EVERSHEDS SUTHERLAND

Updates in a heartbeat

Your quarterly global Health and Life Science newsletter

Editors' Note

Welcome to our 7th edition of Updates in a Heartbeat. Our newsletter provides you with a compilation of key legal developments from the last few months.

A big theme in this latest update is regulatory reform. A number of regulatory authorities across the world, notably in the EU and the UK, have recently announced wide scale general reform proposals for medicines and medical devices regulations to provide better and more efficient outcomes for patients. A key part of the reform agenda is the clinical trials regulatory framework where the UK has recently announced a series of proposed changes to make inward investment more attractive. There are also various initiatives across Europe regarding regulation of healthcare professionals and pharmacies and specific initiatives regarding access to cannabis based drug products.

The accelerating trends of digitisation and rapid advancements in Artificial Intelligence technology are also major drivers of change. The UK government recently released a White Paper outlining its overall approach to AI regulation and to distinguish its approach from the current EU proposals regarding the AI Act. The COVID-19 experience also demonstrated the potential impact that mHealth (or digital health) can have on healthcare delivery and so it is no surprise that a number of countries such as Ireland and Sweden have recently announced various initiatives.

We are closely monitoring these and other developments as they make their way through the system. We expect a lot of the reform agenda will likely come to a head in 2024. We also anticipate that we will start to see some the much-lauded applications of digital health and AI systems finally make their way from the board room to the patients. These are exciting times indeed for the life sciences industry.

If you have any questions or would like to discuss any of the topics in this edition, please do contact us, we would love to hear from you.

Editors

Naomi Bellaiche
Associate, France

T: +33 1 55 73 41 34
naomibellaiche@
eversheds-sutherland.com

Melanie Dubreuil-Blanchard
Associate, France

T: +33 1 55 73 42 09
melaniedubreuil-blanchard@
eversheds-sutherland.com


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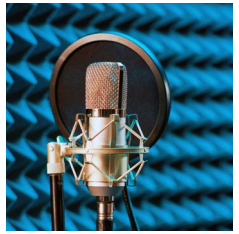
Topic Updates



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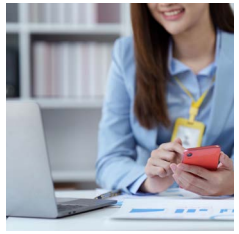

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Advertising and Promotion

Title	Summary	Date	Links	Country
New regulation of social network influencers in the Life Sciences Sector	On 9 June 2023, France passed a new law which defines a new legal framework for how influencers can communicate on the social networks. This law aims at extending the strict advertising regime applicable to medicines, medical devices and in vitro diagnostic medical devices (MD/IVD-MD) to influencers. Influencers will notably be required to obtain express authorisation from the ANSM to advertise such products and are expressly forbidden from advertising products subject to medical prescription or reimbursed by the health insurance scheme. Failure to comply may lead to a penalty of up to two years' imprisonment and the payment of a fine of up to €300,000.	9 June	LOI n° 2023-451 du 9 juin 2023 visant à encadrer l'influence commerciale et à lutter contre les dérives des influenceurs sur les réseaux sociaux (1) – Légifrance (legifrance.gouv.fr) (in French only)	France

Antitrust

Title	Summary	Date	Links	Country
Revised Block Exemption Regulations on R&D and Specialisation Agreements	The Horizontal Block Exemption Regulations are two Commission regulations that define conditions under which horizontal Research & Development agreements and specialisation agreements are exempted from Art. 101 (1) TFEU. They replace the current 2010 regulations and will enter into force 1 July 2023. The new regulations are accompanied by revised Horizontal Guidelines. These updated legal framework intends to simplify the identification whether contracts follow EU competition law.	1 June	European Commission – Information on horizontal block exemptions	EU

