EVERSHEDS SUTHERLAND

Updates in a heartbeat

Your quarterly global Health and Life Science newsletter

Edition one – Autumn 2021

Executive summary

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

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

This edition covers medical devices to clinical trials and reimbursement systems, and is full of newsworthy items from our team members around the globe.

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EU overview

Title	Summary	Links
EU – 6 months into the MDR (Medical Devices Regulation No. 2017/745) and 6 months for the upcoming IVDR (In Vitro Diagnostic Regulation No. 2017/745): the sector is ready, the system is not	The MedTech and the medical devices industries have expressed concerns over the coming into effect of the MDR from May 2021 and the upcoming IVDR due to come into effect in May 2022. The shortage of MDR and/or IVDR-certified Notified Bodies is still creating a bottleneck. Due to capacity issues there is a threat of a CE certification backlog and a high risk to the availability of IVD medical tests in the coming years. The industry has called for solutions for existing and niche devices.	MedTech Europe welcomes the Medical Device Regulation's entry into full application and urges continued work to deploy the new regulatory system - MedTech Europe Industry survey shows an urgent, high risk to the availability of IVD medical tests once the new IVD Regulation fully applies in eight months. - MedTech Europe
EU – AI: the European Commission's proposal for an Artificial Intelligence Act	AI offers immense potential in the life sciences sector, in general, as well as in terms of cyber security. At the same time however, it also presents a number of risks. The proposal for an AI Regulation aims to strengthen Europe's position as a global hub of excellence in AI from the lab to the market, to ensure that AI in Europe respects our values and rules and harness the potential of AI for industrial use.	New rules for Artificial Intelligence – Questions and Answers
Covid-19 pandemic - Key takeaways/trends for the life sciences sector	After two challenging years of Covid-19, a number of key takeaways/trends can be observed that should be acknowledged by the market players to ensure growth and to make the sector future proof: — digitalization of R&D and clinical trials — acceleration of e-medicine — the need for cooperation between the MedTech, health services, pharmaceutical and life sciences industries in respect of the structuring of data — the re-engineering of supply chains to improve resiliency	

EU overview

Title	Summary	Links
EU – CTR (Clinical Trials Regulation No. 536/2014) finally coming into effect by 31 January 2022	The European Commission has confirmed that the CTR will finally come into effect by 31 January 2022. The CTR was meant to come into effect by the end of 2015, but there were technical issues with the IT platform (CTIS) that will become the single entry point for submitting clinical trial information in the EU. The CTR aims to harmonize the legal framework for clinical trials involving medicinal products for human use, improve the collaboration between and within Member States, increase transparency, and set the highest levels of safety for participants, and is expected to cause a major change in the way clinical trials are conducted in the EU. Companies engaging in clinical trials should therefore anticipate the upcoming changes and make sure that their processes and documentation are in order.	Clinical trials - Regulation EU No 536/2014
EU- Initiative to evaluate and revise the EU's general legislation on medicines for human use	The European Commission has launched a public consultation for all private operators on its plan to review European pharmaceutical legislation in the framework of the European Pharmaceutical Strategy. Specifically, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency are proposed for review. The deadline for contributions is 21 December 2021.	Revision of the EU general pharmaceuticals legislation (europa.eu)

Country updates

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China

Title	Summary	Date	Links
New patent linkage system in full action	A new statutory mechanism for resolving patent disputes between pharmaceutical market authorization ("**MA**") applicants and patentees has taken effect in July 2021 together with the implementation of a "China Orange Book" system administered by the Center for Drug Evaluation ("**CDE**") of the National Medical Products Administration ("**NMPA**") of China, which applies to a broad spectrum of pharmaceutical products including chemical compounds, Chinese medicines and biologics. From now on, an MA applicant shall (i) file a declaration with respect to potential infringement against the relevant patents recorded in the China Orange Book, and (ii) notify the incumbent MA holder of the pharmaceutical product concerned in the MA application particularizing the basis of such declaration, so that the incumbent MA holder can take early action to resolve any patent disputes with the MA applicant prior to the grant of MA.	July 2021	China Marketed Pharmaceutical Patent Information Registration Platform
Medical devices registration system reform	The State Administration for Market Regulation ("**SAMR**") promulgated new administrative measures for the registration and recordal of medical devices products in China. Such measures have taken effect on October 1, 2021. New measures stipulate MA holders' obligations with respect to quality management system, post-MA research and risk control planning, adverse event monitoring/re-evaluation, product traceability/recall system, amongst others, and their responsibilities for the safety, quality and efficacy of the registered/recorded products throughout their life cycle. The SAMR together with the NMPA have also included certain conditional approval procedures and emergency use measures for selected urgently needed medical devices products. In addition, the NMPA have measures to accept self-inspection reports for product registration/recordal under certain conditions, reducing cost and enhancing efficiencies for manufacturers to obtain certificates of registration/recordal for their products.	August 2021	SAMR's promulgation

