# EMEA Healthcare & Life Sciences Newsletter

November 2019

Welcome to the November 2019 edition of our newsletter.

The EMEA Healthcare & Life Sciences 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



## Czech Republic

### Czech Republic amends legislation on pharmaceuticals despite MoH criticism

The Chamber of Deputies overruled the Senate despite MoH criticism on September 24, 2019, and adopted the amendment to Act No. 378/2007 Coll., on Pharmaceuticals, including the establishment of the so-called voluntary assumed public service introduced by the additional proposal, as reported in our August issue of the Healthcare Newsletter (**Amendment**). The Amendment will come into force on December 1, 2019 and strengthens the position of distributors towards the marketing authorization holders, as they will be able to obtain the required number of medicinal products distributed to Czech patients.

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For more information please contact Milena Hoffmanova of our Prague office.

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## Europe

### Start International Horizon Scanning Initiative (IHSI)

On October 29, 2019, the International Horizon Scanning Initiative (**IHSI**) was officially launched. The Dutch Minister of Medical Care Bruno Bruins opened the first meeting. Bruins sees the initiative as an important step towards broader international collaboration in the field of pharmaceuticals.

► Read more
For more information please contact Sharon van Norden of our Amsterdam office.

### Public procurement for the supply of medical devices and CE marking

With Judgment No. 6658 of October 3, 2019, the Council of State ruled on the CE marking for medical

devices offered in public tender procedures establishing that said certification must be present at the time of the submission of the relevant offer and cannot be obtained *medio tempore* between the award of the contract and the start of the supply.

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

**EU Medical Device Coordination Group publishes guidance on the qualification and classification of software**

On October 11, 2019, the European Commission published the new Guidance of the Medical Device Coordination Group on the qualification and classification of software, in light of Regulations No. 2017/745 and No. 2017/746 (**Guidance**).

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

**Launch of EUDAMED database delayed by two years**

The launch of the EUDAMED database has been delayed from May 27, 2020 to May 27, 2022, ABHI reports.

**What is the database?**

EUDAMED is a database described in the Medical Device Regulation and the In-Vitro Diagnostic Regulation (**MDR** and **IVDR** respectively), its aim being to:

- inform the public of products on the EU market;
- list certificates issued by Notified Bodies;
- hold unique device identifier (**UDI**) information for traceability purposes;
- provide the public with appropriate clinical investigation and vigilance information;
- enable transparency in Competent Authority and Commission communications;
- hold registration information on 'Economic Operators'; and
- list the results of Post Market Surveillance activities undertaken by manufacturers

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For more information please contact India-Rose May of the London office.

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## Europe - Brexit

**EMA relocation – a few months on**

As reported in our Brexit Blog, one of the first and most visible consequences of Brexit was EMA's relocation to the Netherlands. EMA's seat, formally changed from London to Amsterdam on March 30, 2019, but preparatory work for the move started well before that date.

From the moment the UK triggered Article 50, EMA wasted no time in getting ready for its relocation whilst continuing to deliver on its mission to protect public and animal health.

And yet, the relocation efforts are not fully over. Since March 2019, EMA has worked in temporary premises in the Sloterdijk area of Amsterdam and will move to its new permanent headquarters in Amsterdam Zuidas in January 2020.

At the same time, and as also reported in our Blog, EMA had to handle a battle over its former premises in London. EMA settled a court case with Canary Wharf Group by subleasing its London offices to the shared office group WeWork. However, WeWork has been itself looking vulnerable since its failed IPO and there is uncertainty as to where all this could lead up to, as the sublease is expected to last until the original lease expires in 2039.

How has all this impacted the Agency's mission and work programme?

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For further information, please contact Magda Tovar, Els Janssens or Julia Gillert of our London office.

**How might Brexit affect the duty of continuous supply of medicinal products in the UK?**

The duty of continuous supply by healthcare manufacturers will continue to apply in the UK following a departure of the UK from the EU without a withdrawal agreement. However, with the risk of interruptions to trade with the EU, the UK government has implemented some additional instructions to ensure that healthcare manufacturers can continue to comply with this duty.

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For more information, please contact Jo Ludlam, Sophie Levack, Julia Gillert or Emma Panhuber of our London office.

**DHSC requires pharma and medtech companies to maintain their no-deal readiness for January 2020**

In a letter dated November 6, 2019, Steve Oldfield, chief commercial officer at the Department of Health and Social Care (**DHSC**), expresses gratitude to the industry for the high levels of preparation ahead of the October 31, 2019 Brexit deadline.

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

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## Germany

**Germany passes Digital Care Act: E-health apps to become reimbursable**

On November 7, 2019, German Parliament (*Bundestag*) passed the "Digital Care Act" (*Digitale-Versorgungs-Gesetz*, **DVG**), which introduces a number of measures that aim to strengthen and encourage digital innovation in the German healthcare system.

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For further information, please contact Martin Altschwager of our Frankfurt office.

**Germany prepares to implement MDR**

On November 6, 2019, the German government signed off on the draft "Medical Device EU Alignment Act" (*Medizinprodukte-EU-Anpassungsgesetz*), which starts the legislative process.

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For further information, please contact Martin Altschwager of our Frankfurt office.

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## Italy

**"Pharmacies of Services": the Agreement between Italian state and regions**

On October 17, 2019, the State-Regions Conference adopted the Agreement that will implement, in the period of 2018 to 2020, a pilot project for the supply of new services at the expenses of the NHS in pharmacies of nine Italian regions (**Pharmacy of Services**).

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

**Italian Medicine Agency publishes the 18th National Report on Clinical Trials of Medicines**

On October 3, 2019, the Italian Medicine Agency published on its website the 18th National Report on Clinical Trials of Medicinal Products providing data for the year 2018 (**Report**).

The Report shows that 666 clinical trials have been authorized in 2018 compared to 564 in 2017. Despite a contraction in clinical trials in the rest of Europe, the number of those conducted in Italy is growing, representing more than 20% of the European trials.

With respect to therapeutic areas, the Report shows that about half of clinical trials are conducted in oncology and hemato-oncology and highlights a significant increase in trials focusing on rare diseases, representing 31.5% of the total, compared to 25.5% of 2017.

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

**Italian Medicine Agency's report on pharmaceutical expenditure in the first four months of 2019**

On September 11, 2019, the Italian Medicine Agency published data on the national pharmaceutical expenditure for the period January to April 2019. Data shows that in the relevant period, the overall national expenditure, comprising both the territorial and hospital pharmaceutical expenditure, amounted to EUR 6,658.4 million, compared to EUR 6,271.3 million spent in the first four months in 2018.

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

**New predicate offences listed in legislation impact on pharma and biomedical companies**

Law Decree No. 124/2019, published in the Official Gazette on October 26, 2019, provides for the inclusion, among the predicate offences listed in Legislative Decree No. 231/2001 on corporate liability, of a new article 25-*quinquiesdecies* on "Tax offences", which punishes the crime of fraudulent declaration through the use of invoices or other documents for non-existent transactions (pursuant to Section 2 of Legislative Decree No. 74/2000) with pecuniary sanctions up to EUR 774,500.

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

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## Netherlands

**Soft transition of FMD implementation has ended in the Netherlands**

In the Netherlands, the soft launch period of the implementation of FMD ended on October 1. The Dutch Healthcare Inspectorate (**IGJ**) announced targeted monitoring activities as a new phase in the implementation of the FMD.

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For more information please contact Sharon van Norden of our Amsterdam office.