Antitrust

Title	Summary	Date	Links	Country
China fines two pharmaceutical companies for breach of Anti-Monopoly Law	The State Administration for Market Regulation fined Grand Pharma (China) Co., Ltd ("**Grand Pharma**") and WuHan Healcare Pharmaceuticals Co., Ltd. ("**Wuhan Healcare**") ~USD 40million and ~USD 4.9million respectively for breach of the People's Republic of China (PRC) Anti-Monopoly Law. Grand Pharma and Wuhan Healcare were found to have been implementing a monopolistic agreement regarding the sales of the raw materials of two chemicals that restricted the product quantity and sales volume of commodities. Grand Pharma was additionally found to have engaged in implementing tie-in sales or imposing other unreasonable trading conditions without any justifiable causes. Pharmaceutical companies in the People's Republic of China (PRC) should be aware of the tightening of China's anti-monology regime when conducting their operations.	28 May	Notice of decision (in Chinese only) Judgment for Grand Pharma case (in Chinese only) Judgment for Wuhan Healcare case (in Chinese only)	People's Republic of China (PRC)

Artificial Intelligence

Title	Summary	Date	Links	Country
UK AI White Paper	On 29 March 2023, the UK Government published its AI White Paper "A pro-innovation approach to AI regulation", which is in essence a framework intended to increase public confidence and trust in AI while promoting growth and encouraging innovation. A consultation is open until 21 June 2023. We have published various materials discussing recent developments in AI which are available at the accompanying links.	29 March	AI White Paper ES Article: UK government's white paper on AI – innovation balanced with protection from harm ES Webinar: Demystifying generative AI and the legal issues it raises	United Kingdom
	On 11 April 2023, the Information Commissioner's Office ("ICO") published its response to the UK government's AI White Paper, hot off the heels from publishing its own updated guidance on AI and Data Protection on 15 March. The ICO concludes its overall view that it is aligned and supportive of the UK Government's ambitions to support innovation and sustainable economic and societal growth, which align with the ICO's own strategic ambitions set out in their ICO25 strategic plan.	11 April	ICO response to AI White Paper ICO guidance on AI and Data Protection ES Article: AI UK white paper and regulatory guidance – the ICO response	United Kingdom

Clinical Trials and Other Studies

Title	Summary	Date	Links	Country
Update of ICH Guidelines of Good Clinical Practice (GCP)	The ICH E6(R3) draft Guideline on "Good Clinical Practice (GCP)" has reached Step 2 of the ICH process and does contain a new. Annex 1. It aims to provide information on how the guideline concepts are to be applied appropriately to clinical trials. The guideline is applicable to interventional clinical trials of investigational products intended for submission to regulatory authorities, however, it may also be applicable to interventional clinical trials of investigational products not intended to support marketing authorisation applications.	24 May	ICH News	International
New Institute for Clinical Trials in Ireland	A new institute for clinical trials has been launched in the University of Galway, Ireland. The institute, led by Professor Peter Doran, aims to transform and strengthen Ireland's clinical research landscape. Professor Doran has commented that the new clinical trials institute aims to have an impact "locally, nationally and globally". It is hoped that the institute will benefit the health and well-being of people in Ireland and abroad, whilst also addressing the barriers faced by companies in the MedTech sector who wish to conduct clinical trials in Ireland.	31 May	Press release	Ireland

Clinical Trials and Other Studies

Title	Summary	Date	Links	Country
Final report on independent consultation on UK clinical trials	A final report has been published following an independent review of clinical trials in the UK, as well as the Government's response. The report contains 27 recommendations on how to resolve key challenges in conducting clinical trials in the UK, with the Government's response making five headline commitments: – substantially reduce time taken for approval of commercial clinical trials, with the goal of reaching a 60 day turnaround time for all approvals – deliver a comprehensive and mandatory national approach to contracting – provide real time data on commercial clinical activity in the UK – establish a common approach to contacting patients about research – establish clinical trial acceleration networks	25 May	Report and Government response	United Kingdom
HRA pilots tool for storage of human tissue without human tissue consent	The Health Research Authority (HRA) is piloting a tool to help researchers to use surplus human tissue samples without human tissue consent. The tool aims to provide "*greater consistency and guidance*" to support researchers, helping them to consider ethical issues and possible safeguards at an earlier stage of a project, thereby increasing overall efficiency.	30 March	Press release	United Kingdom

