Baker McKenzie.

EMEA Healthcare Newsletter

February 2019

Welcome to the February 2019 edition of our newsletter.

The EMEA Healthcare Industry Group Newsletter is your regular digest of legal developments affecting the life science and healthcare industries across the region.

If you have any suggestions about the format or content of the newsletter please contact acting editors Julia Gillert and Els Janssens. To add or remove subscribers, please email Bridget Fair.

In This Issue

Belgium

New Belgian law liberalizing distribution channels for medical devices opens opportunities to review supply chain and expand market access

On 28 January, 2019, the Belgian government announced some key changes to the distribution channels of medical devices in Belgium. The Royal Decree of 19 Decemeber, 2018 liberalising the distribution channel of medical devices will have a great impact on how medical devices are accessing the Belgian market.

► **Read more**

For further information please contact Geert Bovy or Evelyn Krott of our the Brussels office.

Europe

Implementing safety features under the Falsified Medicines Directive

The Falsified Medicines Directive (Directive 2011/62/EU) sets out measures to prevent falsified medicinal products for human use from entering the supply chain, and increase security of the manufacturing and delivery of medicines across Europe. The Delegated Regulation 2016/161 (**Delegated Regulation**) applied automatically in all EU Member States from 9 February 2019, and helps to implement the Directive.

► **Read more**

For more information, please contact Jaspreet Takhar or Julia Gillert of our London office.

EMA announces closure of London office from 1 March 2019

The EMA will officially close its London office on 1 March 2019, Politico reports on 22 January, and is already actively moving to its temporary office in Amsterdam (EMA's new permanent headquarters, a tailor-made building in the Zuidas business district of Amsterdam, are planned for completion in November 2019). The move and the fact that around 30% of the staff are not moving with the Agency means that despite best efforts, there are capacity issues currently.

► **Read more**

For more information, please contact Julia Gillert of our London office.

European Commission Report on Competition Enforcement in the Pharma Sector

The European Commission recently published a **report** on the antitrust enforcement activities of the Commission and the individual EU Member State competition authorities for the period 2009 – 2017. This Report follows the Commission's inquiry into competition in the pharmaceutical sector which concluded in July 2009. The Report makes it clear that effective enforcement of competition law in the pharma industry remains a high priority and that competition authorities in Europe will continue to monitor and proactively investigate potential anti-competitive conduct. The Report focuses on medicinal products for human use.

► **Read more**

For further information, please contact Fiona Carlin of our ECLP office in Brussels or Farin Harrison of our London office.

Supplementary protection certificates cannot be granted to medicinal products incorporated by medical devices

With its judgment dated 25 October, 2018, Case No. 527/17, the Court of Justice of the European Union held that, for the purposes of obtaining a Supplementary Protection Certificate (**SPC**), an EC certificate of conformity for a medical device incorporating a medicinal product cannot be considered equivalent to a marketing authorisation.

► **Read more**

For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

EMA's new guidelines on the quality of water for pharmaceutical use

On 15 November, 2018, the EMA launched a public consultation on the draft of new guidelines on the quality of water used during manufacture of active substances and medicinal products for human use ("**Guidelines**"). Besides replacing the previous version of the Guidelines adopted in 2002, the aim of the document is to provide updated guidance on the proper use of water in the manufacturing process of active substances and medicinal products for human use.

► **Read more**
For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

EMA issues new PV paediatric guidelines

On 25 October, 2018, the EMA published the new guidelines on good pharmacovigilance practices in the paediatric population ("**Guidelines**"), which replace the previous version issued in 2007.

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For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

Concerns grow over medical devices supply shortfalls in no-deal Brexit

BSI, the largest EU notified body, has been celebrating its UK arm becoming the first designated notified body under the Medical Devices Regulation (EU) 2017/7/745 (**MDR**). This should be good news for device manufacturers requiring certification under the MDR before its full application from 26 May 2020. However, the designation may be short lived in the case of a no-deal Brexit, at which point no UK based notified body can be EU-27 compliant, and BSI is prepared for this, transferring its clients' current CE certificates from BSI UK to BSI's new office in The Netherlands. BSI-NL is expecting to achieve MDR designation mid-2019.

► **Read more**
For further information please contact Julia Gillert or Emma Panhuber of our London office.

Call for harmonised sunshine and transparency laws across Europe

On 23 January 2019, Mental Health Europe (**MHE**) launched a report in the European Parliament recommending a move towards more transparent cooperation in the healthcare industry, particularly between pharmaceutical companies and HCPs. The MHE's assessment of transparency laws at a national level found that currently only 8 EU countries have enacted laws mandating disclosure of interactions between pharmaceutical companies and HCPs, while the remaining 19 rely on self-regulation.

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For further information please contact Julia Gillert or Emma Panhuber of our London office.

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France

New French “IP box”

The 2019 French Finance Act modified the taxation of revenues derived from intellectual property (**IP**) assets, or “**IP box**” to ensure its compliance with the OECD recommendations and particularly with the Nexus approach. This new regime, applicable to fiscal years beginning on or after 1 January, 2019, decreases the CIT rate down to 10%, and introduces substantial changes to the scope and conditions of application of the French “patent box”.

► **Read more**

For more information please contact Lionel Ochs, Benoît Granel, Marion Brauge of our Paris office.

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Hungary

The GVH imposes a fine on a pharmaceutical company

The Hungarian Competition Authority (**GVH**) have imposed a fine of HUF 95 million (approximately EUR 280,000) on Bayer Hungária Kft. (**hereinafter Bayer or the Company**).

► **Read more**

For more information please contact Helga Bíró or Bianka Tóth of our Budapest office.

New rules on homeopathic products

Act CXVIII of 2018 on certain Healthcare and Health Insurance Matters and on the Amendment of certain Healthcare-related Laws, published in the Hungarian Official Gazette on 20 December 2018, amended several laws such as the Act XCV of 2005 on Medicinal Products for Human Use ("**Medicines Act**"). The

recent amendment of the Medicines Act provides that homeopathic products with therapeutic indications licensed before Hungary joined the European Union may be placed in the market and they may stay there after 1 January 2020, if they comply with the European Directive on the pharmaceutical codex and the domestic laws implementing such directive.

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For more information please contact Helga Bíró or Bianka Tóth of our Budapest office.

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Italy

Medical devices - guidelines for the drafting of tender specifications

On 30 October, 2018, the Ministry of Health published the "Guidelines for the drafting of tender specifications for the purchase of medical devices", which identify the main requirements that awarding authorities shall comply with during the planning and decision-making phases as well as in the subsequent monitoring phase of the performance of public contracts. The Guidelines pursue the primary goal of providing awarding authorities with an effective tool, as standardised as possible, and, at the same time, facilitating economic operators by simplifying the preparation of the tender documentation.

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Bribery in the pharmaceutical sector does not cover nutritional supplements

With its judgment No. 51946 issued on 16 November, 2018, the Court of Cassation established that the crime of bribery in the pharmaceutical sector ("**Comparaggio**"), as laid down in Section 170 *et seq*. of Royal Decree No. 1265/1934, ("**Consolidated Text of Health Laws**"), does not apply in the case where moneys or other benefits are given and/or promised in order to facilitate the sale of parapharmaceutical products (in the case at hand, food supplements).

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Increase in clinical trials in Italy

A recent study carried out by the Italian Federation of Healthcare and Hospital Organizations (**FIASO**) in collaboration with Confindustria and Altems, shows that in the period between 2013 and 2015 the number of clinical trials authoriSed in Italy experienced a significant growth. Indeed, the study reports that, during this period, 6,332 new clinical trials have been authoriSed, of which 1,932 were no-profit trials. Such increase is even more significant in the light of the fact that in the period between 2000 and 2002 only 1,722 trials have been authoriSed.

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Medical devices: The CE marking is sufficient to certify the conformity of the products to the tender requirements

With its decision No. 259 dated 21 November, 2018, the Regional Administrative Court of Trento held that the exclusion of a biomedical company from a public tender procedure for the supply of medical devices due to the lack of certification of requirements that should be proved by the CE marking is illegitimate.

► **Read more**
For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

A medicinal product repackaged for its "off-label" use can be reimbursed by the National Health

System

With its decision dated 21 November, 2018, case C-29/17, the Court of Justice of the EU ruled on the conformity with the EU law of national measures allowing the reimbursement, by the National Health System, of a medicinal product repackaged for its off-label use.

► **Read more**
For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

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Russia

Recent amendments to the procedure for the entry of medicines into civil circulation

The president of the Russian Federation signed on 28 November 2018 Federal Law №449-FZ "On Amendments to Certain Legislative Acts of the Russian Federation Regarding the Entry of Medicines into Civil Circulation" ("**Federal law**"), which introduces amendments to Federal Law № 184-FZ "On Technical Regulation" dated 27 December 2002, as amended, and Federal Law № 61-FZ "On Circulation of Medicines" dated 12 April 2010, as amended. According to Federal law, issues related to the entry of medicines into civil circulation are excluded from the scope of Russian legislation on technical regulation. Therefore, the existing procedure for declaring or certifying medicines' quality has been abolished, whilst a new procedure for the entry of medicines into civil circulation has been adopted.

► **Read more**

For more information, please contact Paul Melling or Alexey Trusov of our Moscow office.

Regulatory change to provision of medicines to citizens suffering from rare (orphan) diseases

This change affects a program known as 7 high cost nosologies, which will now be known as 12 high cost nosologies.

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South Africa

Competition Commission of South Africa's inquiry into the private healthcare sector nears its end

The Competition Commission of South Africa initiated a marketing inquiry into the status of competition in the private healthcare market in South Africa in 2013. The market inquiry was and remains an ambitious undertaking.

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For more information contact Leana Engelbrecht of our Johannesburg office.

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Spain

Impact of Organic Law 3/2018 on personal data protection in the field of data processing in health research

The New Organic Law 3/2018, of 5 December, on the Protection of Personal Data and Guarantee of Digital Rights ("**Data Protection Law**") contains specific provisions concerning data processing in health research (additional provision seventeen).

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For further information, please contact Montserrat Llopart of our Barcelona Office.

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Switzerland

Project to bring Swiss law in line with MDR and IVDR to ensure continued mutual recognition of medical devices in the EEA

Switzerland and the European Union have entered into a mutual recognition agreement by which the conformity assessments for medical devices are mutually recognised. Such mutual recognition requires an equivalent regulation of medical devices. Following the adoption of the Medical Devices Regulation (**MDR**) and the In-vitro Diagnostic Medical Devices Regulation (**IVDR**) in the EU, Switzerland will now have to amend its laws to bring its law in line with EU law. A first amendment of the relevant ordinance already entered was adopted on 25 October , 2017. It regulates, amongst others, how medical devices can be placed on the market and the market surveillance of medical devices during the transitory period until the MDR and the IVD have become fully applicable.

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For more information please contact Peter Reinert of our Zurich office.

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Turkey

TİTCK publishes batch release guideline

The Turkish Medicines and Medical Devices Agency (**TİTCK**) published the Batch Release Guideline ("**Guideline**") on 31 October, 2018. The Guideline provides instructions for companies that will apply to the TİTCK to obtain batch certificates and permissions.

► **Read more**

For more information, please contact Can Sözer or Hilal Temel of our Istanbul office

Turkey to introduce a marketing authorization requirement for medicines procured from abroad

According to Law No. 7151 on Amendment of Several Laws and Decree Laws Related to Healthcare published in the Official Gazette of 5 December 2018, the amendments introduced to Law No. 984 on Stores Selling Toxic and Active Chemical Substances Used in Pharmacies, Arts and Agriculture ("**Law**") establish several requirements related to human medicinal products procured from abroad.

► **Read more**

For more information, please contact Can Sözer or Hilal Temel of our Istanbul office

Cosmetics safety: Turkey continues cracking down on unsafe and noncompliant cosmetic products

The Turkish Medicines and Medical Devices Agency (**TİTCK)** recently announced the results of its cosmetics sector market surveillance and inspection conducted between June and September 2018.

