EVERSHEDS SUTHERLAND

Updates in a heartbeat

Your quarterly global Health and Life Science newsletter

Edition Four – Autumn 2022

Executive summary

Welcome to the fourth edition of our Health and Life Science newsletter.

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

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

Elizabeth Graves
Global Co-Lead of Health and Life Sciences, UK

T: +44 1223 44 3761
M: +44 791 901 4664
elizabethgraves@eversheds-sutherland.com

Tobias Maier
Global Co-Lead of Health and Life Sciences, Germany

T: +49 8 95 45 65 14 4
M: +49 15116776588
tobiasmaier@eversheds-sutherland.com

Bill Warren
Lead for Health and Life Science, US

T: +1 404.853.8081
billwarren@eversheds-sutherland.com

EU overview

Title	Summary	Links
Accelerating Clinical Trials in the EU	The European Commission, the European Medicines Agency and the Heads of Medicines Agencies have published a paper setting out proposals for a transformation initiative of EU clinical trials. The paper includes a roadmap with target dates for 2023 based on the European Pharmaceutical Strategy proposed by the Commission in 2020. One of the 10 key points of the project is the modernisation of the ICH E6 (R2) Guideline for Good Clinical Practice, which comes five years after its last revision.	Accelerating Clinical Trials in the EU
New Joint Guidance for pharmaceuticals and healthcare companies on the use of Social Media and Digital Channels	The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) have developed a new guidance document establishing a set of principles for using social media and digital channels for healthcare organisations when they share information with the public online. One of the key issues covered in the guidance is the involvement of influencers and opinion leaders.	Joint Note for Guidance on social media and digital channels
European Commission has adopted two proposals to adapt liability rules to the digital age	The two proposals include: — modernisation of the existing rules on manufacturers' strict liability for defective products — the harmonization of national AI liability rules	New liability rules on products and AI to protect consumers and foster innovation

EU overview

Title	Summary	Links
EDPB and EDPS publish a Joint Opinion on the proposed Regulation on the European Health Data Space	The EDPB and the European Data Protection Supervisor ("EDPS") have issued a Joint Opinion on the European Commission's Proposal for a regulation on the European Health Data Space ("the Proposal"). The Proposal sets out to: enable individuals to have greater control over their health data; support the use of health data for research innovation and policy making; and allow the safe exchange, use and re-use of health data to benefit both public interests and the interests of individuals. This Joint Opinion highlights a number of concerns around the Proposal, particularly that it may weaken protection of the right to privacy and data protection and will add to an already complex set of provisions across both the EU and Member States' law relating to health data.	Joint Opinion
European Commission proposal: harmonised rules on artificial intelligence (AI) for medical devices in the EU	The European Commission has published an explanatory memorandum laying out a proposal for harmonised rules on artificial intelligence (Artificial Intelligence Act), with a particular focus on medical devices in the EU. The medtech market is given particular consideration, given the potential regulatory overlap of the Artificial Intelligence Act with other regulatory frameworks applicable for medical devices and IVDRs.	Explanatory Memorandum
EU: EMA and HMA issue statement on interchangeability of EU-approved biosimilars	On 19 September 2022, the EMA and the Heads of Medicines Agencies (HMA) issued a statement to clarify that an EU-authorised biosimilar medicine should be regarded as interchangeable with its reference product or with a biosimilar of that same reference product. The press release explains that the intention is to clarify an EU-wide position on interchangeability of biosimilars in order to provide certainty for healthcare professionals and patients within member states.	EMA and HMA statement Press release

Country updates

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Belgium

Koen Devos
Partner
T: +32 2 737 93 60
koendevos@eversheds-sutherland.com

Caroline Schell
Senior Associate
T: +32 2 737 93 53
carolineschell@eversheds-sutherland.com

Stefanie Dams
Junior Associate
T: +32 2 737 93 64
stefaniedams@eversheds-sutherland.com