**Report from the Dutch Healthcare Inspectorate on inducements related to medical devices**

In the Netherlands, initially, rules on inducements related to medical devices were only incorporated in the industry conduct code of the Foundation for the Code of Conduct Medical Devices (**GMH**). As of January 1, 2018, the ban on inducement has a legal basis in Article 10h (3) Medical Devices Act (**MDA**) and in the Inducements Medical Devices Act Policy Rules.

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For more information please contact Sharon van Norden of our Amsterdam office.

**Cloud storage of patient data reviewed by Dutch DPA and found GDPR compliant**

The Dutch Data Protection Authority (**DDPA**) has recently investigated the data processing operations of MRDM, a third-party IT services provider which collects, processes and distributes individual patient-identifiable medical data and information for a number of hospitals in the Netherlands. MDRM is a data controller to such hospitals, and in turn uses a sub-processor for the storage of data. This sub processor is a cloud platform operator that is established outside the European Economical Area (**EEA**).

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For more information please contact Wouter Seinen of our Amsterdam office.

**Conditional authorization of medicines for rare diseases**

On October 22, 2019, the new policy framework with regard to the conditional authorization of medicines for rare diseases in the basic health insurance package came into effect in the Netherlands. This new policy expands the types of healthcare that are eligible for conditional authorization.

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For more information please contact Renate Bik of our Amsterdam office.

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## Poland

**Draft legislation to implement MDR/IVMDR regulates advertising to the public**

On October 11, 2019, the Polish Minister of Health published a draft of a completely new Act on Medical Devices (**Draft**). On the one hand, it adjusts the Polish regulations to MDR and IVMDR, and on the other, it proposes a number of new and important provisions.

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**Poland implements the Falsified Medicines Directive**

On October 23, 2019, an amendment to the Pharmaceutical Law entered into force, which adjusts the regulations to implement the Falsified Medicines Directive. However, the proposed wording may be deemed confusing. New Article 77a regulates the institution of "designated wholesaler" by indicating that a wholesaler may enter into an agreement with MAH on storing and delivering the medicinal products covered by its marketing authorization. However, it also forbids the subcontracting of these activities to a third party, which may cause potential problems on the part of logistics operators that widely subcontract transportation. This specific provision enters into force on July 1, 2020, and the Minister of Health declared that they would like to change it before that date. However, pharmaceutical and logistics companies have started to discuss how to comply with the provision. Moreover, some pharmaceutical companies are worried that the pharmaceutical supervision authorities may misinterpret this provision.
A similar ambiguity arose in other Member States (eg. in the UK), as reported in a previous edition of this newsletter.

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## Russia

**Russian EDL and other lists of medicines for 2020 approved**

The government of the Russian Federation adopted Government Resolution No. 2406-r dated October 12, 2019, (**Government Resolution**), which establishes several lists of medicines for the year 2020. Apart from the list of Essential and Most Important Medicinal Preparations (**ED List**), the Government Resolution contains the list of medicines for persons entitled to welfare benefits, the list of medicines intended for treatment of life-threatening and chronic progressive rare (orphan) diseases (**12 Nosologies List**) and the minimum assortment for pharmacies. Compared to 2019, the ED list has expanded by 23 positions, among which are new anti-tumour medicines, and medicines for treatment of bronchial asthma, hepatitis C and rheumatoid arthritis, etc.

The Government Resolution shall enter into force on January 1, 2020.

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

**Further development of the track and trace serialization system in Russia**

The goal of implementing the track and trace serialization system (**System**) in Russia is to ensure effective quality control of circulated medicines and to combat their falsification. Compulsory labelling with identification marks of all medicines shall take effect on January 1, 2020. Serialization and compliance reporting became mandatory from October 1, 2019 for medicines included in the 12 Nosologies List. This list includes haemophilia, cystic fibrosis, pituitary dwarfism, Gaucher's disease, myeloid leukaemia, multiple sclerosis, immunosuppressive therapy for organ transplant patients, haemolytic-uremic syndrome, juvenile arthritis with systemic onset and mucopolysaccharidosis I, II, and VI types.

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**Russia amends rules on medicines for veterinary use**

Federal Law No. 297-FZ "On Amendments to Certain Legislative Acts of the Russian Federation Regarding the Circulation of Medicinal Products for Veterinary Use" (**Federal Law**) was passed on August 2, 2019. The Federal Law provides that the Russian Ministry of Agriculture shall establish the procedure for the prescription of medicines for veterinary use, as well as the corresponding prescription forms, the rules for their filling, recording and storage.

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

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## Turkey

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

**Recent developments**

The Turkish Medicines and Medical Devices Agency (**TİTCK**) recently announced the results of its cosmetics sector market surveillance and inspection conducted between July and September 2019. Of the 295 cosmetic products inspected by the TİTCK's Cosmetics Supervision Department, 134 were noncompliant and 12 were unsafe. A total fine of TRY 398,654 (approximately USD 68,000) was levied against the responsible companies.

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For more information, please contact Yigit Acar of our Istanbul office.

**Amendments to the Communiqué on Healthcare Practices**

**Recent developments**

The Social Security Institution (*tr.* SGK) amended the Social Security Institution Communiqué (**Communiqué**) on Healthcare Practices on October 9, 2019. Accordingly, the Healthcare Services Pricing Commission (**Commission**) published a decision in the Official Gazette on the same day pursuant to the amendments to the Communiqué.

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For more information, please contact Yigit Acar of our Istanbul office.

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## UK

**Contractors working in Healthcare in the UK face greater tax scrutiny and new rules**

With Brexit uncertainty continuing and a general election on the horizon, it would be easy for companies to dismiss the importance of the changes to the UK tax rules governing contractors or forget about these new rules altogether. However, from April 6, 2020, all companies (except small private companies) that engage contractors through personal services companies (**PSCs**) — either directly or indirectly, as is common across healthcare and many other sectors — will need to ensure that they are compliant with the new rules or face the threat of a protracted HMRC probe and possible material tax liability and fines.

We have already seen HMRC take an aggressive approach to contractor compliance in the healthcare industry. At the end of August, it was reported that HMRC contacted nearly 1,500 self-employed contractors working for Glaxo SmithKline (GSK), informing them that they had been incorrectly operating the current rules (so- called “IR35”' for the previous tax year and demanding payment for their unpaid tax. What is worrying for those involved is that HMRC seems to have adopted a blanket approach to these arrangements, putting the burden on contractors to prove otherwise. Under the current rules, the liabilities as regards paying National Insurance contributions (**NICs**) and applying PAYE rests with the contractors' PSCs. However, from April 2020, this will shift to the person paying the PSC.

For further information on how IR35 is changing, please click here or contact Stephen Ratcliffe or Gill Murdoch of the London Employee and Compensation Team.

**The legal hurdles in using patient data for product development**

We've put together a resource which maps key legal and regulatory hurdles when using patient data for product development. This focuses on the initial product development stages for medical devices, but also looks forward to conformity assessments, commissioning and reimbursement of any developed products. Regulation of data-driven healthcare can seem like a legal minefield. The UK's legal framework for accessing and using patient data is evolving quickly. More obstacles are springing up as the pace of regulation tries to match the pace of innovation.

However, access to patient data is key to developing data-driven healthcare technologies. The UK's National Health Service is a rich source of patient data – it holds millions of electronic medical records on the health of the UK population, from the cradle to the grave. If harnessed properly, this data could be used to develop technologies which improve patient care.

If you would like to hear more on this topic we would love to hear from you. We are advising key players in this area on these issues, and would be delighted to assist you with navigating the legal framework in this space.

