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About our Global Products Law Practice

Hogan Lovells Global Products Law Practice is internationally renowned for its work in product litigation, safety and compliance. We act for clients around the world covering all product sectors including pharmaceuticals and medical devices, cars, tobacco, mobile phones, cosmetics, electrical and electronic products, chemicals and hazardous substances, toys and children's products, food and beverages, sporting goods, aircraft and machinery. Hogan Lovells product litigation and product safety lawyers are supported by an in-house Science Unit and a Project Management Unit.

If you would like more information about Hogan Lovells Global Products Law Practice please contact Lauren Colton at lauren.colton@hoganlovells.com, or any of the partners listed on the back page of this publication.

About *International Products Law Review*

In December 2000, Lovells (as it then was) launched its quarterly European Product Liability Review, the only regular publication dedicated to reporting on product liability and product safety developments in Europe for international product suppliers, and others interested in international product issues. Over the next ten years, this unique publication featured hundreds of articles, from authors across our network, covering issues in Europe and, increasingly, further afield. Reflecting the growing globalisation of product risks, and following the creation of Hogan Lovells through the combination of Lovells with Hogan & Hartson in May 2010, the publication was renamed International Product Liability Review in March 2011.

Hogan Lovells International Products Law Review continues to be the only regular publication dedicated to reporting on global developments in product litigation and product regulation. It is distributed worldwide free of charge to our clients and others interested in international product issues. If you would like additional copies of this publication, please return the form enclosed with this edition, or email a member of the Editorial Team:

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Meet the team

We are pleased to introduce two more members of our Global Products Law Practice who have contributed to this issue of *International Products Law Review*: Agnieszka Majka (Warsaw) and Emmie Le Marchand (London).

Agnieszka Majka
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Agnieszka is one of the key practitioners of the Dispute Resolution practice at the Warsaw office of Hogan Lovells. Having been responsible for building the Dispute Resolution team in Warsaw in the past years, she now heads the Products Law team and the Investigations White Collar and Fraud team at the firm in Warsaw.

Agnieszka is known for her notable expertise in product liability. Together with her team she handles complex product liability matters and life sciences-sector disputes. In this area, she represents her clients in pre-trial and court disputes, as well as in arbitration. She handles regulatory enquiries related to medicinal products, medical device, food and food supplements, as well as cosmetics. She also frequently represents clients from the automotive and diversified industrials sector.

Agnieszka leads the Life Sciences and Healthcare industry sector group that works closely with the firm's employment, IP, TMT, competition and corporate departments to offer clients from this industry sector a full service.

For her clients, she regularly handles internal investigations and advises on anti-bribery compliance. This includes working out complex compliance programmes, training for employees and assistance in case of dawn-raids by the law enforcement authorities. Because of her education and language skills, she often assists German clients.

The 2018 edition of Legal 500 has named her a 'next generation lawyer' in the area of Healthcare and life science and recommended her for internal investigations and compliance.

See page 22 for Agnieszka's article Fuelling healthcare innovation: "Poland creates new Medical Research Agency".

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Emmie is an Associate in the Global Products Law team based in the London office of Hogan Lovells. She has experience advising domestic and international clients in disputes across a number of industry sectors, including mining and energy, aerospace and aviation and manufacturing and construction. She has also assisted clients on regulatory matters in the automotive, technology and consumer product industry sectors. Emmie was recently seconded to Hogan Lovells' Paris office, where she advised on a range of arbitration disputes.

Emmie holds an undergraduate degree in English and French from Duke University and a master's degree in Eighteenth Century Literature and Romanticism from Queen Mary, University of London. She also completed the GDL and LPC with BPP law school, in London.

See page 6 for Emmie's article "The road ahead: product liability and motor insurance implications of the Automated and Electric Vehicles Act 2018".

In this issue...

Feature

The road ahead: product liability and motor insurance implications of the Automated and Electric Vehicles Act 2018

The Automated and Electric Vehicles Act (the "Act"), which received Royal Assent on 19 July 2018, is an important step towards the UK Government meeting its target to have fully self-driving vehicles on UK roads by 2021. Its passage offers a fresh opportunity to consider the challenges and opportunities that lie ahead for manufacturers, software developers and insurers interested in the automated vehicles space. Full implementation of the Act is expected through a series of statutory instruments during the next couple of years.

The Act – A New Approach To Motor Insurance

Traditional motor insurance covers damage caused by the fault of the driver. However, liability in an accident involving an automated vehicle is more likely to arise due to a fault with the vehicle (on the basis the vehicle is the driver). A primary purpose of the Act is to make sure that all victims of an accident caused by a fault with an automated vehicle will be compensated.

To this end, the Act extends compulsory motor vehicle insurance to cover the use of automated vehicles in automated mode. Where an accident is caused by an automated vehicle while that vehicle is driving itself and the "driver", or any other person, suffers injury or damage as a result of that accident, the Act puts first instance liability with the insurer of the automated vehicle. To recover from the insurer, a claimant must prove only that the automated vehicle was at fault.

The idea is to help individuals receive compensation for damage (to themselves or their vehicle) without having to go through the long and costly process of bringing a claim against the manufacturer of the automated vehicle at fault. Instead, the burden of compensation in the first instance falls on the insurer. However, the Act grants insurers the right to subsequently claim against any other person liable to the injured party in respect of the accident (e.g. the vehicle manufacturer or software developer).

The Act defines automated vehicles by reference to a list which will be produced and maintained by the Secretary of State. The list has not yet been produced, but the Act prescribes that it will include motor vehicles that are "designed or adapted to be capable, in at least some circumstances or situations, of safely driving themselves".

Implications For Manufacturers

Under the Act, manufacturers and software developers are out of the immediate firing line where an accident is caused by an automated vehicle. However, manufacturers and software developers do not escape liability; it is just that they will face claims from insurers, rather than individuals. Therefore, manufacturers should prepare to face claimant insurance companies that are more experienced, more sophisticated and better funded than an individual consumer. From a PR perspective, a manufacturer that disputes a claim may find it more palatable to continue in litigation in a dispute with an insurer, as compared to an injured consumer.

Under the Act, an insurer cannot initiate a claim against an implicated manufacturer or software developer until the insurer has settled and paid the claim by the injured party or parties. For manufacturers or software developers, this means there may be a longer time after an accident has occurred before facing a claim. If a manufacturer is unaware of the accident and the original claim against the insurer, they may also find themselves ignorant of a product issue for some time. This could lead to a delay in its analysis of an issue and, consequently, any corrective measures required, which could potentially allow a number of claims to accumulate against them. This further emphasises the need for manufacturers to have robust, proactive post-market surveillance systems in place, to give themselves as much time as possible to investigate and understand any issues.

