MTA Law Working Papers
2021/1

The European Medicines Agency '*Transparency*' Policies, the CJEU and COVID-19: Do the CFREU Provisions Retain Any Relevance?

Daminova, Nasiya

ISSN 2064-4515
http://jog.tk.mta.hu/mtalwp
Társadalomtudományi Kutatóközpont – MTA Kiválósági Kutatóhely
Eötvös Loránd Kutatási Hálózat
Centre for Social Sciences – MTA Centre of Excellence
Eötvös Loránd Research Network

The European Medicines Agency '*Transparency'* Policies, the CJEU and COVID-19: Do the CFREU Provisions Retain Any Relevance?

Daminova, Nasiya [*]

Abstract: The approach of the European Medicines Agency (EMA) to the transparency of the documents submitted by the pharmaceutical enterprises has evolved significantly during the last decade. The gradual development of the EU's secondary legislation, namely the adoption of EMA Policy on access to documents (Policy 0043, 2010) followed by the Policy on publication of clinical data (Policy 0070, 2014) and Clinical Trials Regulation No 536/2014 have raised more issues as they arguably question the substance of the '*commercially confidential information*' notion. The ongoing public health crisis seems to have fuelled the discourse, in view of the EMA calls to urge transparency and collaboration on COVID-19 studies - to facilitate more robust research results. Even though the first attempts were made to investigate the CJEU's approach to the application of the EMA Policies 0043 and 0070, a very important issue - namely, the impact of the EU Charter on the EMA transparency policies - comprising the extra transparency measures for COVID-19 vaccines and therapeutics – still remains unsolved. Considering the *InterMune UK, PTC Therapeutics International, MSD Animal Health Innovation* lines of reasoning, this paper aims to explore if and how the EU Court of Justice applies relevant CFREU provisions, in order to counter-balance the competing interests of the pharma enterpises (confidentiality of the clinical data) and the European Medicines Agency (public access to the documents). The main argument presented is that the CJEU's approach to Art. 7 (*'Respect for private and family life'*) and – sporadically – Arts. 16 *('Freedom to conduct a business'),* 17 *('Right to property')* and 47 (*'Right to an effective remedy and to a fair trial'*) CFREU in these cases has manifested the transition from the general presumption of confidentiality with respect to the company-issued health data to disclosure of such data - with a low likelyhood of changes in the observable future, even in view of the ongoing COVID-2019 developments.

[*] Postdoctoral researcher, Lehrstuhl für Öffentliches Recht mit internationaler Ausrichtung, Universität Konstanz, PhD in Comparative and Transnational Law, Scuola Superiore Sant'Anna (2018), e-mail: nasiya.daminova@gmail.com. Her research is supported by the Alexander von Humboldt Research Fellowship for Postdoctoral Researchers (December 2019-November 2021), and is current as of 12 January, 2021. The author would like to thank Prof. Dr. Marten Breuer, Dr. Fruzsina Gardos-Orosz, Dr. Marton Varju and Dr. Emese Szilagyi for their constructive comments on the earlier version of the paper draft, the project assistant Ms. Cynthia Sturmfels for her notes on structure and style and the Chair's secretary Mrs. Christiane Richter, who kindly assisted in technical matters. All possible mistakes remain the sole responsibility of the author of course.

Keywords: European Medicines Agency, CFREU, transparency policies, COVID-19, commercially confidential information

i. Introduction. The European Medicines Agency (further - EMA) is the European Union (further - EU) body responsible for the scientific evaluation, issue of the centralised marketing authorisation (further - MA) applications and supervision of medicinal products for human and veterinary use. The EMA is responsible for granting approval for effective and safe medicinal products in the form of MA and – indirectly - harmonising research procedures in the EU, in particular through collecting the clinical trials data (further - CTD) submitted as a part of the MA application dossier.[1] Importantly, the EMA decisions are subjected to a judicial review of the Court of Justice of the European Union (further – CJEU) pursuant to Art. 263(1) of the Treaty on the Functioning of the European Union (further – TFEU)[2] and any arbitration clause contained in a contract concluded by the Agency. [3]

As of its establishment the EMA has embraced openness of operation as an important feature: Art. 73 of Regulation (EC) No. 726/2004 prominently declared that the key Regulation (EC) No. 1049/2001 regarding public access to European Parliament, Council and Commission documents shall apply to the Agency as well.[4] Only few exceptions shall be applicable in this regard - such as, for instance, the overriding public policy concerns (public security, defence and military matters, international relations etc.), the protection of personal data, or the commercial interests of a natural or legal person including the protection of the so-called *'commercially confidential information'* (furthermore: CCI).[5]

The Treaty of Lisbon favored further development of the openness, transparency and the right to access documents in EU Law. For instance, Art. 15 TFEU obliged the EU's legislature to act publicly, and established that citizens shall have the right to access documents held by all Union institutions, bodies and agencies. Moreover, the right of access to documents, and its nature as a fundamental right, is further emphasised by Art. 42 of the Charter of Fundamental

[1] Daria Kim, 'Transparency Policies of the European Medicines Agency: Has the Paradigm Shifted?' [2017] 25(3) Oxford Medical Law Review 456, 457.

[2] Art. 263(1) TFEU [The Court of Justice] shall also review the legality of acts of bodies, offices or agencies of the Union intended to produce legal effects vis-à-vis third parties.

[3] In this sense, see for example Case C-513/16 P(R) European Medicines Agency (EMA) v. PTC Therapeutics International Ltd, or Regulation No. 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Art. 72(1).

[4] Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136.

[5] Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents [2001] OJ L 145, Art. 4.

Rights of the European Union (CFREU), which is now of 'the same legal value as the Treaties'.[6] It could be argued that the approach of the European Medicines Agency to the transparency of the documents submitted by the pharmaceutical enterprises, has itself evolved significantly during the last decade – one of the main reasons for these changes was the growing impact of the European Ombudsman on the European Agencies, including the EMA.

In 2010, Mrs. Emily O'Reily delivered a number of decisions that were critical of the EMA approach, including one relating to clinical study reports.[7] In particular, she mentioned the limited access of the EU public to the Agency documents which did not seem to be consistent with the overriding interest in providing sufficient information to the healthcare professionals and patients.[8] However, the follow-up development of the EU's secondary legislation, namely the adoption of EMA Policy on access to documents (Policy 0043, 2010) followed by the Policy on publication of clinical data (Policy 0070, 2014) and Clinical Trials Regulation No 536/2014 has raised more issues as they arguably question the substance of the notion *'commercially confidential information*' (i.e. the information which shall be excluded from public access within the given context, as the disclosure may undermine the legitimate economic interest of the enterprise). Since autumn 2016, the European Medicies Agency published the clinical reports submitted under the centralized marketing authorization procedure once the procedure has been finalized. Prior to this, EMA only released clinical-trial reports *on request* and treated documents in marketing authorization files as generally confidential (Policy 0043).[9]

Even though the European Medicines Agency temporarily suspended the publication of clinical data on December 5, 2018 as a result of the implementation of the third phase of EMA's business continuity plan due to Brexit and the headquarter's move to Amsterdam,[10] *the Agency has reinitiated this activity specifically for COVID-19 medicines in line with its exceptional transparency measures for treatments and vaccines for this desease*.[11] Hence, the issue of balancing the business interests of enterprises and the need to make the EMA activities transparent for the EU patients becomes remains extremely pertinent, considering high costs of research and revelopment in pharmacological sector. Bearing in mind these premises, it could be expected from the pharma enterprises to oppose this developing *'pro-transparency'* trend, by

[6] Charter of Fundamental Rights of the European Union [2012] OJ C 326.

[7] Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency (*The European Ombudsman Official Website, 2010*). Available at https://www.ombudsman.europa.eu/en/decision/en/5459, 10 June 2019.

[8] *Ibid*., paras. 34, 35, 47.

[9] Elisa Stefanini, 'Publication of Clinical Trials Data: A New Approach to Transparency in the European Legislative Framework' [2017] 1(1) Medicine Access: Point of Care 98, 99.

[10] Response to ASK-74893 - EMA transparency policies in light of COVID 19, received on 10 December 2020, p. 3.

[11] *Ibid*., p. 4.

putting forward the Fundamental Rights-centered argumentation in dialogue with the European Medicines Agency.[12]

Even though the first attempts were made to investigate the CJEU's approach to the application of the EMA Policies 0043 and 0070, a very important issue - namely, the impact of the EU Charter on the EMA transparency policies - comprising the extra transparency measures for COVID-19 vaccines and therapeutics – still remains unsolved. In view of the *InterMune UK, PTC Therapeutics International, MSD Animal Health Innovation* lines of reasoning, this paper aims to explore if and how the EU Court of Justice applies relevant CFREU provisions in cases involving the European Medicies Agency transparency policies. Then, the working paper sheds light on the developments in the EMA transparency policies related to the COVID-19 crisis, investigating if the EU Charter had any influence on the development of the Agency dialogue with the EU wide public and pharmaceutical enterprises.

To illustrate these developments, *firstly*, an attempt is made to analyse the scope of protection of the '*commercially confidential information*' within the context of the EMA activities afforded by the Transparency, Authorisation and Clinical Trials Regulations, as well as by the EMA Policies 0043 and 0070. *Secondly*, this paper elaborates on existing CJEU case-law with the CFREU component which creates a legal framework for the implementation of the abovementioned legal acts (*AbbVie/InterMune, PTC Therapeutics International, Pari Pharma, MSD Animal Health Innovation). Thirdly*, the paper probes the reasoning adopted by the European Medicines Agency, European Ombudsman and the members of the research community in course of the development of the EMA COVID-related transparency policies, and sheds light on the authorisation strategy for the Coronavirus vaccines and therapeutics - considering the feedback received from the European Medicines Agency.[13]

The main argument presented is that the CJEU's approach to Art. 7 (*'Respect for private and family life'*) and – sporadically – Arts. 16 *('Freedom to conduct a business'),* 17 *(' Right to property')* and 47 (*'Right to an effective remedy and to a fair trial'*) CFREU in these cases has manifested the transition from the *general presumption of confidentiality* with respect to the company-issued health data to *disclosure of such data*. This narrative could be presumably explained by the prevailing interest in protecting public health and fostering the innovation capacity of European medical research - with a low likelyhood of changes in the observable future, even in view of the ongoing COVID-2019 developments.

