IN
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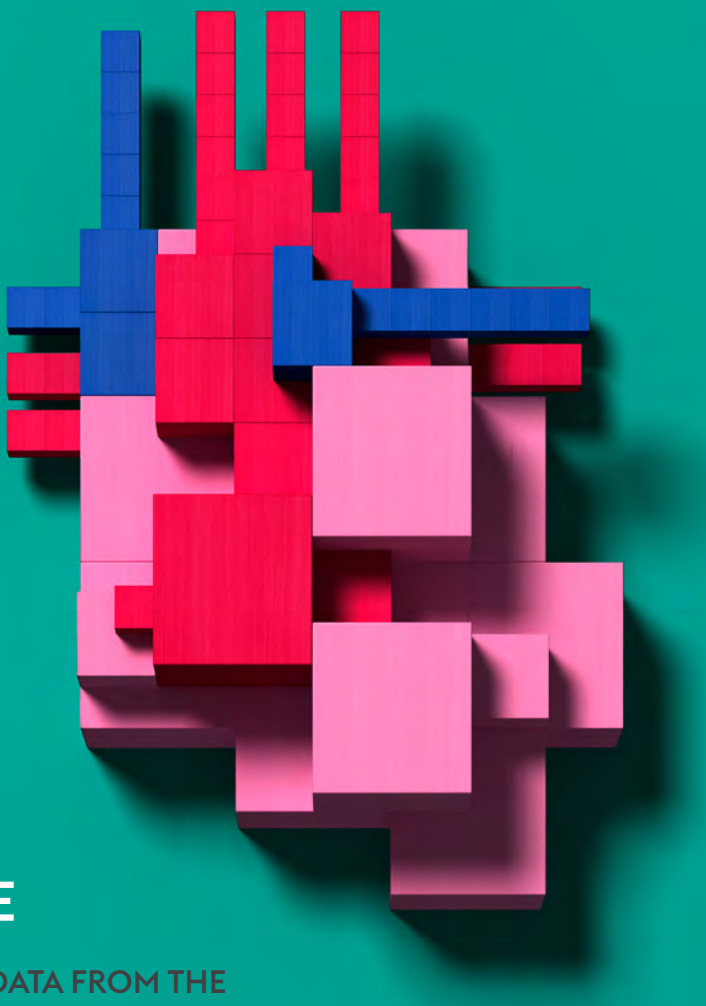
HEALTHCARE

SPOTLIGHT ON THE INDUSTRY



A LOOK INSIDE

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IN THIS ISSUE

The global healthcare industry has had the most challenging year in living memory. But 2021 is a new year. Alongside new challenges, such as whether or not healthcare employers can or should make COVID-19 vaccines mandatory for employees, and the uncertainty surrounding the transfer of European health data post-Schrems II, there are also many new opportunities.

Sovereign Wealth Funds are increasingly seeing the health sector as an attractive investment market, and Social Impact Bonds have emerged as an excellent financing option for development projects that might otherwise find it hard to attract initial funding.

Healthcare companies still, of course, need to pay close attention to their commercial operations. As the market evolves to meet the new normal of an increasingly online and app-centric world, the need for robust agreements with software developers becomes ever more important. And the sector will always be the target of investigations into excessive pricing, and subject to developments relating to key tools such as Supplementary Protection Certificates. But the time has come to be cautiously optimistic and to look to the future of healthcare.

Please contact me if you have any comments on our articles or would like to discuss any of the issues raised.

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SOVEREIGN WEALTH FUND INVESTMENT IN THE GLOBAL HEALTHCARE INDUSTRY

Hamid Yunis

Sovereign Wealth Funds (SWF) seek out investments that are resilient, conducive to their aims and objectives, and reasonably free from market volatility. The global healthcare industry is therefore an attractive market for SWF investment.

Sovereign Wealth Funds are state owned entities that are used as an investment vehicle by a state, and where the original investment funds are usually derived from state generated sources. SWFs in turn make investments into a variety of real and financial assets such as stocks, bonds, real estate, commodities, private equity, and other trading arrangements. They invest both in their domestic markets and also increasingly on a global basis, and are important funding and investment sources alongside traditional investors.

SWF: AIMS AND OBJECTIVES

It is important to understand that SWFs have additional aims and objectives, and different characteristics, when compared with other investors. These manifest themselves in the way SWFs formulate and adopt their risk policies (including appetites and tolerances), the manner of their investment, their liquidity requirements, the length of their investment timelines, and how they organise other priorities.

Occasionally, these priorities can include environmental, social, and corporate governance (ESG) aims. In particular, an SWF may look at the societal benefits of an investment and not just the obvious economic or financial benefits. This is an increasing trend in investment; see page 13 for more information on ESG and social impact finance.

SANTIAGO PRINCIPLES

A good starting point when discussing the investment approach taken by SWFs is the 24 generally accepted principles and practices voluntary endorsed and adopted by SWF members of the International Forum of Sovereign Wealth Fund (IFSWF) in 2008. These principles have developed over the years but the Santiago Principles, as adopted by members of the IFSWF, continue to promote transparency, good governance, accountability, and prudent investment.

Key principles include the following:

- The legal framework for an SWF should be sound and support its operations.
- The policy purposes should be well-defined and publicly disclosed.
- Where activities have significant direct domestic and macro-economic implications, activities should be coordinated with the relevant fiscal and monetary authorities.
- Reporting to the governing body should be conducted on a regular and timely basis.
- Annual audits should be conducted in accordance with recognised international or national auditing standards.
- Where third parties are involved in the operational management, these activities should be conducted in compliance with best practice and based on sound financial and economic principles.
- Professional and ethical standards should be applied as a minimum and be clearly defined and known to all involved in the SWF's management and business.
- Activities should be in compliance with all applicable regulatory and disclosure requirements of the countries and jurisdictions in which the SWFs operate.
- There should be public transparency to demonstrate the economic and financial orientation of the SWF, and to contribute to stability in the international financial markets.
- The investment policies of an SWF should be clear and consistent with defined objectives, and take into account risk tolerance, including leverage, selection of target, *etc*.
- There should be no advantage gained by using privileged, confidential information, or inappropriate influence applied in competing with private or third-party entities.
- Any investment should view the SWF's shareholder ownership rights as a fundamental element of their equity investment. Any exercise of such ownership rights should be done in a manner that is consistent with the SWF's investment policy and with the purpose of protecting the financial value of its investment.

The full extent of the Santiago Principles and their adoption by an SWF, or by its specific fund vehicle or investment entity, are a good indication as to how an SWF will approach a particular investment and should be fully understood by other parties when approaching or dealing with an SWF.

SWFs see the healthcare sector as an attractive, sustainable, and resilient market.

INVESTMENT IN HEALTHCARE

The rapid pace of change in the global healthcare industry has created many opportunities for SWFs to invest and most of the largest SWFs see the healthcare sector as an attractive, sustainable, and resilient market. Developments in technology and innovation in particular have created opportunities for SWF investment.

