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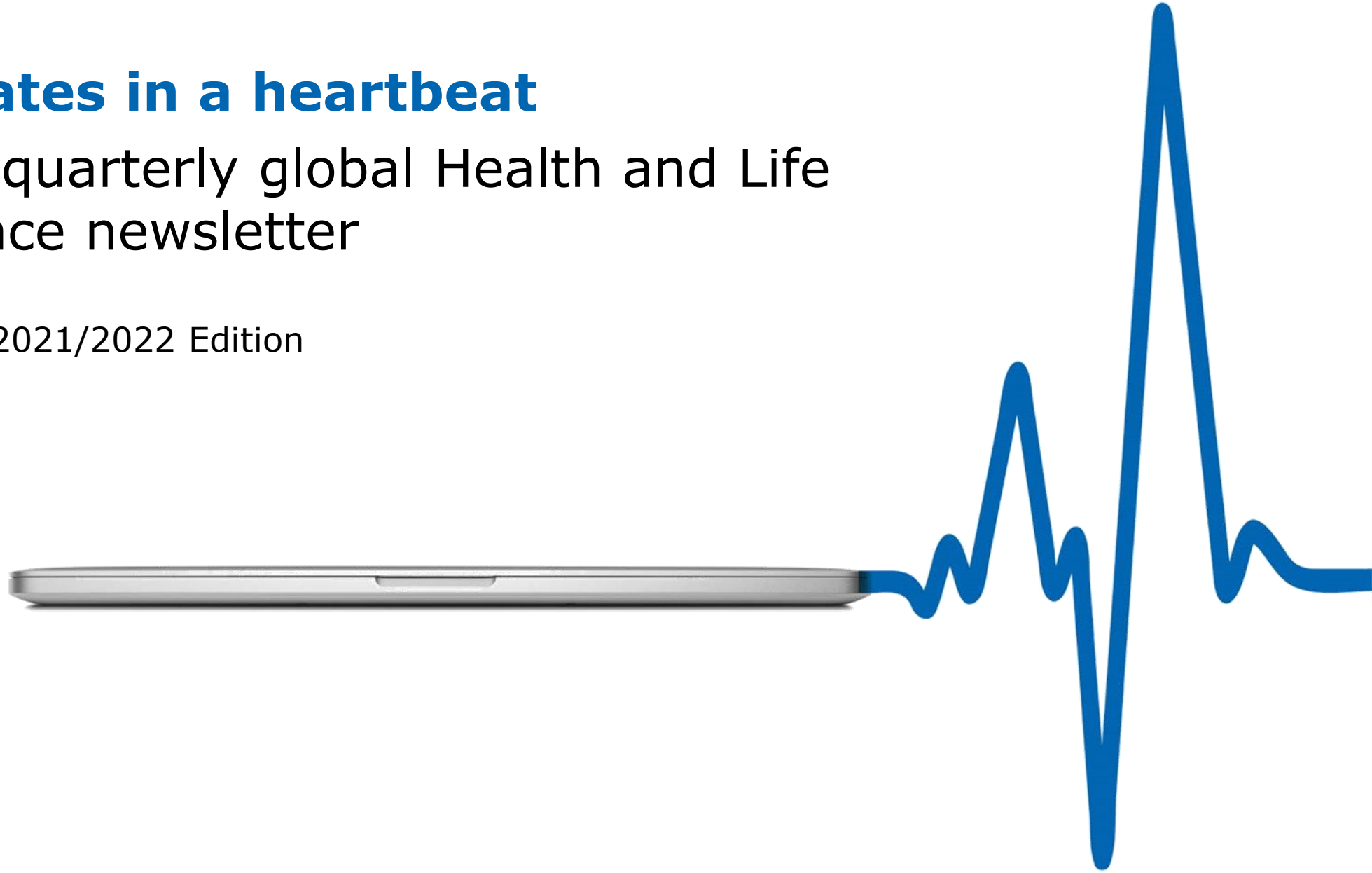
Updates in a heartbeat

Your quarterly global Health and Life Science newsletter

Winter 2021/2022 Edition



Executive summary

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

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

This edition contains a selection of newsworthy items from our team members around the globe, inter alia covering the introduction of new legislation, developments in case law and policy updates in respect of healthcare, (veterinary) medicinal products, medical devices, and cannabis products.

