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JANUARY 2021

For SMEs, policy and policymaking can often seem a low priority when facing the operational demands of running a business. Yet the sector is one of the most highly regulated that there is, and policy decisions are shaping your short- and long-term business environment.

Although your national trade association may help, many issues – particularly at the moment – are being shaped on a European level. Therefore, if you want to know what is likely to impact you, from the re-use of health data to a regulatory framework on artificial intelligence, it's important to ensure you look to the EU horizon also.

Recognizing the demands on your time, COCIR has developed a newsletter specifically geared to the needs of SMEs. It allows you to see – at a glance – what is important and relevant and why it should matter to you.

You can subscribe to our SME newsletter here; it will provide you with an 'at-a-glance' overview of what's important and why it matters for your business.

Next edition will further elaborate on the Multi-Annual Financial Framework and related programmes currently being negotiated. These will determine the European investment environment for the next seven years and opportunities for our industries. If you wish to understand better benefits for your organisation for funding, please contact us.

Nicole DENJOY
COCIR Secretary General

IN THIS EDITION OF THE COCIR SME NEWSLETTER:

IN CASE YOU WANT MORE INFORMATION ON COCIR ACTIVITIES, PLEASE CONTACT US:
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1. LATEST EU POLICY DEVELOPMENTS

THE FOUNDATIONS ARE BEING LAID FOR A EUROPEAN HEALTH DATA SPACE

FIRST PROPOSAL FOR DATA GOVERNANCE RULES APPLYING TO EU DATA SPACES

The European Commission's proposal for a Data Governance Act seeks to install measures that will increase trust in sharing data from the public and private sector for re-use.

WHAT'S HAPPENING?

The Commission's proposal encourages Member States to make available certain categories of more sensitive public sector data. A single point of contact at national level should help improve access to this data.

The proposal also wants to create an authorisation framework - including minimum conditions - for data sharing service providers that intermediate between data holders and those that wish to use that data. The Data Governance Act will apply to all common European data spaces that will be created to realise the European Data Strategy, including the European Health Data Space.

NEXT STEPS:

The Data Governance Act will be complemented with more sector-specific regulation. Rules for the European Health Data Space are expected to be proposed by the end of 2021. From early next year, EU Member States will start preparing the ground through a joint action that will focus on the topic of data governance, while also looking into data quality, technical infrastructure and citizen-controlled data.

IMPLICATIONS FOR SMEs:

The Data Governance Act is setting up the first rules for European data spaces. It can help increase access to public sector data for businesses. The authorisation framework may encourage private data holders to make (more) data available to third parties for re-use. The scope and authorisation conditions for data sharing service providers will however determine to a great extent how this will affect existing business models.

2021 – A PIVOTAL YEAR FOR AI IN HEALTHCARE?

THE FUTURE FOR AI IN THE EU AND THE IMPACT ON MEDICAL DEVICE LEGISLATION

Europe is keen on establishing requirements for trustworthy AI. The European Commission has set out its vision for AI in a White Paper as well as a roadmap of how to get there

WHAT'S HAPPENING?

The European Commission is in the final stages of preparing a legislative proposal that will apply across sectors. It is seeking to define an approach that addresses risks related to safety and fundamental rights, in particular in high-risk AI systems.

NEXT STEPS:

The Commission hopes to publish its proposal by March 2021. In addition, given the upcoming implementation of the Medical Device Regulation in May 2021, the Medical Device Coordination Group is discussing rules and requirements on AI. COCIR has already presented its comprehensive analysis of the likely impact, with recommendations, at the last meeting of the relevant expert group.

IMPLICATIONS FOR SMES:

The Commission proposal will be cross-sector and may introduce obligations that are burdensome or inconsistent with the legal requirements defined by the Medical Device Regulation. This could further increase time and costs of bringing new products to the market.

TOWARDS A NEW CYBERSECURITY STRATEGY – MORE REQUIREMENTS FOR HEALTHCARE?

THE NEED FOR EHEALTH SECURITY

Concerns over the security of health data, and the growing interest of cybercriminals in health targets – exacerbated by COVID-19 – has highlighted the need for stronger cybersecurity measures.

WHAT'S HAPPENING?

