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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.

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Welcome to the December 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.

Germany

Keeping generics off the market under German Law

Dr. Johannes Druschel and Christoph Krieger highlight the laws that keep generics off the German Market in The Patent Lawyer Magazine.

Read more here.

For more information, please contact Dr. Johannes Druschel.

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Italy

The Italian Medicines Agency states that the deposit of promotional materials for medicinal products is only possible in digital form

Following an initial experimental phase that ended in June 2018, the Italian Medicines Agency has announced that the submission of promotional materials for medicines addressed to healthcare professionals can now only be performed in digital form.

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Transparency between pharmaceutical companies and healthcare operators and organizations: the provisions of the Sunshine Act

On September 11, 2018, the Italian Chambers of Deputies commenced the examination of bill No. 491 (the so-called **"Sunshine Act"**), which provides for the obligation, for any party performing manufacturing and marketing activities involving medicines, instruments, equipment, goods or services used in the human and veterinary health sector, to disclose its economic relationships with healthcare operators and organizations.

Read more here.

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

Parapharmacies are allowed to sell medical devices and products for diabetics

With its decision published on October 22, 2018, the Antitrust Authority expressed its position on the distribution and sale of medical devices and products for diabetics by parapharmacies. The decision follows the complaints filed by some parapharmacies and the National Federation of Italian Parapharmacies according to which Italian regions adopt different approaches with respect to parapharmacies' requests for authorization to sell medical devices and products for diabetics reimbursed by the National Health Service.

Read more here.

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

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Russia

The Government of the Russian Federation has approved a new procedure for registering prices for medicines from the vital and essential medicines list

Government Decree No. 1207 dated October 8, 2018 (**Decree**) contains new editions of the Rules for the State Registration of Manufacturers' Maximum Selling Prices for Medicines on the List of Vital and Essential Drugs (**Rules**, **EDL List**), and the Rules for Maintaining the State Register of Manufacturers' Maximum Selling Prices for Medicines on the EDL List. The Decree also adjusts the method of calculating the maximum selling prices set by the medicines' manufacturers.

Read more here.

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

The Ministry of Healthcare has put forward an initiative to improve the protection of

patent rights to medicines

The draft of the federal law (**Draft**) dated October 25, 2018 provides for the obligation of the applicant in a medicine's state registration process to provide information on the existing intellectual property protection for the medicine, as well as to confirm that the medicine's registration will not violate intellectual property rights of third parties.

Read more here.

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

The Ministry of Industry and Trade is planning to exclude medicines from the list of goods subject to conformity assessment

Currently, the entry of medicines into civil circulation in Russia is carried out in the form of a declaration of conformity or a mandatory certification, which is provided with the participation of certified testing laboratories (centers).

Read more here.

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

Spain

The new Price Reference Order of 2018 has been published and it still maintains the groups that were invalidated by the Supreme Court

Finally, Order SCB/1244/2018, November 23, which updates in 2018 the reference price system for medicines in the National Health System, has been published on November 27, 2018, and has entered into force the following date, i.e., November 27, 2018. Link to the publication.

Read more here.

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

Orphan medicinal products: Measures to promote research and development and the current situation in the European Union

The Spanish version of this article was published in the healthcare law magazine "Cuadernos de Derecho Farmacéutico" (July-September 2018, nº 66).

In March of 2018, the judgment of the European General Court in Case T-80/16 *Shire Pharmaceuticals Ireland Ltd v. European Medicines Agency* (**EMA**) clarified the interpretation of key concepts of Regulation (EC) 2000/141 on orphan medicinal products, and held that the EMA's validation of a request for orphan medicinal product declaration should be limited to procedural aspects.

Read more here.

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

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Switzerland

Swiss leading decision on qualification of fertility app as medical device

A recent judgement shows that the purpose and not the description of an app is the central criterion when determining whether or not it must comply with regulations before being marketed in Switzerland. Hence, regulations must be considered at an early stage of the app development process to avoid compliance issues.

Read more here.