To protect themselves against possible claims from insurers, manufacturers and software developers should consider taking out specialised product liability insurance to cover any such claims. A big advantage of the Act for the manufacturer is that the insurers are limited in what they can recover from third parties to

the amount paid to the original claimant(s). As well as limiting the potential value of a manufacturer's liability, this also gives a manufacturer foresight of the value of a claim being brought against them.

A further advantage for manufacturers relates to qualified one-way costs shifting ("QOCS"). In a personal injury claim brought against a manufacturer by an individual claimant, QOCS would protect the unsuccessful individual claimant from being ordered to pay the costs of a successful manufacturer defendant. By way of contrast, an unsuccessful insurer claimant would not benefit from QOCS protection (since they are bringing a subrogated claim). It is therefore much more likely that a manufacturer defendant would be able to recover their costs from an insurer claimant than an individual claimant.

Implications For Insurers

There is no doubt that the increased use of automated vehicles in the UK will have far-reaching consequences for the motor insurance industry. For decades, liability for accidents has rested with the individual driver at fault. The move to driverless technology presents interesting conceptual and practical challenges for insurers. The Act is helpful in that it begins to provide a statutory response to this shifting insurance landscape.

By making them the direct port of call for claimants who have suffered injury or damage from an automated vehicle accident, the Act places a fairly onerous obligation on insurers. The burden is squarely on insurers to pursue any further claims against manufacturers, software developers or other parties deemed to be at fault. This places insurers in the unenviable position of having to pay out to claimants first for 100% of the claim, before facing potentially lengthy legal battles to recover from third parties their share of the loss. However, one potentially bright spot for insurers is that the Act permits them to exclude or limit their liability for damage suffered as a result of prohibited software alterations or failure to install safety-critical software updates.

In the medium to long term, the arrival of automated vehicles presents significant opportunities for insurers. While the need for individual motor insurance policies for drivers is likely to decrease over time, the need for individual policies for automated vehicles is likely to increase; indeed the whole landscape of compulsory motor insurance is likely to change significantly. There may also be increasing opportunity to offer combined policies, covering an individual driver when that driver is in control of an automated vehicle, and covering the vehicle itself when it is driving in automated mode. Traditional motor insurers may, however, need to be prepared for competition from manufacturers, who are likely to see an opportunity to develop new forms of automated vehicle insurance and promote their own insurance products as part of the sale of an automated vehicle.

The large scale use of automated vehicles will also give scope for new lines of insurance cover. For example, specialised forms of cyber insurance may be required since in time automated vehicles will be able to communicate with each other (vehicle-to-vehicle communication) and these networks will be vulnerable to hacking by sophisticated cybercriminals or even cyberterrorists. Another expected area of growth is in large scale product liability insurance for manufacturers and software developers, who will want to protect themselves against the risk of defective automated vehicle parts or software.

But What Is An Automated Vehicle?

The Act defines automated vehicles by reference to a list that will be maintained by the Secretary of State. Adopting a "list" approach helpfully removes the element of self-assessment for interested parties – their vehicle is either on the list and the legislation applies to them, or it isn't – but there are several issues with the Act's approach.

First, maintaining and updating the list will be a burdensome and time-consuming task. There is a real risk that automated vehicle technology will move faster than the Secretary of State will be able to update the list. If an automated vehicle makes it into circulation before the list has been updated, any consequential claims for an accident involving that vehicle would not fall within the scope of the Act.

Second, because the list has not yet been published it remains unclear what level of automation the Government hopes to capture with this Act. An increasing number of vehicles already have automated features such as the ability to self-park or adaptive cruise control: will vehicles with these capabilities be included on the Secretary of State's list? Clearly, the wider the scope of the Act's definition of 'automated vehicle' the more far-reaching the implications for manufacturers, insurers and end-consumers will be.

Comment

The Act indicates the Government's current thinking on how to tackle the liability issues posed by the rapid development of automated vehicle technology. End-consumers should be reassured by the consumer protection focus of the legislation. Meanwhile, manufacturers, software developers and motor insurers should take note of the direction of travel. They should position themselves to make the most of new opportunities brought by this changing landscape, while also avoiding possible pitfalls. For example, manufacturers should be looking for appropriate ways to engage with consumers to find out about any potential product issues as soon as possible and traditional motor insurers should be looking to develop new motor policy products ahead of time.

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Science Update

The development risks defence: how future-proof is it?

Introduction

Article 7(e) of the Product Liability Directive sets out the "development risks defence"

> The producer shall not be liable as a result of this Directive if he proves:
>
> > "that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered."

Although Member states may opt to derogate from Article 7(e), it provides an important defence to producers facing product liability claims in the EU, particularly those involving medicines, medical devices and other complex or innovative products.

Capturing the "state of scientific and technical knowledge" at the time a product was put into circulation can be very difficult. What this means was considered by the Court of Justice of the European Union (CJEU) in the case of Commission v UK,[1] where the Court held that

> "the clause providing for the defence in question does not contemplate the state of knowledge of which the producer in question actually or subjectively was or could have been apprised, but the objective state of scientific and technical knowledge of which the producer is presumed to have been informed." (Paragraph 27)

This was qualified by the criterion of the accessibility of this knowledge

> "However, it is implicit in the wording of the Article 7(e) that the relevant scientific and technical knowledge must have been accessible at the time when the product in question was put into circulation." (Paragraph 28)

Understanding Accessibility

In his Opinion the Advocate-General had illustrated this point by differentiating between a study by an American university, published in an international English-language journal and similar research carried out by an academic in Manchuria, published in Chinese in a local scientific journal that is not circulated outside the region.

Judgment in this case was delivered in 1997 when digital search was still in its infancy. To obtain copies of the materials at that time, it would have been necessary either to physically visit a library which held the relevant journals, or to send written requests for paper copies to institutions such as the British Library.

The subsequent revolution in scientific publishing and accessibility means that it now takes just a few seconds to locate a Chinese journal and, if there is no English version of the webpage available, load the contents into an online translation tool, such as Google Scholar, and access a summary, if not the entire content of the paper instantly.

How does this revolution affect the usability of the development risks defence? Certainly now, and for a number of previous years a lack of accessibility cannot realistically be claimed.

Arguably, there is now a new and potentially more challenging difficulty than accessibility: the ability to assimilate, rationalise and appraise all the relevant literature. A search conducted in 2000 for measles and encephalitis, for example, would have produced a few hundred papers. The same search today would provide many tens of thousands of results for review.

The number of results has been boosted by an expansion in journal numbers and online publishing, as well as by the profusion of "grey literature".[2] The proliferation of such publications, lacking rigorous peer review, means that papers which represent "accurate" knowledge may be lost in a sea of unreplicated, uncontrolled literature which a producer would have little hope of navigating or adequate resources to review.