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France

Title	Summary	Date	Links
E-commerce and medicinal products	A decree of May 14, 2021 repeals the former prohibition for e-commerce websites to be listed in search engines or price comparators for a fee. This decree follows a decision of the Council of State (*Décision du Conseil d'Etat No. 440208*) from March 17, 2021, enjoining the Minister of Health to repeal the prohibition on paid referencing of sites selling medicines listed in the annex to the order of November 28, 2016 on the technical rules applicable to e-commerce websites for medicines. It is no longer forbidden for pharmacists who are authorized to engage in electronic commerce of medicines to have a fee-based presence in search engines or price comparators.	May 2021	Decree of May 14th 2021
Reform of the derogatory access to medicinal products	The authorization scheme to allow derogatory access to medicines has been simplified. The timeframe required to obtain early access to a medicinal product has been shortened, visibility on eligibility criteria has been improved and knowledge about the drug used and its benefits for patients has been strengthened. The existing 6 authorization schemes have been replaced by 2 new access schemes : - **compassionate access** for medicinal products not intended to be marketed for a given condition (assessed and authorized by the national drug and health product safety agency (*Agence Nationale de sécurité du médicament et des produits de santé ANSM*)) - **early access** for medicinal products intended to be marketed for a given condition (assessed and authorized by the High authority for Heath (*Haute Autorité de la Santé HAS*))	July 1, 2021	Law n° 2020-1576 of December 14th 2020 of social security financing for 2021 Decree n° 2021-869 of June 30th on early and compassionate access authorizations for certain drugs

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France

Title	Summary	Date	Links
Request for proposals "Evaluation of the medical and/or economic benefit of digital or artificial intelligence-based medical devices"	In June 2021, the President announced the "Digital Health" acceleration strategy at the Strategic Council for Health Industries (CSIS). Nearly three months after this announcement, the first action of the strategy has now been launched: it is the request for proposals "Evaluation of the medical and/or economic benefit of digital or artificial intelligence-based medical devices". This action is aimed at developers of digital health devices, at the stage of evaluating their clinical or medico-economic usefulness, to support the financing of their study. The request for proposals is **open from September 15, 2021 to March 2, 2022**.	September 15, 2021 to March 2, 2022.	Decree of September 20th 2021 on the approval of the terms of reference for the request for proposals Application page

Country updates

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Germany

Title	Summary	Date	Links
E-Health and reimbursement of digital health apps (DIGAs)	Since 2019/2020, increased new legislation and new processes in terms of e-health and tele-medicine (Digital Care Act - Digitales Versorgungsgesetz – DVG) are tearing down barriers that have so far been responsible for the limited access to digital health services in Germany. Medical Health Apps have become reimbursable by the German statutory health insurance under certain conditions upon prescription (German Digital Health Apps Regulation - DiGAV). For this purpose, the German Federal Institute for Drugs and Medical Devices (BfArM) implemented an assessment process for healthcare apps.	September 2021	BfArM - DiGA Digital Health Apps
Implementing the MDR in Germany	Although the MDR already provides for a broad legal framework, the German legislator introduced an extensive local legal framework supplementing the MDR (e.g. in terms of clinical assessment, labelling, extension of the scope of economic players). The German Medical Devices Act (Medizinproduktegesetz) have been replaced by the newly introduced German Medizinprodukte-Durchführungsgesetz and changes in several other German laws (e.g. the Healthcare Advertising Act, the Fifth Social Security Act). However, the replaced German Medical Devices Act is still to be applied where grace periods are in place under the MDR, or for in vitro diagnostic medical devices.	May 2021	BfArM – Medical Devices Legal Framework