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EU overview

Title	Summary	Links
EU legislative projects for 2022	Leaders of the European Parliament, the European Council and the European Commission signed on 16 December 2021 a Joint Declaration on key legislative initiatives for 2022. Among the total of 138 legislative initiatives is the "Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU". The Proposal provides for a stronger and more comprehensive legal framework within which the Union can respond more rapidly to cross-border health threats like Covid-19, and triggers the implementation of preparedness and response measures across the EU.	Joint Declaration Commission Proposal Cross-Border Threats to Health
European Health Union: a stronger role for the EMA **(medicines)**	On 25 January 2021, the Council has adopted a regulation revising the mandate of the EMA, taking an important step towards EMA's reinforcement in crisis preparedness and management for medicinal products and medical devices. The new rules will allow the EMA to closely monitor and mitigate shortages of medicines and medical devices during major events and public health emergencies and facilitate faster approval of medicines which could treat or prevent a disease causing a public health crisis. The adoption of a stronger mandate for EMA is part of the European Health Union package proposed by the Commission in November 2020.	Regulation Reinforcing EMA's Role
Phased Introduction of IVDR **(medical devices)**	On 20 December 2021 the Council approved the European Commission's proposal for a phased introduction of Regulation (EU) 2017/7466 ("**IVDR**"). For higher risk devices, such as HIV or hepatitis tests (class D), the new requirements will apply as from May 2025. For devices of lower risk (class C), such as certain influenza tests, the date of application is extended until May 2026, whilst for lower risk class devices (class B and A sterile), the application starts in May 2027.	Press Release - In Vitro Diagnostic Medical Devices Regulation

EU overview

Title	Summary	Links
HTA Regulation	After many years of negotiation, the European Parliament adopted the Regulation on Health Technology Assessment (EU) 2021/2282 ("**HTA Regulation**") on 15 December 2021 which entered into force 11 January 2022 and will become applicable 12 January 2025. The HTA Regulation aims to harmonise varying health technology assessment processes within the EU and intends to ensure the quality, safety and accessibility of health technologies within the EU. Further, EU-wide collaboration in respect of health technology assessment shall be strengthened by pooling resources and high-level expertise. A yet to be established coordination group will be responsible for overseeing joint clinical assessments and other joint work carried out by designated national experts organised in subgroups dedicated to specific types of joint work. Via an IT platform to be set up, documentation, e.g., information on planned, ongoing and completed joint clinical assessments, shall be published to provide for more transparency. This should ultimately lead to faster market access and improved accessibility to health technologies for patients.	HTA Regulation
European Chips Act (medical devices)	On 8 February 2022 the European Commission proposed a comprehensive package of measures to ensure the security of supply, resilience and technological leadership in semiconductor technologies and applications within the EU. The European Chips Act is contemplated to strengthen Europe's competitiveness and resilience in respect of both digital and environmental transformation. To address the semiconductor shortage, a semiconductor ecosystem from research to production and a resilient supply chain will be created. The European Chips Act is expected to mobilise EUR 43 billion in public and private investment. If becoming reality, manufacturers in particular of medical devices will likely be impacted both directly and indirectly.	European Chips Act

