Editorial: Human Organs for Transplantation: Self-Sufficiency, a European Perspective

If we are prepared to receive a transplant should we need one, then we should be ready to give.

WHO Task Force on Donation and Transplantation of Human Organs and Tissues

1 Introduction

Over the years, the possibilities of organ transplantation for therapeutic purposes have increased considerably. This contrasts with the number of donor-organs that becomes available. The persistent shortage of organs for transplantation instigates worldwide trafficking. Internet facilitates commercialisation and transplant tourism. Problems of this kind lay at the basis of the World Health Organisation's 1989 Resolution on preventing the purchase and sale of human organs, and of the Council of Europe's Convention against Trafficking in Human Organs. It also explains the commitment pledged by participants at the Pontifical Academy of Sciences Summit on Organ Trafficking to combat illicit and immoral practices 'as a community of stakeholders fulfilling the directive of Pope Francis to combat human – and organ trafficking in all their condemnable forms'.

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1 WHO Transplantation, Transplantation and Donation, online at: www.who.int/transplantation/donation/en/.
2 Organ transplantation from a living donor is not dealt with.
3 In Resolution WHA 40.13, adopted in May 1987, the 40th World Health Assembly requested the Director-General to study, in collaboration with other organizations concerned, the possibility of developing appropriate guiding principles for human organ transplants.
4 CETS 2015, no 216, entrance into force March 2018 at the occasion of ratification by the first five States out of the 22 States who so far had signed the Convention. The five ratifying States were Albania, Czech Republic, Malta, the Republic of Moldova and Norway. The Convention is open to non-member states.
5 2017 Statement of the Pontifical Academy of Sciences Summit on Organ Trafficking and Transplant Tourism.
In response to growing concerns about international trafficking in human organs, the first Istanbul Declaration on Organ Trafficking and Transplant Tourism of July 2008⁶ establishes definitions of practices, and provides for principles to guide policy makers and health professionals. The text underlines the importance of self-sufficiency in organ transplantation, national and subregional, as the optimal approach to prevent unethical practices such as commercialism, organ trafficking and transplant tourism.⁷

2 Self-sufficiency

The third WHO global consultation on organ donation and transplantation ‘Striving to Achieve Self-Sufficiency’⁸ carried forward the principles laid out in the first WHO Guiding Principles on Transplantation, endorsed by the World Health Assembly in Resolution WHA44.25 (1991) and in the 2008 Istanbul Declaration.⁹ The objective of the 2010 Madrid consultation was to confront the self-sufficiency paradigm from a practical perspective, developing a comprehensive strategic framework for policy and practice directed at the global challenges of a shortage of organs for transplantation and unmet patient needs. The ensuing World Health Assembly (WHA) Resolution 63.22 of May 2010 (Madrid Resolution), expresses a pledge to progress in satisfying organ donation and transplantation needs, including a roadmap of how this may be achieved:

Jurisdictions, countries and regions should strive to achieve self-sufficiency in organ donation by providing a sufficient number of organs for residents in need from within the country or through regional cooperation.... At societal scale, self-sufficiency promotes community values such as solidarity and reciprocity.¹⁰

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⁶ WHA Resolution 57.18 (2004) lays at the basis of the 2008 Istanbul Summit convened by the Transplantation Society (TTS) and the International Society of Nephrology (ISN).
⁷ 2008 Istanbul Declaration, para. 5.
⁸ The meeting was held in Madrid, 23-25 March 2010, and was organised by the WHO, the Transplantation Society (TTS), and the Organizacion de Trasplantas (ONT).
⁹ The Declaration of Istanbul Custodian Group (DICG), created in 2010 by TTS and ISN to disseminate the 2008 edition of the Declaration of Istanbul and to respond to new challenges in organ trafficking and transplant tourism, carried out a wide ranging consultation, open to all interested parties, in order to update the 2008 version of the Declaration of Istanbul.
¹⁰ Third WHO Global Consultation on Organ Donation and Transplantation: ‘Striving to Achieve Self-Sufficiency’, 23-25 March 2010, Madrid, Spain; Note from the Secretariat,
This was the first time that the WHA Guiding Principles articulate in a comprehensive manner the importance of pursuing self-sufficiency in organs for transplantation through increased efforts to promote deceased donation in particular. Self-sufficiency requires a comprehensive national programme, including national legislation, a programme of deceased donation integrated into the national health system, and resources that sustain the programme.11

Self-sufficiency in organ donation and transplantation is also one of the principles of the updated edition of the Istanbul Declaration on Organ Trafficking and Transplant Tourism (2018),12 adopted during the International Congress of the Transplantation Society and the Spanish National Transplant Organization in Madrid.

3 Consent Systems and Role of the Family13

The post-mortem organ donation systems of European countries vary from consent (opt-in) to refusal (opt-out). Any post-mortem organ donation legislative system may include a clause that allows the final decision on organ donation to be made by family members. Their role (if any) differs from country to country, as is shown by the following examples below.

3.1 Belgium
Belgium has had an opt out system since 1986, though registration as an organ donor also belongs to the possibilities. A computerised network – unique at that time – allows citizens to register their objections against, or explicit

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11 Francis El Delmonico, Beatriz Domínguez-Gil, Rafael Matesanz, and Luc Noel, ‘Organ Transplantation, A call for government accountability to achieve national self-sufficiency in organ donation and transplantation’, *Lancet* 378(9800) (15 October 2011) 1414-1418, online at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)61486-4/fulltext.

12 Replacing the Declaration originally published in 2008 following the summit convened by the Transplantation Society (TTS) and the International Society of Nephrology (ISN) in response to growing concerns about trafficking in human organs. The Declaration establishes definitions of practices (such as transplant tourism and organ trafficking) and includes principles to guide policy makers and health professionals working in organ donation and transplantation.

13 Organ donation by minors is not dealt with.
consent to donating their organs and tissues after death.\textsuperscript{14} Opting-out via an official form (community level) is the usual procedure, but testamentary or via a letter to a family member also belongs to the possibilities. As the medical doctor needs confirmation of the fact that the deceased did not oppose organ donation, the family becomes involved. In this system it is not excluded that the family expresses its own wishes, possibly resulting in fewer donor organs.

3.2 \textit{Croatia}

Croatia has a legal regulation for an opt-out system since 1988 (non-donor registry). If the deceased is not registered, verification with the family must provide proof that the person did not object to donation. The wishes of the family are always respected. Improving public awareness on organ donation takes place through continuous education, and donor card promotion. National public campaigns organised by the Ministry of Health and non-governmental organizations have contributed a great deal to a successful model for organ donation and transplantation. Information availability and quality is simultaneously improved, especially when information was provided by professionals experienced in transplantation medicine and by recipients who presented their life stories in the mass media. The implementation of a new financing model with donor hospital reimbursement and a donor quality assurance program were other key factors for the success.\textsuperscript{15}

3.3 \textit{England}

In England, the British Medical Association (\textit{BMA}) and politicians alike called for a deemed consent in 2017: consent to donate organs after death is presumed, unless it is explicitly indicated otherwise.\textsuperscript{16} Such a system may be in place in England as of April 2020. However, a 2018 study by the Queen Mary University of London indicates that an opt-out organ-donor registry will not prevent family members from refusing organ donation in case a deceased relative has not opted-out.\textsuperscript{17} According to the researchers, restricting the number

\begin{itemize}
\item \textsuperscript{14} L Roels, transplant coordinator, ‘Opt out registers for organ donation have existed since 1987’, \textit{BMJ} (318)(7180) (6 Feb 1999) 399.
\item \textsuperscript{15} Stela Zivic Cosic and Murela Racki, ‘Development of the Croatian Model of organ donation and transplantation’, \textit{Croatian Medical Journal} (54)(1) (Feb. 2013) 65-70.
\item \textsuperscript{16} BMA Parliamentary Brief, Organ Donation (Deemed Consent) Bill 2017-19, September 2018, bma.org.uk.
\item \textsuperscript{17} Yiling Lin, Magda Osman, Adam J. L. Harris and Daniel Read, ‘Underlying wishes and nudged choices’, \textit{Journal of Experimental Psychology: Applied} 24(4) (Dec 2018) 459-475.
\end{itemize}
of family refusals would require an opting-in system. People must be explicitly offered a way to indicate their wishes to donate or not to do so. This would reduce ambiguity about one's wishes. Family members should be informed of the choices made. Under the Bill, the wishes of families and next of kin would continue to be respected (= soft opt out).

3.4 France
In France, according to a decree of October 1947, removal of organs from cadavers for therapeutic or scientific purposes without family permission was authorised provided the person concerned had not objected. The removal should be done in certain approved hospitals and under certain conditions as to the diagnosis of death. On 1 January 2017, France changed to an opt-out policy: a system whereby one has to sign up on a national 'refusal' register if one does not want to be a donor. Alternatively, one can draw up a written refusal and leave it to a relative to transmit the message to the medical team. France's previous policy required doctors to consult relatives in cases where deceased individuals had not given clear directives regarding organ donation. Relatives refused in almost one-third of the cases. The idea behind the change of system is the expectation that an opt-out program will help alleviate the problem of persistent organ shortages and ever growing transplant waiting lists by capitalising on human being's 'laziness' in choosing the default option.

