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Updates in a heartbeat

Your quarterly global Health and Life Science newsletter

Edition Five – Fall 22/23

Executive summary

Welcome to the fifth 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.

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EU overview

Title	Summary	Date	Links
Revision of the Product Liability Directive (by *Centro de Estudios para el Fomento de la Investigación)* **October – November 2022, Edition Nº83**	The European legal framework for product liability, Directive 85/374/EEC, although it is considered to have provided legal certainty and satisfactory results so far, has shortcomings and needs to be adapted to the current economic and general legal environment of the EU. Furthermore, the current regulation does not provide uniform requirements for certain aspects of non-contractual civil liability for damage caused through the mediation of Artificial Intelligence ("**AI**") systems. Accordingly, the Commission has presented a proposal for a revision of the Product Liability Directive, in order to adapt the regulation to the current challenges, as well as a proposal for a Directive aiming to regulate the adaptation of non-contractual civil liability rules to AI. The eventual adoption of these proposals would have important implications on product liability proceedings and, in particular, on those related to medicines and medical devices.	December 2022	Link to Article (Spanish only)
Guidance on Authorised Representatives Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) ("**MDCG document 2022-16**")	The Medical Device Coordination Group ("**MDCG**") published the new MDCG document 2022-16") on 31 October 2022. The document is addressed to authorised representatives, manufacturers and other economic operators and is intended to provide guidance in relation to the relevant requirements of the MDR and the IVDR regarding the authorised representative, in particular those of Article 11 MDR/IVDR. The ten-page MDCG document 2022-16 provides specific guidance on the topics of designation and mandate, registration and verification obligations, minimum duties and scope of responsibilities of the authorised representative, liability, termination of mandate, change of authorised representative, interaction between the authorised representative and the person responsible for regulatory compliance, market surveillance and transitional provisions. Due to the prominent role of the authorized representative for manufacturers established outside the EU, the explanations regarding the new regulations on liability as well as the responsible person according to Article 15 MDR/IVDR should, in particular, be carefully observed.	31 October 2022	MDCG document 2022-16

EU overview

Title	Summary	Date	Links
European Commission proposal on extending transitional periods under the Medical Devices Regulation (COM(2023) 10 final) ("**Extension Proposal**")	The Extension Proposal extends the transition periods for manufacturers to become compliant with actual medical device regulation ("**MDR**") prerequisites for some products. In summary: • Article 120 paras. 2 and 3, subject to additional conditions, shall be amended extending the validity of CE certificates granted under the old directives until 31 December 2027 (class III, class IIb implantable devices (with exceptions)) or 31 December 2028 (other class IIb, class IIa, class Is, class Im devices). • The Extension Proposal waives the sell-off dates (27 May 2025 in the MDR, 25 May 2025 to 26 May 2028 in the In Vitro Diagnostic Regulation) providing for the possibility of marketing medical devices placed on the market before the end of the transition period without a time restriction. Currently, there are no indications that the Extension Proposal will not be adopted. Manufacturers should begin to assess whether they may benefit from the changes and which products could profit. If products are not eligible for the extensions, respective measures should be undertaken to remain or become compliant.	6 January 2023	Extension Proposal

Country updates

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Title	Summary	Date	Links
New measures for online sales of drugs	On 1 September 2022, the State Administration for Market Regulation ("**SAMR**") issued the Supervision and Administration of Online Sales of Drugs ("Online Drug Sales Measures"), which permits and governs the online sales of prescription drugs across China, with effect from 1 December 2022. The key measures cover: a) Qualification of online drug sellers – Only drug marketing authorisation holders ("**MAHs**") and drug suppliers with the ability to ensure drug safety are eligible to sell drugs online. b) Types of drugs – Vaccines, blood products, anaesthetics, psychotropic drugs, toxic medical drugs, radioactive drugs and pharmaceutical chemical precursors shall not be sold online. The list of prohibited drugs will be maintained by the SAMR and may be updated from time to time. c) Obligations of online drug sellers – Online drug sellers shall establish systems for drug quality and safety management and shall ensure the authenticity of medical prescriptions. Online drug retailers shall also establish online pharmaceutical care systems for reviewing prescriptions and providing guidance on the use of drugs. d) Obligations of third-party platforms **–** Third-party e-commerce platforms shall establish drug quality and safety management mechanisms and undertake regular inspections of online drug sellers' qualification and sales activities.	September 2022	Measures published by SAMR (simplified Chinese only)
Revision of measures for drug recalls	The National Medical Products Administration ("**NMPA**") published the revised *Administrative Measures for Drug Recalls* ("**Revised Measures**") on 26 October 2022, which take effect on 1 November 2022. The Revised Measures highlight that MAHs shall have the primary responsibility to control risks in relation to drugs, while drug manufacturers, drug sellers and drug users shall actively assist MAHs in performing the relevant obligations. The Revised Measures have clarified MAHs' duties to establish a drug recall system, investigate drugs with potential quality issues, and actively announce any drug recalls to the public.	October 2022	Measures published by NMPA (simplified Chinese only)

