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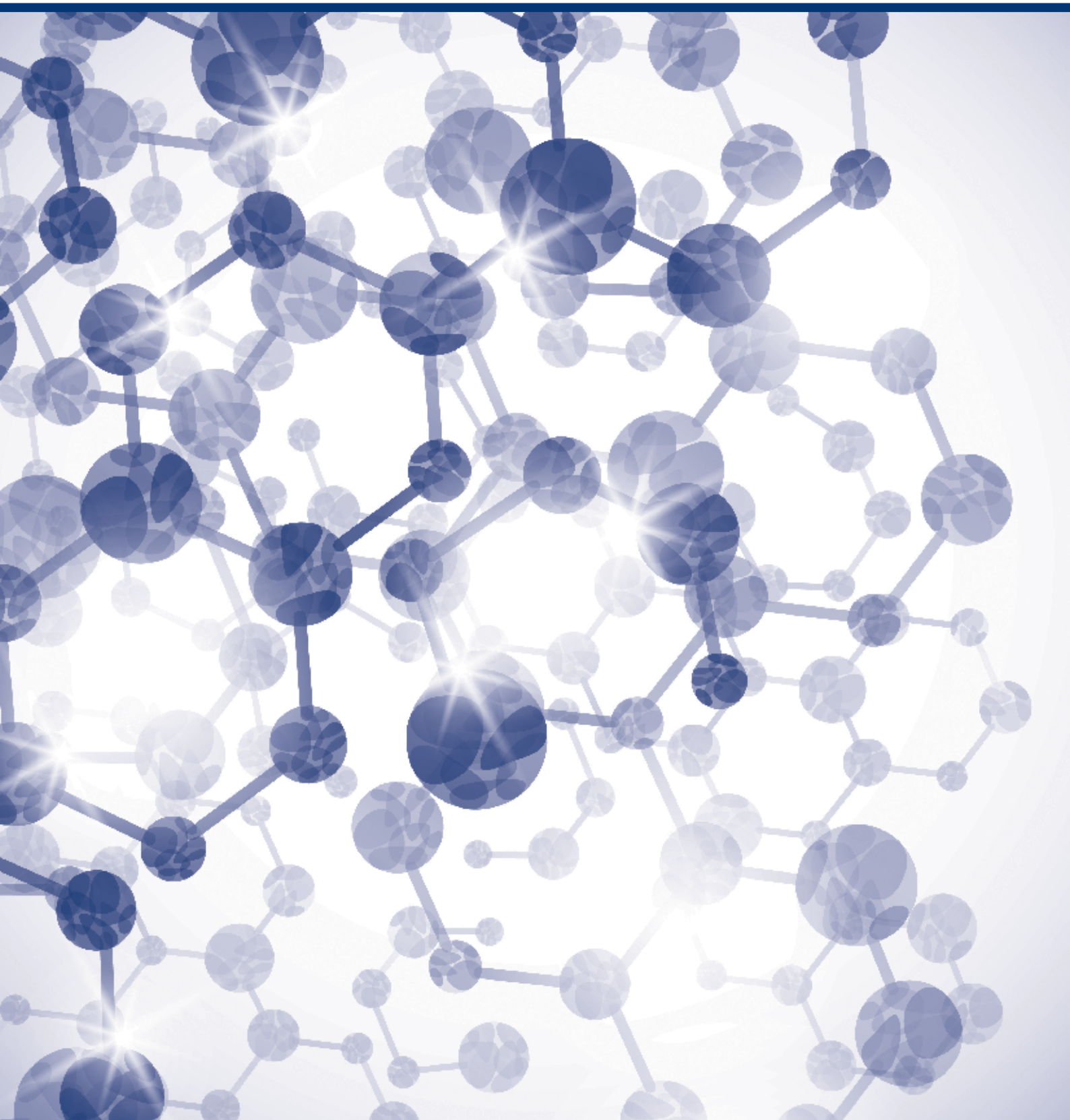

International Bar Association Conferences 2017–2018




2017

6–8 SEPTEMBER 2017 ETC.VENUES, LONDON, ENGLAND
IBA Europe-Caucasus-Asia (ECA) Forum

8–9 SEPTEMBER 2017 ST REGIS, FLORENCE, ITALY
21st Annual Competition Conference

WEBINAR 12 SEPTEMBER 2017, 1300 BST
Legal directories – the bane of the lawyers' lives, or the way to the stars?