Legal cases involving large volumes of scientific literature have for many years relied heavily on empirical measures of quality, such as peer review and statistical significance. Assessing the state of scientific information relied on examining papers which demonstrated a significant result using appropriate methodology, published in a peer-reviewed journal and demonstrating results which could claim statistical significance.

1 *C-300/95* [1997] ECR

However, the peer-review process has been under considerable strain for many years as the increased pressure of publication and production has edged out the worthy role of peer review for many academics and the vaunted status of "statistical significance" has led to its attainment being the starting aspiration of experimental design rather than it being employed as guidance on the interpretation of scientific result.

The ease of publication on the internet now means that a summation of all available knowledge on a topic is unlikely to provide an accurate picture. A 2016 survey reported that "70% of researchers have tried and failed to reproduce another scientist's experiments, and more than half have failed to reproduce their own experiments"[3] citing pressure to publish and selective reporting as the cause.

Selective reporting may be addressed in part by the momentum towards open access[4] : "making research findings available free of charge for readers". But this may provide additional difficulties for those attempting to review the totality of literature available on their product as 'open access' would include making available the underlying research data. Should this also be appraised to assess the state of technical and scientific knowledge?

One should also consider the longevity of much of the information currently accessible. Given the transient nature of websites it is highly unlikely that the current state of knowledge, other than published literature, will be reproducible in a few years' time.

Potentially the issue should now not be so much the practical accessibility of information allowing a defect to become discoverable but more the ability to unearth the relevant accurate/valid information. Any such appraisal, is likely to require extensive resources and expertise.

One solution could be the adoption of artificial intelligence (AI) to support this process. Various providers are developing AI with a view to literature review: Dimensions, Semantic Scholar and others are providing software that aims to answer scientific and/or technical questions by searching and rationalising the search results to make them more accessible.

However, this solution does not address the issues of validity, reproducibility or conflicting findings. Perhaps of even greater potential are organisations such as IRIS.ai which has the ultimate aim of evaluating the literature in addition to providing the search results.

Aware of the need to consider revision of the Product Liability Directive to deal with new technology, the EU Commission convened an expert group on liability and new technologies in 2018. When it reports in mid-2019, it will be interesting to see whether it will provide guidance on the approach to assessing scientific and technical knowledge.

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2 *"That which is produced on all levels of government, academics, business and industry in print and electronic formats, but which is not controlled by commercial publishers."* http://www.greylit.org/about

3 https://www.nature.com/news/1-500-scientists-lift-the-lid-on-reproducibility-1.19970

4 https://ec.europa.eu/programmes/horizon2020/en/h2020-section/open-science-open-access

Europe *EU*

Data protection and "smart" products: a new perspective on safety

More and more "smart" consumer products are being made available on the market by a hugely diverse range of companies. These smart products already offer remarkable functionality. And as they become increasingly sophisticated, they will contain features that would have seemed like science fiction just a few years ago. While this technology space holds out enormous opportunity – both commercially, and for improving many aspects of people's lives – it comes with risks, especially where reliance on a data-driven model is concerned.

Already well versed in processing customer data, many companies will have put in place systems to cope with the regulatory demands for personal data protection. Others may be well established in the technology space, but less familiar with the dynamic of getting products into consumers' hands. And then there will be companies that are completely new to the market – disruptive start-ups, moving at high speed to launch their innovative products ahead of the competition.

It's vital to put safety and cyber security front and centre during any smart product launch – especially for products that rely on the use and processing of personal data. This article focuses on one of the key reasons why: the General Data Protection Regulation (the "GDPR"), which governs personal data protection in the EU and has a major impact on how companies introduce smart products to the market.

What Do You Need To Know About The GDPR?

In force since May 2018, the GDPR's overarching aim is to simplify and harmonise the data protection and privacy regulation landscape across Europe. It created a single set of rules that

- enhance the protection of EU data subjects, including giving data subjects greater control over the use, storage and retention of their personal data
- put greater focus on practical compliance through "data protection by design" and by ensuring companies document compliance
- have extraterritorial reach – just because a company does not operate in the EU, or do business in EU countries, does not mean the GDPR won't apply, and
- grant strong enforcement powers to the European Commission (fines of up to €20 million, or 4% of global turnover, whichever is the highest).

The GDPR applies to all companies that collect or use personal data. That includes information collected at the point of sale, information collected from a consumer to optimise a product's performance, and all personal data in between. Product companies are likely to hold huge amounts of data that will be subject to the GDPR's rules. Typical sources include

- consumer contact details obtained during the course of sales, signing up to mailing lists and marketing materials
- usage data relating to products
- cookie data (user's geolocation or IP address) obtained from website visits, and
- data enabling or optimising a product's performance.

Consumers are increasingly aware of the value placed on their personal data. And, on the back of numerous high-profile corporate data breaches, they understand companies' obligations when it comes to protecting their data. This is felt particularly acutely where smart consumer products are concerned: customers expect their data to be handled safely and securely while also expecting the operability of the product that relies on the very processing of that personal data to be of the highest standard.

At first glance, it may be difficult to see the value in investing in data protection, especially when there are so many other competing challenges facing businesses in the current climate. However, the ubiquity of data in today's world and the potentially catastrophic impacts of getting it wrong, both in terms of regulatory fines and brand damage, should alert decision-makers to the importance of data protection across all consumer products companies.

Successful companies in this space embed data protection principles in everything they do, ensuring that it features as prominently as other more "traditional" risks (such as physical product safety).

How Can Companies Get It Right?

Through their drive to become GDPR-ready, most smart product companies will already be very familiar with data protection and privacy. Listed below are some of the headline topics they have likely addressed.

Gathering personal data

In any scenario where personal data is collected, compliant collection mechanisms must be in place. The scenarios triggering this requirement may not always be obvious and can include, for example, where a customer has made an enquiry or where they have provided consent for data to be collected and used to optimise a product's performance.

All sources from which a customer's personal data is being collected by the business should be identified and companies should ensure collection mechanisms are compliant.

Legal bases

Companies must state the legal basis for gathering personal data and keep a record of the stated basis. There are six permitted bases, all included in article 7 of the GDPR; however, in the context of consumer products, the two most likely bases are consent and "legitimate interests".

Wherever possible, the "legitimate interests" basis for data collection should be used; this avoids the problem of a later withdrawal of consent. In the context of product safety issues, the "legitimate interests" basis should be built into the stated purposes under which all personal data is collected.

Data protection by "design and default"

Data protection "by design and default" is required by the GDPR. This means that companies must have appropriate systems and procedures in place to ensure that data is neither collected excessively nor misused. Where data processing is likely to result in a high risk to individuals, a formal data protection impact assessment ("DPIA") must be carried out to identify any mitigating measures that need to be taken.