SWFs have recently invested in the following areas, amongst others:

- Healthcare services and facilities; including hospitals, specialty hospitals (such as mental health and high dependency units) nursing care, ambulatory care services, teaching or university hospitals, and healthcare professionals.
- Medical devices, equipment and hospital supplies manufacturers: including surgical instruments and supplies; dental and ophthalmic equipment; cancer care/radiotherapy equipment; and digital, remote, telehealth, and fertility equipment.
- Medical insurance, medical services and managed care: including health maintenance organisations, pharmacies, and similar providers or services.

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- Pharmaceuticals and related segments: including research and development, drug development (at the later stages), over-the-counter drugs, biotechnology, biopharmaceutical drugs, generic drugs, vitamins and supplements, and opticians stores.

The increase in the use of technology, and the swift pace of innovation in the global healthcare industry is very attractive to SWFs. As the global pandemic has changed behaviours, working and travel patterns are likely to evolve further, and the opportunity to utilise remote, internet based technology has created new and potentially vast opportunities. In particular, the digital, remote and telehealth sectors present opportunities for rapid growth and investment and innovative partnerships for growth. SWFs can use their investing ability to invest globally in opportunities for technology transfer, and the creation of new and creative business models.

For example, there has been a trend towards innovative capital structures to support research by, and the commercialisation of, companies owned by universities or other educational institutions.

A typical structure would involve the setup of a commercial entity, where both the university and the investor take an equity stake and may also have other roles and responsibilities. An SWF may provide investment and financing to support research originating from the university, in return for a certain percentage of the equity in the vehicle. The ability to reengineer the investment or product back into an SWF's domestic market, and the synergies between the university and the educational and research establishment "back home" can also be persuasive factors.

There are many examples around the world of SWFs involved in healthcare investment and related transactions, including in Egypt, Russia, Turkey, Qatar, UAE, Saudi, Singapore, Malaysia, Canada, Nigeria, and Norway.

COLLABORATION AND/OR CO-INVESTMENT

Unrealistic valuations and asking prices driven by very competitive private equity (PE) demand and stock market/IPO volatility, have all provided challenges for SWFs. As long-term investors looking for value, SWFs have therefore increasingly invested alongside a range of different investment partners, including PE funds.

Notwithstanding the trend towards co-investing, challenges for an SWF's investment activity still exist. These include:

- The limitations of the conventional limited partner/general partner (LP/GP) Fund structures.
- Fee structures generally.
- Fund life cycles.

If it is felt that the basic private equity model does not necessarily create an alignment of interests, or maximise the preferred timeline benefits for an SWF investor, there are possibly other, more favoured structures, such as deal-by-deal co-investment and ongoing evergreen funds.

NATIONAL AND POTENTIAL CONCERNS, INCLUDING FOR FDI

An important point to bear in mind, and particularly relevant where SWFs are investing outside their domestic market, is the restriction around foreign

direct investment (FDI). Investors, like SWFs, that acquire assets outside their domestic markets and are directly or indirectly linked to governments, have to balance their investment profile with the underlying political or economic considerations. Countries that apply FDI restrictions, to a greater or lesser extent, include most of the European Union, the United Kingdom, Australia, Canada, China, India, Japan, and the United States.

Such restrictions move beyond the concept of national security, as this is sometimes considered to be too broad to provide guidance to regulators and participants, for its actual implementation in practice. There is also debate surrounding FDI "acceptability thresholds" in certain jurisdictions that help to determine if FDI in a particular sector is acceptable. This threshold could take into account the landscape in which a business operates, the type of foreign investor, the local political environment, and the influence of other parties.

OPPORTUNITIES

SWFs are keen, active, and important investors in the global healthcare industry. Their aims and objectives are generally conducive to co-investing with other investors, and the economic and financial benefits of their involvement, both in terms of their ability to invest substantial sums and their wider aims and objectives, makes them an attractive partner. They are likely to continue to see the industry as a good opportunity for growth and in need of active investment, which should also help in the ongoing drive for better governance and representation, and perhaps create more impetus for regulatory intervention in cross-border activity.

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IP OWNERSHIP CONSIDERATIONS IN MULTI-JURISDICTIONAL SOFTWARE DEVELOPMENT AGREEMENTS

Edward A. Gordon and Cecilia Choy, Ph.D.

The use of overseas contractors to develop software applications may be cost-effective, but is potentially risky from the point of intellectual property rights.

As a result of the healthcare sector's growing dependence on software, health IT companies are increasingly taking advantage of globalisation to engage contractors in low wage jurisdictions to develop their user-facing software applications.

This can trigger unforseen legal risks owing to the differing laws across jurisdictions related to the ownership and transfer of intellectual property (IP) rights. At the most extreme end, best practices in some jurisdictions are unenforceable or even impermissible in others. In view of these issues, it is strongly recommended that a company looking to take advantage of cross-border contracting for critical development efforts should carefully consider the choice of law provisions in their agreements, and engage with local counsel to ensure proper vesting of intellectual property rights. An inability to demonstrate proper ownership of such rights can be a substantial obstacle for later financings or in corporate activities.

Depending on the jurisdictions involved, a contracting company may need to concern itself with at least three types of IP in the software that is developed on its behalf: copyrights, moral or author's rights, and patents.

COPYRIGHTS

In many countries, software, particularly source code and user interfaces, is protected by copyright law.

In the United States, copyrights related to employee-derived works of authorship automatically vest in the employer under the US Copyright Statute. The same is not true, however, for works developed by independent contractors. Under the Statute, in order for works of authorship to vest directly in a contracting entity, the relevant contractor agreement must explicitly state that the works being developed are "works made for hire." Notably, only certain categories of works of authorship are eligible for consideration as works made for hire.

Although most software development in the United States falls within one of these statutory categories, it's not true in all instances. It is therefore best practice for the contracts governing software development agreements commissioned by a contracting entity based in the United States to include work-for-hire language along with present assignment language for all work product and IP rights that do not constitute work made for hire.

India's copyright ownership laws are similar to those in the United States in that copyrights in employee-generated works automatically vest in the employer, but copyrights in works of authorship (including software) developed by non-employees, such as contractors, do not. These need to be assigned in a written agreement and should include explicit assignment language that indicates the territorial scope of the grant and that the assignment is perpetual without any rights to reversion. If the agreement doesn't include this language, the assignment will be deemed restricted to India and for a duration of five years.

To the extent that an Indian contractor utilises subcontractors to fulfil its contracts, it may also be prudent to conduct diligence into the underlying subcontract agreements to ensure the prime contractor has obtained the necessary rights in the contracted-for deliverables to allow them to be reassigned to the contracting party. Significantly, the applicable law for the subcontracting relationships may not be in the overseas contracting party's control. If it's not possible to undertake diligence, the overseas contracting party should consider risk mitigation, such as contractual covenants or undertakings to obtain assignment of the relevant IP.

In Mexico, work-for-hire language should be included in any software development contract, along with specific assignment language identifying the rights being assigned. Best practice in Mexico additionally includes using a separate work-for-hire agreement, which can be included in as an exhibit or appendix to the contractor agreement. This separate agreement can then be executed by the contractor and any individual programmers who actually carry out the work.

Under Mexican law, the original authors of a copyrighted work are always individuals, and a condition for the work-for-hire transfer of copyrights to be effective is that the author(s) of the work be paid for their services and are fully aware that they are creating the work as a work-for-hire. Having the individual developers execute the separate work-for-hire agreement can serve as evidence that both of these conditions are met, avoiding potential individual ownership claims in the future.