14 SEPTEMBER 2017 MARINA BAY SANDS, SINGAPORE
The Fundamentals of International Legal Business Practice

14–16 SEPTEMBER 2017 HILTON BRUSSELS GRAND PLACE, BRUSSELS, BELGIUM
6th Construction Projects from Conception to Completion

8–13 OCTOBER 2017 INTERNATIONAL CONVENTION CENTRE, SYDNEY, AUSTRALIA
IBA Annual Conference 2017

IBA 2017 Sydney 8–13 OCTOBER
ANNUAL CONFERENCE OF THE INTERNATIONAL BAR ASSOCIATION

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2–3 NOVEMBER 2017 MANDARIN ORIENTAL HOTEL, HONG KONG SAR
Asia Pacific Mergers and Acquisitions Conference

4 NOVEMBER 2017 HANOI, VIETNAM
IBA-APAG International Arbitration Training Day: Introduction of the IBA Soft Laws

4–5 NOVEMBER 2017 QUEEN MARY UNIVERSITY OF LONDON, ENGLAND
IBA-ELSA Law Students' Conference

6–7 NOVEMBER 2017 SÃO PAULO, BRAZIL
Latin American Anti-Corruption Enforcement and Compliance

10 NOVEMBER 2017 MOSCOW, RUSSIAN FEDERATION
9th Annual 'Mergers and Acquisitions in Russia and CIS' Conference

13 NOVEMBER 2017 CORINTHIA HOTEL, WHITEHALL PLACE, LONDON, ENGLAND
Once in a Lifetime Opportunity or Cliff-Edge Threat: The Antitrust Implications of Brexit

15 NOVEMBER 2017 LEVEL 39, 1 CANADA SQUARE, CANARY WHARF, LONDON, ENGLAND
European Start Up Conference 2017

15–17 NOVEMBER 2017 THE GRANGE ST PAULS, LONDON, ENGLAND
8th Biennial Global Immigration Conference

15–17 NOVEMBER 2017 LABADI BEACH HOTEL, ACCRA, GHANA
Rising to the Challenge of Africa's Development

16 NOVEMBER 2017 FOUR SEASONS HOTEL LONDON AT PARK LANE, LONDON, ENGLAND
Private Equity Transactions Symposium

17 NOVEMBER 2017 MONDRIAN LONDON, LONDON, ENGLAND
Building the Law Firm of the Future

30 NOVEMBER – 1 DECEMBER 2017 BUENOS AIRES, ARGENTINA
The New Era of Taxation: How to Remain on Top in a World of Constant Evolution

1 DECEMBER 2017 MOSCOW, RUSSIAN FEDERATION
11th Annual Law Firm Management Conference

7–8 DECEMBER 2017 MILLENNIUM BROADWAY HOTEL, NEW YORK, USA
Investing in Asia

7–8 DECEMBER 2017 JUMEIRAH FRANKFURT, FRANKFURT, GERMANY
4th Annual Corporate Governance Conference

2018

18–19 JANUARY 2018 HONG KONG SAR
IBA Law Firm Management Conference: Growth Prospects for Law Firms in Asia

29–30 JANUARY 2018 ETC.VENUES, FENCHURCH STREET, LONDON, ENGLAND
7th Annual IBA Tax Conference

1–2 FEBRUARY 2018 THE WESTIN PARIS – VENDÔME, PARIS, FRANCE
6th IBA European Corporate and Private M&A Conference

14–16 FEBRUARY 2018 PARIS INTERCONTINENTAL, PARIS, FRANCE
IBA/ABA International Cartel Workshop

23–24 FEBRUARY 2018 HOTEL EUROSTART GRAND MARINA, BARCELONA, SPAIN
3rd Mergers and Acquisitions in the Technology Sector Conference

25–26 FEBRUARY 2018 BUENOS AIRES, ARGENTINA
21st Annual IBA Arbitration Day

5–6 MARCH 2018 LONDON, ENGLAND
23rd Annual International Wealth Transfer Practice Law Conference

8–9 MARCH 2018 HONG KONG SAR
3rd IBA Asia-based International Financial Law Conference

9–10 MARCH 2018 THE TAJ MAHAL PALACE, MUMBAI, INDIA
The Changing Landscape of M&A in India – New Opportunities in a Dynamic India

11–13 MARCH 2018 LONDON, ENGLAND
18th Annual International Conference on Private Investment Funds

14–16 MARCH 2018 HYATT REGENCY HOTEL AND INTERCONTINENTAL PRESIDENTE HOTEL, MEXICO CITY, MEXICO
Biennial IBA Latin American Regional Forum Conference

Full and further information on upcoming IBA events for 2017–2018 can be found at: **bit.ly/IBAConferences** @IBAevents

IN THIS ISSUE

FEATURE ARTICLES

Contributions to this Committee Update are always welcome and should be sent to
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This update is intended to provide general information regarding recent developments in healthcare and life sciences law. The views expressed are not necessarily those of the International Bar Association.