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Title	Summary	Date	Links
Model case on anti-monopoly and anti-unfair competition	The Supreme People's Court ("**SPC**") announced the latest Model Cases on Anti-Monopoly and Anti-Unfair Competition on 17 November 2022 – highlighting, amongst others, the trade secrets infringement case, *Beijing Gendone Biotechnology Co., Ltd.* ("**Gendone**") *v. Shijiazhuang Zexing Amino Acid Co., Ltd.* ("**Zexing**") *& Hebei Daxiao Biotechnology Co., Ltd.* ("**Daxiao**")("**Glycocyamine Case**"). This case outlines the foundation for two important legal issues – the term and scope of confidentiality obligations for licensees of trade secrets ("**Licensees**"). The Glycocyamine Case involved a strategic collaboration and manufacturing arrangement between Gendone, the owner of a certain proprietary synthetic process for manufacturing Glycocyamine (the "**Process**"), and Zexing. The terms of the arrangement specifically prohibited Zexing from any unauthorized disclosure in relation to the Process. In holding that Zexing had infringed Gendone's trade secret by unauthorized disclosure to Daxiao after the termination of the arrangement, the SPC opined that, in the absence of express provisions allowing Licensees to disclose or use information concerning trade secrets after the lapse of confidentiality term, they shall, despite the expiration of the term, remain bound by the confidentiality obligations to only use such information for their own ends. Therefore, Licensees are not only required to observe the "passive" obligations of refraining from infringing upon the legitimate rights of others (e.g. by way of unauthorized disclosure or prohibited use of trade secrets), but also other ancillary obligations arising from the principle of good faith that survive the lapse of any stipulated term of confidentiality.	November 2022	SPC's Announcement on the Model Cases on Anti-Monopoly and Anti-Unfair Competition (simplified Chinese only)
Draft Judicial Interpretation of cases on anti-monopoly	The Consultation Draft on Judicial Interpretation of Cases on Anti-monopoly ("**Draft Interpretation**"), announced on 18 November 2022, clarifies many procedural and substantive issues pertaining to the handling of civil anti-monopoly disputes. It seeks to centralize jurisdiction for first-instance anti-monopoly disputes with the PRC IP Courts and other Intermediate People's Courts designated by the SPC, ascertain the circumstances in which business operators may be deemed to have a dominant market position, and clarify the types of behaviour constituting market abuse, with a focus on the generic drugs sector. The Draft Interpretation clarifies that an agreement under which a patentee provides or undertakes to provide high compensation to a generic applicant in consideration for the applicant undertaking not to challenge the validity of the relevant patent or to defer entry into the market may, *prima facie*, be considered a monopoly agreement under the PRC Anti-Monopoly Law. Drug patentees should carefully assess dealings with generic applicants to ensure they are not at risk of falling foul of the law.	November 2022	SPC's Announcement on the Consultation Draft Interpretation (simplified Chinese only)

