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Welcome to the November 2018 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.

**Europe**

**EMA plans to revive its landmark clinical trials transparency policy**

In the second half of 2019, the European Medicines Agency (EMA) plans to implement a 'reactivation plan', examining how and when it can revive its transparency policy on the proactive publication of clinical trial data. This landmark policy was temporarily suspended on 1 August 2018 as a result of the implementation of the third phase of the EMA's Brexit business continuity plan to prepare for its relocation to the Netherlands. At this point in time, there are very few details on the proposed reactivation plan, with an EMA spokesperson having said, "as of today, [the] EMA can only confirm that no dossier will be published in 2019 on the Clinical Publication website".

Read more [here](#).

For further information please contact [Julia Gillert](#) of our London office or [Els Janssens](#) of our Abu Dhabi office.

**The HTA proposal: Harmonising the clinical assessment process across the EU**

On 4 October 2018, the European Parliament adopted the Report on the Commission Proposal for a Regulation on Health Technology Assessment (HTA). The proposal is to be implemented in the form of a regulation and aims to promote a collaborative approach between EU member states by harmonising the process of clinical assessments. The initiative aims to encourage innovation as well as increase transparency and consistency in this area; one joint clinical assessment as opposed to one per country would translate into quicker access to medical technologies for patients. Health technologies covered by this proposal include medical devices as well as new medicines, medical and surgical procedures and disease prevention measures. There are four main areas proposed for member states to work together in including joint clinical assessments, joint scientific consultations, identification of emerging technologies and continuing voluntary co-operation in other areas.

Read more [here](#).

For more information please contact [Julia Gillert](#), [Elina Angeloudi](#) or [Hester Norman](#) of our London office, or [Els Janssens](#) of our Abu Dhabi office.

**New regulations on medical devices and in-vitro medical devices: the European Commission's guidelines for manufacturers**

In July and August 2018, the European Commission published five documents aimed at providing manufacturers of medical devices with adequate information and guidelines necessary to ensure the proper implementation of the provisions laid down by the new Medical Devices Regulation (MDR) and the new In-Vitro Diagnostic Medical Devices Regulation (IVDR).

Read more [here](#).

For more information, please contact [Riccardo Ovidi](#), [Roberto Cursano](#) or [Giampaolo Austa](#) of our Rome office.

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**Czech Republic**

**Proposed changes to the regulation of vaccination**

On 24 August, 2018, the government of the Czech Republic submitted to the Chamber of Deputies a draft amendment of Act No. 378/2007 Coll., on Pharmaceuticals, as amended, to adapt the Czech legal order to the legislation of the European Union with respect to the prevention of the entry of counterfeit medicinal products into the legal supply chain, in particular to the so-called Falsified Medicines Regulation (*Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features to appear on the packaging of medicinal products for human use*).

Read more [here](#).

For further information please contact [Linda Darilkova](#) of the Prague office.

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**Germany**

**Impact of the new German and Austrian merger control thresholds on licensing agreements**

On 9 July 2018, the German and Austrian competition authorities (the German Bundeskartellamt and Austrian Bundeswettbewerbsbehörde) published final guidance on the application of the value-of-transaction thresholds in their respective merger control laws (the Guidelines).

Read the full article [here](#).

For more information please contact [Lisa Weinert](#) or [Christian Burholt](#).

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**Italy**

**The Italian Medicines Agency publishes the 17<sup>th</sup> Report on Clinical Trials on Medicinal**

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

Please contact Lisa Kaddouri if you wish to subscribe.

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## Products in Italy

On 4 September 2018, the Italian Medicines Agency published the 17<sup>th</sup> Report on Clinical Trials on Medicinal Products in Italy.

Read more [here](#).

For more information, please contact [Riccardo Ovidi](#), [Roberto Cursano](#) of our Rome office. [>Back to top](#)

### Hearing aid specialists can practice in pharmacies and para-pharmacies provided that they comply with technical requirements

With its decision No. 4877/2018, the Council of State annulled the Resolution No. 630/2013 of the Umbria Regional Council which established the prohibition on prosthetic companies as regards testing, adaptation and delivery activities involving hearing aids in establishments where different health and non-health commercial activities take place, (e.g. pharmacies, para-pharmacies, clinics and medical offices).

Read more [here](#).

For more information, please contact [Riccardo Ovidi](#), [Roberto Cursano](#) or [Giampaolo Austa](#) of our Rome office. [>Back to top](#)

### The parallel importer cannot change the name of medicinal products without a just cause

With its decision No. 9050/2018, the Administrative Court of the Lazio Region dismissed the appeal filed by a pharmaceutical company against the decision of the Italian Medicines Agency to allow the parallel import of a medicinal product under the name used in the country of origin, instead of that of the country of destination.

Read more [here](#).

For more information, please contact [Riccardo Ovidi](#), [Roberto Cursano](#) or [Giampaolo Austa](#) of our Rome office. [>Back to top](#)

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## Poland

### The Polish government returns to the idea of reimbursement-related incentives for pharmaceutical investors

In 2016, the Minister of Health together with the Minister of Entrepreneurship and Technology proposed to introduce a mechanism aimed at making selected aspects of the reimbursement application process and the conditions for inclusion into the public financing system dependent on the applicant's investment activity in the territory of Poland.

The proposed factors taken into consideration included the development of research and development facilities, creation of demand for specialised innovation-related services, and the expansion of the production base, with particular emphasis on the production of biotechnological therapies. The above-described program has been called the "reimbursement development scheme" (**RDS Programme**).

Companies included in the programme would be awarded the title of "Partner of the Polish Economy" and would be granted access to specific benefits or preferential treatment measures in the reimbursement proceedings.

Read more [here](#).

For more information please contact [Marcin Fialka](#) in the Warsaw office.

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## Russia

### New rules for identifying a locally originating product

The criteria of country of origin for the purposes of application of preferences within the Russian public procurement of medicines will change starting from the beginning of 2019. Currently, locally manufactured products may qualify as originating from Russia only under the customs rules of sufficient processing. However, starting from 1 January 2019, such product may qualify as originating from Russia under the separate set of local manufacturing rules established by Government Decree No. 719. This change is brought about by Government Decree No. 572, dated 12 May 2018, which amends Government Decree No. 1289, dated 30 November 2015.

Read more [here](#).

### Introduction of a new system of public procurement preferences

The system of public procurement preferences for pharmaceuticals in Russia relies on two types of documents: (i) decrees of the government that set "limitations of access" to procurement, i.e., cases when certain goods may not even take part in the public procurement tenders (e.g., the third one out rule); and (ii) orders of the Ministry of Economic Development that set "conditions of access" to procurement, i.e., cases when financial handicaps apply to foreign goods in the public procurement tenders (e.g., "15% preference").

Read more [here](#).

### Recent amendments to the procedure for determining the initial (maximum) price of a contract

**Decree №386n** of the Ministry of Healthcare of the Russian Federation dated 26 June 2018, which is also known as "On amending the procedure for determining the initial (maximum) price of a contract, the price of a contract entered into with a single supplier (contractor) when carrying out procurement of medicines" (**MOH Decree**), entered into force on 5 August 2018.

Read more [here](#).

### Obligation to submit information to the Ministry of Healthcare becomes effective soon

Under the **Federal Law** No. 425 dated December 28, 2017 "On Amendments to the Federal Law "On the Circulation of Medicines"" (**Federal Law**) holders or owners of the registration certificates of the medicinal preparations, manufacturers of the medicinal preparations, as well as manufacturers of the pharmaceutical substances which are entered into the State Registry of Medicines, if such medicinal preparations and pharmaceutical substances were registered before 1 January 2018, shall send the following information to the Ministry of Healthcare of the Russian Federation [before 1 January 2019](#):

- for Russian entities: Taxpayer Identification Number (INN);
- for foreign legal entities: a country of incorporation, name of the registration authority, registration number, taxpayer's code in the country of registration (incorporation) or its analogue.

Read more [here](#).

For further information please contact [Paul Melling](#) or [Alexey Trusov](#) in our Moscow office.

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## Spain

### **Dual pricing of medicines and parallel imports in the EU: The CNMC once again confirms the compatibility of a dual pricing system for medicines with competition law**

The National Commission on Markets and Competition (CNMC) recently published its decision dated 30 August 2018 for Case S/DC/0608/17, *EAEPC vs. LABORATORIOS FARMACÉUTICOS* (Decision), in which it once again states that the dual pricing policy implemented by certain laboratories does not infringe antitrust rules.

Read more [here](#).

For further information please contact [Valeria Enrich](#) or [Anna Zaragoza](#) from our Barcelona office.

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## Turkey

### **Turkey publishes draft regulation on medical devices manufactured utilizing animal origin tissue**

#### **Recent developments**

The Turkish Medicines and Medical Devices Agency (TİTCK) recently published on its website the draft Regulation on Medical Devices Manufactured Utilizing Animal Origin Tissue (Regulation).

Read more [here](#).

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office.

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### **Cosmetics safety: Turkey continues cracking down on unsafe and non-compliant cosmetic products**

#### **Recent developments**

The TİTCK recently announced the results of its cosmetic sector market surveillance and inspection conducted between April and June 2018

Read more [here](#).

For more information, please contact [Can Sözer](#), [Aybüke Gündel](#) or [Dilşad Sağlam](#) of our Istanbul office.

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### **Turkey publishes draft regulation on authorization of traditional herbal medical products**

#### **Recent developments**

The TİTCK recently published on its website the draft Regulation on Authorization of Traditional Herbal Medicinal Products (Regulation). Within the scope of harmonisation with EU legislation, the Regulation is based on the EU Directives No. 2001/83/EC and 2004/24/EC.

Read more [here](#).

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office.

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### **Turkey publishes draft regulation on foods for medical purposes**

#### **Recent developments**

The Turkish Medicines and Medical Devices Agency (TİTCK) recently published on its website the draft Regulation on Foods for Medical Purposes (Regulation). Within the scope of harmonization with EU legislation, the Regulation is based on the EU Directive 609/2013/EC.

Read more [here](#).

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office

### **Turkey publishes draft regulation on medical devices**

#### **Recent developments**

The Turkish Medicines and Medical Devices Agency (TİTCK) recently published on its website the draft Regulation on Medical Devices (Regulation). Within the scope of harmonization with EU legislation, the Regulation is based on the EU Directive No. 2017/745 (Directive). The TİTCK will collect public opinion for the Draft Regulation until December 16, 2018. Opinions may be submitted to the TİTCK in writing or to the e-mail address [md.reg@titck.gov.tr](mailto:md.reg@titck.gov.tr).

Read more [here](#).

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office

### **Turkey – Announcement on EBS access authorization changes**

In line with companies' requests, certain changes were made concerning users' access authorization to the Electronic Application System (EBS). Company representatives can now grant or restrict its current or new users' access to the Applications, Product, Document Request, Application List, Product License Application, Meeting, Import, Export, Value Transfer and Pricing Applications sections in the EBS. Companies will be responsible for their users' access to the EBS.

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office

#### **Announcement on product recall**

In response to the safety signal the European Medicines Agency published on its website, the Human Medicinal Products Priority Assessment Commission (**Commission**), established within the Turkish Medicines and Medical Devices Agency (**TİTCK**), conducted a Class 1 A level recall (end-user level) for certain products pursuant to the Recall Regulation. The Commission also urged the relevant companies in the healthcare sector to take necessary actions. The product list is available [here](#).

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office

#### **Announcement on production facilities**

Article 4(p) of the Regulation on Human Medicinal Products Facilities defines "secondary packaging" as placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability.

Read more [here](#).

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office

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## **Ukraine**

### **Clinical trials**

#### **Results of pre-clinical studies and clinical trials will be subject to mandatory publication**

On 4 September 2018, the Ukraine Parliament adopted Law of Ukraine **No. 2519-VIII**, "On Amending Article 9 of the Law of Ukraine "On Pharmaceuticals" Regarding Access to the Results of Preclinical Studies and Clinical Trials of Pharmaceuticals" (**Law**). The Law became effective on 4 October 2018.

Read more [here](#).

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

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### **Public procurement and reimbursement**

#### **Changes to the concept of reforming public procurement of pharmaceuticals and medical devices**

On 26 September 2018, the Cabinet of Ministers of Ukraine **approved** amendments to the Concept of Reforming Mechanisms for Public Procurement of Pharmaceuticals and Medical Devices (**Concept**) approved by Resolution of the Cabinet of Ministers of Ukraine No. 582 dated 23 August 2017. The changes to the Concept became effective on 26 September 2018.

Read more [here](#).

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

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### **Intellectual property**

#### **Developments of the draft law weakening patent protection**

On 4 September 2018, the parliament of Ukraine rejected Draft Law of Ukraine **No. 7538** "On Amending Certain Laws of Ukraine on Enhancing Legal Protection for Inventions and Utility Models" (**Draft Law**).

Read more [here](#).

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

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### **Competition law**

#### **Recommendations of the Antimonopoly Committee of Ukraine regarding rules for promotion of pharmaceuticals**

On 13 September 2018, the Antimonopoly Committee of Ukraine sent the MOH a recommendation on approval of legal act(s) with straightforward, transparent and non-discriminative rules to do the following:

- prevent distortion of competition due to the use of marketing instruments within wholesale and retail sales of pharmaceuticals
- provide end users of pharmaceuticals with the possibility of an independent choice of pharmaceuticals in pharmacies
- prevent the sale of pharmaceuticals primarily at increased cost due to the use of marketing instruments

The development of the above-mentioned legal act by the MOH should provide market participants with clear guidance from the regulator on appropriate marketing practices. We will monitor the preparation of this legal act by the MOH and keep you updated in our newsletter.

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

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### **Tax**

#### **Draft law on exempting import and supply of pharmaceuticals and medical devices from VAT**

On 1 October 2018, Draft Law **No. 9146** "On Amending the Tax Code of Ukraine Regarding Decreasing the Cost of Pharmaceuticals for the Population" was registered in the parliament

Read more [here](#).

