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b-solutions

Annex I.a: FINAL REPORT BY THE EXPERT¹

Part of the report is also the information sheet on the advice case to be compiled by the advised entity to be submitted to the Association of European Border Regions (AEBR) attached to the report.

Advice case title:

Applying the GDPR and national legislation in cross-border public health cooperation

Full official name of the advised entity:

Stichting euPrevent

Name of the expert contracted for the advice case:

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Date:

25 October 2021

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I. Description of the legal or administrative obstacle in the specific context

euPrevent is a Euregional network that focuses on promoting health. COVID-19 is a clear example of the cross-border nature of diseases and the importance of cross-border cooperation in health. During the COVID-19 crisis a lot of measures that were imposed by national and regional governments, were somewhat related to the available data of the transmission of the infection. Thus, accurate data provides a solid basis for issuing guidance on how to best respond to the outbreak. However, this is harder in a cross-border setting like in the EMR. On the other hand, the cross-border setting makes it interesting to study possible differences in the effects on national measures. The project 'euPrevent COVID-19 and its impact on the EMR' (euPrevent COVID) focussed on obtaining data to assess the impact of COVID-19 on the EMR. The aim is to gain insight into the effects of COVID-19 in a cross-border region of the EMR and to present this as a showcase for other border regions on what the effect could be for other border regions. To do so, prevalence of COVID-19 antibodies in the EMR will be studied. Here the practical organisation is that two rounds of blood sampling tests will take place in order to see how COVID-19 antibodies have evolved among EMR citizens as a reaction to the various response measures.² From the lab in the Netherlands, south-Limburg, 'packages' are distributed among citizens in the EMR, thus both in the Netherlands as well as across the border to Belgium and Germany. A package includes a survey, a set for a blood sampling and a letter of informed consent to be signed by the participant. The design was that after sampling blood, participants would send back the forms and blood sample to the lab for further study.

Yet, several obstacles were experienced, ultimately leading to a delay of four months.

1. Ethical approval by the Ethics Review Committee

The first obstacle experienced was that ethical committees have difficulty approving studies or projects involving persons from different countries. When requesting approval by the Ethics Review Committee of the Dutch UM, it appeared not to be possible to get full approval for the research activities across the border. In Germany there was no medical ethical check requested, but did require an informed consent. In Belgium there were certain arrangements with statistical and research institutions in Belgium but that did not cover 'foreign' partners. Therefore, it is hard to get approval for a cross-border research project as this one. A formulated wish by the lead in the euPrevent COVID project is the recognition of Ethical approval across the border.

The second obstacle is that German authorities required that the signed informed consents had to stay in Germany. It was thus not possible to directly transport the package with blood samples from the participant in Germany to the lab in the Netherlands. A 'stopover' had to be made in Germany to open the package, get the informed consent and then send it to the lab across the border.

Regarding the informed consent, there was also a different interpretation; in the Netherlands it was requested that participants should have a 'waiting period' after registering for the project, but before receiving the package in order to have the opportunity to refuse the package. Belgium and Germany did not see it that way.

2. Exchanging addresses across the border

Another obstacle was exchanging personal data among project partners. In this case it was about address details of the participants in the study. Of course, the addresses were necessary to be able to send the packages. It appeared not possible to get the addresses of participants across the border from the national administrators. Contact details (addresses) could not be

² <https://euprevent.eu/covid-19/>



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exchanged across the border (prohibited by national legislation). A practical solution was found by appointing 'regional data managers'. In practice this means that the packages had to go from the lab to the regional data manager, who combined the participant code with the address and would send it to the participant. The same was true for returning the package from the participant to the lab (from participant to regional data manager, from manager to lab).

The wish is that the three countries could agree that in cross-border projects such as COVID, this would be possible under certain conditions. On the understanding, of course, that this data can be used by a very limited group solely for the purpose of the project. It would be good to have procedures (ideally, specific harmonised EU law) that allow for cross-border cooperation in border regions in scientific studies and other projects with limited use of personal data.