Title	Summary	Date	Links
Belgian Health Care Knowledge Centre published a study on compulsory licensing for expensive medicines	On 14 June 2022, the Belgian Health Care Knowledge Centre ("**KCE**") published a report on compulsory licensing for expensive medicines. The KCE is a research institute funded by the Belgian federal government, which provides scientific advice on topics related to health care. The study commissioned by the Health and Equal Opportunities Committee in the context of the review of a legislative proposal to facilitate granting compulsory licences in the interests of public health. The study assesses whether compulsory licenses for medicines and treatments sold at excessive prices are feasible and/or effective. The report stresses some legal and economic challenges, such as the fact that patents stimulate and reward innovation; and that compulsory licensing could have negative consequences for a small country like Belgium; but also that compulsory licensing could cause practical problems related to production capacity, access to raw materials, the 'reasonable remuneration' to be paid to the patent holder, etc. The study also provides some policy recommendations - e.g., to develop a robust, transparent and coherent policy on prices and reimbursement of medicines (preferably coordinated with other EU countries); and to consider valuable alternative measures, including the application of competition law, promoting socially responsible licences for inventions emerging from public research institutions and university centers and elaborating the pharmacy exemption.	23 June 2022	Report (English)
Law of 15 June 2022 on *in vitro* diagnostic medical devices transposes Regulation (EU) 2017/746 into Belgian law	The Law of 15 June 2022 on *in vitro* diagnostic medical devices (the "**In Vitro Diagnostic Law**") was published in the Belgian Official Gazette on 30 June 2022. It came into force on the same day, except in relation to certain devices for which entry into force in scheduled for 26 May 2023, 2024, 2025 and 2027, respectively. The In Vitro Diagnostic Law is a transposition and implementation of Regulation (EU) 2017/746. The text aims to ensure the smooth functioning of the internal market for *in vitro* diagnostic medical devices, taking into account a high level of protection of health for patients and users.	30 June 2022	Law (Dutch)/ (French)

Belgium

Koen Devos
Partner
T: +32 2 737 93 60
koendevos@eversheds-sutherland.com

Caroline Schell
Senior Associate
T: +32 2 737 93 53
carolineschell@eversheds-sutherland.com

Stefanie Dams
Junior Associate
T: +32 2 737 93 64
stefaniedams@eversheds-sutherland.com

Title	Summary	Date	Links
Law of 15 June 2022 on *in vitro* diagnostic medical devices transposes Regulation (EU) 2017/746 into Belgian law continued.	Furthermore, it is intended to set high standards of quality and safety for *in vitro* diagnostic medical devices, for example by ensuring that data generated in performance studies is reliable and robust and that the safety of subjects participating in such studies is protected. The In Vitro Diagnostic Law provides for supervision of notified bodies, risk classification, conformity assessment procedures, performance studies and clinical evaluation, vigilance and market surveillance, and transparency and traceability of *in vitro* diagnostic medical devices.		
Healthcare providers are required to offer at least one electronic means of payment to their patients	As of 1 July 2022, Belgian law requires all undertakings to offer at least one electronic means of payment to their customers (*Cfr.* Article VI.7/4 of the Belgian Code of Economic Law). This obligation applies to all undertakings, i.e. all natural or legal entities pursuing an economic aim on a long-term basis (including their associations). Hence, healthcare providers (such as doctors, dentists and pharmacists) are also covered by this requirement. Healthcare providers are nevertheless free to decide which electronic payment method suits them best: fixed or portable payment terminals (e.g. via Bancontact), contactless payments by smartphones (e.g. via Payconiq), etc. This obligation does not imply that healthcare providers are now free to refuse cash payments. Cash must always be accepted on the basis of the status as legal tender. Also, healthcare providers are not allowed to charge more when the patient decides to pay electronically.	1 July 2022	Law (Dutch)/ (French)
Flemish Decree of 24 June 2022 provides technical provisions relating to Flemish health policies	The Flemish Decree of 24 June 2022 containing various provisions on the policy domains of Flemish social protection, health prevention, general hospitals, health and residential care was published in the Belgian Official Gazette on 15 July 2022. The legislation provides some technical adjustments to various decrees relating to health policies, and mainly focuses on solving existing legal problems and bringing legislation in line with the reality in the field.	15 July 2022	Decree (Dutch)

Country updates

China

Cedric Lam
Partner
T: 2186 3202
cedriclam@eversheds-sutherland.com

Roderick Lai
Partner
T: 2186 3264
rodericklai@eversheds-sutherland.com

Gabrielle Honey
Senior Associate
T: 2186 3253
gabriellehoney@eversheds-sutherland.com