EU overview

Title	Summary	Links
Guidance on the management of clinical trials during the COVID-19 (Coronavirus) pandemic – Updated Document **(medicines)**	The EMA, among other institutions, acknowledges the impact of COVID-19 on the health system and broader society, and on clinical trials and trial participants in particular. This calls for extraordinary measures and adjustment of clinical trials, inter alia due to trial participants being in self-isolation/quarantine, limited access to public places (including hospitals), and health care professionals being committed to critical tasks. The EMA has therefore published guidance for market parties on how to deal with the aforementioned situations.	Guidance Management Clinical Trials
Conclusion AG Szpunar: Proposal for a new approach to rebranding (medicines)	Attorney General Szpunar concluded that article 13 of the EUTM, read in the light of Articles 34 and 36 TFEU, must be interpreted as meaning that the proprietor of a trade mark for a reference medicinal product may oppose the use of that mark by a third party for the purposes of parallel trade to replace the trade mark under which a generic medicinal product is marketed by that proprietor or with his consent in another Member State, unless the two medicinal products are substantially identical and the conditions set out by the Court in its judgments of 11 July 1996 in Bristol-Myers Squibb e. a. (C-427/93) are also satisfied with regard to the replacement of the trade mark.	https://curia.europa.eu/juris/document/document.jsf?text=&docid=252161&pageIndex=0&doclang=NL&mode=lst&dir=&occ=first&part=1&cid=8736353
New rules on when IFU for medical devices can be used in electronic form (medical devices)	Implementing Regulation (EU) 2021/2226, which came into effect on 4 January 2022, prescribes under what circumstances medical device instructions for use (IFU) may be provided in electronic rather than paper form. This provides for increased certainty for medical device manufacturers.	https://eur-lex.europa.eu/eli/reg_impl/2021/2226/oj
Study on medicines shortages in the EU (medicines)	On 8 December 2021, the European Commission published a study on medicines shortages in the EU. In the report, the current legal framework is addressed potential solutions are provided to address shortages through various policy measures.	https://op.europa.eu/en/publication-detail/-/publication/1f8185d5-5325-11ec-91ac-01aa75ed71a1/language-en/format-PDF/source-245338952

Country updates

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China

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Title	Summary	Date	Links
Beijing Intellectual Property Court ("BIPC") considered first ever civil case under the new patent linkage system in China	In early November 2021, the BIPC announced its acceptance of the first civil case under the new patent linkage system in China since it took effect in July 2021. Chugai Pharmaceutical, a Japanese drug manufacturer controlled by Hoffmann-La Roche and the proprietor of the patent at issue / holder of the market authorization ("**MA**") of eldecalcitol (a drug for treating osteoporosis), commenced a civil action against Haihe Pharmaceutical, a Chinese generic drug manufacturer, on the basis that Haihe had filed an application for MA of the generic version of eldecalcitol and made a Type IV(2) declaration subsequently published by the National Medical Products Administration ("**NMPA**") under the new system (viz. a declaration that there is a related patent registered in the China Orange Book and the pharmaceutical product under the application for MA does not fall within the scope of protection of such related patent). Upon the BIPC's announcement, the NMPA imposes a 9-month moratorium and suspends the administrative evaluation of Haihe's application for MA, during which the BIPC is expected to conduct substantive hearing to determine whether Haihe's generic drug under application falls within the scope of protection of Chugai's patent. The timing of this first Orange Book litigation in China is unusual in that all claims in the Chugai's patent at issue have been invalidated on 29 January 2022 by the China National Intellectual Property Administration ("**CNIPA**"), the petition of which was filed by Chiatai Tianqing Pharmaceutical, another Chinese generic drug manufacturer, before China's patent linkage system took effect. Chugai has 3 months upon receiving CNIPA's decision to appeal against the invalidation. How the Chinese court is going to handle these intertwined proceedings remains to be seen. Pharmaceutical companies around the world will be monitoring this first patent linkage case in China closely as the BIPC's rulings will likely have impact on their product development and corresponding patent strategies in China and beyond.	January 2022	https://mp.weixin.qq.com/s/KfkyadIIARL8yB9uejPbuQ