3.5 Germany
In Germany, the prevalent opt-in system in the form of a donor card, or, in the absence of a donor's decision, a decision by the direct family, is expected to be replaced by a 'dual' opt-out system. Everyone will automatically be registered as a donor; consent may be revoked during lifetime, while family members can oppose to the post mortem donation. Such a system where organs are donated automatically in the absence of a person's explicit refusal, faces opposition from Germany's Ethics Council. According to the Council, it would

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18 Overall, the researchers perceived the donor's underlying preference to donate as stronger under the default opt-in and mandated choice systems as compared to the default opt-out and mandatory donor systems.
19 BBC News, 'Opt out organ donation plan wins Commons backing, 26-10-2018'.
20 Ana Lita, 'Organ Donation in France: the Opt Out System', Global Bioethics Initiative, 5 January 2017, http://globalbioethics.org/2017/01/05/organ-donation-france-move-opt-system/, retrieved 10 January 2019
21 Act on 'organ and tissue donation, removal and transplantation' (TPG), entered into force 1 August 2012. This law requires every citizen to be asked regularly whether he or she will sign a declaration of willingness to donate organs after death. Signing the Declaration is not compulsory.
bring a fundamental change of paradigm: it would not be any more a question of organ donation out of free will, but rather compulsory organ contribution.22

3.6 Iceland
Since the beginning of 2019, everyone in Iceland is considered a donor unless one has opted out. Hospital leaders explained this change by the fact that the organ transplantation is too time-sensitive to wait for a decision by close relations who are mourning the deceased. However, the law still allows family members to opt-out on behalf of the deceased.23

3.7 Ireland
Ireland developed legislation with a soft opt out system in 2018: one is considered to be an organ donor unless the person has registered the wish not to become a donor. The soft element of this legislation is that the next of kin will always be consulted before any organ is removed.24 The strong element is that all health insurance members of 16 years or older would be frequently asked whether they would be willing to donate organs after death.25 This way citizens are targeted directly rather than through general appeals.26

3.8 The Netherlands
In 2018, the Netherlands changed from an opt-in system to a system consisting of four possibilities: consent, refusal, choice is left to partner or family, choice is left to a designated person. If no choice has been registered, consent may be given by a registered partner or family. In that case, they have the option of preventing organ donation.27 It remains to be seen whether the multiple choices will not lead to confusion.

3.9 Scotland
In 2017, Scotland decided to change from an opt-in system to a soft opt-out system. As indicated by the Public Health Minister Aileen Campbell:

22 Jens Spahn, ‘German Health Minister calls for opt-out organ donation’, News, DW, Made for minds, 3 September 2018, online at: https://p.dw.com/p/34ChN.
23 ICENEWS, ‘News from the Nordics’, 9 January 2019.
24 HSE.ie.
25 A positive declaration could be attached to one’s health insurance card rather than on a separate badge. But there is no legal obligation to issue such a declaration.
26 The choices are: I want (not) to be a donor; some organs only qualify; another person may decide for me. From 14 year onwards, opting out does not need parental approval.
27 The new law becomes effective in 2020.
We need to do all we can to further reduce the number of people in Scotland waiting for transplants. We have made significant progress over the past decade, and moving to an opt out system will be part of driving a long term change in attitudes towards organ and tissue donation.28

The Scottish Human Tissue (Authorisation) Bill contains safeguards to make sure people’s wishes regarding donation are followed and that families will be asked about their relative’s views to ensure donations do not occur where the person would not have wished it. The soft opt-out part of the legislation implies that if the healthcare professionals involved are of the opinion that the organ donation is going to cause undue distress to the family, they have a duty-of-care to them as well.

3.10 Wales
Wales was the first country in the UK to move to deemed consent: if a person has not registered a decision to become an organ donor (opt-in), or a decision not to become an organ donor (opt-out), they will be considered as having no objection to being an organ donor. However, in case individuals do not inform family members of their decision to donate, the family can still override the organ donor’s decision. The legislative change was accompanied by a large educational effort and public campaigns. After two years, the effects of the law on family members seem to have been positive.29

4 Self-sufficiency: Some Requirements

It is unlikely that self-sufficiency in human organs for transplantation purposes will be achieved just by adapting national consent systems and by enhancing co-operation between European countries.30 Important as the prevalent

28 Scottish Government, ‘Changing organ and tissue donation, legislation for a soft opt out system introduced in parliament’, Newsroom, 11 June 2018.
29 Andreas Albertsen (Dept. of Political Science, Aarhus University), ‘Deemed Consent: assessing the new opt-out approach to organ procurement in Wales’, Journal of Medical Ethics, Blog, 7 February 2018.
30 There is no hard proof that an ‘opt out’ system would result in a higher supply than an ‘opt in’ system. Sjef Gevers, Anne Janssen and Roland Friele, ‘Consent systems for post mortem organ donation in Europe’, European Journal of Health Law 11(2)(2 June 2004) 175-186, at p. 184; see also Brian H. Willis and Muireann Quigley, ‘Opt out organ donation: on evidence and public policy’, Journal of the Royal Society of Medicine 107(2) (Feb 2014) 56-60; James Niven and Natalie Chalmers, Rapid Evidence Review, Health and Social Care, Social Research, July 2018, Executive summary, pp. 5-6.
post-mortem system for organ donation may be, neither an opt in, nor an opt out system in itself guarantees national sufficiency.\textsuperscript{31} Research shows that the next-of-kin have a considerable influence on the organ procurement process irrespective of the prevalent consent systems. Rithalia \textit{et al.} concluded that while the introduction of opt-out legislation in different countries was associated with increased donation rates, ‘it cannot be inferred from this that the introduction of presumed consent legislation per se will lead to an increase in organ donation rates’.\textsuperscript{32,33} Culture and religion may also play a role. Whatever this may be, one must be encouraged to timely inform family or other close relations of one’s choices.

In the absence of strong evidence for a specific organ donor system, time and effort spent on legislative change misses the opportunity to focus on non-legislative action which could have important (if not greater) impact.\textsuperscript{34} The way the public is approached, the active co-operation of health personnel and necessary organisational, procedural and financial arrangements are equally important.\textsuperscript{35} Medical personnel involved with the relations of the potential donor must be properly trained for this purpose. In 2005, Ministers of Health of the Council of Europe had already underlined the importance of the availability in hospitals of ‘transplant donor coordinators’. Coordinators must have clearly defined responsibilities for the establishment, management and audit

\textsuperscript{31} Leo Shepherd, Roman E. O’Carroll, and Eamon Ferguson, ‘An international comparison of deceased and living organ donation/transplant rates in opt in and opt-out systems: A panel study’, Biomed Central, the Open Access Publisher, \textit{BMC MED}, published online Sept 2014, retrieved 11 February 2019; see also: Amanda M. Rosenblum et al., ‘The authority of next-of-kin in explicit and presumed consent systems for deceased organ donation: An analysis of 54 nations’, \textit{NEPHROL Dial Transplant} (27 June 2012) 2533–2546; published online 25 Nov. 2011, retrieved 11 February 2019.

\textsuperscript{32} Amber Rithalia, Catriona McDaid, Sara Suekarran, Lindsey Myers and Amanda Sowden, ‘Research: Impact of presumed consent for organ donation on donation rates: a systematic review’, \textit{BMJ} (14 January 2009), e-pub, online at: https://www.bmj.com/content/338/bmj.a3162, retrieved 11 February 2019.

\textsuperscript{33} A. Rhitalia, C. Mc Daid, S. Suekarran G. Norman, L. Myers and A. Sowden, ‘A systematic review of presumed consent systems for deceased organ donation’, \textit{Health Technology Assessment} 13(26) (May 2009), https://doi.org/10.3310/hta13260; Centre for reviews and Dissemination, University of York, UK; B.J. Boyarsky, E.C. Hall, N.A. Deshpande et al., ‘Potential limitations of presumed consent legislation’, \textit{Transplantation}, 93(2) (2012) 136–40.

\textsuperscript{34} Brian H. Willis, Muireann Quigley, ‘Opt-out organ donation: on evidence and public policy’, \textit{Journal of the Royal Society of Medicine} 107(2) (February 2014) 56–60, online at: http://www.ncbi.nlm.nih.gov/pmc/articles/, retrieved 11 February 2019.

\textsuperscript{35} H.D.C. Roscam Abbing, ‘Organ donation, the legal framework’, \textit{Health Policy} (16) (1990) 109.
of a hospital based transplantation system, including potential deceased donor identification and monitoring the donation and procurement process.\textsuperscript{36}

Irrespective of the national systems for organ donation, public awareness raising at regular intervals of the importance of becoming a post-mortem organ donor remains essential for achieving self-sufficiency. For this purpose the Council of Europe yearly organises a European day for Organ Donation and Transplantation since 1996.

As organs donated through cross-border exchanges increases chances of patients to receive a matching organ in time, bilateral arrangements as well as multilateral frameworks for co-operation among European countries have been created. A 24/7 IT platform manages the cross border exchanges.

5 Additional Measures

Medical professionals should be attentive to encourage organ donation. For this purpose, a 36 month ‘Train the Trainers’ program, financed by the European Commission, was set up in 2016 for health care professionals and other key actors involved with organ donation. The idea of the program is that once trained, the participants in the program will become advocates for organ donation and raise social awareness in their region.\textsuperscript{37}

The presence of a transplant co-ordination network that works locally, nationally and at a European level, the quality of public information and the availability of transplant surgeons and trained support staff, as well as the amount of funding are other essential elements for contributing to attain self-sufficiency.

6 Conclusions

To achieve self-sufficiency at European scale, the EDQM \textit{Guide to the Quality and Safety of Organs for Transplantation}\textsuperscript{38} is essential. The CD-P-TO Newsletter

\textsuperscript{36} Recommendation (2005) 11 of the Committee of Ministers to Member States on the role and training of professionals responsible for organ donation (Transplant Donor Coordinators); Resolution CM/res(2015)10 on the role and training of critical care professionals in deceased donation.

\textsuperscript{37} EUDONORGAN, ‘Training and social awareness raising for increasing organ donation in the European Union and neighbouring countries’, www.eudonorgan.eu.

\textsuperscript{38} \textit{The Guide}, presently in its 6th edition (2017) not only contains European rules, but includes also an overview of the resp. systems prevalent in Council of Europe member countries.
Transplant, produced since 1996,\(^{39}\) is a useful tool for sharing necessary information among the Council of Europe Member States (and beyond). Organ transplantation has rightly been excluded from the EU Directive on Cross Border Care.\(^{40}\) This does not imply that there is no need for intense international (European) co-operation in this field.\(^{41}\) Self-sufficiency requires a transplantation infrastructure at national level, but also at European scale. Given that people tend to move around Europe, it is time to introduce a standardised European (non)donor card.\(^{42}\)

_Henriette Roscam Abbing_
Professor emeritus of Health Law
roscamabling@zonnet.nl

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39 The newsletter is produced in conjunction with the Spanish National Organisation for Transplants (ONT).

40 Herman Nys, ‘Editorial: Organ transplantation and the Proposed Directive on Cross Border Care’, _European Journal of Health Law_ 17 (2010) 427-431.