Koon-yiu Tse
Associate
T: 2186 3288
koon-yiutse@eversheds-sutherland.com

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Latest Supreme People's Court ("SPC") decision on a reverse payment pharmaceutical patent settlement agreement	The SPC handed down its first decision on a reverse payment settlement agreement in an antitrust context in a landmark patent infringement appeal case, *AstraZeneca AB v. Jiangsu Aosaikang Pharmaceutical Co., Ltd*. The decision is significant not only because it is the first of its kind, but also because the antitrust review was initiated by the SPC of its own accord. The SPC elucidated the definition of a "*reverse payment settlement agreement*" in a pharmaceutical patent context – where a patentee undertakes to provide direct or indirect compensation to a generic applicant (including by way of disguised compensation where the patentee reduces any detriment sustained by the generic applicant), in consideration for the generic applicant undertaking not to challenge the validity of the relevant patent, or to defer entry into the market of the patented drug. As such, a reverse payment settlement agreement may in effect exclude or restrict competition, thereby possibly constituting a monopoly agreement. The SPC opined that pharmaceutical patent cases between patentees and generic applicants involving settlement agreements which display features of a "reverse payment settlement agreement" should warrant preliminary antitrust review by the relevant court pursuant to the PRC *Anti-Monopoly Law*.	Feb 2022	AstraZeneca AB v. Jiangsu Aosaikang Pharmaceutical Co., Ltd. (2021) (only available in simplified Chinese)
National Medical Products Administration ("NMPA") issues implementation plans for cross-border manufacture of drugs and medical devices in Greater Bay Area ("GBA")	On 29 June 2022, the NMPA issued two Implementation Plans that provide guidelines for Hong Kong and Macao-based marketing authorization holders ("**MAHs**") to contract manufacture drugs and medical devices in the Mainland cities in the Greater Bay Area GBA. Under the nationwide drug MAH system and medical devices MAH system, marketing authorization certificates and manufacturing permits for both drugs and medical devices are separated, allowing MAHs to outsource manufacturing to a contract manufacture organization ("**CMO**"), although in practice this was difficult to achieve due to the need to register drugs and devices domestically. The Implementation Plans introduce a special arrangement to allow Hong Kong and Macao enterprises that have a drug market access permit or medical device marketing permit in Mainland China to contract with CMOs in the GBA without having to register their drugs or medical devices domestically. The Implementation Plans also provide for a clear application process for enterprises who wish to make use of this arrangement.	Jun 2022	NMPA's Announcement on the Implementation Plans (only available in simplified Chinese)

Country updates

China

Cedric Lam
Partner
T: +852 2186 3202
cedriclam@eversheds-sutherland.com

Roderick Lai
Partner
T: +852 2186 3264
rodericklai@eversheds-sutherland.com

Gabrielle Honey
Senior Associate
T: +852 2186 3253
gabriellehoney@eversheds-sutherland.com

Koon-yiu Tse
Associate
T: +852 2186 3288
koon-yiutse@eversheds-sutherland.com

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National Medical Products Administration ("NMPA") issues Rules on Administration of Vaccine Manufacturing and Distribution ("RAVMD")	The NMPA issued the RAVMD with effect from 8 July 2022. The RAVMD clarifies the respective responsibilities of marketing authorization holders ("**MAH**") and the regulatory authorities stipulated under the PRC *Drug Administration Law* and *Vaccine Administration Law*. The key regulations include: — **Major responsibilities of the Vaccine MAHs** include ensuring safety, effectiveness, quality control and legality of market circulation of vaccines (both inhouse/outsourced manufacturing); reporting obligations on key quality concerns. — **Administration of outsourced manufacturing:** To limit segmented manufacturing, MAHs are expected to have the capacity to manufacture the vaccine themselves; if demand exceeds production capacity such that it is necessary to outsource production, the MAH will need to seek approval from the local drug regulatory authority before contracting out any manufacturing process. — **Prohibition on re-importation of foreign vaccines:** The RAVMD forbids the distribution of vaccines manufactured for foreign export within Mainland China and any subsequent re-importation of such vaccines into Mainland China.	Jul 2022	NMPA's Announcement (only available in simplified Chinese)
First decisions of patent infringement disputes with significant nationwide influence	One of the most important amendments to the PRC *Patent Law* that came into effect in June 2021 was that the China National Intellectual Property Administration ("**CNIPA**") was given jurisdiction to adjudicate "patent infringement disputes with significant nationwide influence". The CNIPA issued its first such decisions in Q3 2022. These decisions concerned claims by Boehringer Ingelheim, against two companies, Guangdong HEC Pharmaceutical Co., Ltd. and Yichang HEC Changjiang Pharmaceutical Co., Ltd. ("**HEC Entities**"), for infringing its patent covering the active ingredient of Linagliptin, a drug used to treat type II diabetes mellitus. The CNIPA considered these cases have significant nationwide influence because the HEC Entities were listing and selling their generic version of Linagliptin via a vast number of government-administered public resources trading platforms, crossing 24 local provincial administrative regions in China. The CNIPA ordered the HEC Entities to cease their infringing acts immediately.	Jul 2022	CNIPA's Announcement (only available in simplified Chinese)
World's first inhaled COVID vaccine approved for use in China	On 4 September 2022, the NMPA approved the Recombinant COVID-19 Vaccine (Adenovirus Type 5 Vector) for Inhalation ("**Convidecia Air™**"), the world's first inhaled COVID vaccine, produced by CanSino Biologics Inc. ("**CanSinoBIO**") to be used as a booster dose for emergency purposes in the PRC. Under PRC law, in the event of particularly severe public health or other emergency situations that would pose a serious threat to the public, the NMPA can approve the use of vaccine for emergency purposes within a certain scope and duration. Most vaccines are administered through intramuscular injection. The Convidecia Air™ provides a "non-invasive" option, making use of a nebulizer that changes liquid into an aerosol which is subsequently inhaled through the mouth.	Sep 2022	CanSinoBIO's SHEX Announcement (only available in simplified Chinese)