The European Commission has just announced its EU Cybersecurity Strategy. The Strategy comes with a proposal for a revised NIS Directive, drawing in more healthcare activities into the extended scope. In addition, Member States are also to decide which organisations they consider critical entities for which specific resilience measures should be introduced to prevent significant disruptive effects to society.

Under the revised NIS Directive the list of essential entities (formerly "operators of essential services") regarding health has been extended with specific laboratories, R&D sites and manufacturing facilities of pharmaceuticals and of public health emergency critical medical devices. Next to that, cybersecurity risk management measures are being introduced for all entities manufacturing medical devices and in vitro diagnostic medical devices. Micro and small enterprises are excluded from the scope, with some exceptions.

NEXT STEPS:

The legislative files will be passed on to the European Parliament and the Council. A public consultation has also been launched to provide stakeholders the opportunity to provide feedback. COCIR has been actively contributing to assessments leading up to the revision of the NIS Directive and will continue to engage to clearly articulate the concerns from the industry on these proposals.

IMPLICATIONS FOR SMES:

As it stands, the current proposals will introduce new requirements for many businesses. Some of those will be directly applying, others might trickle down as supply chain requirements. It is very likely that the measures will increase costs for businesses. Furthermore, the proposals fail to address the existing fragmentation and discrepancy of measures between different countries, which might negatively affect the market competitiveness.

GREATER CLARITY NOW AVAILABLE ON PERSONAL DATA TRANSFERS TO NON-EU COUNTRIES

edpb
European Data Protection Board

ENSURING COMPLIANT DATA TRANSFERS TO NON-EU COUNTRIES

The General Data Protection Regulation allows the transfer of personal data to non-EU countries on the condition that an adequate level of data protection can be ensured. The GDPR provides different mechanisms to support such data transfers.

WHAT'S HAPPENING?

An important ruling by the European Court of Justice (the so-called *Schrems II ruling*) has put into question the validity of the existing instruments for data transfer, causing legal uncertainty for companies that are or wish to export personal data to non-EU countries.

The European Data Protection Board has now published recommendations for assessing the level of data protection in third countries. This should help identify whether companies should take any supplementary measures to ensure compliance with GDPR.

The European Commission has at the same time drafted updated Standard Contractual Clauses. This template, containing specific modules to allow for different data transfer scenarios, helps companies to formalise the data transfer between EU and non-EU parties in a compliant manner.

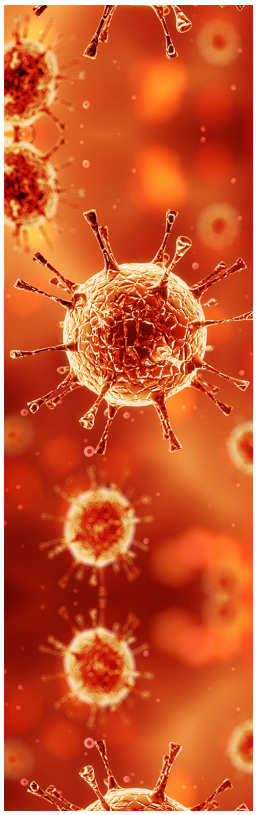
NEXT STEPS:

Public consultations have been organised to offer stakeholders the opportunity to comment on the EDPB

recommendations as well as the Commission's update on the Standard Contractual Clauses. It is clear from the current documents that there are inconsistent views between the data protection authorities and the European Commission, so more changes are expected in the future.

IMPLICATIONS FOR SMEs:

It is the legal responsibility of companies to ensure data transfers to non-EU countries are compliant with the GDPR requirements. The *Schrems II ruling* has forced companies to seriously reconsider their existing data protection practices. The recent updates shed some light on possible ways forward, but are insufficient at this point in time to ensure legal certainty for all existing data flows.



BIGGER ROLE FOR DIGITAL HEALTH FOR EUROPE ON COVID-19?

IMPORTANCE OF EUROPEAN COOPERATION IN BATTLING COVID-19

The COVID-19 crisis and the initial responses from individual countries made it quite clear there was an important role to play for coordination at the EU level. COCIR is closely monitoring this matter and is promoting our sectors' value-add.

WHAT'S HAPPENING?