[12] Daria Kim, 'Transparency Policies of the European Medicines Agency: Has the Paradigm Shifted?' [2017] 25(3) Oxford Medical Law Review 456, 459.

[13] Response to ASK-74893 - EMA transparency policies in light of COVID 19, received on 10 December, 2020.

1. The EMA 'transparency policies' vs. CCI: *the scope of protection*

Before moving on to the disussion on the substance of the EMA pertinent Policies 0043/0070 in light of the fundamental rights concerns of the farmaceutical enterprises, it could be necessary to shed light on the pertinent EU primary law provisions. The definition of the notion of the commercially confidential information shall be interpreted in light of Art. 15(3) TFEU which extends the public right of access to documents of all the Union institutions, bodies, offices and agencies. Despite an evident added value of this provision as a tool to enhance the democratic legitimacy of the European institutions through the involvement of the EU individuals, the application of this provision is – by its nature – rather problematic. On one hand, the EMA shall take into account such factors as the need to inform the public, protect public health effectively and foster the innovation capacity of European medical research. On the other hand, the Agency must consider the business interests of pharmaceutical enterprises – given the lack of general regulation or the classification of 'sensitive' documents in the EU, and the lack of the general mechanism of guaranteeing transparency in that field.[14]

a) The EU's secondary law. The basic Regulation No 1049/2001 regarding public access to European Parliament, Council and Commission documents provides a very broad definition of the EU 'document' which shall be disclosed to the public as *'any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audiovisual recording) concerning a matter relating to the policies, activities and decisions falling within the institution's sphere of responsibility'* (Art. 3(a)). The limitations imposed on the general rule of access could be justified by the considerations of the public interest (Art. 4(1)a), privacy and the integrity of the individual (4(1)b), *protection of commercial interests of the individuals and/or the enterprises* (Art. 4(2)), or/and the effectiveness of the EU institution's decision-making process (Art. 4(3)).

These exceptions shall generally apply for the period during which protection is justified on the basis of the content of the document (and for a maximum period of 30 years), even though in the case of documents covered by the exceptions relating to privacy or commercial interests the exceptions may, if necessary, continue to apply after this period.[15] Moreover, Art. 4(2) prominently offers an additional stage in assessing the proportionality of the limitations in cases involving the commercial interests of the enterprises: the documents which are normally entitled

[14] Henri Labayle, 'Principles and procedures for dealing with European Union Classified Information in light of the Lisbon Treaty' (*European Parliament Official Website, 2010*). Available at http://www.europarl.europa.eu/document/activities/cont/201006/20100601ATT75403/20100601ATT75403EN.pdf, accessed 10 January 2021.

[15] Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents [2001] OJ L 145, Art. 4(7).

to the non-disclosure, still could be made accessible to the public, in case of the *'overriding public interest in disclosure'*.

This very general legal framework defined a need to frame institution-specific rules for the public access procedures and – subsequently – detailed rules on the pertient exceptions for the information which shall be excluded from such an access, in view of the Art. 4(2) clause of Regulation No. 1049/2001 (*'commercial interests of a natural or legal person, including intellectual property rights'*). Regulation No. 1049/2001 on access to the EU documents was primarily drafted to be applicable only to the European Parliament, the Council, and the Commission. However, its application to the EMA activities was extended by virtue of a specific clause in Regulation (EC) No 726/2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ('The Authorisation Regulation'):

'... Article 73 (1). Regulation (EC) No. 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (1) *shall apply to documents held by the Agency*.

Article 73 (1). The Agency *shall set up a register pursuant to Article 2(4) of Regulation (EC) No 1049/2001 to make available all documents that are publicly accessible pursuant to this Regulation*'.

Art. 57(l) of Regulation (EC) No. 726/2004 specifies the form in which the information shall be made availiable to public: the EMA shall run a database ('*Eudravigilance database'*) on medicinal products which have already obtained a marketing authorisation, which is accessible to the general public, and ensure that it is updated, and managed independently of pharmaceutical companies. The subsequent secondary legislation, namely Regulation No 536/2014 on clinical trials for medicinal products for human use ('Clinical Trials Regulation') marked a new step in regulation of the EMA 'transparency' legislation.

The 'Clinical Trials Regulation' modernized rules on public access to clinical trials data, obligating the pharmaceutical company (an applicant) to submit the clinical study report (CSR), for all clinical trials, within 30 days after the marketing authorisation was granted[16] or within one year of the termination of the clinical trial.[17] The pharmaceutical companies' aplications and any communication shall be submitted paperlessly *via* a new electronic EU portal, which is still being developed and shall be fully functional in late 2019.[18] Moreover, following the

[16] Regulation (EU) No. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance [2014] OJ L 158, Art. 37(4)).

[17] *Ibid.*, Art. 37(4).

[18] Ancella Santos Quintano, Till Bruckner, 'Report: Clinical trials in the European Union - a Roadmap to Greater Transparency' (Health Action International Website, 2019). Available at: http://haiweb.org/wp-

development and launch of the EU Clinical Trial Portal and Database, all the clinical trial information included in the application, such as, for instance the study specific documents (Part I of the dossier - the assessment of scientific, therapeutic and safety aspects)[19] and the country/site specific documents (Part II of the dossier – national reports on the biological samples, clinical trial agreements, informed consent, recruitment of subjects etc.)[20] – shall already become availiable to the public.

Importantly, the provisions of Art. 81(4) of the Clinical Trials Regulation elaborate indirectly on the notion of the '*commercially confidential information'* which shall be a subject to the exclusion from the public access. Similarly to the wording of Regulation (EC) No 45/2001, the Clinical Trials Regulation elaborates on the the three stage assessment procedure in cases involving the business interests of the enterprises. According to Art. 81(4), the abovementioned EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified by the '*protecting commercially confidential information, in particular through taking into account the status of the marketing authorisation for the medicinal product, unless there is an overriding public interest in disclosure*'.[21] However, the distinction could be made between the wordings of these two documents: while Regulation No. 1049/2001 protects information which is of *'commercial interest'* for the enterprise, Regulation No 536/2014 directly refers to the term *'commercially confidential information*'. The EMA policies (primarily 0043 and 0070) were aimed at defining the latter notion, in order to provide the legal framework for the abovementioned three-step proportionality test, thus counter-balancing a need to guarantee the business interests of the pharma enterprises and the effective public access to the EMA documents.

b) EMA policies 0043 and 0070. As rightly mentioned by Korkea-Aho and Leino, the EMA's internal guidance differs from that of other EU agencies, in that it seeks to define the concept of commercially confidential information extensively by the means of the internal implementing legislation, namely the EMA policies and guidances.[22] The EMA arguably elaborates on this notion in view of the broader public health protection objective, relying on the

content/uploads/2019/02/Clinical-Trials-in-the-EU-A-Roadmap-to-Greater-Transparency.pdf, 5. Accessed 10 January 2021.

[19] Regulation (EU) No. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance [2014] OJ L 158, Art. 6.

[20] *Ibid.*, Art. 7.

[21] *Ibid.*, Art. 81(4)b.

[22] Emilia Korkea-aho, Päivi Leino, 'Who owns the information held by EU agencies? Weed killers, commercially sensitive information and transparent and participatory governance' [2017] 54(4) Common Market Law Review 1059, 1073-1074.

pertienent provisions of European legislation and case-law concerning competition, the environment, and public access to documents.[23]

For instance, the EMA 'Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents' (2007) carefully avoided a precise definition of this term, proclaiming that the *'commercially confidential information'* shall be generally considered to fall broadly into two categories: (a) confidential intellectual property, 'know-how' and trade secrets (including e.g. formulas, programs, process or information contained or embodied in a product, unpublished aspects of trade marks, patents etc.) and (b) commercial confidences (e.g. structures and development plans of a company).[24]

It has already been mentioned that the shift to the *'pro-transparency'* approach of the EMA policies was defined by the European Ombudsman decision closing her inquiry into complaint 2560/2007/BEH against the European Medicines Agency (2010).[25] While assesing the legality of a request of the Danish researchers to access the EMA clinical study reports and corresponding trial protocols for two anti-obesity drugs, the Ombudsman expressed her opinion in the sense that the competitors shall generally have a right to access the clinical study reports submitted to EMA in course of the authorisation process for the medicine.[26] One of the first EMA responses was the adoption of Policy 0043 on access to documents implementing the provisions of Regulation (EC) No. 1049/2001 and aiming to enhance the transparency of the regulatory decision-making process.[27]

The main novelties brought by EMA Policy 0043 were the detailed procedure for granting public access to the clinical trials data submitted to the EMA in course of the marketing authorisation application, allowing for the *redaction* of the personal data and the commercially confidential information – however, without providing any definition of the latter notion.[28] The EMA Policy 0043 prominently made such an access of an individual or a legal person to the abovementioned CT data conditional upon the request, disclosing the identity of the applicant.[29]

---

[23] Principles to be applied for the deletion of commercially confidential information for the disclosure of emea documents EMEA/45422/2006 (Official EMA Website, 2007). Available at https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/principles-be-applied-deletion-commercially-confidential-information-disclosure-emea-documents_en.pdf, accessed 10 January 2021.

[24] *Ibid*., p. 3.

[25] Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency (*The European Ombudsman Official Website, 2010*). Available at https://www.ombudsman.europa.eu/en/decision/en/5459, accessed 10 January 2021.

[26] *Ibid*., paras. 84-94.

[27] European Medicines Agency policy on access to documents (Policy 0043). Available at https://www.ema.europa.eu/en/documents/other/policy/0043-european-medicines-agency-policy-access-documents_en.pdf, 7. Accessed 10 January 2021.

[28] *Ibid*., 7.

[29] *Ibid*., 5-6.