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For more information, please contact Can Sözer or Hilal Temel of our Istanbul office

TİTCK announces changes for sanctions regarding meeting notification duty

The Turkish Medicine and Medical Devices Agency (**TİTCK**) announced on 5 November, 2018 that companies failing to notify the TİTCK regarding meetings, seminars or symposiums for scientific and educational activities they supported will be sanctioned through the Meeting Notification System.

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For more information, please contact Can Sözer or Hilal Temel of our Istanbul office

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Ukraine

Strategy on implementing the state pharmaceuticals policy may limit IP rights of R&D companies

On 5 December 2018, the Cabinet of Ministers of Ukraine ("**CMU**") approved Regulation No. 1022 "On Approval of the State Strategy on Implementing the State Policy on Providing the Population with Pharmaceuticals for the Period until 2025" ("**Regulation**").

► **Read more**
For more information please contact Olha Demianiuk of our Ukraine office.

The MOH and the MEDT do not recommend that public procurement entities use large multi-item lots and manufacturers' authorization letters

The Ministry of Health of Ukraine ("**MOH**") and the Ministry of Economic Development and Trade of Ukraine ("**MEDT**") issued joint recommendations for public procurement entities to address pitfalls arising during public procurement of pharmaceuticals. By joint letter No. 01.7/33810 dated 19 December 2018 ("**Letter**"), the MOH and the MEDT provided their recommendations to ensure competition among bidders and non-discrimination.

► **Read more**
For more information please contact Olha Demianiuk of our Ukraine office.

SI labeling requirement postponed until 2021

The MEDT postponed the requirement for measurement units on the labeling of products to be in Latin or Greek. This requirement was set forth in Order of MEDT No. 914 dated 4 August 2015 with the aim of introducing the International System of Units in Ukraine. The requirement was to become effective on 1 January 2019 and apply to products placed on the Ukrainian market (with certain exceptions), including pharmaceuticals and medical devices.

► **Read more**
For more information please contact Olha Demianiuk of our Ukraine office.

The CMU approved risk criteria to control compliance with pricing regulations

The CMU established criteria to assess the level of risk of a company from the perspective of compliance with pricing regulations. This is particularly important for pharmaceutical and medical devices companies as their products are subject to multiple pricing regulations. The level of risk assigned to a company determines the

frequency of state inspections over compliance with pricing regulations.

► **Read more**

For more information please contact Olha Demianiuk of our Ukraine office.

NBU cancels registration and maximum interest rate cap for cross-border loans

On 2 January 2019, the National Bank of Ukraine adopted several regulations on currency control issues aimed at implementing revolutionary provisions of the new Law of Ukraine "On Currency and Currency Operations." Among such documents is the Regulation of the National Bank of Ukraine No. 6 setting up new rules on the supervision of cross-border loans extended to Ukrainian borrowers, which comes into effect alongside the FX Law on 7 February 2019. Please refer to this legal alert to learn more about this development.

For more information please contact Olha Demianiuk of our Ukraine office.

Kazakhstan amends its pharmaceutical legislation

On 19 January 2019, certain amendments to the laws of Kazakhstan governing the pharmaceutical industry came into effect. These amendments are part of a bigger package of legislative changes announced at the end of 2018. Please refer to this legal alert to find out about the most important changes introduced by these amendments.

For more information please contact Olha Demianiuk of our Ukraine office.

United Kingdom

MHRA ramps up detail on no-deal plans

Along with other agencies, the Medicines and Healthcare products Regulatory Agency, the MHRA, has removed the word "unlikely" from its references to the possibility of "no deal", and is accelerating its planning for this eventuality, though it is "not [its] policy or … preferred approach".

Further to the consultation launched in October, the MHRA published a response to that consultation by updating its no deal guidance on 3 January and 4 January.

► **Read more**

For more information contact Julia Gillert of our London office.

MHRA requires information from MA Holders regarding "Grandfathering" of EU centrally authorised medicines to UK MAs

The MHRA issued letters to MA holders on 2 January, and published the form of letter on 21 January, regarding the conversion of Centrally Authorised Products (CAPs) to UK MAs.

The MHRA states in its letter that to facilitate the grandfathering process, it has assigned a Product Licence (PL) number to CAPs based on the existing UK practice for national licences, listed in the letter annex. It has allocated a PL number based on each presentation within the product range, rather than a separate number for each pack size, so that there will usually be fewer UK authorisation numbers issued compared with those issued by the EMA.

► **Read more**

For more information contact Julia Gillert of our London office.

Medicines and medical devices availability and stockpiling

The plans for minimising the risks and dangers of medicines and medical supplies during a no-deal Brexit are accelerating and being given increased press attention.

The MHRA published a note on 18 January aimed at the UK public, on getting medication in the event of no-deal.

► Read more

For more information contact Julia Gillert of our London office.

UK/Australia pre-Brexit deal will facilitate trade of medicines and medical devices

UK and Australia last week signed a pre-Brexit deal which provides for reciprocal recognition of conformity assessments and certification for medicines and medical devices. The deal is aimed at streamlining export and import processes by eliminating the need, cost and time for testing and certification in the receiving country. The broad scope of the Australia-Britain Mutual Recognition Agreement on Conformity Assessment (**MRA**) means that if a medicine or medical device has been certified as meeting standards in Australia it is recognised as meeting British standards - and vice versa.

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For more information contact Julia Gillert of our London office.

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International

IFPMA's latest Code of Practice bans gifts and promotional aids

This article first featured in Lexology on 25 January 2019.

The International Federation of Pharmaceutical Manufacturers and Associations' Code of Practice (the "**Code**") has been amended for the first time since 2012.

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For further information please contact Julia Gillert of our London office.

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Recent amendments to the procedure for the entry of medicines into civil circulation

The president of the Russian Federation signed on 28 November 2018 Federal Law №449-FZ "On Amendments to Certain Legislative Acts of the Russian Federation Regarding the Entry of Medicines into Civil Circulation" ("**Federal law**"), which introduces amendments to Federal Law № 184-FZ "On Technical Regulation" dated 27 December 2002, as amended, and Federal Law № 61-FZ "On Circulation of Medicines" dated 12 April 2010, as amended. According to Federal law, issues related to the entry of medicines into civil circulation are excluded from the scope of Russian legislation on technical regulation. Therefore, the existing procedure for declaring or certifying medicines' quality has been abolished, whilst a new procedure for the entry of medicines into civil circulation has been adopted.

In accordance with this new procedure, medicine manufacturers or organisations importing medicine into the Russian Federation are required to submit to the Federal Service for Surveillance in Healthcare (**Roszdravnadzor**) the following:

- Document confirming the medicine's quality (e.g., manufacturer's certificate of analysis confirming the compliance of the imported medicine with the requirements of a pharmacopoeial monograph, if adopted, or normative documentation), and
- Manufacturer's or importer's confirmation certifying the compliance of the medicine with the requirements established during the medicine's state registration.

The first three series or batches of a medicine produced for the first time in the Russian Federation (imported for the first time into the Russian Federation) are under more strict control. Test reports issued by federal state budgetary institutions accredited in the national accreditation system and confirming the compliance of each series or batch with the quality characteristics needs to be submitted to Roszdravnadzor.

Immunobiological medicines manufactured in the territory of or imported into the Russian Federation are to be put into civil circulation on the basis of a special permit issued by Roszdravnadzor. The new procedure for the entry of medicines into civil circulation will take effect on 29 November 2019.

In addition, Federal law requires medicine manufacturers or organisations importing medicines into the Russian Federation to notify Roszdravnadzor and the Ministry of Industry and Trade in the event there are plans to suspend or discontinue the manufacturing or importation of medicines. Such notification shall be made no later than a year before the planned events. This provision of Federal law has already taken effect.

For more information, please contact Paul Melling or Alexey Trusov of our Moscow office.

Regulatory change to provision of medicines to citizens suffering from rare (orphan) diseases

This change affects a program known as 7 high cost nosologies, which will now be known as 12 high cost nosologies.

The government of the Russian Federation has expanded the list of life-threatening and chronic progressive rare (orphan) diseases ("**List**"), the treatment of which is carried out with medicines that are centrally procured at the expense of the federal budget. The corresponding Resolution of the Government of the Russian Federation № 1416 was signed by the prime minister on 26 November 2018 ("**Resolution**"). Until recently, this List included seven diseases: hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant tumors of lymphoid, hematopoietic and related tissues, and multiple sclerosis (the so-called Seven Nosologies list). In addition to the abovementioned, medicines that are essential to the treatment of five more orphan diseases, namely, hemolytic-uremic syndrome, systemic juvenile idiopathic arthritis, and mucopolysaccharidoses of I, II and VI types shall be purchased at the expense of the federal budget starting from 1 January 2019.

This program has been maintained through the regional public procurement tenders for the relevant medicines. This will now be changed and tenders will be centralized. The Resolution correspondingly defines the procedure for the transfer of medicines by the Russian Ministry of Healthcare (**MOH)** to the ownership of the Russian regions. It was specified by the Resolution that the need for the medicine shall be determined taking into account the medical care standards, clinical recommendations (treatment protocols) and the average course dose of the medicine based on data from the Federal Patient Register and the need to keep a 15-month reserve.

The Resolution also provides for the possibility of redistributing medicines between the Russian regions if there is a change in the number of patients. In the event of the patient's departure from the territory of the Russian region, the medicine will be prescribed for the period of the medicine's administration, but not more than six months.

For more information, please contact Paul Melling or Alexey Trusov of our Moscow office.

Impact of Organic Law 3/2018 on personal data protection in the field of data processing in health research

New Organic Law 3/2018, of 5 December, on the Protection of Personal Data and Guarantee of Digital Rights ("**Data Protection Law")** contains specific provisions concerning data processing in health research (additional provision seventeen):

- Use of personal data: The data subject or, as the case may be, their legal representative, may consent to the use of their data for health research purposes. It should be noted that not only may these purposes include specific research (a specific clinical trial), but also categories related to general areas that are linked to a medical or research specialty.

Similarly, and without the need for any specific provision in the consent form, the personal data referred to can be reused for purposes or areas of research related to the field in which the initial study was scientifically included. In this case, a favourable prior report from the research ethics committee will be required. At the same time, it is foreseen that, even though personal data may have been collected prior to the Data Protection Law entering into force, it may also be reused for purposes or areas of research related to the medical or research speciality in which the initial study was scientifically included (transitory provision six).

Finally, and as an exception to the need to obtain the consent of the affected party before carrying out scientific studies, using personal data without consent is authorised if the study is carried out by health authorities and public institutions in circumstances that are exceptionally significant and serious for public health. In this case, there is also an exception to the obligation to separate the patient's identification data from that of a clinical-healthcare nature.

- Use of pseudonymised personal data for health research purposes: This use is considered lawful. If the use of such data is for public health research purposes, the following is required: (i) separation between the research team and those carrying out the pseudonymisation; (ii) the research team's exclusive access to pseudonymised data where there is an express commitment to confidentiality and not to carry out any re-identification activities and specific security measures are taken to prevent re-identification and access by unauthorised third parties; and (iii) such use is subject to a prior report by the research ethics committee provided for in sectoral regulations.

- Limitation of the rights of those affected: The Data Protection Law provides that the rights of access, rectification, limitation and opposition to processing personal data for the purposes of scientific research may be limited, if exercising these rights may make impossible or hinder scientific achievement or if this data is necessary to achieve such purposes, in the following cases: (i) exercise of those rights against researchers or research centres using anonymised or pseudonymised data; (ii) exercise of those rights against the results of the research; or (iii) where the research is aimed at areas of vital public interest related to state security, defence, public health or other important objectives in the general public interest (in the latter case, the exception must be expressly covered by a legally- binding rule).

- Guarantees for processing personal data for public health research purposes: To ensure respect for the rights and freedoms of data subjects: (i) an impact assessment of those rights and freedoms must be carried out; (b) research must be subject to good clinical practice standards; (c) measures to prevent re-identification of data subjects must be taken; and (d) where appropriate, a legal

representative established in the European Union must be appointed.

The Data Protection Law also stipulates that within a maximum of one year from its entry into force, research ethics committees must have a data protection officer or, alternatively, an expert with sufficient knowledge of Regulation (EU) 2016/679, among their members.