More specifically on the Belgian-Dutch side: It was not possible for the Dutch and Belgian partner in the project, as joint controllers, to obtain Belgian National Registry (BNR) data. While there is an arrangement between Sciensano and Statbel that Sciensano can receive personal data like addresses for research. However, this was not possible for a cross-border collaboration containing project partners across the border next to Sciensano. In that case, Statbel refuses to hand over the information. The personal data obtained from the BNR would only be treated by the Belgian partner and under no circumstance cross the national border (in fact, the data would directly be treated by a trusted third party in Belgium). Only a bilateral law between the Netherlands and Belgium or other law implemented by Belgium purely for this kind of research would allow the latter. This requirement is not imposed on the Dutch side.

A practical solution was found to conceal the partners across the border, making only Sciensano as applicant for Statbel. It was perceived as largely diverging interpretations by neighbouring Member States.

A final obstacle was regarding the software company that was based in the Netherlands. The company would store, process and report the gathered data (e.g. blood test result for the participants). Since the company is processing data, a contract has to be made. However, every country wanted to make their own contract, but the company insists on one contract and one contact person.

In general, it was stated that public health organisations including the authorities face severe difficulties in aligning national GDPR implementing legislation across Member States in the context of cross-border cooperation. The general question is how these GDPR challenges in cross-border public health projects and research can be best tackled and what the legal framework is.

II. Indication of the legal dispositions causing the obstacle

The COVID-19 pandemic showed the great importance of collaboration in research across border, both within as well as outside the EU. Here, within the European Union, the General Data Protection Regulation (GDPR) regulates the processing of personal data, also containing health data for research purposes. In the case of health research, the GDPR applies to the processing of 'personal data'; being 'information related to an identified or identifiable natural person'.³ The processing of health data merits special protection and can only be carried out under the specific conditions of Article 9(2) GDPR. With the definition 'personal data related to the physical or mental health of a natural person, including the provision of health care services,

³ Art. 4(1) GDPR



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which reveal information about his or her health status' it may be clear that this could be applicable to the case.

The GDPR foresees in requirements, core principles and safeguards, seeking to find a balance between the protection of personal data on the one hand and promoting research on the other hand. Entering into force in 2018, the objective of the GDPR was to create a harmonised framework for processing data across Europe. Yet, room was left to the Member States, to legislate in some areas and to further specify in other areas.⁴ It is therefore no surprise that it has been observed almost anonymously that there is still a very fragmented landscape of privacy regulations in the EU.⁵ While the GDPR seeks to promote the free flow of data, the mechanisms in the Regulation largely depend on the national implementation. An example is the so-called 'research exemption in the GDPR that states that the prohibition of the processing of special categories of personal data (including health data) does not apply where the processing is necessary for research purposes and "in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject."⁶ The addition of 'or Member State law' leaves room for Member States to regulate the details, thus causing fragmentation. Nevertheless, this exemption could be useful for research as in the present case as it may be one of the legal bases to collect and process data. In the Netherlands for example, a reference to Article 9(2)(j) GDPR has been made, although being limited to certain four cumulative conditions.⁷

For research purposes, the GDPR provides in Article 14(5)(b) also some room for exceptions when data are processed for scientific research purposes as long as Article 89(1) safeguards are in place. By doing so, the research organisation may be exempted from informing the data subject about the use of the data when retrieving this from another party. It is up to the Member States to include such an exception in national law, but most Member States haven't done so.⁸

In this respect, quite recently the study "Assessment of the EU Member States' rules on health data in the light of GDPR" has been published on the request of the European Commission.⁹ In the Annex to this publication, an extensive overview with country fiches for all EU Member States has been made.¹⁰ Avoiding duplication, we refer to the country fiches of the Netherlands (p. 158), Belgium (p.5) and Germany (p.39) for more information on the national legal

⁴ European Commission, *Communication from the Commission to the European Parliament and the Council: Data protection as a pillar of citizens' empowerment and the EU's approach to the digital transition – two years of application of the General Data Protection Regulation*. COM(2020) 264 final.