In the vast majority of cases, EMA granted the requests, but only the applicant was able to receive the documents with the agreed redactions.[30]

The adoption of the 'Clinical Trials Regulation' required further developments of the EMA implementing legislation, namely Policy 0070 on publication of clinical data for medicinal products for human use.[31] The new policy goes a step further by making public the clinical trials data *proactively* - in order to enable public scrutiny and application of new knowledge in future research.[32] The most prominent features of the Policy are the introduction of a publication process on the pertinent EMA website through Terms of Use (Annex 1), as part of the Policy: (a) clinical reports are to be available on-screen for any user, with a simple registration process (for general information) and (b) downloadable clinical reports available to registered identified users (for academic and non-commercial research purposes).[33]

The EMA Policy 0070 also defined the *'commerially confidential information'* as 'any information contained in the clinical reports submitted to the Agency by the applicant/marketing authorisation holder (MAH) that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH'. The general approach to the *redaction* principles is that clinical reports do not contain CCI – even though some exceptions still could be made upon the request of the applicant, provided that the economic interest at stake is 'legitimate'. [34] In such cases the EMA shall consider and assess the applicant's justifications for redactions, but still retains the right to make a final decisions on the volume of the application kit information which shall be disclosed to public.[35]

As the 'Clinical Trials Regulation' and the EMA Policy 0070 entry into legal force and a publication of the first clinical study reports in October 2016 on the pertinent EMA website (https://clinicaldata.ema.europa.eu) predictably met the wave of resistance from the pharmaceutical industry.[36] The European Medicies Agency promtly responded by releasing the 'External guidance on the implementation of the European Medicines Agency policy on the

---

[30] In this sense, see for example Barbara Bierer, Mark Barnes and Rebecca Li, 'Transparency and Clinical Trial Data Sharing: Legal and Policy Issues' or Stefano Marino and Spyridon Drosos, 'The European Medicines Agency's Approach to Transparency', Chapters 13 and 14 in Holly Fernandez Lynch, Glenn Cohen, Carmel Shachar, Barbara Evans (eds.), '*Transparency in Health and Health Care in the United States: Law and Ethics'* (CUP 2019).

[31] European Medicines Agency policy on publication of clinical data for medicinal products for human use (Policy 0070, 2014). Available at https://www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf. Accessed 10 January 2021.

[32] *Ibid*., Section 1.

[33] *Ibid*., Section 4.2.3.

[34] *Ibid*., Section 3.

[35] *Ibid*., Annex3.

[36] Daria Kim, 'Transparency Policies of the European Medicines Agency: Has the Paradigm Shifted?' [2017] 25(3) Oxford Medical Law Review 456, 460-462.

publication of clinical data for medicinal products for human use'.[37] This document provided specific guidelines for companies on the redaction of commercially confidential information and data anonymisation to favor proper implementation of Policy 0070. It could be argued that the Guidance etsblishes a very high threshold for the companies to be achieved for the discolure of the (potentially) commercially confidential information, due to the wague wording of the definitions allowing for their broad interpretation.

For instance, Section 3 lists the following grounds for the refusals for the redaction as the information that is already in the public domain or publicly available,[38] information that does not bear any innovative features,[39] additional information the disclosure of which would be in the public interest,[40] or the information lacking sufficient or relevant justification.[41] The pharmaceutical enterprises are strongly advised to conduct preliminary research on the subject of their MA prior to proposing any redactions - in order to demonstrate the consistency of their claims with the level of information already available in the public domain concerning their product's development (e.g. study design and results) and scientific knowledge and advancements within the relevant (for the particular product) therapeutic area(s).[42] Despite these suggestions - it is exclusively within the discretion of the Agency to determine the need in (or lack of thereof) to delete the dossier information from the public access, on the basis of the investigation of the the grounds for the CCI redaction.[43]

In view of these novelties, the clause of Art. 4(2) of Regulation No 1049/2001 seems to be an additonal threat to the pharmaceutical companies: even though the applicant is able to demonstrate an economic interest in the redaction which satisfies all strict requirements of Policies 0043, 0070 and the External Guidance, even CCI could still be disclosed in case of an *'overriding public interest'* (such as the access to the EMA documents and the protection of the public health in the European Union). For instance, the EU Court of Justice already mentioned in *Sweden and Turco* that the notion of the *'overriding public interest*' within this context shall be

[37] External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use EMA/90915/2016 (External Guidance, 2016). Available at https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data_en-3.pdf. Accessed 10 January 2021.

[38] *Ibid*., Section 3.2.1.

[39] *Ibid*., Section 3.2.2.

[40] *Ibid*., Section 3.2.3.

[41] *Ibid*., Section 3.2.4.

[42] *Ibid*., Section 3.

[43] *Ibid*., Section 3.3.1.

interpreted in light of the principles underlying Regulation No. 1049/2001,[44] such as an effective realisation of the right to public access to the EU documents.[45]

Considering the *'pro-transparency'* approach to the disclosure of the EMA documents which was clearly articulated by the European Ombudsman since 2010, the guidance on such a balancing test from the CJEU, also in view of the *'overriding public interest'* concept was clearly needed. One of the sensitive issues has also been the CJEU's approach to the EU Charter of Fundamental Rights (CFREU) provisions, as the applicants started to put forward the CFREU-based claims, in order to protect the (potentially) commercially confidential information from the disclosure on the basis of the EMA Policies 0043 and 0070.

2. The EMA transparency policies: the CJEU triggering the CFREU provisions

As said by Maulenbelt, since the CJEU generally abstrains from the substanive analysis of the 'science-related' decisions of the EU Agencies, the review of the EMA decisions could be seen as *'marginal'* and thus not providing the adequate legal protection to the pharma companies.[46] In view of the Ombudsman *'pro-transparency'* statements, it could be argued that the Charter of Fundamental Rights of the EU has become a legal basis for the pharma industry attempts to defend the most precious component of the MA applications, namely the scientific research results from the disclosure to the wide public. The research conducted on the CURIA website demonstrated that in total the CFREU provisions was already invoked in 10 judicial acts (including Orders) concerning the EMA approach to the disclosure of the documents submitted as a part of the MA applications by the pharmaceutical undertakings.

Since the Policy 0043 entry into force, several pharmaceutical companies have objected to the EMA's decision to disclose their clinical reports – which resulted in the interim measures suspending the EMA's decisions in order to prevent serious and irreparable harm to the applicant's business interests.[47] The first application was *AbbVie* v. *EMA* concerning the scope of the EMA competence to disclose details of clinical trials involving AbbVie's rheumatoid arthritis drug Humira, one of the world's top-selling prescription medicines.[48] In this case, a

[44] Joined cases C-39/05 P and C-52/05 P, *Kingdom of Sweden and Maurizio Turco v Council of the European Union* [2008] ECLI:EU:C:2008:374, para. 75

[45] Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents [2001] OJ L 145, Recs. 1-4.

[46] Maarten Meulenbelt, 'The Proposed EU Transparency Directive – Will It Support the Evolving Pricing & Reimbursement Landscape for Pharma?' [2012] Scrip Regulatory Affairs (July issue), 8 9.

[47] Daria Kim, 'Transparency Policies of the European Medicines Agency: Has the Paradigm Shifted?' [2017] 25(3) Oxford Medical Law Review 456, 460.

[48] Case T-44/13 R, *AbbVie, Inc. and AbbVie Ltd v European Medicines Agency (EMA)* [2013] Order of the President of the General Court, 25 April 2013, ECLI:EU:T:2013:221, paras. 1-12.

university science student claimed for access to three clinical study reports submitted by AbbVie in connection with the preparation of his Master's thesis.[49]

The AbbVie reiterated its refusal to consent to disclosure of the documents, stating that the three clinical study reports were covered by the exception of Art. 4(2) of Regulation No 1049/2001 *('commercially confidential information'*) and reiterating the concerns expressed in relation to the previous request for access to similar documents concerning Humira. However, the EMA decided to grant the request for access filed by the student on the basis of Policy 0043 (2010), mentioning that *clinical study reports on medicinal products could not be regarded as confidential information.*[50] The company predictably objected the disclosure and submitted the request for the interim measures from the General Court.

Firstly, the AbbVie argued that that disclosure of the disputed reports before the end of the main proceedings would deprive them of the *right to an effective remedy*, enshrined in Art. 47 of the EU Charter (corresponding to Art. 6 of the European Convention on Human Rights).[51] Secondly, the disclosure under Regulation No. 1049/2001 has *erga omnes* effect and thus clearly presents a danger for the business interests of the enterprises, preventing the relevant institution from objecting to dissemination of that document to other parties requesting access and allowing anyone to have access to it (i.e. the science student can arguably provide the document to the competitors).[52] Thirdly, the EMA decision was solely based on new Policy 0043 since 2010 - noted that the lawfulness of that policy has not (at that point of time) been ruled on by the European Union courts. Hence, these factors could *potentially* infringe the applicants' right to respect for its private life (and business secrecy), as guaranteed by Art. 339 TFEU and Art. 7 of the EU Charter (corresponding to Art. 8 ECHR), as the disputed reports shall arguably be considered confidential in nature. A question of such crucial importance cannot be ruled on for the first time by a judge hearing an application for interim measures.[53]

In view of this reasoning, the General Court held that the AbbVie's request for interim measures satisfied the requirement of urgency and was justified in fact and law, since the disclosure of the clinical study reports may irreparably infringe AbbVie's right to protection of its business secrets and its right to a private life – referring both to Arts. 7 and 47 CFREU, as well as Art. 8 ECHR as a part of the legal reasoning. These fundamental rights were likely to be jeopardised if the EMA was allowed to disclose the CSRs before the General Court final judgement in the case. The interim measures was accompanied by the careful statement: 'The

[49] *Ibid*., para. 20.

[50] Case T-44/13 R, *AbbVie, Inc. and AbbVie Ltd v European Medicines Agency (EMA)* [2013] Order of the President of the General Court, 25 April 2013, ECLI:EU:T:2013:221, paras. 14-23.

[51] *Ibid*., paras. 46-68.

[52] *Ibid*., para. 46.

[53] *Ibid*., para. 67.

legal situation created by interim proceedings must be reversible, it must be recalled that the purpose of the procedure for interim relief is merely to guarantee the full effectiveness of the future decision on the main action'.[54] Importantly, the abovementioned Order became a subject to the appeal to the EU Court of Justice – however, the precise scope of the CCI protection in view of Policy 0043 and the CFREU provisions (Arts. 7 and 47) remained without further elaboration at that point of time. The EMA and the pharmaceutical company AbbVie had concluded an agreement, according to which the EMA could grant public access to the *redacted* versions of AbbVie's clinical reports.[55]

The *'twin'* case of *EMA v InterMune UK and Others* concerned the access requested by the pharmaceutical company Boehringer Ingelheim GmbH to the clinical reports submitted for the MAA of InterMune's drug Esbriet for idiopathic pulmonary fibrosis treatment.[56] Under interim decision adopted under similar circumstances, the EMA was ordered by the General Court not to provide the requested documents until a final ruling was given, with a similar legal reasoning based on Arts. 7 and 47 of the EU Charter.[57] In *InterMune UK*, the CJEU prominently set aside the Order and referred the case back to the General Court for assessing the possibility of a *partial disclosure of information* (i.e. with the necessary redactions).