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From the Website Officer

As a new member and Website Officer of the Healthcare and Life Sciences Law Committee, I am truly honoured to introduce this update covering important topics for the industry from all over the world. Once again, our contributors have been keen to join us as part of this exciting opportunity ahead of the coming IBA Annual Conference in Sydney.

From compliance constraints to big data through the fight against drug counterfeiting, to name but a few, the healthcare and life sciences sector currently faces many challenges as well as opportunities. Stakeholders must constantly adapt themselves to this ever-changing society and lawyers or legal counsels have a key role to play to accompany their clients and partners in this more and more globalised landscape.

In light of recent advances across the healthcare and life sciences environment, I am pleased to announce that the main topic chosen by our contributors for this new edition deals with the digitalisation of practices and access to products and data at a national or international level, and how their use represents new sources of value for the healthcare and life sciences industry at large. With increased opportunities also come greater risks, and thus there is the need for solid safeguards to protect all players, including patients, caregivers and businesses, more particularly from a legal perspective.

In this issue, our contributors will cover the following issues:

Health open data

There is no more doubt that data is gold and that its access must be facilitated to foster both the economic and public health interest. On this subject, Yolanda Puiggròs, from Roca Junyent, Barcelona, presents the case of Catalonia (Spain), which has developed two different and subsequent programmes for big data (anonymised data) in healthcare. While the former has been suspended, the latter permits access to big data in healthcare for public entities, research centres and companies.

Another example may be found in France, with a brand new National Register of Heath Data, which was put in place in 2016 and has been accessible since 2017. Open to both public actors and private undertakings subject to specific security and privacy conditions, it is meant to boost research and innovation, help manage expenditures in a more efficient way and more globally improve the functioning of the healthcare system for the whole community. I, Cécile Théard-Jallu, together with Nina Gosse, from De Gaulle Fleurance & Associés, Paris, propose to introduce the main features of this new database, which is in line with the European Union initiative to sustain the free flow of data and the opening of public databases, but also raises the question of how data privacy is ensured in today's big data context.

Online sale of drugs

The online sale of drugs is an important consideration as society's consumption habits rapidly evolve and more drugs are sold online on a global basis.

Sharon Gazit, from Goldfarb, Seligman and Co Law Offices, Tel Aviv, reviews the current legal status of online sale of drugs in Israel, and more precisely, presents the position of the Israeli Ministry of Health with respect to addressing risks of buying medications (whether prescription or over the counter) online.

For their part, Elisa Stefanini and Marco Blei, from Portolano Cavallo, Milan, provide a framework of the Italian regulations around the online sale of drugs, clarifying, in particular: which drugs can be sold online; who can offer such drugs online; and what are the main requirements to meet in order to conduct such an activity.

Counterfeited drugs

A further important and well-known issue is considered by Giovanna Cento, from Luiss Guido Carli University, Rome: 'The Struggle Against Falsified Medicines in the European Framework'. While almost all big nations have launched their anti-counterfeiting programmes through the use of track and trace technologies, the European Union has launched its own through the use of a unique identification number, so called 'serialisation',

to be marked on the packaging and collected in national databases throughout the EU, which are connected through a hub, accessible to a number of stakeholders. The new set of actions and tools will need to be implemented no later than February 2019. This topic is, in fact, closely linked to the preceding ones as a lot of counterfeited drugs are sold online and as these national 'serialisation' databases also contribute to the sharing and free flow of data within the EU.

Another crucial topic is early access to medications. Jordi Faus and Francisco Aránega, from Faus & Moliner, Barcelona, provide us with their input as to how this works in Spain: in this country, a medicine that is not authorised and/or that is pending a decision regarding its reimbursement may be available for use with patients through compassionate use or early access programmes pertaining to medicines that are authorised and already marketed in other countries.