41 EU involvement notably comes to expression in setting quality and safety standards (Directive 2010/53/EU) and in the funding of research projects. The European Commission collaborates closely with expert bodies in the development of practical guidelines that support transplant centres and procurement organisations with the implementation of the Directive.

42 Special Eurobarometer 272, Europeans and organ donation, European Commission, Report, May 2007, p. 20.
Health Research, Consent and the GDPR Exemption

Mary Donnelly and Maeve McDonagh
Law School, University College Cork, Ireland

Abstract

This article analyses the balance which the GDPR strikes between two important social values: protecting personal health data and facilitating health research through the lens of the consent requirement and the research exemption. The article shows that the normative weight of the consent requirement differs depending on the context for the health research in question. This more substantive approach to consent is reflected in the research exemption which allows for a more nuanced balancing of interests. However, because the GDPR articulates the exemption at an abstract and principled level, in practice the balance is struck at Member State level. Thus, the GDPR increases difficulties for EU cross-border health projects and impedes the policy goal of creating a harmonised regulatory framework for health research. The article argues that in order to address this problem, the European Data Protection Board should provide specific guidance on the operation of consent in health research.

Keywords

General Data Protection Regulation (GDPR) – data protection – health research – consent – capacity – research exemption

1 Introduction

For health researchers, the General Data Protection Regulation (GDPR)¹ is a mixed blessing. On the one hand, the GDPR allows for a limited exemption from certain obligations, including the requirement to obtain the data

¹ Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, [2016] OJ L 119/1.
subject’s consent to processing, in respect of scientific research (which includes health research). On the other, because the GDPR leaves delivery on the research exemption to Member States, it perpetuates the fragmented approach to data protection in health research which had been a problem with the Data Protection Directive (DPD). This, in turn, increases the difficulties for EU cross-border health research projects and impedes the policy goal of a harmonised regulatory framework for health research. If this problem is to be addressed, Member States will have to develop overlapping frameworks for the operation of the health research consent exemption. This is no easy task. However, a better understanding of the legal and normative foundations for the GDPR requirement for consent and for the health research exemption will help Member States in formulating and applying legal standards in this regard. The aim of this article is to advance this understanding.

The operation of the GDPR must be considered against the background of the fundamental rights protected by the Charter of Fundamental Rights of the EU (CFEU). The fundamental rights to respect for private life and data protection are clearly relevant to the processing of personal data in the context of health research. The protection of these rights must however be weighed against the need to protect other rights that are relevant to the conduct of health research, such as the right to healthcare and freedom of the arts and sciences.

The article begins with a close analysis of the legal requirement for consent in the GDPR and then moves to a normative analysis of the role of consent to data processing in respect of health research. Drawing on Daniel Solove’s argument that data protection law and policy should address the substance of data usage rather than taking ‘refuge in consent’, it shows that the normative

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2 Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, [1995] OJ L 281/31.
3 See M. Timmers, E. Van Veen, A. Maas and E. Kompanje, ‘Will the EU Data Protection Regulation 2016/679 Inhibit Critical Care Research’, Medical Law Review 27(1) (2019) 59-78.
4 This is an underpinning goal of Regulation (EU) 2014/536 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [2014] OJ L 158/1.
5 [2012] OJ C 326/391; see M. Mostert, A. Bredenoord, M. Biesaart and J. van Delden, ‘Big Data in medical research and EU data protection law: Challenges to the consent or anonymise approach’, European Journal of Human Genetics 24(7) (2016) 956-960, 957.
6 CFEU, Art. 7.
7 CFEU, Art. 8.
8 CFEU, Art. 35.
9 CFEU, Art. 13.
10 D. Solove, ‘Introduction: Privacy Self-Management and the Consent Dilemma’, Harv L Rev 126(7) (2013) 1880-1903, 1880.
weight of the consent requirement differs depending on the context for the health research in question.\(^{11}\) This more substantive approach to the consent requirement is reflected in the research exemption, which allows for a more nuanced balancing of societal interests in data protection with societal interests in facilitating research. However, because the GDPR articulation of the exemption is set out at an abstract and principled level, in order to understand what the exemption means in practice, it is necessary to identify the ways in which it is given effect in Member States. The final part of the article uses the example of Ireland, which gives effect to the research exemption through the Health Research Regulations 2018,\(^{12}\) to facilitate a more in-depth analysis of delivery on the research exemption.

2 \hspace{1em} **The GDPR Requirement for Consent to Data Processing for Health Research**

The traditional approach to data protection in health research tended towards a simple binary: anonymise or obtain consent.\(^{13}\) Although both concepts remain central under the GDPR, as health researchers have long pointed out, in some areas of health research, anonymisation cannot be achieved without fundamentally undermining the quality and contribution of the research. The discussion here begins by identifying the understanding of anonymisation in the GDPR and explaining the challenges that this poses for health research.

2.1 \hspace{1em} **Health Research and Data Anonymisation**

The GDPR applies to the processing of ‘personal data’. This is defined as ‘information relating to an identified or identifiable natural person’.\(^ {14}\) Thus, as recital 26 makes clear, the GDPR has no application to the processing of anonymous data, including for research purposes. Recital 26 describes data as anonymous where it does ‘not relate to an identified or identifiable natural

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\(^{11}\) See also M.C. Ploem ‘Towards an Appropriate Privacy Regime for Medical Data Research’, *European Journal of Health Law* 13(1) (2006) 41-64, 60 who argues that that when developing privacy standards, ‘the specific characteristics of the data processing activity concerned should be taken into account’.

\(^{12}\) Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018).

\(^{13}\) See E. Dove and G. Laurie, ‘Consent and Anonymisation: Beware Binary Constructions’, *British Medical Journal* 350 (2015) h 1139-; Mostert et al., supra note 5.

\(^{14}\) GDPR, Art. 4(1).
person’ or is ‘rendered anonymous in such a manner that the data subject is not or no longer identifiable’.

The Article 29 Data Protection Working Party (WP29) has described anonymisation as a ‘technique applied to personal data in order to achieve irreversible de-identification’.15 Thus, personal data which has undergone pseudonymisation16 and which could be attributed to a natural person by the use of additional information, cannot be described as anonymised for GDPR purposes.17 This means that many of the pseudonymisation techniques commonly used in health research, e.g. key coding of data, may not be sufficient to take the processing outside of the ambit of the GDPR requirements.18 There is inevitably a degree of ambiguity as regards the borderline between pseudonymisation and anonymisation for GDPR purposes. Recital 26 states that, in deciding whether personal data is attributable to a natural person, account must be taken of ‘all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person, directly or indirectly’. In ascertaining whether means are reasonably likely to be used, account should be taken of all objective factors, including costs, time and the availability of technology.19

As several commentators have identified, the constraints of this understanding of anonymisation mean that the possibility of avoiding GDPR requirements through anonymisation is not possible for some categories of health research.20 These include research on rare or unusual conditions; research involving long-term follow up of participants; and research which takes account of social/environmental/economic factors. As Paul Quinn describes, ‘[w]hilst it may be

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15 Opinion, 05/2014 on Anonymisation Techniques, adopted 10 April 2014, 0829/14/EN, 7.
16 This process is defined in GDPR, Art. 4(5) as ‘the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributable to an identified or identifiable natural person’.
17 GDPR, recital 26.
18 See P. Quinn, ‘The Anonymisation of Research Data – A Pyric Victory for Privacy that Should Not be Pushed Too Hard by the EU Data Protection Framework?’, European Journal of Health Law 24 (2017) 347-367.
19 See Case C-582/14 Patrick Breyer v. Bundesrepublick Deutschland [2016] ECLI: EU: C:2016: 779.
20 See e.g. R. Fears et al., ‘Data Protection Regulation and the Promotion of Health Research: Getting the Balance Right’, Quarterly Journal of Medicine 107 (2014) 3-5; Quinn, supra note 18, 362-363.
possible to anonymise such data ... doing so may render it devoid of usefulness in terms of potential research value'.

2.2 **Consent to Data Processing in Health Research**

The requirement for consent to processing in respect of data concerning health derives from two aspects of the GDPR. First, one of the core data protection principles set out in Art. 5 is that personal data must be processed lawfully, fairly and in a transparent manner. Article 6(1) sets out a list of conditions, at least one of which must be satisfied in order for processing to be considered lawful within the meaning of Art. 5. One of these is that the consent of the data subject has been obtained to the processing of the data. Secondly, heightened data protection requirements apply to designated ‘special categories of data’, which category includes data concerning health. This is defined as meaning ‘personal data related to the physical or mental health of a natural person, including the provision of healthcare services, which reveal information about his or her health status’. Article 9(1) prohibits the processing of these categories of personal data except in certain limited circumstances, one of which is that the data subject has given explicit consent to the processing.

The WP29 has underlined that in the case of special categories of data, meeting the requirements of Art. 9 is not necessarily sufficient to ensure lawfulness under Art. 6: analysis has to be undertaken on a case-by-case basis as to whether Art. 9 ‘in itself provides for stricter and sufficient conditions, or whether a cumulative application of both Article [6] and [9] is required to ensure full protection of data subjects’.