Czech Republic

Petra Kratochvílová
Counsel
T: +420 255 706 561
petra.kratochvilova@eversheds-sutherland.cz

Alena Šíchová
Associate
T: +420 255 706 557
alena.sichova@eversheds-sutherland.cz

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Relief from administrative burden and simplification of regulation in the cultivation of cannabis, especially cannabis for medicinal use	A decree on the cultivation and processing of cannabis plants for medicinal use came into force at the end of August. This decree responds to an amendment to the Act on Addictive Substances, which, among other things, increased the limit of THC contained in technical cannabis to 1%. The aim of regulating the process of growing, harvesting and processing the plant is to guarantee the necessary quality so that the substances derived from the plant can be further used for medicinal purposes. The grower must put in place a quality management system which includes, in particular, hygiene standards and staff training requirements. The Decree also lays down requirements for the premises of the cultivation plant and its equipment, the material used for cultivation, the handling and storage of the harvested material. The entire cultivation process must be documented and recorded in detail and the cultivation facility properly secured.	27 August 2022	Link to decree (Czech only)
Advertisement promoting vitamin C infusions	Some health care facilities in the Czech Republic are promoting vitamin C infusions in a significant way, especially through the internet and social networks. Only one medicinal product containing vitamin C for infusion is registered in the Czech Republic, and its dispensing is subject to prescription. For prescription-only medicinal products, the Advertising Regulation Act permits advertising targeted only at professionals, i.e. persons authorised to prescribe or dispense medicinal products, and not at the consumer. Advertising aimed at the general public is therefore not permitted under the Advertising Regulation Act and is an offence punishable by a fine of up to CZK 2 million.	September 2022	Přehled právních předpisů v oblasti léčiv – Ministerstvo zdravotnictví (mzcr.cz)

Germany

Tobias Maier
Global Co-Lead of Health and Life Sciences
T: +49 89 54565 262
tobiasmaier@eversheds-sutherland.com

Magdalena Kotyrba-Hagenmaier
Principal Associate
T: +49 89 54565 262
magdalenakotyrba@eversheds-sutherland.com

Malte Scheel
Associate
T: +49 89 54565 230
maltescheel@eversheds-sutherland.com

Title	Summary	Date	Links
Establishing health kiosks across Germany	The Government is planning to introduce health kiosks throughout Germany (approx. 1,000 kiosks). The main purpose of the kiosks is to improve access to care for patients with special support needs and to coordinate care, particularly for those in socially disadvantaged regions. These health kiosks will: — offer low-threshold consultations which shall provide fast, competent, but unbureaucratic help — provide medical treatment, prevention and health promotion services and guidance on how to use them — promote the health literacy and understanding of people with special support needs and encourage them to lead a healthy lifestyle The kiosks are to be financed primarily by statutory and private health insurance funds, while the municipalities are to set up and run the health kiosks.	August 2022	Press release by the German Ministry of Health
Regulations on triage	On 24 August 2022, the Cabinet approved the draft of a second law amending the Infection Protection Act, which is intended to regulate triage in a special emergency situation. The draft law takes into account criteria such as equal treatment, current and short-term survival probability, exclusion of EX post triage and the multiple eye principle, among others. If there is insufficient intensive care treatment capacity, the current and short-term probability of survival is the decisive criteria for the allocation decision.	August 2022	Proposal for 2nd Amendment of the Infection Protection Act Press release by the German Ministry of Health

Germany

Tobias Maier
Global Co-Lead of Health and Life Sciences
T: +49 89 54565 262
tobiasmaier@eversheds-sutherland.com

Magdalena Kotyrba-Hagenmaier
Principal Associate
T: +49 89 54565 262
magdalenakotyrba@eversheds-sutherland.com