In any case, in accordance with the Data Protection Law, processing data relating to the health of a natural person is permitted when regulated by the laws and implementing provisions provided for therein. The Data Protection Law includes a list of existing regulations in this regard. In these cases, processing health data is considered necessary, among others, for one of the following reasons: (i) grounds of vital public interest; (ii) preventive or occupational medicine, and the provision and management of healthcare or social welfare; (iii) grounds of public interest in the field of public health or to ensure high standards of quality and safety of healthcare and medicinal products or medical devices; or (iv) scientific research.

For further information, please contact Montserrat Llopart of our Barcelona office.

Medical devices - guidelines for the drafting of tender specifications

On 30 October, 2018, the Ministry of Health published the "Guidelines for the drafting of tender specifications for the purchase of medical devices", which identify the main requirements that awarding authorities shall comply with during the planning and decision-making phases as well as in the subsequent monitoring phase of the performance of public contracts. The Guidelines pursue the primary goal of providing awarding authorities with an effective tool, as standardised as possible, and, at the same time, facilitating economic operators by simplifying the preparation of the tender documentation.

Amongst the core elements, the Guidelines identify the following : (i) the definition of criteria for assessing the quality of medical devices, which shall be grounded on their technical/functional characteristics as well as on their safety and efficiency, (ii) the division of the products into lots, on the basis of their standard use or of their clinical indication, (iii) the inclusion, in the tender specifications, of clauses allowing the timely implementation of the necessary technological upgrades and (iv) the traceability of the medical device at any time for safety and efficiency purposes.

Moreover, given the high technological complexity and innovation characterising certain medical devices, the Guidelines emphasize the need for the awarding authorities to involve professionals (such as physicians, pharmacists, clinical engineers, nurses, etc.) who use and/or manage medical devices in different healthcare areas in order to properly identify the characteristics to be included in the technical specifications.

For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

Bribery in the pharmaceutical sector does not cover nutritional supplements

With its judgment No. 51946 issued on 16 November, 2018, the Court of Cassation established that the crime of bribery in the pharmaceutical sector ("**Comparaggio**"), as laid down in Section 170 et seq. of Royal Decree No. 1265/1934, ("**Consolidated Text of Health Laws**"), does not apply in the case where moneys or other benefits are given and/or promised in order to facilitate the sale of parapharmaceutical products (in the case at hand, food supplements).

Indeed, according to the Court of Cassation, the above-mentioned crime, which punishes those conducts aimed at unduly facilitating the sale of medicines and any other product for pharmaceutical use, cannot be extended to also cover nutritional supplements which, under Legislative Decree No. 169/2004, are food products.

Although the Court of Cassation held that the crime of bribery in the pharmaceutical sector does not apply to the case at hand, it upheld, however, the conviction of bribery cases related to acts contrary to official duties pursuant to Section 319 of the Criminal Code for further illegal actions aimed at facilitating the prescription of parapharmaceutical products, such as the giving of money and other benefits to physicians and the hiring of their relatives.

For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

Increase in clinical trials in Italy

A recent study carried out by the Italian Federation of Healthcare and Hospital Organizations (FIASO) in collaboration with Confindustria and Altems, shows that in the period between 2013 and 2015 the number of clinical trials authorised in Italy experienced a significant growth. Indeed, the study reports that, during this period, 6,332 new clinical trials have been authorised, of which 1,932 were no profit trials. Such increase is even more significant in the light of the fact that in the period between 2000 and 2002 only 1,722 trials have been authorised.

The study also highlights that the therapeutic area which employed the largest number of researchers is the oncology ones (372 researchers, equal to 16.5% of the total), followed by paediatrics (218 researchers, equal to 9.7% of the total), haematology (190 researchers, equal to 8.5% of the total), neurology (178 researchers, equal to 7.9% of the total), internal medicine (169 researches, equal to 7.5% of the total) and cardiology (127 researchers, equal to 5.6% of the total).

Lastly, still with reference to the period between 2013 and 2015, FIASO also reports 507 clinical investigations of medical devices, 2,865 other clinical studies and 3,596 observational studies for a total number of 13,300 studies, including those on medicinal products.

For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

Medical devices: the CE marking is sufficient to certify the conformity of the products to the tender requirements

With its decision No. 259 dated 21 November, 2018, the Regional Administrative Court of Trento held that the exclusion of a biomedical company from a public tender procedure for the supply of medical devices due to the lack of certification of requirements that should be proved by the CE marking is illegitimate.

The appellant was excluded from the tender procedure due to the lack of minimum requirements, as the Commission attested to the failure by the company to submit the declaration of conformity and stated that such information was not available in the technical datasheet, nor were elements or symbols that could have proved the existence of said characteristics were available on the products' label.

In this respect, the appellant stated that, pursuant to Legislative Decree No. 46/1997, in order to be placed on the market, a medical device must previously obtain the CE marking, which is granted only if the relevant product meets the essential safety and efficacy requirements provided for by Annex I to said Decree and that, pursuant to the tender documentation, the penalty of exclusion only applied to the lack of minimum requirements.

In light of the foregoing, the Regional Administrative Court held that the CE marking certifies, per se, the conformity of medical devices to the relevant legislation and, therefore, it is sufficient to prove the fulfillment of the prescribed requirements. For this reason, and considering that the appellant filed the manufacturer's declaration and the CE marking certifying the conformity of the medical devices to the essential safety and efficacy requirements, the court resolved that the exclusion from the public tender procedure was illegitimate.

For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

A medicinal product repackaged for its "off-label" use can be reimbursed by the National Health System

With its decision dated 21 November, 2018, case C-29/17, the Court of Justice of the EU ruled on the conformity with the EU law of national measures allowing the reimbursement, by the National Health System, of a medicinal product repackaged for its off-label use.

The decision of the Court of Justice follows a request for a preliminary ruling filed by the Council of State within a dispute between a pharmaceutical company and the Italian Medicines Agency concerning the legitimacy of the latter's decision to allow the reimbursement, by the National Health System, of a medicinal product for use as a treatment not covered by its marketing authorisation for which repackaging was required.

In this respect, the Court of Justice first confirmed that decisions on the matter of organization and management of health services, fixing of prices of medicinal products and their reimbursement by the national health systems are the responsibility of the Member States, although said decisions must comply with the EU law.

The Court of Justice further observed that the EU law prohibits neither the "off-label" use of a medicinal product nor its repackaging for such use but makes this subject to certain conditions, amongst which, the holding of a marketing authorisation and of a manufacturing license. In this regard, the Court of Justice specified that, under the applicable legislation, the repackaging of a medicinal product for its "off-label" use

does not require a new marketing authorisation/manufacturing license to be obtained in so far as the relevant process (i) does not result in any modification of the medicinal product, (ii) is prescribed by a doctor by means of an individual prescription, and (iii) is undertaken by a pharmacy lawfully authorised to that effect, for that medicinal product to be administered in hospitals.

On the basis of the foregoing, the Court of Justice held that the reimbursement by the National Health System of a medicinal product repackaged for its off-label use conforms to the EU law.

For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

Project to bring Swiss law in line with MDR and IVDR to ensure continued mutual recognition of medical devices in the EEA

Switzerland and the European Union have entered into a mutual recognition agreement by which the conformity assessments for medical devices are mutually recognised. Such mutual recognition requires an equivalent regulation of medical devices. Following the adoption of the Medical Devices Regulation (**MDR**) and the In-vitro Diagnostic Medical Devices Regulation (**IVDR)** in the EU, Switzerland will now have to amend its laws to bring its law in line with EU law. A first amendment of the relevant ordinance already entered was adopted on 25 October, 2017. It regulates, amongst others, how medical devices can be placed on the market and the market surveillance of medical devices during the transitory period until the MDR and the IVD have become fully applicable.

To that effect the Swiss government on 30 November, 2018 submitted a proposal to the two chambers of parliament to amend Swiss law in close alignment with the EU law. The suggested amendments of the Federal Act on Therapeutic Products (**Heilmittelgesetz; HMG**) and the Federal Act on Human Research (**Humanforschungsgesetz; HFG**) were published on 8 January, 2019. These amended provisions as well as the ordinances that have to be adopted based on the amended law have to enter into force in the first half of 2020 to ensure equivalence with EU law.

The partial amendment of the HMG relates to the requirements as regards the medical devices, the conformity assessment procedure, the registration and product identification as well as the duties of the economic players and harmonises these with those of the MDR and IVDR.

Furthermore, the equivalence of the substantive and procedural requirements which the authorisation and implementation of human research projects with medical devices have to meet shall be ensured. In particular, the process relating to the audits and authorisations which the cantonal ethics commissions and Swissmedic are carrying out, the terminology as well as the categorisation of the individual research projects will have to be amended. Equally relevant are the higher transparency requirements of the MDR, in particular with respect to the process to obtain the consent of the competent authorities.

The suggested changes will hardly face any fundamental resistance by the two chambers in parliament because it helps maintain the free movement of medical devices within Europe including Switzerland.

For more information please contact Peter Reinher of our Geneva office.

TİTCK publishes batch release guideline

Recent development
The Turkish Medicines and Medical Devices Agency ("**TİTCK**") published the Batch Release Guideline ("**Guideline**") on 31 October, 2018. The Guideline provides instructions for companies that will apply to the TİTCK to obtain batch certificates and permissions.

What's new?
Pursuant to the Regulation on Manufacturing Sites for Medicinal Products for Human Use ("**Regulation**"), companies carrying out batch release activities only on their facilities must apply to the TİTCK to obtain batch certificates with the information and documents specified in Annex 2 of the Regulation. In addition, importers wanting to engage in batch release only must obtain permission from the TİTCK within one year from the date of publication of this Regulation.
In this respect, the TİTCK aims to provide convenient instructions for companies regarding their batch release applications.Companies can review and follow the instructions and information in the Guideline to make batch release applications for their facilities with ease. Guidelines are available on the TİTCK's website.

Conclusion
The TİTCK continues to provide guidance for pharmaceuticals companies. Pharmaceuticals companies should regularly follow the TİTCK's announcements, carefully review the requirements set forth in the Regulation and make their batch release applications in accordance with the Guideline.

Turkey to introduce a marketing authorization requirement for medicines procured from abroad

Recent development
According to Law No. 7151 on Amendment of Several Laws and Decree Laws Related to Healthcare published in the Official Gazette of 5 December 2018, the amendments introduced to Law No. 984 on Stores Selling Toxic and Active Chemical Substances Used in Pharmacies, Arts and Agriculture ("**Law**") establish several requirements related to human medicinal products procured from abroad.

What's new?
The following obligations have been introduced with respect to pharmaceutical companies supplying human medicinal products into Turkey through procurement from abroad. These human medicinal products do not currently hold a marketing authorisation (**MA)** in Turkey, or are not found in the market for various reasons. They are imported by the public institutions and organisations determined by the Ministry of Health, Social Security Institution and Turkish Pharmacists' Association through prescription, and are provided directly to the patients in accordance with the Guidelines on Procurement and Use of Medicines from Abroad.

• The supplier must now apply for an MA within three years after the pharmaceutical is listed as a medicine procured from abroad, and the MA should be obtained at the latest within two years following the application.
• With respect to medicines that do not hold an MA or for which MA applications have not been made in accordance with the above provision, the president is entitled to determine whether to continue procuring these medicines from abroad.
• With respect to medicines procured from abroad prior to 5 December 2018, the three-year period starts on 5 December 2018.
• With respect to medicines for which MA applications were made prior to 5 December 2018, the two-year period for obtaining an MA starts on 5 December 2018.

With the amendment introduced in the law, the Turkish Medicines and Medical Devices Authority may now impose an administrative fine ranging from TRY 2,000 to TRY 20,000 in infringements of the law.

Conclusion
The provisions above, which have entered into force within the scope of Turkey's localisation objectives, require multinational pharmaceutical companies that procure medicines into Turkey through their distributors to apply for an MA within the specified time limits.

Cosmetics safety: Turkey continues cracking down on unsafe and noncompliant cosmetic products

Recent development
The Turkish Medicines and Medical Devices Agency (**TİTCK**) recently announced the results of its cosmetics sector market surveillance and inspection conducted between June and September 2018.