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France

Title	Summary	Date	Links
Increase of the minimum stock of certain drugs of major therapeutic interest (*MIMT*)	The National Agency for the Safety of Medicines and Health Products (ANSM) has decided to increase the minimum stock of 422 medicines considered to be of major therapeutic interest (« médicament d'intérêt thérapeutique majeur » – MIMT). These drugs, whose discontinuation may be life-threatening for patients, are subject to special regulations, including stock requirements. Under the new Article R. 5124-49-4, IV of the French Public Health Code, the director general of the ANSM may decide to increase the safety stock required for certain drugs (to a maximum stock of four months) when there is a risk of stock shortage. From the notification of the decision, the laboratory has 6 months to set up the expected safety stock. The list of affected drugs is available on the ANSM website.	November – December 2021	Décret n° 2021-349 du 30 mars 2021 relatif au stock de sécurité destiné au marché national - Légifrance (legifrance.gouv.fr)
The French highest administrative court (*Conseil d'Etat*) suspends the ban on the sale of CBD flowers and leaves	The Council of State suspended the ban on the marketing and consumption of CBD flowers, (i.e. flowers of varieties of cannabis with no psychotropic effect), on the grounds that a general and absolute ban was disproportionate, creating serious doubts about its legality. This decision follows a recent ministerial decree from December 30th 2021 that, while allowing cultivation, import, export and industrial and commercial use of only those varieties of cannabis sativa L. with a delta-9-tetrahydrocannabinol (THC) content of no more than 0.3%, prohibited the sale of raw flowers and leaves, even if their THC content was below the 0.3% threshold.	January 2022	https://www.conseil-etat.fr/fr/arianeweb/CE/decision/2022-01-24/460055
Introduction of "simplified declaration" to notify the marketing or termination of marketing of a medicine	According to Article L. 5124-6 of the French Public Health Code, any pharmaceutical company wishing to commercialize or stop commercializing a medicine must inform the ANSM: - at least 1 year before the planned date, for drugs of major therapeutic interest; - at least 2 months before the planned date for other drugs. Since February 14, 2022, this declaration can be made via a simplified declaration, performed online on the platform www.demarches-simplifiees.fr.	February 2022	https://www.demarches-simplifiees.fr/commencer/ansm-formulaire-d-intention-d-arret-de-commerciali

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Germany

Title	Summary	Date	Links
New Federal Government – Impact on health system	Since December 2021, Germany has a new Federal Government with some plans for the industry. There are plans to offer pharmacies more flexibility in the implementation of operating regulations in order to improve the supply of drugs in under-served areas.–On-site pharmacies shall be strengthened in order to reward pharmaceutical services and exploit efficiency gains within the financing system which may mean increased mandatory discounts and margin cuts throughout the supply chain, including for manufacturers. For manufacturers of medicinal products, measures to move production of drugs (including APIs and excipients) back to Germany/the EU or to incentivize such moves are planned through a reduction of bureaucracy and various (investment) subsidies. The possibilities of health insurance funds to limit the prices of drugs shall be strengthened. The government is also considering legalizing dispensing of cannabis to adults for consumption purposes.	December 2021	Coalition Agreement
New Veterinary Medicinal Products Act	On 28 January 2022, the Veterinary Medicinal Products Act (*Tierarzneimittelgesetz; TAMG*) entered into force. The TAMG implements Regulation (EU) 2019/6. Accordingly, all regulations on and references to veterinary medicinal products will be removed from the Medicinal Products Act *(Arzneimittelgesetz; AMG)*.	January 2022	TAMG
GIGV – Regulation on Health-IT-Interoperability-Governance	The new regulation *(Gesundheits-IT-Interoperabilitäts-Governance-Verordnung; GIGV)* came into force 15 October 2021. It aims at improving the interoperability of IT systems in the health care sector and addresses all relevant actors within the eHealth sector. It provides aligned standards and guidelines for facilitated cooperation and communication between such actors which will continuously be reviewed and established by an expert panel in order to provide interdisciplinary effective tools.	October 2021	IT-Interoperability-Governance-Regulation