The CJEU's overall approach to the *InterMune UK case* analysis allows to argue that, in view of the Court, just claiming a violation of the EU's fundamental rights (primarily Art. 7 CFREU) in itself was generally not sufficient to substantiate the threat of a serious and irreparable damage, while the commercial value of the information seemed to be a decisive factor.[58] An important clarification of the CCI notion was also made: the professional and commercial importance (value) of such information for the undertaking depends – among other factors – on the utility of that information for other undertakings which are able to examine and use it subsequently.[59] However, just like in *AbbVie*, the case was eventually settled outside of court since the EMA and InterMune UK agreed on the volume of necessary redactions in the requested documents before the disclosure.[60]

The *InterMune UK* case were seen by some scholars as the missed opportunity to provide an interpretation of the *'commercially confidential information'* within the meaning of the EMA

[54] *Ibid*., para. 40.

[55] Case T-44/13, *AbbVie, Inc. and AbbVie Ltd v European Medicines Agency (EMA*) [2014] Order of the President of the Fourth Chamber of the General Court of 17 July 2014, ECLI:EU:T:2014:694

[56] Case C-390/13 P(R), *European Medicines Agency (EMA) v InterMune UK Ltd and Others* [2013] Order of the Vice-president of the General Court from 28 November 2013, ECLI:EU:C:2013:795.

[57] *Ibid*., para. 41-45.

[58] *Ibid*., para. 37-45.

[59] *Ibid*., para. 44.

[60] Case T-73/13, *InterMune UK and Others v European Medicines Agency (EMA)* [2015] Order of the President of the Fourth Chamber of the General Court of 29 June 2015, ECLI:EU:T:2015:531.

Policy 0043, and thus a comprhensive guidance for the (non-) dislosure of such information.[61] The simulataneous intervention of the European Ombudsman could serve as an additional argument in this regard. While the *InterMune UK* was heard by the CJEU, Mrs. Emily O'Reilly criticised the *AbbVie* Orders and encouraged the European Medicines Agency *'in the case of the clinical study reports at issue in the present inquiry, to reconsider the need to retain the remaining redactions, made for the purpose of protecting commercial interests, if it receives new requests for access to these reports'*.[62] The main rationale of the Ombudsman was a need *'to ensure continuing systemic improvements'* of the EMA activities, in view of the *'overriding public interest for documents to be disclosed where the information they hold has clinical value to clinicians and researchers'*.[63]

Hence, the *AbbVie/ InterMune UK* outcomes did not provide a clear legal definition of commercial confidentiality – either in view of Art. 7 and 47 CFREU and/or Policy 0043 provisions, opening the floor for future cases. Three subsequent court cases with the very similar factual background also concerned the EMA's decision to release the documents in accordance with the 'Transparency Regulation'. The claims were brought to EMA by Pari Pharma (disclosure of similarity and superiority reports on an orphan medicine, prepared by the EMA Committee for Medicinal Products for Human use),[64] PTC Therapeutics International (disclosure of a clinical study report)[65] and MSD Animal Health Innovation/Intervet international (five toxicology study reports for a veterinary medicine).[66]

In these proceedings each party sought recourse from the Court to prevent the publication of clinical and nonclinical study reports, arguing that these must be regarded as trade secrets and as such, must not be disclosed. The claimants' position was that the entirety of the information in the clinical trial reports, especially the *compilation of publicly accessible clinical data and the analysis of this data by various third parties, as well as the general authorisation deliberations*,

---

[61] In this sense, see for example Leonor Rossi, Patricia Vinagre e Silva, '*Public Access to Documents in the EU*' (Bloomsbury Publishing, 2017) 264; Sarfaraz K. Niazi, '*Biosimilars and Interchangeable Biologics: Strategic Elements'* (CRC Press, 2018) 93-94; Stefano Marino and Spyridon Drosos, 'The European Medicines Agency's Approach to Transparency', Chapter 14 in Holly Fernandez Lynch, Glenn Cohen, Carmel Shachar, Barbara Evans (eds.), '*Transparency in Health and Health Care in the United States: Law and Ethics'* (CUP 2019) 219.

[62] Decision of the European Ombudsman closing his inquiry into complaint OI/3/2014/FOR concerning the partial refusal of the European Medicines Agency to give public access to studies related to the approval of a medicinal product (*The European Ombudsman Official Website, 2016*). Available at https://www.ombudsman.europa.eu/en/decision/en/68107, accessed 10 January 2021.

[63] *Ibid*., 'Suggestions for improvement' Section.

[64] Case T-235/15, *Pari Pharma GmbH v European Medicines Agency v European Medicines Agency (EMA)* [2018] ECLI:EU:T:2018:65.

[65] Case T-718/15, *PTC Therapeutics International Ltd v European Medicines Agency (EMA)* [2018] ECLI:EU:T:2018:66.

[66] Case T-729/15, *MSD Animal Health Innovation GmbH and Intervet international BV v European Medicines Agency (EMA)* [2018] ECLI:EU:T:2018:67.

must be generally regarded as confidential.[67] Pari Pharma, PTC Therapeutics International, MSD Animal Health Innovation put forward the *AbbVie/InterMune* inspired argumentation, relying on the CFREU provisions as a legal basis for the claims.

For instance, the Pari Pharma representatives elaborated on the substance of fundamental rights as regards private life and confidentiality under Art. 7 of the EU Charter and Art. 8 of the European Convention. The applicant maintained that disclosure of the reports at issue would undermine its business secrets, the Court of Justice having recognised that it may be necessary to prohibit the disclosure of information which is classified as confidential, and the protection provided by those provisions of primary law cannot be undermined by a mere administrative practice, such as the EMA's Policy 0043.[68] Interestingly, the intervener in the PariPharma case which requested the EMA to disclose the reports at issue argued that Art. 47 CFREU (right to an effective remedy even in the administrative proceedings) shall be interpreted as a ground for providing access to the reports at issue. The main argument behind that was the competing business interest, namely the protection of the market exclusivity of its medicinal product TOBI Podhaler and supporting its action for annulment of the decision by which the Commission granted the applicant the MA for Vantobra (PariPharma drug).[69]

In *PTC Therapeutics International,* the claimants mentioned that Art. 42 CFREU guaranteeing the access to the EU documents is a subject to the legitimate limitations, such as the business secrets of the legal persons.[70] Thus, the contested EMA decision shall be seen as infringing, *inter alia*, the first indent of Art. 4(2) of Regulation No 1049/2001, Art. 339 TFEU and the fundamental rights of the enterprise as regards the protection of privacy and of professional data under Art. 7 of the EU Charter and the *Varec* case.[71] In the *MSD Animal Health Innovation GmbH* case, the applicants put forward very similar reasoning, claiming that the contested decision infringes, *inter alia,* Art. 4(2)a of Regulation No 1049/2001, Art. 339 TFEU and their fundamental rights regarding respect for private life and correspondence under Art. 7 CFREU – as there is no emerging *'overriding public interest'* justifying their disclosure.[72] The

[67] In this sense, see Case T-235/15, *Pari Pharma GmbH v European Medicines Agency (EMA)* [2018] ECLI:EU:T:2018:65, paras. 1-9; Case T-718/15, *PTC Therapeutics International Ltd v European Medicines Agency (EMA)* [2018] ECLI:EU:T:2018:66, paras. 1-13; Case T-729/15, *MSD Animal Health Innovation GmbH and Intervet international BV v European Medicines Agency (EMA)* [2018] ECLI:EU:T:2018:67, paras. 1-10.

[68] Case T-235/15 R, *Pari Pharma GmbH v European Medicines Agency (EMA*) [2015] Order of the President of the General Court, 1 September 2015, ECLI:EU:T:2015:587, paras. 26, 40, 57, 58, 67.

[69] *Ibid*., paras 69-70.

[70] Case T-718/15 R, *PTC Therapeutics International Ltd v European Medicines Agency (EMA)* [2016] Order of the President of the General Court, 20 July 2016, ECLI:EU:T:2016:425, para. 75.

[71] *Ibid*., paras. 27, 54, 80, 84.

[72] Case T-729/15 R, *MSD Animal Health Innovation GmbH and Intervet international BV v European Medicines Agency (EMA)* [2016] Order of the President of the General Court, 20 July 2016, ECLI:EU:T:2016:435, paras. 23, 48, 73, 77.

claimants' suggestion was adding a new step in the EMA assesment on the basis of 'Transparency Regulation' and Policy 0043, in order to counter-balance the compteting CFREU rights (i.e. Art. 42 vs. Art. 7) - for instance *'limited disclosure to independent academic researchers who would not use the information for commercial purposes'*.[73]

In view of this reasoning, the claimants asserted not only that the especially sensitive parts of the reports should be covered by confidentiality protection, but rather, that this protection must extend *to the reports as such*, because the sensitive parts are embedded in a series of arguments, which includes questions relating to their respective strategy and together with other public elements of the reports, constitute an inseparable entity with economic value.[74] However, the Court dismissed a general presumption of confidentiality for such documents in all three cases. As for the fundamental rights' arguments of the applicants, the CJEU prominenetly disregarded the Charter-based claims: the *PTC Therapeutics International Ltd* and *MSD Animal Health Innovation GmbH* final judgements do not contain any mention of the Arts. 7 CFREU provisons. In the *Pari Pharma GmbH* case, the Court extensively elaborated on the company pleas, which were complimented by the references to the provisions of Art. 16 ('*Freedom to conduct a business'*) and 17 (*'Right to property'*) of the EU Charter.[75]

The CJEU heavily criticised the parties' assumption that the entire contents of the CT reports are confidential, as a significant part of the information contained in those reports is in the public domain and cannot by definition be regarded as falling within the scope of commercial interest within the meaning of Art. 4(2) of Regulation No 1049/2001. The applicant cannot therefore rely on the possible infringement using Art. 339 TFEU, Arts. 7, 16 and 17 CFREU and Art. 8 ECHR as a relevant legal ground for such a claim since it does not appear that all the data to which it refers are confidential. The importance of the pharma enterprise conduct in bargaining the pertinent redactions was emphasised: '*...it is thus for the applicant to identify and show which information, in its submission, falls within the scope of commercial interests within the meaning of 4(2) of Regulation No. 1049/2001'*.[76]

Hence, the court concluded in all three cases that, pursuant to Art. 2(3) of Regulation No. 1049/2001 that the provisions regarding the public accessibility of EMA documents shall *apply to all documents of the agency, in all of its areas of activity, i.e. to all documents the agency creates or receives and which are in its possession.* In light of the need for strict interpretation of

[73] *Ibid*., para. 68.

