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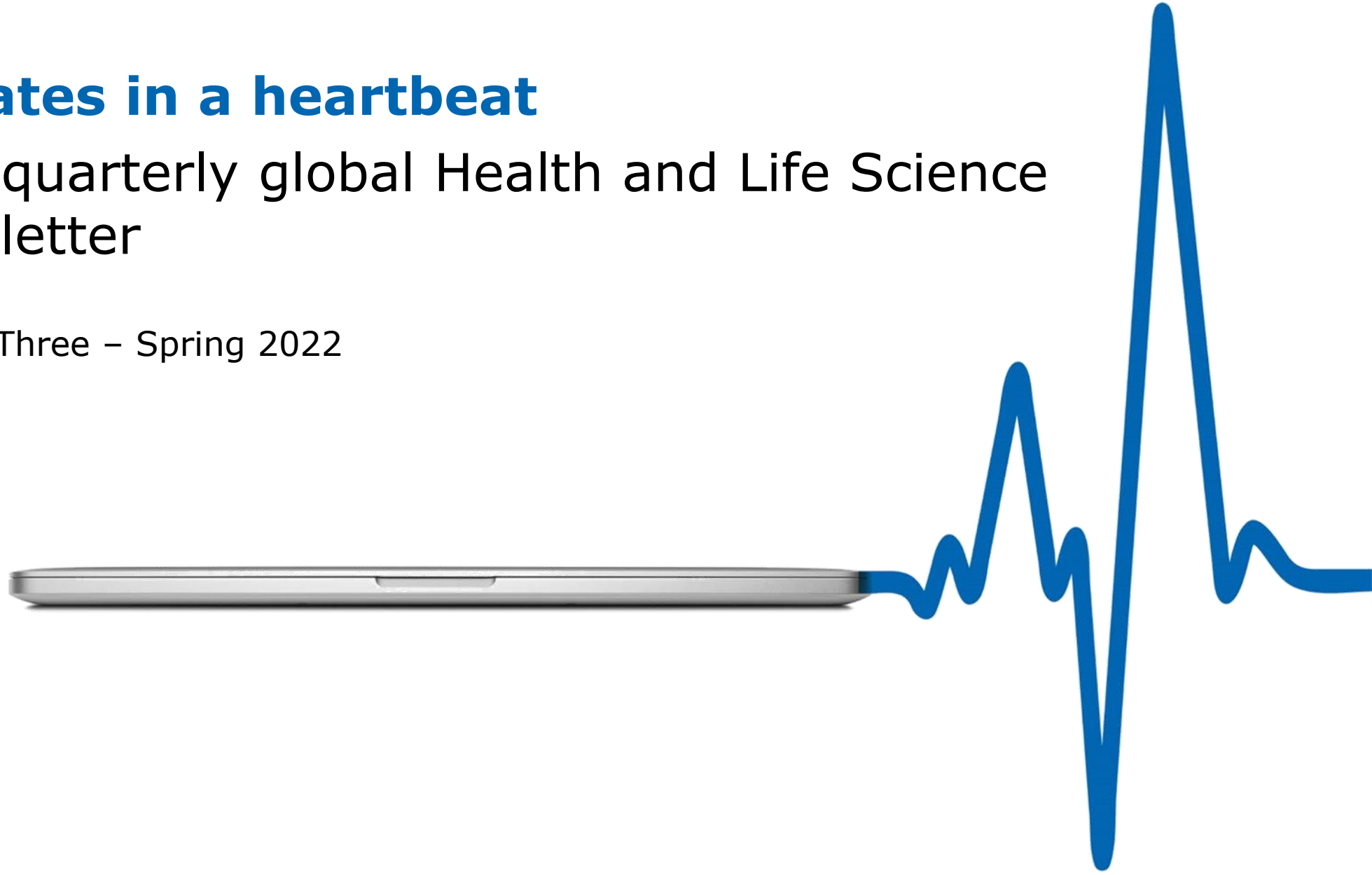
Updates in a heartbeat

Your quarterly global Health and Life Science newsletter

Edition Three – Spring 2022



Executive summary

Welcome to the third edition of our Health and Life Science newsletter!