Hong Kong

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Title	Summary	Date	Links
Oral drugs are now available to fight fifth Covid-19 wave in Hong Kong	Hong Kong's Department of Health ("**DH**") has recently approved the registrations of two oral medications for treating Covid-19, MSD's molnupiravir and Pfizer's Paxlovid, amid the fifth wave of the epidemic in Hong Kong. These drugs are indicated for high-risk patients, including people aged 70 or older, those with chronic diseases such as diabetes, obesity, immune system disorder, kidney or heart failures, or cancer, and those not completely vaccinated, and can only be supplied to and prescribed by designated medical institutions, such as public hospitals, designated clinics and elderly care facilities. These pharmaceutical products have been conditionally approved by the DH as they were filed with limited safety, efficacy, and quality data under public health emergency in order to meet the urgent medical needs caused by a dramatic surge in the number of confirmed cases and related deaths. Accordingly, their registration status are subject to further review by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee of the DH.	March 2022	https://www.drugoffice.gov.hk/eps/drug/productDetail/en/pharmaceutical_trade/138019
Privacy Commissioner cleared Hong Kong's vaccine pass	Hong Kong's vaccine pass arrangements have taken effect on 24 February 2022, which require residents to have received at least one dose of vaccination (or to produce medical exemption certificates) before entering designated premises such as restaurants, shopping malls and supermarkets, as an effort to curb the spread of the Omicron variant prevalent in the fifth wave of the Covid-19 in Hong Kong. Given that a resident's vaccine pass implemented via the LeaveHomeSafe mobile app often contains personal data such as personal identifiers and Covid-19 vaccination or recovery records, concerns have been raised by the public regarding the privacy and security of data collected by the mobile app. The Privacy Commissioner has analysed the design and functionality of the vaccine pass in Hong Kong and found that its operation is in compliance with the requirements of the Personal Data (Privacy) Ordinance. Specifically, privacy-protecting measures have been adopted, including data minimisation techniques, masking, hashing and encryption of visit records. Moreover, any visit records will only be temporarily saved in the "QR Code Verification Scanner" App of a venue operator for 31 days for anti-epidemic purposes, after which, the data in any such visit records will be deleted automatically.	February 2022	https://www.pcpd.org.hk/english/news_events/speech/speeches_202203.html

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The Netherlands

Title	Summary	Date	Links
Voluntary commitment Pfizer (medicines)	After discussion with the Dutch Competition Authority (ACM), which was initiated after the ACM received information on a discount scheme that Pfizer used for its anti-rheumatic drug Enbrel, Pfizer has decided to stop applying its discount scheme to hospitals. According to the ACM , the scheme likely prevented hospitals from switching to another manufacturer, in which case this practice would possibly constitute abuse of dominance. In light of the voluntary commitment, the ACM has decided not to conduct any further investigation into Pfizer. ACM invites market parties to continue reporting these types of discount schemes. Pharmaceutical companies are thus alarmed to carefully analyse their pricing strategies from a competition law perspective in case of (potential) dominance.	February 11, 2022	Drug manufacturer Pfizer to discontinue its steering pricing structure for Enbrel following discussions with ACM | ACM.nl
New Code of Conduct for Medical Devices (medical devices)	The latest version of the Code of Conduct for Medical Devices (GMH) has taken effect as per 1 January 2022. The Code is binding on its members, but more widely considered to reflect industry practice. The main changes relate to: - the possibility to pay patients and patient organizations for services; - the possibility to request from suppliers documentation underlying the interactions reported in the transparency register - new maximum tariffs for provision of services by HCPs When services of HCPs are retained, medical device companies are advised to review the services arrangements that are currently in place to ensure compliance with the maximum tariffs.	January 1, 2022	https://www.gmh.nu/images/GMH_nieuwsbrief_december_2021_-_Aanpassing_GMH_Code.pdf
Working plan 2022 of the Dutch Health and Youth Care Inspectorate (medicines and medical devices)	The Dutch Health and Youth Care Inspectorate (IGJ) published its Working plan for 2022, which is relevant for Pharma, Biotech and MedTech companies operating in the Netherlands. Focus areas in respect of pharmaceuticals include: shortages and availability of medicinal products, the complexity of the distribution chain, pharmaceutical advertising and inducements, pharmacovigilance, GMP, clinical trials and good laboratory practices. Focus areas in respect of medical devices include: compliance with EU PMS obligations, safety of implants, and eHealth software/devices.	January 1, 2022	https://www.igj.nl/publicaties/jaarplannen/2021/12/20/werkplan-2022
Policy Update in respect of Product Information (medicines)	The CBG has revised several policy documents relating to the requirements for product information on medicinal products for human use. Pharmaceutical companies are advised to analyse whether these changes have any impact on the labelling of their products.	December 16, 2021	https://www.cbg-meb.nl/actueel/nieuws/2021/12/16/wijzigingen-in-beleid-productinformatie