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

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### **Medical devices**

## Draft law on introducing licensing for manufacture and sale of medical devices

On 6 October 2017, Draft Law No. 7182 "On Amending the Law of Ukraine "On Licensing Types of Economic Activities" (**Draft Law**) was registered in the Ukraine Parliament.

Read more [here](#).

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

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## UK

### Transferring marketing authorizations as a result of Brexit: key tax considerations

Developing, producing and marketing medicinal products involves a significant amount of regulation grounded in EU law for pharmaceutical companies to navigate.

The regulatory landscape has become even more challenging in light of Brexit as pharmaceutical companies grapple with what they urgently need to do in order to continue to bring medicinal products to the EU market post-Brexit. Following the UK's decision to leave the EU, the European Medicines Agency (**EMA**) confirmed that it will move from London to the Netherlands - following various rounds of highly competitive bids and close votes - and that businesses should not look to rely on any transitional period after the UK officially leaves the EU on 30 March 2019.

As a consequence of the withdrawal of the UK from the EU, pharmaceutical companies are acutely aware of the need to transfer certain functions outside of the UK to the EEA by 30 March 2019 purely for regulatory reasons in order to continue to market and distribute medicinal products across the EEA.

This in turn has wider ramifications for the group to navigate, including tax issues that arise from there structuring and changes to existing supply chains. In this article, we consider some of the key tax issues that arise from the transfer of such functions and assets, particularly in relation to European centralised marketing authorisations (**MA**).

Read the full article [here](#).

For further information please contact [Julia Gillert](#) of our London office.

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## Contact us

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 [Lisa Kaddouri](#).

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**FORWARD****Europe****EMA plans to revive its landmark clinical trials transparency policy**

In the second half of 2019, the European Medicines Agency (EMA) plans to implement a 'reactivation plan', examining how and when it can revive its transparency policy on the proactive publication of clinical trial data. This landmark policy was temporarily suspended on 1 August 2018 as a result of the implementation of the third phase of the EMA's Brexit business continuity plan to prepare for its relocation to the Netherlands. At this point in time, there are very few details on the proposed reactivation plan, with an EMA spokesperson having said, "as of today, [the] EMA can only confirm that no dossier will be published in 2019 on the Clinical Publication website".

Under the transparency policy, introduced in October 2016, the EMA has published clinical data submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure. The EMA anticipated that by proactively publishing clinical data, it would help:

- prevent duplication of clinical trials and encourage the development of new medicines;
- build public trust and confidence in the EMA's scientific and decision-making processes;
- academics and researchers re-assess clinical data.

However, as a result of the policy suspension, companies with authorised products are no longer required to redact commercially- confidential information and personal data from their clinical study reports and submit these to the EMA for disclosure. The EMA will continue to publish clinical data submitted before 1 August 2018, but no new data will be processed and published until further notice.

During this suspension, the EMA plans to update its guidance on the transparency policy to provide the wider industry with practical advice on the procedural aspects of submission and anonymisation of clinical reports, and on the identification and redaction of commercially confidential information. At the Drug Information Association's Global Clinical Trials Transparency conference in September 2018, the EMA confirmed that it was up to each drug company to decide whether they should continue preparing redacted packs to support the publication of clinical data in the future, and that they could use this suspension period to reflect on their approach to anonymisation and on how to improve their anonymisation reports. In addition, it summarised the key updates being made to the guidance, including:

- Clarification for clinical studies where the main period/phase is still ongoing at the time of publication;
- Update of timelines for end-to-end processes;
- New wording to reflect the review of the anonymisation report, including the need to submit an updated anonymisation report and/or written responses to the comments during the process.

For further information please contact [Julia Gillert](#) of our London office or [Els Janssens](#) of our Abu Dhabi office.

**The HTA proposal: Harmonising the clinical assessment process across the EU**

On 4 October 2018, the European Parliament adopted the Report on the Commission Proposal for a Regulation on Health Technology Assessment (HTA). The proposal is to be implemented in the form of a regulation and aims to promote a collaborative approach between EU member states by harmonizing the process of clinical assessments. The initiative aims to increase transparency and consistency in this area; one joint clinical assessment as opposed to one per country would translate into quicker access to medical technologies for patients. Health technologies covered by this proposal include medical devices as well as new medicines, medical and surgical procedures, and disease- prevention measures. There are four main areas proposed for member states to work together in including joint clinical assessments, joint scientific consultations, identification of emerging technologies and continuing voluntary co-operation in other areas.

The proposal envisions that countries will be forced to consider the results of scientific assessments at the EU level and the hope is to inform national regulators, in a centralised and more efficient way, of safe and effective health policies. A scientific approach aims to demonstrate the impact and value-add of new technologies or pre-existing ones, as compared to other health technologies available and in line with standards. A convergence of HTA tools, procedures and methodologies is expected, and removes the need to duplicate labours by HTA bodies and the industry. Further, it will ensure the sharing of best practices and capacity building. The proposal recognises that current approaches lead to "higher costs for industry, delays in access to technologies and a negative effect on innovation".

However, there has been a mixed response. The European Federation of Pharmaceutical Industries and Associations (EFPIA) welcomed the proposal, and EFPIA Director General, Nathalie Moll commented "All Member States conduct clinical assessments as part of national HTA processes. It makes sense to join forces to provide one, high-quality clinical assessment for use across Europe. This will support better decision-making and ultimately benefit all patients across the EU." However, certain EU member states raised concerns that this may lead to the loss of control of their national health systems. It is believed that these assessments will impact price and that the EU Commission should not have this role. On the other hand, smaller countries such as Greece and Portugal see a benefit in the mandatory requirement.

**What this means for the industry?**

The HTA proposal would decrease the burden on companies and would improve alignment for clinical evidence as advocated by pharma lobbyists. Furthermore, the proposal would provide for a greater level of predictability for businesses, as well as improve market access and the speed at which medicines are released to patients. An overarching worry is the sharing of confidential data. However, it should be noted that the proposal does not impose a direct obligation on companies. It merely requests health technology manufacturers to submit documentation necessary for the joint clinical assessment.

**State of play**

Over the summer, the European Parliament released a set of 200 amendments in many of the areas national governments had questioned or opposed, including giving countries the right to also conduct their own assessments on top of EU-level ones, or to complement the EU assessments with data pertinent to their national contexts. However, the parliament's Environment, Public Health and Food Safety Committee (EVNI) adopted a broad slate of compromises in mid-September, covering practically the entirety of the Commission's proposal. It was a victory for the lead rapporteur, Spanish socialist and democrat MEP Soledad Cabezón Ruiz, who spent the summer negotiating with shadow rapporteurs. However, EU member states are struggling to overcome opposition to the mandatory use of joint clinical

assessments, a requirement largely preserved in the proposal. They argue that EU members should only have to consider the HTA assessments, and leave room to ignore the assessments that prove to be inadequate in the context of a nation. For example, one must consider the relevance of a particular disease in a country or the comparable treatments which are available.

Another drawback about the proposal is also the lack of a proper appeal process; which withholds the opportunity for manufacturers to have the scientific data reviewed, and this is a point that must be considered moving forward.

A further contentious amendment is the threshold for decisions on EU-level assessments. Amendments made to the proposal in late September mean that any agreement will need a qualified majority in the Council – which means that 55% of member states must vote in favour of the practice which represent at least 65% of the EU population. MEPs in the EVNI said decisions should be made by a two-thirds majority, rather than the simple majority proposed by the Commission. Such objections revolve around the possibility of a block of smaller countries driving HTA planning decisions.

Finally, key stakeholders of the health sector (e.g patients) were unhappy that they were not included at various stages of the HTA process at the EU level. The EVNI systematically went through the Commission's proposal and downgraded opportunities for patient input during joint scientific consultations, which is when developers can get early advice about what sort of data they will need to provide. For example, where the Commission calls for the group overseeing a given assessment to "ensure" that patients "are given the opportunity to provide comments," EVNI said patients "may submit" comments during the joint scientific consultation.

#### Next steps

The European Parliament has introduced amendments to the original Commission proposal and referred the matter back to the European Parliament lead committee for informal negotiations with the Council and European Commission. The European Parliament, Council and Commission negotiators will now try to come to a compromise regarding the final text of the regulation, which will allow the European Parliament and the Council to formally adopt the regulation at first reading. The Committee hopes to have detailed talks under way before the May 2019 parliament elections.

We will continue to monitor the progress of this important proposal.

For more information please contact [Julia Gillert](#), [Elina Angeloudi](#) or [Hester Norman](#) of our London office, or [Els Janssens](#) of our Abu Dhabi office.

#### New regulations on medical devices and in-vitro medical devices: the European Commission's guidelines for manufacturers

In July and August 2018, the European Commission published five documents aimed at providing manufacturers of medical devices with adequate information and guidelines necessary to ensure the proper implementation of the provisions laid down by the new Medical Devices Regulation (**MDR**) and the new In-Vitro Diagnostic Medical Devices Regulation (**IVDR**).

Said documents include: (i) a factsheet for both manufacturers of medical devices and manufacturers of in-vitro medical devices highlighting the main changes brought by the two regulations in terms of obligations for manufacturers, (ii) two step-by-step guides describing the actions that manufactures must carry out to properly implement the Regulations, amongst which is the drafting of a preliminary action plan and procedures to ensure the constant monitoring of the EU legislation on this matter, and (iii) an exhaustive list of requirements that manufacturers of medical devices must fulfill in order to comply with the regulations.

The regulations, which entered into force in 2017, will be fully applicable from May 2020, with respect to the MDR, and from May 2022, as regards the IVDR. The purpose of the European Commission is to create an international framework, transparent and sustainable, that improves clinical safety and creates fair market access for manufacturers.

The documents published by the European Commission are available at the following link, under the "Information for Manufacturers" section: [https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework\\_en#new\\_regulations](https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en#new_regulations).

For more information, please contact [Riccardo Ovidi](#), [Roberto Cursano](#) or [Giampaolo Austa](#) of our Rome office.

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## Contact us

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FORWARD

WEBSITE

**Europe****Big fine for Facebook: what can healthcare companies do to avoid infringement errors during merger control?**

The EUR 110 million fine imposed on Facebook confirms that the European Commission will not tolerate the supply of misleading or incorrect information during its merger control review process. The European Commission took a strict approach in imposing two separate fines - one in relation to information Facebook provided in response to a request for information and one in relation to information included in the notification itself, even though the underlying information was the same.

Facebook and two pending cases concerning the same offence (one in relation to Merck's acquisition of Sigma-Aldrich in 2015 and one in relation to GE's acquisition of LM Wind earlier this year) also confirm an increased focus by the European Commission on the potential negative effects of mergers on innovation - in all three cases, the incorrect or misleading information related to product development or innovation.

This of particular relevance for companies active in the pharma or medical devices sectors - the likely implication of these cases is that what can already be very lengthy pre-notification discussions in cases involving new markets and/or complex theories of harm will likely become even lengthier. It now becomes even more important to ensure that all theories of harm are out in the open from an early stage and that the parties clearly understand the scope of any follow-up questions from the case team.

In setting Facebook's fine, the EC took into account the fact that Facebook cooperated with the European Commission during the investigation (including acknowledging the infringement and waiving certain procedural rights). The EC also acknowledged that the incorrect or misleading information had no impact on the outcome of the 2014 merger review process. Had the facts been different, Facebook could well have faced an even higher fine.

To avoid any ambiguity or misunderstanding when responding to a request for information from the European Commission:

1. Confirm the scope of any question which seems unclear with the case team (in writing)
2. Ensure you have the support of individuals from within the business with a sufficiently broad understanding of the relevant products, including any still under development
3. Set out your understanding of the scope of a question
4. Be explicit that your response does not go beyond the stated scope of the question and include any limitations on scope of the response as well as any limitations on the scope of the efforts undertaken to identify relevant information
5. Carefully consider whether responses to information requests need to be incorporated into the filing itself. The context of those initial questions might not have been clear at an early stage of the proceedings. As Facebook shows, the European Commission will treat the supply of misleading or incorrect information in response to request for information the notification form itself as separate infringements.

For further information, please contact [Sophia Real](#) from our Brussels office.

**What lessons and trends for EU merger control in healthcare can be learned from South Africa?**

In July, the South African Competition Commission launched an investigation into Aspen, Pfizer and Roche in relation to alleged excessive pricing for certain cancer medicines. What is particularly concerning about the Competition Commission's investigation is the fact that this involves products that are still patent-protected for some time to come. This is a worrying development given the risk that scrutiny of originator pricing prior to patent expiry can seriously undermine incentives to engage in costly R&D programs. The South African investigation follows the EU's probe into Aspen earlier this year and previous UK and Italian penalty decisions for excessive pricing by Aspen.

These cases are unlikely to denote a new enforcement trend, at least at EU level. Authorities have been cautious in their statements on excessive pricing, and the cases themselves seem confined to extreme facts. EU Competition Commissioner Vestager underlined the need for caution: "... when we do take action against excessive prices, we need to make sure we're not taking away the rewards that encourage businesses to innovate." That the bar for intervention in relation to excessive pricing is high was also confirmed by a recent Opinion by European Court of Justice's Advocate General Wahl. However, as the South African investigation shows, non-EU regulators are examining these cases with interest.

In South Africa, Pfizer is suspected of overcharging for the lung cancer treatment xalkori crizotinib and Roche is suspected of having charged excessive prices for the breast cancer treatments Herceptin and Herclon. Aspen, South Africa's biggest generic drug maker, is suspected of having overcharged for Leukeran, Alkeran and Myleran. The press release from the South African Competition Commission expressly refers to the prior Italian investigation involving Aspen as well as the recently opened investigation by the European Commission as a result of which "the Commission has reasonable grounds to suspect that Aspen may be engaging in similar conduct locally." The Competition Commission will also investigate whether Roche may have engaged in so-called 'ever-greening', i.e. delaying and/or preventing generic entry of alternative breast cancer drugs through making minor changes to its medicines close to their patent expiry in an attempt to be granted second generation patent protection. In addition, it will investigate whether Roche used a 'patent thicket' strategy to delay and/or prevent generic entry, i.e. a strategy preventing the development of alternative versions of its medicines by restricting the processes whereby a drug is produced (it also limits the number of forms of the AIP that generic companies can make, thereby eliminating possible substitutable products).