Best practices in some jurisdictions are unenforceable or even impermissible in others.

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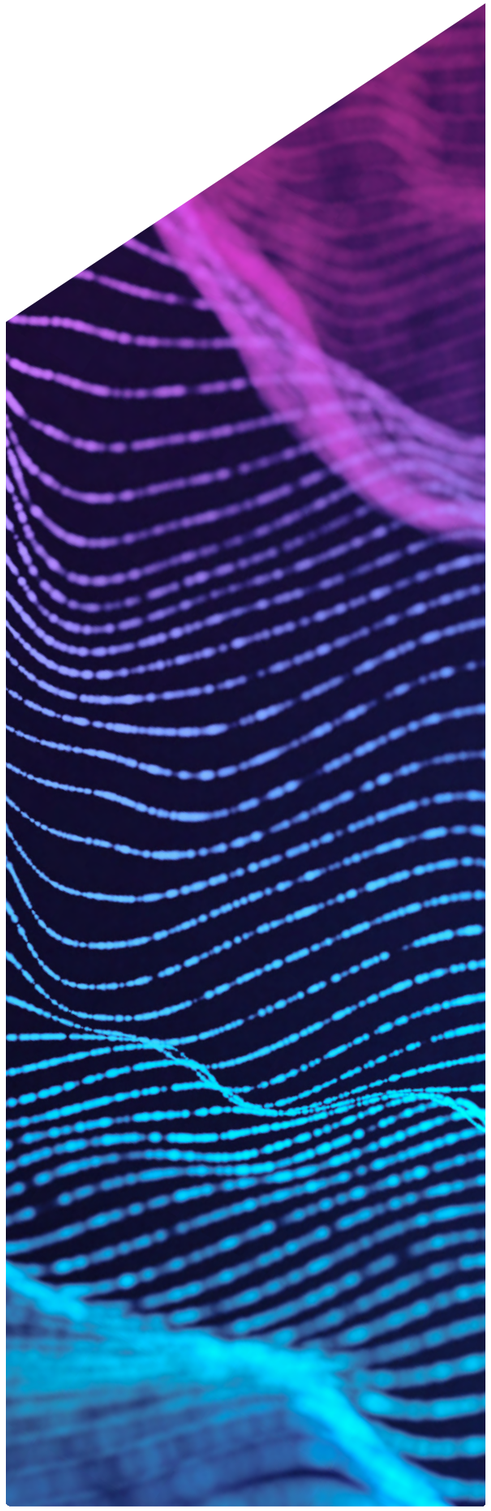

In contrast, in Canada, a provision in the Canadian Copyright Act directly vests ownership of the developed works, *e.g.*, software, in the company for whom the author is under a contract of service as the first owner of the copyright in such works, without the need for any specific present assignment language. The same is not true, however, for other forms of IP, such as patent rights.

A contracting company may need to concern itself with at least three types of IP.

Canadian IP law adds the additional complication that present assignment of future rights, which is best practice in the United States, has been deemed unenforceable in Canada. Best practices for contractor agreements under Canadian law therefore include providing for a present assignment provision (even if potentially unenforceable), an express agreement to assign later-developed IP, and an obligation for the contractor to execute any additional documents necessary to effectuate assignment of such later developed intellectual property.

While Germany does not have a general work-for-hire doctrine, it does have a specific work-for-hire provision in its Copyright Act directed at software development. This provision applies to both employee-generated software and software developed by a contractor under a services agreement. Notwithstanding this provision, it is still considered best practice to include assignment provisions in a German software development contract to address any other IP rights that might result from the development effort.

MORAL RIGHTS

In many civil law jurisdictions, and some common law jurisdictions, the creators of works are vested with moral rights, sometimes also referred to as author's rights.

These include the rights to

- Attribution of authorship with respect to a work.
- Prevention of the mutilation or modification of such work.
- Prevention of the use of the work in a manner that might damage the dignity or reputation of the creator.

These rights are generally personal to the creator of the work. In jurisdictions in which they are recognised, these rights usually cannot be transferred but they can often be waived by contract, and the benefit of a waiver is typically transferrable.

Accordingly, best practice in cross-border software development agreements includes the specific assignments of the author's moral rights or, if not permissible under relevant law, the assignment of the benefit of all waivers of moral rights in, or to, the developed software. In addition, a contractual warranty is recommended in civil law jurisdictions, regardless of the choice of law applied in the contract, which states that that the contractor has obtained waivers or assignments, as applicable, to any moral rights of its employees or subcontractors that might apply to any applicable works generated under the agreement.

PATENTS

In most jurisdictions, certain types of software can be protected through patent rights. If the software cannot be patented directly in a given jurisdiction, it can often be protected in the form of a system configured to carry out a particular function. As with copyright law, laws governing the ownership and assignment of patent rights vary from country to country.

In the United States, for example, rights in a patent initially vest in the named inventors of the patent, and can only be assigned by a written agreement. In Germany, however, although patent rights initially vest in the inventors by statute, the statute also provides employers the right to claim ownership of inventions made by their employees in the course of their employment.

Almost universally, the transfer of patents between corporate entities must be effected through a written agreement, specifying the transfer of patents. Even in jurisdictions that recognise work-for-hire doctrines, either inherently or by specific mention in a contract, such provisions are generally limited in their applicability to copyrights and do not apply to patent rights.

In order to ensure ownership of patent rights that might evolve from a software development project, the governing agreement should include an express assignment of any rights in inventions and patent rights arising from the contractor's efforts. For the greatest protection, the agreement should include present assignment language, obligations to assign rights that arise in the future, and strong further assurance clauses that the contractor execute and obtain all documents necessary to assign rights to the contracting company.

NEXT STEPS

Although potentially challenging from a legal standpoint, the use of overseas contractors is still a financially appealing option. Local counsel with experience of multi-jurisdictional IP agreements are invaluable in this situation to mitigate risk and protect a company's immediate investment and future activities

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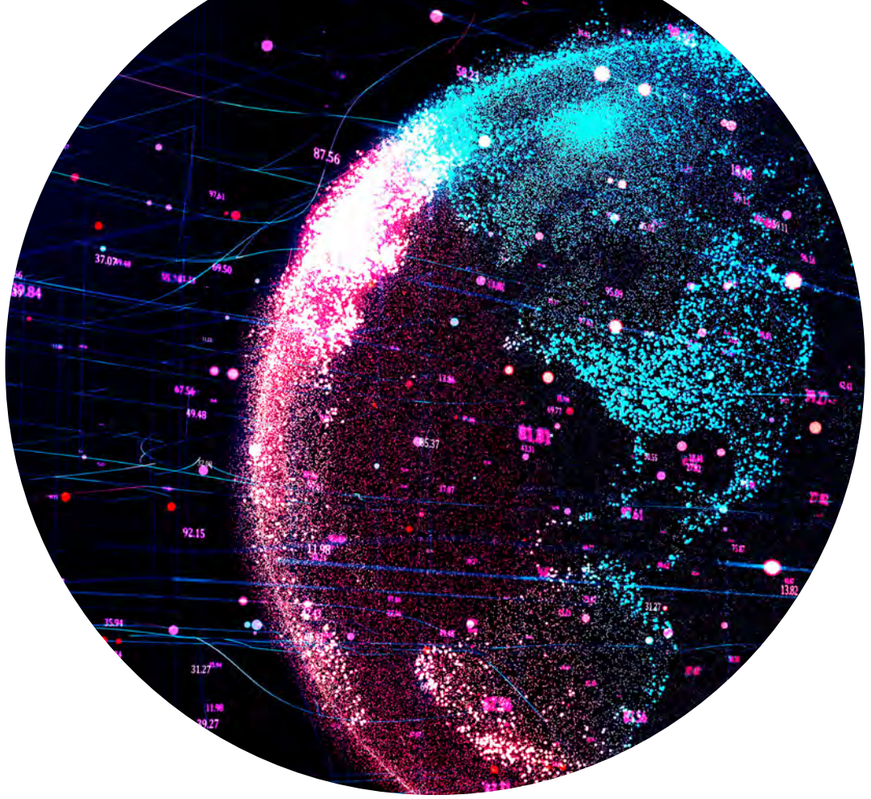