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Title	Summary	Date	Links
New act on limitation of environmental impact of selected plastic products	The new act on the limitation of the environmental impact of selected plastic products (the "**Act**") is a transposition of the European Directives 2008/98/EC on waste and in particular the 2019/904 on the reduction of the impact of certain plastic products on the environment. The Act includes several types of measures - from a complete ban on products, to restrictions on their consumption, to mandatory contributions from producers to clean up municipalities and cities. Only some selected single-use plastic products (e.g., plastic cotton buds, plastic cutlery, straws, food containers, cups, oxo-degradable plastic products) are directly banned from the market. The Act also introduces new obligations for producers, such as the obligation to inform buyers about the correct handling of waste from certain products, the obligation to educate, i.e., to alert customers to the availability of reusable alternatives to plastic products, and the obligation to label plastic products. The Act also strengthens the so-called extended responsibility of producers of selected plastic waste - producers of, e.g., filter cigarettes will participate in the clean-up of waste from their products in municipalities through financial contributions. Fines of up to CZK 5 million (approx. EUR 205,000) may be imposed for the breach of the Act.	1 October 2022 (effective date of the Act)	Link to new Act (Czech only)
New legislation on availability of medicines in crisis situations	This extensive amendment is the legislator's response to the changes in legislation at European level. One of the many areas amended is the purchase of medicines and their availability in crisis situations. In order to prevent disruptions in the supply of medicines to the EU market, the amendment, among other things, provides the Ministry of Health of the Czech Republic ("**Ministry of Health**") with considerable powers in the area of purchasing and distribution of medicinal products and setting the prices of medicinal products. The Ministry of Health will have the power to: (i) purchase or distribute medicinal products, (ii) temporarily set the conditions of the reimbursement or the price for the final consumer, (iii) deviate from the Act on Medicinal Products when ensuring the purchase or distribution in a state of emergency or war, (iv) maintain a list of medicinal products which are essential for the needs of the population and whose distribution abroad distributors are obliged to report to the State Agricultural and Food Inspectorate, and (v) restrict or prohibit the redistribution of the medicinal products (listed in the aforementioned list) abroad.	1 December 2022 (effective date of the new legislation)	Link to new Act (Czech only)

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Title	Summary	Date	Links
New act on medical devices and in vitro diagnostic medical devices	The new act on medical devices and in vitro diagnostic medical devices (the "**Act**") was adopted to bring national regulation regarding medical devices into line with European Regulations 2017/745 on medical devices and 2017/746 on in vitro diagnostic medical devices (the "**Regulations**") and repealed the existing Medical Devices Act. The Act supplements the rules set out in the Regulations, regulates the Medical Devices Information System, and regulates the prescription and dispensing of medical devices and in vitro diagnostic medical devices, their use and the conditions for their servicing.	22 December 2022 (effective date of the act)	Link to new Act (Czech only)
New price regulations of medicinal products and medical devices	On 30 November 2022, the Ministry of Health published the new price regulations applicable from 1 January 2023: the Price Regulation of Medicinal Products and Foodstuffs for Special Medical Purposes and the Price Regulation of Medical Devices and In Vitro Diagnostic Medical Devices (the "**Price Regulation**") which repeals the current regulation of prices of medicinal products and foodstuffs for special medical purposes. The most significant change is the modification of the definition of *other persons supplying a medicinal product to the market* (the "**Definition**"). The Pricing Regulation newly establishes, in relation to the Definition, a new requirement that this person must form a concern with the originator, be authorised in writing by the originator to supply such products to the market in the Czech Republic or be authorised to parallel import a mass-produced medicinal product. The Definition is important from the point of view of price regulation, because other persons supplying a medicinal product to the market are (besides the originator of the medicinal product) the first link in the distribution chain to which price regulation under the Price Regulation applies - these persons may sell the medicinal product to local distributors or persons authorised to dispense medicinal products at a maximum price corresponding to the price ceiling set by the State Institute for Drug Control (the so-called originator price). The maximum amount of the trade mark-up is subsequently based on the originator price.	1 January 2023 (effective date of the new price regulations)	Link to new price regulations (Czech only)

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Title	Summary	Date	Links
Concerns of leaders of French pharmaceutical companies regarding the French Social Security Financing Bill presented by the French Government	The French Social Security Financing Bill ("**PLFSS**") for 2023 was adopted on December 2, 2022, after recourse to Article 49 paragraph 3 of the French Constitution (which allows a controversial bill to be passed without a vote). Pharmaceutical companies have expressed several concerns about the PLFSS, including that: a) The PLFSS does not take into account the increase in drug production costs by passing it through to drug prices. While French people are expected to spend 26.4 billion euros on drugs in 2023, the PLFSS limits reimbursement to 24.6 billion euros. The sector's leaders denounce the negative effect that this will have on the growth of the industry and the risk of this leading to the stoppage of the production of certain medicines, which in turn would lead to supply shortages. b) These cost issues could have a negative impact on national drug sovereignty. Pharmaceutical companies claim that the prices of drugs are too low which may prevent further investments in production lines in France. Before the final adoption of the PLFSS, pharmaceutical companies have asked the French Government to review the envelope allocated for 2023, through a press release published by the Leem (the French professional organization of pharmaceutical companies) on October 13, 2022. However, the PLFSS was finally adopted without the requested changes on 2 December 2022.	2 December 2022	Leem press release Link to PLFSS (French only)