Malte Scheel
Associate
T: +49 89 54565 230
maltescheel@eversheds-sutherland.com

Title	Summary	Date	Links
Strengthening Germany as a location for medical technology announced in the coalition agreement	The Government announced various plans for the coming years which should be monitored: — Health Care Security Act: This is intended to ensure efficient and decentralized stockpiling of medicines and medical products. — Health Data Utilization Act: This aims to improve the use of scientific data. To this end, the aim is to establish a decentralized research infrastructure in which telemedical services, including prescriptions for medicines, remedies and aids, as well as video consultations, teleconsultations, telemonitoring and telephone medical care, are strengthened. — The Government has a focus on solving care problems, by continuing with the digitization strategy in healthcare and nursing. — Bureaucracy Relief Act: This aims to reduce bureaucracy and speed up decisions by the self-governing authorities. The strengthening of innovation promotion and financing and, at the same time, the reduction of bureaucracy is intended to benefit small and medium-sized enterprises in particular. In particular the Health Data Utilization Act in conjunction with the EHDS may have a huge impact for companies involved in research.	By 2025	BVMED summary of legislative plans

Hong Kong

Cedric Lam
Partner
T: +852 2186 3202
cedriclam@eversheds-sutherland.com

Roderick Lai
Partner
T: +852 2186 3264
rodericklai@eversheds-sutherland.com

Gabrielle Honey
Senior Associate
T: +852 2186 3253
gabriellehoney@eversheds-sutherland.com

Koon-yiu Tse
Associate
T: +852 2186 3288
koon-yiutse@eversheds-sutherland.com

Title	Summary	Date	Links
Penalty provision on operation of day procedure centre ("DPC") without licence under the *Private Healthcare Facilities Ordinance* ("PHFO") comes into effect	The penalty provision on the operation of a DPC without a licence under the PHFO took effect on 30 June 2022. Under these provisions, operating a DPC, which refers to "any premises that is used or intended to be used for carrying out scheduled medical procedures on patients without lodging but which does not form part of a hospital", without a licence will be treated as an offence and the offender will be liable on conviction to a fine of level 6 (HKD100,000) and imprisonment for 3 years.	June 2022	Government Press Release
Department of Health's Office for Regulation of Private Healthcare Facilities ("ORPHF") issues guidance notes for management of communicable disease outbreaks in private hospitals	The ORPHF issued Guidance Notes for private hospitals licensed under the *Private Healthcare Facilities Ordinance* (Cap.633), providing guidance on the management of communicable disease outbreaks, including notification and investigation procedures. Failure to comply with these requirements may lead to regulatory action. The actions taken by the ORPHF will depend on the risk level of non-compliance and range from general advice and requirement notices to the suspension of facility services and the cancellation of licences.	July 2022	Guidance Notes
Monkeypox included as a statutorily notifiable disease	The *Prevention and Control of Disease Ordinance* (Cap.599) *and* the *Prevention and Control of Disease Regulation* (Cap.599A) have been amended to include monkeypox as a statutorily notifiable disease. As such, notification of suspected or confirmed cases of monkeypox is now required by law and the monthly notification figures will be available on the Centre for Health Protection website for the prompt control of the monkeypox infection.	July 2022	Government Press Release

Netherlands

Eline van Nimwegen
Senior Associate
T: +31 20 5600 542
elinevannimwegen@eversheds-sutherland.com

Bas Peper
Associate
T: +31 6 3820 3697
baspeper@eversheds-sutherland.com

Title	Summary	Date	Links
Dutch Consumer and Market Authority (*'ACM'*) clarifies competition rules for healthcare ICT Markets	The draft guidance document (*'Goedwerkende markten voor zorg-ICT'*) provides clarity to healthcare ICT companies and healthcare institutions to make markets for healthcare ICT systems work better. The guidance clarifies the competition rules for parties active in healthcare ICT markets and also contains descriptions of which behaviours are prohibited. The ACM aims to finalize the guidance document this autumn.	1 July 2022	ACM Guidance provides clarify on competition rules for healthcare ICT markets
New annual figures of the Health Care Transparency Register	The new annual figures of the Healthcare Transparency Register Foundation show that the total value of reported financial relationships between HCPs, HCOs and patient organisations on the one hand and suppliers of medicines and medical devices on the other was about the same in 2021 as in 2020. In total, a total value of over €83 million was reported last year.	15 July 2022	The Healthcare Transparency Register in 2021
Investigation into Dutch Healthcare Transparency Register	Joint journalistic investigation of *NOS* and *Nieuwsuur* into the Dutch Healthcare Transparency Registry – the register in which payments from the medical industry to HCPs must be reported – shows that the register is incomplete and contains flaws. In a response, the Healthcare Transparency Registry Foundation said it would investigate further the technical shortcomings in the register. This may ultimately impact the transparency rules and/or the way interactions are to be reported in the Netherlands.	15 September 2022	Investigation into Healthcare Transparency Register

Poland

Marta Gadomska-Gołąb
Partner
T: +48 510 087 782
marta.gadomska-golab@eversheds-sutherland.pl