TRANSFERS OF HEALTH DATA FROM THE EUROPEAN UNION TO THE UNITED STATES IN A POST-SCHREMS II WORLD

Amy Pimentel and Romain Perray

The European Data Protection Board and a number of data protection authorities in EU Member States have issued guidance on how to safeguard EU-US data transfers post-Schrems II.

The General Data Protection Regulation (GDPR) and its predecessor laws have always relied on a basic key principle as far as international data transfers are concerned: adequacy. Any transfers of personal data outside the European Union to a third country whose data protection regime is not considered adequate to protect the rights of data subjects, such as the United States, must therefore be restricted.

The aim has always been to ensure that the rights of EU data subjects are not compromised when their data is sent outside the region. The GDPR contains a number of mechanisms for compensating shortcomings in the recipient country laws. For US transfers, the most common mechanisms have been standard contractual clauses (SCC) approved by the European Commission, or self-certification to the EU–US Privacy Shield.

On 16 July 2020, in a case commonly referred to as Schrems II, the Court of Justice of the European Union (CJEU) issued a landmark ruling that invalidated the Privacy Shield on the basis that the US legal regime governing access to personal data by national security agencies does not contain adequate limitations and safeguards. The CJEU also held that SCCs were sufficient to protect personal data, but that a case-by-case assessment was required of the data protection standards provided in the destination jurisdiction.

GUIDANCE FROM EU AUTHORITIES

Current guidance from EU authorities, including the European Data Protection Board (EDPB), does not provide a fully secure solution to complying with Schrems II. Instead it merely offers a protocol based on a new key principle of GDPR: accountability. To that end, the EDPB lists a combination of measures that can be implemented by data exporters to have effective control over the data they transferred overseas.

Businesses may enter into one of the current sets of SCCs templates issued in 2001 and 2004 and then amended in 2010, and may then strengthen the SCCs with additional contractual commitments to safeguard personal data, such as including a more aggressive obligation on data importers to notify their data exporters when they are required to provide data access to local authorities. To be effective, however, local laws must allow the data importer to provide such notification to the data exporter.

The EDPB also suggests that certain organisational measures can be used to effectively safeguard personal data post-transfer. These measures may consist of internal policies and procedures that provide the steps a data importer can take to challenge disproportionate or unlawful requests by local authorities and to provide transparent information to data subjects. These procedures should be supported by training sessions that take into account the specific notice and reporting requirements under the data importers' local laws.

There are some interesting congruencies between the EDPB's recommendations for how to secure personal data transfers and the US the Health Insurance Portability and Accountability Act (HIPAA), which regulates the use and disclosure of protected health information in order to protect patient privacy. For example, de-identification plays a major role under both legal systems as a technique to mitigate the privacy risk to data subjects. Of course, pseudonymisation does not release the parties from their obligations under the GDPR, but it will effectively reduce the privacy risk in many circumstances, especially if the data exporter retains sole control of the algorithm or repository that enables re-identification.

In addition to the EDPB guidelines, a number of Member States have issued their own guidelines or opinions specific to health data transfers. The German authorities have adopted a strict approach to data transfers that prohibits digital health applications from processing personal (patient) data in the United States. The German authorities also explicitly prohibit the use of tools or other services provided by companies that still rely on their Privacy Shield certification to process personal data in the United States.

France adopted a similar approach to the German authorities, in response to the large media coverage about the use of Microsoft as a hosting provider for France's centralised public health database, the Health Data Hub. The French Minister for Health subsequently enacted an order banning the transfer of COVID-19-related personal data outside France.

When conducting their assessment as required under the Schrems II ruling, data exporters in the European Union can also rely on solutions from courts such as the French Administrative Supreme Court. In its 19 June 2020 decision analysing the risks associated with potential requests from US courts/authorities under the Clarifying Lawful Overseas Use of Data (CLOUD) Act to access data hosted within the European Union by an affiliate of a US entity, the Conseil d'Etat opined that the CLOUD Act provisions did not create a major or urgent risk for health data protection.

Businesses should carry out a data mapping exercise that identifies all cross border transfers.

Regarding the risk associated with Section 702 of the Foreign Intelligence Surveillance Act (FISA) and Executive Order 12 333, the Conseil d'Etat ruled on 13 October 2020 that, given the important public interest of maintaining a COVID-19 health database, the risks of access by US authorities, although possible, are not serious enough to justify the suspension of the service and the immediate change of provider.

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STEPS TO COMPLY WITH DATA TRANSFER GUIDANCE

The most immediate action that businesses can take is to understand the extent to which health data is transferred from the European Economic Area (EEA) to the United States and other counties not deemed to have an adequate data protection regime. To do this, businesses should carry out a data mapping exercise that identifies all cross border transfers and the mechanism used to validate them.

Once these transfers have been identified, businesses should then undertake a data transfer assessment that identifies the inherent risks and whether any supplemental measures should be applied to protect the health data post-transfer. It is important to note that branches or subsidiaries of US cloud service providers are not the only entities that may be covered by US surveillance laws. To some extent, an EU parent company that stores health data in the European Union might be subject to US authorities' access requests if one of its affiliates is established within the European Union and has some form of control over the data. A thorough analysis of the applicability of foreign surveillance laws to any provider should thus be conducted during a data transfer assessment.

Because health data is sensitive in nature, businesses should take extra care when assessing what technical and organisational measures are prudent to protect against surveillance. Businesses may consider additional technical safeguards, such as pseudonymisation and encryption in transit and at rest, as well as organisational safeguards like explicit contract provisions that permit onsite/remote audits and, if applicable, prohibitions on the sharing of data with companies that are subject to FISA 702.

Particular care should also be taken where health data can be transferred onward to a third party and where a sub-processor is used, as this will generate a supply chain risk. The safeguards for any onward transfer or use of sub-processor may need to be reviewed, and any US companies engaged in onward transfers will need to conduct a transfer impact assessment as if they were an EU-based data exporter.

In the long term, businesses may consider alternative mechanisms for validating data transfers, such as binding corporate rules, obtaining a certification, or adhering to a code of conduct approved by a supervisory authority (although they all require prior assessment), or considering consent or other derogations in situations where they can be applied.