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Germany

Title	Summary	Date	Links
German court decision impacts Swiss companies importing medicinal products within the EU	According to the German Federal Administrative Court's (BVerwG) decision, Swiss companies may no longer use wholesale licenses issued by Switzerland to sell medicinal products in Germany. Wholesalers of medicinal products may only procure their stocks of medicinal products from entities that hold a wholesale license granted by an EU Member State. A licence to wholesale medicinal products granted under Swiss law is no longer sufficient for this purpose.	February 2021	BVerwG court ruling (25.02.2021 - 3 C 1.20)
Changes in criminal case law provide for more possibilities to market CBD products in Germany	Until recently, in Germany almost all cannabis-derived products were classified as narcotics and marketing of distribution could have led to criminal charges. The most recent decisions of both the European Court of Justice (ECJ, Judgment of 19.11.2020 – C-663/18 on commercialization of CBD) and the German Federal Court of Justice (BGH, Judgment of 24.3.2021 – 6 StR 240/20) have opened up possibilities to market cannabis-derived products legally in Germany, provided that any misuse of the CBD product can be excluded, i.e. the THC content is sufficiently low to ensure that through ordinary consumption intentional abuse can be excluded.	2021	ECJ Press release No 141/20 BGH Decision

Hong Kong

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New guidance on ethical development and Use of artificial intelligence ("AI") issued by the privacy commissioner	The use of AI in product R&D and business development activities has increased significantly in recent years. Such use in the life sciences sector often involves the collection, processing, storing and transferring sensitive personal data (e.g. biometric data, medical and health records, clinical trial data, etc.) and it has been a challenge for life sciences companies using AI to comply with conventional data protection principles set out in the Hong Kong Personal Data (Privacy) Ordinance (Cap. 486) ("**PDPO**"). In response, the Office of the Privacy Commissioner for Personal Data of Hong Kong published the "*Guidance on the Ethical Development and Use of Artificial Intelligence*" ("**Guidance**") in August 2021 to assist organizations in understanding and complying with the relevant requirements of the PDPO in using AI. The Guidance provides key ethical principles for using AI in business activities, including accountability, human oversight, transparency, data privacy, reliability and security, amongst others. It also provides practical pointers for organizations in developing their AI strategies as well as systems of governance, risk assessment and human oversight in compliance with the relevant requirements of the PDPO.	August 2021	Guidance on Ethical Development and Use of AI
Measure for using Hong Kong registered drugs and medical devices in Greater Bay Area ("GBA")	Designated healthcare institutions operating in the Greater Bay Area have been allowed to use Hong Kong registered drugs and medical devices used in Hong Kong public hospitals with urgent clinical use ("**Measure**") since the promulgation of the *Work Plan for Regulatory Innovation and Development of Pharmaceutical and Medical Device in the Guangdong-Hong Kong-Macao Greater Bay Area* ("**Work Plan**") in November 2020. The trial period of the Work Plan was successfully completed on 31 July 2021 with the University of Hong Kong-Shenzhen Hospital making use of nine drugs and two medical devices registered in Hong Kong. On 27 August 2021, the Guangdong Provincial Medical Products Administration ("**GDMPA**") issued the *Interim Provisions on the Administration of Imported Medicines and Medical Devices in Urgent Clinical Use* extending the Measure from Shenzhen to cover other cities and designated healthcare institutions in the Greater Bay Area meeting the relevant requirements. The first batch of designated healthcare institutions includes five hospitals located in Shenzhen, Guangzhou, Zhuhai and Zhongshan.	August 2021	Measure

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Netherlands

Title	Summary	Date	Links
Medical Devices Act	The Medical Devices Act and subordinate legislation, implementing the Medical Device Regulation, came into effect on 26 May 2021. The Medical Devices Act implements the obligations that stem from the MDR, as well as the freedom that the MDR provides, such as in respect of the re-processing of medical devices for single use.	May 26, 2021	https://wetten.overheid.nl/BWBR0042755/2021-07-17
Pharmaceutical company fined for excessive pricing	The Dutch Competition Authority imposed a fine of almost EUR 20 million on Leadiant for abusing its dominant position. Leadiant charged an excessive price for its CDCA drug, which over time had developed from less than 50 to 14,000 euros. This is the first time in many years that the Dutch Competition Authority has fined a company for abusing a dominant position.	July 1, 2021	https://www.acm.nl/en/publications/acm-imposes-fine-drug-manufacturer-leadiant-cdcas-excessive-price
Maximum tariffs for HCPs will increase	The maximum tariffs for HCPs providing services to pharmaceutical companies - as laid down in the industry Code of Conduct for the Advertising of Medicinal Products - will increase from 1 January 2022 (and indexed on a yearly basis). The HCP categories are also updated.	January 1, 2022	https://www.cgr.nl/nl-NL/Nieuws/Nieuwsbrieven/2021/Nr-3-2021-Redelijke-beloning-zorgprofessionals