2.2.1 **The Nature of Consent in the GDPR**

The GDPR defines consent as ‘any freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her’. This means that, as described by

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21 *Ibid.*, 363.
22 GDPR, Art. 6(1)(a).
23 GDPR, Art. 9(1).
24 GDPR, Art. 4(15).
25 GDPR, Art. 9(2)(a).
26 Article 29 Data Protection Working Party, Opinion 06/2014 on the notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC, European Commission, 9 April 2014, 15. The articles referenced in Opinion 06/2014 are Arts. 7 and 8 of the Data Protection Directive which are the forerunners of Arts. 6 and 9 respectively of the GDPR.
27 GDPR, Art. 4(11).
the WP29 Guidelines on Consent (‘WP29 Consent Guidelines’),28 ‘if the data subject has no real choice, feels compelled to consent or will endure negative consequences if they do not consent, then consent will not be valid’.29 A component of this is that the data subject must also have the right to withdraw consent to processing at any time and it must be as easy to withdraw as to give consent.30 The difficulty which this poses for some researchers is acknowledged by the WP29 Consent Guidelines.31 However, unlike some other GDPR rights, for which a derogation is permitted in the context of processing for research purposes,32 there is no provision for derogation from the right to withdraw. Thus, as described by the WP29 Consent Guidelines, ‘if a controller receives a withdrawal request, it must in principle delete the personal data straight away if it wishes to continue to use the data for the purposes of the research’.33

The GDPR requirement for informed consent to data processing aligns with the standard for informed consent to health research as set out in international ethics standards34 and in EU legislation.35 This means that the GDPR conception of consent is one with which all health researchers should be familiar. Informed consent requires the provision of sufficient information to enable the recipient of the information to make an informed choice about whether to participate in the research. The WP29 Consent Guidelines set out the minimum amount of information which should be provided to ensure that consent to data processing is informed. This consists of: the data controller's name (and those of any parties to whom the data will be transferred); the purpose of each of the processing operations for which the consent is sought; what (type of) data will be collected and used; the existence of the right to withdraw consent; information about the use of data for automated decision-making (where relevant); and, the possible risks of data transfers due to absence of an

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28 Guidelines on Consent under Regulation 2016/679, adopted on 28 November 2017, received and adopted 10 April 2018, WP257 rev.01.
29 WP29 Consent Guidelines, 5.
30 Article 7(3).
31 WP Consent Guidelines, 29-30.
32 For example, Arts. 14 (Information to be provided where personal data have not been obtained from the data subject), 17 (right to erasure) and 21 (right to object).
33 WP Consent Guidelines, 30.
34 See e.g., Guideline 9 of the International Guidelines of Health Related Research involving Humans (Geneva, 2016) prepared by the Council for International Organizations of Medical Sciences (CIOMHS) in collaboration with the World Health Organisation (WHO).
35 See e.g., Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, [2014] OJ L 158/1.
adequacy decision or of appropriate safeguards.36 Other information may also be required, with the core question being whether the information provided is sufficient in order to ‘allow the data subject to genuinely understand the processing operations at hand’.37

The procedural conditions for consent to data processing are set out in Art. 7 of the GDPR. This article places the obligation to demonstrate consent on the data controller.38 It also requires that where the consent is given in a written declaration that concerns other matters, the request for consent must be presented in a way which is clearly distinguishable from the other matters and in an intelligible and clearly accessible form, using plain and clear language.39 Thus, in a health research context, consent to data processing must be clearly distinguished from the consent to the research itself.40 The data subject must be informed of his or her right to withdraw consent prior to giving the consent.41 S/he must also be informed as to how to exercise the withdrawal right.42 Again, this resonates with the requirements in respect of withdrawal from the research itself and should not be unfamiliar to health researchers.

For data concerning health, there is the additional requirement that the consent be ‘explicit’.43 The WP29 Consent Guidelines state that the term ‘explicit’ refers to the way consent is expressed by the data subject and requires that the data subject have given an express statement of consent.44 One obvious way to ensure this is to have the data subject expressly confirm their consent in a written statement.45 However, the WP29 Consent Guidelines are clear that a signed statement is not the only way to obtain explicit consent. Thus, in the online context, explicit consent could be given by filling in an electronic form, by sending an email or by uploading a scanned document with a signature.46 The WP29 also states that ‘in theory’ an oral consent could be sufficient to meet the explicit consent requirement although it acknowledges the difficulties for a data controller in demonstrating explicit consent where

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36 WP29 Consent Guidelines, 13.
37 Ibid.
38 GDPR Art. 7(1).
39 GDPR, Art. 7(2).
40 WP29 Consent Guidelines, 28.
41 Art. 7(3).
42 WP29 Consent Guidelines, 22 (drawing on GDPR, recital 39).
43 GDPR, Art. 9(2)(a). This enhanced requirement also applies to other forms of ‘special’ or ‘sensitive’ data.
44 Ibid.
45 Ibid.
46 Ibid.
that consent is oral only\textsuperscript{47} and it is difficult to envisage many circumstances in which a health researcher could safely rely on oral consent to data processing.

2.2.2 Consent to Further Use

One of the fundamental data protection principles provided for in art. 5 is that of ‘purpose limitation’. This states that personal data shall be collected for specified, explicit and legitimate purposes and may not be further processed in a way that is incompatible with those purposes. The effect of this is to prohibit further or ‘secondary’ processing of data which arises where data collected for one purpose are then used for another purpose without the data subject’s consent (unless the research exemption applies). This prohibition is of particular relevance to health research where further use of data is increasingly common, in particular in epidemiological research, including through retrospective cohort studies and through the combination of existing datasets in the context of big data analytics.\textsuperscript{48} As Quinn identifies, the use of data in this way reduces costs in conducting health research and also opens new research possibilities which, given the increases in processing power, may not have been even thought about at the time the data were originally collected.\textsuperscript{49}

Two of the recitals to the GDPR provide further detail on the consent requirements in respect of further use. Recital 32 states that consent should cover all processing activities carried out for the same purpose or purposes and that where the processing has multiple purposes, consent should be given for all of them. However, recital 33, which is concerned with consent to certain areas of scientific research, recognises that it is often not possible to fully identify the purpose of data collection at the time of collection. It therefore stipulates that data subjects should be able to give their consent to the use of their data for certain areas of scientific research when this is in keeping with recognised ethical standards for scientific research. This recital also states that data subjects should be afforded the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.

\textsuperscript{47} Ibid.

\textsuperscript{48} See e.g., M. Paterson and N. Witzleb, ‘The Privacy-Related Challenges Facing Medical Research in an Era of Big Data Analytics: A Critical Analysis of Australian Legal and Regulatory Frameworks’, \textit{Journal of Law and Medicine} 26(1) (2018) 188-203, 197; P. Quinn and L. Quinn, ‘Big Genetic Data and its Big Data Protection Challenges’, \textit{Computer Law and Security Review} 34(5) (2018) 1000-1018.

\textsuperscript{49} Supra note 18, 348.
Further elaboration on the scope of this broader consent is provided by the WP29 Consent Guidelines.50 These make it clear that recital 33 does not disapply the obligations with regard to the requirement for specific consent to the processing of data for scientific research purposes. The Guidelines state that, when regarded as a whole, the GDPR cannot be interpreted to allow a controller to ‘navigate around the key principle of specifying purposes for which the consent of the data subject is asked’.51 This means that where research purposes cannot be fully specified, the controller must seek other ways to ensure that the ‘essence of the consent requirements’ are met.52 The WP29 gives the example of allowing a data subject to consent for a research purpose in general terms and for the specific stages of the research project that are known at this time. Then, as research advances, consent for subsequent stages can be obtained before the next stage begins.53 This resonates with the view of informed consent in contemporary ethical guidance on health research whereby consent is conceptualised as an ongoing process rather than a single, once-off event.54

The WP29 Consent Guidelines also identify other ways in which the deficiencies arising from lack of purpose specification at the outset of the research can be mitigated. These include increased transparency, such as the regular provision of updates as the research project progresses, thus placing the data subject in a position to use his or her right to withdraw; and having a comprehensive research plan in place and available to data subjects, which could compensate for a lack of purpose specification.55

2.2.3 Consent and Capacity

Although the GDPR does not explicitly require that the data subject must have the capacity (or competence) to provide the required consent to data processing, this would seem to be implicit in the requirement that consent must be an ‘informed ... indication of the data subject’s wishes’.56 The issue of capacity to consent arises in respect of two categories of data subjects: children and adults with impaired capacity. The first of these categories is catered for in the GDPR although not in respect of research; the second is not addressed at all.

50 WP29 Consent Guidelines, 28-29.
51 Ibid., 28.
52 Ibid., 29.
53 Ibid.
54 See e.g., Guideline 9 of the CIOMHS Guidelines.
55 WP29 Consent Guidelines, 29.
56 GDPR, Art. 4(11).
The GDPR recognises that children merit special protection in respect of their personal data\(^ {57}\) because ‘they may be less aware of the risks, consequences and safeguards concerned and their rights in relation to the processing of personal data’.\(^ {58}\) However, the issue of children’s consent to data processing is addressed only in the context of the provision of ‘information society services’.\(^ {59}\) The age of consent to data processing in this context is set at 16 years although Member States are permitted to provide for a lower age, subject to a limit of 13 years.\(^ {60}\) The general rules relating to consent provided for in the GDPR also apply to consent given by children. The WP29 Consent Guidelines recognise the need for special care to be taken in ensuring that sufficient information is supplied to children to render their consent informed. It states that where the targeted audience includes data subjects who are underage, data controllers are expected to make sure that such information is understandable for minors.\(^ {61}\) The GDPR makes specific reference to children in terms of transparency. Art 12 requires data controllers to take appropriate measures to meet their transparency obligations ‘in a concise, transparent, intelligible and easily accessible form, using clear and plain language, in particular for any information addressed specifically to a child’. This provision is supported by recital 58 which states that where processing is addressed to a child, any information provided should be in such clear and plain language that the child can easily understand it.

Beyond these limited measures, the matter of children’s consent to data processing is not specifically addressed in the GDPR but is left to be dealt with by Member States. In the UK, for example, the Information Commissioner has expressed the view that ‘the general rule in the UK is that you should consider whether the individual child has the competence to understand and consent for themselves (the ‘Gillick competence test’).’\(^ {62}\) The matter of adults who lack capacity to consent to data processing is not addressed at all in the GDPR.

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57 See recitals 38 and 75.
58 GDPR, recital 38.
59 GDPR, Art. 8(1). As summarised by WP29 Consent Guidelines, 24 this covers contracts and other services that are concluded and transmitted online.
60 GDPR, Art. 8(1). For children below this age, consent to processing is lawful only if given by the holder of parental responsibility over the child.
61 WP29 Consent Guidelines 14.
62 UK Information Commissioner, Guide to the General Data Protection Regulation: Consent: https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/consent/what-is-valid-consent/#what; see further M. Taylor, E. Dove, G. Laurie and D. Townend, ‘When Can the Child Speak for Herself?: The Limits of Parental Consent in Data Protection Law for Health Research’, Medical Law Review 26(3) (2017) 369-391.
Given the wide range of approaches to consent and capacity across the EU member states, it is easy to understand the lack of engagement with the issue by the GDPR. Nonetheless, as discussed below this creates significant problems for certain kinds of health research.