For further information, please contact [Sophia Real](#) from our Brussels office.

**New value-based filing thresholds in European merger control regimes – implications for healthcare and life sciences companies**

Germany and Austria recently introduced new alternative merger control thresholds based on transaction value. At EU level the introduction of a value-based filing threshold is also being discussed. The new value-based filing thresholds are designed to capture deals in the digital and healthcare sectors in particular, where the target generates little if any revenue. For healthcare and life sciences companies this means that acquisitions of start-ups as well as potentially licensing transactions involving upfront payments, milestone and royalty payments may require upfront merger control. Failing to notify a transaction or implementing a transaction before receiving merger clearance (so-called "gun jumping") can result in the imposition of very high fines by the relevant competition authorities.

**Germany**

On 9 June 2017, the ninth amendment to the German Act against Restraints of Competition (ARC) came into force, which inter alia, introduces a new alternative merger control filing threshold based on the value of a transaction.

Under the new merger control regime (cf. section 35 (1a) ARC), a merger filing is required if:

- the combined aggregate worldwide annual turnover of all parties concerned exceeded EUR 500 million; and
- the turnover in Germany of one party concerned exceeded EUR 25 million; and
- no other party concerned had turnover exceeding EUR 5 million; and
- the "value of the consideration paid in return for the transaction" is more than EUR 400 million; and
- the target is significantly active in Germany.

According to the explanatory memorandum to the amendment, the new value-based threshold shall enable the German Federal Cartel Office (FCO) to review high-value transactions involving target companies without significant turnover – e.g. the acquisition of pharmaceutical, medical device, and life sciences targets with innovative products which have not yet come to market.

#### Austria

In Austria, a new alternative transaction value threshold will enter into force on November 1, 2017 triggering notification if:

- the parties' combined worldwide annual turnover exceeded EUR 300 million; and
- the parties' combined turnover in Austria exceeded EUR 15 million; and
- the "value of consideration paid in return for the transaction" exceeds EUR 200 million; and
- the target undertaking has "significant" activities in Austria.

#### "Value of consideration paid in return for the transaction" and "significant domestic activities" under the new German and Austrian merger control law

Under the new German law, the "value of the consideration paid in return for the transaction" will include all consideration paid for the assets and any other consideration of monetary value that the acquirer receives from the seller in connection with the transaction, including any liabilities assumed by the acquirer (cf. section 38 (4a) ARC).

The German explanatory memorandum clearly states that milestone payments and considerations based on earn-out clauses etc. also have to be taken into account when calculating the value of the transaction. The exact calculation of the value of the transaction, however, – in particular with regard to milestone and royalty payments – is hotly debated. Based on our experience in one of the first merger control proceedings concerning the new value-based filing threshold, the FCO takes into account the so-called net present value ("NPV") with regard to earn-out payments (including milestone payments) – i.e. the FCO considers the time value of money.

The "value of consideration paid in return for the transaction" is not defined under the Austrian draft law, but the explanatory memorandum uses wording similar to that of the German amendment.

The FCO has indicated in the above mentioned precedent that there are strong indications for "significant activities in Germany" if it can be expected that the German turnover of the target will exceed EUR 5 million in the current business year.

Please note, however, that both the calculation of the value of consideration as well as the requirement of significant domestic activities under the new German and Austrian merger control law has to be assessed on the merits of each individual case.

Acknowledging that uncertainties persist, the FCO and the Austrian Federal Competition Authority (Bundeswettbewerbbehörde, "BWB") are currently both working on a joint information memorandum they intend to publish which will contain guidance on how the consideration, as well as the domestic activities of an undertaking, should be assessed. It would be welcome if the FCO and the BWB would take a uniform approach and would publish a joint guideline memorandum."

#### EU

Back in 2016, Margrethe Vestager, European Commissioner for Competition, announced that the European Commission was considering whether the current turnover-based thresholds under EU merger control law should be complemented by a value-based threshold ([https://ec.europa.eu/commission/2014-2019/vestager/announcements/refining-eu-merger-control-system\\_en](https://ec.europa.eu/commission/2014-2019/vestager/announcements/refining-eu-merger-control-system_en)): "The issue seems to be that it's not always turnover that makes a company an attractive merger partner (...) In the pharmaceutical sector, it might be a new drug that's been developed but not yet approved for sale. (...)".

From October 2016 – January 2017, the European Commission conducted a public consultation on the "evaluation of procedural and jurisdictional aspects of EU merger control".

It remains to be seen whether the discussion at EU level will result in a legislative proposal comparable to the recent developments in Germany and Austria. While there is support for change initial signs are that the introduction of a new value-based filing threshold under EU merger control appears unlikely in the short term.

Nevertheless, healthcare and life sciences companies have to consider German and Austrian merger control laws even if they acquire a target or a license with no or a minimal turnover. In cases of doubt, it is possible to send a non-jurisdiction letter to the German and/or Austrian competition authority in order to confirm that no filing(s) will be required. But there are neither statutory deadlines for answering a non-jurisdiction letter by the competition authority nor will the submission of such a letter affect the statutory deadlines of a potential subsequent merger control filing. Companies have been notified to factor in such filings in terms of deal timing and feasibility.

Baker McKenzie's Global Merger Analysis Platform (GMAP) provides in-depth guidance on the multi-jurisdictional assessment of merger control requirements – also with regard to the new filing thresholds in Germany and Austria.

For more information, please contact **Jane Hobson** of our London office, **Fiona Carlin** of our Brussels office, **Christian Burholt** of our Berlin office or **Andreas Faugott** of our Vienna office.

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**FORWARD****WEBSITE****Italy****The Italian Medicines Agency publishes the 17<sup>th</sup> Report on Clinical Trials on Medicinal Products in Italy**

On 4 September, 2018 the Italian Medicines Agency published the 17<sup>th</sup> Report on Clinical Trials on Medicinal Products in Italy.

This report shows that, in 2017, 564 clinical trials were authorised in Italy (with a reduction of 14.5% compared to 2016), of which half was conducted in the oncological and hematologic-oncological field. Against such reduction, which affected almost all therapeutic areas, the report shows an increase in clinical trials for rare diseases, representing the 25.5% of the total, the 80% of which consists of for-profit trials. The data published by the Italian Medicines Agency also shows a percentage increase of non-profit clinical trials in relation to the total trials carried out in Italy, which in 2017 increased to 26.4%.

Lastly, the report provides data relating to Italy's participation in the Voluntary Harmonization Procedure for the harmonised assessment of clinical protocols carried out in several EU member states. Also in this case, the report shows that in 2017, there was a reduction in the number of trials conducted in Europe, accompanied by a reduction in the number of clinical trials filed by Italy, which decreased from 209 trials in 2016 to 191 in 2017.

For more information, please contact [Riccardo Ovidi](#), [Roberto Cursano](#) or [Giampaolo Austa](#) of our Rome office.

**Hearing aid specialists can practice in pharmacies and para-pharmacies provided that they comply with technical requirements**

With its decision No. 4877/2018, the Council of State annulled the Resolution No. 630/2013 of the Umbria Regional Council which established the prohibition on prosthetic companies as regards testing, adaptation and delivery activities involving hearing aids in establishments where different health and non-health commercial activities take place, (e.g. pharmacies, para-pharmacies, clinics and medical offices).

As stated by the Umbria Region, such prohibition was grounded on Section 102 of the Consolidated Text of Health Laws, which provides that "*the attainment of more than one degree or diploma entitles to the cumulative practice of the relevant healthcare professions or arts, with exception of the practice of pharmacy, which cannot be combined with other healthcare professions or arts*".

In this respect, the Council of State held that Section 102 of the Consolidated Text of Health Laws does not prevent the performance of the hearing care activity in a pharmacy, provided that such activity is performed by an individual other than the pharmacist. The Council of State also held that, without prejudice to the technical and size requirements for carrying out the prosthetic activity, the location of a hearing centre in a multifunctional establishment is not only possible but it also makes it easier for patients - who often face mobility problems - to reach centres.

For more information, please contact [Riccardo Ovidi](#), [Roberto Cursano](#) or [Giampaolo Austa](#) of our Rome office.

**The parallel importer cannot change the name of medicinal products without a just cause**

With its decision No. 9050/2018, the Administrative Court of the Lazio Region dismissed the appeal filed by a pharmaceutical company against the decision of the Italian Medicines Agency to allow the parallel import of a medicinal product under the name used in the country of origin, instead of that of the country of destination.

In this respect, the Administrative Court held that the parallel import must be performed under the name used in the country of origin, in order to not violate the industrial and commercial property rights of the relevant owner. The court also stated that said rule may be departed from only in case the use of said name causes restrictions on or impediments to the marketing of the product in the country of destination or where it poses a risk of being confused with medicinal products having a similar name, therefore endangering the public health.

Since the appellant failed to submit any evidence of possible restrictions on or impediments to market access or of risks to public health arising from the possible confusion amongst different medicinal products, the administrative judge dismissed the appeal holding that the request for importing the medicinal product under the name of the country of destination was motivated by the desire to exploit the commercial advantage deriving from the market position of the same medicinal product in Italy.

For more information, please contact [Riccardo Ovidi](#), [Roberto Cursano](#) or [Giampaolo Austa](#) of our Rome office.

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**FORWARD****WEBSITE****Spain****Dual pricing of medicines and parallel imports in the EU: The CNMC once again confirms the compatibility of a dual pricing system for medicines with competition law**

The National Commission on Markets and Competition (**CNMC**) recently published its decision dated 30 August 2018 for Case S/DC/0608/17, *EAEPIC vs. LABORATORIOS FARMACÉUTICOS (Decision)*, in which it once again states that the dual pricing policy implemented by certain laboratories does not infringe antitrust rules. The CNMC thus maintains the stance it has defended for years and which was explained at length in its decision of 19 January 2017 in Case S/DC/0546/15 *PFIZER/COFARES*, the legal basis of which is largely reproduced in the Decision.

In summary, in 2009, the National Competition Commission (**CNC** –CNMC's predecessor) decided not to launch sanction proceedings and closed the complaint filed by the European Association of Euro-Pharmaceutical Companies (**EAEPIC**) against several pharmaceutical laboratories (Pfizer S.L.U., Janssen-Cilag, S.A., Merck Sharp & Dohme de España, S.A., Lilly, S.A., Sanofi Aventis, S.A. and Novartis Farmacéutica, S.A.) for their dual pricing policy implemented in the early 2000s, bearing in mind that there was insufficient evidence that such a policy infringed competition law.

1. However, the National High Court and the Supreme Court annulled this closing based on an insufficient study of the matter by the CNC, thus obliging the competition authority to launch proceedings and carry out a more in-depth analysis of the issue.

2. In compliance with the legal mandate, the CNMC launched proceedings that led to the Decision. This time, the Decision contained an exhaustive analysis of the facts and applicable legal framework, allowing it to conclude what it already suspected in 2009: the laboratories' policy of setting up dual pricing for medicines according to whether they are sold to the National Health Service or on the free market does not infringe competition rules.

As we have mentioned, the Decision literally reproduces a great deal of the assessment made in its decision of 19 January 2017 in the Pfizer/Cofares case. Below we have summarised the main arguments:

The CNMC believes that the dual pricing policy implemented by the laboratories does not constitute a practice that is contrary to Article 1 of Law 15/2007, of 3 July, on the Defence of Competition (*Ley de Defensa de la Competencia* or **LDC**) or Article 101 of the Treaty on the Functioning of the European Union (**TFEU**) because it is the result of a legal imposition and not of the will of the laboratories. In this sense, Article 4 of the LDC contemplates an exemption for such conduct arising from the application of a law. The authority underlines the fact that, "...the essential element of this practice, the voluntary fixing of two different prices depending on the destination of the medicines and the purpose of which is to avoid parallel trade in medicines, is not applicable. (...) This lack of autonomy means that their conduct cannot be deemed liable to infringe the rules of competition (...)."

Since Spanish legislation sets the price of medicines that are included in the National Health System and dispensed in Spain, it is entirely legitimate (and legal) for laboratories to set a free and different price for those medicines that are excluded from that national health system. In fact, the authority deems that, in principle, laboratories set a single price for their medicines freely under the protection of freedom of enterprise, and only subsequently do they apply the price set by the Administration, when the wholesaler demonstrates that the medicine is intended for use by the National Health System and that it has been dispensed in Spain: "In this context, Pfizer cannot be regarded as having carried out a policy of dual pricing in selling its medicinal products, since the laboratory only disposes voluntarily of the "Pfizer price", and the other price is imposed by the administration, therefore the essential element of that practice, namely the voluntary fixing of two different prices depending on the destination of the medicines and the purpose of which is to prevent parallel trade in medicines, is not applicable."

Note that the validity of the dual pricing policy derives from the fact that one of these "two prices" is a price imposed by the Administration: therefore, the Decision does not protect a dual pricing policy that does not correspond to the application of a legal regime.

As a novelty in relation to the Pfizer/Cofares decision, the Decision considers that there is no evidence that the laboratories entered into agreements to implement their dual pricing policies. In this regard, the CNMC considers that the fact that these laboratories implemented these policies at the same time derives, on the one hand, from the legislation, and, on the other hand, from the concentration of the sector.

Notwithstanding the foregoing, the Decision can be appealed before the National High Court and subsequently in cassation before the Supreme Court. Therefore, it is still possible that the CNMC's conclusion on the legality of dual pricing policies for medicines under competition law will be altered.

Interestingly enough, the General Court of the European Union recently handed out a ruling by which it confirms the rejection of a complaint that the EAEPIC filed against the dual pricing policy of GlaxoSmithKline. The case was different and the rejection of the complaint is confirmed based on procedural arguments, but at least for the moment, the balance seems to have shifted to a slightly more favourable climate for manufacturers.