Jowita Prokop
Associate
T: +48 506 687 585
jowita.prokop@eversheds-sutherland.pl

Title	Summary	Date	Links
Drug prices may increase after the reform of the reimbursement system	A report summarizing industry concerns about the new draft law on reimbursement has been published. The main concerns set out in the report are: — a significant increase in prices due to the change in the value of the flat fee from 3,20 PLN to 0,2% of the minimum wage for work — the possibility of a unilateral change in the payment for drugs by the Health Minister Moreover, new margins for pharmaceutical wholesalers are to be introduced.	August 2022	https://legislacja.gov.pl/projekt/12348505/katalog/12799488#12799488 (Polish only)
Stricter MAH obligations on quality testing	From 2 September 2022, stricter reporting obligations of MAH have been introduced when a new drug is placed on the market, the Polish Registration Office must be informed when a sample is sent for quality testing. Penalties for non-compliance can amount to PLN 100.000 (EUR 21.000) and PLN 300.000 (EUR 63.000), respectively.	September 2022	https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20220001733 (Polish only)
Stricter control over pharmacies	From 1 September 2022, the President of the National Health Fund concludes and settles contracts for reimbursement drugs, FSMP and prescription medical devices. No refund will be made if the pharmacy does not provide the correct information. The President may impose a penalty on pharmacies or charge interest. A new contract template has also been introduced.	September 2021	https://legislacja.rcl.gov.pl/projekt/12363702/katalog/12909059#12909059

Portugal

Margarida Roda Santos
Partner, Head of Life Sciences and IP
T: +351 21 357 75 31
mrodasantos@eversheds-sutherland.net

Paulo Sampaio Neves
Principal Associate
T: +351 21 357 75 31
psampaioneves@eversheds-sutherland.net

Title	Summary	Date	Links
Information Circular issued by INFARMED (Portuguese Health Products Regulator) on the application of the Regulation on Medical Devices for *in vitro* diagnosis	Notwithstanding the Regulation (UE) no. 2017/746 coming into force, INFARMED provided the following guidance relating to the national obligations which remain in force: — registration of *in vitro* diagnostic medical devices by authorised manufacturers and wholesale distributors in accordance with current SIDM registration procedures; — Notification of manufacturing activity and wholesale distribution according to current procedures, where the review is ongoing; — Notification of serious incidents and corrective security actions, according to current procedures, but in accordance with the deadlines defined in the Regulation.	26 May 2022	Information Circular on the surviving local rules on Medical Devices for *in vitro* diagnosis (Portuguese only)
Information Circular issued by INFARMED regarding a new Regulation on allergen medicines for a specific patient	The new local new Regulation on allergen medicinal products for a specific patient has been published to simplify the registration process and commercialization of this type of product. Manufacturers, or their representatives, of allergen medicinal products shall submit to INFARMED an online request for simplified registration of each mother-solution submission within 6 months of the Resolution entering into force. It is not necessary to submit a new application for registration for the entities that made an application for simplified registration in accordance with local Resolution 873/2013 of March 6.	7 June 2022	Information Circular on the new regulation on allergen medicines (Portuguese only) New Regulation on allergen medicines (Portuguese only)

Portugal

Margarida Roda Santos
Partner, Head of Life Sciences and IP
T: +351 21 357 75 31
mrodasantos@eversheds-sutherland.net

Paulo Sampaio Neves
Principal Associate
T: +351 21 357 75 31
psampaioneves@eversheds-sutherland.net

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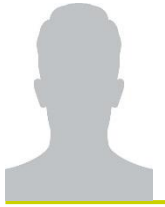
Information Circular issued by INFARMED clarifying the affixing of self-adhesive labels on the labelling of cosmetic products	Considering paragraph 1 article 19 of the Regulation (EC) 1223/2009 of 30 November, INFARMED clarifies that the inclusion of new information on the labelling by placing self-adhesive labels on the original labelling of the container and/or packaging can only be done by the distributor and to comply with the local language requirements regarding the information contained in paragraphs 1 b), c), d) and f) of article 19 of the Regulation. Therefore, INFARMED states that no self-adhesive label may be affixed to the original labelling of cosmetic products which modifies any of the above mentioned mandatory labelling.	9 June 2022	Information Circular on the labelling of cosmetic products by INFARMED (Portuguese only)
Updated list of medicines whose export or distribution to the other EU Member States requires prior notification to INFARMED	The availability of medicines is controlled by INFARMED and one of the measures that aims to ensure the balance between the regular supply of the market and the export of medicines is the compliance with the local Regulation on prior notification of medicine transactions abroad. The list of medicines whose export or distribution to other EU Member States requires prior notification to INFARMED has therefore been updated. Updated by Resolution No 096/CD/2022 of 23 September, the mentioned list has the following as criteria: percentage of consumption satisfied; percentage of prescription satisfied; number of absences reported; relationship between export/absences reported; number of drugs marketed with the same CNPEM; critical INN; narrow therapeutic margin. The notification is made electronically on the SiExp platform by AIM holders, distributors and intermediaries and pharmacies.	28 September 2022	Medicine list update from INFARMED (Portuguese only) Control of the availability of medicines