2.3 The (Varying) Normative Case for the Consent Requirement to Data Processing in Health Research

As Daniel Solove identifies, since the 1970s, the basic components of the legal framework for data protection have remained largely unchanged.63 Solove describes this approach as ‘privacy self-management’.64 The approach ‘attempts to be neutral about substance – whether certain forms of collecting, using or disclosing personal data are good or bad – and instead focuses on whether people consent to various privacy practices’.65 However, Solove argues that for a range of reasons,66 ‘[p]rivacy self-management cannot achieve the goals demanded of it, and it has been pushed beyond its limits’.67 This does not mean that the requirement for consent to data processing should be abandoned but rather indicates the need for a more reflective approach to consent. Part of this, Solove argues, should encompass a move towards evaluating the substance of the data usage in question when making policy decisions about data protection rather than relying on consent to do all the normative work.68

If we adopt this more substantive approach to data processing in health research, it becomes clear that there are differences in the ways in which consent works to strike a balance between societal interests in protecting personal data and societal interests in facilitating research. Separating these out is a first step in evaluating the ways in which Member States approach the health research exemption. We can begin with the ‘normal’ situation of an adult with capacity where data is being collected for use in the future. Most of the time, in this

63 Supra note 10, 1880.
64 Ibid.
65 Ibid.
66 These include the difficulties caused by individuals’ cognitive biases and bounded rationality and by the structural problems in contemporary data usage: see Solove, supra note 10, 1881.
67 Ibid., 1903. For similar assessments, see e.g., A. Mantelero, ‘The Future of Consumer Data Protection in the EU: Rethinking the ‘Notice and Consent’ Paradigm in the New Era of Predictive Analytics’, Computer Law and Security Review 30 (2014) 643-660; F. Cate and V. Mayer-Schönberger, ‘Notice and Consent in the World of Big Data’, International Data Privacy Law 3(2) (2013) 67-73; E. Gratton, ‘Beyond Consent-Based Privacy Protection’, available at https://eloisegratton.openum.ca/files/sites/4/2016/07/Gratton_Beyond-Consent-based-Privacy-Protection_-July2016.pdf.
68 Ibid., 1902-1903.
situation a strong normative case may be made that a requirement for consent to data processing should operate alongside the requirement for consent to research. It is true that a requirement to obtain consent to data processing (and to carry out the necessary steps in respect of further processing) adds to researchers’ administrative burdens. However, the mere fact of administrative inconvenience is not sufficient to outweigh the benefits of informed consent, which include showing respect for the contribution of the research participants whose data is used and without whom the research would be impossible.69 Possibly the most persuasive case for an exemption from the consent requirement is where, because of the nature of the data in question, the withdrawal of consent would fundamentally undermine a research project which is of significant public interest. There may be other justifications depending on the specific feature of the research in question.70

The issue becomes more complex in respect of historic data sets collected prior to the coming into force of the GDPR. While the DPD required explicit consent to data processing (and made no provision for an exemption for research), Member States gave effect to this requirement in very different ways.71 Moreover, in some cases, the possibilities for further use of data in health research were not even contemplated at the time when consent was obtained. A retrospective strict application of the consent requirement could result in valuable data being ‘wasted’. This has an ethical dimension arising from a failure to maximise existing data. The normative balance is therefore shifted. Again there is a case to be made for the requirement for informed consent to data processing. However the ethical principle of maximising data and avoiding waste must be part of the analysis. This approach is supported by the need to take account of the right to healthcare (including ‘preventive healthcare’72) and freedom of the sciences. It can be argued that a retrospective strict application of the consent requirement in the health research context could hinder preventive approaches to healthcare. Freedom of the sciences and in particular freedom of research has been described as creating ‘optimal conditions

69 As described by Alan Wertheimer, ‘(Why) Should we Require Consent to Participation in Research?’, Journal of Law and the Biosciences 1(2) (2014) 137-182, 181-182, ‘as a general ethical principle, we are not entitled to ask others to spend time on our projects – whatever they are – without their undeceived consent’.

70 See analysis of possible justifications for non-consensual research in L. Gelinas et al., ‘When and Why is Research without Consent Permissible?’, Hastings Center Report 46(2) (2016) 1-9.

71 For a (rather outdated) overview, see D. Beyleveld et al., The Data Protection Directive and Medical Research across Europe (Ashgate, 2004); see also summary in Timmers et al., supra note 3, 63-70.

72 CFEU, Art. 35.
for our collective search for knowledge\textsuperscript{73} and the imposition of a retrospective consent requirement would clearly stand in the way of such a search for knowledge.

The consent issue become even more complex where the data subjects do not have capacity to give personal consent to data processing. As identified above, the GDPR is largely silent on how the consent requirement should operate in respect of data processing for health research for two categories of data subjects for whom capacity to consent to data processing is an issue: children and adults who lack capacity to make decisions about consent. Most European jurisdictions operate on the basis of proxy consent to health research in these situations and this is also the approach taken in applicable European legislation. The Clinical Trials Directive\textsuperscript{74} the Clinical Trials Regulation\textsuperscript{75} and the Medical Devices Regulation\textsuperscript{76} all require that consent to participation in a clinical trial by a ‘minor’\textsuperscript{77} or an ‘incapacitated subject’\textsuperscript{78} must be given by his or her legally designated representative (i.e. proxy consent).\textsuperscript{79} In both the Clinical Trials Regulation and the Medical Devices Regulation, the proxy consent is supplemented by the requirement that the researcher provide information to the minor/incapacitated subject in a manner which facilitates his or her understanding\textsuperscript{80} and the requirement that the minor/incapacitated subject’s express wish not to participate in or to withdraw from the trial should be respected where s/he ‘is capable of forming an opinion and assessing the

\textsuperscript{73} T. Wilholt, ‘Scientific Freedom: Its Grounds and Their Limitations’, Studies in History and Philosophy of Science Part A 42(10) (2010) 174-181, 175.
\textsuperscript{74} Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, [2001] OJ L 121/34.
\textsuperscript{75} Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, [2014] OJ L 158/1.
\textsuperscript{76} Regulation (EU) No 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, [2017] L 117/1.
\textsuperscript{77} This is defined as a ‘subject who is, according to the law of the Member State concerned, under the age of legal competence to give informed consent: see Reg (EU) No 536/2014, Art. 2(18).
\textsuperscript{78} This is defined as a ‘subject who is, for reasons other than the age of legal competence to give informed consent, incapable of giving informed consent according to the law of the Member State concerned: see Reg (EU) No 536/2014, Art. 2(19).
\textsuperscript{79} Reg (EU) No 536/2014, Art. 31(i)(a) (incapacitated subjects); Art. 32(i)(a) (minors).
\textsuperscript{80} Reg (EU) No 536/2014, Art. 31(i)(b) requires that the incapacitated subject have received relevant information ‘in a way that is adequate in view of their capacity to understand it’ while Art. 32(i)(b) requires that information must be provided in a way adapted to the minor’s ‘age and mental maturity’. See also Regulation (EU) No 2017/745, Arts. 64(1)(b) and 65(1)(b).
There are also other protective/balancing measures relating to risk and benefit specific to the clinical trials/clinical investigations context.

Proxy consent (whether to participate in research or to data processing in the context of the research) does not carry the same normative force as personal consent. Instead, it ‘imitate[s] the checks and balances normally provided by the subject’ while leaving unresolved the fundamental (and ethically complex) question of the basis on which a proxy decision-maker can make the decision to consent to health research (or to accompanying data processing). This is one reason why the contemporary legal measures which utilise proxy consent to health research include a broader range of protective/balancing measures. There are conceptual questions to be asked around the legitimacy of proxy consent to data processing in all events (although these are not within the scope of this article). For present purposes, the relevant point is that there may be better ways of protecting the privacy rights of data subjects who cannot give personal consent than relying on proxy consent.

In addition to the normative issues around proxy consent, there are also practical matters which make the operation of the consent requirement more difficult especially in respect of consent to further use of data. The WP29 has posited that where proxy consent has been given in respect of a minor, the minor may revoke this consent on reaching the age of majority and that if processing of health data is to continue after the age of majority, the fresh consent of the data subject must be obtained. The WP29 also appears to envisage a period of parallel consent whereby as the child advances in maturity, the consent of both child and parents is obtained. While this is consistent with the Convention on the Rights of the Child, as Mark Taylor and colleagues identify, it leaves researchers in a difficult position in determining the scope of their ob-

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81 Reg (EU) No 536/2014, Art. 31(1)(c) (incapacitated subjects); Art. 32(1)(c) (minors); Regulation (EU) No 2017/745, Art. 64(1)(c) and Art. 65(1)(c).
82 K. Liddell et al., ‘Medical Research Concerning Incapacitated Adults: Implications of the EU Clinical Trials Directive 2001/20/EC’, Medical Law Review 14(3) (2006) 367-417, 398.
83 See R. Berg, ‘An Ethical Analysis of Proxy and Waiver of Consent in Critical Care Research’, Acta Anaesthesiologica Scandinavica, 57(4) (2013) 408-416.
84 It is difficult to see that proxy consent to data processing (or indeed to research) is compatible with Art. 12 of the United Nations Convention on the Rights of Persons with Disabilities, A/RES/61/106 Annex 1, at least as interpreted by the Committee on the Rights of Persons with Disabilities in General Comment No 1: Art. 12 Equal Recognition before the Law, CRPD/C/GC/1.
85 Article 29 Data Protection Working Party, Opinion 2/2009 on the Protection of Children’s Personal Data (General Guidelines and the Special Case of Schools) 398/09/EN, WP 160, 5.
Similar practical issues arise in respect of adults lacking capacity. Contemporary legal approaches reject the view of incapacity as a fixed or immutable state but instead recognise that capacity/incapacity are time and task specific. Thus, even if proxy consent is legally recognised, its status persists only so long as the ‘incapacitated subject’ lacks capacity. This then opens up the question of what steps a researcher must take to ensure the ongoing status of proxy consent.