In order to better map, contain and mitigate the spread of COVID-19 infections there are currently 20 EU countries where a national contact tracing app is operational..

The European Commission has set up a European Federated Gateway Service, which is able to pass on identifiers between the different apps. To date, nine countries - Croatia, Denmark, Germany, Ireland, Italy, Latvia, Netherlands, Poland and Spain – are connected to the Gateway Service. More countries will be connected in the upcoming weeks. This should ensure interoperability between the different systems and is considered particularly useful once lockdown measures are being lifted and travel picks up again.

NEXT STEPS

With the focus now moving to vaccination strategies, the European Commission is trying to play a stronger coordinating role from the beginning. Within this context they have started to discuss with the Member States how best to consider digital solutions in support of vaccination and a possible return to normal.

IMPLICATIONS FOR SMEs:

Depending on the development of discussions, there may be opportunities for companies that offer digital health solutions that deal with or link to vaccination or tackling other issues related to COVID-19.

2. EXPECTED IN JANUARY

GDPR STUDY ON HEALTH DATA. The European Commission set up a range of workshops in early 2020 to understand from various stakeholders (Member State authorities, data protection authorities, industry, healthcare professionals, patient groups) how the application of the GDPR has impacted the use of and access to health data for care provision, scientific research and public health response. The outcome of this study is expected in the coming weeks.

EUROPEAN HEALTH DATA SPACE. Complementing their recent proposal of a Data Governance Act, the European Commission is expected to publish its preliminary views on a data governance framework for the European Health Data Space in January, This may give further indications how the European Commission considers the role of data permit authorities and how interoperability and data protection principles should be integrated.

3. COCIR ACTIVITIES ON DIGITAL HEALTH

COCIR is the leading industry voice on digital health, with expert working groups on the following areas:

- ARTIFICIAL INTELLIGENCE IN HEALTH TASK FORCE
- DATA PROTECTION & CYBERSECURITY FOCUS GROUP
- EHR AND INTEROPERABILITY FOCUS GROUP
- INTEGRATED CARE / BLUEPRINT TASK FORCE
- mHEALTH TASK FORCE

DIGITALISATION OF HEALTHCARE – THE NEW NORMAL

In November COCIR held a successful webinar on how health systems can be made more resilient and the vital role for digital health. Featuring high-level and expert speakers, these discussions were further developed with two specific use cases; on how to best manage patients with chronic conditions, and how to ensure best exchange of health data to optimise patient treatment.

Presentations and a report of the event are available here.

COCIR IS WORKING ON BUILDING TRUST IN AI IN HEALTH

AI USE CASES. Since Jan. 2020, COCIR is periodically collecting and publishing AI use cases from its members. We now have 16 use cases accessible through our website.

AI AND MDR. In the upcoming months COCIR will increase its outreach activities to key EU policy makers to promote the value of AI in health and to emphasise the strength of the Medical Device Regulation in addressing the safety and reliability of AI-based systems.

COCIR SHARES ITS VIEWS ON DATA PROTECTION

COCIR has provided detailed comments on the EDPB's guidance on the concepts of controller and processor. COCIR has also been actively participating in an EDPB stakeholder workshop with limited audience that focused on the topic of legitimate interest. COCIR will continue to monitor closely the development and progress.

MARKET ACCESS PATHWAYS FOR DIGITAL HEALTH SOLUTIONS

COCIR has published a paper on market access pathways for digital health solutions. Drawing on the experiences of its Corporate and National Trade Associations members, COCIR assessed the current situation of market access for digital health solutions at national level.

Member States must learn from each other, evaluate and share best practices, and - in collaboration with industry - construct clear and efficient pathways for reimbursement of digital health solutions. COCIR offers recommendations to policy makers to ensure digital health solutions can reach and benefit all European citizens.

4. COCIR INVOLVEMENT IN EUROPEAN PROJECTS

BLUEPRINT / WE4AHA

COCIR has been a Blueprint champion since 2017 and active within the WE4AHA project that is now coming to a close. A dedicated site is under construction that will make the personas available that have been developed within the project. Personas identify patient profilies and help to explore unmet needs that can be addressed through digital health solutions.