⁵ A.o. Becker R, Thorogood A, Ordish J, Beauvais MJ. COVID-19 Research: Navigating the European General Data Protection Regulation. *J Med Internet Res* 2020;22(8):e19799; Becker, R., Thorogood, A., Ordish, J., & Beauvais, M. (2020). COVID-19 Research: Navigating the European General Data Protection Regulation. *Journal of medical Internet research*, 22(8), e19799. <https://doi.org/10.2196/19799>

⁶ Article 9(2)(j) GDPR; Donnelly, M. & McDonagh, M., Health Research, Consent and the GDPR Exemption, *European Journal of Health Law* 26 (2019), 97-119.

⁷ See Article 24 Uitvoeringswet Algemene verordening gegevensbescherming, <https://wetten.overheid.nl/BWBR0040940/>

⁸ EUHealthSupport consortium (2021), Assessment of the EU Member States' rules on health data in the light of GDPR, https://ec.europa.eu/health/ehealth/key_documents_en#anchor1, p. 84.

⁹ EUHealthSupport consortium (2021), Assessment of the EU Member States' rules on health data in the light of GDPR, https://ec.europa.eu/health/ehealth/key_documents_en#anchor1

¹⁰ *County fiches for all EU MS, Annex to the study 'Assessment of the EU Member States' rules on health data in the light of the GDPR'*.



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frameworks. After analysing the law and performing expert workshops and interviews, the report concludes regarding to the GDPR and research “that there are different rules and regulations governing access to health data both within and between Member States, which impact researchers both in the context of in-country and cross-border research. They make it hard for researchers to understand how the rules governing the processing of health data apply in their intended research, this issue is more evident for research using genetic data, but is seen by researchers working in most areas. These differences have an effect on the accessibility of health data in themselves, and they also relate to a number of other factors that affect the availability and accessibility of health data, including the respect of data subjects’ rights.”¹¹

However, it is not only the national divergences in the application of the GDPR, also the interplay of data protection with ethical requirements were highlighted. Ethical reviews are performed by a Research Ethics Committee (REC) that are differently organised among Member States: at institutional level, regional or national level but some Member States also require approval by the National Data Protection Authority. Next to this organisational maze, individual interpretation can have an important role within ethics committees, leading to variable and unpredictable outcomes both across Member States as well as within a Member State.¹²

III. Roadmap towards a possible solution of the obstacle with indication of the entities to be involved in the possible solution

The solution would be to realise more harmonisation among the national implementations. In reports several other possible solutions have been proposed to improve the situation, such as standard contractual clauses¹³, derogations, public interest, new health sector specific EU level legislation and Codes of Conduct.¹⁴

In COM(2020) 264 final on two years of application of the GDPR the Commission already acknowledged the problems that can arise from the fragmentation and diverging approaches in the national implementation of the GDPR. Next to assessing the national legislation, the Commission also announced to support the establishment of code(s) of conducts ‘that would contribute to a more consistent approach in this area and make the cross-border processing of personal data easier.’ The Commission will also provide input to the future guidelines of the European Data Protection Board (EDPB). The EDPB can issue guidance to Member States under Article 70 GDPR on the application of the GDPR. This was also one of the recommendations of the recent Assessment-study as non-legislative measure.

As addressed in its Communication ‘A European strategy for data’¹⁵, the Commission also aims to ‘facilitate the establishment, in accordance with Article 40 of the GDPR, of a Code of Conduct for processing of personal data in health sector’ as part of the greater goal of a Common European *health data space*. A Code of Conduct was also proposed in the Assessment-report, in that case on EU level. A Code of Conduct is a soft law tool of Chapter 4 of the GDPR, included in

¹¹ EUHealthSupport consortium, 2021, p. 80.