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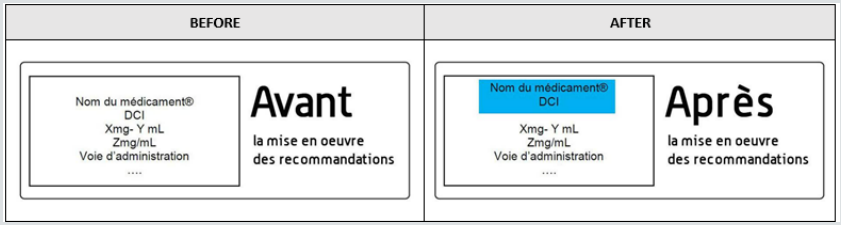
Title	Summary	Date	Links
Modification of the labelling of containers and other small packages of injectable drug solutions	In order to avoid any risk of confusion when administering small-volume injectable drugs, the ANSM (the French agency for the safety of medicines and health products) updated its recommendation on the labeling of these drugs on December 28, 2022. These types of injectable solutions are active substances often used in case of emergency and of low therapeutic margin, which can therefore lead to serious consequences in case of error. The name of the specialty will now have to be surrounded by a colored box, with a specific color associated with each distinct pharmacological class (see below):  The recommendation specifies that the labelling should not prevent the user from checking the appearance of the solution. These new packages will be distributed gradually starting from June 2023 and all labels must be updated no later than October 2023. There will be no recall of batches that do not comply with these labeling rules. This is only a recommendation and is therefore not binding on pharmaceutical companies. However, any other type of labelling must be justified in the market authorisation application file.	28 December 2022	Link to pdf article

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Title	Summary	Date	Links
Supplement to the Analgesics Warning Notice Ordinance (*Analgetika-Warnhinweis-Verordnung*)	Due to the application risks of over-the-counter ("**OTC**") analgesics, the Analgesics Warning Notice Ordinance (the "**Ordinance**") was issued on 18 June 2018 which requires: (i) pharmaceutical entrepreneurs to provide finished medicinal products, and (ii) pharmacies to provide and (ii) pharmacies to provide self-made drugs (so-called Rezeptur and Defektur), with a warning notice. On 1 November 2022, an amendment to the Ordinance came into force expanding its scope to include medicinal products that contain the APIs acetylsalicylic acid, diclofenac, ibuprofen, naproxen, paracetamol, phenazone or propyphenazone and that are not covered by an exemption provision. Pharmaceutical entrepreneurs may continue to market affected OTC analgesics without a warning notice until 31 October 2024. In case of violations, administrative fines and criminal prosecution may apply. Wholesalers and pharmacies may continue to market affected products by pharmaceutical entrepreneurs without any time limit. Pharmaceutical companies should assess whether their OTC analgesics are or may be affected.	1 November 2022	Analgesics Warning Notice Ordinance (Analgetika-Warnhinweis-Verordnung) (German only)

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Title	Summary	Date	Links
Withdrawal from e-prescription pilot project by the Association of Statutory Health Insurance Physicians of Westphalia-Lippe (*Kassenärztliche Vereinigung Westfalen-Lippe; KVWL*)	Digitization is tough, digitization involving personal health data is tougher and digitization involving personal health data in Germany is almost impossible. This is the experience faced by the KVWL as it suspended the broad introduction of the e-prescription in a pilot project. The KVWL felt compelled to do so because of the decision of the Federal Data Protection Commissioner (Bundesdatenschutzbeauftragter) to veto its plan to use customers' insurance cards for e-prescriptions in September. The KVWL region of Westfalen-Lippe was the last remaining pilot region in Germany where the e-prescription was to be introduced on a large scale which leaves only voluntary basis use of e-prescriptions. To put this in perspective, as at December 2022, only around 0.105% of all prescriptions (nation-wide) were e-prescriptions. Notwithstanding this low percentage of e-prescriptions to date, the federal plan is nationwide rollout of e-prescriptions in 2023. It remains to be seen whether and how this is achievable.	3 November 2022	KVWL Press Release (German only)