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

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# Austria

Insert the full article here...

**Draft legislation to implement MDR/IVMDR regulates advertising to the public**

On October 11, 2019, the Polish Minister of Health published a draft of a completely new Act on Medical Devices (**Draft**). On the one hand, it adjusts the Polish regulations to MDR and IVMDR, and on the other, it proposes a number of new and important provisions.

The key new regulation is the introduction of provisions on the advertising of medical devices. The current Act on Medical Devices of 2010 does not practically regulate this issue, which gives great freedom for carrying out marketing activities. The Draft contains provisions similar to the ones already in force with respect to medicinal products. Below, key points on the proposed rules for advertising medical devices have been enumerated:

- There is no definition of "advertising", which gives room for disputes concerning its interpretation.
- There is no distinction between advertising medical devices to the public and to professionals — only public advertising is regulated.
- Public advertising will need to contain information on the: (i) name of the device; (ii) anticipated usage; (iii) contraindications; (iv) possible risks connected with the use of the device; (v) the manufacturer and authorized representative (if appointed). This information will need to be visible and clear.
- Public advertising will need to include a warning similar to the one used in commercials for medicinal products: "*Before using, read the product instructions and label or consult a physician (as this device may not be suitable for you - in case of devices with contraindications)*". It will need to be read clearly in Polish, last at least eight seconds (in case of audio-visual and audio advertisements) and cover at least 20% (in case of audio-visual) or 10% (in case of visual) of the area of the advertisement.
- The Draft contains a list of forbidden features or elements of advertisements, analogical to the ones currently pertaining to medicinal products, e.g., using an image of HCPs or persons purporting to be HCPs or presenting only positive information on the device and omitting negative information.
- Only a manufacturer or authorized representative may promote medical devices.
- The president of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (**President of the Office**) will be entitled to order: (i) the remedy of observed breaches; (ii) ceasing the publishing, presenting or conducting of advertising that is non-compliant with the law; or (iii) publication of the decision in places or the mass media where the advertising appeared, or publication of a corrigendum.
- The templates of commercials and information on where it has been distributed must be kept for two years as of the end of the calendar year in which it was published.
- The Draft envisages that the breach of advertising regulations will be subject to a financial penalty of up to PLN 2 million (approximately EUR 500,000) and in case it is deemed misleading communication, up to PLN 5 million (approximately EUR 1.25 million).

The Minister of Health has removed all provisions envisaging a penal liability for non-compliance with the new regulations (as such provisions are usually ineffective) and has introduced an extremely wide catalogue of financial penalties. The Draft assumes that almost any breach of MDR, IVDR and the Draft is subject to financial penalties of up to PLN 5 million (approximately EUR 1.25 million).

For more information, please contact Juliusz Krzyzanowski of our Warsaw office.

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A similar ambiguity arose in other Member States (e.g in the UK), as reported in a previous edition of this newsletter.

For more information, please contact Juliusz Krzyzanowski of our Warsaw office.

**Contractors working in Healthcare in the UK face greater tax scrutiny and new rules**

**What is IR35?**

IR35 is designed to ensure that the same tax attaches to individuals providing personal service to companies through PSCs as that which applies to traditional employees.

The test for IR35 will remain the same: where there would be an employment relationship if (hypothetically) the individual providing the personal service was directly engaged by the client receiving the personal service (**End Client**), then all payments should be subject to income tax and National Insurance deductions in a similar way to earnings of employment.

So what's actually changing and why is this so important?

1. PAYE and NICs liability: HMRC will shift the liability for PAYE and NICs from the PSC itself up the contractual chain to the party which pays the PSC (**Fee Payer**) will the aim of increasing compliance.
2. Status Determination Statement: Further, the End Client (the party to which the worker provides his or her services) will be responsible for determining whether IR35 applies in relation to each engagement. The End Client will need to provide a status determination to its contractual partner and the worker directly, along with reasons for its determination (**SDS**). If the End Client fails to make or fails to take reasonable care in making the SDS, the PAYE and NICs liability will shift to the End Client.
3. End Client–led Disagreement Process: The End Client will be required to implement a process for both the worker and the Fee Payer to dispute the SDS. Upon notice of the reasons for disagreement, the End Client has 45 days to reconsider its decision. If the End Client fails to complete the disagreement process or inform the worker/Fee Payer of the outcome within that period, the PAYE and NICs liability will shift back to the End Client.

**Timing**

The new rules will apply for payments deemed to have been made on or after April 6, 2020, regardless of when the services were actually performed. Although the rules are still in draft form, as HMRC has already delayed the implementation of these rules by a year, we are expecting that the rules will go live on April 6, 2020.

For more information on IR35, please see our client alert here.

For more information contact Stephen Ratcliffe or Gill Murdoch of the London Employee and Compensation Team.

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The Government Resolution shall enter into force on January 1, 2020.

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

**Further development of the track and trace serialization system in Russia**

The goal of implementing the track and trace serialization system (**System**) in Russia is to ensure effective quality control of circulated medicines and to combat their falsification. Compulsory labelling with identification marks of all medicines shall take effect on January 1, 2020. Serialization and compliance reporting became mandatory from October 1, 2019 for medicines included in the 12 Nosologies List. This list includes haemophilia, cystic fibrosis, pituitary dwarfism, Gaucher's disease, myeloid leukaemia, multiple sclerosis, immunosuppressive therapy for organ transplant patients, haemolytic-uremic syndrome, juvenile arthritis with systemic onset and mucopolysaccharidosis I, II, and VI types.

Recently, several documents aimed at ensuring the System have been adopted. These include the following:

- Recommendations for participants in the experiment on labelling medicines with identification marks and tracing the circulation of certain types of medicines approved by Federal Service for Surveillance in Healthcare (**Rosdravnadzor**) on October 2, 2019 (**Recommendations**). The Recommendations provide for, *inter alia*, coding rules; requirements for equipment used for applying and reading codes; the procedure for the transfer and exchange of information, etc.
- Standard form contract on the provision of labelling codes approved by Order of the Ministry of Industry and Trade (MIT) No. 3381 dated September 11, 2019. Under the document, the operator of the System undertakes to form, in accordance with the requests of an issuer of identification means, the number of labelling codes indicated in the requests and provide them to an issuer of identification means, while the latter is obliged to pay for the provision of these labelling codes. The fee for the provision of labelling codes is 50 kopecks (less than EUR 0.01) per labelling code, excluding VAT.
- A standard form contract on the provision of an emission recorder to subjects of medicines circulation approved by Order of the MIT No. 3326 dated September 5, 2019; A standard form contract on the provision of an emission recorder to subjects of medicines circulation by way of providing remote access to it free of charge was approved by Order of the MIT No. 3325 dated September 5, 2019. Pursuant to standard form contracts on the provision of an emission recorder, the operator of the System either grants — on a free-of-charge basis — to an issuer of identification means an emission recorder for temporary use and possession, or provides it with the right to use such emission recorder by way of providing remote access to it. The decision on the equipment mode is made by the issuer of identification means.

It is important to note that the Russian Parliament has conducted a public hearing regarding the current status of the System. It is rather likely that it will recommend the involved state bodies of the executive branch, including the government itself, to change approach to entry of the System into force. Instead of its entry starting from 2020, a "gradual transition" will most likely be recommended. Such "gradual transition" will be proposed to last until June 1, 2020, but there are still no details as to what exactly this gradual transition means.