These practical problems make research involving participants who cannot give personal consent to data processing very difficult and run the risk that this kind of research would become so administratively difficult that it would effectively cease. This in turn raises an issue of distributive justice. Children and adults with impaired capacity should have an equal entitlement to the benefits of health research as other members of society who can give personal consent. Their exclusion from participation would mean that their specific needs would not be met. Thus, the situation of children and adults lacking capacity provides a strong normative argument in favour of an approach to data processing for health research purposes in these situations which is not reliant on (proxy) consent.

3 Consent and the (Health) Research Exemption

The express recognition of a research exemption is one of the defining features of the GDPR. While research is not defined in the body of the GDPR, recital 159 states that research should be interpreted broadly and outlines a range of examples of activities coming within the scope of scientific research. These clearly are sufficiently broad to encompass both publicly and privately/commercially funded health research.

3.1 The Operation of the Research Exemption

The GDPR’s research exemption is set out in Art. 9(2)(j). This states that the prohibition on the processing of special categories of personal data (which

86 Supra note 62, 377.
87 This approach is generally given effect through the functional approach to capacity assessment; see e.g., the Mental Capacity Act 2005 (EW).
88 They include technological development and demonstration, fundamental research, applied research and privately funded research, and studies conducted in the public interest in the area of public health.
89 See K. Pormeister ‘Genetic data and the research exemption: is the GDPR going too far?’, International Data Privacy Law 7(2) (2017) 137-146, 138.
includes health data) does not apply where the processing is necessary for inter alia scientific research purposes and is

in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

Thus, this serves as an alternative to the explicit consent requirement, as set out in Art. 9(2)(a).

Article 9(2)(j) must be read in conjunction with the standards for lawful processing under Art. 6(1). The WP29 has indicated that unless Art. 9 ‘in itself provides for stricter and sufficient conditions’ for the processing of personal data than Art. 6,90 a cumulative application of both articles is required to ensure full protection of data subjects. As there are substantive differences between the research exemption in Art. 9(2)(j) and the lawful processing grounds in Art. 6, and Art. 9(2)(j) is not simply a more demanding version of any of the grounds for lawful processing provided for in Art. 6, it is clear that the processing of personal data for research purposes must also meet the lawful processing requirements of Art. 6.91

Two bases (besides consent) for lawful processing are potentially relevant to health research. The first is where the processing is necessary for the performance of a task carried out in the public interest.92 Unsurprisingly, the WP29 has confirmed that health research can be viewed as task carried out in the public interest93 and that this may be the case even where the research is carried out by a private sector body or commercial entity.94 However, this is not inevitably the case; it is possible to conceive of health research which has an entirely commercial purpose and cannot be regarded as being in the public interest. The UK Medical Research Council has identified this basis as the one

90 Supra note 26, 15.
91 This is supported by the UK Medical Research Council, General Data Protection Regulation (GDPR): Consent in Research and Confidentiality: Guidance Note 3 (March 2018, updated May 2018).
92 GDPR, Art. 6(1)(e).
93 Many of the developments in contemporary healthcare, which have been of enormous public benefit, are derived from the efforts by researchers, especially in the latter half of the 20th century: see e.g., J. Le Fanu, The Rise and Fall of Modern Medicine (London: Abacus, 1999).
94 WP29 supra note 26, 22 recognises the increasing tendency to outsource processing in health research to the private sector.
that UK public bodies such as universities, the NHS and research council institutions are most likely to rely on for the processing of personal data for research purposes, on the grounds that such authorities are funded by the public purse in order to conduct tasks that are considered to be in the public interest.95

The second lawful processing ground is where processing is necessary for the purposes of the legitimate interests pursued by the data controller or by a third party.96 Reliance on the legitimate interests condition is restricted to the extent that art.6(1)(f) states that any such interests can be overridden by ‘the interests or fundamental rights and freedoms of the data subject’. The WP29 has taken the view that application of the legitimate interests condition calls for a balancing test in which the legitimate interests of the controller (or third parties) must be balanced against the interests or fundamental rights and freedoms of the data subject.97 Guidance as to the meaning of ‘legitimate interests’ can be found in recital 47 which states that controllers should take into account ‘the reasonable expectations of data subjects based on their relationship with the controller’. The legitimate interests ground does not apply to processing carried out by public authorities in the performance of their tasks. It could, however, be relied upon by private and/or commercial entities that carry out health research. This ground is identified by the UK Medical Research Council as being likely to provide the most appropriate basis for the processing of personal data for health research purposes by charitable research institutes that are not public authorities, and by commercial companies.98

In addition to the lawful processing requirement, in order to avail of the research exemption, the research must also comply with the framework developed by the Member State in which it is conducted in accordance with the requirements of Art. 89(1). Article 89(1) requires that the framework must be proportionate to the aim pursued and must respect ‘the essence of the right to data protection’ and provide for ‘suitable and specific measures’ to protect the rights of the data subject. Article 89(1) also requires that processing for scientific research purposes must be subject to appropriate safeguards for the rights and freedoms of the data subject, including that technical and organisational measures are in place, in particular to ensure the principle of data minimisation.

While setting out general parameters, Art. 89(1) leaves the detail of the framework to be developed by Member States. As identified in the Introduction, the

95 Guidance Note 3, supra note 91, 2.
96 GDPR, Art. 6(1)(f).
97 WP29, supra note 26, 9.
98 Guidance Note 3, supra note 91, 3.
result is continued fragmentation in data protection standards for health research across the EU. The final part of this article presents a flavour of this fragmentation by focussing on the approach taken in one Member State, namely Ireland. Viewing the matter through a jurisdiction-specific lens allows for a better understanding of the challenges faced in establishing an appropriate balance between data protection/privacy and right to health/scientific freedom norms.

4 Delivering on the Health Research Exemption: The Irish Experience

In Ireland, those elements of the GDPR which are left to the discretion of Member States, including the research exemption, are given effect in the Data Protection Act 2018 (DPA 2018) and, in the case of health research, in the Health Research Regulations 2018 (HRR). The HRR came into force on 8 August 2018. In addition to setting out the required ‘suitable and specific measures’ under art.89(1), the HRR also provide a mechanism for researchers to apply for an exemption from the consent requirement.

Health research is broadly defined in the HRR as covering scientific research for the purposes of human health. It encompasses research regarding innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury; research with the goal of improving the diagnosis and treatment of human disease and injury and of improving the quality of life of individuals; research with the goal of understanding normal and abnormal functioning at molecular, cellular, organ and whole body levels; research with the goal of improving the efficiency and effectiveness of health professionals and the healthcare system; and, research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status.

99 The DPA 2018, s. 54 permits the processing of data concerning health where this is necessary and proportionate for scientific research purposes subject to ‘suitable and specific measures being taken to safeguard the fundamental rights and freedoms of data subjects’ and respect for the principle of data minimisation.

100 HRR, reg. 5(1). On the HRR, see M. Donnelly and M. McDonagh, ‘Health Research and Data Protection: Researchers’ Obligations under the GDPR Framework’, Medico-Legal Journal of Ireland 24(2) (2018) 80-92.

101 HRR, reg. 3(2).
4.1 ‘Suitable and Specific Measures’

The HRR set out the ‘suitable and specific measures’ with which data controllers must comply. These obligations are cumulative and therefore the other obligations all continue to apply notwithstanding the consent exemption.

First, arrangements must be in place to ensure that personal data is processed ‘as is necessary to achieve the objective of the health research’ and not in such a way that damage or distress is or is likely to be caused to the data subject. First, arrangements must be in place to ensure that personal data is processed ‘as is necessary to achieve the objective of the health research’ and not in such a way that damage or distress is or is likely to be caused to the data subject.102 Secondly, appropriate governance structures must be in place. These include ethical approval of the research by a research ethics committee (REC);103 specification of the controller/joint controllers of the data; specification of any data processors involved; specification of anyone who provides funding for, or otherwise supports, the research project; specification of any person other than a joint controller/data processor with whom it is intended to share any of the data collected (including where this data has been anonymised/pseudonymised); and, the provision of training in data protection law and practice for the individuals involved in carrying out the health research.104 Thirdly, designated processes and procedures relating to the management and conduct of the health research must be in place. This requires that there must be an assessment of the data protection implications of the research and where this indicates a high risk to the rights and freedoms of individuals, a data protection impact assessment (DPIA) must be carried out.105 Measures must also be in place that demonstrate compliance with the data minimisation principle and to protect the security of the personal data, as must arrangements to anonymise, archive or destroy personal data once the health research has been completed. There must also be in place technical and organisational measures designed to ensure that processing is carried out in accordance with the GDPR, as well as processes for testing and evaluating the effectiveness of these measures.106 Fourthly, there must be arrangements to ensure that personal data is processed in a transparent manner.107

Finally, there is a requirement that the explicit consent of the data subject have been obtained (unless the exemption applies) prior to the commencement

102 HRR, reg. 3(1)(a).
103 HRR reg. 4(2) sets out a range of issues which must be consider ethical issues (and therefore part of the review process by the REC).
104 HRR, reg. 3(1)(b).
105 The Irish Data Protection Commission provides a List of Types of Data Processing Operations with require a DPIA: see https://www.dataprotection.ie/sites/default/files/uploads/2018-11/Data-Protection-Impact-Assessment.pdf, accessed 12 March 2019.
106 HRR, reg. 3(1)(c).
107 HRR, reg. 3(1)(d).
of the health research.\textsuperscript{108} The consent in question may be in relation to a particular area of the research or can be more general in relation to research ‘in that area or a related area of health research, or part thereof’.\textsuperscript{109} A question arises as to whether this is sufficiently precise to be consistent with the WP29 Consent Guidelines as regards purpose specification.\textsuperscript{110} The consent requirement is retrospective, in that it applies also to any further processing of data collected prior to the coming into force of the HRR. However, data controllers were afforded a period (up to 30 April 2019) to get the required explicit consent in place.\textsuperscript{111} There is no reference in the HRR to how consent should be addressed in situations involving minors or adults who lack the capacity to consent.