For more information please contact Julia Schieber or Markus Winkler of our Zurich office.

UK

Legalisation of medicinal cannabis in the UK

As of November 1, 2018, patients can now access cannabis-based medicinal products on prescription by doctors on the General Medical Council specialist register in accordance with *The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018* (**2018 Regulations**).

Read more here.

For more information, please contact Julia Gillert, Elina Angeloudi or Tiarna Meka of our London office.

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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 witholds 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.

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

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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 theses 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 (Bundeswettbewerbsbehörde, "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): *"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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Italy

The Italian Medicines Agency states that the deposit of promotional materials of medicinal products is only possible in digital form

Following an initial experimental phase ended on June 2018, the Italian Medicines Agency has announced that the submission of promotional materials for medicines addressed to healthcare professionals can now only be performed in digital form.

In this respect, Section 120 of Legislative Decree No. 219/2006 establishes that pharmaceutical companies willing to promote their medicinal products to healthcare professionals, must first submit the relevant material to the Italian Medicines Agency. However, the method adopted so far, i.e., the submission in paper form, involved difficulties with timings in contrast with the need for operational speed, which is instead permitted by currently available technologies. For these reasons, the Italian Medicines Agency established that the promotional material intended for medical-scientific information can only be submitted through the dedicated digital platform "*Front End*".

Among the advantages offered by said platform, the most relevant include the speed-up of submission activities, the immediate and unequivocal identification of the date to be affixed on the promotional material, as well as the possibility to set up, in the future, an archive available to pharmaceutical companies, including all the promotional material submitted to the Italian Medicines Agency since 2009.

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

Payback on medicinal products: possible solution within the 2019 Budget Law

A solution to the problems related to the payback system for medicinal products, which requires pharmaceutical companies to share the costs connected with the possible overrun of the relevant expenditure ceiling and whose application is currently hindered by several claims filed by the same companies challenging its implementing measures, could be found within the 2019 Budget Law.

In particular, the 2019 Budget Law could provide a unique opportunity not only for breaking the deadlock concerning the amounts due for the past years (2013-2015, 2016 and 2017) but also for implementing a structural reform of the method for calculating the payback, by providing for the replacement of the current method based on company budgets by a new one according to which the amount due by each pharmaceutical company should be calculated on the basis of the impact of the relevant market share on the total overrun.

Pending further legislative developments on the payback, it should be noted that currently available estimates on the pharmaceutical expenditure for 2018 show, with respect to the direct purchase of medicines, an overrun of the relevant ceiling exceeding the 2% (amounting to € 2.4 billion approximately), whereas, as regards the purchase through pharmacies, the compliance with the relevant parameters with a surplus of approximately € 700 million.

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

Farmindustria publishes its Position Paper on biosimilars

On October 11, 2018, Farmindustria published a Position Paper on biosimilars that shows an alignment with the position and principles already expressed by the Italian Medicines Agency on the matter.

In particular, Farmindustria's Position Paper reaffirms the importance and the value of the doctor's freedom of prescription, as the doctor is still considered the only person able to assess and establish the most suitable therapeutic approach in the patient's best interest with respect to medicinal products, such as biological drugs, which are not automatically interchangeable. In this respect, the Position Paper points out that, although biosimilars grant undeniable advantages to the National Health Service in terms of reduction of financial expenditure and improvement of patients' access to medical treatments, the adoption of a pure economic approach, which is only aimed at optimizing purchase costs and does not take into account the specific precaution needs and the management complexity related to biological drugs, could jeopardize the advantages connected to the proper use of biosimilars.

Lastly, the Position Paper places great importance on patients' information about the risks and benefits related to the selected treatment. Indeed, the prescribing doctor has the fundamental task of providing clear and thorough information on same, which is considered an essential element of the communication between doctors and patients in order to ensure the latter's full involvement in the relevant treatment path.