For further information please contact [Valeria Enrich](#) or [Anna Zaragoza](#) from our Barcelona office.

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**FORWARD****WEBSITE****Turkey****Turkey publishes draft regulation on medical devices manufactured utilising animal origin tissue****Recent developments**

The Turkish Medicines and Medical Devices Agency (TİTCK) recently published on its website the draft Regulation on Medical Devices Manufactured Utilizing Animal Origin Tissue (**Regulation**).

**What's new?**

In the scope of EU harmonisation, the draft Regulation was prepared and is based on EU Regulation No. 722/2012 to establish the particular requirements for introducing into the market and/or putting into service medical devices, including active implantable medical devices that were manufactured utilising animal tissue.

Before filing an application for a conformity assessment for these medical devices, manufacturers must carry out the risk analysis and risk management scheme set out under the draft Regulation. The conformity assessment considers the justification for the use of animal tissues or derivatives, the manufacturer's control of raw materials sources, finished products, production process, testing and subcontractors.

The draft Regulation and a comparison chart of the draft Regulation and EU Regulation No. 722/2012 are available [here](#) (in Turkish).

**Conclusion**

The TİTCK continues to provide guidance for companies operating in the healthcare sector. Companies should carefully review the requirements set forth under the draft Regulation before placing on the market or putting into service their medical devices and filing an application for a conformity assessment.

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office.

**Cosmetics safety: Turkey continues cracking down on unsafe and non-compliant cosmetic products****Recent developments**

The TİTCK recently announced the results of its cosmetic sector market surveillance and inspection conducted between April and June 2018.

**What do the results say?**

The TİTCK's Cosmetics Supervision Department detected unsafe and noncompliant cosmetic products as a result of its cosmetic market surveillance and inspection conducted during the second quarter of 2018. Of the 93 compliant cosmetic products, 54 were local and 39 were imported. Of the 210 noncompliant cosmetic products, 33 were local and 177 were imported. Of the 13 unsafe cosmetic products, nine were local and four were imported. A total fine of TRY 590,603 (approximately USD 88,946) was levied against the responsible companies.

**Conclusion**

The TİTCK continues to demonstrate its commitment to the 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 noncompliant products.

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office.

**Turkey publishes draft regulation on authorization of traditional herbal medical products****Recent developments**

The TİTCK recently published on its website the draft Regulation on Authorization of Traditional Herbal Medicinal Products (**Regulation**). Within the scope of harmonisation with EU legislation, the Regulation is based on the EU Directives No. 2001/83/EC and 2004/24/EC.

**What's new?**

The Regulation sets out the procedures and principles for the authorisation, packaging and distribution of medical herbal products. The Regulation aims to increase the efficiency and reliability of these products and ensure that they meet the required quality standards.

Products that do not comply with the Regulation will not be authorised and therefore will not be placed into the market. The Regulation lists the required documents and sets out the procedure for the authorisation process. The Regulation clarifies the evaluation process and the objection mechanisms concerning the evaluation process in detail.

The Regulation also introduces certain requirements for the packaging of herbal medicinal products. Medical herbal products must contain usage instructions prepared in line with the requirements under the Regulation. The draft Regulation on Authorization of Traditional Herbal Medical Products is available [here](#) (in Turkish).

**Conclusion**

The TİTCK continues to provide guidelines for companies in the healthcare sector in line with EU regulations. Companies under the scope of the Regulation should follow the authorisation, packaging and distribution requirements set forth under the draft Regulation before introducing their products to the market.

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office.

**Turkey publishes draft regulation on foods for medical purposes****Recent developments**

The Regulation on Data Controllers Registry, prepared by the Data Protection Authority, was published on 30 December 2017. The Regulation entered into force on 1 January 2018.

**Background**

The TİTCK recently published on its website the draft Regulation on Foods for Medical Purposes (**Regulation**).

Within the scope of harmonisation with EU legislation, the Regulation is based on the EU Directive 609/2013/EC.

#### What's new?

The Regulation sets out the labelling rules, procedures and principles for the authorisation and packaging of products intended for medical use. The Regulation aims to ensure that the products do not endanger human health and food safety.

The formulation of the products for medical purposes must be based on internationally recognised principles of medicine and nutrition. Companies must also ensure that the products meet the specific nutritional requirements when used in accordance with the specified instructions, and that the products are scientifically proved to be useful and effective.

In addition, companies must obtain an authorisation certificate from the TITCK before they introduce their products to the market. Companies should submit the relevant information and documents for the products listed under the Regulation to the TITCK.

The draft Regulation on Foods for Medical Purposes is available [here](#) (in Turkish).

#### Conclusion

The TITCK continues to provide guidelines for companies in the healthcare sector in line with EU regulations. Companies under the scope of the Regulation should follow the authorisation, packaging and distribution requirements set forth under the Regulation before introducing their products to the market.

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office.

#### Turkey publishes draft regulation on medical devices

##### Recent developments

The TITCK recently published on its website the draft Regulation on Medical Devices (**Regulation**). Within the scope of harmonisation with EU legislation, the Regulation is based on EU Directive No. 2017/745 (**Directive**). The TITCK will collect public opinion on the Draft Regulation until 16 December 2018. Opinions may be submitted to the TITCK in writing or to the email address [md.reg@titck.gov.tr](mailto:md.reg@titck.gov.tr).

#### What's new?

The Regulation aims to protect the health of patients, healthcare professionals or persons who use medical devices. It sets out high standards of quality and safety for medical devices. Within this scope, the Regulation establishes the principles and procedures concerning the placing on the market, making available on the market or utilisation of, medical devices and their accessories.

Products that do not meet the requirements under the Regulation cannot be placed on the market or utilised. In this respect, companies are required to demonstrate the conformity of their products with the general safety and performance requirements under the Regulation. The Regulation also prohibits using texts, names, trademarks, pictures or other signs that might mislead the user or the patient concerning the devices' intended purpose.

The Regulation introduces significant obligations for both importers and manufacturers. Manufacturers must ensure that their products are designed and manufactured in line with the standards set out under the Regulation, whereas importers are required to verify that the devices are accompanied by an EU declaration of conformity and the required instructions for use.

The draft Regulation on Medical Devices, the Directive, and a comparison chart of the Regulation and the Directive are available [here](#).

#### Conclusion

The TITCK continues to provide guidelines for companies in the healthcare sector in line with EU regulations. Companies should benefit from this opportunity to cooperate with the TITCK and further improve the draft Regulation and follow the principles and procedures before placing their products on the market.

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office.

#### Turkey – Announcement on EBS access authorisation changes

In line with companies' requests, certain changes were made concerning users' access authorisation to the Electronic Application System (**EBS**).

Company representatives can now grant or restrict their current or new users' access to the following sections in the EBS: Applications, Product, Document Request, Application List, Product License Application, Meeting, Import, Export, Value Transfer and Pricing Applications. Companies will be responsible for their users' access to the EBS.

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office.

#### Turkey – Announcement on product recall

In response to the safety signal the European Medicines Agency published on its website, the Human Medicinal Products Priority Assessment Commission (**Commission**), established within the TITCK, conducted a Class 1 A level recall (end-user level) for certain products pursuant to the Recall Regulation.

The Commission also urged the relevant companies in the healthcare sector to take necessary actions. The product list is available [here](#).

For more information, please contact [Can Sözer](#) or [Hilal Temel](#) of our Istanbul office.

#### Turkey – Announcement on production facilities

Article 4(p) of the Regulation on Human Medicinal Products Facilities defines "secondary packaging" as any outer packaging material or container wherein a sealed primary package is placed. This also includes any labelling of the material that could be used for identification or traceability.

In line with this definition, a manufacturing license is issued by the TITCK for facilities where the labelling or coding processes are conducted, even if the facility is not involved with the process of placing the primary packages within any outer packaging material.

Facilities conducting only the coding or labelling processes are considered secondary packaging facilities. Companies should make the relevant applications according to Article 7(a) of the variations guideline regarding the changes they wish to make in their facilities.

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**FORWARD****WEBSITE****Ukraine****Clinical trials****Results of pre-clinical studies and clinical trials will be subject to mandatory publication**

On 4 September 2018, the Ukraine Parliament adopted Law of Ukraine No. 2519-VIII, "On Amending Article 9 of the Law of Ukraine "On Pharmaceuticals" Regarding Access to the Results of Preclinical Studies and Clinical Trials of Pharmaceuticals" (**Law**). The Law became effective on 4 October 2018.

The Law sets forth that reports on pre-clinical studies and clinical trials of pharmaceuticals should be published on the website of the Ministry of Health of Ukraine (**MOH**). The templates of these reports must be adopted by the MOH by 4 April 2019.

The Law however remains silent on the timelines for publishing reports and the possibility of redacting commercial confidential information by companies. Furthermore, the wording of the Law does not provide a straightforward response to the question of whether such reports should be submitted with respect to all studied pharmaceuticals, including those which are not submitted for state registration due to, e.g., poor results of a pre-clinical study or a clinical trial, or only to those pharmaceuticals that are submitted for state registration. These issues may be addressed in the bylaw(s) to be adopted by the MOH in the course of implementing the Law.

The Law should contribute to the transparency of clinical data. At the same time, if the bylaw(s) to be developed by the MOH do not provide for the possibility of companies redacting commercial confidential information and/or if the template report contains excessive information, this may create additional regulatory hurdles for companies conducting clinical trials in Ukraine. We will monitor the MOH's preparation of these bylaws and will update you on these developments in our newsletter.

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

**Public procurement and reimbursement****Changes to the concept of reforming public procurement of pharmaceuticals and medical devices**

On 26 September 2018, the Cabinet of Ministers of Ukraine **approved** amendments to the Concept of Reforming Mechanisms for Public Procurement of Pharmaceuticals and Medical Devices (**Concept**) approved by Resolution of the Cabinet of Ministers of Ukraine No. 582 dated 23 August 2017. The changes to the Concept became effective on 26 September 2018.

By way of background, the Concept provided for the establishment of a central procurement agency (**Agency**), which should be created by and be accountable to the MOH. Based on the Concept, the Agency should have been established in the second half of 2017. Considering that to date the Agency has not been established, the following changes to the Concept were introduced:

- The Agency should be established in 2018.
- The Agency will be provided with the function of strategic procurement whilst maintaining the centralised and local procurement frameworks focused on less-critical procurement needs.
- Starting in 2018, the Agency should procure products for fulfilling the programs of the Global Fund to Fight AIDS, Tuberculosis and Malaria. The transitional period during which the Agency should procure medical products in parallel with specialised procurement agencies should last until 2021. Thus, it may be expected that the term of procurement by specialised procurement agencies (UNDP, UNICEF and Crown Agents) will be extended to 2021.
- Public procurement reform should be streamlined with healthcare financing principles reform. In particular, the cost of certain pharmaceuticals, medical devices and other items of medical utility should be included into the cost of the medical service that will be guaranteed by the state. These services will be financed by the National Health Service, a newly created agency responsible for allocating funds for financing medical care (for more details about the National Health Service see our [legal alert](#) and [May 2018](#) newsletter).
- The reimbursement program should be extended.
- The Agency must be permitted to delegate the procurement function to specialised procurement agencies.
- Legislation must be amended to allow the direct participation of non-residents in procurement procedures.
- Framework agreements and e-procurement by the Agency must be utilised.
- Legislation must be amended to allow group contracting, price negotiations with manufacturers and the use of international trading platforms.
- Legislation should also be amended to allow the flexible settlement terms in relations with suppliers, as well as advance payments, foreign currency payments, etc.
- Quality control of imported pharmaceuticals should be simplified.

To implement these changes, the MOH, the parliament, the Cabinet of Ministers of Ukraine and other government authorities will need to develop and approve a number of laws and bylaws.

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

**Intellectual property****Developments of the draft law will weaken patent protection**

On 4 September 2018, the Ukraine Parliament rejected Draft Law of Ukraine No. 7538 "On Amending Certain Laws of Ukraine on Enhancing Legal Protection for Inventions and Utility Models" (**Draft Law**).

Changes stipulated in the Draft Law include the following:

- Exclusion of novel forms of pharmaceuticals (salts, ethers, etc.), new dosage forms, new characteristics or new use of a known pharmaceutical from patent protection
- Introduction of a supplementary certificate of patent protection for the extension of the validity term of the intellectual property rights to an invention (The rights to supplementary protection will be limited to the product and its use.)
- Permitting the use of the invention (utility model) in studies conducted for the purpose of preparation and submission of information for the registration of a pharmaceutical

On 17 September 2018, a group of members of the parliament registered a new draft law, No. 9088, which includes the same limitations on patent protection of pharmaceuticals.

The adoption of the Draft Law would considerably weaken the patent protection of pharmaceuticals in Ukraine. We will keep you updated on the developments of the status of this draft law.

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

## Competition law

### Recommendations of the Antimonopoly Committee of Ukraine regarding rules for promotion of pharmaceuticals

On 13 September 2018, the Antimonopoly Committee of Ukraine sent the MOH a recommendation on approval of legal act(s) with straightforward, transparent and non-discriminative rules to do the following:

- prevent distortion of competition due to the use of marketing instruments within wholesale and retail sales of pharmaceuticals
- provide end users of pharmaceuticals with the possibility of an independent choice of pharmaceuticals in pharmacies
- prevent the sale of pharmaceuticals primarily at increased cost due to the use of marketing instruments

The development of the above-mentioned legal act by the MOH should provide market participants with clear guidance from the regulator on appropriate marketing practices. We will monitor the preparation of this legal act by the MOH and keep you updated in our newsletter.