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

**Russia amends rules on medicines for veterinary use**

Federal Law No. 297-FZ "On Amendments to Certain Legislative Acts of the Russian Federation Regarding the Circulation of Medicinal Products for Veterinary Use" (**Federal Law**) was passed on August 2, 2019. The Federal Law provides that the Russian Ministry of Agriculture shall establish the procedure for the

prescription of medicines for veterinary use, as well as the corresponding prescription forms, the rules for their filing, recording and storage.

Pursuant to Federal Law, the requirements to the registration dossier for the purposes of expert examination of immunobiological medicinal products for veterinary use have been adjusted. Information on the pharmaceutical substance in terms of impurities, specifications, series analysis results and stability data was excluded from the dossier. However, it is necessary to provide additional information about the strain.

In addition, the report on the results of preclinical trials of a medicinal product for veterinary use has been expanded. It should describe methods for determining the residual amounts of the active substance that reaches systemic circulation in products of animal origin after the use of the medicine, as well as provide documentary evidence (validation) of these methods.

If a medicinal product is obtained using GMOs or contains such organisms, then the registration dossier should contain information on the state registration of these GMOs.

Finally, holders or owners of the registration certificates must report on the results of pharmacovigilance once every six months for two years after the state registration of the medicine in the Russian Federation, then annually for the next three years and once every three years thereafter.

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

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

**Recent developments**

The Turkish Medicines and Medical Devices Agency (**TİTCK**) recently announced the results of its cosmetics sector market surveillance and inspection conducted between July and September 2019. Of the 295 cosmetic products inspected by the TİTCK's Cosmetics Supervision Department, 134 were noncompliant and 12 were unsafe. A total fine of TRY 398,654 (approximately USD 68,000) was levied against the responsible companies

**What do the results say?**

The cosmetic products safety results reveal that there is an increase in the number of inspected products and noncompliant products. On the other hand, however, the total amount of administrative fines has significantly decreased compared to the Q2 results of 2019. The TİTCK continues to strictly inspect the healthcare sector to increase the compliance of cosmetic products with the technical legislation.

The Cosmetics Inspection Department's Q3 results of 2019 is available here (in Turkish).

**Conclusion**

The TİTCK continues to demonstrate its commitment to periodical market surveillance and inspection in 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 noncompliant products.

For more information, please contact Yigit Acar of our Istanbul office.

**Amendments to the Communiqué on Healthcare Practices**

**Recent developments**

The Social Security Institution (*tr.* SGK) amended the Social Security Institution Communiqué (**Communiqué**) on Healthcare Practices on October 9, 2019. Accordingly, the Healthcare Services Pricing Commission (**Commission**) published a decision in the Official Gazette on the same day pursuant to the amendments to the Communiqué.

**What's new?**

The amendments to the Communiqué introduced a new calculation method of the number of medical examinations that ophthalmologists working at private health service providers can conduct.
The SGK introduced new regulations on certain ophthalmologic operations conducted in private health service providers that are billed to the SGK. The SGK also updated Annex- 4/C of the Communiqué, which provides a list of pharmaceuticals supplied from abroad and the prices the SGK will pay. The amendments are available here (in Turkish).

Pursuant to the amendments to the Communiqué, the Commission published a decision on the repricing of certain medicines. The decision is available here (in Turkish).

**Conclusion**

The Social Security Institution continues to take active steps for the implementation of the Communiqué on Healthcare Practices. In this respect, companies in the healthcare sector and private health service providers must carefully review the amendments to the Communiqué and take necessary actions to ensure full compliance.

For more information please contact Yigit Acar of our Istanbul office.

## Czech Republic amends legislation on pharmaceuticals despite MoH criticism

The Chamber of Deputies overruled the Senate despite MoH criticism on September 24, 2019 and adopted the amendment to Act No. 378/2007 Coll., on Pharmaceuticals, including the establishment of the so-called voluntary assumed public service introduced by the additional proposal, as reported in our August issue of the Healthcare Newsletter (**Amendment**). The Amendment will come into force on December 1, 2019 and strengthens the position of distributors towards the marketing authorization holders, as they will be able to obtain the required number of medicinal products distributed to Czech patients.

The system established by the Amendment gives the distributor a privileged position in relation to MAH. Once the distributor makes a written declaration to the MAH that a specific medicinal product or products are required for the purposes of care for patients in the Czech Republic, the MAH has a supply obligation towards such distributor (**Supply Obligation**). That means the MAH is obliged to supply this distributor medicinal products in such quantities and frequency which enable the distributor to hold sufficient stock to meet an *average two-week demand* by the pharmacies (or physicians in case of vaccines, etc.) purchasing those medicinal products from the distributor. In turn, the distributor is obliged to supply those medicinal products to the respective pharmacy within two business days after receiving an order for supply from such a pharmacy. Furthermore, the distributor is expressly forbidden to export the provided medicinal products outside of the territory of the Czech Republic

The Amendment, however, provides for exceptions from the Supply Obligation of MAH, if:

i. the distributor has at least one monetary debt *vis-à-vis* the MAH for a period longer than 30 days past the due date;
ii. the distributor has been fined by the State Institute for Drug Control for breaching an export ban; or
iii. the placing of the particular medicinal product on the market is suspended or terminated in the Czech Republic.

The Amendment was adopted despite the negative opinion expressed by the Ministry of Health of the Czech Republic, as well as by the Czech Office for the Protection of Competition, which pointed out its anti-competitive nature. Due to this fact, as well as the ambiguities arising of the Amendment in this respect, the Supply Obligation might, in fact, become unenforceable in practice.

For the sake of completeness, please also note that the separate government proposal is to be discussed by the Chamber of Deputies in the first reading, which introduces new rules with respect to ensuring the availability of medicinal products on the Czech market through the so-called emergency system.Therefore, if adopted, these rules would replace the Supply Obligation described above.

For more information please contact Milena Hoffmanova of our Prague office.

**Soft transition of FMD implementation has ended in the Netherlands**

In the Netherlands, the soft launch period of the implementation of FMD ended on October 1. The Dutch Healthcare Inspectorate (**IGJ**) announced targeted monitoring activities as a new phase in the implementation of the FMD.

In February of this year, the Falsified Medicines Directive (**FMD**) became applicable, requiring manufacturers to place safety features — a unique identifier and anti-tamper device — on all prescription medicines. The IGJ expected false alerts due to technical issues at the first implementation stage. To safeguard the continuation of medicine provision, the IGJ established a soft launch period, until June 9, 2019 and extended this to October 1.

During the soft launch period, the pharmacist or wholesaler could hand over or distribute the medicines after an alert in case there was no reason to think the package was falsified. Only in cases of doubt does the pharmacist or wholesaler have to notify the IGJ.

The IGJ decided to end the soft launch period on October 1 because the system is stable and the number of alerts decreased significantly. However, the total number of alerts is still too high to investigate each alert. Therefore, the pharmacist or wholesaler can still hand over or distribute the medication if there is no reason to think that the alert is justified. In case of a false alert, the pharmacist or wholesaler has to investigate the cause of the alert and have to remove this cause.

The IGJ announced that as of October 1, it will start monitoring compliance with the FMD. The IGJ will initially focus on stakeholders who are not connected, do not or hardly scan the medicines or cause structural alerts. IGJ's monitoring will initially have a stimulating nature, but if patient safety is at risk, it will take appropriate action.

For more information please contact Sharon van Norden of our Amsterdam office.

**Report from the Dutch Healthcare Inspectorate on inducements related to medical devices**

In the Netherlands, initially, rules on inducements related to medical devices were only incorporated in the industry conduct code of the Foundation for the Code of Conduct Medical Devices (**GMH**). As of January 1, 2018, the ban on inducement has a legal basis in Article 10h (3) Medical Devices Act (**MDA**) and in the Inducements Medical Devices Act Policy Rules.