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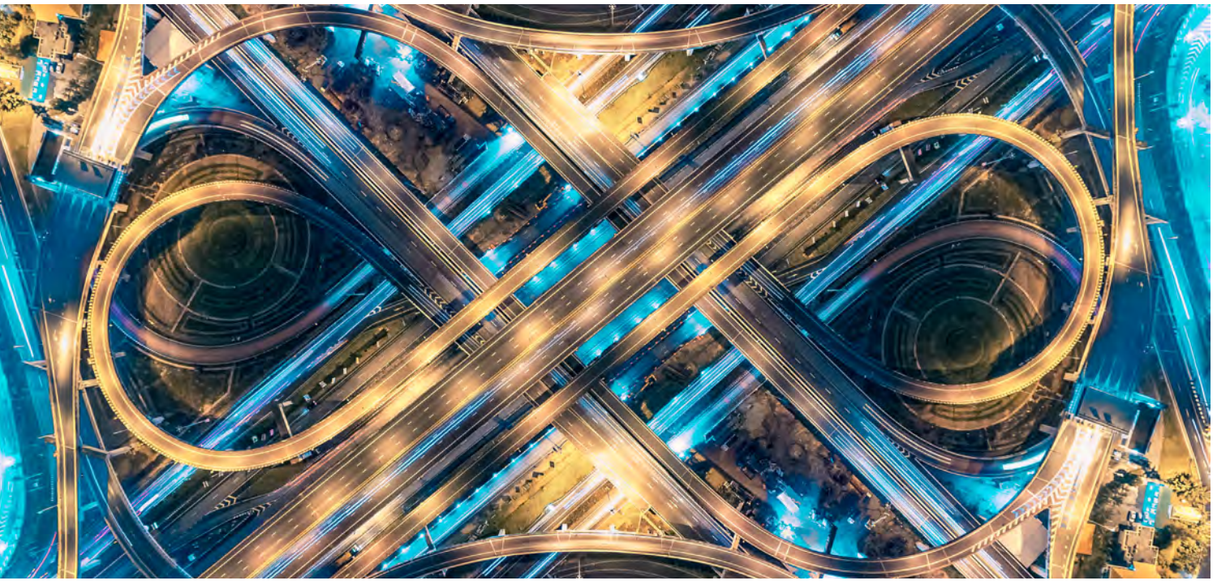

IMPACT FINANCE: INNOVATIVE SOLUTIONS TO TARGET GLOBAL HEALTH ISSUES

Ranajoy Basu and Carl J. Fleming

While the basic investment infrastructure needs to be developed, impact investment is becoming a stable and sustainable alternative for institutional investors and high-net-worth individuals. Private Equity funding is well suited as a powerful vehicle to address significant healthcare, social, and environmental issues.

Between 2020 and 2024, global health spending is expected to rise at a 3.9% compound annual growth rate. Investments in preventative health may result in quality of life improvements, fewer visits to doctors and hospitals, and lower claims costs for employers. At present, however, there are few incentives for those responsible for buying healthcare services (payors) to invest in preventative healthcare, even if preventative measures ultimately cost less than treatment.

To complicate matters, there may be legal or regulatory barriers to extracting growth, depending on how healthcare is funded. It is to the payor's benefit to find alternative ways to invest the extra money, which is where social impact bonds come in.

SOCIAL IMPACT INVESTMENTS

Social impact investments can take a variety of forms.

Loan Guarantees

There are a number of international institutions that provide credit support for projects. The Bill and Melinda Gates Foundation, for example, now issues loan guarantees, rather than direct funds, to some of the enterprises it supports.

Quasi-Equity Debt Structures

A quasi-equity debt security is particularly useful for enterprises that are legally structured as non-profits and therefore cannot obtain equity capital. This security is technically a form of debt, but it has one important characteristic of an equity investment: its returns are indexed to the organisation's financial performance, providing the enterprise with strong incentives to manage the business efficiently. Although the security holder does not have a direct claim on the governance and ownership of the enterprise, covenants on these loans are often added to avoid mission drift from the social goals.

Social investors purchase these securities, which perform the function of equity and enable social enterprises to offer banks and other profit-seeking lenders a competitive investment opportunity.

Pooling

Techniques that involve pooling funds have also opened new financial doors to social enterprises, because the pooling institution can tailor its liabilities to the needs of different kinds of investors.

One example is Gavi's COVAX Facility initiative. Gavi, a public–private global health partnership aiming to strengthen access to immunisation, leads in the development of COVAX, a mechanism through which demand and resources are pooled to support procurement of and equitable access to COVID-19 vaccines. Countries participating in COVAX benefit by securing affordable access to vaccine supply and are offered a compelling return on investment through delivering COVID-19 vaccines as quickly as possible.

THE CASE FOR IMPACT BONDS IN HEALTHCARE

The term "bonds" can be misleading when used to describe such transactions: these are performance-based contractual arrangements rather than capital

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market “securities”. Social Impact Bonds (SIBs) are seen as a complementary source of development aid, rather than as a rival to traditional funding. They can attract new sources of finance to bridge the huge demand for resources needed to achieve the UN’s Sustainable Development Goals.

The SIB is a results-based financing instrument that enables investors to finance development programmes to achieve specific target outcomes. Private investors, donors, or governments that have agreed upon a shared development goal, provide initial funding to development programmes, where the eventual financial returns are linked to verifiable, pre-determined development goals. If these development goals are met, the outcome funder or funders make payments to the initial finance providers based upon pre-agreed payment criteria.

SIBs offer an innovative model that may be of benefit to development projects that might otherwise find it hard to attract initial funding. For bilateral private donors, they are an attractive way to partner with private sector investors, and demonstrate that both types of capital can be deployed through these structures to effectively achieve their social outcomes.

Since an SIB focuses on the actual outcomes rather than the underlying activities that are carried out to achieve those outcomes, they typically incorporate a series of mechanisms that measure results to provide transparency to the investors, outcome funders, and other stakeholders, to demonstrate the extent of which their funding is having a positive impact. This is a key differentiator from traditional approaches to development funding models, which may fail to deliver what was agreed on, or simply lack the means to measure it.

This key aspect of an SIB transaction also helps ensure cost efficiencies and effective implementation during the life of a project. For healthcare-related SIBs, impact can commonly be measured by accessing data sourced from payors or regulatory bodies as part of their regulatory licencing obligations.

Key Parties to The Transaction

The partnership model of an SIB typically involves four principal transaction parties:

1. The service provider, which delivers social intervention to a specified target population, typically a hospital or community healthcare provider.
2. The investor(s), which provide upfront capital (the investment) to fund the programme delivery and bear some or all of the financial risk.
3. The outcome payer, which could be the government or the payor, pays investors if agreed outcomes are met. These payments repay the investment, plus a return on capital that depends on the degree to which the outcomes are achieved.
4. The intermediary, which is the counterparty to the outcomes contract with the outcome payer.

The role of the SIB delivery organisation includes brokering relationships between key stakeholders, sourcing capital, leading deal construction, and managing ongoing performance of the SIB programme. In some cases, the SIB delivery organisation or intermediary may identify and select service providers.