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

## Tax

### Draft law on exempting import and supply of pharmaceuticals and medical devices from VAT

On 1 October 2018, Draft Law **No. 9146** "On Amending the Tax Code of Ukraine Regarding Decreasing the Cost of Pharmaceuticals for the Population" was registered in the parliament. This draft law sets forth that the following operations should be exempt from VAT:

- importation and supply of registered pharmaceuticals
- importation and supply of medical devices that were registered or have undergone conformity assessment procedures under applicable technical regulations

The above pharmaceuticals and medical devices should be exempt from VAT if they are on the list to be approved by the Cabinet of Ministers of Ukraine.

If adopted, this draft law will decrease the tax burden on companies selling pharmaceuticals and medical devices in Ukraine.

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

## Medical devices

### Draft law on introducing licensing for manufacture and sale of medical devices

On 6 October 2017, Draft Law **No. 7182** "On Amending the Law of Ukraine "On Licensing Types of Economic Activities" (**Draft Law**) was registered in the Ukraine Parliament.

The Draft Law provides for the introduction of licensing for the manufacturing and importation, as well as the wholesale and retail sale of medical devices in Ukraine. The authors of the Draft Law claim that the purpose of the Draft Law is to prevent the falsification of medical devices. However, they did not provide comprehensive justification for introducing yet another regulatory requirement for suppliers of medical devices, in addition to conformity assessment procedures.

For more information, please contact [Olha Demainiuk](#) of our Kyiv office.

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**FORWARD****WEBSITE****France****Medical Device Summary of Product Characteristics**

The law "Modernization of our health system" of 26 January 2016 strengthened the monitoring and traceability of medical devices by introducing an obligation for manufacturers and their authorized representatives to communicate to the ANSM, the French regulator, a summary of product characteristics (SPC) before putting into service medical devices on the French market (codified in article L. 5211-4-1 of the French Public Health Code, "FPHC").

Decree No. 2016-1716 of December 13, 2016, which came into force 1 July 2017, sets out the contents of the SPC and further specifies how it must be provided to the ANSM.

Pursuant to the Decree, these new obligations apply to medical devices of Class III and implantable medical devices with the exception of custom-made medical devices. The ANSM specifies that investigational devices and accessories to medical devices should also be excluded. The SPC must be sent to the ANSM electronically at the moment when the relevant products are put into service on the French market for the first time (i.e. made available to a final user). The Decree lists the elements which must be included in the SPC and specifies that any significant change (i.e. capable of impacting the device's security, vigilance, performance or claims) to an element must be immediately reported to the ANSM by the manufacturer, its authorized representative, or a distributor. While the Decree also refers to a distributor, the above article L. 5211-4-1 of the FPFC places this obligation solely on manufacturers and their authorized representatives. The ANSM also specifies that in practice the Decree should be understood as creating this obligation only for the manufacturers or their authorized representatives.

Failure to comply with this obligation not only prevents putting the product into service, but is also sanctioned by a fine of up to EUR 150,000 for individuals, and 30% of the turnover in the last financial year for the product or group of products within the limit of EUR 1 million, for companies.

This trend of heightened transparency is in line with the new EU Medical Devices Regulation, which will come into force in 2020. The new Regulation also provides for a summary of safety and clinical performance to be submitted by manufacturers as part of the conformity assessment of implantable devices and Class III medical devices (other than custom made or investigational devices). It is to be made available to the public via Eudamed (European database on medical devices).

For more information, please contact [Sara Koski](#) in our Paris office.

**Publication of interpretation guidelines on transparency law**

On 29 May 2017, the General Directorate of Health of the French Ministry of Health published a Note No. DGS/PP2/2017/180, which replaces the previous interpretative circular letter, No. 2013-224 of May 29, 2013.

The main changes in the Note stem from recent changes to the applicable transparency rules (in particular Law No. 2016-41 of January 26, 2016 and Decree No. 2016-1939 of December 28, 2016). However, a number of additional guidelines are also included to comment upon the new provisions.

In line with the statutory changes, the Note recalls that the subject matter of agreements must be disclosed by selecting one of the subject matters listed in an ordinance of March 22, 2017 and that the amount of the agreement is now among the information to be disclosed. Regarding the amount of the agreement, the Note specifies that the *amount corresponds to financial information contained in the agreement* and that the *amount to be disclosed is that contemplated upon execution of the agreement*. In summary, the amount therefore seems to correspond to the aggregate amount of all payments and advantages made pursuant to the agreement. The Note also provides that an intentional failure to disclose such an item of information regarding the amount can give rise to sanctions set out in Article L. 1453-1 of the French Public Health Code (including in particular criminal fines). While the disclosure obligation of the amount is clearly set out in the above referenced Law and Decree, this precision is of interest as the above specified that the amount of the agreement does not need to be disclosed. In this respect it is recalled that the ordinance in any case cannot alter the obligation resulting from the Law and Decree.

The Note also provides guidance regarding disclosure of remuneration and the concepts of direct and indirect beneficiaries. As a reminder, the above referenced Law of 26 January 2016 requires the disclosing companies to disclose direct and indirect beneficiaries of remuneration and advantages granted to the targeted beneficiaries. This specification could lead to disclosing several times the same amounts. In this respect, the Note specifies that the contracting parties (or the direct beneficiaries) are *required to provide to the [disclosing] company all information of which they are aware allowing to identify possible final beneficiaries of remuneration or of advantages*. The Note further adds that where several companies are required to make disclosures, they should determine which one will make the disclosure so as to avoid double disclosures of amounts granted to the final beneficiary. The above guidelines do not however, allow avoidance of multiple declarations of the same payment if all beneficiaries of the chain are targeted by the transparency obligations (i.e. each reception of funds gives rise to a separate declaration).

The Note also specifies that the term "remuneration" should be construed as referring to *amounts paid in exchange for work or service provided by one of the persons mentioned in article L. 1453-1 of the [French] Public Health Code* (i.e. the article setting forth the transparency obligations) to the targeted disclosing companies.

For more information, please contact [Sara Koski](#) in our Paris office.

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**FORWARD****WEBSITE****Germany****CJEU decision on VAT treatment of discounts granted to private health insurances**

In its decision of December 20, 2017 (C-462/16), the Court of Justice of the European Union (CJEU) ruled that the divergent treatment of discounts on medical products paid to private and statutory health insurances for VAT purposes violates EU law. The court held that discounts granted to private health insurance companies are - same as discounts to statutory health insurances - to be treated as reduction in remuneration for purposes of VAT.

**Background**

German pharmacies sell medical products to persons with [statutory health insurance](#) under a framework contract between the pharmacy and the statutory health insurance. Pharmacies are obliged to grant discounts to the statutory health insurance. Pharmaceutical companies have to reimburse pharmacies or - where wholesalers are involved - the wholesalers for the discounts in respect of prescription only medicinal products. For purposes of VAT, the discount is treated as a reduction in remuneration.

Persons with [private health insurance](#), however, receive medical products from the pharmacies under an individual contract with the pharmacies. The private health insurance does not purchase the medical products but merely reimburses the persons insured by it, upon request by them. In such case, the pharmaceutical company are obliged to reimburse the private health insurance. German tax authorities do not treat this reimbursement as reduction in remuneration for the purpose of VAT arguing that the private health insurance is not part of the supply chain from the pharmaceutical company to the final consumer.

**Dispute in the main proceedings**

The case relates only to discounts granted to private health insurance companies. The taxpayer is a pharmaceutical company which manufactures and supplies medicinal products and supplies those products, subject to VAT, to pharmacies via wholesalers. In the context of its annual VAT declaration the taxpayer deducted reimbursements paid by it from the taxable amount. The tax authority rejected this deduction. The taxpayer filed an appeal with the State Finance Court Rhineland-Palatinate which was successful. Upon appeal lodged by the tax authority the Federal Tax Court referred the following question to the CJEU: "whether a pharmaceutical company is entitled to a reduction of the taxable amount under Article 90 of the VAT Directive where it supplies medicinal products via wholesalers to pharmacies which sells those medicinal products to persons it insures?"

**Decision of the CJEU**

The CJEU followed the view of the General Advocate and ruled that a taxable person is not required to be directly contractually bound with the beneficiary of the discount in order to be able to consider the discount in the calculation of the taxable amount. According to the CJEU the discount granted to private health insurance companies results in a reduction of the taxable amount of the pharmaceutical company, provided that

- it supplies those medicinal products to pharmacies via wholesalers,
- the pharmacies sell those products, subject to tax, to persons with private health insurance,
- the private health insurance company reimburses the persons insured by it for the costs of purchasing the medicinal products, and
- the pharmaceutical company is required to pay a "discount" to the private health insurance company pursuant to a statutory provision.

According to the CJEU, for purposes of VAT the private health insurance companies are to be regarded as the final consumer of a supply made by the pharmaceutical company with the result that the amount payable to the tax authority may not exceed the amount paid by the final consumer. With this decision the CJEU confirms its principles for the determination of the taxable basis in respect to discounts laid down in its judgment of October 24, 1996, *Elida Gibbs*, C-317/94. In light of the principle of fiscal neutrality, the CJEU extends those principles to matters where payer and payee are not part of the same supply chain.

**Different approach of CJEU vs. German courts**

The judgment demonstrates once more that the CJEU is prepared to refine the law based on overall principles of law. In the case at hand, the CJEU first established the result that would appear fair and in line with the overall VAT neutrality, i.e. a pharmaceutical company should not need to remit VAT calculated from a (gross) amount that would be higher than what the company ultimately received. And in a second step the CJEU provides legal arguments mainly based on general VAT principles to support this result.

The German courts on the other hand, were more concerned with the wording of the law and the prior case law (CJEU e.g. in *Elida Gibbs*, *Ibera Tours et al.*), which would have rather suggested that the taxable base could be decreased only if the rebate would have been paid to a recipient in the same supply chain.

To the contrary, the CJEU even argues that the concept of German (social) law, under which privately insured patients have individual contracts with the pharmacies in Germany (and hence the German individuals and not their insurances are "recipients" of the supplies in Germany), should rather be regraded as a "legal fiction". The CJEU refers to the attorney General's opinion on this point who concluded that the private insurances could in fact be regarded as "VAT recipients" of the relevant supplies. This line of argument underlines the essential difference of the (rather flexible) interpretation of EU law by the CJEU in contrast to the German Federal Courts' (more formalistic) efforts to adhere to the wording of the law and the prior case law to determine the supply-recipient relationship and thus to help taxpayers to more reliably determine (or anticipate) the VAT treatment of their supplies.

**Outlook**

Pharmaceutical companies who, so far, have not declared discounts granted to private health insurance companies should review the status of assessments and, to the extent possible, consider correcting the respective declarations or appealing the assessment notices.

For more information, please contact [Jana Fischer](#) or [Jochen Meyer-Burow](#) of our Frankfurt office.

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**FORWARD****WEBSITE****Guest Feature****EMA plans to revive its landmark clinical trials transparency policy**

In the second half of 2019, the European Medicines Agency (EMA) plans to implement a 'reactivation plan', examining how and when it can revive its transparency policy on proactive publication of clinical trial data. This landmark policy was temporarily suspended on 1 August 2018 as a result of the implementation of the third phase of the EMA's **Brexit business continuity plan** to prepare for its relocation to the Netherlands. At this point in time, there are limited details on the proposed reactivation plan, with an EMA spokesperson having said "as of today, [the] EMA can only confirm that no dossier will be published in 2019 on the *Clinical Publication website*".

Under the transparency policy, introduced in October 2016, the EMA has **published clinical data** submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure. The EMA anticipated that by proactively publishing clinical data it would help:

- avoid duplication of clinical trials and encourage development of new medicines;
- build public trust and confidence in the EMA's scientific and decision-making processes; and
- academics and researchers to re-assess clinical data.

However, as a result of the policy suspension, companies with authorised products are no longer required to redact commercially-confidential information and personal data from their clinical study reports and submit these to the EMA for disclosure. The EMA will continue to publish clinical data submitted before 1 August 2018 but no new data will be processed and published until further notice.

During this suspension, the EMA plans to update its guidance on the transparency policy to provide the wider industry with practical advice on the procedural aspects of submission and anonymization of clinical reports and the identification and redaction of commercially confidential information. At the Drug Information Association's Global Clinical Trials Transparency conference in September 2018, the EMA confirmed that it was up to each drug company to decide whether they should continue preparing redacted packed to support the publication of clinical data in the future, and that they could use this suspension period to reflect on their approach to anonymization and on how to improve their anonymization reports. In addition, it summarised the key updates being made to the guidance, including:

- Clarification for clinical studies where the main period/phase is still ongoing at the time of publication;
- Update of timelines for end-to-end process; and
- New wording to reflect the review of the anonymization report, including the need to submit an updated anonymization report and/or written responses to the comments during the process.

For further information please contact Julia Gillert of our London office or Els Janssens of our Abu Dhabi office.

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**FORWARD****WEBSITE****France****Research tax credit: seconded researchers' expenses may be included in operating costs***(Council of State, January 25, 2017 n° 390652, Intuigo)*

The Council of State has recently ruled, in contrast to the trial judges, that personnel expenses eligible for research tax credit are not limited to expenses in connection with the beneficiary enterprise's salaried personnel, but may also cover the expenses of personnel seconded by a third party in order to carry out research operations in its premises, using its facilities.

In this case, the appellant company, in calculating its research tax credit, included the fees it paid to an individual company in exchange for a secondment agreement for a computer engineer approved by the Research Ministry. Although the tax authorities effectively considered these expenses as eligible for research tax credit, they considered that they did not fall strictly speaking into the category of personnel expenses (referred to in b of article 244 quater B of the French tax code) but into the category of outsourcing expenses, entrusted to private research organisms (referred to in d bis of the same article). By refusing to classify the litigious expenses as personnel expenses, the tax authorities did not allow the enterprise to take them into account for the calculation of operating costs (the amount of which includes 50% of personnel expenses) and therefore refused the refund of part of the research tax credit receivable that the company was claiming.

The Council of State overturned the decision by the Court of Appeal of Versailles (Court of Appeal of Versailles, April 2, 2015 n° 12VE03423) which sided with the tax authorities. It considered that the Versailles judges could not rule out the qualification as personnel expenses on the sole grounds that the engineer seconded to the company was not an employee of the company, without establishing whether he had been seconded to the company for the purpose of carrying out research operations, in the company's premises and using its facilities.