Retention practices should be reviewed against the data minimisation rules; data should only be kept for as long as necessary to achieve the stated purpose for which it was collected. The retention period will vary according to the product and could, for example, be informed by usage data that might show a period of inactivity, leading to a trigger for data deletion.

Data subject rights

The key rights of a data subject are

- the right to be informed
- the right of access
- the right to rectification
- the right to erasure
- the right to restrict processing
- the right to data portability
- the right to object, and
- rights relating to automated decision-making and profiling.

Companies should be mindful of an individual's right to access and request the deletion of their personal data. Most requests will have a 30-day maximum period for response, and companies must put in place the resources and systems needed be able to handle such requests promptly. Companies and their employees should be particularly aware from the outset that an individual may one day see all the information collected about them, so high standards of communication diligence should be encouraged throughout the business.

Cookies

The GDPR has changed the position of the ePrivacy Directive in that "opt-out" consent is no longer a sufficient justification for the use of non-essential cookies. To justify non-essential cookie use, the GDPR requires that consent must be clear, affirmative, and involve the consumer "opting in". Non-essential cookies include those used for marketing, advertising and analytics. It must also be as easy to withdraw consent as it is to give it.

In practice, companies often make access to their website conditional on the user's acceptance of non-essential cookies. It remains to be seen whether this approach is permissible in the eyes of the regulator,

or whether they will take a strict stance in interpreting the GDPR's consent requirements. A reasonable assumption would be that consumer rights and safety regulators will resist the imposition of conditions which restrict either the consumer's ability to exercise their rights, or to access safety information posted on a website. This means that where safety information or usage instructions can be found on company websites, and where customers can lodge warranty claims on the website, the customer should have full access, without any requirement to accept non-essential cookies.

GDPR in times of a safety event

The corrective actions taken in the wake of a safety incident must also comply with the GDPR. The ideal scenario is for a company's data collection practices to allow for customers to be contacted directly if a safety event occurs. Where this is not the case, or where the customer data is not being held, companies must ensure data collection and processing is GDPR compliant, applying the necessary technical and security controls to the use and retention of that data.

Companies must also ensure that any third parties engaged to assist with corrective actions, such as logistics companies or third-party communications agencies, handle personal data in a safe and secure way, limited to the execution of the corrective action. To ensure a swift and effective incident response can be executed, these checks should ideally occur proactively before the occurrence of a safety incident.

Data breach and reporting

Companies must have robust protocols for detecting, investigating and reporting on data breaches. Where such a breach is accompanied by a safety risk – for example a car's on-board computer system could be hacked, resulting in brake disablement – the company will have to consider the relevant reporting requirements of both the data regulator and the relevant safety regulator. The triggers for reporting and the processes for doing so will vary across regulators. If the incident is multi-jurisdictional, the company will have to satisfy the requirements of multiple regulators (each with different protocols and reporting deadlines), while also carefully handling media and reputational issues. Given the propensity of regulators to talk to each other, the consistency of messaging is crucial, as well as the need to ensure a clear and coherent company response.

Companies should be aware that a failure to report a breach can, by itself, result in a significant fine. On top of regulatory liability, the company could face civil claims for the misuse of personal data if security systems are deemed inadequate.

Comment

The GDPR was introduced with the protection of consumers firmly in mind, so it follows that consumer product companies will be under the spotlight from regulators.

On the whole, when it comes to data security and privacy, companies should place as much emphasis on these issues as they would on more 'traditional' product safety liabilities. In such a complex field, with products subject to myriad intersecting regulatory requirements, product companies that keep an eye open to regulatory and commercial developments are most likely to thrive.

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With thanks to Ranulf Barman

Europe *France*

Protecting consumer data: closer collaboration between French Data Protection Authority and French Consumer Protection Authority

Emphasising the need to increase consumer confidence in the digital environment, in 2008, the European Parliament recommended that data protection and privacy rules be included in any consumer strategy.[1] Following this recommendation, the French Consumer Council *(Conseil National de la Consommation)* set up a working group dedicated to the protection of consumers' personal data and issued 27 proposals targeted at improving and strengthening consumers' rights.[2] Perhaps most important of all, the French Consumer Council recommended that the expertise and control capabilities of the French Data Protection Authority *(Commission Nationale de l'Informatique et des Libertés, the "CNIL")* should be strengthened.

CNIL and the French General Directorate of Competition, Consumer Affairs and Fraud Control (Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes, the "DGCCRF") decided to join forces to increase the protection of consumers' personal data. In January 2011, they entered into a general cooperation protocol (the "Cooperation Protocol").

Early Stages Of Collaboration

The main goal of the Cooperation Protocol was to raise consumer awareness and gather information on non-compliance with data protection. Both CNIL's control department and DGCCRF's national investigation department can conduct on-site investigations.
The protocol initially set up three cooperation principles

1. Exchange between CNIL and DGCCRF of information gathered during investigations. When potential violations of data protection laws are identified in investigations by the DGCCRF, that department must inform CNIL. The same applies when potential violations of consumers' rights or anti-competitive practices are identified by CNIL; they must notify DGCCRF.
2. Work and controls on matters of common interest. CNIL and DGCCRF can decide to jointly conduct investigations.
3. Training of staff. Under the Cooperation Protocol, CNIL should deliver specialist training to DGCCRF's staff and vice versa.

Since 2011, key areas of collaboration between CNIL and DGCCRF include the processing of personal data by social networks, deceptive commercial practices related to compliance with the European General Data Protection Regulation (GDPR) and the use of personal data in e-commerce.

The 2019 Cooperation Protocol: One Step Further

On 31 January 2019, CNIL and DGCCRF signed a new Cooperation Protocol. This updated version is designed to reinforce the collaboration between these two departments. With the increase in online consumerism and the Internet of Things (IoT), areas of common interest between DGCCRF and CNIL are expected to grow. This made it necessary to adapt the initial Cooperation Protocol to take account of new digital issues and challenges.

On their websites,[3] CNIL and DGCCRF each specifies the principal areas of cooperation and their objectives:

- improving consumers' awareness of the risks at stake when they communicate personal data and supporting the spread of professional best practice in this area
- enabling easier information exchanges where non-compliance with consumer law and consumer personal data protection law is in issue
- conducting joint controls
- jointly supporting proposals for action at the European level
- pooling skills (particularly investigation tools) and
- sharing their analyses of the evolution of the legislative and regulatory framework governing protection of consumers and their personal data.

1 European Parliament resolution of 20 May 2008 on EU consumer policy strategy 2007-2013 (2007/2189(INI)), §17.

2 French Consumer Council, report dated 18 May 2010, available in French at: https://www.economie.gouv.fr/files/files/directions_services/cnc/avis/2010/180510protection_donnees_perso.pdf.