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Title	Summary	Date	Links
COVID restrictions on inbound travellers lifted	The Hong Kong Government has announced relaxation of its inbound control measures for inbound travellers, with effect from 29 December 2022. Travellers to Hong Kong are no longer required to take a PCR test upon arrival at the Hong Kong airport, but they shall conduct an RAT test within 24 hours, or undergo a nucleic acid test within 48 hours, prior to the scheduled time of flight departure, and obtain a negative test result for entry to Hong Kong. The "0+3" compulsory medical surveillance requirement has also been lifted, meaning travellers can move around the city freely. However, non-Hong Kong residents are still required to fulfil relevant vaccination requirements and mandatory mask-wearing remains in place for now.	December 2022	Hong Kong Government's website on COVID restrictions on inbound travellers
Availability of COVID-19 vaccines in private market	The Hong Kong Government has approved the registration of three types of COVID-19 vaccines, which are currently supplied in Hong Kong by two drug manufacturers, as pharmaceutical products in compliance with the Pharmacy and Poisons Regulations. The registration of these vaccines re-confirms their safety, efficacy and quality. More importantly, the relevant drug manufacturers may now market and supply the respective vaccines to private healthcare professionals, meaning that COVID-19 vaccines will now be available in the private market in Hong Kong.	December 2022	Hong Kong Government's announcement on provision of COVID-19 vaccines by private market

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Title	Summary	Date	Links
Payback mechanism on medical devices	On 15 September 2022 the Italian Official Bulletin (*Gazzetta Ufficiale*) published the Decree of the Ministry of Health and the Ministry of Finance dated 6 July 2022 ("**Decree**"), which established that the national health expenditure ceiling for medical devices, set at 4.4%, had been exceeded for the period 2015 – 2018. The Ministry of Health, therefore, in accordance with the provisions of Article 18 of Decree-Law No. 115 of 2022, ordered the Italian Regions to ask medical device suppliers to contribute to the coverage of national healthcare expenditure for the period 2015 - 2018, for a total amount of approximately € 2.1 billion. If medical device suppliers fail to contribute the requested amount, they are open to prosecution by the Italian tax authorities for tax violations. Over 400 appeals were filed by medical devices suppliers to the Regional Administrative Court of Lazio challenging the Decree. The hearing date for examination of the appeals has been set for 17 January 2023.	15 September 2022	Decree of the Ministry of Health of July 6th 2022 (Italian only)
Legislative Decrees implementing Regulation (EU) No. 2017/745 on medical devices and Regulation (EU) No. 2017/746 on in vitro diagnostic medical devices	On September 28th, 2022 there entered into force Legislative Decrees No. 137 and No. 138 of 5 August 2022 ("**Decrees**"), implementing Regulation (EU) No. 2017/745 on medical devices ("**MDR**") and Regulation (EU) No. 2017/746 on in vitro diagnostic medical devices ("**IVDR**"). The most relevant outcome of the Decrees is the establishment of the first sanctions regime for violations of the new MDR and IVDR regulations, which provides for harsher penalties than the old regime. Notably, Article 27 of the Decrees provides for administrative fines of up to EUR 150,000 for violations related to the provisions of MDR and IVDR.	28 September 2022	Legislative Decree No. 137 of August 5th 2022 (Italian only) Legislative Decree No. 138 of August 5th 2022 (Italian only)

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Title	Summary	Date	Links
Netherlands issues new price announcement rules for 2023	The Dutch government published the new rules on price reductions through so-called 'from-for discounts' (in Dutch: '*van-voor-prijzen*') implementing obligations from the Omnibus or Modernisation Directive. The new rules apply to all consumer sales and will enter into force on 1 January 2023. Life sciences companies selling products directly to consumers are advised to check their pricing communication practices.	13 December 2022	Link to announcement
Authority for Consumers and Markets takes medical device sector under scrutiny	The Dutch Authority for Consumers and Markets ("**ACM**") has commissioned an exploratory study into the market for medical devices. ACM identifies competition risks in several market segments, such as prostheses and implants for the heart and lungs and suture materials. Medical device companies are advised to monitor the outcome of the study in order to assess whether any risks need to be addressed in their current business practices.	25 November 2022	ACM press release
Finalization of the guideline on competition rules for health care IT markets of the ACM	The ACM published the draft guideline 'Well-functioning markets for healthcare IT' for consultation during the summer of 2022. All responses have been summarized in a consultation report and incorporated into the final guideline. The final guideline provides clarity about the application of the competition rules to improve the functioning of the market for IT systems in healthcare.	22 November 2022	ACM guidelines on competition rules