Following the conclusions of the Rapporteur Public, Romain Victor, the Council of State considered that personnel expenses, such as referred to in b, II of article 244 quater B of the French tax code, could not be considered to exclude non-salaried persons working for the beneficiary company. It agreed with the analysis made by the Rapporteur Public that the enumeration, in II of the above-mentioned article, of expenses eligible for research tax credit is made on the basis of a distinction between research operations carried out "in or outside the enterprise" and not between operations carried out by salaried or non-salaried employees. There is no objective reason to justify different treatment for expenses incurred for a salaried employee and expenses incurred for a non-salaried employee, when both participate, at the enterprise, in the same research project, using the same installations and with access to the same rights and services as all the employees.

It is interesting to see that the administration itself has taken a position which seems to go against the one it took in this case, since it stipulated in the doctrine applicable at the time of the facts, that expenses relating to research personnel for whom the enterprise is not the employer but who are seconded by another enterprise, may be considered as personnel expenses, on the condition that this personnel is directly and exclusive assigned to research operations and that the corresponding charges are invoiced by the employer for the exact amount that it effectively bears (BOI-BIC-RICI-10-10-10-30 n° 90, May 6, 2015). It is surprising that this doctrine was not invoked by the appellant before the judges. The reason for this may lie in a decision of the Administrative Court of Appeal of Paris dated January 16, 2016 (n°14PA04836, Filiassur). In this decision, which also concerned a request for a refund of the research tax credit receivable by an enterprise to which personnel had been seconded by a third party for the purpose of carrying out research operations, the trial judges ruled, (i) on the one hand, that "personnel expenses which may give rise to research tax credit include the remuneration and the obligatory related social contributions paid exclusively for salaried personnel of the enterprise concerned", and as such expenses could not, "on the basis of tax law, give rise to the research tax credit", and (ii) on the other hand, that the above mentioned doctrine could not be invoked by the taxpayer since the rejection of a claim for reimbursement could not be considered as a recovery or reassessment procedure and did not constitute a reassessment.

As far as the Intuigo decision is concerned, the Supreme Court invalidated the position of the trial judges and adopted the analysis proposed by its Rapporteur Public, based on the reality of the operations carried out at the enterprise and not on whether or not the researcher was a salaried member of staff. It had already adopted this viewpoint when judging, in a decision dated May 25, 2007, that personnel expenses linked to a managing director, who was not legally an employee of the company, were eligible for research tax credit on condition that the latter effectively took part in research operations.

The case has been referred to the Administrative Court of Appeal of Versailles: the judges will have to examine whether the litigious expenses qualify as personnel costs or not, based on whether the research operations are located and carried out in the premises of the enterprise, with its installations and resources, irrespective of the qualification of the agreement which links the enterprise and the researcher concerned (employment contract or secondment).

For more information, please contact [Hervé Quéré](#) or [Iris Bouffartigue](#) in our Paris office.

**Research tax credit: a patent application may justify eligibility for research tax credit for a prior period***(Court of Appeal of Marseille, December 29, 2016 n° 14MA04933)*

The Administrative Court of Appeal of Marseille handed down an unprecedented decision on the research tax credit eligibility conditions for an enterprise. It effectively ruled that the filing of a patent application could justify a posteriori taking into account expenses for research carried out previously for research tax credit purposes.

In the case in question, the appellant company, which manufactures and sells industrial chemicals, was refused the benefit of research tax credit for expenses incurred in 2007 and in 2008 in connection with a research program into new industrial processes for gas and liquid drying, with the implementation of a pilot unit. The tax authorities based their refusal on the content of a report by an expert appointed by the Research Ministry department, which concluded that the expenses in question related to the development of existing techniques without any innovative research being carried out.

However, during the same year, in 2007, the company was considered eligible for the status of young innovative enterprise as a result of its research work, following an opinion issued by an expert appointed by the tax authorities. This opinion relied on an expert's report, which was corroborated by a considerable amount of scientific documentation attesting to the innovative nature of the research work in question. In addition, in 2010 the company filed a patent application with the French industrial property office, INPI, for an industrial process, for which the patent was granted in 2013.

In view of this context, the Marseille judges did not stop at the report issued by the Research Ministry, but took into account all the elements related to the activity of the enterprise and to its research work, including elements prior to the claim. They therefore considered that, even if the patent had been issued during the year following the period for which the research tax credit was refused, the patent represented a continuation of the research

work carried out by the company since 2007 through a pilot installation, in the context of its activity in the chemicals sector and therefore attested to the innovative nature of the research. As such, the research work carried out upstream by the appellant company should be regarded as contributing, through its novelty factor, to the substantial improvement of the existing materials, mechanisms, products, processes or systems and was therefore eligible for research tax credit.

The court opted for a pragmatic analysis, favorable to the company, but which is justified in this case by the numerous documents attesting to the innovative nature of the work carried out by the enterprise. Although the filing of a patent application seems to have played an important part in the judges' decision, we recall nonetheless that the tax authorities refuse to consider that the mere patentable nature of an invention makes the corresponding expenses eligible for research tax credit. Nevertheless, the administration agrees that this may be an indicator of the existence of research and development work. The Council of State has also ruled that filing for a patent is insufficient in itself to render research expenses eligible for research tax credits (Council of State 13-11-2013 n° 341432).

For more information, please contact **Hervé Quéré** or **Iris Bouffartigue** in our Paris office.

#### **The modified French Sunshine Act disclosure regime is applicable**

French health sector laws have set out transparency provisions introduced by the so-called French Sunshine Act, article 2 of the law No. 2011-2012 of December 29, 2011 (the "FSA"). The Law of Modernization of our Healthcare System, dated January 26, 2016 strengthen the obligations set forth by the FSA. The entry into force of these provisions was pending the adoption of an implementing decree, which was adopted on December 28, 2016. However, the entry into force of the implementing decree was in turn pending adoption of a ministerial order. This order was adopted on March 22, 2017, bringing such provisions of the FSA into force (the "Order").

Pursuant to the FSA, as amended all companies manufacturing or selling healthcare products falling within the jurisdiction of the ANSM (the French National Agency for Health Care Products' Safety) or providing services relating to such products ("**Companies**") are required to disclose information relating to (i) the existence of agreements entered into with, (ii) the remunerations paid to and (iii) in-kind or in-cash benefits granted directly or indirectly to certain healthcare professionals and health sector actors.

#### **Information to be disclosed under the new regime**

The Order (i) requires disclosure of certain information that is not required under the implementing decree (indicated in capital letters), and (ii) specifies that certain information that was required to be disclosed pursuant to the 2016 Decree is not mandatory (indicated below with an asterisk (\*)).

##### 1) Information on agreements

- Information regarding identity of the parties;
- Execution date, EFFECTIVE DATE, and termination date\* of the agreement when it is known on the execution date;
- Precise subject matter of the agreement. The Order provides for a non-exhaustive list of subject matters to be indicated:
  1. purchase of scientific documentation
  2. purchase / rental of stands at scientific events;
  3. purchase / rental of advertising space;
  4. hospitality;
  5. donation / sponsorship (*mécénat*);
  6. prize awards;
  7. study grants;
  8. partnership;
  9. sponsorship (*parrainage*);
  10. scientific research;
  11. investigation / study / market study (excluding research);
  12. scientific expert agreement, research agreement, consultancy agreement.
  13. advice / expertise other than scientific;
  14. provision of other services;
  15. training;
  16. equipment loan;
  17. assignment of rights / operating license;
  18. edition;
  19. speaker agreement at an event;
  20. interview agreement;
  21. congress registration;
  22. assessment product cosmetic;
  23. cosmetic product vigilance;
  24. other: details required.
- For promotional and scientific events in addition to the above : the organizer\*, the date\*, the name\* and the venue of the event\*;
- Amount of the agreement\*. Pursuant to the implementing decree, in order to ascertain traceability of the benefits and remuneration, the contracting parties must provide the declaring entity with all information known to them to identify possible indirect and final beneficiaries. Disclosure of indirect and final beneficiaries is required by the 2016 Law, but no specific modalities have been set out for their disclosure on the single public website for the moment.

##### 2) Information on benefits

- Information regarding identity of the parties;
- Amount of the benefit including VAT rounded to the nearest euro (if equal or beyond EUR 10);
- Date and type of the benefits received by each beneficiary;
- Half year during which the benefits are granted\*.

##### 3) Information on remuneration

- Information regarding identity of the parties;
- Amount of the remuneration rounded to the nearest euro (if equal or beyond EUR 10),
- Half year during which the remuneration is granted\*.

#### **Disclosure schedule**

Moreover, the disclosure schedule has been harmonized (all information must be disclosed twice a year pursuant to a same calendar contrary to before, where agreements were disclosed 15 days after their execution date) and the disclosure dates have also been slightly amended. Information will now have to be disclosed :

- by 1 September for the agreements entered into force, remunerations paid and other benefits granted during the first half year; and
- by 1 March of the following year for agreements entered into force, remuneration paid and other

benefits granted during the second half year.

These new disclosure requirements are applicable since the adoption of the order and will be reflected as of the next step of the disclosure schedule, on September 1, 2017.

#### Focus on disclosure of remuneration preceding the entry into force of the new disclosure regime

While the new regime now is applicable to disclosure of remuneration for coming disclosure periods, many had hoped that the implementing decree and the Order clarify the situation regarding preceding disclosure periods. No clarification however has been provided.

The questions stems from a circular letter of French Ministry for Health of May 29, 2013 that specified remunerations were excluded from the scope of the FSA and did not have to be disclosed. However, a decision of the French supreme administrative court (*Conseil d'Etat*) dated February 24, 2015 ("**Decision**") repealed this interpretation of the Circular and specified that remuneration should be disclosed as it represents a benefit in cash.

This means that the disclosure obligation of remuneration as benefits should be seen to exist from 2012. From a pragmatic standpoint, it would seem possible to disclose it under the new category of "remuneration" and not under the previous category as a "benefit". This position has been also been expressed by the French DGS.

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**FORWARD****WEBSITE****UK****Don't Go Faking My Heart - English High Court Highlights Healthtech IP Risks**

## Summary

A recent decision from the UK (*Technomed Ltd vs. Bluecrest Health Screening Ltd [2017] EWHC 2142*) has emphasised the importance of considering IP ownership in the creation and provision of healthtech services. The court concluded that a combination of database rights and copyrights subsisted in the cloud-based ECG screening technology that was offered by specialist healthtech company Technomed; and that these were infringed when they were passed on by screening provider Bluecrest to its new supplier. The case serves as an important reminder that both suppliers and consumers of tech-based healthcare services need to carefully consider the ownership, use and transfer of IP rights that exist within their commercial relationships.

*The Case*

The parties entered into an agreement in late 2012 whereby Technomed agreed to provide Bluecrest with a cloud-based ECG analysis and reporting system. The system enabled ECG readings to be analysed remotely by a cardiologist, who would then generate a report (with the assistance of Technomed's technology) to be distributed to a GP or to the patient directly. Unfortunately, the relationship soured around a year later and Bluecrest sought to obtain similar services from a competitor. An alternative provider was identified and Bluecrest made the switch, requesting that the new provider mirror key elements of Technomed's software, processes and reports. Technomed claimed infringement of a number of its intellectual property rights, in particular copyright in aspects of its software, databases and end report, and also standalone database rights.

*The Lessons*

Ultimately, the court found in favour of Technomed on virtually all fronts. Whilst the judgment is significant from an IP law perspective (the court ruled that both PDF and XML formats could be protected in ways not previously recognised) it also highlights key considerations for those in the healthcare sector working with emerging technologies. When partnering, parties should carefully consider what IP they own at the outset, what (if any) new IP will be developed as part of the commercial relationship, and most importantly how ownership should be treated in the event of contractual termination. Companies using and creating innovative technological solutions need to be completely clear what elements of the technology or service can and should be protected, and how this is to be achieved.

So what sort of things can help protect against IP heartache?

- Know your rights - whether you're a supplier or a consumer of healthtech services, having knowledge of the IP rights that subsist around the services is key to obtaining adequate protection and usage rights.
- Sensible contracting - when drafting agreements ensure you consider IP ownership and usage, and clearly lay out who owns what, for how long, and how each party may use the IP.
- Licensing - if it makes more sense for one party to retain ownership of certain IP, but for another to make use of it, negotiate an appropriate licence.

Forward planning - whether the technology is proprietary or bespoke, both parties need to be crystal clear on what happens to ownership of the IP in the event that the relationship ends, and to what extent the recipient can continue to use any outputs. Consider transition periods when moving to a new supplier.

For further information, please contact [Hiroshi Sheraton](#), [Tanvi Shah](#) or [Josh Boyden](#) of our London office.

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**FORWARD****WEBSITE****UAE****Mecomed members agree to stop sponsoring individual healthcare professionals to attend third party conferences as of January 1, 2018**

In June 2017 the Board of Mecomed, the Middle Eastern industry association for medical technology manufacturers approved a new Code of Ethical Business Practice. The Code took centre stage at the October meeting of the association ahead of its coming into effect on January 1, 2018. The new code will not only require regional compliance and business leaders to implement changes to their local compliance policies and business practices. They will also need to ensure that employees and distributors are adequately trained on the new requirements and that healthcare professionals are properly informed. Given the magnitude of the changes implementation will need to be closely monitored.