3 https://www.cnil.fr/fr/la-cnil-et-la-dgccrf-font-evoluer-leur-protocole-de-cooperation-pour-renforcer-la-protection-des and https://www.economie.gouv.fr/dgccrf/cnil-et-dgccrf-font-evoluer-protocole-cooperation-pour-renforcer-protection-des-consommateurs (in French).

An annual report will be drafted to ensure monitoring of this cooperation.

The 2019 Cooperation Protocol has not yet been published.

Comment

Less than one year after the application of the GDPR, this new Cooperation Protocol illustrates the French authorities' will to reinforce their control of companies' compliance with the new data protection principles and obligations.

Companies operating in France should expect the multiplication and reinforcement of joint controls by CNIL and DGCCRF. These joint controls may be unannounced (as they are when CNIL or DGCCRF implements their own controls).

It should also be noted that consumer associations in France are very active in the field of data protection. They can file a complaint for data breach with CNIL and communicate information to DGCCRF which may trigger investigations. Consequently, companies need to be prepared for unannounced on-site controls and should be able to demonstrate that processing takes place in accordance with data protection laws.

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Europe *Italy*

Mobile phones and exposure to EMF: stay tuned for more information, soon

Ongoing discussion has been rekindled in Italy over the potential risks of exposure to electromagnetic fields ("EMF").

In a decision handed down on 15 January 2019, the Regional Administrative Court of Lazio ("TAR Lazio") ordered the Ministry of Environment, the Ministry of Health and the Ministry of Education, Universities and Research (the "Ministries") to launch a campaign providing information to the public on "any short or long-term health risks due to the use of mobile phones".

The facts

Before the order by tar lazio, the ministries had previously been sued by a citizens group, the association for the prevention of and fight against electrosmog ("a.P.P.L.E"). This group describes itself as "promoting protection of health and integrity of human beings and environment from the exposure to electromagnetic fields."

A.P.P.L.E's action was based on the provisions of law no. 36/2001 (The "law"). This sets out the basic principles for protecting workers and members of the general public from the effects of overexposure to electric, magnetic and electromagnetic fields. It also covers the promotion of research into potential effects of exposure, and environmental and landscape protection via the promotion of emf-minimising technology.

Referring to article 10 of the law in particular, the claimant argued that the ministries should have promoted information and environmental education campaigns. Their inactivity in that respect was unjustified, according to the claimant.

To support its claim and highlight the need for education campaigns, a.P.P.L.E filed some scientific studies in court. These, it claimed, showed that use of mobile and cordless phones could have harmful effects on human health due to exposure to emfs, especially for children whose psychophysical development may be negatively affected by these fields.

The decision

Tar lazio's decision acknowledged the existence of a note issued by the ministry of health[1] in 2012, in response to a previous request submitted by a.P.P.L.E. The note informed a.P.P.L.E that an information campaign was being prepared by the ministry of health, and specified that

- The issue of possible health risks arising from the use of mobile phones was already under its scrutiny, particularly following the classification – by the international agency for cancer research – of electromagnetic fields as possibly carcinogenic to humans (category 2b) and
- In 2011, the higher health council (consiglio superiore di sanità) had recommended an information campaign to promote safe and responsible use of mobile phones, especially with children coming into contact with these devices at an increasingly early age. It maintained that the hypothesis of a causal relationship cannot be completely excluded in connection with frequent use of mobile phones, although there is no scientific certainty about possible causation between exposure to radio frequencies and cancer.

Because the information campaign first announced in 2011 has yet to be implemented, tar lazio ordered the government to launch a similar campaign within six months from the service of its decision. This would provide advice to the public on the availability of information dealing with the use of mobile and cordless phones, as well as any potential health and environmental risks associated with their use.

1 http://www.salute.gov.it/portale/news/p3_2_4_1_1.jsp?lingua=italiano&menu=salastampa&p=comunicatistamp&id=3439

Comment

The tar lazio decision, which received significant media coverage, is likely to reignite debate in italy around over electromagnetic exposure and mobile phones. This is a live issue that the italian courts have been faced with before. In 2017, the court of ivrea and the court of florence found that damage had been caused by the extensive work-related use of mobile phones and ordered the national insurance provider ("inail") to compensate the affected workers with a lifelong payment. These courts were apparently following in the footsteps of the italian supreme court which, in a landmark 2012 case brought by a worker against inail, ruled that a causal link exists between mobile phone use and cancer. The supreme court held that the benign tumour developed by the plaintiff on the left side of his face (allegedly due to using a mobile phone for around 5-6 hours a day) entitled him to an 80% disability pension.[2]

With this information campaign likely to be launched in the next six months, mobile and cordless phones manufacturers should monitor developments and respond as necessary.

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2 See also Christian Di Mauro and Mauro Teresi, "Mobile phones and cancer: Italian courts follow path set out by Supreme Court", International Product Liability Review, 68 (September 2017), p.6

Europe *Netherlands*

The wait is over: collective actions for damages are here

On 19 March 2019, the Dutch Senate finally approved legislation introducing collective damages actions in the Netherlands (the "Legislation"). This introduces the option to claim monetary damages in a "US style" class action.

Collective Action For Damages

When the Legislation will enter into force has not yet been determined. Its scope has, however: it will apply to harmful events which took place on or after 15 November 2016.

The key features of the Legislation are:

- An option to claim monetary damages in a collective action on an opt-out basis. The Legislation lifts the current prohibition on representative organisations claiming monetary damages in a collective action. The proposed action can either result in a judgment in which the court will award damages or in a collective settlement held to be binding by the court.
- The Dutch legislator chose an opt-out mechanism, inter alia, because this will create closure for the defendant – preventing new collective actions being brought on the same facts and about the same legal issues once a collective action has finished. Initially, the legislator had international ambitions; the draft legislation did not limit the size of the (opt-out) class. Provided the scope rule (see below) was met, the class could include international class members. But after some heavy criticism, the Dutch legislator decided on an amendment to limit the class to Dutch class members only, giving foreign class members the opportunity to opt in. No rule without an exception: upon request by one of the parties, the court may also apply the opt-out regime to those foreign class members who are "easily identifiable".
- An "exclusive representative" can be appointed if there is more than one collective action organisation seeking to bring an action for the same circumstance(s), on similar points of law and fact. This compares with a "lead plaintiff" in the USA. The exclusive representative will litigate on behalf of all collective action organisations involved in the procedure. This means it will be important for the organisations to coordinate with each other. After the appointment of the exclusive representative, class members can opt out.
- Once the exclusive representative is appointed, the court will set a period for the parties to try to negotiate a settlement agreement. If a settlement agreement is reached and declared binding, there's a second opt-out opportunity for class members. If no settlement agreement is reached, the proceedings will continue.
- However, if, at some point in the proceedings, the court deems it appropriate, it can order the parties to file a settlement proposal. On the basis of this proposal, the court can determine the amount of compensation to be paid. The possibility of reaching a settlement is laid down in the collective action for damages procedure.
- Enhanced standing and admissibility (eg in terms of governance, funding and representation) are introduced for collective action organisations. These will be assessed at an early stage of the proceedings (comparable to the US "motion to dismiss"). Among other actions, the collective action organisations must appoint a three-headed board, a supervisory board and an accountant. In addition, each collective action organisation needs to have a website and communicate with its stakeholders. The persons behind the organisation are not allowed to make a profit.
- One of the admissibility requirements is that the action must have a sufficiently close connection with the Dutch jurisdiction (the so called "scope rule"). This connection will exist if any of the following conditions are met:
  - the majority of the individuals on whose behalf the collective action is initiated reside in the Netherlands
  - the defendant resides in the Netherlands or
  - the circumstance(s) on which the collective action is based took place in the Netherlands.

