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Healthcare and Life Sciences News

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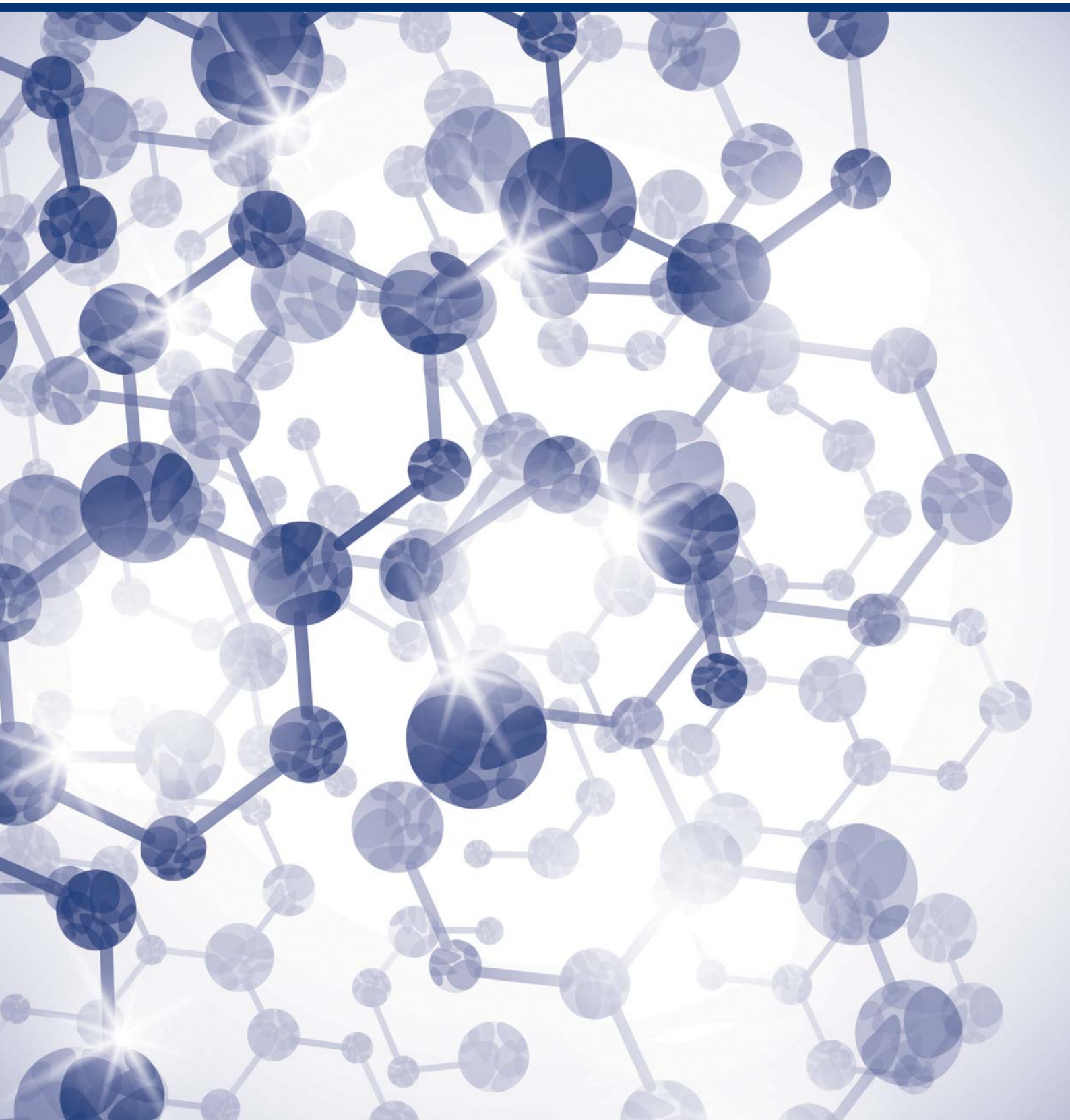