Collaborations and Technology Transfer

Title	Summary	Date	Links	Country
High Court interprets royalty payment provisions	In the case of *Eteboxagu AB v Cycle Pharmaceuticals Ltd*, the High Court considered a dispute as to the scope of a royalty payment in the context of a pharmaceutical collaboration. The contract provided for a royalty payment to be calculated as a percentage of "Relevant Revenues", which were defined as "[Defendant's] gross income from the sale of and/or generated by the Product excluding VAT and transport costs". A dispute arose as to whether "gross income" meant income before or after the Defendant had deducted rebates given to customers purchasing the Products. The Court found in favour of the Defendant, namely that it was entitled to deduct the rebates before calculating the royalty payment. This was a matter of contract construction, largely based on the fact that the natural meaning of "income" is monies actually received, and it makes little or no sense for this figure to include monies that are never received (because they have been netted off as rebates). The case acts as a reminder to make it clear what monies are in and out of scope when working out the figure used to calculate royalties.	6 March	Judgment	United Kingdom

Digital Health

Title	Summary	Date	Links	Country
Irish Health Information Bill 2023	The General Scheme of the Irish Health Information Bill 2023 was announced on 25 April 2023 and underwent pre-legislative scrutiny on 10 May 2023. In essence, the Bill aims to modernise and digitise the Irish healthcare system as a whole. Irish Minister for Health, Stephen Donnelly, has commented that "*The purpose of this important legislation is to make sure that patients and staff can benefit directly from the digital transformation of healthcare*".	April/May	Press release	Ireland

Digital Health

Title	Summary	Date	Links	Country
Intensified supervision against manufacturers of medical device software in Sweden	During 2023, the Swedish Medical Products Agency ("MPA") will be initiating several supervisory activities in the area of e-health, including software with a medical purpose to which EU common regulations on medical devices apply. The aim is to ensure that the medical device software available on the Swedish market is safe and meets applicable regulatory requirements and that its manufacturers have the required knowledge of the regulatory framework. According to the MPA, there is a high rate of innovation in the area of e-health that is growing rapidly both within professional health care as well as the home and leisure environments. In light of this, the Agency sees a need for intensified supervision and information activities in relation to software medical devices. The MPA will carry out both proactive and reactive supervision as well as information efforts throughout the year. As a first step, the Agency will gather information to create a situational picture that will serve as basis for the continued activities. This initiative by the MPA concerns software manufacturers in several categories, for example, software that is CE marked according to the medical device regulations, software covered by transitional provisions (so-called legacy products), and software that is not CE marked but has a medical purpose.	25 April	Press release by the MPA (in Swedish only) https://www.lakemedelsverket.se/sv/nyheter/startar-tillsynsaktiviteter-mot-tillverkare-av-medicinteknisk-programvara	Sweden

Healthcare Compliance

Title	Summary	Date	Links	Country
BVMed sets orientation value for hospitality in its Codex Medical Devices	For hospitality of healthcare professionals a new reference value is being introduced. The German Medical Technology Association (Bundesverband Medizintechnologie, BVMed) has determined a value for hospitality in its industry Medical Devices Codex ("Codex Medizinprodukte"). EUR 75 for hospitality now is considered to be socially acceptable in Germany. Medical devices industry to update their healthcare compliance rules and processes.	31 May	BVMed – press release re Update of its Codex Medical Devices (German only)	Germany
China issues Trial Measures for Ethical Review of Science and Technology	On 4 April 2023, the People's Republic of China (PRC) Ministry of Science and Technology sought public comment on the Trial Measures for Ethical Review of Science and Technology (Draft for Comments) on 4 April 2023 ("Trial Measures"). The consultation period ended on 3 May 2023. Amongst other things, the Trial Measures proposed that healthcare institutions, universities, scientific research institutes, and enterprises engaged in life sciences, medicine, artificial intelligence and other technology activities should be the responsible entities for ethical review. The Trial Measures further proposed obligations which responsible entities may need to comply with, such as the obligation to establish an ethics review committee. Clients engaged in the above activities in China should be sure to monitor the development of the Trial Measures.	4 April	China Briefing's news article on the Trial Measures	People's Republic of China (PRC)