Our newsletter provides you with a compilation of key legal developments from the last months.

This edition is full of newsworthy items from our team members around the globe.

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EU overview

Title	Summary	Links
The European Medicines Agency (EMA) consults on draft Guidance on Protection of Personal Data and Commercially Confidential Information in Clinical Trial Information System (CTIS)	EMA has published a draft guidance on the protection of personal data and commercially confidential information in the CTIS for consultation, which will end on 8 September 2022. The EU Clinical Trials Regulation No 536/2014 was introduced to increase the availability of information regarding clinical trials including their results and facilitated the establishment of the EU Clinical Trials Portal and Database, both of which points are important to ensure transparency of clinical trials and associated information and serve as the source of public information on clinical trials. Whilst the Regulation aims to increase transparency, it also sets out requirements in relation to personal data and commercially confidential information. The guidance focuses on the following: The CTIS structure, including a description of the functionalities and publication rules for clinical trials information uploaded to CTIS; the protection and management of personal data, including anonymisation and pseudonymisation; the protection of commercially confidential information; and the protection of personal data and commercially confidential information in inspection reports.	Draft guidance
Podcast: Legal status of cannabis-derived products in Germany and Poland – Q&A	As cannabis-derived products are becoming more and more popular in Europe, in many countries it remains unclear what types of goods and under what circumstances may actually be marketed. Magdalena Kotyrba-Hagenmaier (Senior Associate, IP, Health and Life Sciences, Germany) and Jowita Prokop (Associate, Commercial, Life Sciences and Regulatory, Poland) discuss in the podcast: 1. Cosmetics, foods, medicines. What types of cannabis-derived products may be marketed in Poland and Germany? 2. THC levels and type of hemp in marketed products. 3. What is the criminal law perspective? 4. What are novel foods?	Listen to the podcast here >

EU overview

Title	Summary	Links
Single Basic Act establishing the Joint Undertakings under Horizon Europe, including Innovative Health Initiative, was adopted	In February 2021, the European Commission released a proposal to create the Innovative Health Initiative, a new public-private partnership between the EU and the European life science industries. The proposal was adopted and came into force in November 2021. The general objectives of the IHI are the following: 1. Turn health research and innovation to patients' and society's benefit 2. Deliver safe, effective health innovations that cover the entire spectrum of care – from prevention to diagnosis and treatment – particularly in areas where there is an unmet public health need 3. Make Europe's health industries globally competitive. In addition, IHI has a number of operational objectives, such as increasing the involvement of patients and citizens in health innovation The legislation creating IHI also creates eight other joint undertakings, which share broader objectives (e.g., boosting the EU's competitiveness; strengthening scientific excellence etc.).	Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe Proposal for a Council Regulation establishing the Joint Undertakings under Horizon Europe Podcast: The Innovative Health Initiative (IHI): the future of Research and Innovation in healthcare in Europe IHI: Mission and objectives
Proposal for a Regulation of the European Parliament and the Council on the European Health Data Space (EHDS) COM/2022/197	On 3 May 2022, the European Commission presented the proposed European Health Data Space legislation. It is meant to set up a common framework across EU Member States for the sharing and exchange of health data, such as patients' health records. It will address health-specific challenges to electronic health data access as well as sharing and is a priority of the European Commission in the area of health. EHDS aims to create a common space where people can easily control their electronic health data and shall make it possible for researchers, innovators and policy makers to use this data in a trusted and secure way that preserves privacy. It remains to be seen whether EDHS will truly lead to an improved healthcare delivery, better health research and innovation and whether it will be aligned with existing EU legislation, such as the MDR, the GDPR, etc.	Proposal for a Regulation on the European Health Data Space (EDHS) COM/2022/197 The European Health Data Space Regulation: an opportunity to harness the power of health data