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Poland

Title	Summary	Date	Links
MDR and its implementation in Poland	The government adopted the draft legislative proposal on implementing the MDR in Poland on 19. October 2021. 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 regenerated in Poland. The new high administrative financial penalties are still to be introduced. The new law will apply only 14 days after the official publication of the final act. Before final acceptance, the draft should be revised by, among others, Parliament and the Senate.	October 19, 2021	https://legislacja.gov.pl/projekt/12335403
Deep reform of Polish reimbursement system may hit foreign pharmaceutical companies	The newly published draft law on reimbursement provides for new powers for the Minister of Health to change reimbursement decisions during its validity period without the consent of the pharmaceutical company. In addition, the so-called "statutory payback" will be 100% shifted to the pharmaceutical companies (and not 50% which was the case so far). The draft bill provides preferential reimbursement conditions for companies that manufacture medicines and active substances in Poland, e.g. preferential setting the official sales price.	June 2021 (publication) August 2021 (modification)	https://legislacja.gov.pl/projekt/12348505/katalog/12799488#12799488
Additional costs related to the clinical trials may arise if the new legislation is adopted in Poland	The Polish government plans to modernize the regulation on clinical trials and attract more innovation in Poland. In April 2021, a new draft Act on clinical trials was published. The Act introduces a new, more decentralized system of revision of motions to approve clinical trial to speed up the process. It creates a new public fund to protect in clinical trials' participants. The compensation will be available for participants suffering health damages in quasi administrative proceedings supported by experts instead of expensive general court proceedings.	April 2021	https://legislacja.rcl.gov.pl/projekt/12346302/katalog/12784810#12784810

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Russia & EAEU

Title	Summary	Date	Links
Russian Government tests the waters of remote distribution of Rx medicines	Starting from January 2021 experimental legal regimes can be introduced in relation to innovative products. The regime can be applied in relation to online sales of Rx medicines. A corresponding draft paper was proposed by the Ministry of Economy.	June 2021	https://regulation.gov.ru/projects#npa=117151
EEC has clarified criteria of products defined as medical devices	The EEC has amended the list of criteria that define whether a particular product can be viewed as a medical device. A new version of the criteria resolves some of the practical issues by way of adding and excluding some products and providing additional rules on medical software.	June 2021	https://docs.cntd.ru/document/551663485
MoH allowed using drugs provided by the patient or charity fund	In response to some practical cases of difficult access to certain medicines, MoH established that medical institutions in certain instances may use the medicines provided by the patients themselves or by charity funds.	July 2021	http://publication.pravo.gov.ru/Document/View/0001202107290023
Transition period for registration of medical devices was extended	EAEU member states are gradually moving towards unified rules on registration of medical devices. Previously established transition period for re-registration under EAEU rules was prolonged from 31 December 2021 to 31 December 2026.	July 2021	http://publication.pravo.gov.ru/Document/View/0001202107300041?index=0

Country updates

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Spain

Title	Summary	Date	Links
Project for a Royal Decree regulating medical devices	The draft legislation, which has already passed the consultation period, transposes Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Its objectives include: (i) establish the requirements and procedures for the regulation of the implantation card; (ii) regulate the language regime; (iii) the regulation of the reprocessing of single-use medical devices and; (iv) the creation of a national public register of distributors and manufacturers.	July 10, 2021	https://www.mscbs.gob.es/normativa/audiencia/docs/RD_productos_sanitarios.pdf
Draft Order updating the reference price system for medicines in the Spanish National Health System in 2021	The main novelty of this Spanish Reference Price Order (RPO), with respect to the previous one, is that all the sets have been formed based on the ATC-5 classification, in accordance with the latest amendment of Royal Legislative Decree 1/2015 of 24 July 2015, approving the revised text of the Law on guarantees and rational use of medicines and health products.	July 13, 2021	https://www.mscbs.gob.es/profesionales/farmacia/pdf/2021_Notif_Tramite_Audiencia_Proyecto.pdf