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- Artificial intelligence, ethics & data governance
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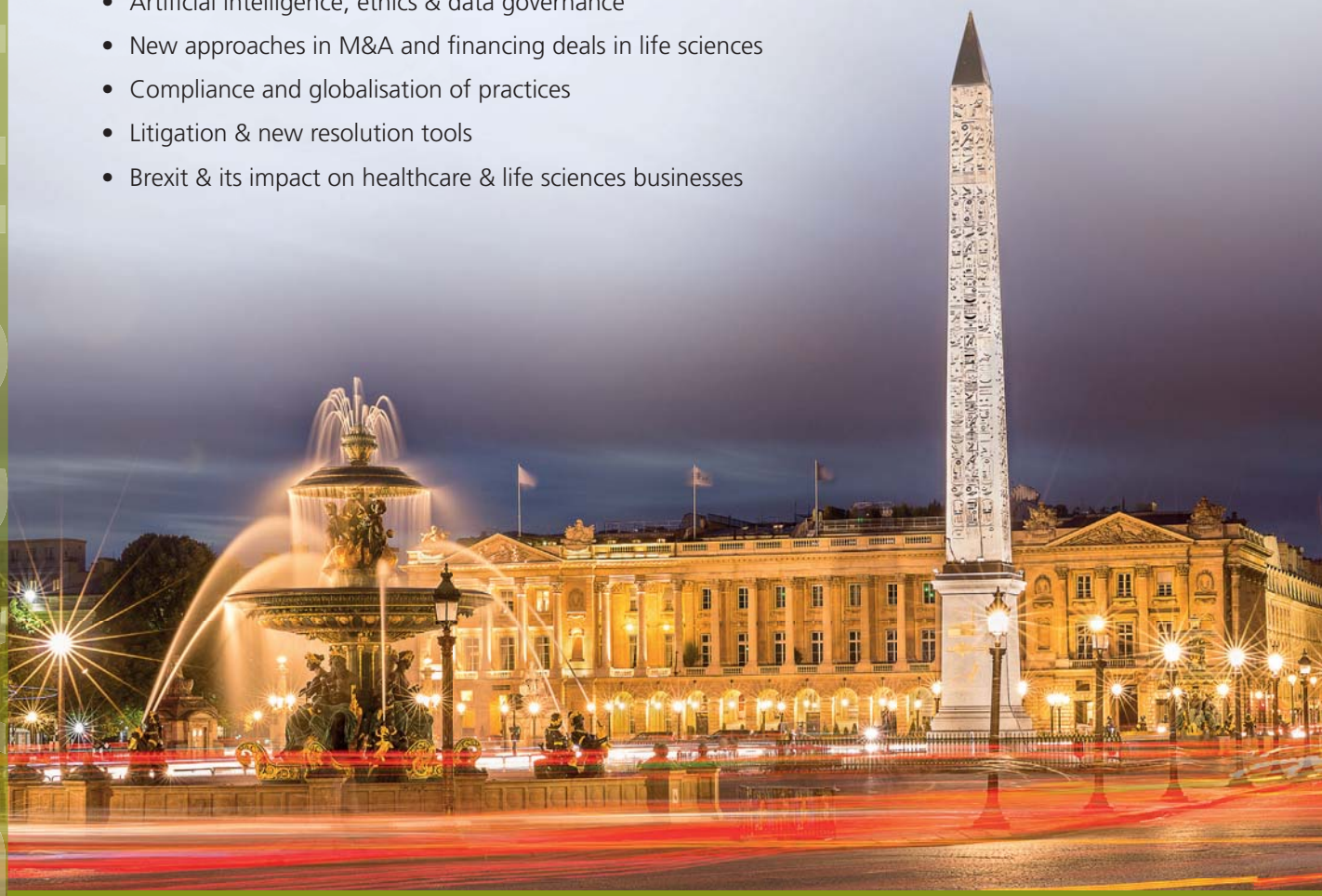
- Compliance and globalisation of practices
- Litigation & new resolution tools
- Brexit & its impact on healthcare & life sciences businesses



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IN THIS ISSUE

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From the Co-Chairs

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Dear IBA Healthcare and Life Sciences Law Committee colleagues,

It is a pleasure to share with you one of our biggest-ever Committee Updates, packed with fascinating articles from around the world. We are very grateful to Cécile Théard-Jallu, our Newsletter Officer, for compiling this publication, and to all the authors who contributed. These articles are sure to raise lots of talking points and we urge you to post your thoughts on the Committee's discussion board. You can find this at **www.ibanet.org/LPD/Law_Individual_Rights_Section/Healthcare_Lifescience/Default.aspx**. Click on 'This Committee's Menu' at the top of the page and you will find it in the drop-down menu.