Farmindustria's Position Paper is available at the following link:

https://storage.googleapis.com/jb-wp-uploads2/farmindustria-staging-web/2018/10/PP-biosimilari-Farmindustria_1018.pdf

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

Transparency between pharmaceutical companies and healthcare operators and organizations: the provisions of the Sunshine Act

On September 11, 2018, the Italian Chambers of Deputies began the examination of the bill No. 491 (the so-called "**Sunshine Act**"), which provides for the obligation, for any entity performing manufacturing and marketing activities involving medicines, instruments, equipment, goods or services used in the human and veterinary health sector, to disclose its economic relationships with healthcare operators and organizations.

Actually, disclosure obligations envisaged by the bill are already implemented by pharmaceutical and medtech companies in compliance with their respective Codes of Ethics. However, in case of its approval, the bill would still have a significant impact on the healthcare sector not only because the disclosure of transfers of value would become a legal obligation for all companies operating in this sector, regardless of their participation in their industry associations, but also because it would align the Italian legislation to that of other European countries that have already adopted similar legal provisions and increase the number of economic operators subject to disclosure obligations.

In its current version, the bill provides for the disclosure of agreements and transfers of money, goods, services or other benefits to: (i) healthcare operators, in case the same have a unit value exceeding € 10.00 or a total annual value exceeding € 100.00, and (ii) healthcare organizations, in case of a unit value exceeding € 500.00 or a total annual value exceeding € 1,000.00. Disclosure obligations also apply to interests, direct or indirect, consisting in the participation, whether free of charge or for a consideration, in conferences, training events, advisory boards or scientific committees or in the establishment of consultancy, teaching or research relationships.

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

Parapharmacies are allowed to sell medical devices and products for diabetics

With its decision published on October 22, 2018, the Antitrust Authority expressed its position on the distribution and sale of medical devices and products for diabetics by parapharmacies. The decision follows the complaints filed by some parapharmacies and the National Federation of Italian Parapharmacies according to which Italian Regions adopt different approaches with respect to parapharmacies' requests for authorization to sell medical devices and products for diabetics reimbursed by National Health Service.

In this respect, the Antitrust Authority specified that the existing legislation does not include any provision which strictly identifies the sales channels for medical devices, products for diabetics or other healthcare products, or which prohibits the sale of said products through channels different from pharmacies.

On the contrary, the Antitrust Authority recognized the importance of parapharmacies for the development of competition in the sale and distribution of healthcare products and affirmed that the exclusion of parapharmacies from the possibility to expand their offer in terms of products and services would be detrimental to the rules and principles protecting competition.

In light of said considerations, the Antitrust Authority upheld that the refusal by some Regions to enter into agreements with parapharmacies for the sale of medical devices and products for diabetics constitutes discrimination among different sales channels, with negative effects on competition.

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

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Spain

The new Price Reference Order of 2018 has been published and it still maintains the groups that were invalidated by the Supreme Court

Finally, Order SCB/1244/2018, November 23, which updates in 2018 the reference price system for medicines in the National Health System, was published on November 27, 2018, and entered into force the following day, i.e. November 28 2018.

This year, the publication of the Order has once again been considerably delayed, though, unlike the previous year, there are no new judgements pending application. Last year, the publication delay was due to the fact that the Supreme Court ruled in favour of a certain number of judgments by the Supreme Court that invalidated some of the new groups per the Orders of 2014 and 2015. The Department of Pharmaceutical Law at our Barcelona office had the honor to represent some of our clients in said appeals estimated by the Supreme Court. Nevertheless, despite the numerous appeals brought against the 2016 and 2017 Orders, there are no decisions on them yet. As such, the delay in this year's publication cannot be attributed to any judicial rulings.

As in previous Orders, the reference groups are separated into two different annexes: one that includes the presentations sold in pharmacies (**Annex 1**), and another that includes the hospital presentations (**Annex 2**). In this case, the new groups are those numbered from C-506 to C-525 of Annex 1, and from H-129 to H-147 of Annex 2 , no clinical packaging has been created.

Annex 7 of the Order includes those presentations that, on the date on which the elaboration of the new Order started, have not yet been included in the National Health System, that is, their inclusion date is after April 18, 2018. Also in this Annex, is a list of the medicinal presentations indicating the reference group in which they will be included and the industrial reference price for each presentation.