Market Access

Title	Summary	Date	Links	Country
EU to allow MHRA to authorise drug placement on the market in Northern Ireland	EU Regulation 2023/1182 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland has been published in the OJEU and entered into force on 21 June. It will apply from 1 January 2025, subject to compliance with certain conditions by the UK. The purpose of the Regulation is to allow imports of British investigational medicinal products into dependent markets (permanently for NI, and for a three year period for other markets) without manufacturing and import authorisation. In the meantime, the MHRA has issued guidance on the centrally authorised products bridging mechanism that will operate to allow patients in Northern Ireland to access novel medicines approved by the MHRA, but not the EMA, prior to 1 January 2025.	21 June	Regulation	United Kingdom
Promotion and sale of energy drinks will be harder	Polish Sejm passed new draft on reimbursement of medicinal products and now the draft will be proceed by Senat. According to the draft persons below 18 years of age will not be able to buy energy drinks in Poland. The sale of Energy drinks in vending machines is to be banned. MPs crossed out initial restrictions on advertising of energy drinks in radio, television, Internet and public spaces. However, they added requirement to label the products with name "energy drink".	13 July	Deputies' bill amending the Public Health Act	Poland

Market Access

Title	Summary	Date	Links	Country
UK Government announces £650 million growth package for life sciences sector	The UK Government has announced a £650 million "war-chest" to boost the UK's life sciences sector as part of its "Life Sci for Growth" package. The package includes (i) £121 million to enhance clinical trials to bring new medicines to patients faster; (ii) up to £48 million to enhance scientific innovation to prepare for future health emergencies; (iii) £154 million to increase the capacity of the UK's biological data bank; and (iv) £250 million to incentivise pension schemes to invest in science and technology firms. The Government also announced plans to re-launch the Academic Health Science Network as "Health Innovation Networks" to bring together the NHS, local communities, charities, academia and industry to share best practice.	25 May	Government press release	United Kingdom
MHRA announces new recognition routes for medicines with seven countries	The Medicines and Healthcare products Regulatory Agency (MHRA) has announced new regulatory recognition routes for medicines will be established using approvals from Australia, Canada, the EU, Japan, Switzerland, Singapore and the US. The recognition route, which are expected to be in place by Q1 2024, will allow the UK to leverage the expertise of other international partners to facilitate quicker access to the UK market for novel medicines.	26 May	Press release	United Kingdom

Market Access

Title	Summary	Date	Links	Country
MHRA announces new regulatory pathway to support access to innovative medical technologies	The MHRA has announced a new regulatory pathway to facilitate development of innovative tech, the Innovative Devices Access Pathway, which is due to launch later this year. It is intended that the pathway will provide innovators and manufacturers with a "multi-partner support service", including targeted scientific advice, to get products to patients sooner. Innovators of medical technologies are now able to register to receive further information ahead of the planned pilot launch. The lessons learned from the pilot will then be used to create *"an end-to-end visible framework that supports innovators generate the evidence they need to achieve regulatory approval, heath technology assessment decisions, and patient access in the NHS"*.	26 May	Press release	United Kingdom
Information Circular issued by INFARMED (Portuguese Health Products Regulator) on the list of medicines which exportation is temporarily suspended	With the aim of ensuring the normalisation of the supply of critical medicines that are in stock break, as well as the medicines that are being supplied under exceptional use authorisation, INFARMED has updated the list of medicine for which export is temporarily suspended.	12 May	Information Circular on the list of medicines which exportation is temporarily suspended (Portuguese only)	Portugal