What do the results say?
The TİTCK's Cosmetics Supervision Department published the list of unsafe and non-compliant cosmetics products detected during the third quarter of 2018. Of the 354 cosmetic products inspected, 99 were non-compliant and 22 were unsafe. A total fine of TRY 845,300 (approximately USD 150,000) was levied against the companies responsible.The cosmetic products safety results reveal that there is a significant decrease in the number of non-compliant products.
However, the total amount of administrative fines have increased remarkably compared to the Q2 results, despite the decreasein the number of non-compliant products. The TİTCK's continuous inspection of the healthcare sector has become stricter to increase the compliance of cosmetic products with the technical legislation.

Conclusion
The TİTCK continues to demonstrate its commitment to periodical market surveillance and inspection of the cosmetics sector. All cosmetic products in circulation must fully comply with the applicable Turkish laws and regulations, and manufacturing companies must ensure they do not sell or distribute unsafe or non-compliant products

TİTCK announces changes for sanctions regarding meeting notification duty

Recent development
The Turkish Medicine and Medical Devices Agency (**TİTCK**) announced on 5 November, 2018 that companies failing to notify the TİTCK regarding meetings, seminars or symposiums for scientific and educational activities they supported will be sanctioned through the Meeting Notification System.

What's new?
Sales centers are required to comply with the rules set forth in the Regulation on Sales, Advertisement and Promotion of Medical Devices ("**Regulation**") in order to support scientific and educational activities for healthcare professionals and technical personnel in health institutions and organisations. Accordingly, companies must notify the TİTCK regarding congresses, seminars, symposiums and similar meetings they organise or contribute to.
In this respect, companies can make their notifications through the Meeting Application System. Sanctions will automatically be imposed through the system for the violation of notification rules pursuant to the Regulation. Therefore, companies will not receive an official letter of notification. The changes will be implemented as of N 9 November, 2018.
Companies can review the Scientific and Educational Activity Meeting Application Guideline to make their notifications. Guidelines are available on the TİTCK's website.

Conclusion
The TİTCK continues to provide guidance to companies in the medical device sector. Companies should follow the TİTCK's announcements, comply with the procedures and principles under the Regulation, and the TİTCK regarding their contributions to the scientific and educational activities.

For more information, please contact Can Sözer or Hilal Temel of our Istanbul office

Competition Commission of South Africa's inquiry into the private healthcare sector nears its end

The Competition Commission of South Africa initiated a marketing inquiry into the status of competition in the private healthcare market in South Africa in 2013.The market inquiry was and remains an ambitious undertaking. When this process commenced in 2013 it was anticipated that the inquiry would be finalised by the end of 2016 but its conclusion has been substantially delayed.The sheer scale of the inquiry, procedural challenges and indulgences to allow for procedural fairness throughout the inquiry had resulted in several delays in finalising this inquiry.

This market inquiry is expected to be finalised by 29 March 2019 - the date announced for the publication of the final report detailing the findings and recommendations of the inquiry. This report was anticipated during November 2018, but this deadline was further extended to enable the inquiry panel to process various submissions received on its provisional report published in July 2018.

The outcome of this inquiry is highly anticipated, as its findings and recommendations are likely to be used to support legislative and regulatory reform in the private and public healthcare sector that is currently being proposed by the South African government - most notably, the introductions of national health insurance. As mentioned above, the provisional findings and recommendations of the inquiry was published in July 2018 and it is unlikely that the inquiry will substantially diverge from its provisional findings in its final report. In its provisional report, the inquiry concluded, amongst others, the following in respect of the state of competition in the private healthcare market in South Africa:

• The South African private healthcare market is complex and opaque, with numerous interrelated stakeholders participating in this market. Features of the private healthcare market are believed to prevent, restrict or distort competition.

• In South Africa, there is a private healthcare sector as well as a public healthcare sector. The inquiry found, however, that the public healthcare sector does not pose any significant competitive constraint on the private healthcare sector. Competitively relevant interactions between the two healthcare sectors are also limited, as the public healthcare sector is not a substantial purchaser of services from the private healthcare sector - a position that will change if a national health insurance regime is introduced.

• The private healthcare market is categorised by high and increasing costs (the above inflationary increases having informed the initiation of the inquiry in the first place).

• Consumers do not have free access to information regarding quality of services, value or prices - this information asymmetry enables the above inflationary increases and prices and lack of competition in the private healthcare sector.

• Many healthcare funders are active in the private healthcare sector in South Africa. Despite this, there seems to be little competition between these market participants as member premiums and out of pocket payments continue to increase.

• The private healthcare sector in South Africa provides high-quality care.There is, however, no standardisation that will allow consumers of healthcare services to compare quality of healthcare services or outcomes relative to the price of those services.

• Regulation of the South African private healthcare sector is insufficient. The incomplete regulatory regime has resulted in a lack of monitoring compliance within this sector.

• Ethical rules that regulate the private healthcare sector are believed to contribute to lack of innovation in the market and hence, to reduced competition. Even where innovation occurs, private healthcare funders

have been slow to adopt such an innovations, hence competition is further halted.

• Although there are numerous medical schemes active in the South African private healthcare sector, there is a concentration at the point of management of these schemes through medical scheme administrators. Hence there is higher concentration in these markets, further illustrated by the fact that there has not been a substantial entry into the medical funders' markets over at least a decade, and no disruptive competition strategies.

• Three big hospital groups dominate the highly concentrated private hospital market - a market that is not constrained by the public hospital system.These hospital groups, hence, exercise substantial buyer power against funders and administrators, that is cannot counteracted by medical schemes and administrators.

The healthcare inquiry accordingly made their various recommendations to cure the ills within the private healthcare sector in South Africa. These recommendations are mainly aimed at ensuring that an appropriate regulatory environment is put into place to ensure: (i) transparency of information in the market to enable consumers to make informed decisions regarding purchasing healthcare and health insurance; (ii) that there is a regime in place that can effectively measure the value of healthcare outcomes and to manage these value outcomes in the market.

For more information, contact Leana Engelbrecht of our Johannesburg office.

The GVH imposes a fine on a pharmaceutical company

The Hungarian Competition Authority (GVH) imposed a fine of HUF 95 million (approximately EUR 280,000) on Bayer Hungária Kft. (**hereinafter"Bayer"or"the Company"**).

According to the decision of the GVH, the commercials of Bayer concerning the non-prescription medicine “Berocca Performance” and the food supplement tablet “Berocca effervescent” were misleading and contained information that was not compliant with sectoral regulations. In its commercials relating to the effervescent tablet, the Company made claims that went beyond the actual and proven effects of the product. Furthermore, the exact component allegedly giving rise to the stated improvement in performance was not specified. As regards the non-prescription medicine “Berocca Performance”, the GVH objected to the fact that the product category to which it belonged was not indicated. Additionally, the claim made in the commercial that the product was effective within a short period of time was not in line with the product characteristics, which stated that it took four weeks to take effect.

Having regard to the foregoing, the GVH imposed a fine. The amount of the fine to be paid is "only" HUF 95 million (approximately EUR 280,000) since the GVH reduced the fine taking into consideration (i) the Company's partial acknowledgement of the infringement; (ii) the fact that the Company has made compliance efforts (cooperation, presentations, submission of evidence, etc.); and (iii) the fact that certain commercial communications and the content and manner in which they were displayed contained not only unlawful information.

Whilst in its decision the GVH referred to the fact that it is not forbidden to use an umbrella brand under which various categories of products can be offered, it also stated that undertakings must pay attention to which product are covered by certain commercial communications and the content and manner in which these are displayed. Adequate information must always be provided in relation to all products.

New rules on homeopathic products

Act CXVIII of 2018 on certain Healthcare and Health Insurance Matters and on the Amendment of certain Healthcare-related Laws, published in the Hungarian Official Gazette on 20 December 2018, amended several laws such as the Act XCV of 2005 on Medicinal Products for Human Use ("**Medicines Act**"). The recent amendment of the Medicines Act provides that homeopathic products with therapeutic indications licensed before Hungary joined the European Union may be placed in the market and they may stay there after 1 January 2020, if they comply with the European Directive on the pharmaceutical codex and the domestic laws implementing such directive.

According to an additional amendment, healthcare service providers are required to provide patients with written information regarding the homeopathic product if they recommend such products to patients. The information shall include, amongst others, the followings: the patient's health condition and the physician's judgement of the condition; the recommended examinations, interventions and their planned date, the proposed lifestyle; and possible alternative treatment methods. It will clearly place a great additional burden on healthcare service providers in case they want to recommend homeopathic products to patients. Failure to comply with the above provisions will qualify as a non-criminal offence.

For more information, please contact Helga Bíró or Bianka Tóth of our Budapest office.

New French “IP box”

The 2019 French Finance Act modified the taxation of revenues derived from intellectual property (**IP**) assets, or “**IP box**”, to ensure its compliance with the OECD recommendations and particularly with the Nexus approach. This new regime, applicable to fiscal years beginning on or after 1, January 2019, decreases the CIT rate down to 10%, and introduces substantial changes to the scope and conditions of application of the French “patent box”.

Reminder of the previous regime

Until 31 December 2018, revenues derived from the license or sale (excl. to associated enterprises) of IP assets falling within the scope were taxed at a reduced CIT rate of 15%. Pursuant to this regime, royalties were taxed only after the deduction of expenses related to the routine management of the license. As such, the R&D expenses incurred by the enterprise for the creation and development of eligible IPs were deducted from the income taxable at the standard CIT rate (and not from the income taxable at the reduced rate).

Presentation of the new regime

- **Eligible assets**

The list of eligible IP assets has been notably amended to (i) include software protected by copyright and (ii) restrict the eligibility of patentable inventions with certain conditions. Patents and other related IP assets remain eligible.

- **Option**

The benefit of the French IP box is optional. The option can be made on a global basis or by asset or group of assets contributing to the manufacturing of a product/service or a family of products/services. The possibility to opt by product specifically fits the way the pharmaceutical industry generally organizes its research activities and the exploitation of its IPs. Hence, this may enable the industry to better benefit from the new regime.
After it has chosen, the enterprise may change its choice, but will then definitively lose the benefit of this regime for the asset (or group of assets) concerned.

- **Determination of net income taxable at the reduced rate**

The reduced rate is applied to the net income of each asset (or group of assets) for which the enterprise opted. For the purpose of determining the net income:

- Revenues correspond to those derived from the license or sale (for the latter, excl. to associated enterprises and provided it has not been acquired with consideration in the past two years) of the IP assets.
- Deductible expenses are R&D expenses incurred by the enterprise, directly related to the creation, acquisition and development of the asset (or group of assets), including expenses incurred prior to the fiscal year on which the enterprise opted for the regime (this "recapture" mechanism shall be further specified by the French tax authority). This is a major change from the previous regime and will significantly affect companies that have so far benefited from this regime on the gross amount of their eligible revenue. This loss may not be compensated by the decrease in the tax rate from 15% to 10%.

If the net income determined above is negative, it will be carried forward indefinitely to the net incomes determined during the subsequent fiscal years for the same asset (or group of assets).
For French tax groups, this calculation will be made at the level of each group member.

- **Inclusion of a "nexus" ratio**

The new French IP box includes a “nexus” mechanism which aims to tie the tax advantage resulting from the benefit of this regime to the R&D expenses incurred by the taxpayer itself or outsourced to third-parties. Thus, under this mechanism, a taxpayer outsourcing most of its R&D activities to a foreign associated enterprise will no longer be able to fully benefit from the reduced tax rate on the income derived from the asset (or group of assets) for which it opted.

- **Documentation**

Any enterprise that opted for the application of the IP box regime will have to keep at the disposal of the French tax authority a documentation justifying the determination of the taxable base and monitors the assets (or groups of assets) for which the enterprise opted. Failure to provide this report upon request of the French tax administration may result in a fine amounting to 5% of the income taxed pursuant to this regime.

- **Practical consequences**

In practice, the application of this new regime requires all enterprises benefiting so far from the IP box to carry out a global review of their eligible assets under the new regime and to set up internal mechanisms to monitor the costs and income associated with the assets for which the enterprise will opt.

For more information, please contact Lionel Ochs, Benoît Granel, Marion Brauge of our Paris office.