¹² Ibid, p. 69.

¹³ The Commission has recently published standard contractual clauses; Commission Implementing Decision (EU) 2021/915 of 4 June 2021, PB L 199/18.

¹⁴ EUHealthSupport consortium, 2021, p. 131 & Allea, Easac & FEAM, 2021, *International Sharing of Personal Health Data for Research*, www.doi.org/10.26356/IHDT

¹⁵ European Commission, *Communication from the Commission to the European Parliament and the Council: A European strategy for data*, COM(2020) 66 final.



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Article 40. With a Code of Conduct, associations and other bodies representing categories of controllers or processors can specify the application of the GDPR. This can foster the proper application of the GDPR, as well as provide clarity and guidance by serving as a guidebook. A Code of Conduct can enhance transparency for doing research by using plain languages and fostering the further specification of terms and principles such as the nature and format of consent.¹⁶ In this regard also the term 'broad consent' has to be mentioned, that is one consent for multiple potential future research projects, instead of an 'explicit consent'.¹⁷ The applicability and forms of consent differs significantly among Member States. Here, a Code of Conduct can provide clarity.

A Code of Conduct cannot change or replace existing legislation, making it still necessary to adhere to national implementations. Yet, it can be an instrument for addressing the relationship between collaborative research in the EU and providing more clarity to the implementation of important concepts and terms. Thus a Code of Conduct can be a powerful tool to create a more consistent approach and make cross-border processing of personal data easier. It is often initiated via a bottom-up approach, started by stakeholders. These can start the procedure with the foreseen supervising authority, for example the Dutch Autoriteit Persoonsgegevens. In the present case, it would concern a Code of Conduct on the trans-border processing of data by stakeholders in the EMR. This wish can be justified by its scientific collaborations and vast cooperation between partners in the neighbouring regions. Furthermore, the EGTS EMR as well-established Euregional organisation can play a role as accommodator for negotiations. Nevertheless, the development of a Code of Conduct can take quite a lot of time and work, following the procedures of the GDPR and the necessary steps that have to be made. "While such mechanism would allow the scientific community to build a bottom-up solution, it is important to consider that their initiation validation, approval and implementation will require considerable time and resources, therefore creating impediments to scientific research.", as rightfully stated by the ALLEA, EASAC and FEAM.¹⁸

Thus, while a Code of Conduct may be a welcoming tool for the present case to boost cross-border research collaborations in the EMR, the further developments of the European Data Space should be encouraged for health research.

IV. Pre-assessment of whether the case could be solved with the European Cross-Border Mechanism

In its Communication from 2017 "Boosting growth and cohesion in EU border regions", the European Commission proposed different instruments to overcome barriers to cross-border cooperation.¹⁹ In 2018, the Commission has presented a proposal for a "Regulation on a mechanism to resolve legal and administrative obstacles in a cross-border context" - the so called European cross-border mechanism (ECBM).²⁰ Following earlier initiatives on financial support (INTERREG) and institutional obstacles (the European Grouping for Territorial Cooperation; EGTC) for cross-border cooperation, the next step would be to overcome the legal

¹⁶ EUHealthSupport consortium, 2021, p. 132.

¹⁷ Hallinan, D. (2020) Broad consent under the GDPR: an optimistic perspective on a bright future. *Life Sci Soc Policy* 16, 1. <https://doi.org/10.1186/s40504-019-0096-3>

¹⁸ Allea, Easac & FEAM, 2021, *International Sharing of Personal Health Data for Research*, www.doi.org/10.26356/IHDT, p. 30.

¹⁹ European Commission, Communication "Boosting growth and cohesion in EU border regions", COM(2017) 534 final, p. 14.

²⁰ Proposal for a Regulation of the European Parliament and of the on a mechanism to resolve legal and administrative obstacles in a cross-border context COM(2018) 373 final.