Market Access

Title	Summary	Date	Links	Country
Royal Decree 192/2023 of 21 March on the regulation of medical devices.	This registration must be carried out prior to the marketing activity through the channel provided for this purpose in the electronic headquarters of the AEMPS (Article 18); (vii) Any manufacturer who places custom-made products on the market shall notify the Register of Persons Responsible for placing them on the market of the AEMPS, through the channel provided for this purpose in the electronic headquarters of the AEMPS. This obligation shall extend to authorized representatives established in Spain (Article 21); (viii) The AEMPS, in addition to the certificates of free sale, may issue export certificates at the request of other economic operators having their registered office in Spain (Article 29); (ix) Clinical investigations carried out to demonstrate the conformity of products are subject to prior authorization by the AEMPS, while in the case of clinical investigations carried out with CE marked products, regardless of their intended purpose, only prior notification of the investigation to the AEMPS will be required. (Articles 31 and 34). The new regulation will adapt the national legislation to the current EU regulations.	23 March	Royal decree	Spain

Pricing and Reimbursement

Title	Summary	Date	Links	Country
Government begins negotiations for a new medicine pricing scheme	The UK Government has entered into negotiations with the pharmaceutical industry on a new branded medicines pricing scheme to replace the voluntary scheme for branded medicines, pricing and access (VPAS). It is hoped that the new scheme will (i) promote better patient outcomes and a healthier population; (ii) support UK economic growth; and (iii) contribute to a financially stable NHS. Negotiations are expected to conclude in Autumn 2023, with the new scheme to start on 1 January 2024.	4 May	Press release	United Kingdom
Bigger profits for wholesalers and pharmacies	Polish Sejm passed new draft on reimbursement of medicinal products and now the draft will be proceed by Senat. Under a new law, it will be possible to reimburse a medicinal products in OTC category. Producers of Polish medicines or Polish active substance can request for financial and non-financial incentives such as: reduction of the administrative fees, shortening the duration of reimbursement approvals, exemption from the negotiation with Economic Committee, etc. The government is planning to increase the statutory margin for pharmaceutical wholesaler and pharmacies. The pharmacist will gain the right to qualify patients to COVID and influenza vaccines.	13 July	Bill amending the act on health care services financed from public funds and the act on reimbursement of medicines, foodstuffs for particular nutritional uses and medical devices	Poland

Pricing and Reimbursement

Title	Summary	Date	Links	Country
Free medicines for young people and elderly	Polish Sejm passed new draft on providing free medicinal products and now the draft will be proceed by Senat. According to the new draft, certain medicines included in the official list will be provided to patient below 18 years of age and above 65 years of age, free of charge.	13 July	Government bill amending the act on health care services financed from public funds and the act on reimbursement of medicines, foodstuffs for particular nutritional uses and medical devices	Poland

Regulatory Reform

Title	Summary	Date	Links	Country
A Pharmaceutical Strategy for Europe	The Commission proposed a new pharmaceutical legislation to revise and replace existing pharma laws. The reform covers two legislative proposals. A new Directive shall provide for requirements of authorisation, monitoring, labelling and regulatory protection, placing on the market and other regulatory procedures for medicinal products. In addition, a new Regulation offers additional rules for medicines authorised at EU level as well as rules on coordinated management of critical shortages and security of supply of critical medicines. According to the current draft, pharmaceutical and life sciences companies will need to adapt to several (potentially challenging) changes in the pharmaceutical legislation.	26 April	European Commission – press release: Commission proposes pharmaceuticals reform for more accessible, affordable and innovative medicines	EU

Regulatory Reform

Title	Summary	Date	Links	Country
Europe's new patent systems launch in June 2023: The Unified Patent Court and the unitary patent	On 1 June 2023, two new patent systems launched in the EU. The new unitary patent (UP) allows protection of inventions in 17 EU Member States by a single patent. The Unified Patent Court (UPC) started its work on the same day. From now on, there are three different ways of resolving patent disputes in Europe: In addition to the existing national litigation systems and the EPO system, the UPC system allows the resolution of both, infringement and validity in one case for multiple countries. The pharmaceutical industry is hoping that the new system will stimulate research, development and investment in innovation as well as boost growth and competitiveness in Europe.	1 June	Website of the UPC EFPIA response to launch of Unitary Patent System in Europe	EU