Implementing safety features under the Falsified Medicines Directive

The Falsified Medicines Directive (Directive 2011/62/EU) sets out measures to prevent falsified medicinal products for human use from entering the supply chain, and increase security of the manufacturing and delivery of medicines across Europe. The Delegated Regulation 2016/161 (**Delegated Regulation**) applied automatically in all EU Member States from 9 February 2019, and helps to implement the Directive.

The Delegated Regulation will require manufacturers to place the following safety features on all medicines:

• a 2D matrix code (a unique identifier); and
• an anti-tampering device (e.g. a seal on the outer packaging) that can verify whether the packaging has already been opened.

The new requirements come with an additional cost for manufacturers and may influence decisions on bringing older and lower-cost drugs to market. The impact will be particularly felt in markets such as the Netherlands where drug prices are typically lower. Margins on such older and/or generic drugs are very small and may be squeezed out according to the generic industry. While the Dutch Ministry of Health has expressed its willingness to revise prices upward it is unclear if health insurers will agree to such price increases.

One change in the Delegated Regulation which has garnered some interest relates to those in the supply chain who are required to verify the authenticity of medicinal products. At a high level, wholesalers will not always be required to verify the authenticity of a unique identifier of a medicinal product which is in its possession.

For example, wholesalers will not be required to verify the authenticity of a unique identifier of a medicinal product if that wholesaler receives products from any of the following parties:

• the manufacturer; or
• another wholesaler holding the marketing authorization (**MA**); or
• another wholesaler designated by the MA holder, by means of a written contract, to store and distribute the products covered by the MA holder's MA on his behalf (sometimes referred to as a **Designated Wholesaler**).

In practice, this means that if any of the above apply to a medicinal product received by a wholesaler (i.e. the product is received by the wholesaler from the manufacturer, or another wholesaler holding the MA, or a Designated Wholesaler), that recipient wholesaler is excluded from having to authenticate that product under Article 20 of the DR.

The future of the scheme is uncertain in the UK, which would lose access to the European centralised databank following a no-deal Brexit, and there is speculation that the UK would set up its own standalone falsified medicines scheme in such circumstances.

In the short term, the UK is fully bound by the scheme, but the MHRA has issued some guidance indicating that it may apply a light touch approach to enforcing the rules at this early stage. It notes that this has been a complex scheme to set up and that it is anticipated that issues will arise especially during the initial / implementation phase, and that such issues must not compromise confidence in the medicines supply chain. The MHRA notes that several Member States have formally advised those who may receive ‘unknown’ error messages to dispense anyway and that "therefore, the MHRA will also be taking a pragmatic, flexible approach to how we enforce the new legal requirements, as long as the normal checks are carried out, and there is no reason to think that the medicine is falsified."

For more information, please contact Jaspreet Takhar or Julia Gillert of our London office.

EMA announces closure of London office from 1 March 2019

The EMA will officially close its London office on 1 March 2019, Politico reports on 22 January, and is already actively moving to its temporary office in Amsterdam (EMA's new permanent headquarters, a tailor-made building in the Zuidas business district of Amsterdam, are planned for completion in November 2019). The move and the fact that around 30% of the staff are not moving with the Agency means that despite best efforts, there are capacity issues currently.

The EMA, which has had a staff of 900 in London, held a ceremony on 25 January, as many staff left the Canary Wharf office for the last time, tweeting: “Today, EMA staff lowered the 28 EU flags and symbolically said goodbye to their London offices. [EMA executive director,] Guido Rasi expressed his thanks to the UK for its contribution to the work of the Agency and for having been a gracious host of EMA since 1995.” Key figures in the UK industry expressed their sadness at the move; Jeremy Farrar, the director of the Wellcome Trust, said it was a “very sad day for the UK” and “a great day for the Netherlands”. The loss to the UK not only of the EMA itself, but of the UK's extensive participation in the EMA, is significant. The head of the ABPI, Mike Thompson, has said it has been akin to watching a “British success story” being broken up.

For more information, please contact Julia Gillert of our London office.

European Commission Report on Competition Enforcement in the Pharma Sector

The European Commission recently published a **report** on the antitrust enforcement activities of the Commission and the individual EU Member State competition authorities for the period 2009 – 2017. This Report follows the Commission’s inquiry into competition in the pharmaceutical sector which concluded in July 2009. The Report makes it clear that effective enforcement of competition law in the pharma industry remains a high priority and that competition authorities in Europe will continue to monitor and proactively investigate potential anti-competitive conduct. The Report focuses on medicinal products for human use.

Enforcement Statistics (2009 – 2017)
Antitrust

- 29 antitrust decisions by European competition authorities (13 national competition authorities plus the Commission) against pharma companies, with fines totalling over EUR 1 billion (http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/list_cases.pdf).
- They have also adopted 17 infringement or commitment decisions in cases concerning medicinal devices and 23 in cases related to other healthcare matters.
- In 24 of the 29 cases involving pharmaceuticals, the case was closed with a prohibition decision finding an infringement of EU competition law. Fines were imposed in 21 cases (and in 87% of all infringement decisions)
- In 5 cases, the investigation could be closed without finding an infringement or imposing fines because competition concerns were sufficiently addressed by the commitments of the investigated companies.
- The anticompetitive practices ranged from (i) exclusionary conduct to delay the entry of generic medicines into the market, to (ii) market sharing/price fixing practices and (iii) pay-for-delay agreements, where originator and generic companies colluded to keep the generics off the market and shared the originator's profits from doing so. Several investigations concerned (iv) excessive prices charged for off-patent medicines.
- 45% of cases were abuse of dominance cases; 31% were restrictive horizontal agreements such as pay-for-delay agreements; the rest were outright cartels such as bid-rigging; and vertical restrictions such as clauses preventing distributors from promoting and selling products of competing manufacturers.
- The authorities investigated more than 100 other antitrust cases while over 20 cases of possible infringements are currently being examined.

Mergers

- The EC examined more that 80 mergers in the sector. Antitrust concerns were identified in 19 cases and all were cleared with remedies.

- The potential competition concerns identified related mainly to the risk of (i) price increases for some medicines in one or several Member States; (ii) depriving patients and national healthcare systems of some medicinal products; and (iii) diminishing innovation in relation to certain treatments developed at European or even global level. The issues identified by the Commission typically involved a small number of medicines compared to the overall size of the companies' portfolio.
- The intervention rate in the pharmaceutical sector was around 22 %. In comparison, the total intervention rate across all sectors during the period was only 6 %.

Market monitoring and advocacy

- The competition authorities took also more than 100 market monitoring and advocacy activities (http://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/list_monitoring_advocacy.pdf). Monitoring activities include sector inquiries, market studies and surveys to identify obstacles to the proper functioning of competition.
- Advocacy activities include consultative opinions, ad hoc advice and other measures that promote – for instance vis-a-vis legislative and administrative bodies – approaches and solutions that are conducive to effective and fair competition in a given sector or market.
- Of the 30 sector inquiries or market studies undertaken, around a third focused on retail distribution of medicines and competition between pharmacies. Another main focus was the wholesale distribution of medicines, including specific competition issues related to parallel trade or pricing issues. A third main focus of the monitoring activities related to the penetration of generic medicines.

Enforcement activities have focused on two main objectives: access to cheaper medicines and access to innovative medicines.

Access to cheaper medicines

- European competition authorities have investigated and sanctioned practices that lead to higher prices. Landmark decisions were taken by both the Commission (Lundbeck, Fentanyl and Servier cases) and the United Kingdom authority (Paroxetine case) against pay-for-delay deals.
- There have been several recent investigations into the pricing of certain off-patent medicines, and several authorities have found such pricing practices to be unfair and abusive, namely in Italy (the Aspen case), the United Kingdom (the Pfizer/Flynn case) and Denmark (the CD Pharma case).
- Higher prices may also result from mergers of pharmaceutical companies. The Commission has intervened in a number of mergers that could have led to price increases, in particular for generic products (e.g. the Teva/Allergan case) or biosimilar products (e.g. the Pfizer/Hospira case) – both deals were cleared subject to divestment remedies.

Access to innovative medicines

- The Commission's focus appears to be on preserving competition in pipeline products when applying the merger control rules. The Commission has intervened to protect innovation competition in a number of cases which, for example, threatened to thwart advanced R&D projects for life-saving cancer drugs (Novartis/GlaxoSmithKline Oncology) or for pipeline insomnia medicines at an early stage of development (Johnson & Johnson/Actelion).

For further information, please contact Fiona Carlin of our ECLP office in Brussels or Farin Harrison of our London office.

Supplementary protection certificates cannot be granted to medicinal products incorporated by medical devices

With its judgment dated 25 October, 2018, Case No. 527/17, the Court of Justice of the European Union held that, for the purposes of obtaining a Supplementary Protection Certificate (**SPC**), an EC certificate of conformity for a medical device incorporating a medicinal product cannot be considered equivalent to a

marketing authorisation.

In particular, the above-mentioned decision follows a request for a preliminary ruling on whether Section 2 of Regulation (EC) No. 469/2009 - which provides that an SPC may be granted only where the medicinal product has obtained a valid marketing authorisation pursuant to Directive 2001/83/EC - must be interpreted as meaning that an EC certificate of conformity of a medical device incorporating a medicinal product is to be treated as a valid marketing authorisation.

In this respect, the Court of Justice clarified that a substance, like that at issue in the main proceeding, which forms an integral part of a medical device and acts upon the body in a manner ancillary to that device, may not be regarded as a medicinal product capable of being the subject of a marketing authorisation procedure as laid down in Directive 2001/83/EC. On the basis of the foregoing, the Court of Justice established that such substance cannot be classified independently from the medical device into which it is incorporated and that, therefore, it shall not fall within the scope of Regulation (EC) No. 469/2009.

For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

EMA's new guidelines on the quality of water for pharmaceutical use

On 15 November, 2018, the EMA launched a public consultation on the draft of new guidelines on the quality of water used during manufacture of active substances and medicinal products for human use, ("**Guidelines**"). Besides replacing the previous version of the guidelines adopted in 2002, the aim of the document is to provide updated guidance on the proper use of water in the manufacturing process of active substances and medicinal products for human use.

In this respect, the draft Guidelines highlight that water is one of the major commodities used by the pharmaceutical industry in the manufacturing of drugs, as it may be present as an excipient or used for reconstitution of products, during synthesis, during production of the finished product, or as a cleaning agent for equipment, primary packaging materials, etc. The Guidelines also specify that different grades of water quality are required depending on the different pharmaceutical uses. In light of the foregoing, the Guidelines emphasize that control of the quality of water, in particular the microbiological quality, is a major concern and that the pharmaceutical industry devotes considerable resources to the development and maintenance of water purification systems.

Lastly, the EMA clarifies that validation and qualification of water purification, storage and distribution systems are a fundamental part of Good Manufacturing Practice and that the Guidelines should be considered to evaluate the quality of the water for new marketing authorisation applications, as well as any relevant variation application to existing marketing authorisations.

The deadline for comments is 15 May, 2019.

For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

EMA issues new PV paediatric guidelines

On 25 October, 2018, the EMA published the new Guidelines on good pharmacovigilance practices in the paediatric population ("**Guidelines**"), which replace the previous version issued in 2007.

The adoption of the Guidelines is due to a number of changes in the scientific and regulatory environment that occurred after the entry into force of the EU Pediatric Regulation and which had direct consequences for the conduct of pharmacovigilance in the pediatric population, amongst which: (i) the development of new paediatric medicines reflected by a growing number of paediatric indications for innovative medicines, newly authorised paediatric age-specific formulations and new paediatric indications for medicines with an existing marketing authorisation for adults, and (ii) new pharmacovigilance legislation, i.e. Directive 2010/84/EU and Regulation (EU) No 1235/2010, providing for strengthened pharmacovigilance processes for all medicines, irrespective of their authorised indication(s) and population(s).

Besides reflecting such a different scientific and regulatory framework, the new Guidelines also provide for specific instructions on how to conduct, in the most efficient way, pharmacovigilance in the paediatric population, taking into account the specific characteristics of this sector, such as (i) the differences in adverse reactions between the paediatric and the adult population in terms of frequency, nature, severity and presentation, (ii) the limited numbers of clinical trials conducted, (iii) the greater severity of possible

medication errors, and (iv) the "off-label" use in paediatric patients of medicines intended for adults.