You will also find our session programme for the IBA 2019 Annual Conference in Seoul in this issue. We are leading sessions on internationalisation and digitalisation of healthcare as well as a legal discussion on genomics. We have some great speakers arranged to lead on these topics, but the success of any session depends on participation from the floor. We all benefit from everyone who comes along to share their thoughts and experiences so please don't be shy – come along to the sessions and take an active part so that we all come away having had our ideas challenged and learning something new.

We will also have to start planning for next year's activities in Miami, so please share your ideas either on the discussion board or by approaching one of the Healthcare and Life Sciences Law Committee Officers if you are going to be in Seoul.

Last but not least, please reserve the first weekend of June 2020 in your calendar to attend the 8th Annual World and Life Sciences Conference, which shall take place in Paris. We are very much looking forward to seeing as many of you as possible there then, as well as in Seoul this coming September.

Best wishes,
Stephan Rau and Steve Weiner

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From the Newsletter Officer and Discussion Forum Moderator

Looking forward to Seoul

The healthcare and life sciences sector is undergoing important development and related legal challenges. Their resolution will condition its sustainable development in an ever-changing digitalised and globalised world.

At the recent IBA 7th Annual World Life Sciences Conference in Philadelphia on 31 May to 1 June 2019, we shared views and know-how, covering a wide range of issues targeting healthcare and life sciences as a global sector, not merely as a legal practice. The event gave us the opportunity to hear professional experts from law firms or industry, financial or academic organisations from across the world.

We are now looking forward to the IBA Annual Conference in Seoul on 22–27 September 2019, especially the Healthcare and Life Sciences Law Committee sessions and events.

This year, once again, 25 authors from 13 law firms located in more than ten jurisdictions, have seized the opportunity of the sector's vivacity to contribute to our annual newsletter, providing content on a large variety of topics.

Many thanks to all our authors for their thoughtful and dynamic analyses.

Here's a summary of what this newsletter's topics deal with.

Drug patent, generics and the rise of trade secrets

Two articles approach the protection of intangible assets and development of intellectual property legislation.

The first, on EU drug patent extension law reforms aimed at bolstering EU generic competitiveness, is written by Charlotte Tillett and Astrid Arnold, from the UK law firm Stevens & Bolton. The article examines the manufacturing waiver introduced in July this year to the EU 'SPC' patent extensions regime, and explains how the waiver will work and its impact on the generic and innovative life sciences market.

The second article is co-authored by Jeff Vockrodt, Alexander Spiegler, Sanjeev Mahanta and Sanum Patel, from the US firm Arent Fox. It focuses on the rise in trade secret protection in the life sciences following the decline in patent eligibility. While the protection of intellectual property in the biotech industry is critical and patents have traditionally taken a lead role in this respect, the enactment of the Defend Trade Secrets Act (DTSA) has reinvigorated trade secret protection in the US, and led to a significant increase in the number of trade secret misappropriation claims involving biotechnology. The article explores three situations where the DTSA provides advantages for protection of biotech IP relative to patents, suggesting the strong role this form of protection will play in the future.

High-cost medicine

Excessive pricing is a concern in many countries today. Contributors from both South America and Europe focus on this issue.

First, Ignacio Torres Negreira and Rodrigo Felló, from Bergstein, Uruguay, write on the conditions necessary for accessing high-costs medicine in their country and the way the Uruguayan system works to accompany their mandatory or non-mandatory supply and related recourses.

Enzo Marasà, from Portolano Cavallo, Italy, discusses how Aspen Pharmaceutical complied with the Italian Competition Authority's (AGCM) decision to cease and desist from applying excessive pricing for certain drugs. The case relates to a fine for abuse of dominance imposed on Aspen by the AGCM, which has spurred much debate across the European Union and prompted the launch of a similar investigation by the European Commission and national competition authorities into excessive pricing practices in the pharmaceutical sector.

Genomic research and manipulation of the human genome

Genomic research, that is, the study of genes and their functions and related techniques, triggers a series of legal and ethical issues that two authors have covered this year.

Alison Choy Flannigan, from Hall and Wilcox, Australia, deals with unnatural selection practices and their risks. Time is fast approaching where the development of technology is testing boundaries in terms of the potential to manipulate the human genome to eradicate genetic abnormalities. The author raises the question of whether or not the law (and legal protection) will keep pace.