Spain

Kiko Carrión
Partner
T: +34 914 294 333
kcarrion@eversheds-sutherland.es

Marta González
Partner
T: +34 914 294 333
mgonzalez@eversheds-sutherland.es



Carmen Gimeno
Lawyer
T: +34 914 294 333
cgimeno@eversheds-sutherland.es

Title	Summary	Date	Links
Judgment of the Madrid High Court of Justice. Contentious Chamber, No. 724/2022 dated 13 July 2022	A gynecology institute was fined €90,001 for committing a serious infringement involving the online sale of a medicinal product (human papillomavirus vaccine). On its website, the entity offered a voucher that included a consultation with a doctor for the prescription of the vaccine and its administration.	Published 30 September 2022	Link to Judgment (Spanish only)
CEFI, (Centro de Estudios para el Fomento de la Investigación) organised on 26, 27 and 28 September, the Course on Pharmaceutical Law, Biomedicine, Medicines and Public Health.	The important event, in which our partners Kiko Carrión, Marta González and Alberto Dorrego participated, was attended by César Hernández (General Director of the Spanish Basic Portfolio of Services of the National Health System and Pharmacy) who declared that the proposal of the Spanish Law of Guarantees and Rational Use of Medicines will become public by the end of this year.	27th September 2022	Link to event programme and content (Spanish only)

Sweden

Linda Kempe
Partner
T: +46 76 623 03 18
lindakempe@eversheds-sutherland.se

Ida Malmén
Associate
T: +46 72 252 61 00
idamalmen@eversheds-sutherland.se

Title	Summary	Date	Links
Governmental investigation regarding preparations with a low content of THC	At the end of 2021, the Swedish Medical Products Agency (MPA) was commissioned by the Government to investigate the developments within preparations with a low content of tetrahydrocannabinol (THC) and related areas on national, EU and international level, and to work to achieve coordination between national authorities and law enforcement bodies. Low-THC-content-preparations have in recent years given rise to demarcation issues between widely divergent product categories, including agricultural and medicinal products, foodstuffs, and cosmetics, as well as legal uncertainty in respect of EU level product-categorization versus potential illegality under national drug legislation. On 29 August 2022, the MPA published an interim report describing the work of the authorities concerned and the current legal positions of low-THC-content substances in different product categories. The authorities generally stated that their work would be facilitated by consensus in the EU regarding low-THC-content substances. Today, products that are legally produced and put on the market within a certain product category in one Member State may be categorised as illegal in another Member State. The report also describes challenges that law enforcement bodies face as regards analysing these substances and determining in a reliable way whether seized products constitute narcotics. The MPA are due to present a final review report in September 2023.	29 August 2022	The MPA's webpage The interim report (Swedish only)

Country updates

United Kingdom

Elizabeth Graves
Global Co-Lead of Health and Life Sciences
T: +44 1223 44 3761
elizabethgraves@eversheds-sutherland.com

Sasha Willmott
Principal Associate
T: +44 1223 44 3856
sashawillmott@eversheds-sutherland.com

Liz Fitzsimons
Partner
T: +44 1223 443808
lizfitzsimons@eversheds-sutherland.com

Ben Johnson
Associate
T: +44 1223 443661
benjohnson@eversheds-sutherland.com

Title	Summary	Date	Links
Government intends to revoke EU-derived legislation by 31 December 2023	On 22 September 2022, the UK Government published a first draft of the Retained EU Law (Revocation and Reform) Bill, which aims to revoke EU-derived subordinate legislation and retained direct EU legislation by 31 December 2023, unless otherwise preserved. This could lead to significant changes in the law. In terms of employment law there could be significant changes in terms of TUPE, holiday/working time, agency workers and fixed term employee rights in the UK. Further detail and clarification from the Government on how this will be achieved is eagerly anticipated.	22 September 2022	Retained EU Law (Revocation and Reform) Bill
UK Government Policy Paper 'Data saves lives: reshaping health and social care with data'	This aims to ensure health and care professionals are given the information they need to provide the best possible healthcare; to empower researchers with the data they need to develop life-changing treatments, diagnostics, models of care and insights and to develop the right technical infrastructure to do so.	15 June 2022	Policy Paper
CMA issues guidance on vertical agreements	The Competition and Markets Authority ("CMA") has now published its final form guidance on the UK Competition Act 1998 (Vertical Agreements Block Exemption) Order 2022 ("VABEO") which came into force on 1 June 2022, replacing the retained EU law version of the Vertical Agreements Block Exemption Regulation. The Guidance explains how the CMA applies the rule against anti-competitive agreements (the Chapter I prohibition) to vertical agreements (meaning agreements between businesses operating at different levels of the supply chain, e.g. suppliers of raw materials, manufacturers, wholesalers and retailers). It is intended to help businesses assess their vertical agreements and establish whether they benefit from the block exemption provided by the VABEO or otherwise comply with competition law.	12 July 2022	Guidance