At the final moment, an amendment was filed by a few members of parliament to prevent this scope rule from leading to an upsurge in collective actions against Dutch companies. The Legislation now states that if the connection is based on the condition that the defendant resides in the Netherlands, to fulfil the requirement of "a sufficiently close connection", the circumstances should also indicate a connection with the Dutch legal sphere. To be assessed by the court in each action, this could be the case if the revenue of a large multinational passes – to a significant extent – through its Dutch subsidiary.

- As well as mandating requirements for the collective action organisation, the Legislation also introduces requirements for the action itself. To proceed, a collective action must be shown to be more efficient and effective than initiating individual claims, because (i) the factual and legal questions to be answered are sufficiently common (ii) the number of persons whose interests are protected by the claim is large enough and (iii) if the claim (also) relates to the award of damages, these persons alone or together need to have a sufficiently large financial interest.
- The Dutch government anticipates an increase in third-party litigation funding. The Legislation gives the court the opportunity to ask the claim vehicle to substantiate that it has sufficient means to finance the collective action. The court will also assess whether the claim vehicle has sufficient control over the claim. The funder may not, for example, decide whether or not the claim vehicle should enter into a settlement. Finally, the court will establish that the claim is not prima facie unfounded. To prevent nonsense claims, the Legislation – by way of a last-minute amendment – provides that the court can order the plaintiff to pay five times the normal court-approved scale of costs if the claim does not pass the prima facie unfounded-test. This cost order is still far from the "loser pays all" principle, but it's more than can be awarded under normal circumstances.

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Europe *Poland*

Fuelling healthcare innovation: Poland creates new Medical Research Agency

In March 2019, the new law creating a Medical Research Agency ("the Agency") entered into force in Poland. This new entity is intended to play a similar role to institutions like the UK's Medical Research Council, the National Institutes of Health in the US, the Danish Medicines Agency, and Inserm in France.

Scope Of Agency Responsibilities

The new Agency brings together a specialised body of experts to work on innovation in Polish medicine. With the focus on areas related to oncology, haematology and rare diseases, Agency activities will consist mainly of co-financing scientific research and development (R&D) work, as well as interdisciplinary projects. There's a special emphasis on clinical, observational and epidemiological research.

The Agency can initiate and carry out its own scientific R&D. It will also work on expanding international cooperation and can provide expert opinions to administrative bodies and other entities within the field of medicine and health science.

Financing scientific R&D

To start with, the Agency will most likely focus on research competitions to identify and select research projects that it will be co-financing. The choice of projects will be based on their:

- scientific value
- impact on improving citizens' health
- level of innovation
- predicted economic impact
- effectiveness for use in health protection and
- the material and human resources that will be required.

Competitions will be open to various entities. These include Polish organisations that conduct scientific R&D, entrepreneurs with the status of R&D centres, and university healthcare institutions. Large companies are not excluded. The Polish Ministry of Health recognises that it's often pharmaceutical and medical device companies that can bring the most resources to bear. But the Agency's primary objective is to promote R&D that might not be profitable.

According to the Ministry of Health, the first research competitions will be announced in the second half of 2019.

Supporting Innovation

The Agency's aim is to facilitate innovation in Poland. One of its key roles is to support businesses pursuing innovation in the field of medicine and health science. Such support will not require any research competitions. Unfortunately, however, it's not yet clear what the Agency's approach will be in this respect.

Clinical Trials

The Agency will focus on clinical trials (commercial and non-commercial). The Ministry of Health wants the Agency to promote clinical trials in Poland by acting as a commercial partner to the firms that conduct them. Over time, it could assume responsibility for all clinical trials in Poland (not just the ones that it's actually involved with).

According to the Ministry of Health, the Agency's main area of interest when it first becomes operational will be non-commercial clinical trials of medicinal products and medical devices (in all phases). While these currently constitute only around 1% of the total number of clinical trials in Poland, it's hoped that the Agency's involvement will see this rise to 20-30%.

Business Activities

The Agency can create companies in connection with its own research activities. It can also conduct business activities related to, among other things, carrying out research, advisory and expert services, organising conferences and training, as well as commercialisation of scientific R&D.

Agency Budget

Budget in 2019 will amount to approximately PLN 50 million, rising to around PLN 1 billion by 2028. The Agency will be financed by the state budget and a write-off from the National Health Fund ("NFZ") of 0.3% of its revenues. The money from the NFZ write-off will be used only for non-commercial clinical trials. The Agency may also be financed from other sources, including donations, the EU budget, international research programmes or from its own business activities.

Comment

By providing institutional support for the financing of analysis and scientific research in healthcare, the Agency is expected to contribute to the growth of innovation in Polish medicine. The Ministry of Health hopes that the Agency's launch later this year will encourage international investors to choose Poland for their research activities. We'll keep readers updated on developments.