Ionna Michalopoulou, Vicky Tatsi and Isidoros Skavdis, from Michalopoulou, Greece, raise the issue of genomic research and gene editing, with the specific case of CRISPR, in relation to data protection. Genetic and genomic research are growing fast with fantastic promise for human healthcare. However, a general lack of regulation that surrounds the technology may hinder its development. This is most particularly true with the impact gene editing has with respect to data privacy. The three authors explain why and how.

An update on GDPR one year on, and new data privacy insights from Brazil

Data privacy awareness is now largely on target in the EU: safeguarding measures are being progressively implemented and the first sanctions have been announced while the General Data Protection Regulation (GDPR) marked its first anniversary on 25 May 2019. Although many organisations still have much to do to achieve the level of data protection required, the past few months have shown an international expansion of the GDPR's spirit as jurisdictions have updated their legislation accordingly. In addition to Japan and its bilateral adequacy decision with the EU in January 2019, Brazil is a key example in this sphere. Fabio Alonso Vieira, from Kestener, Granja et Vieira, Brazil, and myself, Cécile Théard-Jallu, from De Gaulle Fleurance & Associés, France, discussed the topic at the 7th World Life Sciences Conference in Philadelphia and prepared a teaser for that occasion which we are happy to share with you.

Artificial intelligence, medical apps, telemedicine and digitalisation

New technologies and data are at the heart of the healthcare sector's development globally. Again this year, several authors tackle the issue and describe recent outcomes in their respective countries.

Sonja Read, from MinterEllison**,** Australia, describes how health apps are regulated in Australia, depending on whether they constitute medical devices or not, with a perspective on the related numerous legal challenges raised and currently proposed reforms.

In India, Arjun Krishnamoorthy, from J Sagar Associates, approaches the impact of AI. The Government of India has expressed considerable interest in artificial intelligence and constituted various committees and commissioned strategy papers on its implementation. The 2019–2020 Budget Speech envisages a 'National Programme on Artificial Intelligence' to take the benefits of AI to the people and healthcare as one of the key sectors for its implementation. The article gives insights into its possible effects on Indian law.

As far as Europe is involved, Stephan Rau and Karolin Hiller, from McDermott Will & Emery, Germany, bring their view on the latest legal initiatives taken by the German government to promote the digitalisation of healthcare, telemedicine services and their funding by the taxpayer.

Cannabis for medical use

Legalisation on cannabis for medical use is spreading in many jurisdictions all over the world.

Brazil is among those countries having made the step. Rubens Granja and Cesar Borlina, from Kestener, Granja and Vieira, Brazil, explain how substantially the regulation on cannabis-derived products has changed in the last four years in Brazil, from a general prohibition to intricate rules. These now allow the registration of cannabis-derived medicines and the direct import of cannabis-derived products by patients for medical purposes, even the judicially obtained right by a few patients to cultivate the plant and extract compounds for personal use.

It is also an important topic in Peru as explained by Maritza Reategui and Cécilia Alarçon, from Estudio Rodrigo, Elias and

Medrano Abogados. Their article covers the main features of the Peruvian regulations, providing a strict framework for cannabis-based products intended for medicinal and therapeutic purposes only.

E-cigarettes

Sameer Sah and Avantika Govil, from Khaitan & Co, India, give us the opportunity to discover e-cigarette related controversies in their country. With the introduction of the electronic nicotine delivery system, e-cigarettes and similar devices such as e-nicotine flavoured hookah and vape, which enable nicotine delivery, have gained substantial popularity in India. Until recently, there were several uncertainties surrounding the regulation of these devices. It now appears that the Ministry of Health and Family Welfare of India has decided to implement a blanket ban on their manufacture, import, trading, distribution and sale, although a formal notification is awaited.

Looking ahead

With my co-officers of the Healthcare and Life Sciences Law Committee, it is our hope that you will gain new insights from these articles and that they will lead us to share further views on the sector's key topics and recent developments in our respective countries. As always, the Committee is happy to help these discussions continue.

For those attending the IBA Annual Conference in Seoul, we look forward to discussing these topics and others with you, especially during our Committee's sessions.