PRIVATE EQUITY’S ROLE IN IMPACT INVESTING

Private equity (PE) funds have emerged as vital intermediaries for aggregating the capital of the typically smaller investors that have traditionally been the most active impact investors. They are particularly well-suited to the needs of both impact investors and the social enterprises in which they invest.

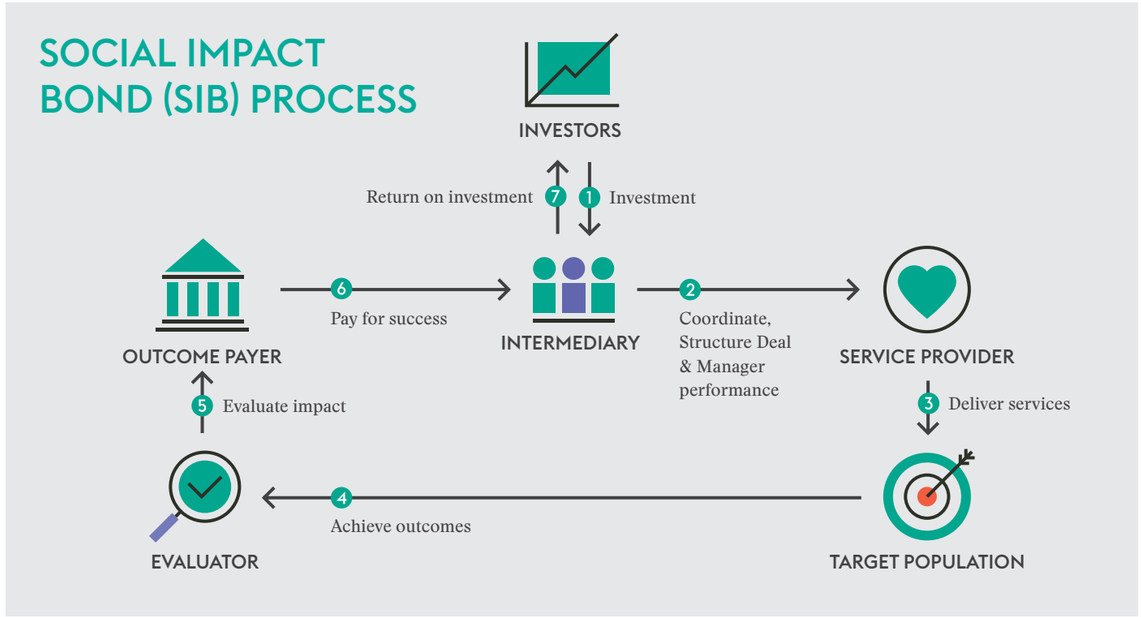
PE funds offer investors the ability to leverage the expertise of a fund manager to invest at scale, drive higher returns, and access specific industries. In impact investing, where i) investable opportunities are relatively scarce, ii) investee companies pursue strategies that balance financial return with social impact, and iii) models for measuring social impact are varied and often bespoke, an experienced fund manager is an even greater asset.

PE funds also offer a powerful means of mitigating some economic challenges posed by impact investing, which is often characterised by small transactions that are more complex than their larger, traditional commercial counterparts. By aggregating the capital of several investors and paying a fund manager to deploy capital, investments can be made more efficiently and common standards can be applied across investments, for example, with respect to measuring social return on investment. In addition, the familiarity of PE provides an excellent springboard for bringing new investors to the impact investing table.

Just as PE provides an attractive model for investors looking to engage in impact investing, it also provides a model that fits well with the capital/resource needs and growth trajectory of many social enterprises seeking capital from impact investors.

Growth-stage social enterprises generally need ample time to generate attractive financial returns and achieve their social impact goals. Private equity, with its focus on close engagement with management to build lasting value, is well suited to meeting this need. PE funds are illiquid by nature and most have five-year investment periods with harvest periods of five-to-seven years, meaning investee companies have a built-in time period to grow.

A longer version of this article can be found here.



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COVID-19 VACCINATION: FIVE KEY CONSIDERATIONS FOR HEALTHCARE EMPLOYERS

Paul McGrath and Carole Spink

The question of whether or not to make vaccinations mandatory for workers is being considered by employers globally, particularly those in the healthcare sector. There are a number of key considerations that should be taken into account.

The basic case for healthcare workers to be vaccinated against Coronavirus (COVID-19), particularly those working on the front-line and directly exposed to the virus, is clear.

The legal reality, however, is not so binary. Employees can be reluctant to have the vaccine for a variety of reasons. Plus differences in applicable local employments laws and national approaches to vaccination programs are likely to make a one size fits all approach impractical for multi-jurisdictional companies. But the issues that need to be considered are common to every jurisdiction.

MANDATORY OR VOLUNTARY?

The initial question will be whether or not to make employee vaccination a mandatory requirement. This will primarily depend on whether local law will permit it. In the United States, for example, an employer can mandate the vaccine, subject to some conditions and exceptions. Under guidance issued by the federal Equal Employment Opportunity Commission (EEOC), a mandatory vaccine policy must be job-related, consistent with business necessity, or justified by a direct threat. The COVID-19 virus in the workplace has already been deemed a "direct threat" by the EEOC.

In other countries, however, it may not be possible for employers to make vaccination mandatory. In France and Germany, employers cannot require employees be vaccinated against COVID-19. In the United Kingdom, any mandatory requirement is unlikely to be legally justifiable for many employers, but it may in principle be justified for employers in the healthcare sector, including in light of the legal duties owed to patients and the public. Nevertheless, consideration should still be given to individual factors such as the workplace and role in question, and any personal circumstances.

More generally, employers considering a mandatory policy will want to weigh up the risk of personal injury claims being brought in the event that an employee were to suffer an adverse reaction to the vaccination. Equally, this will need to be balanced against the risk of an unvaccinated employee catching and spreading COVID-19, or being unavailable for work while they recover.

The availability of the vaccination in the country in question also has to be taken into account. For instance, in the United Kingdom, the vaccine is currently only being made available *via* the National Health Service and is being administered in priority order (based on age, health conditions, and front line health and social care worker status) mandated by the Government.

Employers will want to weigh up the risk of personal injury claims.

It is possible, and to be hoped, that national laws and risk factors will become clearer when further information is known about the efficacy and effectiveness of the available vaccines, including what, if any, impact they have on transmissibility.

UNLAWFUL TREATMENT, DISCRIMINATION, AND OTHER RISKS

Even if an employer may lawfully mandate that its employees take the COVID-19 vaccine, there are a number of legal compliance requirements that will need to be considered when implementing such a policy. For example, the employer may be required to provide reasonable accommodations to individuals with disabilities, protected religious beliefs, or other protected status or characteristics, *e.g.*, pregnancy, under applicable regional, country, state, or local laws, which may prevent them from getting vaccinated.

Local laws may also provide other bases on which employees may seek to object to vaccination, including laws relating to what is reasonable to protect health and safety, or comply with human rights laws. For instance, the European Convention on Human Rights provides individuals with the right to respect for private and family life, which generally protects against unnecessary and disproportionate intrusion by an employer, which employees in some countries may try to argue is the case with mandatory vaccinations.

Employers will need to ensure that managers and HR professionals are adequately trained to handle employee accommodation requests and other concerns, many of which may be specific to the individual concerned and/or the role they perform.