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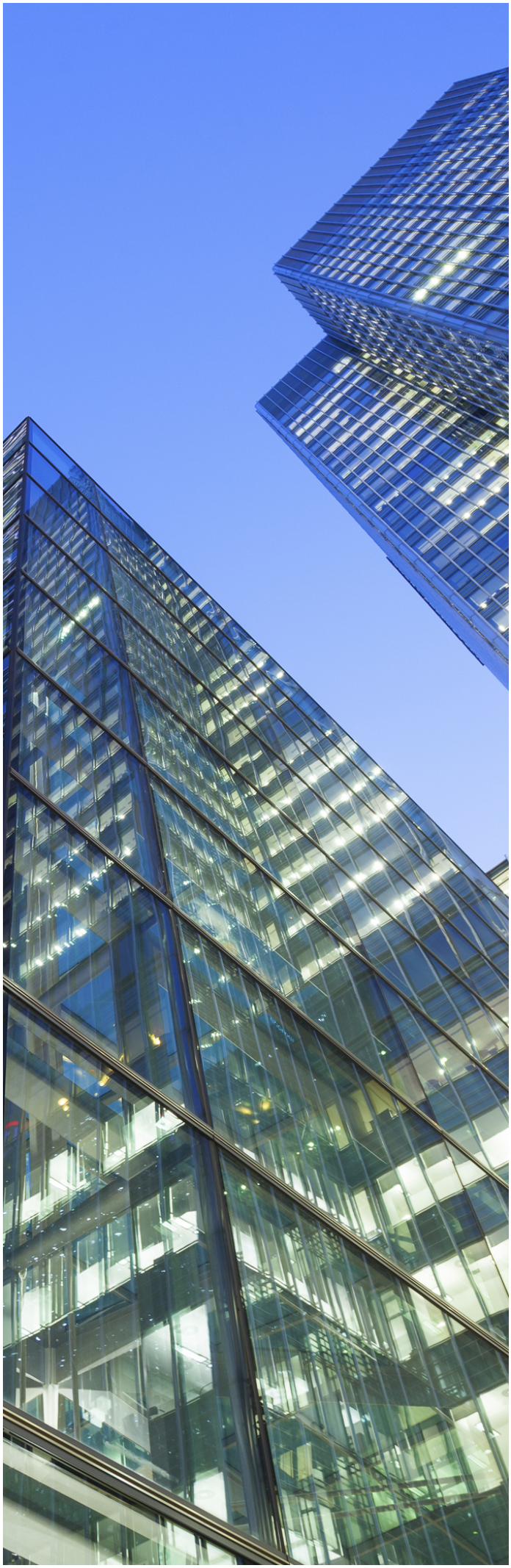

US

FDA Releases Strategy for the Safety of Imported Food

The U.S. Food and Drug Administration (FDA) recently released the "FDA Strategy for the Safety of Imported Food" (the "Strategy"), which outlines the agency's approach to ensuring the safety of the ever-rising volume of imported foods.[1] The Strategy sets out four food safety goals: 1) preventing food safety problems in the foreign supply chain prior to entry; 2) detecting and refusing entry of unsafe foods at the border; 3) quickly responding to unsafe imported food; and 4) developing and publishing metrics to monitor FDA progress. This article provides an overview of the agency's strategy, explains the guiding principles behind this strategy, and summarizes the methods the agency plans to use to accomplish its four goals.

Strategy and Guiding Principles

The US imports about 15 percent of its overall food supply – 32 percent of fresh vegetables, 55 percent of fresh fruit, and 94 percent of seafood – from more than 200 countries or territories representing about 125,000 international food facilities and farms. The same US food safety requirements apply to all food consumed in the United States, regardless of where it was produced.

FDA has developed what it calls "a multilayered safety net" for imported food, specifying distinct roles for manufacturers, importers, third-party auditors, foreign regulatory bodies, FDA, and other stakeholders. FDA aims to use the new requirements under the FDA Food Safety Modernization Act (FSMA) regulations to collect and analyze information from these sources to form a more complete picture of the risk of imported food. The agency also plans to use data analysis to allocate resources in a more targeted way, identifying areas of greater risk where supplemental training or focused outreach efforts can be most beneficial.

FDA identifies seven guiding principles for its strategy:

1. Protecting public health is the first priority
2. Partnering with others to build prevention-based systems is the key to success
3. Maintaining scientific expertise and innovation as the foundations of FDA's food safety work
4. Sustaining a level playing field for domestic and foreign food producers
5. Allocating resources according to risk is the most effective method for protecting public health, and data analytics is the key to prioritizing according to risk
6. Requiring measurement and ongoing refinement to ensure success
7. Establishing transparency as the standard.

FDA's Goals and Objectives

FDA's imported food safety goals fall into three categories: (1) preventing food safety problems in the foreign supply chain prior to entry into the United States, (2) effectively detecting and refusing entry of unsafe foods at the border, and (3) rapidly responding when FDA learns of unsafe imported foods. An overarching fourth goal is to create an effective and efficient food import program, with metrics to measure progress. The strategy outlines several methods the agency plans to use to accomplish these goals including strategies for each objective, as summarized below.

Goal 1: Food Offered for Import Meets US Food Safety Requirements

To ensure the safety of food imports, FDA will pursue objectives related to verification, enhanced compliance, and increased data and information sharing. Specifically, FDA will optimize the use of foreign inspections and ensure importer use of verified foreign suppliers through implementation of the Foreign Supplier Verification Programs (FSVP) regulation. FDA seeks to strengthen the capacity of foreign suppliers to produce safe food by increasing awareness of and training on food safety requirements and incentivizing importers to use verified suppliers of safe food through the Voluntary Qualified Importer Program (VQIP). The agency also intends to work cooperatively with domestic and foreign regulatory counterparts to establish data and information sharing agreements designed to leverage each other's food and facility oversight.

1 FDA Strategy for the Safety of Imported Food (Mar. 2019), available at: https://www.fda.gov/downloads/Food/GuidanceRegulation/ImportsExports/Importing/UCM631864.pdf

Goal 2: FDA Border Surveillance Prevents Entry of Unsafe Foods

The agency will continue to enhance and refine the import screening and entry review processes at the 300 plus US ports of entry by improving testing methodologies and tools used to determine admissibility of food offered for import and optimizing the use of physical examinations and sampling of imported foods. FDA also plans to strategically use import alerts and import certifications (one of the new tools under FSMA).[2]

Goal 3: Rapid and Effective Response to Unsafe Imported Food

FDA will take steps to enhance the efficiency and effectiveness of imported food safety recalls, such as by using information-sharing opportunities with regulatory counterparts with strong food safety systems. When appropriate, FDA will exercise the mandatory recall authority granted to the agency by FSMA.

Goal 4: Effective and Efficient Food Import Program

Longer term, the agency hopes to develop a comprehensive global inventory of food facilities and farms that intend to distribute food in the United States, which will allow FDA to assess the cumulative oversight applied to the imported food inventory. The global inventory will also assist in accountability – FDA intends to publish performance measures and outcome metrics, as well as non-confidential data about imported food, foreign suppliers, and imports.

Comment

The FDA's import strategy for foods shows that FDA continues to place a high emphasis on ensuring the safety of food imported into the US and finding ways to efficiently use its limited resources to target the highest risks. FDA will never have the resources needed to inspect foreign facilities at the same frequency as domestic facilities, so working smarter matters more than working harder. As FDA implements this strategy, food companies may experience increasingly stringent FSVP inspections, additional testing at the border, and continued use of import alerts. We will continue to monitor developments involving FDA's import strategy.