EU overview

Title	Summary	Links
Request for input from the European Commission relating to supplementary protection certificates (SPCs)	The European Commission has held a consultation on medicinal and plant protection Products regarding Single Procedure for the issue of SPCs. The request for input was recently closed and the proposal is now awaiting the Commission's adoption. The aim of the proposal is to: 1. increase legal certainty surrounding the procedure for issuing SPCs 2. provide unitary SPC protection in relation to unitary patents 3. make information relating to SPCs more transparent (clearer, more accessible and understandable) 4. reduce costs and burden of obtaining and maintaining SPC protection in the EU.	Medicinal & plant protection products – single procedure for the granting of SPCs (europa.eu)
WTO agrees on partial patent waiver for vaccine production on 17 June 2022	On 17 June 2022, the WTO's 12th Ministerial Conference adopted a decision on a waiver of certain procedural obligations under the TRIPS Agreement, which was primarily based on EU proposals. It was agreed to temporarily remove intellectual property barriers around patents for COVID-19 vaccines and postpone the discussions on extending the waiver to treatments and tests by six months. On the same day the EU welcomed the waiver. According to the Executive Vice-President Dombrovskis, it will allow for the swift manufacture and export of COVID-19 vaccines without the consent of the patent owner, while maintaining a functioning intellectual property framework. The decision was, however, criticised by many as the one, which would unlikely make a significant difference in global access to COVID-19 vaccines since the final decision is too narrow in comparison to the original proposal.	Draft Ministerial Decision on the Trips Agreement (Revision) of 17 June 2022 Statement by Executive Vice-President Dombrovskis Council conclusions at the end of the 12th WTO Ministerial Conference WTO decision on TRIPS Agreement fails to set rules that could save lives WTO 12th Ministerial Conference secures key outcomes on fisheries subsidies, pandemic response

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Title	Summary	Date	Links
New Belgian Act of 18 May 2022 containing various urgent provisions relating to health	The Belgian Act of 18 May 2022 containing various urgent provisions relating to health (Act of 18 May 2022) was published in the Belgian Official Gazette on 30 May 2022. On 9 June 2022, most of the provisions entered into force. The Act of 18 May 2022 amended 149 Articles, covering a wide range of topics, such as the operations of the Federal Agency for Medicines and Health Products, the organisation of the national federations of the health insurance funds, the organisation of health care professions, transparency and accessibility in the billing/health care, audits of hospitals, the Euthanasia Act, the regulation of aesthetic medicine, the framework for clinical trials with medicines for human use, the power of pharmacies and the rules for blood donations. The health care system will, thus, be affected on many levels by the Act of 18 May 2022.	18 May 2022	Draft legislation Publication in the Belgian Official Gazette (in French or in Dutch)

China

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Title	Summary	Date	Links
China's National Medical Products Administration ("NMPA") solicits public opinions on new draft Implementation Regulations of the Drug Administration Law	The current *Implementation Regulations of the PRC Drug Administration Law* was enacted in 2019 pursuant to the PRC *Drug Administration Law* (DAL) and the PRC *Vaccine Administration Law* (VAL). Such regulations have been a key set of rules relating to marketing authorization (MA), manufacturing, distribution and promotion of pharmaceutical products. The NMPA issued a notice on 9 May 2022 to solicit opinions from the public on its latest draft *Implementation Regulations* seeking to align some provisions with DAL and VAL and to provide for certain new pharmaceutical regulatory and administrative procedures. The latest draft *Implementation Regulations* contains provisions in areas that are crucial to pharmaceutical businesses operating in China, such as pharmaceutical R&D and registration, MA holder of pharmaceutical products, drug manufacturing, operations of pharmaceutical business, guaranteed supply of certain drugs. Key proposed regulations relevant to foreign drug companies with active operations in China include: 1. **MA holder system:** a new chapter is included to regulate qualifications for MA holders of pharmaceutical/vaccine products; designation and change of domestic agents for foreign MA holders; MA holder's obligations regarding product traceability, commissioning arrangements, risk management, post-MA R&D and product evaluation; approval requirements for assignment of MA of product. 2. **Patent linkage and market exclusivity:** the early mechanism to resolve pharmaceutical patent disputes between a patentee and MA holder has been consolidated. In particular, the first generic chemical drug that successfully changes the relevant patent and is approved for MA will be granted a 12-month market exclusivity period. 3. **Online sales of drugs:** new provisions are included to regulate the conduct of online drug sale businesses and to stipulate the requirements and obligations of third-party online platforms that are neither MA holders nor registered operators for pharmaceutical products.	May 2022	China's National Medical Products Administration

