU Member States. This will lead to an improvement of the regulatory framework harmonisation of the European Member States promoting, at the same time, cross-border exchanges.

It is worth mentioning among the most innovative provisions: (i) the establishment of a SoHo Coordination Board, that will support the full implementation of the Regulation, and (ii) the creation of an EU SoHo Digital Platform, aimed at facilitating the exchange of information related to the activities concerning SoHo.

The EU Council's approval and publication in the EU Official Gazette is now expected, even though the majority of the provisions will come into force three years after the publication of the Regulation.

Health data: the EU Parliament approved a new Regulation to create a European Health Data Space (EHDS)

On 24 April 2024, the EU Parliament approved a new Regulation concerning the implementation of a European Health Data Space (EHDS). This Regulation represents an important step towards the creation of a European Health Union. The new provisions contained in Articles 3-10 of the Regulation will ensure that EU citizens have access to their health data electronically wherever they are. Moreover, patients will have the possibility to share their data with healthcare providers, even though they are located in different Member States, by using a special platform called MyHealth@EU (so called "primary use").

In addition, the Regulation sets out rules for the use of health data for statistical and research purposes (so called "secondary use"). In any case, patients will still have the right to refuse the use of their data.

For the full implementation of the Regulation, the EU Council's approval and the subsequent publication in the EU Official Gazette is now expected, even though the majority of the provisions will come into force two years after the publication.

Pharmaceutical products: the EU Parliament adopted its position on the pharmaceutical reform proposed by the EU Commission

On 10 April 2024, the EU Parliament adopted its position on the EU Commission's proposal to revise European pharmaceutical legislation. The pharmaceutical reform consists in a new directive and a new regulation aimed at ensuring efficient and quality pharmaceutical products, promoting the innovation and empowering the scientific research on new antibiotics. The pharmaceutical reform will repeal EU Directive no. 2001/83 (concerning medicinal products) and EU Directive no. 2009/35 (concerning the colouring agents which may be added to medicinal products).

Some of the most notable changes proposed by the EU Parliament to the pharmaceutical reform include:

- the reduction of the data protection period - which is currently eight years - (*i.e.*, the period during which other companies cannot access the product data) from the six years proposed by the EU Commission to seven and a half years, with the possibility to extend the data protection period if certain conditions are met. For instance:
  i. the medicinal product addresses an unmet medical need;
  ii. a significant part of the research is carried out within the EU and in collaboration with public entities located in the EU, including university hospital institutes.

The newly appointed EU Parliament - following the elections scheduled on 6-9 June 2024 - will follow up the inter-institutional negotiations on the reform.

Medical Assisted Reproduction (MAR): the Italian Ministry of Health adopted the new 2024 guidelines

The Italian Ministry of Health, by means of the ministerial decree dated 20 March 2024, adopted the new guidelines on Medical Assisted Reproduction (MAR), that replace the previous version dated 2015.

The new guidelines focus mainly on the consent given by the couple to MAR and transposed the main case law developments on the subject into an institutional act. More specifically:

- the guidelines implement judgement no. 161/2023 of the Italian Constitutional Court, which, as a result of a complex weighing up of the various interests involved, deemed the deadline for revoking consent to MAR up to assisted fertilisation of the egg, reasonable and constitutionally legitimate, since it protects, on the one hand, the shaping of the will of the future parents and, on the other hand, the right to life of the unborn child - clearly express the principle that it is possible to proceed with implantation even if some conditions for access to MAR ceased to exist, such as the end of the couple's relationship, an event that can happen even more frequently when implantation of the embryo is postponed to protect the woman's health;
- still on the subject of consent to MAR, the guidelines state that - when accessing the techniques of MAR - applicants must be told, among other things, clearly and in writing, that after the assisted fertilisation of the egg, consent to MAR cannot be revoked and the woman may request for implantation of the embryo even if her partner has passed away (recalling judgement No. 13000/2019 of the Italian Supreme Court of Cassation);

- the guidelines, implementing judgement no. 229/2015 of the Italian Constitutional Court, introduce the possibility to not proceed with implantation when the preimplantation genetic diagnosis detected a serious pathological disorder of the embryo;
- the guidelines also provide a change concerning the costs of cryopreservation of embryos that are not immediately transferred. In the absence of a legal provision to this effect, the previous guidelines provided that such costs should be borne exclusively by the healthcare facility providing MAR services. The new guidelines, however, state that facilities will only have to bear the costs for the first year, after this period the costs will be borne by the couple opting for MAR.

National Health Service (NHS): the Italian Council of Ministers adopted a new Law-Decree and a bill to combat, among the others, the problem of waiting lists

On 4 June 2024, the Italian Council of Ministers adopted a Law-Decree and a bill to combat, among other things, the problem of NHS' waiting lists.

To combat this problem, the Law-Decree provides a new set of rules, including:

- the creation of a national platform for waiting lists run by AGENAS (the Italian National Agency for Regional Healthcare Services), which will monitor the timing of delivery of healthcare services among different Regions;
- the creation of a single regional or infra-regional reservation centre (so called CUP) that will gather all the available public healthcare structures and private ones which are subject to public reimbursement;
- a system to remind the patient of the reservation of the medical examination, that will also give the patient the chance to cancel the reservation;
- a system aimed at ensuring that the requested medical service will be provided by the NHS within a certain time (depending on the gravity of the illness). In the event such timing is not respected, private healthcare structures reimbursed by the NHS will provide the medical service;
- the possibility of carrying out medical examinations during the weekend;
- an increase of the spending cap for the recruitment of healthcare personnel in 2024 and the abolition of such cap starting from 2025;
- a flat-tax of 15% for overtime carried out by doctors, independent from the total income of the healthcare professional.

On 7 June 2024 the Law-Decree has been published in the Italian Official Gazette. Following this, Parliament will have 60 days to convert the Law-Decree into law.

Other measures to combat the problems with waiting lists are included in the bill mentioned above. For instance: (i) the creation of a register held by the Italian Ministry of Health to report problems relating to the management of waiting lists, (ii) an increase of the funds allocated for the reimbursement of the services provided by private healthcare structures, (iii) the possibility to provide healthcare services in pharmacies, and (iv) the introduction of reward and penalty measures depending on the actions implemented for the reduction of waiting lists.

The bill now needs to be examined by the Parliament.

Contacts
healthcare@legance.it

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Edited by
Legance

Graphic Design
VitamineD