INCENTIVISATION

If an employer chooses to make a COVID-19 vaccination program voluntary, it may be tempting to incentivise employees to have the vaccine in order to encourage take-up.

It is vital, however, that employers are careful not to appear to be pressuring employees to act, plus there are compliance obligations to consider. In the United States, if the employer sponsors onsite or near-site vaccine programmes, or contracts with a third party to administer vaccines, it has likely created a benefit plan subject to the Employee Retirement Income Security Act (ERISA), which triggers certain documentation, reporting, funding, and confidentiality obligations. Moreover, under the EEOC's voluntary rule, employers may offer no more than a *de minimis* incentive to encourage employee participation in wellness

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programmes. In addition, any financial incentive, to the extent permitted, may also be taxable as earnings.

In many cases, paid time off to attend vaccination appointments, or time off sick for vaccine side effects, may be the most effective and practical incentive.

DATA PRIVACY RIGHTS

Information regarding whether or not an employee has been vaccinated (and why) will be sensitive personal data, potentially constituting health data in some jurisdictions. In some countries, such as Germany, most employers are not allowed to ask employees about their vaccination status.

Where allowed, employers still need to carefully manage this data in accordance with applicable data protection laws. For example, in the United States, although the vaccination and confirmation of vaccination status itself are generally not disability-related inquiries or medical examinations that must be kept confidential under the Americans with Disabilities Act, pre-screening questionnaires will likely elicit medical information that does need to be kept confidential. It is also important for employers to be clear on what data is being collected and why, and how it is being stored safely.

See page 10 for more information on the legal challenges surrounding the transfer of health data from the European Union to the United States, which will be a significant concern for multi-national businesses.

IMPLEMENTATION

There are also a number of considerations an employer must take into account when implementing a COVID-19 vaccination programme, particularly if it is mandatory.

At some level, employers will likely need to track uptake and, where any form of mandatory policy is adopted, manage non-compliance to confirm the safety reasons justifying the programme.

There will also be an increased burden for managing employee requests for exceptions, and undergoing the necessary process when deciding on an appropriate response. If the employer administers the programme, or contracts with a third party to do so, there are also protected information requirements to follow.

In some jurisdictions, the roll out of vaccination programmes, or vaccination-related policies, may trigger consultation rights.

For example, in France, where mandatory programmes are not permissible, even simple information campaigns necessitate consultation with occupational health services and employee representatives. In Germany, co-determination of the works council is required if the employer is granting incentives to employees for vaccination. In the United Kingdom, even absent a trade union, employers are required generally to consult with appropriate employee representatives regarding health and safety matters. In the United States, there will be additional complexities for unionised workforces.

NEXT STEPS

Until governments take a stand on the issue of mandatory vaccinations for adults (to the extent that they can), the issue will be left to employers to handle as best they can.

There is precedent for government-mandated vaccination, albeit for children, not employees, in countries where it's lawful. For instance, France requires that children are vaccinated against a variety of illness before they are permitted to attend school, and all 50 US states require vaccinations for school age children. UK law, however, prohibits the UK Government from requiring any person to undergo medical treatment, including vaccination.

Whatever approach is taken, clear communication of an employer's position, consultation with employees, and engagement with any questions or concerns raised, will be essential to maintaining employee relations.

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EUROPEAN COMMISSION AND NATIONAL AUTHORITIES TAKE A STAND AGAINST EXCESSIVE PRICING BY THE PHARMACEUTICAL INDUSTRY

Hendrik Viaene and Karolien Van der Putten

On 10 February 2021, the European Commission concluded its first excessive pricing investigation in the healthcare sector by accepting commitments from Aspen. The decision highlights competition enforcers' efforts to improve patient access to affordable and essential medicines.

The European Commission and national competition authorities (NCAs) are very actively fighting a number of anticompetitive practices in the pharmaceutical industry. Enforcing the prohibition against excessive pricing has become a particular area of focus for competition authorities in Europe.

The European approach to excessive pricing differs from that followed in the United States, where excessive pricing does not amount to a violation of antitrust laws.

In the European Union (and the United Kingdom, for now), dominant businesses are not allowed to directly

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The Commission's decision sends an important message to pharmaceutical companies.

nor indirectly impose unfair purchase or selling prices. The Court of Justice of the European Union (CJEU) has established a two-pronged test for use in investigating excessive pricing. It must be determined i) whether the difference between costs actually incurred and the price actually charged is excessive, and, if yes, ii) whether or not a price has been imposed that is either unfair in itself or when compared to competing products.

In practice, competition authorities have historically been wary of prosecuting excessive pricing, partly because they do not want to act like price regulators, and partly because it can be difficult for an authority to establish that a price is excessive. In the last couple of years, however, the Commission and several NCAs have overcome their reticence.

THE INVESTIGATION AGAINST ASPEN

In 2017, the Commission launched its first excessive pricing investigation in the pharmaceutical industry, against Aspen, a South Africa-based company. The Commission suspected that Aspen had been implementing significant price increases for five off-patent cancer medicines throughout the European Economic Area (EEA). The Italian Competition Authority had already imposed a fine of EUR 5 million on Aspen in 2016 for implementing unfair price increases of up to 1500%, so the Commission did not include Italy in its investigation.

The Commission discovered that Aspen had, indeed, increased prices of five off-patent cancer medicines, Alkeran, Lanvis, Leukeran, Myleran, and Prunethol, starting in 2012. The Commission also found that Aspen earned very high profits from the sales of these medicines, both in absolute terms and compared to the profit levels of similar companies. There were no appropriate justifications for Aspen's high profit levels. The medicines concerned had been off-patent for 50 years, so research and development costs should already have been recouped. Even though Aspen's costs had slightly risen between 2013 and 2019, the price increases were disproportionate to the additional costs the business incurred. On average, Aspen's prices exceeded its relevant costs by almost 300%, considering a reasonable rate of return.

According to the Commission, Aspen was able to increase its prices because there were mostly no alternatives available to their medicines. When national authorities tried to oppose Aspen's requests for price increases, Aspen threatened to withdraw the medicines from the national list of reimbursable medicines, or even to withdraw normal supply.

In light of the Commission's findings, Aspen offered commitments without acknowledging that it had breached competition laws. By its 10 February 2021 decision, the Commission made the following commitments legally binding on Aspen.

Price Commitments

Aspen offered to reduce its prices for the medicines concerned by 73% on average throughout the EEA. These reduced prices are set per country and are, overall, below the prices charged in 2012, when Aspen started to increase its prices.

Aspen committed to implement these reduced prices for a period of 10 years as of the commitment decision date, plus they apply retroactively from October 2019. The business has committed to make payments (including interest) in the form of transitory rebates, *i.e.*, payments amounting to the difference between Aspen's actual sales in each country and its hypothetical sales if the same quantities had been sold at the reduced prices.

Supply Commitments

Aspen agreed to ensure appropriate and continued supplies of the medicines concerned for a period of five years. During the five years thereafter, Aspen will continue commercialising the drugs, but may also sell its market authorisation to a third party.