2 Note that the Strategy does not provide any examples of the situations when FDA would use its import certification authority.

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Asia Pacific *Japan*

Balancing safety and efficiency: updating the regulation on pharmaceuticals and medical devices

It's been five years since both the name and the content of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the "Act")[1] were changed in 2014. Now the government's once again planning to update this primary source of regulation for pharmaceuticals, cosmetics, medical devices and utensils. On 25 December 2018, a committee (the "Committee") appointed by the Ministry of Health, Labour and Welfare (the "MHLW") issued an opinion setting out the principles and framework of the amendment to the Act.[2] The Cabinet submitted the draft amendment to the Act to parliament on 19 March 2019 (the "Amendment"), aiming to have it passed during 2019.

The Amendment covers various aspects of the pharmaceutical industry. Most significantly, it contemplates achieving a) rapid access to innovative pharmaceuticals and medical devices and b) tighter governance of manufacturing, distribution and sales enforced through administrative surcharges. The focus is on creating a system where beneficial pharmaceuticals and medical devices can be rapidly developed for use in Japan (ie minimising time-lag in drug and device development). The Regulation's aim is also to ensure safety by introducing a more efficient quality management system with advanced technology and data collected in a regulated manner.

Rapid Access To Innovation

New pharmaceuticals must be approved by the Pharmaceutical and Medical Devices Agency (the "PMDA") before being launched on the market; ordinary screenings take around 11.8 months, with priority screenings taking approximately 8.3 months (in approximately 80% of cases in 2018).[3] The median of the screening period for new active substances ("NAS") was 333 days in 2018.[4] Although this isn't a bad score, the PMDA wants to find ways to expedite the process for advanced medicines. To this end, the Amendment will formally enact and add clearer conditions for the temporary schemes included in the SAKIGAKE Designation System (launched in 2015[5]) and the Conditional Rapid Authorization System (launched in 2017[6]).

The SAKIGAKE Designation System includes prioritisation in the consultation and review process. It was introduced to ensure early practical application of innovative pharmaceuticals and medical devices by encouraging R&D and early clinical research/trials in Japan[7] (reducing the screening period by up to six months).

The Conditional Rapid Authorization System allows for acceleration of the practical application of unapproved/off-label drugs[8] (especially orphan drugs) for serious but rare diseases. It enables Phase III clinical trials to take place before practical application,[9] subject to certain conditions. These include limiting facilities where a product can be administered and requiring post-approval test and report of safety and efficacy on a continuous basis. It allows for the use of real-world data ("RWD") in certain circumstances, especially where the number of targeted patients is significantly small.

For medical devices, the Committee has issued an opinion on improving the Innovative Medical Devices Conditional Rapid Authorization System. It enables authorization to be extended quickly to a) use of devices for other parts of the body, and b) any improvements made after the manufacture and sale of the devices in accordance with approved improvement plans.

1 Act No. 145 of 1960 as amended

2 Opinion on the amendment of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (in Japanese) https://www.mhlw.go.jp/content/11121000/000463479.pdf

3 Achievement of the Operation in 2018 and Future Actions (PMDA, December 2018) https://www.pmda.go.jp/files/000227251.pdf

4 Ibid

5 Under the SAKEGAKE Designation System, five pharmaceuticals were designated in 2015, five in 2017 and six in 2018; one medical device was designated in 2016, three in 2017 and two in 2018.

6 Under the Conditional Rapid Authorization System, two pharmaceuticals were designated in 2018.

7 To qualify for the SAKIGAKE Designation System, the pharmaceutical must be: i) an unprecedented invention; ii) targeted at a serious disease; iii) significantly effective against the target disease; and iv) applied for clinical use in Japan and/or worldwide.

8 Strategy of SAKIGAKE by the Ministry of Health, Labor and Welfare https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/140729-01.html

9 To qualify for the Conditional Rapid Authorization System: i) the target disease must be serious (ie life-threatening, with an irreversible and substantial impact on the daily life of the patient, or other reasons); ii) the pharmaceutical or medical device is highly effective to the target disease because there is no existing medication or the pharmaceutical or medical device is more favourable than existing medication; iii) phase III clinical trial is difficult or takes extensive period of time due to the small number of patients etc.; and iv) the pharmaceutical or medical device has been proven to be effective and safe to a certain level by clinical trials or other methods other than phase III clinical trial.

The Committee also indicated tightened regulation of clinical trials, improved traceability, and globally-harmonised quality management methods. This will include revising reviews of conformity with "Good Manufacturing Practice" ("GMP") and "Good Gene, Cellular and Tissue-based Products Manufacturing Practice" ("GCTP") on a facility, instead of a manufacturer, basis. It also includes relaxing requirements for reviews of the "Quality Management System" ("QMS"), and risk-based approaches to changes in approvals.

Introducing Tighter Governance

The Committees made various suggestions for introducing tighter governance of manufacturing, distribution and sales. These include enforcing a barcode system, improving the traceability of pharmaceuticals and medical devices through the supply chain, and tightening the approval system for authorised manufacturers and sellers of products. The most significant suggestion of all is for the introduction of administrative surcharges on false or misleading advertisements, and sales of unapproved pharmaceuticals. While these are already prohibited under the Act, the scope of criminal liability is narrow and fines are relatively low (maximum JPY 2 million for an individual and JPY 100 million for a company) – unlikely to deter future violations when some blockbusters can bring in many billions of dollars in revenues.[10] This was raised following recent scandals where several companies delayed reporting side effects, manipulated clinical data, and manufactured certain pharmaceuticals without authorisation. The surcharge will be calculated as up to 4.5% of revenues from pharmaceuticals or medical devices sold as a result of unlawful advertising or acts.

Comment

Many stakeholders have been waiting for this update of the Act. And although it's challenging to achieve a balance between speedy procedure and safety protection, the Amendment will definitely bring more foreseeability to the process and create a more favourable environment for effective clinical development, manufacturing and distribution of pharmaceuticals and medical devices in Japan.

Tighter governance of the end-to-end supply chain for pharmaceuticals and medical devices will help ensure integrity and compliance in the industry. This will benefit not just patients but all market participants, including doctors, researchers and pharmaceutical companies. At this point, it's not certain whether the Amendment will be passed by parliament this year. But as the Committee has said, and regardless of the Act, all parties need to think about how they can improve the quality, effectiveness and safety of pharmaceuticals and medical devices.

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10 Although the Act also provides a penalty of imprisonment of up to 2 years for a case of misleading or false advertisement, Japanese prosecutors are cautious about bringing criminal charges for this kind of crime under a concern for balancing crimes with appropriate punishments. In addition, ethical violations at the development stage or in the communication not amounting to a prohibited false "advertisement" are not effectively regulated.

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