Regulatory Reform

Title	Summary	Date	Links	Country
Royal Decree 192/2023 of 21 March on the regulation of medical devices.	On Thursday 23 March 2023, came into force the Royal Decree 192/2023, of 21 March (hereinafter, the "Royal Decree"), which regulates medical devices, replacing former Royal Decree 414/1996 of 1 March 1996. Some of the main changes introduced by this Royal Decree are as follows: (i) Non-medical and active implantable products are included within the scope of application; (ii) Information on medical devices must be included at least in Spanish at the time they are made available on the market (Article 5.3); (iii) The concrete requirements for the manufacturing of products by hospitals for their exclusive use by the hospital itself are specified (Article 9); (iv) The necessary requirements on who and how may carry out the reprocessing activity are regulated (Articles 11 to 15); (v) Any economic agent marketing products in Spanish territory, other than custom-made products, must be included in the Marketing Register of the Spanish Agency for Medicines and Medical Devices ("AEMPS") (Article 18); (vi) Any manufacturer who intends to place in the market custom-made products shall notify the Register of Persons Responsible of the AEMPS (Article 21); and, (vii) The AEMPS may issue export certificates at the request of other economic operators having their registered office in Spain (Article 29). The new regulation will adapt the national legislation to the current EU regulations.	23 March	Royal decree	Spain

Regulatory Reform

Title	Summary	Date	Links	Country
New medical professions. Greater restrictions on recruitment	Polish Senat passed the bill on a new bill on certain new medical professions. There will be several new medical professions in Poland, including dental assistant, dental hygienist, speech therapist, nursing assistant, pharmacy technician, massage therapist technician, orthopaedic technician, occupational therapist. The new provisions introduces the specific requirements in relations to the education, language and others, as well as, it introduces requirements on ongoing learning, registration, etc. Those facilities that hire those types of workforce, will need to verify their ability to maintain their position and scope of work.	13 July	Act on Certain Medical Professions	Poland
Hundreds of pharmacies could lose their licences	Polish Senat received a new bill influencing currently held pharmacy permits in Poland. The new law has the potential to open retrospectively completed pharmacy licensing proceedings. Pharmacies may lose licences previously lawfully obtained, as the inspectorate will be entitled to examine the anti-concentration requirements (maximum 4 pharmacies for one entity) for the period prior to the entry into force of the aforementioned requirements. Constitutionalists point out that this is a clear violation of acquired rights. The new regulations could result in the closure of hundreds of pharmacies in Poland.	13 July	Act amending the act on export insurance guaranteed by the State Treasury and certain other acts	Poland

Regulatory Reform

Title	Summary	Date	Links	Country
A year-long wait – China issues the Implementing Rules on the Administration of Human Genetic Resources	Significant updates in the Implementing Rules (the "Rules") on the Administration of Human Genetic Resources ("HGR") have been made, confirming, among other matters that definition of "HGR Information" will exclude clinical data and classification as "foreign entities" will capture institutions under actual control of foreign individuals/entities (e.g., through VIE structure). The Rules ease the once extensive requirements in relation to the ownership of IPRs generated by the People's Republic of China (PRC)-foreign collaboration through the use of Chinese HGRs previously proposed in its draft, allowing greater flexibility in the IPR ownership arrangements of collaborative R&D results between Chinese and foreign parties (e.g. no explicit restriction against foreign entities to solely own IPRs derived from collaborative R&D results). Given the short time frame between the issuance of the Rules and it taking effect, PRC and foreign clients looking to participate in HGR collaborations must take heed of the latest requirements and audit its current mechanism to ensure compliance as soon as possible.	Date of pro-mulgation: 1 June 2023 Effective date: 1 July 2023	State Council Information Office's press release regarding the Rules	PRC
Act no. 9/2023, of 3 March (transposes the Delegated Directive 2022/1326 and amends the Decree-law no. 15/93, of 22 January	Includes new psychoactive substances in the definition of drugs in legal framework applicable to trafficking and consumption of narcotic drugs and psychotropic substances.	3 March	Act no. 9/2023, of 3 March (Portuguese only)	Portugal