If any of the laboratory's medicines have been included in this Order, and does not agree with it and or/ with the established reference price, please take into account that it is possible to file an appeal against said Order before the Minister of Health within one month from the date of publishing. Accordingly, the deadline falls on December, 27. It is also possible to directly submit an administrative-contentious appeal before the National High Court, within two months (i.e. until January 27 2019, which is a Sunday, so the appeal could be lodged until January 28 2019).

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

Orphan medicinal products: Measures to promote research and development and the current situation in the European Union

The Spanish version of this article was published in the healthcare law magazine "Cuadernos de Derecho Farmacéutico" (July-September 2018, nº 66).

In March of 2018, the judgment of the European General Court in Case T-80/16 *Shire Pharmaceuticals Ireland Ltd v. European Medicines Agency* (**EMA**) clarified the interpretation of key concepts of Regulation (**EC**) 2000/141 on orphan medicinal products, and held that the EMA's validation of a request for orphan medicinal product declaration should be limited to procedural aspects.

Read the full article here.

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

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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 TİTCK 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 TİTCK.

The draft Regulation on Foods for Medical Purposes 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 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 TİTCK 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 TİTCK will collect public opinion on the Draft Regulation until 16 December 2018.
Opinions may be submitted to the TİTCK in writing or to the email address 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 TİTCK 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 TİTCK 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 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.

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 TİTCK 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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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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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 FPHC 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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Germany

Keeping generics off the market under German Law

Dr. Johannes Druschel and Christoph Krieger highlight the laws that keep generics off the German Market in The Patent Lawyer Magazine.

Read more here.

For more information, please contact Dr. Johannes Druschel.

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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.

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 ameneded 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 (*mécenat);*
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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UK

Legalisation of medicinal cannabis in the UK

As of 1 November 2018, patients can now access cannabis-based medicinal products on prescription by doctors on the General Medical Council specialist register in accordance with *The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018* ("**2018 Regulations**").

The 2018 Regulations amend the approach taken under *The Misuse of Drugs Regulations 2001* ("**2001 Regulations**") and *The Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015* ("**2015 Order**"), where cannabis-based products were previously categorized under Schedule 1 of the 2001 Regulations and were subject to the greatest restrictions.

Products that fall within the new definition of 'cannabis-based product for medicinal use in humans' will be rescheduled to Schedule 2 of the 2011 Regulations and de-designated from the 2015 Order.
The change in law was led by Mr. Sajid Javid, the UK Home Secretary, as a result of recent high-profile cases where young sufferers of severe epilepsy were initially denied access to cannabis oil treatments that were not legally available in the UK.
Although access to cannabis-based medicinal products has increased, the 2018 Regulations impose special control for the use and supply of these products to prevent unintended use. For example, the order and supply must be:

- for use in accordance with the prescription and/or direction of a specialist medical practitioner (not a GP);
- an investigational medicinal product for use in a clinical trial in humans; or
- a medicinal product with a marketing authorisation.

Smoking of cannabis and cannabis-based products for medicinal use remains prohibited.
Mr. Javid was clear in noting that the lines drawn in the 2018 Regulations will not necessarily remain the government's position for very long. A long-term review is set to be conducted by the ACMD and that National Institute for Health and Care Excellence has been commissioned with an aim to educate and provide advice for clinicians by October 2019.

A copy of the 2018 Regulations and explanatory note can be found here.

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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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Russia

The Government of the Russian Federation has approved a new procedure for registering prices for medicines from the vital and essential medicines list

Government Decree No. 1207 dated October 8, 2018 (**Decree**) contains new editions of the Rules for the State Registration of Manufacturers' Maximum Selling Prices for Medicines on the List of Vital and Essential Drugs (**Rules**, **EDL List**), and the Rules for Maintaining the State Register of Manufacturers' Maximum Selling Prices for Medicines on the EDL List. The Decree also adjusts the method of calculating the maximum selling prices set by the medicines' manufacturers.