From the moment the MDA became applicable, until March 31, 2019, the Dutch Healthcare Inspectorate (**IGJ**) had investigated 10 medical device suppliers, reviewed 50 service provision contracts and held 18 meetings. The IGJ also had meetings with industry organisations affiliated with the GMH. The IGJ published a report with the results of this investigation on October 7, 2019.

The report shows that all investigated services were documented in a service provision contract. However, none of the 50 reviewed service provision contracts were complete. Required sections like the content, nature, duration, scope, purpose, compensation and expenses were not sufficiently described and not transparent.

In the past year, the focus was on creating awareness. The investigation was aimed at the description of the compensation and services in the service provision contract. The IGJ did not impose administrative fines.

Next year, the IGJ will start a follow-up investigation with a focus on the reasonableness of the compensation. It will look at actual payments and proof of payment. Besides suppliers, the IGJ will also investigate healthcare professionals. The IGJ can impose administrative penalties if it establishes a violation of the ban on inducements.

For more information, please contact Sharon van Norden of our Amsterdam office.

**Cloud storage of patient data reviewed by Dutch DPA and found GDPR compliant**

The Dutch Data Protection Authority (**DDPA**) has recently investigated the data processing operations of MRDM, a third-party IT services provider which collects, processes and distributes individual patient-identifiable medical data and information for a number of hospitals in the Netherlands. MDRM is a data controller to such hospitals, and in turn uses a sub-processor for the storage of data. This sub processor is a cloud platform operator that is established outside the European Economical Area (**EEA**).

The DDPA has conducted an explorative inquiry regarding storage by MRDM's sub-processor of patient data in the cloud. In the course of this investigation, the DDPA interviewed MRDM's data protection officer and reviewed standard operation procedures relating to the cloud storage of patient data.

In this particular setup, the patient data is stored on servers located in the Netherlands. Moreover, the cloud storage provider had, in its agreement with MRDM, warranted that no personal data was to be transferred outside the EEA. After having reviewed the standard operating procedures and the sub-processing agreements, and having investigated the technical and organizational security measures, the DDPA has decided not to commence a regulatory investigation into this matter. This decision was published by the DDPA on September 30, 2019.

Formally, the decision not to pursue an investigation cannot be viewed as a blessing by the DDPA, and reflects that the cloud storage of patient data is, in the case at hand, compliant with the GDPR. In practice, however, the DDPA is generally thorough in its reviews. Against that background, the decision to not take further (enforcement) steps is a meaningful sign that GDPR compliance can be achieved in respect of cloud-based processing of patient data.

**Background**

The processing of personal data in the healthcare sector — and more particularly the data security aspects thereof — is one of the key priorities of the DDPA. At the same time, hospitals, research institutions and other players in the sector are increasingly using cloud services for the exchange and storage of patient data. For these actors, and their technology suppliers, the outcome of the DDPA's exploration provides at least some comfort and guidance.

The notice of the DDPA (in Dutch) can be found here.

For more information, please contact Wouter Seinen of our Amsterdam office.

**Conditional authorization of medicines for rare diseases**

On October 22, 2019, the new policy framework with regard to the conditional authorization of medicines for rare diseases in the basic health insurance package came into effect in the Netherlands. This new policy expands the types of healthcare that are eligible for conditional authorization.

In the Netherlands, the basic healthcare insurance package is compulsory and covers the essential types of medical care, medicines and medical aids. The cover provided by the basic package is determined by the Dutch government. Generally, medical care, medicines and medical aids are automatically included in the basic package if their effectiveness had been proven. However, it is often difficult to prove the effectiveness of medicines for rare diseases (the so-called *orphan medicinal products*). To provide (temporary) access to such medicines, the Dutch Ministry of Health, Welfare and Sport expanded the conditional authorization. Zorginstituut Nederland is entitled to assess whether a medical is eligible for conditional authorization.

To be eligible for conditional authorization, the manufacturer must reduce the price of the medicine during the period of conditional authorization and publish the total expenditure of the medicine. Furthermore, the manufacturer must conduct further research in enhancing the effective use of medicines. Lastly, the manufacturer must comply with ZonMW's conditions relating to Open Access and Fair Data Principles. According to the Dutch Minister for Medical Care, these requirements qualify as the preconditions for the conditional authorization.

For more information please contact Renate Bik of our Amsterdam office.

**"Pharmacies of Services": the Agreement between Italian state and regions**

On October 17, 2019, the State-Regions Conference adopted the Agreement that will implement, in the period of 2018 to 2020, a pilot project for the supply of new services at the expenses of the NHS in pharmacies of nine Italian regions (**Pharmacy of Services**).

Pursuant to the Agreement, services reimbursed by the NHS will include services for monitoring patients' adherence to pharmacological therapies; front-office services aimed at collecting patients' consent, activating and accessing Electronic Health Records in pharmacies; first instance analytical treatments (e.g., monitoring of blood sugar, cholesterol and triglycerides) and screening campaigns. Moreover, the Agreement establishes the allocation of funds, the time and methods for recruiting pharmacies and patients, including their number, and the criteria for the remuneration of the involved pharmacies.

Data collected in the context of the pilot project, which will be transmitted to the Ministry of Health, will be used to identify the potential impacts of the "Pharmacy of Services" on both patients and the NHS in terms of increase or saving of economic resources.

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

**Italian Medicine Agency publishes the 18th National Report on Clinical Trials of Medicines**

On October 3, 2019, the Italian Medicine Agency published on its website the 18th National Report on Clinical Trials of Medicinal Products providing data for the year 2018 (**Report**).

The Report shows that 666 clinical trials have been authorized in 2018 compared to 564 in 2017. Despite a contraction in clinical trials in the rest of Europe, the number of those conducted in Italy is growing, representing more than 20% of the European trials.

With respect to therapeutic areas, the Report shows that about half of clinical trials are conducted in oncology and hemato-oncology and highlights a significant increase in trials focusing on rare diseases, representing 31.5% of the total, compared to 25.5% of 2017.

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

**Italian Medicine Agency's report on pharmaceutical expenditure in the first four months of 2019**

On September 11, 2019, the Italian Medicine Agency published data on the national pharmaceutical expenditure for the period January to April 2019. Data shows that in the relevant period, the overall national expenditure, comprising both the territorial and hospital pharmaceutical expenditure, amounted to EUR 6,658.4 million, compared to EUR 6,271.3 million spent in the first four months in 2018.

The report highlights that the main pharmaceutical expenditure is the hospital, with a deficit of EUR 1,241 million compared to the planned expenditure (expenditure of EUR 3,856 million against a ceiling of EUR 2,614 million). With respect to territorial expenditure, net of the payback paid by pharmaceutical companies to regions, the report indicates that it amounted to EUR 2,802.57 million, against a planned expenditure of EUR 3,020.35 million, thus generating a surplus of EUR 217.79 million.

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

**New predicate offences listed in legislation impact on pharma and biomedical companies**

Law Decree No. 124/2019, published in the Official Gazette on October 26, 2019, provides for the inclusion, among the predicate offences listed in Legislative Decree No. 231/2001 on corporate liability, of a new article 25-*quinquiesdecies* on "Tax offences", which punishes the crime of fraudulent declaration through the use of invoices or other documents for non-existent transactions (pursuant to Section 2 of Legislative Decree No. 74/2000) with pecuniary sanctions up to EUR 774,500.