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Sweden

Title	Summary	Date	Links
New national law prohibits unfair trading practices in business-to-business relationships in the agricultural and food supply sector	To implement Directive (EU) 2019/633 on unfair trading practices in business-to-business relationships in the agricultural and food sector (including food-supplements) the Swedish government has adopted a new law referred to as the "UTP-law", imposing stricter obligations and more far-reaching prohibitions on buyers than required in the directive. Effective from 1 November 2021, buyers within said sector with an annual turnover of SEK 2,000,000 or more (approximately EUR 200,000) are prohibited from, inter alia, paying later than after 30 days, cancelling an order with less than 30 days notice, and unilaterally enforcing amendments to terms of an agreement regarding range, method, location, time, or volume for deliveries, quality requirements, payment, or price. Violations of the UTP-law are sanctioned by injunctions and penalty fees amounting to a maximum of one percent of the violating parties' sales the previous financial year.	October 18, 2021	https://eur-lex.europa.eu/legal-content/SV/TXT/?uri=CELEX:32019L0633

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United Kingdom

Title	Summary	Date	Links
UK Laws on medical devices and clinical trials to potentially diverge from EU regulatory framework - The EU is currently struggling to implement a change in how medical devices are regulated. Instead, the UK is seeking to create a bespoke regulatory system	The Medicines and Healthcare Products Regulatory Agency has just launched a consultation inviting members of the public, including developers, manufacturers, and suppliers, to provide their views on possible changes to the regulatory framework for medical devices in the UK. Their aim is to develop a future regime for medical devices which enables; Improved patient and public safety; Greater transparency of regulatory decision making and medical device information; Close alignment with international best practice, and More flexible, responsive and proportionate regulation of medical devices. The consultation documents offers a very detailed set of possible proposals for consultees to comment on in an online survey, from a reformed system of classification for medical devices to stricter requirements for insurance coverage in the event of product liability claims. For manufactures, any divergence from EU rules and approaches, could create additional cost and complexity of putting their devices through the UK processes on top of the updated European process.	October 20, 2021	Read the consultation.
CMA imposes fines exceeding £260 million for anti-competitive conduct in the supply of hydrocortisone tablets	On 15 July 2021, the CMA fined Auden Mckenzie and Actavis UK (now Accord-UK) over £260 million for charging the NHS excessively high prices for hydrocortisone tablets between 2008 and 2018 in breach of UK competition law. The CMA also found that Auden Mckenzie paid off certain potential competitors to stay out of the market.	July 15, 2021	CMA Press Release Link

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United States of America

Title	Summary	Date	Links
Public comments on patent subject matter eligibility highlight disparate views from tech and life sciences, complicating path to reform under potential new USPTO director	The US Patent and Trademark Office concluded a request for public comments on the **current state of patent subject matter eligibility jurisprudence** on October 15 2021. Many companies in the life sciences sector expressed their views that recent Supreme Court decisions in the area had made the **law unclear in fields such as diagnostics and personalized medicine, thereby reducing investment and development.** Conversely, many companies in the software sector praised the current state of law, arguing that recent developments have prevented overly broad patents from being enforced and stifling innovation. **It remains to be seen what impact these comments will have on the USPTO's report to Congress in due in March 2022,** particularly in light of the recent nomination of Kathi Vidal, who represented numerous tech companies while in private practice, as the potential new USPTO director. **This remains a space to watch for life sciences companies over the coming months.**	October 15, 2021	https://www.regulations.gov/document/PTO-P-2021-0032-0004

Our resources

Title	Summary	Link
Our global vaccines and vaccination law capabilities	Eversheds Sutherland has expertise in many areas of vaccines and vaccination law and is ideally placed to guide you through the range of issues that you may face whether as a developer or manufacturer of vaccine.	Download the brochure here >
Podcast: Self-tests for laymen in Poland and Germany – Q&A	Self-tests for laymen in Poland and Germany – Q&A by our German and Polish team (Magdalena Kotyrba-Hagenmaier, Principal Associate, IP & Life Sciences, Germany, and Martyna Gałdecka, Associate, Commercial, Poland) discuss: - Are self-tests considered medical devices? - How are they marketed (certification requirement of emergency approval procedure)? - How to label self-tests for laymen?	Listen to the podcast here >
Six months to go: FAQs on IVDR	Similar to the EU Regulation on Medical Devices (for further details, please see "One year to go: Q&A on EU Medical Devices Regulation"), the EU In Vitro Diagnostics Regulation (IVDR)(1) entered into force on 25 May 2017 and will fully apply from 26 May 2022. This article focuses on important questions and the main changes that the new regulation brings.	ILO article - Six months to go: FAQs on IVDR

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