The changes stipulated by the Decree mainly concern the Rules for the re-registration of medicines. For instance, the Decree sets forth that the registered manufacturer's maximum selling price for a medicine may be re-registered no more than once in a calendar year, only for the purpose of increasing the price. However, there are no limitations on re-registering a lower price. Apart from the relevant application of the medicine's manufacturer/registration certificate holder, another ground for price re-registration for the purpose of increasing the price is submitting a set of documents containing an economic analysis of the proposed price, the methodology for which is also established by the Decree.

It has also been established that the prices for reproduced medicines (generics) cannot be higher than the registered prices for reference medicines with regard to both the registration and the re-registration of the maximum selling prices for medicines.

The Decree envisages that for the reference medicines' manufacturers indicated on the registration certificate and for the Eurasian Economic Union (**EAEU**), reproduced medicines' manufacturers must have an established unified maximum selling price for each medicinal form, dosage and total quantity on the consumer packaging (without taking into account the form of release).

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

The Ministry of Healthcare has put forward an initiative to improve the protection of patent rights to medicines

The Draft of the federal law (**Draft**) dated October 25, 2018 provides for the obligation of the applicant in a medicine's state registration process to provide information on the existing intellectual property protection for the medicine, as well as to confirm that the medicine's registration will not violate intellectual property rights of third parties.

The Draft indicates that a medicine's state registration application must be supplemented by information on the existence of a valid patent in the territory of the Russian Federation (with the indication of the patent number, the date of issue, period of validity and the patent's owner), information on the existence of a trademark registration in the Russian Federation (with the indication of the certificate number, the date of issue, period of validity and the holder) and confirmation that all data in the registration dossier was obtained in a proper manner and does not violate the intellectual property rights of third parties. The prospective amendments were due to the necessity to unify Russian laws, regulating state registration of medicines with EAEU legislation.

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

The Ministry of Industry and Trade is planning to exclude medicines from the list of goods subject to conformity assessment

Currently, the entry of medicines into civil circulation in Russia is carried out in the form of a declaration of conformity or a mandatory certification both of which are provided with the participation of certified testing laboratories (centers).

The Draft Law dated October 10, 2018, which was developed by the Ministry of Industry and Trade, provides for the exclusion of medicines from the unified list of goods, the confirmation of conformity of which is carried out in the form of adoption of a declaration of conformity or a mandatory certification. One of the reasons for introducing these amendments is that the current system does not ensure the necessary level of control over the quality of medicines while being unnecessarily burdensome and formal in part.

In this regard, back in March 2018, it was also suggested to amend the Federal Law "On the Circulation of Medicines" so that medicines, with the exception of immunobiological ones, can be introduced into civil circulation on the basis of the manufacturer's documents verifying the quality of the medicines and confirmation of the manufacturer's authorized person/importer that the medicines comply with the quality requirements established for state registration.

When the first three series (batches) of a medicine are manufactured in the Russian Federation/imported into the territory of the Russian Federation for the first time, an organization must additionally submit a testing (examination) transcript. The testing must be conducted by an accredited organization, which is within the jurisdiction of the Ministry of Healthcare or the Federal Service for Surveillance in Healthcare (**Roszdravnadzor**).

Each batch (series) of immunobiological medicines is proposed to be introduced into civil circulation on the basis of special permission granted by Roszdravnadzor.

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equivalent, in such a law firm. Similarly, reference to an "office" means an office of any such law firm.

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.

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 Bíró 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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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.

For more information, please contact Mike van Rensburg, Tanya Seitz or Kimberley Barker of our Johannesburg office.

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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 prearranged 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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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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Switzerland

Swiss leading decision on qualification of fertility app as medical device

A recent judgement shows that the purpose and not the description of an app is the central criterion when determining whether or not it must comply with regulations before being marketed in Switzerland. Hence regulations must be considered at an early stage of the app development process to avoid compliance issues.

Read more here.

For more information please contact Julia Schieber or Markus Winkler of our Zurich office.

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