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Poland

Title	Summary	Date	Links
Cannabis products	In February, parliament passed two draft bills on cannabis products. 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. The second contains proposals for introducing a register of hemp producers and entities purchasing such hemp.	February 8, 2022 (voting in parliament)	https://www.sejm.gov.pl/Sejm9.nsf/PrzebiegProc.xsp?nr=1611 https://www.sejm.gov.pl/Sejm9.nsf/PrzebiegProc.xsp?nr=1699
Medical professions	A new draft bill currently under review aims to regulate additional medical professions, such as dietitians, massage therapists, speech therapists, and occupational therapists. The draft provides for the creation of a central register for medical professions and introduces rules on professional liability including special procedures conducted by committees. In the event a profession is practiced without the right qualifications, criminal charges may be faced.	January 21, 2022	https://legislacja.rcl.gov.pl/projekt/12355717
Organic farming	Work is underway in committee on the draft act enabling the application of the EU regulation on organic production in Poland. The act facilitates the obtaining of organic farming entitlements, and increases the system's transparency by introducing, inter alia, a single base of organic producers instead of many fragmented bases. In addition, the draft provides for penalties for the unlawful inclusion of ecological production references in advertisements.	May 31, 2021 (publication) February 9, 2022 (works in committies)	https://legislacja.gov.pl/projekt/12347351/katalog/12791401#12791401
MDR and its implementation in Poland	The Polish parliament is finalizing its voting process on the draft legislative proposal on implementing the EU Medical Device Regulation in Poland. According to the draft, the advertising of medical devices will be restricted, especially if health experts are involved. Secondly, regenerated single-use medical devices cannot be used in Poland. Finally, new high administrative financial penalties will be introduced.	June 2020 (publication) March 8, 2022 (voting)	https://www.sejm.gov.pl/sejm9.nsf/PrzebiegProc.xsp?nr=1764

Spain

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Title	Summary	Date	Links
The Spanish Data Protection Agency (AEPD) has approved the Code of Conduct regulating the processing of personal data in the field of clinical trials and other clinical research and pharmacovigilance.	The Code regulates how sponsors of clinical trials with medicinal products and Contract Research Organisations (CROs) that decide to adhere to it must apply data protection regulations. It is national in scope, although it aspires to be a benchmark at European level as it is the first code in this field to be approved in Europe.	25 February 2022	https://www.aepd.es/es/prensa-y-comunicacion/notas-de-prensa/presentacion-primer-codigo-de-conducta-sectorial-aprobado-aepd (in Spanish only)
Publication of Royal Decree 1157/2021 of 28 December, regulating industrially manufactured veterinary medicinal products.	The new RD, which complements the European Regulation, lays down rules concerning the placing on the market, manufacture, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products	28 January 2022	https://www.boe.es/buscar/act.php?id=BOE-A-2021-21662 (in Spanish only)
Spanish courts decide on the inclusion of orphan medicines in the Spanish Reference Pricing System (*Sistema de Precios de Referencia*).	In its ruling of 2 December 2021, the Provincial Court concluded that orphan medicinal products included in the pharmaceutical provision of the NHS should not be subject to the Spanish reference price system. This provision would constitute an obstacle to achieving the objective pursued by their designation as orphan medicinal products in European Regulation 141/2000, and this should prevail over the national regulation. This is challenged by the Supreme Court in its ruling of 3 February 2022, concluding that it would not be possible to argue that the European regulation implies the non-application of article 98 of the Royal Legislative Decree 1/2015 based on the principles of primacy and direct effect of EU law.	2 Decenber 2021 3 February 2022	https://www.poderjudicial.es/search/TS/openDocument/be8bdd55575e263a/20220214 (in Spanish Only)