DIGITAL HEALTH EUROPE

On 12 -13 November COCIR joined the DigitalHealthEurope consortium meeting to discuss with other project members the next steps in this project supporting the digital transformation of health and care. The project has recently helped to map patient expectations on sharing health data.

UNICOM

COCIR joined the UNICOM consortium meeting on 19 and 20 November, taking stock of the current progress on implementing ISO IDMP standards for the univocal identification of medicinal products.

X-eHEALTH

COCIR will contribute to the X-eHealth project as a collaborative partner. The X-eHealth project will strengthen the cross-border exchange of health data by helping to develop the EHR exchange format for medical imaging, lab results and hospital discharge reports.

EURAMED ROCC-N-ROLL

COCIR has begun working on the EURAMED rocc-n-roll project, which will coordinate research and innovation in medical applications of ionising radiation, including digitalisation.

InteropEHRate

COCIR has been invited to join the External Stakeholder Board of the InteropEHRate project that wants to establish a functional framework putting people in control of their electronic health records.

5. DEEP DIVE: TRANSFERS OF PERSONAL DATA TO NON-EU COUNTRIES

The General Data Protection Regulation (GDPR) requires that where personal data is transferred to non-EU countries, the recipient country must have an equivalent standard of data protection. Importantly, the onus is on the company transferring the data to verify this. Non-compliance can be a major liability. The GDPR offers different instruments to ensure compliant data transfers, in particular:

1. ***Adequacy:*** Adequacy is similar to a 'white-listing' of countries that the European Commission has assessed and confirmed as having an adequate level of protection. In principle data exporters do not need to take any specific or additional measures to establish the data transfer to the countries (see below for a list of approved countries).

2. ***Standard Contractual Clauses:*** Standard Contractual Clauses allow the data exporter and data importer enter into a contractual agreement that ensure appropriate safeguards are put into place.

3. ***Binding Corporate Rules:*** This approach is specific for members of a group of undertakings or group of enterprises that are engaged in a joint economic activity. Binding Corporate Rules are subject to approval by data protection authorities.

To date, the European Commission has only granted adequacy to a very limited number of countries. A special regime was set up for data transfers to the United States whereby only certified US companies would be considered to provide an adequate level of protection. Following a legal challenge, the so-called 'Safe Harbour' arrangement was invalidated and had been replaced by the EU-US Privacy Shield.

SCHREMS II RULING

The *Schrems II* ruling in July 2020 by European Court of Justice invalidated the EU-US Privacy Shield, but upheld the validity of standard contractual clauses (SCCs) for transfers of personal data to third countries. The Court clarified however that controllers or processors, acting as data exporters, are responsible for verifying on a case-by-case basis, if the third country provides an equivalent level of data protection. The Court indicated that supplementary measures may be required to safeguard that protection.

Whereas the invalidation of the Privacy Shield directly impacted data transfers between the EU and the United States, the confirmations regarding the Standard Contractual Clauses have much wider ramifications, putting additional burden on companies, and SMEs in particular.

NEW GUIDANCE ON ESSENTIAL GUARANTEES AND SUPPLEMENTARY MEASURES

Responding to the *Schrems II* ruling, the European Data Protection Board (EDPB) updated its Recommendations on European Essential Guarantees (EEG) for surveillance measures These recommendations help to determine whether surveillance measures allowing access to personal data by public authorities in a third country, can be regarded as a justifiable interference. The EEG form an important part of the assessment whether a third country provides an equivalent level of data protection.

The EDPB identifies 4 European Essential Guarantees:

A. Processing should be based on clear, precise and accessible rules

B. Necessity and proportionality with regard to the legitimate objectives pursued need to be demonstrated

C. An independent oversight mechanism should exist

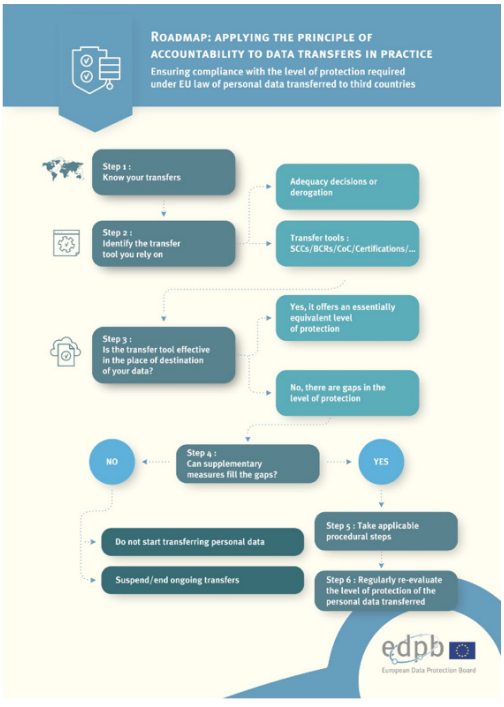
D. Effective remedies need to be available to the individual

Where the law of the third country does not comply with the EEG requirements, there is no equivalent level of protection and it is up to the individual data exporter to assess, on a case-by-case basis, whether supplementary measures may be required or if data transfers to that country should be stopped altogether.

This is where the new Recommendations from the EDPB on supplementary measures come in. The EDPB considers such supplementary measures part of an internal assessment process. There is a need to document the assessment and supplementary measures, and this may need to be made available upon request of a competent supervisory authority.

The EDPB advises companies to undertake following steps:

1. ***Know your transfers*** – mapping transfers, also taking into account onward transfers, remote access from a third country and/or storage in a cloud outside the European Economic Area (EU27, Iceland, Liechtenstein, Norway)
2. ***Identify your transfer tools*** – adequacy decisions, SCCs, binding corporate rules, codes of conduct, certification, ad hoc contractual clauses, Art. 49 derogations
3. ***Assess effectiveness of the transfer tool*** – check the afforded level of data protection in the third country for all actors participating in the transfer, taking into account legal context of the transfer (purposes, entities, sector, categories of data, access/storage/format of data, onward transfers) and based on the four European Essential Guarantees
4. ***Adopt supplementary measures*** – supplementary measures can be of contractual *(clauses on technical measures, transparency, review, consent)*, technical *(encryption, pseudonymisation, split processing)* or organisational *(internal policies, documentation, transparency reports,...)* nature. Contractual and organisational measures alone may be insufficient. Annex 2 sets out a number of scenarios, indicating whether or not effective measures could be found. For time being and under certain scenarios, the EDPB considers there are no effective measures for (1) transfers to cloud service providers or other processors which require access to data in the clear, and (2) remote access to data for business purposes
5. ***Take applicable procedural steps*** – the EDPB is currently still evaluating the need for additional guidance in the area of binding corporate rules and ad hoc contractual clauses
6. ***Regularly re-evaluate the level of protection***



UPDATED STANDARD CONTRACTUAL CLAUSES

The European Commission has drafted updated Standard Contractual Clauses for the transfer of personal data to non-EU countries, still the most popular data transfer mechanism. It replaces the old pre-GDPR templates and takes into consideration the *Schrems II* ruling. The current proposal allows more flexibility by providing specific modules for different data transfer scenarios:

- controller-controller
- controller-processor
- processor-processor (NEW)
- processor-controller (NEW)

The proposal sets out a one-year transitional period after publication during which the current standard contractual clauses can still be used, in combination with supplementary measures, where necessary.

BREXIT

Under the agreed deal between the EU and the United Kingdom, transfers of personal data to the UK shall for a limited time not be considered as a transfer to a third country. Unless the EU adopts an adequacy decision for the UK, this provision will only last for six months. It is still unclear whether the UK will be granted adequacy eventually. In absence thereof, at latest from 1 July 2021 all transfers of personal data from the EU to the UK are considered transfers to a non-EU country and data exporters should take appropriate measures to ensure compliance

CONCLUSION

The measures by the European Commission and the European Data Protection Board are trying to help organisations navigate the challenging legal situation created by the Schrems II ruling. Despite these tools, it still remains challenging and unclear for companies to assess the validity and effectivity of the safeguards put in place when transferring data to non-EU countries.

In absence of more flexibility provided by the data protection authorities, businesses will have to weigh their options: face the time-consuming burden of reassessing their data transfer agreements, stop exporting data to non-EU countries or take the risk of being found out.

GENERAL INFORMATION ABOUT COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org).

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