The Code regulates interactions between industry and healthcare professionals and organisations. It is closely aligned with the European Medtech Code of Conduct and it adopts international best practice standards in the MENA region. The Code can be found here: <http://www.mecomed.com/wp-content/pdf/code.pdf>

The most important change is that Mecomed members as of January 2018 will no longer be allowed to pay a healthcare professional directly for expenses related to travel, accommodation and registration fee for third party organized educational events. Instead members can offer educational grants to healthcare organisations for attendance third party educational events approved by the association's conference vetting system. Educational grants must be publicly disclosed on an annual basis as of January 1, 2019. As in the European Medtech Code of Conduct, third party educational events (e.g. conferences, seminars) are distinguished from third party organized procedure training. These are courses organized by third parties which typically take place in a clinical environment and are aimed at developing medical skills relevant to medical procedures (rather than related to a specific product) including practical demonstrations. Member companies can still financially support individual healthcare professionals for such courses provided the courses are approved through the conference vetting system and are not connected to a third party educational event. The prohibition of direct sponsorship does also not prevent a member company from inviting healthcare professionals to a company organized event provided that all criteria for events and hospitality are met. With the association looking at third party organized educational events and trainings, company organized events are likely to be taking up more time of internal compliance going forward.

Another notable change is that the new Mecomed Code no longer provides for an exception that allowed member companies to facilitate (but not pay) travel logistics for a spouse or male family member. Such exception was foreseen in the past recognizing that women healthcare professionals may be required to be accompanied by their spouse or a male family member but has now been abandoned bringing the device industry in line with the MEA pharma industry and their code of promotional practices.

The Mecomed Code provides for an internal escalation mechanism in case of violation of the Code by Member Companies or third party intermediaries (e.g. local distributor).

The prohibition of direct sponsorship and the obligation of annual disclosure of educational grants places the devices industry in the Middle East ahead of the pharma industry in terms of transparency. It is an area that needs to be followed. The Saudi regulator SFDA published last year a draft for consultation in relation to payment disclosure obligations for the pharma industry. Until today the document remains in draft form. The UAE MOH is also reported to be working on a code for promotional practices and expressed itself favorably about the moves recently taken by Mecomed.

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**FORWARD****WEBSITE****Russia****New rules for determining a locally originating product**

The criteria of country of origin for the purposes of application of preferences within the Russian public procurement of medicines will change starting from the beginning of 2019. Currently, locally manufactured product may qualify as originating from Russia only under the customs rules of sufficient processing. However, starting from January 1, 2019 such product may qualify as originating from Russia under the separate set of local manufacturing rules established by Government Decree No. 719. This change is brought about by **Government Decree No. 572** dated May 12, 2018, which amends Government Decree No. 1289 dated November 30, 2015.

The new rules provide that the Ministry of Industry and Trade will issue conclusions confirming that industry products (including medicines) are manufactured on the territory of the Russian Federation in one of the following three cases:

- there is a special investment contract concluded with the Russian Federation (some other additional parties are also allowed), under which a company undertook to create and/or modernize and/or organize manufacturing of its products in Russia so that in three years they will meet the requirements of either of two criteria below;
- products meet substantive criteria set in Government Decree No. 719;
- products meet criteria set in the customs rules of sufficient processing.

Substantive criteria set in Government Decree No. 719 require a medicine to pass through the technological process of formulation (manufacturing of final medicinal form), packaging and quality control release in Russia to qualify as locally manufactured.

Government Decree No. 719 also sets criteria for pharmaceutical substances, but meeting those is not necessary to have a medicine qualify as locally manufactured. A pharmaceutical substance needs to pass through the technological process of chemical synthesis and/or biotechnology synthesis and/or obtaining from natural mineral raw materials and/or obtaining from biological and/or animal sources and/or obtaining from plant sources.

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

**Introduction of a new system of public procurement preferences**

The system of public procurement preferences for pharmaceuticals in Russia relies on two types of documents (i) decrees of the government that set "limitations of access" to procurement, i.e., cases when certain goods may not even take part in the public procurement tenders (e.g., the "third one out rule"), and (ii) orders of the Ministry of Economic Development that set "conditions of access" to procurement, i.e., cases when financial handicaps apply to foreign goods in the public procurement tenders (e.g., "15% preference").

Government Decree No. 1289 dated 30 November 2015, which established the "third one out rule", as amended by **Government Decree No. 572** dated 12 May, 2018, is the first document that establishes the new system of public procurement preferences using the new criteria of country of origin discussed above and introduces an additional "super-preference" to those medicines that are manufactured in Russia from the active substances manufactured in Russia that are discussed below. The new system of public procurement preferences is not established yet due to the lack of an updated order from the Ministry of Economic Development.

However, the new system of public procurement preferences is likely to rely on the following mechanisms. First of all, all foreign medicinal preparations competing with local medicinal preparations will still face the 15% price handicap ("15% preference"). Secondly, in case there are two or more local products competing at a tender, the foreign product will not be allowed to bid ("third one out rule"). These are already known mechanisms that will be supplemented with a so-called "super-preference". It will apply only if the "third one out rule" has been triggered and at least one of the local medicines remaining at a tender is fully locally manufactured, including its substance. In this case, the other local medicines that do not contain a locally manufactured substance will be subject to a price handicap. The amount of this handicap is not defined yet due to lack of an updated order from the Ministry of Economic Development, but it is rumoured that it will be around 15% as well.

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

**Recent amendments to the procedure for determining the initial (maximum) price of a contract**

**Decree №386n** of the Ministry of Healthcare of the Russian Federation dated 26 June 2018, which is also known as "On amending the procedure for determining the initial (maximum) price of a contract, the price of a contract entered into with a single supplier (contractor) when carrying out procurement of medicines" (**MOH Decree**), entered into force on 5 August 2018.

The document adjusts the procedure for determining the initial (maximum) price of a contract and the price of a contract entered into with a single supplier (contractor) when procuring medicines. In particular, the **MOH Decree** provides for peculiarities of use of the wholesale mark-up when calculating the initial (maximum) price of a contract. The use of the reference price (i.e., the price that is calculated automatically in the Unified State Health Information System) when determining the initial (maximum) price of a contract is postponed until 1 January 2019.

Until 1 July 2019, when calculating the unit price of the medicine, one had to take into account the data of the existing contracts excluding VAT, whilst after the indicated date — only the data of the executed contracts, excluding VAT and the wholesale mark-up, has to be considered. What should be understood about the unit price of the medicine that will be purchased is also specified.

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

**Obligation to submit information to the Ministry of Healthcare becomes effective soon**

Under the **Federal Law** No. 425 dated 28 December 2017, "On Amendments to the Federal Law "On the Circulation of Medicines"" (**Federal Law**), holders or owners of the registration certificates of the medicinal preparations, manufacturers of the medicinal preparations, as well as manufacturers of the pharmaceutical substances that are entered into the State Registry of Medicines — if such medicinal preparations and pharmaceutical substances were registered before 1 January 2018 — shall send the following information to the Ministry of Healthcare of the Russian Federation before 1 January 2019:

- For Russian entities: Taxpayer Identification Number (INN)
- For foreign legal entities: a country of incorporation, name of the registration authority, registration number, taxpayer's code in the country of registration (incorporation) or its analogue

The Federal Law is silent on the mode of submission of this information. However, since this information is now a part of newly submitted applications for registration of products in Russia and will end up in the State Registry of Medicines, the most reliable way of delivering this type of submission is through filing a variation of the registration dossier of the relevant product.

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**FORWARD**

**WEBSITE**

**Hungary**

**The National Institute of Pharmacy and Nutrition (OGYÉI) published Guidelines on cosmetic product claims.**

Article 20 of Regulation No 1223/2009 of the European Parliament and of the Council on cosmetic products contains the provisions regarding cosmetic product claims. Under Article 20 (1), in the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.

The Commission Regulation No 655/2013 laid down harmonized common criteria in order to comply with uniform and harmonized principles at the level of the Union to ensure a high level of protection of consumers. With the help of the criteria laid down in the Commission Regulation it can be assessed whether or not a certain claim can be used.

The six common criteria contained in the Commission Regulation is the following: legal compliance, truthfulness, evidential support, honesty, fairness and informed decision-making. Regarding the common criteria, the OGYÉI published Hungarian-language Guidelines on its website which can be reached directly through the following link: [http://www.ogyei.gov.hu/dynamic/Kozmetikai\\_utmutato.pdf](http://www.ogyei.gov.hu/dynamic/Kozmetikai_utmutato.pdf).

We highlight some of the significant points of the Guidelines below without aiming to give an exhaustive list:

1. **Legal compliance:** The acceptability of a claim shall be based on the perception of the average end user of a cosmetic product, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors in the market in question. Conditional sentences are often used regarding the effect of the product (e.g. "may help to reduce wrinkles") but it also qualifies as a claim and requires verification as if the claim was not formulated in a conditional sentence. Claims which imply that a product has a specific benefit shall not be allowed if the benefit of the product derives merely from compliance with minimum legal requirements. E.g. the claim, "the skin care product does not contain hydroquinone", shall not be allowed because in case of this type of product, the use of hydroquinone is forbidden under the provisions of European Union law regarding cosmetics.
2. **Truthfulness:** If it is claimed that the product contains a specific ingredient, the ingredient shall indeed be present in the product. For instance, products which claim directly or indirectly that they contain honey, in order to be credible, they shall really contain honey not just a honey flavored matter or aroma. Ingredient claims referring to the properties of a specific ingredient shall not imply that the finished product has the same properties when it does not. That is why the claim, "the product contains hydrating aloe vera", shall not be allowed if the product which contains only aloe vera as a hydrating matter does not have a demonstrated hydrating effect.
3. **Evidential support:** Claims for cosmetic products, whether explicit or implicit, shall be supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them, including where appropriate expert assessments. The nature of the demonstration depends on the claim itself. If a claim is related to a chemical/physical quality (e.g. "skin neutral"), the given claim shall be certified through a chemical/physical test, instrument measures. A demonstration of an effect (e.g. "not irritates", "not sensitizing") must be certified with human tests and information should be provided about the test and the method of the certification of the effect. Statements of clear exaggeration which are not to be taken literally by the average end user shall not require substantiation. The claim, "this perfume gives wings" shall be treated as such.
4. **Honesty:** Presentations of a product's performance shall not go beyond the available supporting evidence. E.g. the electronically manipulated "before"/"after" pictures are misleading. Claims shall not attribute to the product concerned specific (i.e. unique) characteristics if similar products possess the same characteristics so the following claim shall not be allowed: "It is the specific characteristic of the shampoo that it brings comfort to scalp and reduces itching right after the first use."
5. **Fairness:** Claims for cosmetic products shall be objective and shall not denigrate the competitors, nor shall they denigrate ingredients legally used. The claim, "contrary to product X, this product does not contain limonene which is a well-known allergenic matter" shall not be allowed. Claims for cosmetic products shall not create confusion with the product of a competitor. So e.g. the claim, "Use this product because you deserve it too!" shall not be applied unless it is related to a product of L'Oréal.
6. **Informed decision-making:** Claims shall be clear and understandable to the average end user and they should be clearly and explicitly worded. Claims are an integral part of products and shall contain information allowing the average end user to make an informed choice. From the point of use, useful information shall not be kept back (e.g. in case of a face cream the vicinity of eyes should be avoided, in case of shampoos get in touch with eyes should be avoided). Risk phrases which are mandatory to use regarding a given product, shall be marked e.g. "Keep out of reach of children", "Should not get in touch with eyes".

For more information, please contact **Helga Biró** of our Budapest office.

**The Competition Office imposed a fine on Sandoz due to unlawful promotion of medicinal products**

In its decision dated November 3, 2017, the Competition Office stated that Sandoz Hungary Kft. (Sandoz) infringed the laws on advertising when it advertised its OTC product, called ACC by using statements beyond the summary of product characteristics (SPC). The advertisements promised rapid effect regarding the whole mode of action of the product, while the SPC referred to rapidness solely relative to the adsorption of the product. The Competition Office imposed a fine of HUF 105 million on the company.

The Competition Office assessed - among others - the following statements:

- *Rapid solution for catarrh coughing!;*
- *Quickly cleans the respiratory tracks!;*
- *ACC, it effects rapidly.*

The above statements were published in press and TV advertisements, posters displayed in pharmacies and medical waiting rooms as well as in pharmacy journals.

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**FORWARD****WEBSITE****South Africa****New SA medicines regulator expected to address past ailments**

On June 1, 2017, the South African Health Products Regulatory Authority (SAHPRA) was officially established as the new regulatory body for medicines, scheduled substances, complimentary medicines, clinical trials and medical devices in South Africa.

Due to enduring backlogs and delays in issuing marketing authorisations, SAHPRA's predecessor, the Medicines Control Council (MCC), has long been criticised by industry stakeholders for being a major obstacle to the introduction of much needed new pharmaceutical products into the South African market - in the past 50 years, the MCC assessed and registered only 13,000 new medicines.

According to the Innovative Pharmaceutical Association of South Africa (IPSA), a local industry body representing multinational drug firms holding the patents on brand-name products, it currently takes around 3-5 years for a new chemical entity to be approved by the MCC. Even medicines prioritised by the MCC, such as those for the treatment of HIV and tuberculosis, can take up to 2 years to get the green light.

It thus comes as no surprise that SAHPRA has been anxiously awaited, as it is anticipated to be more efficient than the MCC at processing registration applications for medicines and clinical trials. SAHPRA's wider mandate, which for the first time will bring oversight to the medical device sector, is also expected to result in improved consumer protection.

In addition, SAHPRA will oversee the registration and regulation of complementary medicines, foodstuffs and cosmetic or in vitro diagnostic medical devices (IVDs) and, importantly from the perspective of innovators active in South Africa, will allow for fast-tracking of generic medicines brought to market.

**SAHPRA's composition**

SAHPRA is a statutory regulatory body created on June 1, 2017 under the Medicines and Related Substances Amendment Act, 72 of 2008 and the Medicines and Related Substances Act, 14 of 2015 (Amendment Act). It will make decisions and act through its board.

The board, appointed by Health Minister Aaron Motsoaledi in mid October 2017, consists of 15 members and is chaired by Professor Helen Rees, a respected scientist and current head of the MCC. The SAHPRA board will combine expertise in the fields of medicine, medical devices, clinical trials, good manufacturing practice and public health, as well as law and good corporate governance. To assist it in performing its functions, the board may appoint committees from among its members.