Country updates

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Sweden

Title	Summary	Date	Links
Repeal of national legislation on restrictions due to Covid-19 - the disease is no longer considered dangerous to the public or society	The Swedish government has proposed to repeal the national legislation on restrictions due to Covid-19 effective from April 1, as the disease should no longer be considered dangerous to the public or society. If accepted by the Parliament, the repeal will result in the removal of all public restrictions (health of personnel not included). One is that testing or reporting of Covid-19 will no longer be mandatory. Also, the government will no longer be able to impose any restrictions such as requirements on quarantine or isolation. The national Covid-19 legislation was enacted in January 2021 as a result of the pandemic. Covid-19 was also listed as a notifiable disease according to public health law and categorized as dangerous to public health and society.	March 4, 2022	https://www.government.se/government-policy/the-governments-work-in-response-to-the-virus-responsible-for-covid-1/

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United Kingdom

Title	Summary	Date	Links
ICO reprimands Scottish Government over need to be upfront about NHS Scotland COVID Status app's use of people's details	Following an investigation, the UK Information Commissioner's Office ("ICO") issued a reprimand to the Scottish Government and NHS National Services Scotland (NHS NSS) over their failure to provide people with clear information about how their personal data is being used by the NHS Scotland COVID Status app. The ICO considered that both organisations failed to (i) process personal data (including special category data such as health data) in breach of the transparency principle set out in Article 5(1)(a) UK GDPR and (ii) provide clear information about the processing of personal data in breach of Article 12 UK GDPR. The ICO required Scottish Government and NHS NSS to implement specific compliance steps, namely redrafting its privacy notice to fulfil the information and transparency requirements of Articles 12 and 13 UK GDPR. Although the reprimand does not legally compel Scottish Government and NHS NSS to make the changes, the ICO reserves its rights to exercise its powers to issue an enforcement notice if the changes are not completed within 30 days of the reprimand.	February 25, 2022	Reprimand ICO's statement

Country updates

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United Kingdom

Title	Summary	Date	Links
ICO consults health organisations to shape thinking on privacy-enhancing technologies	The ICO invited organisations in the health sector to participate in workshops on privacy-enhancing technologies (PETs). PETs refer to a broad range of processes and approaches for protecting personal data and help organisations implement measures such as data protection by design. The ICO wants "to set out how PETs can facilitate safe, legal and valuable data sharing in health and understand what's needed to help organisations use these technologies". The ICO will use the conclusions of the workshops to suggest solutions and roadmaps which enable safe and lawful data sharing in sectors beyond healthcare. Interested organisations are encourage to participate in the workshops.	February 2, 2022	ICO consults health organisations to shape thinking on privacy-enhancing technologies
ICO and NHS Test and Trace agree data protection improvements following consensual audit	Following a consensual audit agreed with the UK Department for Health and Social Care, the ICO has issued NHS Test and Trace with recommendations to strengthen the protection of people's personal data. The ICO and DHSC agreed to focus the audit on "Governance and Accountability" (looking at the policies and procedures introduced to keep data secure) and "Processor and Third Party Supplier Relationship Management" (looking at how NHS Test and Trace manages external processors and contractors to ensure they maintained high data protection standards). The audit revealed a number of key requirements that were not yet in place and provided recommendations to ensure that steps are taken to remedy them.	December 21, 2021	executive-summary-of-the-nhs-test-and-trace-audit-report.pdf (ico.org.uk) ICO statement