4.2 \textit{The Public Interest Exemption from Consent}

The HRR allow health researchers to apply to the Health Research Consent Declaration Committee for a declaration of exemption from the consent requirement. The Committee, which was established under the HRR, must comprise between 15 and 21 members who, in the view of the Minister for Health, are suitably qualified, including having knowledge of data protection, research ethics and statistics.\textsuperscript{112} Decisions of the Committee may be appealed to an Appeal Panel which must be specially constituted by the Minister for Health\textsuperscript{113} within 40 working days of the receipt of the request.\textsuperscript{114}

4.2.1 Basis for the Exemption

The HRR reflect the normative difference regarding the timing of the data collection identified above. Thus, they distinguish between the requirements for a declaration in respect of research commenced before the HRR came into force (8 August 2018) and research commenced after this time. For research commenced after 8 August 2018, the application made is for a declaration that the public interest in carrying out the research significantly outweighs the public interest in requiring the consent of the data subject.\textsuperscript{115}

\textsuperscript{108} HRR, reg. 3(1)(e).
\textsuperscript{109} HRR, reg. 3(1)(e).
\textsuperscript{110} See text following \textit{supra} note 50.
\textsuperscript{111} HRR, reg. 6(1).
\textsuperscript{112} HRR, reg. 7; see Schedule to the HRR.
\textsuperscript{113} HRR, reg. 11(1). The Appeal Panel consists of three persons, none of whom is a member of the Committee, and may determine its own procedure: reg. 11(3).
\textsuperscript{114} HRR, reg. 11(2).
\textsuperscript{115} HRR, reg. 5(1).
application, the data controller must carry out a DPIA; obtain the approval of
the research by an REC and appoint a data protection officer. There is also
a lengthy set of procedural requirements. Written information must also be
provided which demonstrates that the public interest in the research signifi-
cantly outweighs the public interest in obtaining explicit consent and sets out
why it is proposed not to seek consent. The Committee may only make the
declaration that consent is not required where all of the requirements under
the HRR are met and it is satisfied that the public interest in carrying out the
research significantly outweighs the public interest in obtaining consent.

For research already commenced by 8 August 2018, the controller may apply
for a declaration that explicit consent is not required for processing or further
processing after 8 August 2018 on one of two grounds. The first is the signifi-
cant public interest ground, as outlined above. The second is that the control-
er obtained the consent of the data subject to the processing of the data under
the Data Protection Acts 1988 and 2003 (DPA 1988 and 2003) and that this con-
sent has not been withdrawn. Unlike the GDPR, the right to withdraw consent
is not explicitly stated in the DPA 1988 and 2003 and there is no requirement
to inform data subjects of the existence of this right. It might therefore be pre-
sumed that few data subjects were, in fact, aware of their right to withdraw. The
procedural requirements are the same as those for post-8 August 2018 applica-
tions, with one difference: if the data controller applies on the basis of having
obtained the consent of the data subject under the DPA 1988 and 2003, he or
she must demonstrate that he or she has made reasonable efforts to contact
the data subject for the purpose of reobtaining consent from that data subject.
The Committee may only make the declaration that explicit consent is not re-
quired where all of the requirements under the HRR are met and it is satisfied
that the public interest in carrying out the research significantly outweighs the
public interest in obtaining consent or that the data subject had consented
under the DPA 1988 and 2003 and this consent has not been withdrawn.

116 HRR, reg. 5(3).
117 HRR, reg. 5(4)(c)(vi). The functions of a “data protection officer” are outlined in DPA 2018
s.88(5).
118 HRR, reg. 5(4)(a).
119 HRR, reg. 5(4)(e).
120 HRR, reg. 5(5).
121 HRR, reg. 6(4).
122 HRR, reg. 6(7)(e)(ii).
123 HRR, reg. 6(8)(b).
4.3 The Irish Approach in Perspective
Although the HRR give effect to the research exemption, they do so rather begrudgingly. The underlying policy message is that consent is always the ideal. This is reflected in several aspects of the HRR. First, the standard which the Committee must apply is that the public interest in the research significantly outweighs the public interest in obtaining explicit consent. This wording, which goes beyond what is required by the GDPR, restricts the scope of the Committee in granting applications for a declaration. The normative balance is struck in favour of obtaining consent, even in those situations where, for the reasons identified above, consent lacks normative force because the data subject lacks capacity to give consent. Secondly, the procedures and requirements which the HRR require are likely to quell the enthusiasm of even the most enthusiastic researcher. Every research project in which a consent exemption is sought (no matter how small) will require REC approval; a DPIA; the appointment of a data protection officer and compliance with substantial procedural requirements. Taken together, these requirements are likely to have a chilling effect on health research, especially in respect of participants for whom personal consent is not an option.

The Irish position is in striking contrast with that adopted in the UK. The Medical Research Council (UK) advises that “consent is not likely to be ... the condition to process special categories of personal data, for research”124 and that the ‘GDPR’s consent requirements don’t often apply to research’.125 Thus, we see two neighbouring jurisdictions, both in the common law tradition, with entirely different approaches to the role of consent and the application of the research exemption.

5 Conclusion
This article reflects the ongoing tension between two important social values: protecting personal health data on the one hand and facilitating health research, with its attendant benefits, on the other. In a contemporary context, this tension is played out against a backdrop of data commodification, market pressures and monetary incentives.126 In addressing this tension, the

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124 Guidance Note 3, supra note 91, 4.
125 UK Medical Research Council, GDPR and Data Protection Act 2018: Key Facts for Research (13 June 2018), available at https://mrc.ukri.org/documents/pdf/gdpr-key-facts-for-research/, retrieved 13 March 2019.
126 BIS Research, Global Big Data in Healthcare Market: Analysis and Forecast, 2017-2025 (2018) estimated that in 2017, the global market for big data in healthcare was worth $14.25 billion and that it was expected to grow to $68.75 billion by 2025.
GDPR reiterates the importance of consent and elevates the requirement for consent to processing for certain categories of data, including health data. In this, the GDPR position is largely consistent with the universally accepted legal and ethical requirement for informed consent to health research. However, the GDPR also recognises that in some circumstances, the requirement for consent should be made subordinate to other requirements (provided there are suitable and sufficient safeguards for the data subject’s rights).

The article has argued that the subordination of the consent requirement is most likely to be justified where a data subject’s withdrawal of consent would fatally undermine health research of significant public interest; where data collected pre-GDPR, in accordance with the relevant Member State’s consent requirements of that time, would be wasted; and, where a data subject is unable (because s/he is a child or lacks the required capacity) to provide personal consent. Consent to further data processing in the context of big data also poses problems for contemporary researchers but it is difficult to see that these should provide a basis for an exemption from the consent requirement in the absence of a strong public interest argument.

The main difficulty with the GDPR health research exemption is its lack of detailed guidance for Member States. The need for a nuanced compromise is recognised at a policy level only and it is left to Member States to operationalise this. As this article has shown, for a jurisdiction, like Ireland, which adopts a demanding (and undifferentiated) approach to the consent requirement, the consequences may well be exclusion from European-wide health research projects and an overall reduction in research projects involving research participants/data subjects who are unable to provide personal consent. Other jurisdictions may take quite a different approach to the research exemption, using it to diminish the consent requirement across the board and rendering the important principle of consent essentially meaningless. Inconsistencies in Member State approaches to the health research exemption need to be addressed at a European level. The most obvious way to do this is through guidance from the European Data Protection Board.127 A careful analysis by the Board of the norms at stake would provide Member States with the tools to develop appropriate and consistent legal frameworks around consent to data processing in health research.

127 The Board, established under Art. 68 may ‘examine, on its own initiative, on request of one of its members or on request of the Commission, any question covering the application of this Regulation and issue guidelines, recommendations and best practices in order to encourage consistent application of this Regulation’: Art. 70(1)(e).
What Is Possible and What Is Not? The Development of a Legal Framework for Drug Pricing Mechanisms in the EU

Gisela Ernst
Researcher, Institute of State- and Administrative Law, Department of Medical Law, University of Vienna, Vienna, Austria
gisela.ernst@univie.ac.at

Abstract

As a result of the constantly increasing number of innovative but exceedingly high priced medicines, many Member States have implemented price-regulating mechanisms to ensure the financial viability of their healthcare systems. However, the European Court of Justice applies strict criteria to these measures – some of them have already been suspended for the purposes of the free movement of goods. The European Union (EU) allowed the development of an ever-stricter case law on one hand, without changing the legal frame on the other hand. Considering the importance and the binding nature of the Court's judgements, this leaves great uncertainty for national legislators about which measures to remedy the pricing problem are legally possible and which are not. In order to provide clarity, this article seeks to analyse the development of the case law and to define the legal scope for pharmaceutical pricing mechanisms in the EU.

Keywords

EU pharmaceutical pricing – innovative medicines – free movement of goods – medicinal products – healthcare
1 Introduction

The pharmaceutical market is one of the most stringently regulated globally, especially within the EU. The irregularity in this sector – where one person (the doctor) chooses the product, a second one (the patient) uses it, and a third party pays for it – has led to a rapid rise in public expenses for drugs.¹ The ageing population and the technological advances along with intellectual property (IP) rights that protect them further contribute to this effect. Following legal acts about the authorisation of medicinal products in the 1960s² and a framework for the testing of proprietary medicinal products in the 1970ies³ the EU therefore started to adopt legislation on pharmaceutical pricing almost 30 years ago.⁴ Recent developments of annual therapy costs exceeding 800,000 USD⁵ demonstrate the importance of addressing this new phenomenon.

The problem has already gained ground in many areas of law, such as competition law, where exceedingly high prices of drugs dominate legal procedures under national and EU law.⁶ The free movement of goods however, has been of particular importance with regard to the rising expenses for pharmaceuticals in Member States. The initiating factor to enact EU law in this field was the complex tension between the internal market principles and the persistent aim of the Member States to implement measures that guarantee a high level of public health protection and the financial viability of healthcare systems.⁷

¹ J. Snell, ‘Free Movement of Pharmaceutical Products: An Overdose of Cheap Drugs?’, European Business Law Review 14(5) (2003) 507-521.
² Council Directive 65/65/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, OJ 369 of 26 January 1965 (replaced by Directive 2001/83/EG).
³ Council Directive 75/318/EEC on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products, OJ L 147 of 9 June 1975.
⁴ Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, OJ L 40 of 11 February 1989.
⁵ See e.g. K. Stone, ‘The most Expensive Prescription Drugs in the World’, The Balance, 30 December, https://www.thebalance.com/the-8-most-expensive-prescription-drugs-in-the-world-2663232, retrieved 12 February 2019.
⁶ N. Meershoek, ‘Excessive prices in the Pharmaceutical Sector: Re-inventing United Brands as a fairness-mechanism’, European Competition Law Review 39(4) (2018) 167-174.
⁷ Most Member States have implemented price-regulating mechanisms to control their drug expenses, to ensure the sustainability and efficiency of their healthcare systems. See Commission Staff Working Document – Impact Assessment on the Strengthening of the EU Cooperation on Health Technology Assessment (HTA) Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on health
The freedom of the EU aims to remove obstacles, whereas public health policies tend to draw them up – for the protection of health.