[74] In this sense, see Case T-235/15, *Pari Pharma GmbH v European Medicines Agency (EMA)* [2018] ECLI:EU:T:2018:65, paras. 1-9; Case T-718/15, *PTC Therapeutics International Ltd v European Medicines Agency (EMA)* [2018] ECLI:EU:T:2018:66, paras. 1-13; Case T-729/15, *MSD Animal Health Innovation GmbH and Intervet international BV v European Medicines Agency (EMA)* [2018] ECLI:EU:T:2018:67, paras. 1-10.

[75] Case T-235/15, *Pari Pharma GmbH v European Medicines Agency (EMA)* [2018] ECLI:EU:T:2018:65, paras. 33, 104 - 118.

[76] *Ibid*., para. 107.

Art. 4(2) exceptions (confidential business information), the CJEU said that the EU's legislator presumed that the integrity of the authorisation process is not impaired by the absence of such a presumption of confidentiality. For all these reasons, the General Court concluded that shall be no general presumption of confidentiality for CT reports; it is not possible to presume that these reports are subject to general confidentiality that would cover them *in their entirety* based on the exception to protect the economic interests of the applicant. Even though the economic value of the dossier is important for the pusposes of the Policy 0043 application, it is not sufficient on its own to classify as a *'commercially confidential information'* and therefore as confidential. Rather, it is up to the EMA to ensure, by conducting a specific, individual examination of each individual document in the administrative file to determine whether the document is covered as an exception for trade secrets within the meaning of Art. 2(4)a Regulation No. 1049/2001.

An initial CJEU's rulings in *PTC Therapeutics International* and *MSD Animal Health Innovation/Intervet international* were thus in favour of EMA. They went to appeal and, in September 2019, an AG Hogan released Opinions with a very *'pharma enterprises friendly*' argumentation.[77] However, the CFREU-based reasoning did not even appear in the texts - except for a very brief mention in the introductory parts paving way to the legal analysis. Advocate General preferred to put forward another arguments to defend the incorporation of the presumption of general confidentiality as the lack of effective safeguard clauses stemming from EU secondary legislation, which - moreover – is applicable *only* within the territory of the European Union/European Economic Area (EEA). This circumstances presumably open the floor for the usage of the costly *´R&D´* commercial data in non-EEA countries. Crucially, such presumption would give companies at least a right to an injunction, forcing the CJEU to consider the merits of a particular case and assess an objective need in a disclosure, instead of simply disregarding the CCI protection claims automatically.[78]

The appeal judgements in two of these cases however demonstrated the lack of the CJEU´s intention (1) to consider even a possibility to implement the presumption of general confidentiality of the clinical trial reports submitted as a part of the EMA authorisation kit or (2) to consider the CFREU provisions as a tool to defend the commercial interests of the pharmaceutical enterprises. Both in *PTC Therapeutics International* and *MSD Animal Health*

[77] Maria Isabel Manley, Zina Chatzidimitriadou, 'Crucial Development on the Presumption of Confidentiality in the Access to Document Saga (PTC Therapeutics v EMA and MSD Animal Health Innovation, Intervet v EMA)' (*Sidley Website*, 19 September, 2019). Available at: https://www.sidley.com/-/media/publications/crucial-development-on-the-presumption-of-confidentiality.pdf?la=en, accessed 12 January, 2021.

[78] Case C-175/18 P, *PTC Therapeutics International Ltd v European Medicines Agency*, Opinion of Advocate General Hogan delivered on 11 September 2019 [2019] ECLI:EU:C:2019:709, paras. 90-97, 104-157; Case C-178/18 P, *MSD Animal Health Innovation GmbH, Intervet international BV v European Medicines Agency*, Opinion of Advocate General Hogan delivered on 11 September 2019 [2019] ECLI:EU:C:2019:710, paras. 78-81, 92-108.

Innovation/Intervet international appeal judgements, the Court did not follow the AG suggestions. The Luxembourg judges pointed out that the claimants have not provide sufficient evidence, in order to demonstrate that the disclosure of the CCI in question could be considered *potentially harmful* to their business interests. From the judges' point of view, the mere *risk* that a competitor uses the data for economic purposes cannot be considered a sufficient ground for application of general presumption of the confidentiality.[79]

Even though the rulings – predictably – continue the '*pro-transparency'* trend, an important technical clarification was made on how to deal with information which shall – from the point of view of the pharma enterprise – be defended from the disclosure, in absence of the presumption of confidentiality. Pharmaceutical companies that want to prevent third parties from viewing the documents from the EMA authorisation kit are now requested to justify explicitly a need in an individual application of the exemptions laid down in Art. 4 of Regulation No 1049/2001. Based on this reasoning, the EMA can then individually assess whether or not to provide the requested information in accordance with the detailed description of the (a) type, (b) subject matter, (c) scope of this data, as well as (d) the explanation of how the dissemination of CCI can *realistically* affect the business interests of the enterprise.[80]

The recent CJEU's judgement in *Intercept Pharma Ltd/Intercept Pharmaceuticals* confirmed the well-established practice, and demonstrated the final demise of the CFREU provisions in cases involving the EMA *'transparency'* policies. The claim concerned an EMA decision to grant an access pursuant to Regulation No. 1049/2001 to a document containing periodic benefit-risk evaluation report submitted to the EMA as part of the application for marketing authorisation of a medicinal product for human use called Ocaliva. The specificity of the dispute was defined by the fact that the requesting party was a counterpart of *Intercept Pharma Ltd* in the legal dispute being considered in the United States of America, as such access would not be possible in accordance with American laws.[81]

In view of the specific legal context of the dispute and – presumably – the ealier Court judgements completely ignoring the EU Charter-based arguments of the pharamceutical industry, the claimant referred to Art. 4(2)2 of Regulation No. 1049/2001 according to which a request for access to documents can be denied if disclosure would be undermining the *protection of court proceedings and legal advice* (i.e. of the dispute ongoing in the USA court), unless there is an

[79] Case C-175/18 P, *PTC Therapeutics International Ltd v European Medicines Agency* [2020] ECLI:EU:C:2020:23, paras. 51-68; Case C-178/18 P, *MSD Animal Health Innovation GmbH and Intervet International BV v European Medicines Agency* [2020] ECLI:EU:C:2020:24, paras. 48-65.

[80] Case C-175/18 P, *PTC Therapeutics International Ltd v European Medicines Agency* [2020] ECLI:EU:C:2020:23, paras. 92-116; Case C-178/18 P, *MSD Animal Health Innovation GmbH and Intervet International BV v European Medicines Agency* [2020] ECLI:EU:C:2020:24, paras. 111-119.

[81] Case C-576/19 P, *Intercept Pharma Ltd and Intercept Pharmaceuticals, Inc. v European Medicines Agency* [2020] ECLI:EU:C:2020:873, paras. 6-28.

overriding public interest in disclosure. The CJEU found that the contested report has neither been drafted for a judicial process in question, nor had it been the subject of such a procedure. Hence, making the application of the exception relating to ongoing trial(-s) between the applicant and the (legal) person requesting an access to the EMA marketing authorisation kit *as such* would unacceptably broaden the scope of the Art. 4 of Regulation No. 1049/2001 exception. The Court therefore decided to reject the appeal in full and to confirm the sentence of General Court and the earlier EMA decision,[82] hence – again – deliberately confirming its well established *'pro-transparency'* case-law.

Finally, the 'Clinical Trials Regulation' implementation can arguably bring even more challenges to the EMA/pharma enterprises relationship, in view of the final move towards the proactive publication of the CT data. One could also remember that – upon the planned launch of the 'Clinical Trial Data Portal/Database' in late 2021[83] – the implementing provisions of EMA Policy 0070 are also likely to become a fruitful basis for the litigation before the EU Court of Justice. The first evidence of this development is the *Amicus Therapeutics UK and Amicus Therapeutics v EMA* case, regarding public access to a document containing information submitted in the context of a request for marketing authorisation for the medicinal product Galafold.[84] Even though the case concerned the implementation of Policy 0043, the EMA also referred to the text of new Regulation (EU) No. 536/2014 ('Clinical Trials Regulation') and, in particular, to Arts. 37(4), 80 and 81 and recitals 67 and 68 thereof, in order to support its submissions.[85]

The CJEU prominently disregarded the applicants' fundamental rights' claims, referring to the *Deza* v *ECHA* case outcome. Both Art. 8 ECHR, Art. 7 and Art. 17 of the EU Charter cannot be interpreted as laying down an automatic exception to the principle of disclosure for documents drawn up in the course of a private entity's commercial activity. Even though new Regulation No. 536/2014 on clinical trials on medicinal products for human use was considered inapplicable in the present case, the Court saw the wording of the abovementioned provisions as an additional indication that EU legislature was specifically aiming at the maximum transparency of the EMA documents.[86] Hence, it was emphasised that the objectives of (applicable) Regulation No. 1049/2001 and EMA Policy 0043 exclude the existence of a *general*

[82] *Ibid*., paras. 39-50.

[83] 'Clinical data publication'. Available at: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication, accessed 10 January, 2021.

[84] Case T-33/17, *Amicus Therapeutics UK Ltd and Amicus Therapeutics, Inc. v European Medicines Agency* [2018] ECLI:EU:T:2018:595.

[85] *Ibid*., paras. 9, 50, 66.