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and administrative obstacles. In preparation for the ECBM, a study has been done to the legal and administrative obstacles in EU border regions.²¹ The study categorised the gathered obstacles into three types:

1. *EU-related legal obstacles*: caused by the specific status of an EU-border or by EU legislation (or the implementation thereof), where the EU has exclusive or shared competency;
2. *Member State-related legal obstacles*: caused by different national or regional laws, where the EU has no or only limited competence;
3. *Administrative obstacles*: caused by non-willingness, asymmetric cooperation or lack of horizontal coordination, or by different administrative cultures or languages.

The ECBM intention is: “to allow for the application in one Member State, with regard to a cross-border region, of the legal provisions from another Member State, where the application of the legal provisions of the former would constitute a legal obstacle hampering the implementation of a joint Project”.²² Therefore, the ECBM is aimed at resolving a legal conflict due to different national laws or administrative obligations that are applicable at the same time for the same specific project. Projects in this respect are defined as “any item of infrastructure with an impact in a given cross-border region or any service of general economic interest provided in a given cross-border region”.²³

The current case of data regulations in the field of cross-border health research collaborations belongs to category 1, while sharing characteristics with categories 2 and 3. The problem is greatly caused by a diverging implementation of the GDPR in national legislation. Furthermore national characteristics regarding e.g. ethical review processes can hamper cross-border collaboration. Hence, the problem is a mismatch of national rules, implementing the EU rules. In these cases, the ECBM appears to be of relevance, as it is concentrated at solutions by providing deviations in national rules.²⁴ A cross-border research project can act as concrete project as stipulated in Article 1. Article 1(2) of the proposal stipulates how the legal or administrative obstacle can be solved by the ECBM: either via a Commitment or via a Statement. The former stands alone, where specific rules of a Member State are applied in the other Member State, but the latter has to be translated in the adoption of national rules. Via Commitment or Statement, the national implementation of the GDPR of one of the neighbouring legal systems can be chosen. The question is then whether the other neighbouring countries would be willing to accept another legislative implementation of the GDPR. euPrevent or the partners collaborating in euPrevent could be the ‘initiator’ as mentioned in Article 8 of the Commission’s proposal for a ECBM. euPrevent and the collaborating partners address the need for structural cross-border cooperation and data sharing. Essential here is what could be seen as a ‘project’. Recital 16 of the proposed ECBM mentions in this regard: “The term project should be understood in a broad sense, covering both a specific item of infrastructure or a number of activities with regard to a certain territory or both.” In this regard, the Euregion Meuse-Rhine, in which euPrevent is active, could be seen as defined territory. However, the question remains what could be seen as an adequate and acceptable demarcation of ‘a number of activities’ and what the Member States would be willing to accept, if the Regulation will be adopted. The health research activities within euPrevent could act as demarcation, as the Commission might have envisaged when proposing the ECBM and drafting the legislative text. Yet a more narrow scope might be necessary for Member States to adopt a Commitment or Statement.²⁵ Thus the proposed ECBM is not precise in defining ‘projects’. Hence, it is not clear whether the ECBM has to be applied

²¹ J. Pucher, T. Stumm & P. Schneidewind, *Easing legal and administrative obstacles in EU border regions*, Luxembourg: Publications Office of the European Union, 2017

²² Article 1 of the proposed ECBM.

²³ Article 3(2) of the proposed ECBM.

²⁴ Via a Commitment or a Statement, Article 1(2) of the proposed ECBM.

²⁵ This is already the experience with the creation of a Code of Conduct within the framework of the GDPR.



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every time for every research project as ‘project’ separately, which could be insufficiently satisfying, or could serve as structural solution for cross-border collaboration in health research in the EMR.