Proper staff resourcing, including through the hiring by SAHPRA of full time reviewers, are commonly seen as a key determinant of the body's future success.

**Powers and functions**

SAHPRA's objectives as stipulated by the Amendment Act, are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices; and related matters in the public interest.

To achieve these goals, it has the typical suite of regulatory powers, including to:

- determine which medicines, medical devices or IVDs will be subject to registration;
- grant, impose conditions on, or reject applications for the issue of registration certificates (marketing authorisations);
- publish separate registers listing marketing authorisations for medicines, medical devices and IVDs on its website;
- under specific circumstances, authorise the sale of a specified quantity of any particular product, medical device or IVD, which is not yet registered; and
- approve labelling and authorise any deviation from the container and packaging requirements specified in the Amendment Act.

SAHPRA further has a broad discretionary power to disclose information to the public regarding prohibited sales, prescribing, dispensing, administration and use of medicines and scheduled substances, if it deems disclosure of such information to be expedient and in the public interest.

**Registration and Licencing - Transitional Period and Going Forward***General Requirement for Product Registration (Marketing Authorisation)*

No medicine, medical device or IVD may be sold in SA without it being registered and SAHPRA having issued a registration certificate in respect of that product.

*Who to register with?*

The MCC will continue to perform its functions as at June 1, 2017, until the day before the first meeting of the SAHPRA board (SAHPRA Commencement). The date for the first meeting must still be determined through public announcement by the SA Minister of Health, who has not yet provided an indication of when this would be.

*Medicines Registration*

Medicines already registered with the MCC as at June 1, 2017, will be regarded as having been registered by SAHPRA and be entered into the relevant SAHPRA register. Registration of any medicine which was pending on June 1, 2017 will continue to be dealt with by the MCC in the interim, and by SAHPRA from SAHPRA Commencement.

Should a medicine's registration expire after June 1, 2017 and prior to SAHPRA Commencement, application for the re-registration of the medicine must still be addressed to the MCC. Post SAHPRA Commencement, all applications for registration and re-registration must be addressed to SAHPRA.

*Medical Device Registration*

SAHPRA indicated that the registration for the first time of medical devices and IVDs, will commence in 2018. In the meantime, trading in medical devices and IVDs which are currently, or as at December 9, 2017 will be, available in the South African market, are permitted to continue on an un-registered basis until the particular medical device is called up for registration. Registration will then be required within 6 months after the date of publication by the MCC or SAHPRA (as applicable) of a declaration that registration of the relevant medical device or IVD is peremptory.

*Licence to manufacture, distribute or wholesale medical devices*

An application for a license to act as a manufacturer or distributor of medical devices was required to be

submitted to the MCC during the period February 24, 2017 to August 24, 2017. Applications for a license to act as a wholesaler of medical devices, must be submitted with the MCC (or SAHPRA if operative) by February 24, 2018.

Failure to have applied for a manufacturer's or distributor's licence by August 24, 2017, or to apply by February 24, 2018 in the case of a wholesaler's licence, will constitute a contravention of the provisions of the Amendment Act.

#### Registration re-evaluation and revocation

In addition to its powers mentioned above, SAHPRA is further entitled (and mandated) to periodically re-evaluate or re-assess and monitor, medicines, medical devices and IVDs.

Included in this authority, is the right for SAHPRA to revoke a product registration. It is currently unclear from the legislation when SAHPRA will be entitled to exercise its revocation powers, but it seems that it will be in instances where the initial requirements which were satisfied when the marketing authorisation was first granted, are no longer present.

#### Keys to SAHPRA's success in fulfilling its mandate

The long awaited creation of the new regulator has mostly been met with cautious optimism and been welcomed as a positive step in the right direction. Sceptics amongst pharma manufacturers are however not expecting a short-term fix from SAHPRA.

Refinancing of the regulator and adequate capacity building, including through employment by SAHPRA of full time reviewers, are generally viewed as the key ingredients for SAHPRA's future success. This is expected to be a medium to long-term project.

Time will tell whether it will succeed in the long run in its key objectives of streamlining the local regulatory environment and improved end-user protection.

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**The Netherlands**

**A shift in discussion on pricing and reimbursement of medicines in the Netherlands**

Debate between the Dutch government, on the one hand, and representatives and stakeholders of the pharmaceutical industry, on the other, indicates that there is a shift in the discussion on Dutch medicine pricing. The main areas of focus of these conversations are set out in this update.

**Legal framework**

In general, the main prerequisite for medicines to become part of the national basic health insurance scheme is based on their proven positive effect. However, with regards to more expensive medication, the Dutch Minister of Health, Welfare and Sport (the "Minister") provided for a more stringent policy in 2015 by introducing an additional approval process with the aim of negotiating a reduction in the price of costly medication on a case-by-case basis. A proposal to amend the Dutch legislation and provide for a general approach to negotiations on medication is pending.

The Minister also sets maximum prices for specific medicines, all listed in the Maximum Prices for Medicines Regulation (*Regeling maximumprijzen geneesmiddelen*). The prices set in Belgium, Germany, the UK and France are currently used as a benchmark. The Medicine Prices Act (*Wet geneesmiddelenprijzen*) does not allow pharmacies to purchase medicines exceeding these prices. Health insurers contribute to managing the pricing system usually by way of only compensating the cheapest alternative to the medicine involved, which is known as the 'preference policy' (*preferentiebeleid*).

The pharmaceutical industry is sceptical about the changes in pricing policy suggested by the Dutch government. Several studies have demonstrated that the average research and development costs of a single medicine range from hundreds of millions of euros to amounts exceeding EUR 1 billion. Also, most medicines will not end up on the market because they have little effect or there is insufficient proof of their effectiveness. Industry parties have voiced their opinion that the negotiations on pricing are unfair and one-sided, as developing new medicines involves huge risks for the pharmaceutical company.

**Main topics**

Apart from the negotiations on the pricing and reimbursement of medicines, stakeholders across the industry and representatives of the Dutch government have suggested several other changes which could lead to a better pricing system. Said changes have become part of the larger pricing discussion.

*Efficient use of medicines*

The current system focuses primarily on large groups of patients. Various industry parties have suggested targeting the specific needs of an individual patient instead of an entire group of patients. This would lead to a system in which medicines are only provided to patients with a specific need for such medicine. A more expensive medicine is only prescribed if a cheaper available alternative is insufficient. Consequently, expensive medicines will only be prescribed when the doctor or pharmacist can explain that doing so fulfils specific needs, which cannot be fulfilled with a cheaper alternative. In line with this argument, industry parties plead for a central registration system that keeps track of patients and their use of medicines. With such a system, a better indication can be given regarding a patient's need for a particular medicine. Issues of data privacy have been addressed in investigating the implementation of such a system in light of the European General Data Protection Regulation (the "GDPR"). To this end, the data should either be anonymized or fall within one of the grounds of article 6 of the GDPR (e.g., the patient giving his/her consent or a legal obligation for processing the data). This means that either a specific legal basis would have to be created or significant investments must be made to allow for fully anonymized processing of patient and treatment data.

*Change in patent system*

While the legal framework for obtaining and extending patents can only be changed top-down by the European Commission, some plead for a local change in the legislation of patent rights to provide for shorter exclusive rights periods. This could limit the risk of pharmaceutical companies with long-term monopoly abusing their right to extend their exclusive right to manufacture and market specific medicines. The Dutch government could, for example, set transparency rules with regard to the costs of research and development. To this end, pharmaceutical companies would then be under the obligation to publish the grounds for extending their patents. In view of Europe's efforts to move to a more uniform patent law system, it is uncertain whether such national deviations will get widespread support in Dutch parliament.

*Avoid time-consuming development process*

One of the complaints of the pharmaceutical industry is that the length of the development process generates extraordinary costs. Eliminating steps in the process would lead to a faster and less expensive process that could drive down the price of the marketed medicine. One of the suggestions made is to extend Phase II in clinical studies, while eliminating or minimizing the length of Phase III to lead to a faster introduction of medicines.

*Value-based pricing*

Finally, some believe that altering the current system for payment could benefit the pricing and reimbursement of medicines. Instead of paying for the potential effect of a medicine, one would pay for medicines based on the actual effect, i.e., value-based pricing. Again, this would require an adequate registration system of patients and their use of medicines, in line with the existing data privacy laws.

**Going forward**

Despite the absence of concrete measures at this stage, the current discussions have led to politicians advocating changes with regard to matters including transparency, a system for cooperative purchase of medicines between hospitals and health insurers and, finally, cooperation with other countries with regard to the pricing of medicines. These initiatives will be introduced in the coming weeks and should be regarded as a first step in the potential change of the Dutch legislative process. Several discussions will follow before the House of Representatives, and the Dutch Senate will eventually vote for any proposals of this type to come into effect.

This October, the Dutch coalition agreement has been announced including statements on the pricing and reimbursement of medicines and medical devices. The coalition parties intend to effect savings to the amount of EUR 467 million by decreasing expenses on medicines and medical devices. The pricing policy, as introduced by the Minister, will therefore remain in force. Additionally, coalition parties hope to save EUR 1.9 billion by entering into arrangements with respect to rearranged maximum expenses of hospitals.

The discussion on the pricing of medicines was due on 22 November 2017 with a general meeting of the members of the House of Representatives at which the above topics were to be discussed. If you have any questions, please feel free to reach out to us.

For more information, please contact [Martine van de Laar](#) of our Amsterdam office.

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**Poland****The Polish government returns to the idea of reimbursement-related incentives for pharmaceutical investors**

In 2016 the Minister of Health together with the Minister of Entrepreneurship and Technology, proposed to introduce a mechanism aimed at making selected aspects of the reimbursement application process and the conditions for inclusion into the public financing system dependent on the applicant's investment activity in the territory of Poland.

The proposed factors taken into consideration included the development of research and development facilities, creation of demand for specialised innovation-related services, and the expansion of the production base, with particular emphasis on the production of biotechnological therapies. The above-described program has been called the "reimbursement development scheme" (**RDS Programme**).

Companies included in the programme would be awarded the title of "Partner of the Polish Economy" and would be granted with an access to specific benefits or preferential treatment measures in the reimbursement proceedings.

After a period of time when legislative work on the project seemed to have been suspended, the publication of the strategic document titled "Drug Policy of the State 2018-2022" revealed that the discussed idea is still in the pipeline. According to this document, the government is considering excusing the pharmaceutical companies included in the programme from their duty to participate in the so-called "pay-back payments" towards the National Health Fund (i.e. the public payer responsible for financing drug reimbursement costs). These payments are triggered every time reimbursement costs incurred by the public payer exceed the planned budget. This is particularly interesting taking into account the fact that another idea of the government is to increase the default participation rate of the pharmaceutical companies in the pay-back payments from 50% (another 50% is charged to the NHF) to 100%. That would mean that all the economical risks connected with exceeding the planned reimbursement budget would be transferred on the pharmaceutical companies and only the companies classified as "Partners of the Polish Economy" under the discussed programme would be partially or completely excluded.

Notwithstanding the fact that the works on the programme are in a very early phase and the final shape thereof is still unknown, all the stakeholders potentially interested in the project underlined that the project originators must ensure that all the measures within the programme will comply with the state aid law of the European Union.

For more information please contact **Marcin Fialka** in the Warsaw office.

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**FORWARD****WEBSITE****Czech Republic****Proposed changes to the regulation of vaccination**

On 24 August, 2018, the government of the Czech Republic submitted to the Chamber of Deputies a draft amendment of Act No. 378/2007 Coll., on Pharmaceuticals, as amended, to adapt the Czech legal order to the legislation of the European Union with respect to the prevention of the entry of counterfeit medicinal products into the legal supply chain, in particular to the so-called Falsified Medicines Regulation (*Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features to appear on the packaging of medicinal products for human use*).

The proposed draft amendment only allows health service providers to verify the safety features and decommission the unique identifier with respect to vaccines that are reimbursed from public health insurance, whilst in the case of vaccines that are optional and not covered by public health insurance, verification and decommissioning must be made by the pharmacies. Thus, in contrast to the current regulation and practice, where all vaccines may be supplied by the distributors directly to the physicians, resulting in convenience for patients who may both obtain the vaccine and get vaccinated as part of the same visit to a physician's office, the regulation proposed by the draft amendment leads to a situation where in one case, patients would both obtain the vaccine and get vaccinated during the same visit to a physician's office, whilst in another case, patients would have to visit the physician's office to undertake a medical check and/or to obtain the prescription for the vaccine, then go to a pharmacy for the vaccine to be dispensed and then take the vaccine to the physician to get inoculated, depending solely on whether the concerned vaccine was reimbursed from public health insurance or not. The optional vaccines currently include, for example, human papillomavirus (HPV) vaccines, influenza vaccines, tick-borne encephalitis (TBE) vaccines and most of the travel vaccines.

The Coalition of Private Physicians and the Association of Private Gynaecologists have issued a joint statement in which they express their opinion that the proposed concept of dispensing vaccines at pharmacies will be dangerous and uncomfortable for patients. They particularly highlight the risk that, as the transportation from a pharmacy to a physician's office would very likely lead to a breakdown in the cold chain (i.e. storage and distribution requirements relating to temperature-control), it might result not only in decreased efficacy of the vaccines transported, but possibly even in the increased occurrence of adverse events. They also voiced concerns that, consequently, physicians might be held liable for such transport-related negative effects to the vaccines over which they had no control.

In contrast to the above mentioned statement, the new concept of dispensing vaccines is strongly supported by the Czech Chamber of Pharmacists, which claims that the positive aspects of such process significantly outweigh the negative aspects. In its opinion, such benefits include, in particular, patients receiving professional instructions at the dispensing of the vaccines from the pharmacists, increased price transparency and a potential for a greater vaccination rate related to the future prospect of the legality of patients being vaccinated directly at the pharmacy, pointing out that under the legal regulation of certain other member states pharmacists are authorised to apply vaccines to patients.

For further information please contact [Linda Darilkova](#) of the Prague office.

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