Regulatory Reform

Title	Summary	Date	Links	Country
Government Order no. 97/2023, of 31 March (amends the Government Order no. 224/2015, of 27 July and the Government Order no. 126/2018, of 8 May)	Aiming to improve the response in primary health care and to reduce bureaucracy in order to facilitate access to the national health system, the period of validity for prescriptions for medicines and complementary diagnostic and therapeutic resources is extended to 12 months.	31 March	Government Order no. 97/2023, of 31 March (Portuguese only)	Portugal
Transitional period for UKCA marking of medical devices extended	The Medical Devices (Amendment) (Great Britain) Regulations 2023 (SI 2023/627) have been published. These extend the period during which CE-marked medical devices can be placed on the market in Great Britain: – until 30 June 2030 (or expiry of the product's certificate if sooner) for devices that comply with EU MDR or EU IVDR – until 30 June 2028 (or expiry of the product's certificate if sooner) for devices that have a valid certification and/or declaration of conformity under the EU MDD or EU AIMDD The MHRA has updated its guidance to reflect the changes.	27 April	Legislation MHRA	United Kingdom

Regulatory Reform

Title	Summary	Date	Links	Country
The Swedish Medical Products Agency investigates the possibility of introducing pharmacist assortments	The Swedish Medical Products Agency ("MPA") has been commissioned by the government to investigate the possibility of introducing so-called pharmacist assortments in Swedish pharmacies. This would allow the pharmacies to sell certain medicines that normally require a prescription as over-the-counter medicines, subject to mandatory advice from a pharmacist. Pharmacist assortments are already available today in several European countries. A pharmacist assortment may include a great variation of medicines, for example, medicines designed to reverse overdoses of opioids. The MPA are to investigate what effects pharmacist assortments could have on both accessibility and patient safety, as well as on healthcare. The Agency will also look at how a national regulation of pharmacist assortments could be designed. The MPA is to submit their final investigation report to the government on 31 May 2024 at the latest. The Agency stated in their press release that they welcome dialogue with relevant actors along the way.	13 June	The MPA's press release (in Swedish only) The government assignment in full (in Swedish only)	Sweden

Special products

Title	Summary	Date	Links	Country
Public Health (Tobacco Products and Nicotine Inhaling Products) Bill 2023	On 30 May 2023, Irish Minister for Health Stephen Donnelly received approval to bring forward the Public Health (Tobacco Products and Nicotine Inhaling Products) Bill 2023. The Bill provides for the introduction of the following new measures: – a licensing system for the retail sale of tobacco products and nicotine inhaling products – restrictions on the sale of tobacco products and nicotine inhaling products including a blanket ban on the sale of such products to those under the age of 18 – restrictions on the advertising of nicotine inhaling products – additional enforcement powers being granted to the Environmental Health Service The Bill marks another significant step towards Ireland's ultimate objective of a '*Tobacco Free Ireland*'.	30 May	Bill 2023 (as initiated)	Ireland

Special products

Title	Summary	Date	Links	Country
Amendment to Act on Protection of Health against Harmful Effects of Addictive Substances	The amendment aiming for protecting the health of children and adolescents sets new regulation of the sale of nicotine pouches, incl. the administrative sanctions. The following restrictions newly apply: – prohibition on sales to persons under 18 years of age; prohibition on sale through vending machines, unless sales to persons under 18 cannot be excluded – method of sale same to tobacco products – distance sale allowed only if the retailer takes measures to exclude the sale to persons under 18 The Ministry of Health has also introduced a decree which sets out the requirements for nicotine pouches, such as requirements for their composition, appearance, labelling, quality and characteristics including prohibited elements etc	23 March 2023 (effective date)	Act No. 59/2023 Coll.	Czech Republic