United Kingdom

Elizabeth Graves
Global Co-Lead of Health and Life Sciences
T: +44 1223 44 3761
elizabethgraves@eversheds-sutherland.com

Sasha Willmott
Principal Associate
T: +44 1223 44 3856
sashawillmott@eversheds-sutherland.com

Liz Fitzsimons
Partner
T: +44 1223 443808
lizfitzsimons@eversheds-sutherland.com

Ben Johnson
Associate
T: +44 1223 443661
benjohnson@eversheds-sutherland.com

Title	Summary	Date	Links
Data Protection and Digital Information Bill introduced to Parliament	The Data Protection and Digital Information Bill (the "Bill"), formerly referred to as the Data Reform Bill, has been introduced to Parliament. This follows the Government's response to its consultation, 'Data: a new direction', published in June. As mentioned in the previous edition of this newsletter, the Bill is intended to ease burdens on businesses, boost the economy and increase innovation creating a new more flexible "trusted UK data protection framework" centred on privacy outcomes. The first reading of the Bill took place on 18 July 2022. A date for the second reading, which was originally due to take place on 5 September 2022, is due to be announced. At the Conservative Party Conference on 3 October 2022 the newly-appointed Secretary of State for Digital, Culture, Media and Sport, Michelle Donelan, stated that the Government is reconsidering the UK's approach to data protection and indicated a move away from the UK GDPR regime in favour of a "business and consumer-friendly, British data protection system" with a view to removing "unnecessary red tape" on businesses. It is therefore possible that additional (perhaps significant) changes may be made to the Bill in due course.	3 October 2022	Current version of the Bill Michelle Donelan's Speech

United States of America

Bill Warren
Partner and Lead of Health and Life Sciences, US
T: +1 404.853.8081
BillWarren@eversheds-sutherland.us

Lindsay Kriz
Associate
T: +1 404.853.8323
lindsaykriz@eversheds-sutherland.com

Title	Summary	Date	Links
Bipartisan Group Aims to Halt 'Downward Slide' of IP System	Experts have become concerned that the United States' intellectual property system is currently in a "downward slide," which may leave the United States susceptible to technological inferiority in the coming years. The bipartisan coalition, formed in part by two former US Patent and Trademark Office (USPTO) directors and a former Federal Circuit Judge, seeks to educate lawmakers as to the importance of intellectual property and its connection to an innovative economy, with the hope of preventing an economically damaging deterioration of the US IP system.	September 2022	Link to pdf article
US Patent Trial and Appeal Board Issued Sanctions 31 Times for IPR Abuse	In response to Senators Thom Tillis and Mazie Hirono questioning the authority of the USPTO to punish those filing inter partes review (IPR) petitions in bad faith, USPTO Director Kathi Vidal wrote a letter detailing sanctions that have been issued in the last decade since the inception of the America Invents Act (AIA). 31 sanctions have been made against parties abusing the IPR system.	September 2022	Link to pdf article
Moderna sues Pfizer/BioNTech over COVID patent: 3 Key Questions	As the COVID-19 pandemic is seemingly coming to an end, experts question whether Moderna's recent lawsuits against Pfizer alleging infringement of patents related to mRNA vaccine technology will be successful, or if Modern has jumped the gun in view of its 2020 and 2022 patent pledges. This articles summarises the 3 key questions as the infringement lawsuits progress.	August 2022	Link to pdf article

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Contacts

Elizabeth Graves
Global Co-Lead of Health and Life Sciences

T: +44 1223 44 3761
elizabethgraves@eversheds-sutherland.com

Tobias Maier
Global Co-Lead of Health and Life Sciences, Germany

T: +49 8 95 45 65 14 4
tobiasmaier@eversheds-sutherland.com

Bill Warren
Partner and Lead of Health and Life Sciences, US

T: +1 404.853.8081
BillWarren@eversheds-sutherland.us

Editor

Sasha Willmott
Principal Associate

T: +44 1223 44 3856
sashawillmott@eversheds-sutherland.com

EVERSHEDS SUTHERLAND

eversheds-sutherland.com