[86] *Ibid*., para. 50.

presumption of confidentiality[87] – which means that EMA must specifically examine the various data concerned by the request for access.[88] In order to justify a refusal to grant access to a document, it is not even sufficient for that document to fall within an activity mentioned in Art. 4 of Regulation No 1049/2007 – on the ground that there is an *overriding public interest* in disclosure, namely a need to ensure that the a marketing authorisation procedure operates correctly, and a disclosure of the report at issue cannot alter that procedure.[89]

In sum, the EU Court of Justice tended to analyse the objectives of the Transparency Regulation, Authorisation Regulation, and the pertinent provisions of Policy 0043, interpreting Art. 7 of the EU Charter or - later - simply avoiding the CFREU-based arguments to favor the ever increasing transparency through both reactive and proactive publication of the MA files components. It could be stated that the CJEU's approach to the interpretation of the abovementioned Charter provisions in years to come, is unlikely to be changed. This creates, *inter alia*, the growing risk of the (possible) violation of the rights of the pharmaceutical companies (for instance, Arts. 16, 17 and 47 CFREU), as well as the deriving need in intensification of the dialogue between the pharma enterprises and the European Medicines Agency ('redaction' process). However, the CJEU also indicated how the fundamental rights of pharmaceutical companies shall be protected in course of the latter procedure – and which level of the business guarantees the CJEU and EMA see as sufficient within this context. The *'commercially confidential information'* still can be redacted (even though not excluded from the public access in its entirety), if the enterprise concerned is able to demonstrate how access to that document could specifically and actually undermine the interest protected by an exception laid down in Art. 4 of Regulation No 1049/2001 and that the risk of that interest being undermined is reasonably foreseeable and not purely hypothetical.[90]

3. The EMA ´transparency´ policies & COVID-19: is the CFREU still relevant?

As of October 2020, more than 4 million COVID-19 cases have been reported in the EU/EEA and the United Kingdom; nearly all countries belonging to this area were experiencing high levels or sustained increases of their 14-day COVID-19 case notification rate.[91] Predictably, the enexpected COVID-19 pandemia caused an unprecedented public interest in medicine being developed specifically for this desease, as well as the need to provide access to

[87] *Ibid*., paras. 50-51.

[88] *Ibid*., para. 59-61.

[89] *Ibid*., para. 41.

[90] Case T-33/17, *Amicus Therapeutics UK Ltd and Amicus Therapeutics, Inc v European Medicines Agency (EMA)* [2018] ECLI:EU:T:2018:595, para. 59.

[91] Communication from the Commission to the European Parliament and the Council, COM(2020) 680 final, p. 2.

more information than usual in course of the European Medicines Agency authorisation procedures.[92] The pan-European race to produce COVID-19 treatments, ranging from immunomodulators, antivirals and hyperimmune serums was also seen as a possibility for regulators and drug companies to lobby for a more harmonised approvals process,[93] considering both the prevailing public interest in coping a disease and respecting the commercial interests of the pharmaceutical enterprises.[94]

Within the framework of Decision 1082/2013/EU on serious cross-border threats to health, and in view of the emerging health threat to humans in the European Union territory, the COVID-19 EMA Pandemic Task Force (COVID-ETF) was established.[95] One of the key objectives of this emergency Group was articulated as *managing and coordinating the discussions* '…on development, authorisation and surveillance of relevant medicinal products, which are under the remit of EMA, and post-authorisation follow-up of all relevant EU authorised medicinal products to be used to address the health threat'.[96] Importantly, the basic EMA transparency documents, namely EMA Policies 0043 and 0070 were not urgently revised either due to these developments, or due to the CFREU-based applicants' arguments of the *AbbVie/InterMune* lines of reasoning.[97]

The inquiry of the scientists from IQWiG and the Cochrane Collaboration to the European Medicines Agency (EMA)[98] was one of the first public responses to these novelties. The academics called for the accelerated publication of all clinical study reports on all COVID-19 drugs and vaccines as soon as they are approved for the EU/EEA market – in order to pool the strengths of international research community to combat the pandemic.[99] Their request was followed by the open letter of the European Ombudsman: on 29 July, 2020, Mrs. O'Reilly

[92] Milad Haghani, Michiel Bliemer, 'Covid-19 pandemic and the unprecedented mobilisation of scholarly efforts prompted by a health crisis: Scientometric comparisons across SARS, MERS and 2019-nCoV literature' (2020) 125 Scientometrics 2695. Avaliable at: https://doi.org/10.1007/s11192-020-03706-z, accessed 10 January 2021.

[93] Editorial: 'COVID vaccines: the world's medical regulators need access to open data' (2020) 588(7837) Nature 195. Avaliable at: https://www.nature.com/articles/d41586-020-03458-z, accessed 10 January 2021.

[94] Adam Cohen, Joop van Gerven, Juan Garcia Burgos, 'COVID-19 vaccines: the importance of transparency and fact-based education' (2020) 86(11) British Journal of Clinical Pharmacology 1. Avaliable at: https://bpspubs.onlinelibrary.wiley.com/doi/pdf/10.1111/bcp.14581, accessed 10 January 2021.

[95] EMA/166423/2020 (31 March 2020), 'Biological Health Threats and Vaccines Strategy Mandate, objectives and rules of procedure of the COVID-19 EMA pandemic Task Force (COVID-ETF)'. Avaliable at: https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-covid-19-ema-pandemic-task-force-covid-etf_en.pdf, accessed 10 January 2021.

[96] *Ibid*., p. 1.

[97] Policy 0043 is expected to be reviewed before 31 October, 2021 – considering the outcomes of the COVID-19 outbreak, BREXIT implications and deriving developments in the EMA implementing documentation. Response to ASK-74893 - EMA transparency policies in light of COVID 19, received on 10 December 2020, p. 3-4.

[98] EMA should support the international research community by publishing Clinical Study Reports on medicine and vaccine trials at the time of marketing authorisation' (IQWiG, 14 May 2020). Available at: https://www.iqwig.de/printprodukte/2020-05-14open20letter20to20emafinal.pdf?rev=117386, accessed 10 January, 2021.

[99] *Ibid*., p. 1, 2.

requested the information on the EMA's intention (1) to follow earlier *'pro-transparency'* decisions of the European Ombudsman in the activities of the COVID-ETF Group, and (2) to ensure sufficient degree of transparency of its COVID-19 related activities, including the possibility of rapidly publishing clinical data for the products in question.[100] Surprisingly, the EU Charter provisions were not mentioned either by the European Ombudsman, or by the EMA Executive Director. In his replies, Dr. Rasi simply wrote that EMA's activities in relation to COVID-19 deserve the highest possible level of transparency and, in keeping with our commitment, the Agency will take appropriate action to share information publicly.[101] This position was predictably retained in the EMA response to the second open letter from the members of academic community concerning the transparency and evaluation of vaccines for COVID-19.[102]

Moreover, it was underlined that, despite all challenges related to the COVID-19 outbreak, the maximum efforts should be put into implementing exceptional transparency measures with regard to the relevant medicines being assessed under accelerated procedures such as rolling review.[103] For instance, such exceptional measures for COVID-19 medicines assesment comprise the (online) publishing of the list of the relevant medicines that have received scientific advice by the European Medicines Agency on the appropriate tests and studies required in the development of a medicine or on the quality of a medicine or guidance from the EMS COVID-ETF Group, announcement of the news on compassionate use of the unauthorised drugs outside a clinical study in individual patients within 1 day of the Committee for Medicinal Products for Human Use (CHMP) opinion, on the start of rolling review of such medicines within 1 day after the review start, as well as on the submission of the marketing authorisation application within 1 day after such application was made.[104]

---

[100] Letter to the European Medicines Agency (EMA) concerning the transparency and independence of the work of the EMA in supporting the development and evaluation of COVID-19 medicines (CASE SI/5/2020/DDJ, 29 July, 2020). Available at: https://www.ombudsman.europa.eu/en/correspondence/en/130852, accessed 10 January, 2021.

[101] EMA/516771/2020 (30 September 2020), 'Reply to the European Ombudsman's letter concerning transparency and independence of the work of the European Medicines Agency in supporting the development and evaluation of COVID-19 medicines'. Available at: https://www.ema.europa.eu/en/documents/other/reply-european-ombudsmans-letter-concerning-transparency-independence-work-european-medicines-agency_en.pdf, accessed 10 January, 2021.

[102] EMA/565800/2020 (29 October, 2020) Reply to open letter concerning the transparency and evaluation of vaccines for COVID-19. Available at: https://www.ema.europa.eu/en/documents/other/reply-open-letter-concerning-transparency-evaluation-vaccines-covid-19_en.pdf, accessed 10 January, 2021.

[103] *Ibid*., p. 1.

[104] 'Transparency: exceptional measures for COVID-19 medicines'. Available at: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/transparency-exceptional-measures-covid-19-medicines#comparison-with-standard-transparency-section, accessed 10 January, 2021.

The major changes concerned the authorisation process as such. For example, the publication of the EMA COVID-related European public assessment report (EPAR, i.e. a set of documents describing the evaluation of a medicine and including the product information) shall be made *within 3 days of granting marketing authorisation*, with the updates following major post-authorisation changes – while normally being published at least 2 weeks after marketing authorisation granting. In case of the COVID medicines, the risk management plans (RMP, i.e. a detailed description of the activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicines) shall be *released fully* (not as a summary), with the updates following major post-authorisation changes.[105]

The COVID-19 clinical trials data shall be published on *Clinical data website*[106] after granting marketing authorisation, with an additional data also released after major changes to authorisation.[107] Hence, even though the COVID-19 pandemic did not have an impact on the overall development of the CT Portal, with the publication of clinical trials data remaining suspened for all other medicinal products until further notice,[108] the abovementioned documents related to COVID medicines development became availiable both to the EU public, as well as the non-EU individuals and enterprises. Pharmaceutical companies were encouraged to contact EMA as soon as possible concerning publication of clinical data if they planned to submit an application for the COVID-19 related medicinal products.[109]

In line with this *'pro-transparency'* strategy, the European Medicines Agency has already published an information on more than 70 COVID-19 medicines that had received EMA advice. Among them, 8 vaccines, 18 immunomodulators, 1 immunoglobulin, 1 challenge agent for human infection models, 24 antiviral drugs and 4 other therapeutics.[110] Importantly, the EMA's *conditional marketing authorisation (CMA)* mechanism was used for the COVID-19 medicines as they potentially addressed an unmet medical need, with the benefit of immediate availability outweighing the risk – on the basis of less comprehensive data than normally

[105] *Ibid*.

[106] 'European Medicines Agency online access to clinical data for medicinal products for human use'. Available at: https://clinicaldata.ema.europa.eu/web/cdp/home, and https://www.clinicaltrialsregister.eu, both accessed 10 January, 2021.

[107] 'Transparency: exceptional measures for COVID-19 medicines'. Available at: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/transparency-exceptional-measures-covid-19-medicines#comparison-with-standard-transparency-section, accessed 10 January, 2021.