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Title	Summary	Date	Links
New Guideline on advertising of medicinal products	On the basis of the obligation for marketing authorisation holders who advertise one or more medicines to keep a copy of every advertising message that originated from them, a new guideline has been drawn up: the 'Guideline on advertising of medicines and medical devices'. The purpose of this guideline is to alleviate administrative burdens on licence holders and to move with the times when more and more matters are stored digitally and arranged online regulated. Pharmaceutical companies are advised to take note of this guideline when publishing any advertising messages.	25 November 2022	Link to new Guideline (Dutch only)

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Title	Summary	Date	Links
New yearly fees for authorisations	The goverment seeks to reform the Pharmaceutical Inspection by its centralization and introduction of the new rights and measures available for the Inspection, e.g. the supervision over medicinal laboratories. Additionally, the fees for pharmaceutical wholesaler licenses, pharmacy licenses, market authorisation holder licenses, etc., will be charged not once, but yearly with the possibility to increase them.	November 2022	Link to Legislation
Authorization needed for medical activity	Private hospitals, clinics and other entities conducting medical activities will need to obtain a new authorisation if their activity is wholly or partially financed from public funds in Poland. The authorisation is granted by the President of the National Health Fund for 5 years in the form of an adminitrative decision. Additionally, all entities, regardless of funding, will be obliged to introduce a quality system to better report medicinal incidents.	December 2022	Link to Government Bill
Stricter supervision over medicinal laboratories	On 10 December 2022 the new Act on laboratory medicine came into force. The Act introduces new requirements for becoming a laboratory diagnostician and laboratory manager, as well unifying the POCT (Point-of-care testing) standards.	December 2022	Link to the Act (Polish only)
New version of reimbursement act may ease the price policy	A new version of the Reimbursement Act ("**Act**") was published as a response to heavy criticism from the market and experts. Among the provisions removed from the Act by the Ministry of Health were the so-called "price corridors" which offered reimbursement only for drugs with prices which were within the range of prices offered by the Asian manufacturers. The changes should mitigate the risk of the increase of the prices of these drugs going forward.	December 2022	Link to the Act

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Title	Summary	Date	Links
Information Circular issued by INFARMED (Portuguese Health Products Regulator) on the Review on the risk of nitrosamine impurities in human medicines	The review on the risk assessment of the presence of nitrosamines in medicines started in 2019 with three steps on market authorisation holders ("**MAH**"): 1. risk evaluation with the outcome reported to the competent authorities in 2021; 2. confirmatory testing of the products at risk of contamination with a deadline of September 26, 2022; and 3. updating marketing authorisations with the necessary changes to the manufacturing process resulting from this review by October 1, 2023 for chemical medicines and July 1, 2023 for biological medicines. INFARMED highlights the responsibility of the MAH to communicate the results of steps 1 and 2.	26 September 2022	Information Circular on the Risk Assessment of the presence of nitrosamines in medicines
Information Circular issued by INFARMED regarding the streamlining of the parallel import authorization	With the aim of speeding up the procedure to allow the parallel import of medicines, INFARMED has updated information required and the application form.	7 December 2022	Information Circular on changes for parallel import authorization
Information Circular issued by INFARMED on the authorisation to market medicines without a valid authorisation or registration	INFARMED may authorise the marketing of medicines without valid authorisation or registration in Portugal, for reasons of public health, for the purpose of speeding the procedure and approval procedure. INFARMED has consequently updated the application form and the related instructions to reflect this.	7 December 2022	Information Circular on the update of documents in the SAR request