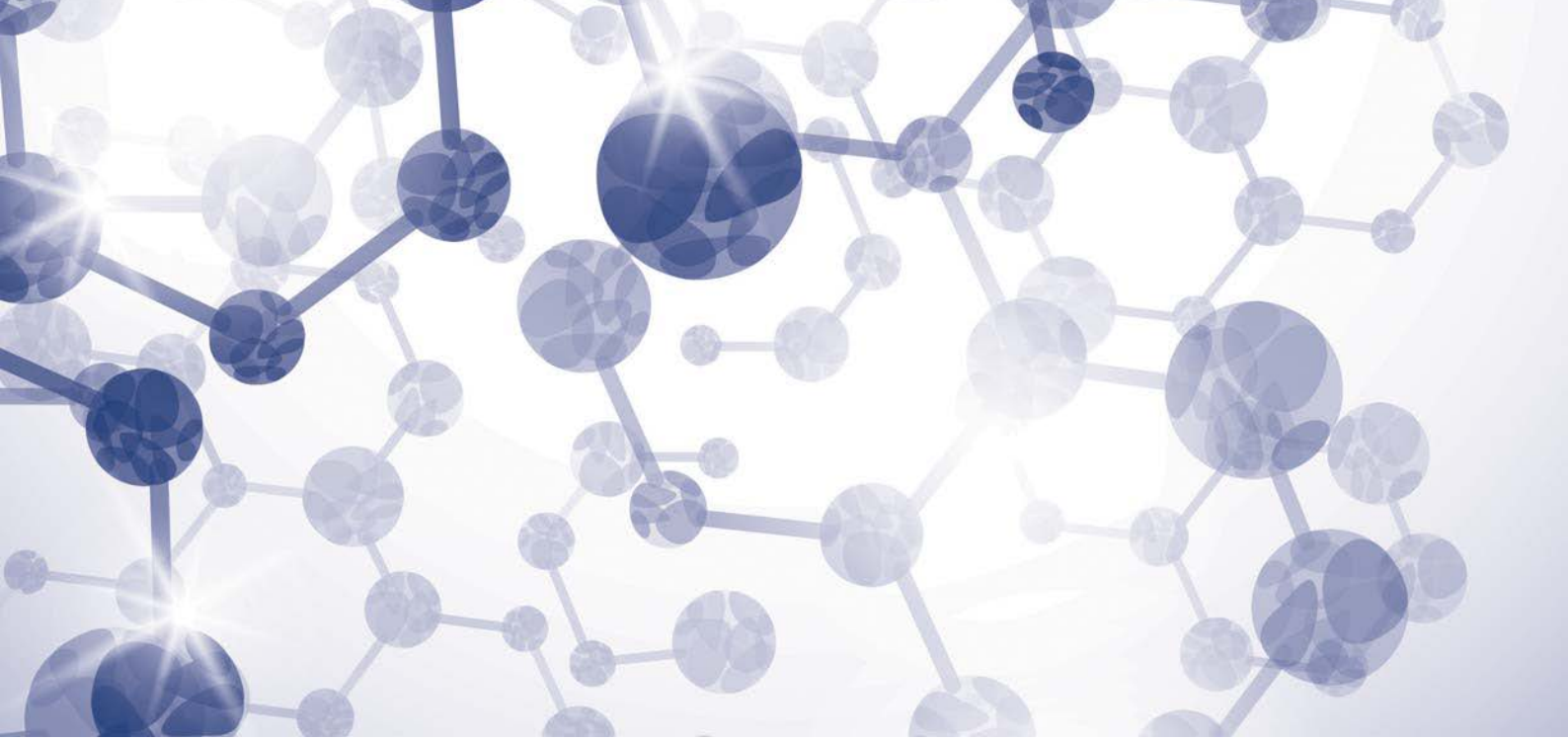
For those who are unable to attend, please feel free to post questions and new articles via the Committee's webpages at any time. Access is available to Committee members all year round.

We may also organise webinars to enhance your expertise among our entire community.

And finally, please remember to register for the next IBA Annual World Life Sciences Conference – the 8th, which will take place on 5–6 June 2020, in a new venue, Paris!

Thank you for reading and let's make business law together.

Cécile Théard-Jallu



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The GDPR: one year on

Introduction

The European Union General Data Protection Regulation (GDPR) became compulsary on 25 May 2018. It promised stronger data protection and value-added changes in the data processing practices of public and private organisations, while necessitating huge investments and new processes for implementation. This is especially true in the healthcare sector where patient's safety may be at stake as health-related data is considered sensitive and therefore deserving a reinforced level of protection compared to 'ordinary' data.

How do things stand now, after this first year of GDPR's existence? What are the international perspectives? How might foreign legislation evolve to work in conjunction with GDPR at an international level? The case of Brazil is particularly significant in having substantially revamped its data protection legislation and created a new data protection authority directly inspired by GDPR. This subject was discussed during a dedicated roundtable at the recent 7th IBA World Life Sciences Conference in Philadelphia on 31 May 2019. Here is the summary the material we prepared for the roundtable.