This decree, which shall have to be converted into law, brings forward the provisions of the European Delegation Law 2018, effective as of November 2, 2019, delegating to the government the supplementation of the provisions of Legislative Decree 231/2001 by including crimes affecting the Union's financial interests, in accordance with Directive (EU) 2017/1371 on the fight against fraud to the Union's financial interests by means of criminal law.

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

**EMA relocation – a few months on**

As reported in our Brexit Blog, one of the first and most visible consequences of Brexit was EMA's relocation to the Netherlands. EMA's seat, formally changed from London to Amsterdam on March 30, 2019, but preparatory work for the move started well before that date.

From the moment the UK triggered Article 50, EMA wasted no time in getting ready for its relocation whilst continuing to deliver on its mission to protect public and animal health.

And yet, the relocation efforts are not fully over. Since March 2019, EMA has worked in temporary premises in the Sloterdijk area of Amsterdam and will move to its new permanent headquarters in Amsterdam Zuidas in January 2020.

At the same time, and as also reported in our Blog, EMA had to handle a battle over its former premises in London. EMA settled a court case with Canary Wharf Group by subleasing its London offices to the shared office group WeWork. However, WeWork has been itself looking vulnerable since its failed IPO and there is uncertainty as to where all this could lead up to, as the sublease is expected to last until the original lease expires in 2039.

How has all this impacted the Agency's mission and work programme?

**Business Continuity Plan**
To ensure business as usual with the minimum disruption, EMA developed a detailed business continuity plan, which prioritised tasks and activities according to their impact on public health. Under the plan, lower priority activities were temporarily suspended to allow focus on activities of high priority related to the authorisation and supervision of medicines. The plan was last updated in June 2019 and some previously suspended activities were reinstated whilst others, such as guideline development or working party meetings, still remain on hold.

**Regulatory preparedness**
In addition to work related to the relocation, EMA and the European Commission worked actively on the development of guidance to ensure that pharmaceutical companies are ready for Brexit and can guarantee continued supply of medicinal products.

EMA also adapted the centralised regulatory procedures to the planned UK's withdrawal from the EU. This involved the redistribution of existing UK (co)rapporteurships (i.e., contracts for assessment of medicines) amongst the national competent authorities of the EU-27. Assessment of over 370 centrally authorised products was gradually transferred and no new rapporteurships have been awarded to the UK since. The new rapporteurs obtained the full responsibility of these assessments in March 2019 (date when the UK was initially expected to withdraw from EU).

EMA designed the redistribution policy under the scenario that the UK would become a third country as of March 2019, hence the redistribution ahead of time. Until Brexit date, the UK continues to participate in all formal meetings and retains its voting rights.

**Staff losses**
One of EMA's main concerns during the relocation process has been staff retention. At the end of 2018, before the physical move to Amsterdam, EMA's staff count was 901. In June, the number had decreased to 776 and at the latest management board meeting held in October 2019, EMA's executive director announced a further 6% staff reduction, with a headcount of approximately 730.

This is seen as a challenge given the additional workload that is required at present for the implementation of the new legislation for veterinary medicines, medical devices and clinical trials.

EMA has carried out selection procedures to compensate for these losses. However, it has also announced that it does not expect to reach the numbers held before the relocation.

**Regulatory Science to 2025**
Despite the challenges of Brexit, EMA has made clear its determination to not lose focus on its mission to protect public health and its drive to remain at the forefront of medicines development.

The best reflection of this is the EMA Regulatory Science to 2025 strategy published in 2018 following a six-month consultation process. The Agency's priority is to be prepared for the fast-paced developments in

science and innovation of current times.

**Structural reorganisation**
At the last management board meeting in October 2019, the Agency also announced that it is planning a review of its organisational structure, with an aim to focus on key priority areas such as digital business transformation, data analytics and methods, regulatory science and innovation, clinical trials and a manufacturing strategy. The reorganisation is also aimed at strengthening the therapeutic focus in the area of human medicines.

**So… what next?**

Brexit has had an inevitable impact on the work of EMA in the last few years. The Agency has joined efforts to ensure business as usual and avoid disruption as far as possible. EMA has also been keen to promote its role as a regulator able to support and promote innovation. Will EMA be able to fully focus on this and leave Brexit behind? Time will tell.

For further information, please contact Magda Tovar, Els Janssens or Julia Gillert of our London office.

**How might Brexit affect the duty of continuous supply of medicinal products in the UK?**

The duty of continuous supply by healthcare manufacturers will continue to apply in the UK following a departure of the UK from the EU without a withdrawal agreement. However, with the risk of interruptions to trade with the EU, the UK government has implemented some additional instructions to ensure that healthcare manufacturers can continue to comply with this duty.

This post will set out why the duty of continuous supply will continue to apply in the UK. It will also examine the additional instructions from the government, namely the mandatory requirements of notification and the multi-layered approach. And finally, it will consider why it is so important that healthcare manufacturers comply with these instructions.

*Duty of continuous supply*

In the UK, the holder of the marketing authorisation for, and the distributor, of a medicinal product that has been placed on the UK market has a duty to continue the supply of that medicinal product so that the needs of patients in the UK are covered. This duty of continuous supply comes from EU Directive 2001/83/EC, Article 81.

This duty will continue to apply in the UK following the UK's departure from the EU, even in the event of a no-deal exit, due to the European Union (Withdrawal) Act 2018 (**EUWA**). The EUWA states that EU law will be incorporated into UK domestic law as of the day the UK leaves the EU. Moreover, the EUWA empowers Ministers of the Crown to enact regulations into order to correct any deficiencies (a term broadly defined under the EUWA) in the retained EU law. To date, the Secretary of State of Health & Social Care has enacted four Regulations under the EUWA to ensure the continued sale of, and access to, medicines, medical devices and clinical trials.

The latest of these Regulations, the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (**2019 Regulation**), updates and amends the Health Service Products (Provision and Disclosure of Information) Regulations 2018. These updates and amendments will come into force on the day that the UK leaves the EU (currently 23:00 on 31 October 2019).

*Mandatory requirements added to the duty of continuous supply*

The Health Service Products (Provision and Disclosure of Information) Regulations 2018, mentioned above, imposes mandatory requirements onto manufacturers, distributors and suppliers[1] of medicines and medical devices, and the amendments by the 2019 Regulation confirm that these mandatory requirements will continue to apply following the UK's departure from the EU.

Most notably, the manufacturers of medicines will continue to be required to notify the Secretary of State of Health & Social Care that they intend to discontinue the manufacturing or supply of a medicine, or that they consider that a supply shortage of a medicine is likely to occur (Regulations 29(1) and (2)). The notification must be provided "*at least six months before the day on which the manufacturing or supply will cease*" (or as soon as practicable after the decision is made), or "*at least six months before any anticipated impact on any patient who takes the presentation is realised*" (or as soon as practicable after the manufacturer becomes aware that there may be a shortage) (Regulation 29(3)).

If the Secretary of State considers that a manufacturer has not complied with Regulation 29, then, by written notice, it may require that the manufacturer provide specific information to the Secretary of State. If the manufacturer fails to comply with this notice from the Secretary of State, then the Secretary of State may impose a daily penalty of up to EUR 5,000 for the first 13 days of noncompliance, and EUR 10,000 for the subsequent days, until the manufacturer starts to comply.