[108] Response to ASK-74893 - EMA transparency policies in light of COVID 19, received on 10 December 2020, pp. 1, 2.

[109] 'Support for industry on clinical data publication'. Available at: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication/support-industry-clinical-data-publication, accessed 10 January, 2021.

[110] 'COVID-19 medicines that have received EMA advice'. Available at: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines-covid-19#authorised-medicines-section, accessed 10 January, 2021.

required.[111] The application for the marketing authorisation of *Remdesivir* - a treatment against COVID-19 for adults and adolescents as from age 12 with pneumonia who require supplemental oxygen - was submitted to the European Medicines Agency on 8 June, 2020.[112]

In course of the latter procedure, an information on the key COVID sympthomatic treatment *Remdesivir*, including 18 clinical trials protocols,[113] product information, EPAR and and EMA Committee for Medicinal Products for Human Use (CHMP) Opinion were published online.[114] *An applicant (Gilead Sciences Ireland CU) did not attempt to invoke the EU Charter provisions (Arts. 7, 16, 17, 47 and 42 for instance) as a ground to block access of the third persons to the application kit submitted to the EMA (as a 'commercially confidential information' exception), or as a ground for the redaction of the CMA application kit.*[115] On 3 July, 2020 - after the EMA's recommendation and subsequent approval of the Standing Committee on Medicinal Products for Human Use - *Remdesivir* became the first treatment to be authorised for a conditional marketing under abovementioned accelerated procedure.[116] This EMA decision allowed to implement it widely as a COVID-19 symptomatic treatment in clinical practice across the European Union.[117]

The second essential COVID-19 treatment, namely *Dexamethasone* for the usage in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) who require supplemental oxygen therapy – was authorised for the European Union in accordance with the Art. 5(3) of Regulation (EC) No 726/2004 (*'Submission and examination of applications — Authorisations'*). *Dexamethasone* is a corticosteroid medicine that has been authorised in the EU by national medicines authorities and has been available for several decades for treating a range of inflammatory conditions and for reducing the body's immune response in the treatment of

[111] 'Conditional marketing authorisation'. Available at: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation, accessed 10 January, 2021.

[112] 'Veklury'. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/veklury, accessed 10 January, 2021.

[113] 'EU Clinical Trials Register: Clinical trials for remdesivir'. Available at: https://www.clinicaltrialsregister.eu/ctr-search/search?query=remdesivir, accessed 10 January, 2021.

[114] 'Veklury: Authorisation Details'. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/veklury#authorisation-details-section, accessed 10 January, 2021.

[115] Response to ASK-74893 - EMA transparency policies in light of COVID 19, received on 10 December 2020, p. 6.

[116] 'COVID-19: how EMA fast-tracks development support and approval of medicines and vaccines'. Available at: https://www.ema.europa.eu/en/news/covid-19-how-ema-fast-tracks-development-support-approval-medicines-vaccines, accessed 10 January, 2021.

[117] Vesa Halimi, Armond Daci, Nevenka Ridova and others, 'The use of remdesivir outside of clinical trials during the COVID-19 pandemic' (2020) 13 Journal of Pharmaceutical Policy Practice 61.

allergies and autoimmune diseases.[118] At the same time, the 'Randomised Evaluation of COVID-19 therapy' ('RECOVERY') clinical trials conducted in the United Kingdom[119] indicated a potential benefit of dexamethasone in adult hospitalised patients with COVID-19 receiving invasive mechanical ventilation or oxygen supplementation and in hospitalised patients with more than 7 days after symptom onset.[120]

On 17 July 2020, the EMA Executive Director - following preliminary discussion with the COVID-ETF Group - asked the CHMP to assess the impact and give a scientific opinion on potential clinical use of Dexamethasone in the treatment of hospitalised adult patients with COVID-19, for oral and intravenous medicinal products.[121] In accordance with Art. 5(3) of Regulation (EC) No. 726/2004, the opinion of the Committee shall be made publicly accessible.[122] Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.[123] *However, the CFREU provisions (Arts. 7, 16, 17, 47 or 42) were not referred to as a ground to block access of the third persons to the application kit (as a 'commercially confidential information' exception), or as a ground for the redaction of the RECOVERY clinical trials reports submitted to the EMA.*[124] On the basis of CHMP positive Opinion from 17 September 2020, the EMA endorsed use of dexamethasone in COVID-19 patients on oxygen or mechanical ventilation, and the pharmaceutical companies producing/distributing *Dexamethasone* were encouraged to request this new use to be added to their product's license by submitting an application to national medicines agencies or to European Medicines Agency.[125]

Predictably, the COVID-19 *vaccine* development was supported by the transparent and continuous dialogue between the pharameceutical companies and the EMA COVID-ETF

[118] 'EMA endorses use of dexamethasone in COVID-19 patients on oxygen or mechanical ventilation'. Available at: https://www.ema.europa.eu/en/news/ema-endorses-use-dexamethasone-covid-19-patients-oxygen-mechanical-ventilation, accessed 10 January, 2021.

[119] The RECOVERY Collaborative Group, 'Dexamethasone in Hospitalized Patients with Covid-19 — Preliminary Report' (2020) The New England Journal of Medicine 1.

[120] 'Assessment report: Dexamethasone in hospitalised patients with COVID-19', EMA/509632/2020 (CHMP, 17 September 2020). Available at: https://www.ema.europa.eu/en/documents/other/dexamethasone-covid19-article-53-procedure-assessment-report_en.pdf, p. 4. Accessed 10 January, 2021.

[121] *Ibid*.

[122] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance) (2004) OJ L 136.

[123] 'Assessment report: Dexamethasone in hospitalised patients with COVID-19', EMA/509632/2020 (CHMP, 17 September 2020). Available at: https://www.ema.europa.eu/en/documents/other/dexamethasone-covid19-article-53-procedure-assessment-report_en.pdf, 4. Accessed 10 January, 2021.

[124] Response to ASK-74893 - EMA transparency policies in light of COVID 19, received on 10 December 2020, p. 6.

[125] 'EMA endorses use of dexamethasone in COVID-19 patients on oxygen or mechanical ventilation'. Available at: https://www.ema.europa.eu/en/news/ema-endorses-use-dexamethasone-covid-19-patients-oxygen-mechanical-ventilation, accessed 10 January, 2021.

Group,[126] which led to the European Commission preliminary supply contracts with several pharmaceutical companies, comprising BioNTech-Pfizer, Moderna, AstraZeneca, Sanofi-GSK and Janssen Pharmaceutica NV and CureVac.[127] This approach was aimed at the creation of the broad portfolio of vaccines to be provided in the EU Member States, once all the vaccines in question have been proven to be safe and effective and authorised by EMA.[128] At the time of writing, two effective vaccines against COVID-19 – namely *Comirnaty* (BioNTech and Pfizer) and *Moderna* (Moderna) - have also been granted a *conditional authorisation* for use in the European Union, following positive assessment of the preliminary research results by the European Medicines Agency.[129] The clinical studies are not yet complete, and the pharmaceutical companies are expected to provide the final results of their COVID research in the forthcoming years. This means that the final clinical trials reports are still in the progress of development, and shall be released upon full completion and assessment of Moderna and Comirnaty clinical trials.[130]

The first authorised vaccine is *Comirnaty* developed by BioNTech and Pfizer, aimed at preventing coronavirus disease in people aged 16 years. The effective substance contains a molecule called RNA messenger with guidance for producing a protein from SARS-CoV-2, the virus that causes COVID-19.[131] The applicant (*BioNTech Manufacturing GmbH*) submitted an application for marketing authorisation on 30 November 2020, through the centralised authorisation procedure under Regulation (EC) No. 726/2004.[132] The effectiveness of the vaccine

[126] 'First "ERAvsCorona" action plan: short-term coordinated research and innovation actions (April, 2020)'. Available at: https://ec.europa.eu/info/sites/info/files/research_and_innovation/research_by_area/documents/ec_rtd_era-vs-corona.pdf, accessed 10 January, 2021.

[127] 'Coronavirus: Commission concludes exploratory talks with Valneva to secure a new potential vaccine'. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_21_51, accessed 10 January, 2021.

[128] 'Coronavirus vaccines strategy'. Available at: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/coronavirus-vaccines-strategy_en, accessed 10 January, 2021.

[129] 'Treatments and vaccines for COVID-19: medicines under evaluation'. Available at: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/treatments-vaccines-covid-19-medicines-under-evaluation, accessed 10 January, 2021.

[130] Marco Cavaleri, Harald Enzmann, Sabine Straus, Emer Cooke. 'The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines' (13 January, 2021) Lancet (Online First). Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00085-4/fulltext, accessed 10 January, 2021.

[131] 'Comirnaty: Product Information as approved by the CHMP on 8 January 2021, pending endorsement by the European Commission'. Available at: https://www.ema.europa.eu/en/documents/other/comirnaty-product-information-approved-chmp-8-january-2021-pending-endorsement-european-commission_en.pdf, accessed 10 January, 2021.

[132] COMMISSION IMPLEMENTING DECISION of 21.12.2020 granting a conditional marketing authorisation under Regulation (EC) No. 726/2004 of the European Parliament and of the Council for "Comirnaty - COVID-19 mRNA Vaccine (nucleoside modified)", a medicinal product for human use (Text with EEA relevance) C(2020) 9598 final. Available at: https://ec.europa.eu/health/documents/community-register/2020/20201221150522/dec_150522_en.pdf, accessed 10 January, 2021.

was demonstrated by the results on the clinical trials conducted in the United States, Turkey, Germany, South Africa, Brazil, Argentina, and confirmed by the national inspection resports, such as ones prepared by the Regierungspräsidium Karlsruhe and Paul-Ehrlich-Institut (Germany), Food and Drug Administrations (USA Regulatory Authority) and National Administration of Drugs, Foods and Medical Devices (Argentinian Regulatory Authority) enclosed with the EMA application.[133]

The *Comirnaty* EPAR was adopted by the Committee for Medicinal Products for Human Use and released online with all information of a commercially confidential nature deleted.[134] *The CFREU provisions (Arts. 7, 16, 17, 47 or 42) were not referred to as a ground to block access of the third persons to the application kit (as a 'commercially confidential information' exception), or as a ground for the redaction of the BNT162b2 application file submitted to the European Medicines Agency.*[135] On 21 December 2020, following the CHMP´s preliminary positive assessment of quality, safety and efficacy of the vaccine, *Comirnaty* was granted a conditional marketing authorisation for the distribution in the European Union.[136]The European Commission already approved the contracts with BioNTech-Pfizer for the purchase of 400 million doses on behalf of all EU Member States (total), and proposed to the EU Member States the purchase of an additional 300 million *Comirnaty* vaccine doses (total).[137]

The second COVID vaccine authorised in the European Union is *Moderna* developed by Moderna Biotech Spain, which can be used to prevent disease in people from 18 years of age. The effective substance – just like in *Comirnaty* - contains similar RNA molecule-messenger with instructions for producing a protein from the virus that causes the Coronavirus.[138] The second vaccine was also assesed under accelearted procedure, with the start of the CHMP's rolling review even before the pharmaceuttical company's application for the product authorisation - in order to speed up the assessment of a medicine addressing a public health

[133] 'Comirnaty: Assessment report, EMA/707383/2020' (CHMP, 21 December 2020). Available at: https://www.ema.europa.eu/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf, pp. 56-57. Accessed 10 January, 2021.