Czech Republic

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Title	Summary	Date	Links
Relief from administrative burden and simplification of regulation in the cultivation of cannabis, especially cannabis for medicinal use	Starting from January 2022 the cultivation of technical hemp is no longer subject to official authorisation. The limit of the maximum of the psychoactive substance tetrahydrocannabinol (THC) contained in technical hemp increased to 1%. The growers do not have to prove the THC content of hemp plants, as it is now sufficient only to prove the origin of the seed. Hemp with a THC content of more than 1% already falls into the category of cannabis for medicinal use. There has been a major liberalisation of the market since anyone, rather than a single supplier selected by the state, can now grow cannabis. The interested party should only apply to the state authority and meet the conditions set out by law, such as obtain a license and necessary authorisations, have a grow house at the time of application, comply with the rules of Good Agricultural Practices, etc. An implementing decree, laying out the details, is expected to be issued shortly.	January 2022 (effective date of the law)	Act on Addictive Substances
VAT on marketing fees for pharma companies in the Czech Republic	Pharma companies using their Czech contractors or subsidiaries as distributors and marketing service providers, must be careful to properly apply VAT. In a recent judgement the Czech Supreme Administrative Court set out the proper tax treatment (3 Afs 54/2020-73; ELI LILLY ČR v Appellate Financial Directorate). For VAT purposes, if a Czech company provides marketing services to a foreign company in connection with the sale of pharmaceuticals in the Czech Republic, the marketing services are not an integral part of the main supply (i.e. sale of pharmaceuticals). There is not a single taxable supply, rather two separate supplies. Therefore, consideration for the marketing services may not be included in the same tax base but must be separated from the sale of pharmaceuticals for VAT purposes.	November 2021	Judgement of the Czech Supreme Administrative Court

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France

Title	Summary	Date	Links
Medical Research on Human Embryo	The Law 2021-1017 of 2 August 2021 on bioethics has led to the evolution of legislation in favor of research on the human embryo and its stem cells. A new decree published on 1 March 2022 recasts the applicable regulatory framework for these types of researches and lays down the implementing measures for the following: 1. The authorisation regime for research on the human embryo 2. the declaration regime prior to research on human embryonic stem cell lines; and 3. the declaration regime for certain research with specific ethical issues on human induced pluripotent stem cells. The decree specifies that only a legal person may declare a research protocol involving human embryonic stem cells.	March 2022	Decree No. 2022-294 of 1 March 2022 on research on the human embryo, human embryonic stem cells and human induced pluripotent stem cells
Good practice charter for the promotion of and information on Medical Devices	This new charter provides a framework for commercial and promotional practices which relate to reimbursed medical devices and associated services to ensure that these will not be detrimental to the quality of healthcare or lead to unjustified expenditures for the French compulsory health insurance (AMO; *Assurance Maladie Obligatoire*). Companies that exploit or distribute (retail) these medical devices must ensure the quality of the information provided on these products to health professionals and follow specific sets of rules when organizing commercial visits on premises.	March 2022	Order of 4 March 2022 establishing the quality charter for the professional practices