Lastly, you will find in our update the point of view of Christian Lopez-Silva from Baker McKenzie, Mexico City, regarding the increased interest of the Mexican Antitrust Authority in the life sciences industry. In line with what is happening in many other jurisdictions, several actions and cases concluded or initiated recently show the various tendencies going on in Mexico in this domain. This includes, for instance, the launching of a large market investigation in relation to medicines whose patent protection has expired, or of several cartel investigations on both the public and private markets, including the manufacture, distribution and commercialisation of drugs, as well as the public acquisition of blood bank and diagnostics services.

It is our hope that you will gain new insights from these articles and that they will encourage all of us to further discuss these new tendencies in our respective countries. The Healthcare and Life Sciences Law Committee will be happy to help these discussions going forward.

For those attending the IBA Annual Conference in October in Sydney, we look forward to discussing these topics and others with you there. For those who will not be attending, let's create opportunities to get together electronically through our committee's website, where you can post questions and articles at any time – and, of course, we hope to see you in Rome next year.

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

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Unlocking the value of health data: implementation of a new 'National Register of Health Data' in France

Summary

In 2016, France established a new 'National Register of Health Data', bringing together its main existing public health databases. It aims to improve knowledge on medical care, facilitating research in the field of health, and more globally improving the functioning of the healthcare system for the whole community. This is in line with the European Union initiative to sustain the free flow of data and the opening of public databases. However, it raises the question of how data privacy is ensured for the data that will be accessed through this new register in today's big data context.

Introduction

In January 2016, the French Parliament enacted a new Act on the modernisation of the French health system (the 'Act').[1] Among other topics, it introduced provisions in the French Public Health Code (the FPHC)[2] creating the conditions for an open access to health data, mainly through:

- the creation of the National Register of Health Data (NRHD – Système National des Données de Santé or SNDS), that is, a new database gathering different pre-existing medico-administrative databases which were so far subject to special access and security conditions; and
- the creation of the National Institute on Health Data (INDS – Institut National des Données de Santé), to control the quality and confidentiality of health data and facilitate its access and use through the NRHD.

Thanks to the NRHD, the smarter analysis of the now accessible huge volume of data collected by health professionals or organisations is considered capable of ameliorating public healthcare knowledge and management, including through: a better understanding of pathologies and the ways to prevent them; an identification of effective versus ineffective treatments; a support to healthcare innovative research or sanitary supervision; or a targeted reduction of public health expenditure. In other words, the NRHD's ambition is to allow for a large-scale exploitation of health data for the benefit of the whole society.

However, this initiative has been controversial, considering the highly sensitive stake it relates to, that is, centralising and making available personal data concerning the health of 66 million French citizens.

Let's see at a glance, how this new database works; how data privacy is meant to be preserved despite the introduction of an increased access right to health data; and how this fits into the wider tendency of leveraging value from big data.

Overview of the NRHD's modus operandi: an increased access to pre-existing large-volume databases

Decree No 2016-1871 of 26 December 2016, which entered into force on 1 April 2017, specifies the NRHD's operating procedures. While managed by the National Health Insurance Fund for Employees (CNAMTS – Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés), the NRHD puts together several national pre-existing public health databases including:[3]

- health insurance data (SNIIRAM);*
- hospital data (PMSI);*
- data on the medical causes of deaths (CepiDC);**
- data related to handicaps (CNSA);** and
- samples of data from complementary health insurance bodies.**

Based on the above, the NRHD's ambition is to gather a large range of data about

such varied subjects as care receivers (eg, gender, date and place of birth, medico-administrative information), compulsory/complementary health insurance schemes, health professionals or medico-social actions.

Data will be retained in the NRHD for up to 19 years plus the year of data collection and then archived for a further ten-year period.

Outside the NRHD, some anonymous datasets, which do not allow for the identification of individual persons, will be made available to, and freely reusable by, all stakeholders (under certain conditions). For other (pseudonimised) data, not made freely available to the public, two types of accesses shall exist:

- a 'permanent access', for the benefit of an identified list of public services or public bodies (eg, the National Agency for Health Products Safety or Regional Health Agencies) for the accomplishment of their missions, within the limits set by the above Decree No 2016-1871; or
- a 'one-time access', subject to a prior authorisation by the French Data Protection Authority (CNIL – Commission Nationale de l'Informatique et des Libertés), for other bodies (eg, private structures) or organisations theoretically authorised to permanently access the NRHD but willing to do so under conditions exceeding the limits of the Decree.