[134] *Ibid*., p. 1.

[135] Response to ASK-74893 - EMA transparency policies in light of COVID 19, received on 10 December 2020, p. 6.

[136] COMMISSION IMPLEMENTING DECISION of 21.12.2020 granting a conditional marketing authorisation under Regulation (EC) No. 726/2004 of the European Parliament and of the Council for "Comirnaty - COVID-19 mRNA Vaccine (nucleoside modified)", a medicinal product for human use (Text with EEA relevance) C(2020) 9598 final. Available at: https://ec.europa.eu/health/documents/community-register/2020/20201221150522/dec_150522_en.pdf, accessed 10 January, 2021.

[137] 'Coronavirus vaccines strategy'. Available at: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/coronavirus-vaccines-strategy_en, accessed 10 January, 2021.

[138] 'Product Information as approved by the CHMP on 6 January 2021, pending endorsement by the European Commission. Available at: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-product-information_en.pdf, p. 23. Accessed 10 January, 2021.

emergency.[139] The safety of the vaccine was assessed on the basis of results of the clinical trials conducted in the United States involving 30,351 participants 18 years of age and older.[140]

The CHMP summary of positive opinion for COVID-19 Vaccine *Moderna*, Product information and the Risk-management-plan were published on the EMA website on 6 January, 2021,[141] with the EPAR being prepared for the publication at the time of writing.[142] *The CFREU provisions (Arts. 7, 16, 17, 47 or 42) were not referred to as a ground to block access of the third persons to the application kit (as a 'commercially confidential information' exception), or as a ground for the redaction of the Moderna application file submitted to the European Medicines Agency*.[143] Following a positive EMA assessment, Moderna was granted a conditional marketing authorisation for the distrubuton and usage in the European Union on 6 January, 2021.[144] The European Commission approved the suppy contracts with Moderna for the purchase of 80 million doses of COVID-19 vaccine (total), plus an option to request up to a further 160 million doses (total), to be supplied once a vaccine has proven to be safe and effective.[145]

At the time of writing, the EMA considers another application for conditional marketing authorisation of COVID-19 vaccine developed by AstraZeneca and Oxford University. The CHMP opinion on the marketing authorisation is expected to be released online on the EMA website by 29 January, 2021.[146] The applications from 5 other pharmaceutical companies are expected in due course. They are likely to be processed under the similar conditions, i.e. the *'fast-track'* authorisation procedure, with the immediate publication of pertinent Product information, European public assessment reports and the Risk-management-plans – and with the

[139] 'EMA starts rolling review of mRNA COVID-19 vaccine by Moderna Biotech Spain, S.L.'. Available at: https://www.ema.europa.eu/en/news/ema-starts-rolling-review-mrna-covid-19-vaccine-moderna-biotech-spain-sl, accessed 10 January, 2021.

[140] 'Product Information as approved by the CHMP on 6 January 2021, pending endorsement by the European Commission'. Available at: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-product-information_en.pdf, accessed 10 January, 2021.

[141] 'COVID-19 Vaccine Moderna' Available at: https://www.ema.europa.eu/en/medicines/human/summaries-opinion/covid-19-vaccine-moderna, accessed 10 January, 2021.

[142] 'EMA recommends COVID-19 Vaccine Moderna for authorisation in the EU'. Available at: https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-moderna-authorisation-eu, accessed 10 January, 2021.

[143] Response to ASK-74893 - EMA transparency policies in light of COVID 19, received on 10 December 2020, p. 6.

[144] 'EMA recommends COVID-19 Vaccine Moderna for authorisation in the EU'. Available at: https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-moderna-authorisation-eu, accessed 10 January, 2021.

[145] 'Coronavirus vaccines strategy'. Available at: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/coronavirus-vaccines-strategy_en, accessed 10 January, 2021.

[146] 'EMA receives application for conditional marketing authorisation of COVID-19 Vaccine AstraZeneca'. Available at: https://www.ema.europa.eu/en/news/ema-receives-application-conditional-marketing-authorisation-covid-19-vaccine-astrazeneca, accessed 10 January, 2021.

final clinical trials reports are to be submitted in 2-3- year period.[147] It is also most likely that the applicants will choose the same strategy of the application kits' redaction, namely skipping the CFREU-related arguments as a ground to invoke Art. 4 of Regulation No. 1049/2001 (a *'commercially confidental'* information exception).

ii. Conclusion. In this paper an attempt was made to shed some light on the influence of the CFREU provisions on the practice of the Court of Justice of the European Union concerning the European Medicines Agency '*transparency'* policies, as well as the (possible) impact of the EU Charter on the development of the Agency extra transparency measures for COVID-19 vaccines and therapeutics. The author analysed the Court's usage of Arts. 7, 16, 17, 47 and 42 of the EU Charter for interpretation of the *'commercially confidential'* information in light of the key Regulation (EC) No 1049/2001, Regulation (EC) No 726/2004, Regulation 536/2014/EU and the implementing EMA Policies 0043 (2010) and 0070 (2014).

The main arguments presented were that the interpretation of the EU Charter provisions within this context, primarily Arts. 7 ('Respect for private life'), 17 ('Right to property') and 47 ('The right to an effective remedy') remains a *challenging task* for the Luxembourg Court - due to (1) the complexity of the science-based analysis which is to be conducted in light of (2) the continuous scrutiny by the European Ombudsman, and (3) a need to counter- balance the interests of the pharma enterprises (protection of the business secrets) and the EMA move towards the maximum transparency of the MA dossiers (enhancing the research in the EU healthcare field).

In sum, it is possible to agree with Bache, Flear and Hervey who argue that this area of EU pharmaceutical law is more focused on ethics and human rights of patients than on a straightforward analysis of business risks within the framework of the market for pharmaceuticals[148] - which seems to a rationale for the restrictive approach chosen. The CJEU has elaborated on the way the EMA Policy 0043 shall be applied in the *PTC Therapeutics International Ltd, MSD Animal Health Innovation GmbH* and *Pari Pharma GmbH* – clearly prioritizing the public access to the CTR data over the business interests and fundamental rights of the pharma enterprises. The most recent CJEU's jurisprudence have demonstrated the clear demise of the CFREU role as a guardian of the commercial interests of the pharmaceutical industry (*Intercept Pharma Ltd/Intercept Pharmaceuticals*).

[147] Marco Cavaleri, Harald Enzmann, Sabine Straus, Emer Cooke. ' The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines' (13 January, 2021) Lancet (Online First) https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00085-4/fulltext, accessed 10 January, 2021.

[148] Mark Flear, Anne-Maree Farrell, Tamara Hervey, and Thérèse Murphy, 'The Defining Features of the European Union's Approach to Regulating New Health Technologies', Chapter 2 in Flear, Farrell, Hervey and Murphy (eds), *'European Law and New Health Technologies'* (OUP, 2013) 37-38, 41.

It is worth mentioning that the COVID-19 pandemia did not seem to bring any change on the ground. To date, no applications were submitted by the pharmaceutical enterprises to the EU Court of justice on the basis of the EMA decisions concerning the implemenation of the Extra transparency measures for COVID-19 vaccines and therapeutics. At the same time, none of the companies attempted to invoke the EU Charter provisions (Arts. 7, 16, 17, 47 and 42 for instance) as a ground to block access of the third persons to the application kit submitted to the EMA while submitting the application kits for the COVID-19 medicines and vaccines. Neither did the CFREU-based arguments appear in the Agency ongoing dialogue with the European Ombudsman, or the members of the EU academic community.

This could be seen both as a response to the extraordinary pandemic situation and the unprecedented transparency EMA measures applied under these circumstances as such. However, it could also serve as an indication of the (possible) discouragement of the companies in usage of the CFREU as a relevant tool to defend their commercial interests, due to the forming body of the CJEU's case-law clearly demonstrating the demise of the EU Charter relevant guarantees in the Court's reasoning. The EMA pertinent *´transparency´* policies are not likely to be revised in view of Charter-based arguments either. The Agency believes that Regulation No. 1049/2001 and the pertient CJEU´s case-law specify to a sufficient extent how the key fundamental rights to property (Art. 17 CFREU) and one of access to the EU documents (Art. 42 CFREU) are balanced: there is no general presumption of confidentiality, but the pharmaceutical companies still can attempt to explain and justify the confidentiality in a specific case.[149] All in all, even though the EMA ´transparency' policies implementation is clearly aimed at boosting the research, including the COVID-related clinical studies, this approach is capable – at the later date - of discourgaing the EU and the third country phrmaceutical enterprises from attempts to obtain a marketing authorisation for the distribution of the medicinal products in the European Union market.

[149] Response to ASK-74893 - EMA transparency policies in light of COVID 19, received on 10 December 2020, p. 5.

MTA Law Working Papers

Kiadó: Társadalomtudományi Kutatóközpont (MTA Kiválósági Kutatóhely

Székhely: 1097 Budapest, Tóth Kálmán utca 4.

Felelős kiadó: Boda Zsolt főigazgató

Felelős szerkesztő: Kecskés Gábor

Szerkesztőség: Hoffmann Tamás, Mezei Kitti, Szilágyi Emese

Honlap: http://jog.tk.mta.hu/mtalwp

E-mail: mta.law-wp@tk.mta.hu

ISSN 2064-4515