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France

Title	Summary	Date	Links
Medical Device Ordinance adapting MDR	On 20 April 2022, the French government adopted an ordinance, adapting French law to EU Regulation 2017/745 on medical devices (MDR). In addition to the necessary amendments to the French Public Health Code (FPHC), a new chapter was created to lay down specific provisions applicable to clinical trials, involving medical devices for human use or their accessories, in particular the conditions under which an ethical review by committees for the protection of individuals (CPP) is carried out. The updated FPHC also provides for specific criminal and financial sanctions in case of violations of the MDR.	April 2022	Order No 2022-582 of 20 April 2022 adapting French law to the MDR

Germany

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Title	Summary	Date	Links
Artificial Intelligence in MedTech	The Health Research Data Centre at the Federal Institute for Drugs and Medical Devices would like to convert highly sensitive health data into "synthetic" data sets for the purpose of anonymization. Data should be accessed in protected virtual environments, where researchers could examine them with the help of artificial intelligence. Such initiative is meant to allow analysis of synthetic health data in order to develop an optimal therapy for a patient, detect serious diseases and do research while simultaneously protecting sensitive health data.	31 December 2024 (estimated completion date of the project)	Research Meets Data Protection: Analysis of Synthetic Heath Data by Means of Artificial Intelligence
Digital Health Applications (*Digitale Gesundheitsanwendungen; DiGA*)	DiGA are apps for the detection, monitoring, treatment or alleviation of medical conditions. This initiative is part of the 2019 Digital Healthcare Act and opens up a wide range of possibilities in diagnosis and treatment of diseases, as well as supporting a healthy lifestyle. On 18 March 2022, the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte; BfArM*) published an updated version of the Fast Track Guide for DiGA. The new version includes, among other things, the changes resulting from the Digital Care and Nursing Modernization Act and the first DiGA Amendment Ordinance (*DiGA-Änderungsverordnung; DiGA-ÄndV*). Its objective is to explain to manufacturers the most important issues regarding the application process and inclusion in the DiGA directory. This includes aspects such as the requirements for inclusion in the directory, the requirements for security, quality and data protection, the process flow and the costs incurred.	March 2022	Fast-Track Process for DiGA DiGA Directory and Guide

Hong Kong

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Title	Summary	Date	Links
Import and Export of Unregistered Pharmaceutical Product for Treatment of Covid-19	On 6 April 2022, the Department of Health (DH) issued a notice to all holders of Wholesales Dealer License in Hong Kong that new measures have been implemented by DH and the Customs and Excise Department (C&ED) to enhance import and export controls of unregistered pharmaceutical products for treating Covid-19, with a view to prevent diversion of such products into the Hong Kong market. Starting from 14 April 2022, applications for license to import for re-export of unregistered drugs for Covid-19 treatment will no longer be accepted and processed by DH's online Pharmaceuticals License Application and Movement Monitoring System (PLAMMS). Manual submission of paper import and export license forms to the DH Drug Office will be required for obtaining the requisite licenses to enable import and re-export of unregistered drugs for Covid-19 treatment. DH and C&ED will continue to strengthen their inspections as regards such unregistered drugs.	April 2022	DH's Drug Office Import and Export of Unregistered Pharmaceutical Product for the Treatment of COVID-19
Launch of Electronic Clinical Trial System	DH has recently notified all holders of Certificate for Clinical Trial/Medicinal Test that an Electronic Clinical Trial System (e-CTS) will be launched on 30 June 2022. Manual submission of applications for Certificate for Clinical Trial/Medicinal Test will no longer be accepted upon the launch of the e-CTS. Any prospective sponsor for such Certificate shall apply for a Hong Kong Post e-Cert in advance as it is necessary for e-CTS account creation, login and submission of application. A corporate applicant needs an e-Cert (Organisational) certificate and a sponsor-investigator needs an e-Cert (Personal) certificate for accessing the e-CTS.	June 2022	DH's Drug Office Launch of Electronic Clinical Trial System (e-CTS)