How do things currently stand with GDPR?

On 22 May 2019, EU Commissioner Vera Jourova described GDPR as: 'a one-year old baby who has an appetite and is very agile.'

A year of GDPR at a glance:

- Thanks to GDPR, there is a stronger awareness of citizens and businesses – 2/3 of EU players getting on track;
- a huge and continuing increase in the number of complaints – around 144,000 in 12 months;
- no significant increase in financial sanctions yet – however there has been a €50m fine against Google in France, €400,000 against a Portuguese Hospital, and ongoing procedures against Big Data players in Ireland;[1] plus 89,000 formal notifications of complaint addressed;
- the tolerance period is about to end; and
- big groups are progressively getting ready while many SMEs are still not compliant. More practical guidelines and education is needed. Impediments to spread of knowledge include a lack of resources, HR culture, change management costs, insufficient legal security, etc.

The meaning and scope of a number of GDPR's principles and notions are still unclear or challenging for businesses, including:

- a legal basis to justify data processing activities (Article 6 GDPR) – consent, enforcement of a contract or pre-contract, enforcement of a legal obligation, vital interest of a person, enforcement of a public interest or public authority mission, legitimate interest of the data controller, unless fundamental rights and liberties

prevail including for children;
- for health and genetic data ('sensitive' data') there is a need to follow the strict legal regime of the GDPR's article 9 and related provisions – health data processing is unlawful unless falling into exceptions, possibly completed by EU national legislations;
- anonymisation v pseudonimisation;
- identifying roles between data controllers, joint controllers, data processors and sub-processors;
- when is a private impact assessment (PIA) necessary before any processing (article 35 GDPR)?;
- ensure the integrity and confidentiality of data – physical and digital security standards, internal and external procedures (eg, management of vulnerabilities), outsourced services management and use of certified health data hosting providers where applicable (eg, in France)?
- archiving/data storage duration identification and management;
- develop privacy by design and by default IS and project management tools (article 25 GDPR);
- for international data transfers, absence of updated standard contractual clauses or lengthy process for BCRs – what about future codes of conduct or standards?
- staff training, organising and managing data protection project team including selecting data protection officers (DPOs) and enabling them to work and insufflating the data protection culture in organisations; and
- data governance and related process to be defined for the evaluation of health care practices.

The GDPR has turned from a restrictive and funds-intensive regime into a value and trust-adding tool for businesses, though, for some players, it is still seen as an obstacle to commercial trade and innovation.

The implementation of the GDPR across the EU

- Around 50 exemption zones left by the GDPR are to be checked in each EU Member State national legislature;
- 25 out of 28 EU Member States have adopted implementation laws:
  - Portugal, Greece and Slovenia's bills are still under discussions with increasing pressure from the European Commission;[2]
- unequal health data processing legal framework in the EU;
- data security: the top priority of the EU data privacy authorities in the healthcare sector. The main issue raised over the last year is cybersecurity breaches. Reports consider that most companies are vulnerable to cyberattacks. The year 2018 exceeded the previous year's vulnerability influx, with a reported 12 per cent rise over 2017's total of vulnerabilities published;[3]
- the first fine under GDPR in the health sector took place in Portugal, by the Comissão Nacional de Protecção de Dados (CNPD): €400,000 fine against the Centro Hospitalar Barreiro Montijo for GDPR security violations;
- a reminder of GDPR maximum fines:
  - up to €10m or, in the case of a company, two per cent of their global annual turnover for a first level of breaches such as privacy by design, privacy by default, PIA, etc; (article 83/4 GDPR);
  - up to €20m or, in the case of a company, four per cent of global annual turnover for a second level of breaches, in particular of individuals' rights – rights of access, rectification, opposition, deletion, right to be forgotten, etc. (article 83/5 GDPR); and
- end of the tolerance period in April 2019, as announced by the CNIL (French Data Protection Authority).

Worldwide influence of GDPR

The GDPR has had a powerful influence across the world with extended geographical coverage. A number of states have updated their data privacy regulation. For instance:

In the summer of 2018, Brazil passed a law inspired by GDPR, with measures ensuring a similar level of data protection (see below).