Special products

Title	Summary	Date	Links	Country
Ban on the sale of flavored heated tobacco	In May, an amendment to the Act on the Protection of Public Health transposing an EU Directive was approved. The amendment, among other things, introduces a ban on the sale of flavored heated tobacco. The reason for the ban is both the high chemical content and the desire to reduce the number of under-age smokers who find the flavored alternative attractive.	23 October 2023 (effective date)	Act No. 258/2000 Coll.	Czech Republic
Regulation of CBD, HHC and kratom	After the announcement of the European Commission to include CBD and other substances derived from cannabis on the list of so-called novel foods, the Czech legislators have begun to prepare a new regulation of these substances, which should include, among other things, a new list of so-called psycho-modulatory substances, on which CBD, HHC and kratom should appear, including conditions for their disposal.	Effective date unknown		Czech Republic

Special products

Title	Summary	Date	Links	Country
Preparation of Czech legislation on legalization of Cannabis	The new legislation draft should allow for self-growing, establishment of cannabis clubs and determine a model of licensed producers, distributors and sellers. The draft legislation should address the following points: – sale and production under licenses granted to producers and sellers – rules for buyers (buying cannabis upon registration in a non-public state system) – limits of the amount of cannabis grown and purchased; limit of the means in which cannabis could be used legally The legislation draft also includes, e.g., a ban on advertising and promotion of cannabis, and licensing fees from which pharmacies should be exempted.	2024 (expected effective date of the act)		Czech Republic
Government Order no. 64/2023, of 3 March (amends the Government Order 83/2021, of 15 April)	The cultivation of the cannabis plant for industrial purposes is restricted to the varieties listed in the Common Catalogue of Varieties of Agricultural Plant Species and which contain a low tetrahydrocannabinol (THC) content. The THC content for industrial uses is increased from 0,2% to 0,3%, being now aligned with the Regulation (EU) 2021/2115.	3 March	Government Order no. 64/2023, of 3 March (Portuguese only)	Portugal

Contributors

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

Czech Republic

Radek Matouš
Partner
T: +420 255 706 554
radek.matous@eversheds-sutherland.cz

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

Barbora Bugová
Associate
T: +420 255 706 523
barbora.bugova@eversheds-sutherland.cz

France

Gaëtan Cordier
Partner
T: +33 1 55 73 40 73
gaetancordier@eversheds-sutherland.com

Mélanie Dubreuil-Blanchard
Associate
T: +33 1 55 73 42 09
melaniedubreuil-blanchard@eversheds-sutherland.com

Naomi Bellaiche
Associate
T: +33 1 55 73 41 34
naomibellaiche@eversheds-sutherland.com

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

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

Ireland

Tony McGovern
Partner, Head of Life Sciences
T: +353 1 6644 204
tonymcgovern@eversheds-sutherland.com

Vanessa Lawlor
Associate
T: +353 1 6644 226
vanessalawlor@eversheds-sutherland.com

Italy

Alessandro Greco
Partner
T: +39 06 8932 7022
alessandrogreco@eversheds-sutherland.com

Lorenzo Maniaci
Associate
T: +39 06 8932 7023
lorenzomaniaci@eversheds-sutherland.com

Alberto Venditti
Associate
T: +39 06 8932 7051
albertovenditti@eversheds-sutherland.com

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

Contributors

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

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

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

Eduardo Buitron
Senior Associate
T: +34 914 294 333
ebuitron@eversheds-sutherland.es

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

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 44 3808
lizfitzsimons@eversheds-sutherland.com

Ben Johnson
Associate
T: +44 1223 44 3661
benjohnson@eversheds-sutherland.com

Indradeep Bhattacharya
Partner
T: +44 207 919 4696
indradeepbhattacharya@eversheds-sutherland.com

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

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Your Contacts

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
Partner, Head of Company Commercial, Germany

T: +49 89 54565 144 **M:** +49 15116776588
tobiasmaier@eversheds-sutherland.com

Bill Warren
US Lead for Health and Life Science, USA

T: +1 404 853 8081
billwarren@eversheds-sutherland.com

EVERSHEDS SUTHERLAND

eversheds-sutherland.com

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