Ireland

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Title	Summary	Date	Links
Directive 2022/642/EC entered into force to ensure continued supply of medicines from the United Kingdom into Northern Ireland	On 20 April 2022, Directive 2022/642/EC (Directive) entered into force to ensure the continued supply of medicines from the United Kingdom into Northern Ireland. The Directive also, for a transitional period of three years, allows for medicinal products from the United Kingdom to be placed on the market in Ireland, Malta and Cyprus under derogations from the requirement for authorisation holders to be established in the European Union. The Directive applies retroactively from 1 January 2022 and 31 January 2022 respectively until 31 December 2024. The European Commission has indicated that they plan to provide for longer-term solutions in respect of access to medicines by the end of this year.	20 April 2022	Directive 2022/642/EC
Irish Health Service Executive entered into important agreements relating to medicines	On 15 December 2021, the Irish Health Service Executive and the Irish Pharmaceutical Healthcare Association entered into a four-year agreement effective from 1 October 2021 to 30 September 2025 in relation to the pricing and supply of on-patent and originator medicines. Additionally, the Irish Health Service Executive entered into a four-year agreement with Medicines for Ireland, effective from 1 December 2021 to 30 November 2025. This agreement provides for enhanced price cuts in the case of generic and bio-similar medicines.	1 October 2021, 1 December 2021 (dates of effectiveness of agreements)	Minister Donnelly announces Framework Agreements on Pricing and Supply of Medicines 2021-2025
Model clinical trial agreement for use between clinical trial sites and sponsors	On 2 December 2021, the Irish Pharmaceutical Healthcare Association published a final version of a model clinical trial agreement for use between clinical trial sites and sponsors in Ireland. This is the first time a model clinical trial agreement has been published by an industry body in Ireland.	2 December 2021	IPHA Model Template Clinical Trial Agreement

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Netherlands

Title	Summary	Date	Links
NVWA publishes Handbook on Nutrition and Health Claims	The Dutch Food and Consumer Product Safety Authority (NVWA) has recently published a Handbook on Nutrition and Health Claims as an aid for the industry to comply with legal obligations when advertising nutrition and/or health claims. The Handbook covers (non-) permitted claims, the European and Dutch regulations on nutrition and health claims, as well as includes several step-by-step plans for qualifying these claims.	15 March 2022	Handboek Voedings- en gezondheidsclaims | Publicatie | NVWA
Amendment of Dutch Code of Conduct for Medical Devices (GMH Code)	Two changes will be made to the GMH Code and explanatory notes (effective from 1 May 2022). In both cases it concerns clarification of provisions regarding the publication of information in the Transparency Register for Health Care. Some references in Article 15 have been corrected. 1. Article 22, subsection 3 - clarification of exception to the duty to report for research that is subject to the WMO 2. Article 23 clause 3 - clarification of reporting of hospitality costs.	1 May 2022	GMH Nieuwsbrief 5 - Aanpassingen GMH Code

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Poland

Title	Summary	Date	Links
Medical Device Regulation (MDR) and its implementation in Poland	On 9 May 2022, the Parliament adopted a bill implementing the MDR in Poland. According to the draft, the advertising of medical devices will be restricted, especially if health experts are involved. Secondly, single-use medical devices cannot be recycled (reused) in Poland. The new, high administrative financial penalties are still to be introduced. The new law will applied from 26 May 2022, except for the provisions on advertisement, which will apply from 1 January 2023.	9 May 2022 (publication in the official journal)	New regulation implementing MDR in Poland
New regulation on basic conditions for running a pharmacy	New regulation on basic conditions for running a pharmacy (new version of the draft) was published. The draft modifies the rules governing IT systems in pharmacies. Individual access to IT systems, system failure procedures, backup requirements, etc. are to be introduced. Premises where pharmacists prepare drugs, and where drugs are stored, are to be monitored as regards temperature, humidity and sunilght.	17 May 2022 (new version of the draft)	New draft regulation on the basic conditions for running a pharmacy (limited access; only accessible from Poland)
New warnings in advertising of medicinal products	New mandatory warnings in advertising of medicinal products are to be introduced in accordance with the new draft.	8 April 2022 (publication of the draft)	New draft regulation on warnings in advertising of medicinal products (limited access; only accessible from Poland)
Cannabis products	In April two bills on cannabis products were published. The first concerns the increase of the THC limit to 0.3% in dry matter and the possibility of cultivating non-fibrous hemp and harvesting the hemp herb for pharmaceutical raw material production by research institutes. Another draft contains proposals for introduction of a register of hemp producers and entities purchasing such hemp.	6 April 2022 (publication in the official journal)	New regulations on cannabis products: 1 and 2 (limited access; only accessible from Poland)