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Title	Summary	Date	Links
Judgment of the Court, 17 November 2022, in case C-224/20, between Merck Sharp & Dohme and others.	This decision is motivated by the legal claims heard by the Danish Commercial and Maritime Court. In these claims, the manufacturers of medicines and brand owners were opposed by the companies involved in the importation of medicines into Denmark. The manufacturers claim that the original packaging of the medicines had been replaced without there being any real need to do so. This would be contrary to good practice on parallel importation of medicines, which sets strict requirements on when such replacement of packaging is permissible, and always gives preference to less intrusive conduct, such as new labeling and replacement of internal leaflets. Through the court upholding the manufacturers' position, the current situation regarding the existing requirements on the repackaging of parallel imported medicinal products is reconfirmed. In this way, the free movement of medicinal products is defended against disadvantages that may arise from a lax interpretation of the directive on falsified medicinal products.	17 November 2022	Link to Judgment
Unconstitutionality appeal againts Foral Law 17/2021, 21 October, modifying Foral Law 2/2018, 13 April, of Navarra's Public Contracts.	The Law introduces a measure modifying the traditional system for the purchase of medicines for hospital use in order to make it more flexible. This Law also excludes from the scope of application of the public procurement regulations, the purchase of all medicines that have a resolution of financing by the National Health System and with a public financing price set by the Ministry of Health.	21 October 2022	Link to appeal (Spanish only)

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Title	Summary	Date	Links
Gross procedural error: Rejected supplementary protection certificate for a medicinal product should have been subject to preliminary ruling	The Swedish Patent and Market Court of Appeal ("**PMCA**") rejected an application for a supplementary protection certificate ("**SPC**") for a medicinal product. SPCs offer extended protection as compensation for a patent holder's long wait to get the medicine approved for use. One of the conditions for receiving an SPC is that it must not have been issued before. In the current case, the PMCA rejected the application because an SPC had previously been granted based on the same patent – but for a different medicinal product. The Supreme Court decided that it was a gross breach of procedure that the PMCA did not first obtain a preliminary ruling from the EU Court given the decision cannot be appealed and interpretation of EU law was decisive. As a consequence of the gross breach of procedure, the Supreme Court set aside the PMCA's decision and returned the case to the PMCA for the continuation of proceedings.	20 December 2022	Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products
Environmental premium in the pharmaceutical benefit system	The introduction of an environmental premium in the pharmaceutical benefit system to reduce pharmaceutical manufacturing emissions has been discussed for a long time in Sweden. In October, three governmental authorities, including the Swedish Medical Products Agency ("**MPA**"), presented a final plan on how to introduce the premium. Among other things, the MPA proposed two mandatory criteria for a company to receive an environmental premium: it must stay within new limit values for emissions of active substances and meet certain management requirements in relation to waste of active substances. It was also proposed that the companies should apply for the premium to the MPA. The government will now take a position on the proposals.	31 October 2022	Trial for environmental premium, progress report issued by the MPA in May 2022 (in Swedish only)

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Title	Summary	Date	Links
Information Commissioner's Office issues warning on use of emotional analysis technologies	The Information Commissioner's Office ("**ICO**") has issued a warning to organisations that use (or are considering use of) emotional analysis technologies. These technologies process and analyse certain data such as eye and facial movements, sentiment analysis, gait analysis, heartbeats, expressions and skin moisture. The ICO has stated that it has not yet seen any technologies of this kind that meet the proportionality, fairness and transparency requirements imposed by data protection law, and is currently drafting a biometric guidance document that is due to be published in Spring 2023.	26 October 2022	ICO warning
Use of CE marking in Britain extended	The period during which CE marks can be used on British products (including medical devices) has been extended for two years. Businesses will have until 31 December 2024 (rather than 31 December 2022) to apply new UK Conformity Assessed ("**UKCA**") marks to products. Until then either the CE or the UKCA mark can be used.	14 November 2022	BEIS press release
UK Specialisation and R&D Block Exemption Orders published	The UK Specialisation and R&D Block Exemption Orders ("**BEOs**") have now been published which contain exemptions from the prohibition in Chapter I of the Competition Act 1998 (which prohibits agreements between firms that prevent, restrict or distort competition) for certain R&D and specialisation agreements provided that certain conditions are met. These come into force on 1 January 2023 and will replace the current retained EU law versions of the block exemptions (from which point the UK and EU regimes will diverge). Changes from the EU regime include (i) expansions to the definitions of "specialisation agreement" and "research and development" for the purposes of the BEOs (thereby allowing more agreements to benefit); (ii) simplifications to the grace periods applicable when market share increases above the relevant exemption threshold; and (iii) the introduction of a power of the Competition and Markets Authority to cancel the BEOs or request information.	5 December 2022	SABEO R&D BEO