V. Other relevant aspects to this case

The Benelux Union

The proposed ECBM stipulates an ‘opt out’ option, to opt for another existing formal or informal structure that can solve the legal or administrative obstacle.²⁶ Since this particular case covers the cross-border area between the Netherlands and Belgium, the Benelux Union could be such a structure. The Benelux Union might be relevant and could be another solution to the problem, regardless whether the ECBM will ever be adopted or not.

The Benelux Union institutionalises the cross-border cooperation between the Netherlands, Belgium and Luxembourg. As of 2008 a renewed Benelux Treaty was signed, establishing the Benelux Union. The main aims within this Treaty are the continuation and further development of the economic union, encompassing the objectives of the previous Treaty, as well as sustainable development, and cooperation in the field of justice and internal affairs.²⁷ To do so, the Benelux Union has four legal instruments for policymaking:

1. Decision²⁸ (‘beschikking’) in which one or more provisions of the Treaty are implemented. These are directly binding on the three parties;
2. Agreements (‘overeenkomsten’) that are legally binding, but needs to be adopted by each party in national policy;
3. Recommendations (‘aanbevelingen’) about the functioning of the Benelux. These have no legal binding effect, but are more a commitment between the parties;
4. Directives (‘richtlijnen’) to the Benelux Council and general-secretariat.

Nowadays, the Benelux Union is not limited to the geographical delineation of the Netherlands, Belgium and Luxembourg. More and more initiatives are started in collaboration with Germany, more specifically Nord-Rhine Westphalia, and France.²⁹ Digitalisation and the challenges it brings, is at the work program 2021-2024 of the Benelux Union. With the ambition of acting as a “EU role model for promoting the digital single market”³⁰, initiatives to create a more coherent framework in data regulation do fit well. Relevant actions can be undertaken within the setting of the Benelux Union, such as very concrete already has been done with the Decision on the cross-border exchange of electronic personal data about health.³¹ As articulated in Article 1: “the purpose of this Decision is to provide a complementary legal framework to the cross-border exchange of such personal data in order to ensure continuity of cross-border healthcare and optimise the quality of cross-border healthcare, ensuring the exchange of no more personal data than necessary for that purpose”, a similar initiative can be undertaken in the field of (health) research.

²⁶ Article 4 (2) of the ECBM.

²⁷ Article 2(2) of the Benelux Treaty.

²⁸ A relevant decision is that of the establishment of a Benelux Treaty on cross-border and interterritorial cooperation (M(2014)2).

²⁹ See for example *Jaarverslag 2020*, https://www.benelux.int/files/7716/1657/1944/JAARVERSLAG_2020_-_DEF.pdf

³⁰ Benelux Union, Common Work Program 2021-2024, <https://benelux.int/nl/publicaties/publicaties-overzicht/gemeenschappelijk-werkprogrammameenschappelijk-werkprogramma-2021-2024>

³¹ BESCHIKKING van het Benelux Comité van Ministers betreffende de grensoverschrijdende uitwisseling van elektronische persoonsgegevens over de gezondheid – M (2020) 5.



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Priority on EU level

As already indicated, the Commission is aware of the practical obstacles to (cross-border) research and data processing due to different national implementations of the GDPR. On the other hand it is also aware that data and digital innovation is key for the EU in the upcoming years, as also acknowledged as priority 'A Europe fit for the digital age'.³² Not only for research and health care cross-border exchange of data is necessary, also for, e.g., cross-border employment services data sharing is essential to make it work.³³ Also the cooperation between universities such as YUFE or the European Universities Initiative can be mentioned here. Data sharing across borders is key for the future.

As the topic is so topical and urgent, the authors encourage research initiatives to this matter as well as wish to promote and/or initiate a workshop.

VI. References and Appendix/Appendices if any³⁴

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DOI 10.53252/BS2116

³² https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age_en

³³ See for example the Regio Deal Parkstad Limburg that also covers the cross-border employment services.

³⁴ The authors thank prof. dr. Paolo Balboni for his time and contribution to this topic.