For more information, please contact Riccardo Ovidi or Roberto Cursano of our Rome office.

Concerns grow over medical devices supply shortfalls in no-deal Brexit

BSI, the largest EU notified body, has been celebrating its UK arm becoming the first designated notified body under the Medical Devices Regulation (EU) 2017/7/745 (**MDR**). This should be good news for device manufacturers requiring certification under the MDR before its full application from 26 May 2020. However, the designation may be short lived in the case of a no-deal Brexit, at which point no UK based notified body can be EU-27 compliant, and BSI is prepared for this, transferring its clients' current CE certificates from BSI UK to BSI's new office in The Netherlands. BSI-NL is expecting to achieve MDR designation mid-2019.

Under the MDR, medical devices (apart from self-certified devices) require certification by a designated notified body. Currently, we are in the transition period where certificates issued under the Medical Device Directive are valid (and will remain so for up to four years after the date of issue) and devices can also be certified under the MDR. BSI UK's designation comes six months earlier than expected and hopefully signals the next phase in the implementation of the MDR with more designations in the coming months.

However, in a no-deal Brexit scenario, all UK based notified bodies will be de-designated from 30 March 2019 and their certificates (including CE certificates issued under the current Directive) will no longer be valid in the EU-27. (For this reason, BSI UK will accept submissions for conformity assessment under the MDR for those manufacturers wishing to place product on the UK market only.) Post a no-deal Brexit, manufacturers will no longer be able to transfer CE certificates to an EU notified body. A new EU conformity assessment will be required and EU market access may be interrupted while that assessment is conducted (which is likely to take some time with many manufacturers looking to re-certify products post-Brexit).

If enforced by the EU-27, this has the potential to become a significant public health issue across the region, where any products that were conformity assessed by UK notified bodies (and 50% of medical devices are estimated to be certified by UK notified bodies) could not be placed upon the EU-27 market. This has resulted in an increase of calls (e.g. last week from Dutch hospitals) for emergency legislation to allow the acceptance of UK notified body certified devices in the EU-27 post a no-deal Brexit to avoid major supply shortfalls affecting patients.

The UK's MHRA has said that it will continue to accept such products for the UK market. However, an additional problem for the UK market post a no-deal Brexit will be that UK notified bodies will be unable to issue certificates of conformity for *new* products being placed upon even the UK market only, as they will no longer be competent to do so under the Directive.

For further information please contact Julia Gillert or Emma Panhuber of our London office.

Call for harmonised sunshine and transparency laws across Europe
On 23 January 2019, Mental Health Europe (**MHE**) launched a report in the European Parliament recommending a move towards more transparent cooperation in the healthcare industry, particularly between pharmaceutical companies and HCPs. The MHE's assessment of transparency laws at a national level found that currently only 8 EU countries have enacted laws mandating disclosure of interactions between pharmaceutical companies and HCPs, while the remaining 19 rely on self-regulation.

MHE is essentially calling for an EU equivalent to the United States' *Physician Payments Sunshine Act* introduced in 2013. Its report acknowledges that self-regulation is a "substantial step forward" but concludes that "fully transparent cooperation…can only be ensured through legally binding laws implemented across Europe."

MHE's recommendations include a harmonised, legally binding approach to disclosure of interactions between, amongst other actors, pharmaceutical companies, HCPs and healthcare organisations which comprises, at a minimum (amongst other things):

- mandatory disclosure at an individual level;
- no or low thresholds for transfers of value;
- a centralised database of disclosed information; and
- monitoring mechanisms.

In a press release regarding the event, MHE reports that experts attending the launch of the report in the European Parliament agreed that there is room for improvement of EU transparency laws. Will legislators take steps towards harmonised transparency laws? With increasing regulation of the healthcare industry worldwide, and particularly following the Sunshine Act, this is an area to watch.
A copy of MHE's report can be found here.

For further information please contact Julia Gillert or Emma Panhuber of our London office.

Baker McKenzie.

International

IFPMA's latest Code of Practice bans gifts and promotional aids

This article first featured in Lexology on 25 January 2019.

The International Federation of Pharmaceutical Manufacturers and Associations' Code of Practice (the "**Code**") has been amended for the first time since 2012. The Code applies to IFPMA's members and anyone acting on their behalf. The amended Code came into effect on the 1st of January 2019 and comprises two important changes in relation to its previous version. First, it bans gifts and promotional aids for prescription medicines. Second, the Code presents a shift from a rules-based to a values-based approach.

As the introduction indicates, several provisions have been updated, in particular on gifts and promotional aids. These, so-called "goodies", are now fully banned for prescription-only medicines (**POM**s). Although the 2012 Code banned gifts for the personal benefit of healthcare professionals (**HCP**s), it did permit exceptions like customary gifts for significant national, cultural or religious events (for example mooncakes and condolence payments). Such exceptions have now been removed. The ban also includes stationary items such as pens, post-it's and block notes (when not being offered for the sole purpose of taking notes during a conference). The aim of this change is to avoid "any perception of potential influence" of an HCP while prescribing a POM.

Further, a new category of informational and educational items has been added to the Code. This category includes scientific books, journal subscriptions and memory sticks with educational data. These items may be provided to HCPs for their own education or for the education of patients, provided that the items do not have independent value and are not branded. The same applies to products of medical utility used to train patients (such as inhalers or self-injectors) which also may not be branded.

Over-the-counter (**OTC**) products, when not prescribed by an HCP, are of lower concern, since it is the patient itself who makes the choice whether or not to buy a particular product. Therefore, the Code still permits promotional aids of minimal value and quantity, related to OTC products, to be provided by member companies to HCPs. But only if it is relevant to their practice.

Already in 2014, the European Federation of Pharmaceutical Industries and Associations (**EFPIA**), updated their code to ban gifts in relation to prescription medicines.This tightening of the rules to fully ban gifts by IFPMA brings its code into line with current US and European guidance and rules.

The second reason given for amendment of the Code is the introduction of an IFPMA Ethos to shift from a rules-based approach to a code based on values and patients' trust. According to the IFPMA's news release, the new ethos aims to go beyond and seeks to instil a culture of ethics and integrity. This new ethical framework must guide business behaviours and interactions between IFPMA members and the healthcare community, no matter how testing the circumstances.

Thomas Cueni, who became Director General of IFPMA in 2017, states in the foreword of the Code that the new Code represents IFPMA setting the bar higher, and that the new code "seeks to embody a deeper and broader appreciation of business integrity", being "principle-based".

Many national and regional pharmaceutical trade associations rely on the IFPMA Code for their own codes of conduct, and, whilst companies may also be following their local codes, the IFPMA Code acts "as a default" for any complaints about the activities of member companies in countries where there is no national code, no appropriate regulations, or where a member company is not part of the local association.

For further information please contact Julia Gillert (London) or Martine van de Laar (Amsterdam)

United Kingdom

MHRA ramps up detail on no-deal plans

Along with other agencies, the Medicines and Healthcare products Regulatory Agency, the MHRA, has removed the word "unlikely" from its references to the possibility of "no deal", and is accelerating its planning for this eventuality, though it is "not [its] policy or … preferred approach".

Further to the consultation launched in October, the MHRA published a response to that consultation by updating its no deal guidance on 3 January and 4 January.

In this guidance, which covers medicines, clinical trials and medical devices, the MHRA states that if there's no deal, then from the point of Brexit:

Medicines

• the **UK's participation in the EMRN will cease**
• the **UK will no longer be a part of the EU centralised, mutual recognition and decentralised procedures**
• the **MHRA will take on the functions currently undertaken by the EU** (via EMA) for the UK market, requiring changes to UK law, via the Human Medicines Regulations 2012
• the **MHRA proposes to continue using, until further notice, the EU GMP and GDP guidelines**
• transitional legislation will ensure that all currently granted CAPs, or Centrally Authorised Products, automatically become UK MAs ("grandfathering"), giving MAHs:

- a short period (later clarified as up to 22 April) within which to opt out of having a UK MA
- a year to provide the MHRA with baseline data for the CAPs that are converted (and the MHRA will accept a 'basic' baseline data set initially to enable variations and other post-authorisation submissions to be processed, even when the full baseline data is still pending)

• for **CAP applications that are pending** at the point of Brexit:

- if the application submitted to EMA must also be submitted to the MHRA
- if the CHMP has issued an opinion already, the MHRA will make its decision taking into account that opinion
- if no CHMP opinion has yet been issued, the MHRA will continue to assess the application as a national procedure, taking into account any CHMP assessment that has already taken place for mutual recognition or decentralised procedure applications that are pending at the point of Brexit, a transitional provision will be made and the MHRA will complete the assessment and if successful, they will be approved as UK MAs

• **UK MAs** based on EU reference products that have been granted (or are pending) prior to Brexit will remain valid in the UK
• **UK MAs** already approved in decentralised and mutual recognition procedures will remain valid in the UK
• **for generic** MAs, the MHRA will not have access to the data provided in support of EU approved products and therefore new generic applications would need to be based on reference products that have been authorised in the UK
• MA applications for **ATMPs** to be marketed in the UK, whether for an initial, variation or in progress application, or a conversion from a CAP, would be treated in line with other MAs
• **abridged procedures** for obtaining an MA in the UK would remain but would be amended as it will not be possible to rely on a European reference product for any new applications submitted after Brexit
• sharing of common systems, and formal exchange and recognition of data submitted between the UK and EU would cease; the MHRA will have oversight of all **pharmacovigilance** activities in the UK (this includes

risk management plans, reports of suspected adverse drug reactions from the industry, UK and non UK ICSRs, PSURs and PASS)
• the MHRA will offer **new assessment procedures** for applications for products that would until now have been made to the European Medicines Agency for CAPs, alongside its existing 210 day national licensing route, with a 67 day timeframe for products containing new active substances or biosimilars submitted to the EMA and received a CHMP positive opinion
• the MHRA plans to work to **reduce the 210 day timetable to 180 days** and to offer a 'rolling review' for new active substances and biosimilars to allow companies to make an application in stages throughout the product's development, and a full accelerated assessment as a choice for new active substances, in 150 days (it will publish further guidance regarding these proposals in due course)
• the EU criteria for **orphan medicines** will be adopted by the MHRA, though some UK specifics will be incorporated in due course
• decisions on **paediatric investigation plans** (PIPs) will be made by the MHRA (it has expressed an intent to ensure incentives remain to encourage such medicines onto the UK market)
• **data and market exclusivity periods** will not change in the UK, and will start on the date of authorisation in the UK or EU, whichever comes first
• **rules on legal presence in the UK for MAHs** will be in place:

- an **MAH should be established in the UK by the end of 2020** (and a change of ownership will need to be submitted to MHRA to change from an EU MAH to a UK MAH for UK MAs)
- a **QPPV should be established in the UK on day one**, but until the end of 2020, an EU QPPV may assume responsibility for UK MAs until a QPPV who resides and operates in the UK can be established (a variation must be submitted to the MHRA to change QPPV)
- a **QP for products manufactured in the UK** or directly imported into the UK from a country not on an approved country list (which will include the EU and EEA) must reside and operate in the UK
- where the MAH is not established in the UK on exit day, companies must put in a place a **UK-based contact person within four weeks of Brexit**