NATIONAL EXCESSIVE PRICING ENFORCEMENT ACTIONS

In 2016, the UK Competition and Markets Authority (CMA) imposed fines on pharmaceutical company Pfizer and distributor Flynn Pharma for charging excessive and unfair prices in the United Kingdom for phenytoin sodium capsules, an anti-epilepsy drug. After Pfizer sold the distribution rights to Flynn Pharma in 2012, Flynn Pharma genericised the drug, which meant that prices were no longer subject to regulation. Pfizer continued to produce the drugs and supplied them to Flynn Pharma at prices of between 780% and 1600% higher than before. Flynn Pharma subsequently sold the products at prices that were between 2300% and 2600% higher than the price that wholesalers and pharmacies previously paid.

The fines imposed on Pfizer and Flynn Pharma amounted to £84.2 million and £5.2 million respectively, plus the CMA ordered both companies to reduce their prices. Following appeal procedures before the Competition Appeal Tribunal and the Court of Appeal, the CMA is currently conducting its remittal investigation.

In 2018, The Danish Competition and Consumer Authority found that CD Pharma abused its dominant position through a 2000% price increase levied on the drug Syntocinon supplied to Amgros, a wholesale buyer for hospitals. Following a tender, Amgros sourced its supplies from a parallel importer that turned out to not be fully capable of supplying the quantities needed. Amgros therefore turned to CD Pharma, the only alternative supplier on the Danish market. CD Pharma exploited its dominant position and increased its price from DKK45 to DKK945.

At the time of going to press, a number of NCAs, including the Dutch Competition Authority, are investigating high prices charged by Leadiant for chenodeoxycholic acid. The CMA is conducting investigations into excessive and unfair pricing, anticompetitive agreements, and abusive conduct concerning hydrocortisone tablets and, separately, Concordia's pricing of liothyronine tablets in the United Kingdom.

Even though Aspen wasn't actually fined, the Commission's decision sends an important message to pharmaceutical companies. The Commissioner for Competition, Margrethe Vestager, noted that it sends "a strong signal to other dominant pharmaceutical companies not to engage in abusive pricing practices to exploit our health systems." The decision should also be seen as a crucial element of the Commission and NCA's overall competition enforcement action in the pharmaceutical industry. The Commission considers that overall competition enforcement ensures access to cheaper medicines and to a broader choice, plus it stimulates innovation.

Although the focus on excessive pricing cases has increased, it should be noted that the Commission and NCAs are also tackling practices such as exclusionary conduct to delay the entry of generics in the market, and pay-for-delay agreements, to help to achieve fair prices for pharmaceutical products.

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ACCESS TO DIGITAL HEALTH APPLICATIONS AND DIGITAL CARE APPLICATIONS IN GERMANY

Dr. Stephan Rau and Dr. Karolin Hiller

On 20 January 2021, the German Federal Cabinet approved the draft law on the digital modernisation of healthcare and nursing care. The draft has been criticised for not taking into account lessons learned from the implementation of the 2019 digital health applications law.

The legally enforceable right of patients insured in the Germany statutory healthcare system (SHI) to be able to access digital health applications (DiGAs) was included in the German SHI code (SGB V) at the end of 2019.

DiGAs are low-risk medical devices (risk class I and IIa) that are primarily based on digital technologies and support the detection, monitoring, treatment, or alleviation of diseases, injuries, or disabilities. Under the SGB V, DiGAs have to be approved by the German Federal Institute for Drugs and Medical Devices (BfArM) and included in the DiGA List before doctors can prescribe them to their patients on an individual basis and at the SHI's expense. Among the DiGAs listed by BfArM since the first listing in October 2020, are those that support patients with light depression, insomnia, obesity, or tinnitus.

The two main legal challenges that have arisen from this new SHI healthcare service are i) finding an adequate price mechanism that balances the interests of patients, DiGA producers and SHI funds; and ii) determining a data protection law-compliant way of enabling DiGA producers to involve US IT service providers in the processing of personal data created or processed by DiGAs. Under current DiGA law, and as a result of Schrems II (see page 10 for more information), German personal data may currently not be processed in the United States.

The modernisation of the German healthcare system continues this year, as the right for individuals in need of care to use digital care applications (DiPAs) at the SHI's expense is planned to become law during 2021.

DiPAs will be approved if they are essentially based on digital technologies and intended to be used by individuals who are in need of care either in person for themselves, or through interaction with their relatives and/or outpatient carers in order to improve, or combat the deterioration of, their independence or abilities. Examples include apps that help with fall prevention; provide memory games for dementia patients; and improve communications between patient, carers, and relatives.

As is the case for DiGAs, BfArM will be responsible for the DiPA approval process and will establish a list that recognises DiPAs approved for SHI services. As part of the legislative process, the German Parliament has been criticised for not learning from the failings in the DiPAs legal regime, particularly the issues surrounding the planned price mechanism. In addition, people who live in care homes are excluded from the use of SHI-funded DiPAs, fuelling further controversy. It is to be hoped that the Parliament amend its draft to deal with these issues before the right for DiPAs becomes law in the course of 2021.

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PARIS COURT OF APPEALS REJECTS PHARMACEUTICAL SUPPLEMENTARY PROTECTION CERTIFICATE APPLICATIONS

Katya Ascher and Edouard Becker

The Paris Court of Appeals has applied the recent Court of Justice of the European Union judgement in *Royalty Pharma* to confirm the French patent office's rejection of three Supplemental Protection Certificate applications

One of the conditions for obtaining an SPC is that "the product is protected by a basic patent in force". The Court of Justice of the European Union (CJEU) clarified to what extent a product must be identified by the claims to meet this condition in *Teva*, *Eli Lilly*, and *Royalty Pharma*.

In *Eli Lilly*, the CJEU notes that an active ingredient which is not identified in the claims of a basic patent by means of a structural or functional definition cannot be considered to be "protected by a basic patent."

The active ingredient does not, however, have to be identified in the claims by a structural formula. A functional definition of the active ingredient may suffice if it is possible to reach the conclusion on the basis of the claims (interpreted in light of the description of the invention) that they relate "implicitly but necessarily and specifically, to the active ingredient in question."

In *Royalty Pharma*, the CJEU confirmed that the product must, from the point of view of a person skilled in the art and in the light of the description and the drawings of the basic patent, necessarily come under the invention covered by that patent; and the person skilled in the art must be able to identify that product specifically in the light of all the information disclosed by the patent on the basis of the prior art at the filing date or priority date of the patent concerned.

A product is not protected by a basic patent in force if, despite being covered by the functional definition given in the claims of that patent, it was developed after the filing date of the application for the basic patent, following an "independent inventive step".

In the three cases before it, the Paris Court of Appeals considered that the patents did not claim the specific structure, and were instead functional in that they were directed to molecules that bind to a certain target protein.

The appellate court upheld the FPO's decisions, holding that the relevant products were not "specifically identifiable" by a person skilled in the art from the basic patent. The court considered that further "independent inventive steps" would be required to identify the relevant active ingredients, and highlighted that it took applicants years to file patent applications directed to the specific structures.

Although consistent with CJEU case law, these decisions restrict the choice as to which patents an applicant can rely on to obtain an SPC, and add a level of complexity to the examination of SPC applications by national courts and patent offices where the basic patent contains functional patent claims.

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