In the US, the California Consumer Privacy Act (CCPA), 'GDPR Lite', will come into force in 2020. There have also been discussions at federal level and a public consultation on data privacy launched by the Trump Administration in September 2018. Big tech players such as Microsoft and Apple are calling for stricter rules.

India's most recent relevant legislation includes the IT Act 2000, Rules and Clarification in 2011,

and the 2017 Privacy Judgement in 2017. The Indian Government has formed a committee to examine issues relating to data protection and a bill could be published in the coming months.

Fostering international data transfer?

- 13 Decisions of adequacy taken by the European Commission (Article 45) – Andorra, Argentina, Canada (for commercial businesses and data flows), Faeroe islands, Guernsey, Israel, Isle of Man, Jersey, New Zealand, Switzerland, Uruguay, US (privacy shield), Japan (since January 2019);
- privacy shield under scrutiny by the European Commission;
- ongoing discussions with South Korea for an inclusion in the 'team';
- a risk that Canada's adequacy decision could be withdrawn?
- what about other issues such as Brexit and the US Cloud Act?

Brazil's new Data Protection Law

On 14 August 2018, the Brazilian Data Protection Law (LGPD) was adopted and is expected to come into force on 16 August 2020. Brazil's data protection legislation is now more comprehensive and closely mirrors GDPR.

Over 35 legal provisions in the Brazilian Legal Framework address data protection, such as, the Consumer Protection Code, Telecommunication General Law, Internet Civil Framework, Access to Information Law, Charter of Rights of Health Users', Code of Medical Ethics and Good Pharmacy Practices, among others.

The main aspects of the LGPD:

Applicability

- Territorial:
  - the data processing shall be carried out in the Brazilian territory;
  - data processing activities' purpose is the supply of goods or services or concerns individuals located in Brazil; and
  - the data has been collected in Brazil.
- Material:
  - Processing of personal data, including by digital means, carried out by a natural person or legal entity governed by public or private law.

What is data?

- Personal data: any information related to an identified or identifiable natural person; and
- sensitive personal data: personal data on racial or ethnic origin, religious belief, political opinion, affiliation with a trade union, or religious, philosophical or political organisation, data relating to the health or sex life, genetic or biometric data, whenever related to a natural person.

Anonymisation and pseudonymisation

- The use of reasonable technical means available at the time of processing, through which the data loses the possibility of direct or indirect association to a natural person; and
- it is the processing technique, though which the data loses the possibility of direct or indirect association to a natural person, except for the use of additional information kept separately by the controller in a safe, controlled environment.

Legal grounds for processing personal data

- Consent;
- compliance with law or regulation;
- execution of public policies;
- study by research institutions;
- performance of a contract/preceding a contract;
- regular exercise of rights;
- protection of life;
- protection of health;
- credit protection; and
- controller/third party's legitimate interest.

Brazil's National Supervisory Authority (ANPD)

The ANPD shall be created with no increase in expenditure and as a federal public administrative body that is part of the Presidency of the Republic. The ANPD shall be responsible for:

- ensuring data protection;
- editing rules and procedures on the protection of personal data;
- interpreting the LGPD, its powers and omissions;
- requesting information at any time from the controllers and operators of personal

data that carry out operations of processing personal data;
- implementing mechanisms for recording complaints about the processing of personal data;
- inspecting and issuing sanctions;
- preparing studies on national and international practices for the protection of personal data and privacy; and
- promoting cooperation with data protection authorities of other countries.

Impact of the LGPD on the health sector

Hospitals and health clinics

These establishments process data for screenings, check-ups, and appointments. It is necessary to control the information as of the first contact with the patient.

Applications

The transfer of personal data and sensitive personal data through the internet shall observe good faith and follow principles such as purpose, adequacy, need, free access, quality of data, transparency, security, prevention, non-discrimination, liability, and accounting.

Patient's records

Healthcare professionals may only collect necessary information for the rendering of healthcare services and must store the information for the period determined by law.

Health insurance companies

Data subjects have the right to request the portability of their personal data and sensitive personal data from one service provider to another.

Clinical trials

Trials are regulated by specific laws in Brazil. These laws provide the manner and type of information that may be processed and collected from the data subject depending on the structure of the trial.

Notes

1 Since our roundtable on 31 May 2019, other important decisions have been taken by local protection authorities such as a possible £183m sanction against British Airways or £99m against Marriott in the UK (8-9 July 2019).
2 As of 10 July 2019.
3 Skybox, *Vulnerability and Threat Trends Report*, 2019.