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Spain

Title	Summary	Date	Links
Draft of Spanish Royal Decree on Waste and Packaging: period for submitting comments	This Royal Decree represents a first step in reducing the consumption of plastic bags and raising awareness amongst consumers about environmental issues. The regulation will introduce a new obligation regarding industrial products (previously not included) based on the Extended Producer Responsibility regime. The cost of managing the waste, which will be generated by the products placed on the market, will be shifted to the producer. Thus, large waste producers, including pharmaceutical companies, should pay close attention to this draft.	6 May until 8 August 2022 (consultation period)	Draft of Spanish Royal Decree on Waste and Packaging
Spanish Congress of Deputies approves draft General Law on Audiovisual Communication	The proposed General Law on Audiovisual Communication aims at transposing EU's Audiovisual Media Services Directive and updating the regulation of the sector. The new draft prohibits the following: 1. Audiovisual commercial communication for medicinal products and medical devices, which does not comply with requirements laid down in the Spanish regulations governing advertising. 2. Audiovisual commercial communications of products, materials, substances or methods with a pretended health purpose that do not comply with the provisions of Spanish Royal Decree 1907/1996.	6 June 2022	Draft General Law on Audiovisual Communication

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Sweden

Title	Summary	Date	Links
New law proposal facilitating administration of biobanks	The current Swedish Biobank Act came into force in 2003 with the aim of strengthening the privacy protection for sample donors. Due to developments and new laws in the area of health and medical care, the Biobanks Act has become obsolete. The proposal for a new Biobanks Act, submitted by the Government on 14 April 2022, entails several changes that facilitate, among other things, administration of biobanks. For example, under current legislation a special consent is required for patients when they submit samples to be saved for the purpose of their care in a biobank. The law proposal suggests to exclude this requirement. Instead, it should be sufficient that the sample donor has been informed and consented to care or treatment in accordance with the legislation under which the patient is treated, e.g., the Patients Act or the Dental Care Act.	14 April 2022	Information on the New Biobank Act
Foreign investments and ownership in Swedish healthcare	At present, the regions, i.e., state authorities that administer and finance most of Swedish healthcare, lack legal basis for investigating ownership structures in healthcare. On 12 June 2022, the Swedish Minister of Social Affairs declared that the Government is deeply concerned that undemocratic states are allowed to influence Swedish healthcare through investments and ownership. On 13 June 2022, the Swedish Defense Research Agency (*Totalförsvarets forskningsinstitut; FOI*) was commissioned to review risks associated with foreign investments and ownership in Swedish healthcare. FOI will present its conclusions on 28 February 2023.	12 June 2022	Government is concerned about foreign ownership in healthcare