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Title	Summary	Date	Links
Employers to have greater responsibility to protect against sexual harassment	A recent report into sexual harassment in healthcare services globally, indicates that this is an ongoing issue for the sector. In England alone, the report refers to six NHS staff per week typically reporting sexual harassment by a patient or colleague through the reporting platform #healthtoo. Looking ahead in the UK, all employers, including those in the healthcare sector, will need to be more proactive in protecting their employees. The Government is supporting proposed legislation which would introduce employer liability if an employee is harassed in the course of their employment by third parties (such as patients or colleagues) and the employer fails "to take all reasonable steps to prevent the third party from doing so". The Bill, which could become law in 2024, if passed, would also introduce a new duty on employers to "take all reasonable steps to prevent sexual harassment" of their employees in the course of their employment. Employers will also be keenly awaiting a new Code of Practice and guidance on preventing sexual harassment for some clarity over what "reasonable steps" will support their defence in the event of a claim.	December 2022	Women in Global Health Report December 2022 Worker Protection (Amendment of Equality Act 2010) Bill
Retained EU (Revocation and Reform) Bill	With a view to reducing costs to UK business by £1 billion, the Retained EU (Revocation and Reform) Bill aims to revoke certain EU-derived employment laws by 31 December 2023, unless otherwise preserved (or extended to 2026), and to give courts new discretion to depart from retained EU case law. If enacted, therefore, the Bill will have considerable legal and practical implications for employers, potentially impacting issues such as maximum working hours and holiday entitlement, TUPE protection, family-related leave, flexible working and agency workers' protection but it will also affect existing and future employment litigation. Clarification of specific Government proposals and of their time frame is awaited so that employers can start to prepare, as necessary.	By December 2023	Retained EU Law (Revocation and Reform) Bill - Parliamentary Bills - UK Parliament

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Title	Summary	Date	Links
The lawfulness of terminating care home workers' employment for refusing COVID-19 vaccination	In what is thought to be the first British Employment Tribunal judgment on this issue, five employees (four of which were frontline care workers) lost unfair dismissal claims after their employer dismissed them for refusing to be vaccinated against COVID-19, without a medical exemption. The Tribunal accepted that the reason for the employer's introduction of its vaccine policy was to reduce the risk of death and serious illness amongst care home residents, its staff and any visitors, and that this could justify their dismissal. It did not mandate vaccination, meaning that the employees chose whether to be vaccinated or not. The employees' human rights and religious/belief discrimination claims also failed, the Tribunal deciding that the employer's aim was legitimate, it acted proportionately and fairly, having been guided by Government guidance, public health authorities, lead medical practitioners, employee consultation and a risk assessment. It should be noted that this decision is not binding and reflects the particular facts of the case, including the pandemic context in the first and second quarters of 2021.	December 2022	Link to the Tribunal judgment

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Title	Summary	Date	Links
Senators Want Info As US Ponders Extending COVID IP Waiver	Given the skepticism surrounding the WTO's COVID-19 vaccine waiver, concerns regarding the proposed extension to include diagnostic tests and treatments has raised some alarm. A bipartisan group of senators have come together and are seeking clarity from the US Trade Representative as to how this will impact American industries, especially because the benefits (if any) of the COVID-19 vaccine waiver have yet to be reported.	October 2022	Link to pdf article
Senator Lee Floats Bill to Drop Biosimilar Hurdle	In an effort to reduce ever-growing prescription drug prices in the US, Senator Mike Lee (R-Utah) introduced a bill to ease the burden of generic drug manufactures producing and selling biological agents. This bill seeks to reduce the level of FDA testing for biosimilars in order to reduce the to-market time for generic biologics.	November 2022	Link to pdf article
Supreme Court Will Tackle Patent Enablement In Amgen Case	The U.S. Supreme Court recently announced that it will be reviewing patent enablement under 35 USC 112, particularly in the context of the biopharmaceutical industry. It has been almost a decade since the Supreme Court last considered this issue. Here, the Supreme Court will review two Amgen patents to determine whether enablement requires that a patent specification must enable the full scope of an invention, or whether disclosure sufficient to make and use the invention is sufficient.	November 2022	Link to pdf article

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