This 'one-time' access may only be authorised for research, study or evaluation activities conducted for a 'public interest reason' and subject to specific conditions, including a post-study communication obligation. The 'public interest' criterion is not defined in the Act. Consequently, the INDS will be left with the important task of determining the basis for its existence. On a project-by-project basis, the INDS may be required to do so by the CNIL or the French Health Minister. It may also decide to rule on this notion on its own initiative. In any case, the INDS will ask for the opinion of an expert committee and be required to provide its answer within one month following the request of a data access applicant.[4] Industrial or research operators are waiting for this open access mechanism to be enforced and insist on a clear and reliable doctrine around the notion of 'public interest' to be established, so as to get some visibility for their contemplated research activities. A working group has already been set up within the French National Industry Council to work on this topic and has underlined that the 'public interest' can be assessed by the capacity of a study to produce a collective benefit (eg, medical research involving a very large number of people, such as on the care pathways for people with long-term illnesses).[5]

In any event, access to the NRHD will be prohibited if it is for:

- promoting health products to healthcare professionals or healthcare centres; or
- excluding an individual, or a group of individuals presenting the same risk, from the benefit of insurance contract guarantees or modifying their insurance premiums.

Conditions are even more stringent for healthcare and insurance companies when following a commercial purpose, as these entities may only access the NRHD provided they can prove that: (1) the procedures for implementing the data processing make it impossible to use the data for any of the above-mentioned prohibited purposes; or (2) they will resort to the services of a research laboratory or a private or public study office (*bureau d'études*) to conduct the processing.

Data access shall be free for studies or evaluations requested by the public authority or those performed by entities entrusted with an administrative public service mission.

The need for data protection safeguards when implementing open access

To date, the data collected in the NRHD is only pseudonymised, that is, it does not allow to directly identify an individual (no first name, last name, social security number or mail address for instance) but still permits a re-identification. This has raised concern, as health data is considered 'sensitive' data under the French Data Protection Act No 78-17 of 6 January 1978, as amended (LIL – Loi Informatique et Libertés)[6] and, as such, is subject to a restrictive regime. Indeed, its processing is prohibited unless specific exceptions apply, such as:

- the collection of the individual's express consent;
- any processing that is necessary for the purposes of preventive medicine;
- medical diagnosis;
- the provision of healthcare or a medical treatment; or
- for the management of healthcare services carried out by a member of the medical profession;
- statistical processing carried out by the

French National Institute of Statistics and Economic Studies (INSEE); or
- processing necessary for medical research purposes.

Consequently, the challenge faced by the French Parliament was to find the right balance between this protective legal regime and the need to allow for the open access to health data and their valorisation aimed at improving the healthcare system.

On 13 October 2016, the CNIL gave its opinion regarding the creation of the then future NRHD.[7] It stressed that the then considered security measures were not sufficient, raising criticism of reliability of the database and emphasising the obsolescence of the encryption algorithm to be used. Noting that up to 3,000 potential users will have access to the NRHD, it consequently requested a close follow-up of all authorisations granted, data access conditions and strong access management. Lastly, the CNIL requested some communication and strong security commitments on the part of the data controller of the NRHD.

Following this statement, a new safety reference framework (describing a series of security measures) was instituted by a Ministerial Order of 22 March 2017.[8]

In addition to the NRHD, this safety reference system will need to be observed by all information systems dealing with health data coming from the NRHD. Two years are granted to reach full compliance with the new standards. In the meantime, data controllers shall design compliance action plans and conduct risk assessments to ensure personal data protection. Additionally, they shall immediately enforce the necessary measures to ensure data confidentiality and integrity as well as access traceability. The Order expressly mentions the importance for operators to be able to prove their compliance with both the LIL and the GDPR (the latter being enforceable as of 25 May 2018).

Individuals shall be informed of the constitution of the NRHD and the possible reuse of their data for research purposes through specific notices described on the website of data controllers and posters in their premises, and/or the delivery of dedicated documents. They shall have the right to object if not willing to have their data contained in the NRHD, except for those processing activities implemented by state services or certain public institutions in the scope of their missions (eg, monitoring of an epidemic or health surveillance). Rights of access, rectification and, where applicable, opposition, can be exercised with the sponsor of the study, establishment or health professional, or the director of the beneficiary's health insurance fund concerned.