• the UK will continue to recognise **QP certification** from EU / EEA countries but UK holders of Wholesale Authorisations must notify the MHRA within six months to continue to import medicines QP certified in the EU / EEA to revise their WDA and put in place an assurance system to ensure any medicines they import have been QP certified
• **packaging and leaflets for UK** products will have to be amended by end of 2021 to comply with UK requirements, including UK administrative information such as the UK MAH's name and address, etc., with more urgent updates required earlier
• the MHRA will continue to accept proposals for **packaging and leaflets in the English language** that include information on other jurisdictions (e.g. **Ireland)**, providing UK requirements are met
• it is expected that UK stakeholders will not be able to comply with the requirement under the **Falsified Medicines Directive** to verify and authenticate and therefore the legal obligations related to this would be removed for all players in the UK supply chain
• the UK will unilaterally align to the EU/EEA exhaustion regime from Brexit to provide continuity in the immediate term for businesses and consumers so that parallel imports of goods including medicines can continue from the EU/EEA
• medicines that hold an MA in another Member State or are CAPs, and are "essentially similar" to a product granted a UK MA, may still be imported under a **parallel import licence**
• **parallel import licence holders must in future be established in the UK**; those currently holding licences have until 31 December 2020 to effect this change if currently established elsewhere in the EU/EEA but only four weeks from Brexit to put in place a UK-based contact person (who will no longer be required once a UK licence holder is established)
• holders of **parallel distribution notices**, issued by the EMA, in respect of CAPs will, where the UK is listed in that notice as a destination country, be automatically, and with no fee, issued with a parallel import licence, providing specified information is given to the MHRA by 21 April 2019
• for batches of **immunological medicinal products** or a medicinal product derived from human blood or plasma, the UK is unlikely to still be part of the OMCL but would work to put in place mutual recognition of Official Control Authority Batch Release (OCABR) batch testing with other countries, such as Switzerland and Israel. For countries where there is no mutual recognition agreement, the MHRA will require UK certification of batches by the UK's NIBSC before the medicine can be placed onto the market. There will be a risk-based approach regime taking into account an approved country list, which will include all EU/EEA countries upon the point of Brexit
• UK-based online sellers would no longer be required to display the EU common logo to sell into the UK; the MHRA proposes to explore requiring a **new 'UK logo' for UK-based online sellers from 2021**
• the MHRA will **charge fees** for the tasks taken on from the EMA, such as GBP 62,421 for a major

application for an MA for a new active substance

Clinical Trials

• the **UK's participation in the European regulatory network for clinical trials will end**
• the **MHRA will take on the responsibilities for the UK that are currently undertaken through the EU system**
• the UK will continue to **recognise existing approvals** – both for regulatory and ethics
• the UK would require **the sponsor or legal representative of a clinical trial to be in the UK or country on an approved country list,** which will initially include EU/EEA countries
• the MHRA's contact point idea has been dropped following stakeholder feedback during the consultation, therefore, note that **the EU's current position is that where trials are pan-EU, sponsors or legal representatives must be based in the EU**
• the **UK's current regulatory framework,** as per the 2004 Regulations, will remain in force but will be modified under the EU Withdrawal Act to ensure it still works post Brexit
• the new **EU Clinical Trials Regulation** 536/2014 will not be in force in the EU at the time of Brexit and so will not be incorporated into UK law at that point. The UK has issued an update on the Regulation, with a clear **commitment to align** with it where possible without delay when it does come into force in the EU, subject to UK parliamentary approvals
• for **IMPs** coming into the UK, the UK will recognise **QP certification** done in an approved country (which will initially include all EU/EEA countries) but note that the EU's current position is that QP certification of IMP must be undertaken within the EU/EEA
• all importers of IMPs into the UK will require a Manufacturers Licence (MIA), and clinical trial sponsors will have 12 months from Brexit to comply with the following rules:

  - IMPs being supplied directly from EU/EEA states permitted
  - IMPs coming from countries on the approved list, the MIA (IMP) holder must put in place an assurance system overseen by a QP to check these IMPs have been QP certified in the EU/EEA
  - IMPs coming from other countries would, as today, require QP certification in the UK by the MIA (IMP) holder

• as now, the MHRA will require sponsors to submit all UK relevant SUSAR reports but they must be submitted via UK based IT systems, as they will no longer be able to report via EMA systems
• as now, the MHRA will require sponsors to submit annual safety reports for all UK trials
• the ability for UK patients to participate in multinational trials will not change
• as now, UK clinical trial applications will continue to be authorised by the MHRA and ethics committees
• as now, clinical trial applications require the contact details of the principal investigator(s) at UK sites
• post-Brexit, the MHRA will be **improving processes for clinical trials** to enable closer working with ethics bodies and allowing a single application and a single national decision in the UK
• the UK intends to **align transparency provisions** with those currently operating in the EU, to avoid duplication by companies; in the short term, the MHRA advises continued registration with EudraCT, ISRCTN, ClinicalTrials.gov and in the longer term, the UK will have its own specific hub that will give both UK patients and researchers a single reference point for all UK trials by the time the EU's new portal goes live as part of the CTR

Medical Devices

• the **UK's participation in the European regulatory network for medical devices will cease**
• the **MHRA will take on the functions currently undertaken through the EU system for the UK market**
• during a time limited period, the **MHRA will continue to allow devices to be placed on the UK market that are in conformity with the applicable EU Directive**
• relevant l**abelling requirements will continue** to apply regarding CE marks and CE certificates
• the UK will **comply with all key elements of the MDR and IVDR**
• **UK-based Notified Bodies will no longer be recognised by the EU after Brexit,** meaning the devices they have certified will no longer be in conformity with the applicable EU Directive and as such those **products will not be able to be placed on the EU market**
• the **MHRA will give UK-based Notified Bodies an ongoing legal status** and continue to recognise the validity of certificates that they issued prior to Brexit, allowing those products to be placed on the UK market
• the MHRA will continue to accept **labelling in the English language** that include information from other jurisdictions (e.g. **Ireland**), providing UK requirements are met
• the UK will continue to **recognise existing clinical investigation approvals** – both for regulatory and ethics approvals – and there will be no need to re-apply

• the MHRA will continue to perform **market surveillance of medical devices** on the UK market and be able to take a decision over the marketing of a device in the UK, regardless of the position of the EU regulatory network, or any decision of the CJEU
• all **medical devices, active implantable medical devices, IVDs and custom-made devices will need to be registered** with the MHRA prior to being placed on the UK market, and grace periods of 4-12 months depending upon the product will apply to allow time for compliance. The registration requirements will require:

- the GMDN code, meaning that **groups of similar products can come under a single registration**
- once the MDR and IVDR fully apply (from May 2020 and May 2022 respectively), the UK will then mirror the new requirements within the legislation, which will mean **individual registration of all products**

• medical device manufacturers not established in the UK must have a **UK Responsible Person** established in the UK with a UK registered address to take responsibility for the product in the UK (but no labelling changes will be required to reflect this)

For more information contact Julia Gillert of our London office.

MHRA requires information from MA Holders regarding "Grandfathering" of EU centrally authorised medicines to UK MAs

The MHRA issued letters to MA holders on 2 January, and published the form of letter on 21 January, regarding the conversion of Centrally Authorised Products (CAPs) to UK MAs.

The MHRA states in its letter that to facilitate the grandfathering process, it has assigned a Product Licence (PL) number to CAPs based on the existing UK practice for national licences, listed in the letter annex. It has allocated a PL number based on each presentation within the product range, rather than a separate number for each pack size, so that there will usually be fewer UK authorisation numbers issued compared with those issued by the EMA.

In the letter, the MHRA sets out a list of actions for each MA holder to take concerning its list of products, as follows:

1. check the list of currently authorised CAPs and advise the MHRA as soon as possible of any errors or omissions in that list
2. review the list of assigned UK MA numbers and contact the MHRA as soon as possible with any queries in relation to the number of different UK MAs numbers allocated
3. advise the MHRA of any CAPs that you do not want to be converted into UK MAs
4. advise the MHRA of the UK marketing status of each of the products
5. inform the MHRA if any of the products / presentations have been withdrawn or cancelled
6. inform the MHRA if the MAH company number assigned to the list of products is incorrect
7. advise the MHRA of a single point of contact for all the products (in the case of a company group, a contact for each MAH affiliate within that group)

Important points to note:

- Further to (3) above, MAHs can opt-out of the grandfathering process for all or some of their CAPs by notifying the MHRA in writing by 22 April 2019, in which case after that date their product(s) will no longer be licensed in the UK and can no longer be placed on the UK market. However, the MHRA asks if MAHs could please inform it by 31 January if they are planning to opt out and not have a UK licence for a product, by a separate communication if the full response is still pending.

- MAs for CAPs that are not currently marketed in the EU or UK can still be converted to UK MAs. The period of three years for the Sunset Clause will be restarted from the date of conversion to a UK MA.

- The MHRA will not apply a fee for the CAP conversion, but the annual periodic fee will be payable

for converted CAPs from 1 April 2019.

For more information contact Julia Gillert of our London office.

Medicines and medical devices availability and stockpiling

The plans for minimising the risks and dangers of medicines and medical supplies during a no-deal Brexit are accelerating and being given increased press attention.

The MHRA published a note on 18 January aimed at the UK public, on getting medication in the event of no-deal.

- In the guidance, the MHRA notes that around 75% of the medicines and over 50% of the medical devices and one-use medical products (such as syringes) that the NHS uses, come into the UK via the EU.
- The MHRA states that the government has analysed the supply chain, and given instructions to pharmaceutical companies (and medical devices companies) to ensure they have adequate stocks to cope with any potential delays at the border.
- On 23 August 2018, Matt Hancock, Minister of Health, wrote to pharma companies to request suppliers to:
    - increase their medicines stocks by at least 6 weeks on top of their usual buffer stocks
    - ensure plans are in place to air freight products with a short shelf life that cannot be stockpiled
- On 23 October 2018, the Minister wrote to medical devices companies to request suppliers that source products from other EU countries to review their supply chains and determine what measures they need to take (i.e. including stockpiling) so that they can continue to provide products in the event of a no deal exit.

- The actual costs of stockpiling medicines and devices are to be met by the taxpayer, but there are of course wider costs to the industry. David Meek, Chief Executive of Ipsen, is reported in the Financial Times as saying that Ipsen was spending in the tens of millions of Euros on Brexit preparations, the equivalent of the cost of a phase-one trial. The same report included details of Eisai's early planning resulting in a six month stockpile of its cancer and epilepsy products, with its factory production running an extra four hours a day, and every weekend. Eisai alone has transferred licences for about 60 medicines to Germany — at a cost of about €7,200 each simply to change the name of the licence holder from “Eisai Europe in Hatfield” to “Eisai GmbH in Frankfurt”.
- Politico has reported that AstraZeneca has increased the number of finished medicines available to pharmacies and hospitals in the UK and EU by 20% to minimise the risk of shortages in a no-deal situation, spending £40 million in no-deal preparation, including building laboratories in Sweden to duplicate product testing functions. Relatively little detail is publicly available across the industry on this, however; the Department of Health & Social Care confirmed in December it had entered into 16 non-disclosure agreements with companies, and 10 with trade associations, to restrict what can be said publicly about no-deal plans and the costs being incurred.

- The Department of Health has consulted on plans to give pharmacists powers to switch prescriptions to available alternatives in the event of shortages, amid concerns to public health.
- Following the consultation, the government has now laid before parliament draft legislation to give pharmacists the authority to substitute treatments from a prescription when the prescribed medicines are in short supply, the "Serious Shortage Protocol". The legislation is due to come into force early next month.
- Although the speed with which the government has responded has been welcomed by key stakeholders such as the Pharmaceutical Services Negotiating Committee, which represents the interests of community pharmacists, key concerns about the practicalities involved remain.

- Dr Keith Ridge, the Chief Pharmaceutical Officer, wrote to pharmacists on 17 January, giving

additional guidance on how the Serious Shortage Protocols would be developed, saying that it would be done so with input from clinicians, and could cover dispensing a different quantity, pharmaceutical form, strength or a generic or therapeutic equivalent. Dr Ridge also warns pharmacists that it is "not helpful or appropriate" to stockpile medicines themselves, as this can risk additional pressure on supplies for patients in other parts of the country.

- The Independent reports that around 10,000 passengers who had booked with Brittany Ferries between 29 March and mid-May have had their bookings cancelled and rebooked onto different departures. Passengers affected by this were informed by the Roscoff-based company that their original sailing had been cancelled due to "the government's initiatives to create additional ferry capacity for the transportation of critical goods (such as medicines) across the Channel". Britanny Ferries (France's largest employer of sea-farers), the Danish ferry firm DFDS and a start-up company, Seaborne Freight (which proposes a Ramsgate-Ostend link, but has no ships at present) were the three companies awarded the Department for Transport contract outside the normal tendering process, allowed "for reasons of extreme urgency brought about by events unforeseeable".