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ENISA publishes ninth edition of Threat Landscape report	The European Union Agency for Cybersecurity ("ENISA") released the ninth edition of its Threat Landscape Report, which identifies the prime threats and trends in relation to cybersecurity and reports on relevant mitigation measures that may be implemented. The report states that "the health sector was targeted significantly, and this activity shows signs of increasing during the last few months of the reporting period (May-July 2021)". The report notes that the COVID-19 pandemic "created opportunities for targeted ransomware attacks since the potential disruption of organisations within the healthcare and public health sector […] targeting small and medium-sized hospitals and clinics". ENISA considers that the "healthcare and public health sector will certainly continue to be heavily targeted by ransomware groups as long as the pandemic lasts".	October 27, 2021	ENISA report
ICO data sharing code of practice under DPA 2018 has now come into force	On 5 October 2021 the ICO's statutory data sharing code of practice, issued under Section 121 of the Data Protection Act 2018 ("DPA 2018"), came into force. The code provides practical guidance for organisations on how to share personal data in compliance with the requirements of the UK General Data Protection Regulation and DPA 2018, including transparency, the lawful basis for processing, the accountability principle and the need to document processing requirements. It will be a key consideration for future data sharing between controllers (it does not cover the sharing of personal data between controllers and processors). The code contains practical examples and case studies relating to health data, such as the information sharing framework in healthcare, and considerations for a healthcare data sharing agreement.	October 5, 2021	Data sharing: a code of practice | ICO

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United Kingdom

Title	Summary	Date	Links
Open Life Data Framework report published to encourage discussion around how data can be used to improve health levels of UK population	The All-Party Parliamentary Group for Longevity ("AAPGL") has published the Open Life Data Framework report, which aims to: stimulate conversation and encourage collaboration between public and private sectors; and, assist researchers, policymakers and entrepreneurs to establish what types of health-relevant data (outside of the NHS and care system) provide the most insight into helping disadvantaged individuals keep healthy, as well as enhancing overall health resilience at a population health level. The APPG formed an expert group to define the requirements for an open health system (drawing from pre-existing models like the Open Banking ecosystem) to harness data-intensive technologies to extend the healthy life spans of British citizens. The AAPGL plans to work with a range of organisations to develop the framework. It is seeking funding and other support for the next stage, including testing assumptions of the framework in the real-world, on use cases, sandboxes and pilot projects.	November 18, 2021	Open Life Data Framework — All Party Parliamentary Group for Longevity (appg-longevity.org)
ICO guidance on Covid-19 topics	The ICO has published guidance on Covid-19 related topics such as the ICO's regulatory approach during the COVID-19 pandemic, guidance for employers and organisations that (i) are planning on asking people if they have experienced COVID-19 symptoms or are planning to introduce testing, (ii) are planning on using CCTV, thermal cameras or other surveillance methods as part of testing or ongoing monitoring of staff, (iii) collect and retain customer and visitor information, for a limited time period, for the purposes of a COVID-19 contact tracing scheme in accordance with government guidelines and (iv) share personal information related to the COVID-19 vaccine. The ICO maintains its guidance on a regular basis and occasionally provides separate statements such as the statement on mandatory vaccination.	Ongoing	Data protection and coronavirus – advice for organisations | ICO

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United States of America

Title	Summary	Date	Links
Broad Institute, MIT Win Patent Battle Over CRISPR	The Patent Trial and Appeal Board has determined that the Broad Institute and the Massachusetts Institute of Technology invented the use of the gene-editing technology CRISPR-Cas9 in plants and animals before the Nobel Prize-winning scientists at the University of California and University of Vienna.	March 1, 2022	Read here >

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