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United Kingdom

Title	Summary	Date	Links
Improved artificial intelligence (AI) and data protection risk toolkit finalised by the Information Commissioner's Office (ICO)	The ICO has launched an updated version of its AI toolkit, designed to provide practical support to organisations to reduce the risks to individuals' rights and freedoms caused by use of AI systems. The toolkit divides the risks and controls by high-level lifecycles stages, to provide a guide as to what risks and controls individuals should consider when using AI systems. The toolkit further aligns risk assessment factors with relevant data protection legislation to enable individuals to comply with their legal obligations.	4 May 2022	Toolkit
Queen's Speech 2022 announces Data Reform Bill	The Queen's Speech announced the Data Reform Bill (Bill) designed to reform the UK's data protection regime (though some measures will only apply to England and Wales). The Bill is intended to ease burdens on businesses, boost the economy and increase innovation by creating a new more flexible "trusted UK data protection framework", centred on privacy outcomes and ultimately creating a greater culture of data protection (including by strengthening the powers of the Information Commissioner's Office). The briefing notes emphasise the intention for simplified rules around research, combined with clarifications on personal data use, to aid scientific and technological progress. It is hoped that the Bill will increase participation in smart data schemes, providing people with greater control over their data. At the same time it is expected to improve the delivery of services, particularly in relation to health and social care, allowing public bodies to share data whilst providing a "gold standard" level of protection.	10 May 2022	Queen's Speech and briefing notes

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United States of America

Title	Summary	Date	Links
Six senators ask the United States Patent and Trademark Office (USPTO) to address patent thickets	In an open letter to the USPTO's director, six senators, including Sen. Patrick Leahy, who heads the Senate Judiciary Committee's intellectual property subcommittee, asked the USPTO's director to eliminate large numbers of patents on a single invention. In the drug industry, with the most minor, even cosmetic, tweaks to delivery mechanisms, dosages, and formulations, companies are able to obtain dozens or hundreds of patents for a single drug. This practice impedes generic drugs' production, hurts competition, and can even extend exclusivity beyond the congressionally mandated patent term. The letter asks the director to issue a notice of proposed rulemaking or a request for public comments, based on six questions including, how eliminating terminal disclaimers may affect patent quality and whether fees for continuation applications should be increased.	June 2022	Letter to the U.S. Patent and Trademark Office on repetitive patents
Biden administration withdraws 2019 policy statement on remedies for standard-essential patents	The Biden administration withdrew on 8 June 2022 a 2019 policy promoting the right of standard-essential patent holders to pursue injunctions. The withdrawal, issued by the USPTO, the National Institute of Standards and Technology, and the U.S. Department of Justice, Antitrust Division, stated removal of the 2019 policy best serves the interests of innovation and competition.	June 2022	Withdrawal of 2019 Standards-Essential Patents (SEP) Policy Statement Sens Urge Vidal to Block Drug Patent Thickets Early

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Title	Summary	Date	Links
Novavax's Covid-19 vaccine approval may be delayed	An FDA Advisory Panel recommended Novavax's Covid-19 vaccine be granted emergency authorization on 7 June 2022, despite concerns over rare cardiac side-effects. If approved, the Novavax vaccine will be the first protein-based COVID-19 vaccine approved in the United States. The FDA is not obligated to follow the Advisory Panel's recommendation. The FDA has yet to give final approval to the vaccine stating it is reviewing recent changes to Novavax's manufacturing process.	June 2022	FDA advisers greenlight Novavax COVID-19 vaccine Press article on FDA decision
U.S. Supreme Court held that HHS $1.6 billion cuts for 340B hospitals unlawful	The U.S. Supreme Court reversed a D.C. Circuit ruling on 15 June 2022 which upheld a Department of Health and Human Services (HHS) program to reduce drug reimbursement rates for 340B hospitals, which serve low income or rural populations. Holding that because the HHS did not conduce a survey of hospitals' acquisition costs, the HHS acted unlawfully by reducing the reimbursement rates for 340B hospitals.	June 2022	U.S. Supreme Court's Opinion in American Hospital Association et al. v. Becerra et al.
US supports WTO TRIPS Waiver for COVID-19 vaccines	US supports the WTO Agreement for TRIPS waiver authorizing the use of patents required for the production and supply of COVID-19 vaccines without the consent of the patent owner.	June 2022	Draft Ministerial Decision on the TRIPS Agreement Statement from Ambassador Katherine Tai

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