For more information contact Julia Gillert of our London office.

UK/Australia pre-Brexit deal will facilitate trade of medicines and medical devices

UK and Australia last week signed a pre-Brexit deal which provides for reciprocal recognition of conformity assessments and certification for medicines and medical devices. The deal is aimed at streamlining export and import processes by eliminating the need, cost and time for testing and certification in the receiving country. The broad scope of the Australia-Britain Mutual Recognition Agreement on Conformity Assessment (**MRA**) means that if a medicine or medical device has been certified as meeting standards in Australia it is recognised as meeting British standards - and vice versa.

This is an important development for the healthcare sector, in both the UK and Australia, as the deal covers all relevant aspects of the MRA currently in place between the EU and Australia and ensures that these arrangements continue to exist, even if the UK leaves the EU without a deal.

According to Liam Fox, Britain's Trade Secretary, "This agreement will help give UK and Australian businesses, exporters and consumers the certainty they need to continue trading in confidence as the UK leaves the EU." Australian High Commissioner George Brandis stated that the MRA "… guarantees continuity of arrangements that have long boosted trade between our two countries." The MRA, which is composed of one agreement dealing with the manufacturing sector and the other dealing specifically with wines, covers approximately one-third of British goods exports to Australia, and is of particular importance in ensuring the continued smooth flow of British-made pharmaceutical and medical products into Australia. The MRA was signed on January 18, 2019 and now needs to be formally ratified by the British and Australian parliaments before Brexit.

For more information contact Julia Gillert of our London office.

State pharmaceuticals policy

Strategy on implementing the state pharmaceuticals policy may limit IP rights of R&D companies

On 5 December 2018, the Cabinet of Ministers of Ukraine ("**CMU**") approved Regulation No. 1022 "On Approval of the State Strategy on Implementing the State Policy on Providing the Population with Pharmaceuticals for the Period until 2025" ("**Regulation**").

The Regulation provides for an action plan that consists of a number of various measures, including the following:

- introducing the EU system of importation of pharmaceuticals (in 2023)
- introducing the Good Promotional Practice (in 2021)
- automatically acknowledging GMP certificates issued by the regulatory authorities participating in PICS (in 2023)
- amending legislation on insurance of liability of sponsors, clinical sites and investigators in clinical trials (in 2021)
- approving regulations of non-interventional trials (in 2021)

Some of the proposed measures may have a negative impact on innovative pharmaceuticals' turnover in Ukraine, such as:

- establishing additional terms for the patentability of objects containing pharmaceuticals (in 2021)
- optimizing the compulsory licensing of objects containing pharmaceuticals (in 2019)
- introducing the possibility of limiting the data exclusivity of pharmaceuticals for social purposes (in 2021)
- introducing the "Bolar principle" into Ukrainian legislation (planned for 2021; allows for the submission of an application for the state registration of a generic pharmaceutical before the expiry of the patent for the reference pharmaceutical)
- abolishing the verification of the pharmaceuticals' patent status during the state registration procedure (in 2021)
- introducing parallel importation of pharmaceuticals (in 2019)

The Regulation is expected to become a basis for changing the current legislation on turnover of pharmaceuticals. Its approval shows that the government intends to increase the accessibility of pharmaceuticals for the population, including through limitation of IP rights of R&D companies.

No implementing regulations stating details of specific measures listed above are currently available. We will monitor the developments and keep you updated.

For more information please contact Olha Demianiuk of our Ukraine office.

Public procurement and reimbursement

The MOH and the MEDT do not recommend that public procurement entities use large multi-item lots and manufacturers' authorization letters

The Ministry of Health of Ukraine ("**MOH**") and the Ministry of Economic Development and Trade of Ukraine ("**MEDT**") issued joint recommendations for public procurement entities to address pitfalls arising during public procurement of pharmaceuticals. By joint letter No. 01.7/33810 dated 19 December 2018 ("**Letter**"), the MOH and the MEDT provided their recommendations to ensure competition among bidders and non-discrimination. These recommendations include the following:

- establishing individual lots for each international non-proprietary name ("**INN**") of a pharmaceutical

if the cost of each INN is UAH 50,000 or more and the total cost of the procurement item is UAH 200,000 or more. This does not apply to combination drugs containing two or more INNs
- including all existing forms and dosages of a pharmaceutical into tender documentation, unless this is not consistent with the National Essential List of Medicines (a list of pharmaceuticals that should be primarily procured by public procurement entities)
- calculating the quantity of the product in the smallest units (e.g., a tablet or a vial)
- avoiding discriminating qualification criteria, such as significant experience in performing similar contracts (five years or more), experience in performing contracts with certain procurement entities (for example, with municipal institutions), performance of contracts with a value exceeding the expected cost of the procurement item
- avoiding requirements on providing "guarantee" (authorization) letters of the products' manufacturer, as such letters do not safeguard the timely supply of products and may discriminate against potential bidders

The Letter was issued in line with the recommendations of the Antimonopoly Committee of Ukraine dated 30 March 2018 for the MOH and the MEDT to take actions aimed at increasing competition on the pharmaceutical market during public procurement.
The Letter is of a non-binding nature, but public procurement entities are encouraged to follow it to increase the efficiency of public procurement of pharmaceuticals.

For more information please contact Olha Demianiuk of our Ukraine office.

Labeling

SI labeling requirement postponed until 2021

The MEDT postponed the requirement for measurement units on the labeling of products to be in Latin or Greek. This requirement was set forth in Order of MEDT No. 914 dated 4 August 2015 with the aim of introducing the International System of Units in Ukraine. The requirement was to become effective on 1 January 2019 and apply to products placed on the Ukrainian market (with certain exceptions), including pharmaceuticals and medical devices.

To date, measurement units on the labeling of pharmaceuticals and medical devices are generally indicated in Ukrainian. Since companies were not able to comply with the new labeling requirements starting from 1 January 2019, the MEDT postponed them until 1 January 2021 by Order No. 1938 dated 18 December 2018.

Furthermore, the MOH has stated that it is negotiating the exclusion of pharmaceuticals and medical devices from the scope of Order of MEDT No. 914 dated 4 August 2015 with the MEDT. We will keep monitoring the outcome of these negotiations and will inform you of any developments.

For more information please contact Olha Demianiuk of our Ukraine office.

Pricing

The CMU approved risk criteria to control compliance with pricing regulations

The CMU established criteria to assess the level of risk of a company from the perspective of compliance with pricing regulations. This is particularly important for pharmaceutical and medical devices companies as their products are subject to multiple pricing regulations. The level of risk assigned to a company determines the frequency of state inspections over compliance with pricing regulations. In Resolution No. 1064 dated 12 December 2018, the CMU established the following criteria to determine a company's level of risk:

1. market position (i.e., whether a company enjoys a natural monopoly/monopolistic (dominant) position)
2. past violations of pricing legislation, if any, within the previous three years
3. reasonable claims on violation of pricing legislation, if any, within the previous three years

Within each criteria, a company is assigned a certain amount of points (e.g., a company may be assigned 41 points if it has committed violations of pricing regulations within the previous three years or it may be assigned 0 points if it did not commit any such violations). The total amount of points scored determines the general level of risk from a pricing control compliance perspective. Specifically, the correlation between the number of points and the level of risk is as follows:

- 41-100 points — high risk
- 21-40 points — medium risk
- 0-20 points — low risk

The frequency of state pricing control inspections is established as follows:

- for high-risk companies — not more than once in two years
- for medium-risk companies — not more than once in three years
- for low-risk companies — not more than once in five years

If a company does not commit any violations of pricing regulations within six years (for medium-risk companies) or 10 years (for high-risk companies) before an inspection, the next inspection may only be conducted after the relevant period of time multiplied by 1.5.

Although certain provisions of this resolution lack clarity (e.g., it is not clear how the regulator will decide whether or not the claim on violation of pricing legislation is reasonable), approval of this resolution should make the procedure of state inspections over compliance with pricing regulations more predictable and transparent.

Currency control

NBU cancels registration and maximum interest rate cap for cross-border loans

On 2 January 2019, the National Bank of Ukraine adopted several regulations on currency control issues aimed at implementing revolutionary provisions of the new Law of Ukraine "On Currency and Currency Operations." Among such documents is the Regulation of the National Bank of Ukraine No. 6 setting up new rules on the supervision of cross-border loans extended to Ukrainian borrowers, which comes into effect alongside the FX Law on 7 February 2019. Please refer to this legal alert to learn more about this development.

Kazakhstani law amendments

Kazakhstan amends its pharmaceutical legislation

On 19 January 2019, certain amendments to the laws of Kazakhstan governing the pharmaceutical industry came into effect. These amendments are part of a bigger package of legislative changes announced at the end of 2018. Please refer to this legal alert to find out about the most important changes introduced by these amendments.

New Belgian law liberalizing distribution channels for medical devices opens opportunities to review supply chain and expand market access

On 28 January, 2019, the Belgian government announced some key changes to the distribution channels of medical devices in Belgium. The Royal Decree of 19 December, 2018 liberalizing the distribution channel of medical devices will have a great impact on how medical devices are accessing the Belgian market. Here below we have answered some key questions:

What is the big change?
Until now, the distribution and sale of certain medical devices has been the prerogative of defined healthcare professionals and healthcare organizations (e.g. hospital or retail pharmacists and dental practitioners). The distribution of active medical devices was restricted to hospital pharmacists only.
This will change with the entry into force of the new legislation. New actors will be able to dispense those medical devices directly to patients and healthcare professionals, including supermarkets and manufacturers themselves.
Self-evidently, these new actors will need to comply with the same levels of quality and safety and will be subject to the same requirements under the applicable legislation (including the FAMHP Good Distribution Practices (GDP)). This implies that any new distributor will need to be registered with the Belgian Federal Agency for Medicines and Health Products (FAMHP). However, this obligation of registration does not currently apply to manufacturers, the FAMHP clarified.

Why?
The changes to the existing framework have been introduced to:

- align the distribution model for medical devices with evolving patient needs and new standards in patient care;
- align Belgian legislation with the EU principle of free movement of goods for CE marked medical devices and remove restrictions which are not motivated by safety reasons;
- overcome barriers to international trade by removing the classification rules applied in Belgium but not elsewhere.

When does the new legislation kick in?
The new legislation will become applicable as of 7 February, 2019.

Does it apply to all medical devices?
No. From the outset it should be noted that not all medical devices were subject to restricted distribution through defined distribution channels. Certain medical devices were already freely available.
The new legislation liberalizes the distribution of medical devices, such as, but not limited to, the following:

- sterile medical equipment that comes into contact with a patient (such as dressing materials, compresses);
- sterile injection-, perfusion-, transfusion-, or drainage equipment, probes and catheters, and any equipment intended for medical or obstetric interventions that is presented as sterile, including irrigation solutions and concentrates for hemodialysis;
- implantable medical devices (sterile or not);
- medical devices intended for birth control and/or those intended for the prevention of sexually transmittable diseases;
- medical devices similar to drugs and/or that have been previously registered as such (so-called "drug look alikes" such as eye drops);
- medical devices used in dentistry, including custom-made devices (such as amalgams, crowns and prostheses);

- systems and kits consisting of medical devices referred to above;
- active medical devices.

Finally, it should be noted that restrictions to the distribution of specific medical devices can be imposed when this is justified on the basis of safety reasons.
It is expected that the liberalization will affect primarily medical devices for day to day use (such as sterile dressings).

I am a manufacturer of medical devices - how does it affect me?

- check if your medical devices are affected by the changes;
- you can consider selling medical devices directly (possibly online);
- the changes will create more competition in the supply chain and generate cost savings - it is expected that patients will be able to benefit from savings through more affordable prices;
- you can enter into new distribution arrangements with supermarkets, para-pharmacies and other actors (provided they are duly registered with the FAMHP).

(New) Distributors should be aware of specific local rules in Belgium that may apply, such as the obligatory registration on the FAMHP web portal, the FAMHP GDP, compliance with anti-gift provisions and Belgian transparency reporting obligations.

For further information please contact Geert Bovy or Evelyn Krott of our Brussels office.