This mandatory requirement to notify the Secretary of State reinforces the duty of continuous supply: even in cases where the manufacturer is not responsible for a shortage in the supply of the medicine, the manufacturer is still required to notify the government of the shortage as soon as practicable after it becomes aware of it, and it must show the steps taken by the manufacturer to address the shortage (Regulation 29(2)(f)). By adding this mandatory requirement, the government ensures that manufacturers continue to assess the potential shortage of supply of their own product. This way, the onus is on the manufacturer to ensure that there is no shortage of their products after the UK leaves the EU.

*Other requirements: the multi-layered approach*

The Department of Health & Social Care has published numerous communications to members of the

healthcare and medical industry in order to provide guidance in the lead-up to the UK's departure from the EU. In particular, the Secretary of State of Health & Social Care has recently updated the Department's multi-layered approach to "*help ensure the continuation of medicines and medical supplies across the UK*" in the event of a no-deal exit ("Written Statement by the Secretary of State of Health & Social Care" (Matt Hancock) on 8 October 2019 in the House of Lords).

Some of these components of the multi-layered approach will be taken on by the department, such as securing freight capacity, changing or clarifying regulatory requirements, and growing the support unit, in particular with regard to the National Supply and Disruption Response unit. Healthcare manufacturers will apply the remaining recommendations: improving trader readiness for new border arrangements, building up buffer stocks of six weeks above the business-as-usual inventory, and securing extra warehousing space for stockpiled medicines.

As with the mandatory requirements discussed above, the multi-layered approach puts a lot of responsibility on healthcare companies to help the government ensure that medicines and medical supplies are distributed across the UK following a no-deal exit of the EU.

*Inability to blame Brexit for shortage of supply*

By involving the private entities of the healthcare industry in its safeguard against medicine shortages in the UK after a no-deal exit from the EU, the government has essentially put the onus on manufacturers and distributors to ensure that shortages do not occur. Moreover, as the duty to continuously supply medicinal products will continue after a no-deal Brexit, these private entities have been given the means to mitigate any shortage of supply.

However, this means that it will be difficult for healthcare companies to blame Brexit for any interruption of the supply of their products. Accordingly, if a healthcare company fails to ensure appropriate and continued supplies pursuant to Article 81 of Directive 2001/83/EC, then it will not be able to claim that the interruption of the supply was out of its control.

It is clear from the mandatory requirements discussed above that the government can impose penalties on companies that are not complying with their duty to notify the Department of Health & Social Care that they intend to discontinue a medicine, or that they foresee a supply shortage for a particular medicine. However, whether the government would take legal action against a company for not having taken adequate preventative measures (such as stockpiling) in the event of the interruption of supply of a medicine is uncertain.

Instead, it is more likely that the government will take legal action based on a breach of the duty of continuous supply, as this breach is easier to determine. As mentioned above, in such a case, the healthcare company may not succeed in blaming Brexit for the interruption of the supply if it had a hand in ensuring that there would be no shortage of supply post-Brexit. In such a situation, its only defence might be its compliance with the mandatory requirement to notify the government of the impending shortage of supplies at the earliest practicable time, along with a description of the steps taken by the company to address the impending shortage. In other words, the best protection healthcare companies can secure at this time is to comply with the government's mandatory requirements and multi-layered approach. Not only might this mitigate the consequences of a no-deal Brexit, but it will likely be the companies' best legal safeguard against accusations of a breach of their duty of continuous supply in the event that Brexit interrupts the supply of medicines in the UK.

For more information, please contact Jo Ludlam, Sophie Levack, Julia Gillert or Emma Panhuber of our London office.

**DHSC requires pharma and medtech companies to maintain their no-deal readiness for January 2020**

In a letter dated November 6, 2019, Steve Oldfield, chief commercial officer at the Department of Health and Social Care (**DHSC**), expresses gratitude to the industry for the high levels of preparation ahead of the October 31, 2019 Brexit deadline.

However, he states that the multi-layered approach put in place by the DHSC remains central to helping ensure the continued supply of medicines and medical products across the UK if we leave without a deal on January 31, 2020.

In the letter, DHSC provides updates on the six components of the multi-layered approach it has required of the industry in its no-deal Brexit planning, summarised as follows:

1) Improving trader readiness for new border arrangements (the dedicated trader readiness 'Support Unit' remains operational)

2) Building up buffer stocks (the DHSC states that "whilst we recognise that the end of year period creates specific challenges regarding inventories, nevertheless, we ask that suppliers make every effort to retain the level of stockpiles they had in place in advance of October 31)

3) Procuring extra warehouse space for stockpiled medicines (DHSC to make these available "at market rates")

4) Securing freight capacity (the Department for Transport put in place a four-year framework for freight capacity, which DHSC is able to call off against as needed. The current government freight contracts, announced on October 11 provides six months' worth of capacity covering all the requirement for medical products, therefore covering the next possible no-deal date of January 31, 2020. The DHSC's procured Express Freight Service is on hold until January 2020 when it expects to "remobilise" the service)

5) Clarifying or changing regulatory requirements (the no-deal legislation on medicines, medical devices and clinical trials put out by DHSC remains in place)

6) Strengthening the processes and resources used to deal with shortages (the serious shortages protocols (see previous blog posts on these powers) remain in place but the National Supply Disruption Response (NSDR) function has been reduced to core operating hours pending being stood up again for extended hours if we approach January 31, 2020 without a ratified deal)

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

**Germany passes Digital Care Act: E-health apps to become reimbursable**

On November 7, 2019, German Parliament (*Bundestag*) passed the "Digital Care Act" (*Digitale-Versorgungs-Gesetz*, **DVG**), which introduces a number of measures that aim to strengthen and encourage digital innovation in the German healthcare system.

The most visible measure are "health apps on prescription": Patients insured by the statutory health insurance providers will be entitled to receive digital healthcare apps upon a doctor's prescription or consent of the health insurance provider (see our article in the July 2019 edition).

Health app developers seeking to make their health apps reimbursable must apply for their apps to be entered into a registry of reimbursable apps. Apps will only be registered if their developers prove that the app:

- complies with/meets the basic requirements of safety, functionality and quality,
- complies with data protection rules, data security standards and accessibility standards, and
- provides positive effects on care by either improving patient-relevant therapeutic endpoints or by improving the process and/or structure of providing healthcare.

The German Ministry of Health is expected to issue an implementing regulation which shall specify in more detail the standards of proof and necessary documentation to be submitted by the developer.

If a health app is registered in the registry of reimbursable apps, the app will, for an initial term of 12 months, be reimbursed at the sales price set by the developer, but the developer must then negotiate with the health insurance association the reimbursement price which will apply after the initial term. As the reimbursement price shall be materially driven by the effectiveness of the app, establishing adequate proof of the app's positive effects on care will be key for developers to obtain a favourable reimbursement price.

The legislative process still requires the involvement of the Federal Council (*Bundesrat*). The legislation may be expected to enter into force in early 2020. The timing of the implementing regulations and guidance is still unclear, but developers should plan ahead to maximize their readiness when the legislation becomes effective.

For further information, please contact Martin Altschwager of our Frankfurt office.

**Germany prepares to implement MDR**

On November 6, 2019, the German government signed off on the draft "Medical Device EU Alignment Act" (*Medizinprodukte-EU-Anpassungsgesetz*), which starts the legislative process.

The key component of the Act is the new "Medical Device Law Implementation Act" (*Medizinprodukte-Durchführungesetz*, **MDG**), which will supersede the current Medical Device Act (Medizinproduktegesetz, **MPG**) on May 26, 2020. By its nature as implementing act for the EU Medical Devices Regulation, the MDG provides for the enforcement of the MDR by designating national and local competent authorities and establishing criminal or administrative liability for violations of material MDR provisions. Generally, the draft legislation will provide the federal authorities with more supervision and enforcement competence, to the loss of the local regulatory authorities. On criminal liability, the draft MDG provides if not a tougher, but for a much wider catalogue of criminal sanctions. Companies should upgrade their controls for ensuring compliance with MDR requirements.