The re-identification of a patient may occur in exceptional cases, in particular to warn them of a serious health risk to which they would be exposed, or to propose a contribution to a specific research programme, provided there is no other alternative for their treatment. This information will be entrusted to a separate 'trusted third party' – to be designated by a decree – responsible for ensuring the security of the patient's data and delivering it to the applicant, subject to authorisation by the CNIL.[9]

Despite the above measures, some concerns remain (for instance, among the medical profession)[10] about whether they will be sufficient in practice. A watchful eye will need to be kept on the interpretation given to the 'public interest' criterion, guarantees of anonymity and the non-reuse of data for commercial purposes.

Modern health systems: leveraging value from big data for better health outcomes

There is no more doubt for both public and private organisations that data is giving rise to a new economy and value, so much that it is called the new 'gold', 'soil' or 'fuel' of the future. Data is not only a valuable asset, but also has the power to benefit society as a whole. From this point of view, the movement of opening health data must be fostered and is in line with the new 'free flow of data' initiative currently supported by the European Union as part of its strategy for the Digital Single Market.[11] On top of EU data flow legislation announced for autumn 2017, the EU Commission also announced that, by spring 2018, it will introduce an initiative to encourage public authorities to share data. The new French NRHD is therefore fitting this initiative.

However, it raises the question of ethics around the holding and exploitation of health data. The French NRHD introduces a new occasion to observe that, under French law, individuals do not have a right of ownership over their personal data, which rather must be seen as an extension of the human body that remains under their control.[12] This peculiar nature of health data

'empowers' individuals with some rights but these rights are not unlimited, especially when the public interest is involved. This emphasises the basic principle that non-anonymised health data may not be the subject of a commercial transfer, even with the data subject's consent.[13]

In this respect, a distinction shall be made between personal data and other types of data, even when the demarcation line is thin. A topical example may be found with the serialisation of pharmaceutical drugs. Indeed, with the publication of the EU Delegated Act on safety features[14] on 9 February 2016, those who manufacture, sell or dispense medications in the EU have until February 2019 to comply with new track and trace measures at the packaging level, as outlined in the Falsified Medicines Directive (FMD).[15] The Delegated Act makes a clear distinction between personal data and other data generated by actors of the pharmaceutical supply chain; on the second category of data, those actors have a right of ownership and access (see for instance Articles 351 (h) and 38 of the EU Delegated Act).

Although this does not apply to the same data, it seems worth comparing the NRHD with the principles around the new serialisation databases, which will soon be established throughout the EU. Indeed, serialisation also presents exciting opportunities for the industry (greater transparency, enhanced monitoring of and efficiency in processes, increased consumption visibility, reduction of costs). In both cases, there is room for companies to drive value beyond compliance and the above developments share one objective: being ready for the Digital Health Revolution.

* Became accessible as of 1 April 2017.
** Will gradually become available by 2019.

Notes

1 Act No 2016-41 of 26 January 2016.
2 Article L1460-1 et seq of the FPHC.
3 Article L1461-1 of the FPHC.
4 Article 54 of the French Data Protection Act No 78-17 of 6 January 1978, as amended.
5 National Industry Committee, CSF report, 'Promote an active approach to facilitate access to health data for public health purposes, research and industrial development', 29 March 2017.
6 A very similar approach is followed by the EU General Data Protection Regulation 2016-679 of 27 April 2016 (or 'GDPR'): for the first time, the GDPR provides for a definition of the notion of health data that is wide in its scope as covering the past, present and future mental or physical health status of a person.
7 Opinion No 2016-316 of 13 October 2016 on the NRHD.
8 Ministerial order of 22 March 2017 regarding the safety reference system applicable to NRHD.
9 Article L1461-4 of the FPHC.
10 Communication by the French Physicians Labour Union (Fédération des Médecins de France) against the allegedly 'approximate protection of health confidentiality' and 'general and hasty conclusions' in relation to the NRHD of 6 April 2017 www.fmfpro.org/la-fmf-dit-non-a-la-diffusion-des-donnees-de-sante-a-tous-vents.html.
11 In January 2017, the European Commission announced the preparation of several initiatives to develop a data-driven European economy including to reduce barriers around data locations, and foster data access and transfers, data portability, interoperability and standards http://europa.eu/rapid/press-release_IP-17-5_en.htm.
12 See the position of the French Digital Council (the CNNum) set in two reports of 2015: 'Ambition numérique' and 'La santé, bien commun de la société numérique' and, more recently (May 2017), its opinion on the European free flow of data initiative.
13 Article 1111-8 of the FPHC.
14 Commission Delegated Regulation 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC.
15 Directive 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, regarding the prevention of the entry into the legal supply chain of falsified medicinal products.

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