In addition to establishing a national enforcement framework buttressing the MDR regulation, the MDG makes use of the numerous opening clauses in the MDR to further strengthen, modify or shape the material regulation provided by the MDR on the following points:

- Clinical trials with medical devices on humans are subject to more extensive or stricter prior approval or notification requirements. Under the current MPG, clinical trials will also require a prior positive assessment by the competent ethics review board. The MDG contains a number of further provisions that regulate clinical trials beyond the requirements set out in the MDR.

- The MDG contains a specific prohibition regarding falsified medical devices.

- The federal authority, BfArM, may, in accordance with Article 59 MDR, authorize the placing on the market of devices without prior conformity assessment procedure in the interest of public or patient

health; an implementing regulation by the German Ministry of Health shall provide details on the necessary authorization procedure and subsequent marketing rules.

- BfArM will become the sole national authority to adjudicate device qualification and risk classification disputes between manufacturers and their notified bodies.
- Sales representatives continue to be subject to qualification requirements. However, MDG no longer requires the appointment of a dedicated safety officer (the currently required equivalent of a QPPV for medical devices).

The signing off of the draft bill by the German government launches the legislative process. As the draft legislations shifts certain oversight and enforcement competence from the local regulators to the federal regulators and the bill must be approved by the Federal Council (Bundesrat) representing the German federal states, the legislative process for the MDG may prove more difficult than for other healthcare bills currently pending. However, it may be expected that the final MDG will be passed in the coming months before the MDR becomes applicable. We will monitor the legislative process.

For further information, please contact Martin Altschwager of our Frankfurt office.

**Start International Horizon Scanning Initiative (IHSI)**

On October 29, the International Horizon Scanning Initiative (**IHSI**) was officially launched. The Dutch Minister of Medical Care Bruno Bruins opened the first meeting. Bruins sees the initiative as an important step towards broader international collaboration in the field of pharmaceuticals.

The IHSI is a new partnership between countries that will analyse and share information about new and important medicines before they reach the market. This information will empower political decision makers and payer organisation negotiators to drive better pricing in medicinal products and to enable timely decision making. In time, medical devices are to become part of the initiative as well.

Bruins aimed to start the initiative with 10 countries. Besides the Netherlands, Belgium, Ireland, Denmark, Luxembourg, Norway, Portugal, Sweden, Switzerland are part of the initiative. Bruins recently announced that Canada will join as well and is meeting with other interested countries. He hopes to welcome more countries in the near future.

At the moment, IHSI is preparing the tender for its activities. The first horizon scan results are expected in late 2020.

More information about IHSI can be found on the website https://ihsi-health.org

For more information, please contact Sharon van Norden of our Amsterdam office.

**Public procurement for the supply of medical devices and CE marking**

With Judgment No. 6658 of October 3, 2019, the Council of State ruled on the CE marking for medical devices offered in public tender procedures establishing that said certification must be present at the time of the submission of the relevant offer and cannot be obtained *medio tempore* between the award of the contract and the start of the supply.

Under the judgment, the Council of State established, on the one hand, that the marketing of a medical device, the phase in which the law requires the presence of the CE marking, begins at the time of the submission of the offer and, on the other hand, that the principles of impartiality and good administration and the principles of freedom of economic initiative and competition require equal treatment between tenderers. According to the administrative judge, the application of said principles requires that all offered products must be assessed simultaneously on the basis of the requirements held by the tenderer at the time of submission of the offer and that such an assessment must refer to comparable products which already comply with the tender specifications, including the CE marking for all medical devices covered by the tender procedure.

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

**EU Medical Device Coordination Group publishes guidance on the qualification and classification of software**

On October 11, 2019, the European Commission published the new Guidance of the Medical Device Coordination Group on the qualification and classification of software, in light of Regulations No. 2017/745 and No. 2017/746 (**Guidance**).

This document is primarily addressed to manufacturers of medical software and provides the criteria for the qualification and classification of software to establish whether the products in question meet the definition of medical device or in vitro diagnostic device, thus enabling manufacturers to comply with all regulatory fulfilments provided for by the applicable legislation.

As regards qualification, the Guidance clarifies that, in order to qualify as a "medical device", software must have a medical purpose on its own and that, in this respect, particular importance must be given to the intended purpose as established by the manufacturer. Moreover, the document provides that, to be qualified as "medical device software", the product must be intended to be used, alone or in combination, for one of the purposes referred to in the definition of "medical device" or "in vitro diagnostic device" laid down in the abovementioned Regulations, regardless of whether the software is independent, or drives or influences the use of a device.

The Guidance also sets out that when a software does not meet the definition of medical device or in vitro diagnostic medical device, but is intended by the manufacturer to be an accessory for said device, the software falls, in any case, under the scope of the respective Regulation.

With respect to classification, the Guidance confirms that all software qualifying as medical devices will be classified from Class IIa up to Class III and that only software that does not have a medical purpose shall be classified in Class I. Last, software that drives or influences the use of a medical device, the Guidance clarifies, will fall within the same Class as the device they influence.

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

**Launch of EUDAMED database delayed by two years**

The launch of the EUDAMED database has been delayed from May 27, 2020 to May 27, 2022, ABHI reports.

**What is the database?**

EUDAMED is a database described in the Medical Device Regulation and the In-Vitro Diagnostic Regulation (**MDR** and **IVDR** respectively), its aim being to:

- inform the public of products on the EU market;
- list certificates issued by Notified Bodies;
- hold unique device identifier (**UDI**) information for traceability purposes;
- provide the public with appropriate clinical investigation and vigilance information;

- enable transparency in Competent Authority and Commission communications;
- hold registration information on 'Economic Operators'; and
- list the results of Post Market Surveillance activities undertaken by manufacturers

**What are the consequences of the delay?**

The MDR will likely face the biggest consequences of the delay, as this database is a key element in facilitating greater transparency, public data accessibility, safety vigilance and traceability across Europe. The delay may also result in the proliferation of other national databases that will require close monitoring to ensure high standards.

IVDR, on the other hand, is unlikely to suffer, as the new anticipated date for EUDAMED's launch coincides with the end of the IVDR transition. Moreover, the forms that are to be used to input vigilance data into EUDAMED will still be implemented in Europe at the beginning of 2020 and it is unlikely that any other MDR/IVDR functionality will be prevented from coming online before May 2020. The use of UDI will also be largely unaffected as it will be used irrespective of the launch date of EUDAMED. Finally, the delay will provide more time for the population of the database and for the honing of the EUDAMED modules, says MedTechDive.

**Brexit and EUDAMED**

As the nature of Brexit continues to be debated, the UK's future input into EUDAMED is undetermined, but ABHI is arguing for a high level of UK involvement, particularly in terms of ensuring the highest standards of vigilance systems across Europe.

However, the UK has also had to consider the development of its own national registration database, which could be implemented ahead of EUDAMED and which may bolster confidence in the UK HealthTech Industry. Although it is likely to be less accessible and functional than the EUDAMED database, and some ABHI members have already highlighted various deficiencies, if it is ready in advance of the EUDAMED database, the ABHI should not delay its implementation while it waits for EUDAMED to go live.

For more information please contact India-Rose May of the London office.