The European Court of Justice applies ever-stricter criteria to these measures. Some have already been suspended for the purposes of the free movement of goods. Considering the importance and the binding nature of CJEU judgements, this leads to a great deal of uncertainty for national legislators about which measures to remedy the pricing problem are legally possible, and which are not.

This article therefore seeks to mark the scope for drug pricing mechanisms that have been substantially narrowed due to the CJEU’s case law. To this end, it examines the existing legal framework for drug pricing within the EU, and addresses the development of the case law of the Court concerning the free movement of goods in Section 2. In Section 3, the article compares the latest rulings to the status quo of the written law and former decisions in this field, showing how the requirements of the jurisdiction exceed the demands set up by written law. In this section, the article further defines the scope for drug pricing mechanisms in Member States.

2 Background

In order to examine the legal framework for drug pricing within the EU, the different levels of the provisions and the influence of the EU institutions play a central role. The following examination of the background therefore provides an overview on the legislation at Treaty level, as well as at the secondary law level, followed by an analysis of a range of CJEU judgements on the topic of pharmaceutical pricing.

2.1 The Legal Framework for Drug Pricing within the European Union

2.1.1 Primary Law

In the field of public health, the competence of the EU to enact legislation has been extended during the development of the Union. It was not until 1993, that the Member States agreed to make some areas of public health a responsibility...
of the EU.\textsuperscript{10} The Treaty on the Functioning of the EU finally introduced an extended legislative competence to adopt measures in this field in 2007.\textsuperscript{11}

In this context, Article 2 of the Treaty\textsuperscript{12} distinguishes between exclusive and shared competences of the EU. Even though Article 168 led to a substantial expansion of the Union’s responsibilities, it only contains a comparatively ‘weak’ type of competence, a so-called ‘coordinated power’.\textsuperscript{13} Article 168 paragraph 2 thus states:

The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

This paragraph also lays down the specific legislative procedure for these measures as well as setting high standards of quality and safety for medicinal products and devices for medical use.\textsuperscript{14} However, the provision does not contain guidelines for the institutional and financial organisation of the Member States’ healthcare systems, which also include drug pricing mechanisms.

In addition, paragraph 7 states that every Union measure must respect the responsibilities of the Member States concerning their health policies. These responsibilities ‘shall include the management of health services and medical care and the allocation of the resources assigned to them’.\textsuperscript{15} Therefore, the primary law clearly states that health services and their funding belong to the responsibilities of the Member States.

Yet, public health is of greater importance for the EU law system and its division of competences than it may seem on first sight, and definitely exceeds the mere coordination of measures in certain areas. First, Article 9 TFEU stipulates that the Union shall take human health into account when defining and implementing all its policies.\textsuperscript{16} Furthermore, Article 6 paragraph 17 requires

\begin{thebibliography}{9}
\bibitem{10}Treaty on European Union Art. 129 (Maastricht text), OJ C 191 of 29 July 1992, p. 49.
\bibitem{11}Treaty on the Functioning of the European Union Art. 168 (hereafter: TFEU), OJ C 202 of 7 June 2016, p. 122.
\bibitem{12}Ibid., Art. 2, p. 50.
\bibitem{13}See e.g. I.N. Militaru, ‘The principle of the empowerment in the European Union’, Juridical Tribune 1(2) (2011) 42-50.
\bibitem{14}Supra note 11, Art. 168, p. 122.
\bibitem{15}Ibid.
\bibitem{16}Ibid., Art. 9, p. 53.
\bibitem{17}Ibid., Art. 6, p. 52.
\end{thebibliography}
EU legislation to comply with Article 35 of the Charter of Fundamental Rights of the EU,\(^{18}\) which contains the right to access to healthcare. The Court also referred to this fundamental right in the case law discussed below.

Second, Article 114 paragraph 2 contains a competence that is vital, not only for the internal market, but also for the health market. It enables the Union to adopt measures whose object is the establishment and functioning of the internal market.\(^{19}\) Although Article 168 TFEU clearly does not go this far, Article 114 can be used to harmonise health policies that affect the internal single market.\(^{20}\) Third, not only the competences, but the EU freedoms set down in the Treaties also play an important role in this area.

The free movement of goods is an especially central part of the EU framework for pharmaceutical pricing. Article 34 TFEU\(^{21}\) states: ‘Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States’. This principle is equally binding for the internal health market, as it is for other market areas, and plays a particularly important role in the pharmaceutical sector. As in other sectors, in general, marketing, pricing and reimbursement policies must not discriminate against foreign products or constitute impediments for the internal market. These principles have a major impact on the domestic law in the Member States.\(^{22}\)

However, as public health constitutes a central value in the legal framework and the society of the EU, exceptions to this rule are allowed to ensure the protection of health. Article 36 TFEU\(^{23}\) states that prohibitions or restrictions on imports and exports can be justified on grounds of public morality, public policy or public security, the protection of health and life of humans (and other reasons); these are called the mandatory requirements. This cornerstone in the form of a principle-exception model in favour of public health constitutes the red threat in the legislation as well as in the jurisprudence of the health-sector in the EU.

\(^{18}\) Charter of Fundamental Rights of the European Union Art. 35, OJ C 326 of 26 October 2012 [hereafter: Charter of Fundamental Rights or CFR].

\(^{19}\) TFEU, supra note 11, Art. 114, p. 94.

\(^{20}\) More specifically, it can be used as a legal basis if the aim of a measure is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws. The emerge must be likely and the measure must be designed to prevent the obstacles. See Tabacco Advertising, Case C-376/98 [2000], E.C.R I-8419, para. 86.

\(^{21}\) TFEU, supra note 11, p. 61.

\(^{22}\) T.K. Hervey, ‘EU law and national health policies: problem or opportunity?’, Health Economics, Policy and Law 2(1) (2007) 1-6, DOI:10.1017/S1744133106006219.

\(^{23}\) TFEU, supra note 11, p. 61.
2.1.2 Secondary Law

When it comes to pharmaceuticals, a complex and wide ranging system of regulations and directives is in force that coordinates and harmonises many areas of the pharmaceutical market. This framework does not only address the authorisation and registration of medicines, but also their placement on the market, as well as marketing and selling requirements. In addition, patents and supplementary protection certificates as well as the safety and the surveillance of pharmaceuticals underly the EU law frame.

Concerning the pricing however, only one legislative act has been passed by the EU so far, namely Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use. This so-called ‘Transparency Directive’ seeks to provide transparency about measures by the Member States controlling the pricing and reimbursement of pharmaceuticals. It addresses a variety of national instruments, which include procedural time limits for the setting of prices, price increases in systems of pre-established prices, price freezes, positive, and negative lists of drugs that are reimbursed and controls of direct or indirect market access decisions.

The Directive sets procedural requirements for each of these instruments, such as the implementation of legal remedies or the obligation to report to the commission. In particular, it demands that pricing decisions ‘shall contain a statement of reasons based on objective and verifiable criteria’. However, the provisions of the Transparency Directive only seek to ensure that national decisions do not create obstacles to the internal market. The Directive explicitly states that it does ‘not affect national policies on the setting of prices and the

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24 H.D.C. Roscam Abbing, ‘Twenty Year WHO Principles of Patients’ Rights in Europe, a Common Framework: Looking Back to the Future’, European Journal of Health Law 21(4) (2014) 323-337.
25 See e.g. Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, OJ L 311 of 28 November 2011.
26 Council Regulation 1768/92/EC concerning the creation of a supplementary protection certificate for medicinal products (codified as Regulation 469/2009/EC of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products), OJ L 183 of 2 July 1992.
27 Regulation 726/2004/EC 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, OJ L 136 of 30 April 2004.
28 Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, OJ L 40 of 11 February 1989, 8-11. [hereafter: Transparency Directive].
29 Ibid., Art 2-8 at 8-11.
organisation of social security schemes, except as far as necessary to achieve transparency’. Therefore, the central competence remains with the Member States.

As the competences of the EU only cover the issue of drug pricing to a certain degree, so far, there is no further European secondary law in this field. However, due to the constantly increasing number of innovative but exceedingly high priced drugs almost all Member States have introduced various measures to curb expenses for pharmaceuticals on the national level. These measures also include health technology assessment (HTA) policies to improve the efficiency of their healthcare systems. Consequently, a draft for a Regulation for a Union-wide HTA system was set up in 2018. Based on the before-mentioned Article 114 (because harmonised HTA procedures could stimulate the internal market) and Article 168 paragraph 4, this Regulation could enter into force within the next few years.

However, it is important to underline that even though this legislation would have a considerable impact on the national systems, Member States will still take pharmaceutical pricing and reimbursement decisions at national level. Therefore, the analysis of the discussed competences and legislative acts shows that neither the primary or the secondary law provide a competence to actually regulate prices at EU level.

2.2 Case Law of the CJEU

2.2.1 Landmark Cases for the Free Movement of Goods

As already shown above, the free movement of goods plays a significant role concerning pharmaceutical pricing policies. The starting point of the analysis of the jurisprudence in this field is the Dassonville-formula:

All trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be regarded as measures having an effect equivalent to quantitative restrictions.

30 The Directive does not deal with the substance of the issue but merely controls the process of adopting these measures, see supra note 1, p. 509.

31 HTA is ‘a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner’. See SWD (2018) 42 final on the Strengthening of HTA, supra note 7, p. 6.

32 Ibid., p. 15.

33 Ibid., p. 41.

34 Proceur du Roi v. Dassonville, Case C-8/74, [1974] E.C.R. I-0873, para. 5.
Laws that fall under this definition are so-called ‘measures having equivalent effect’. Following the Keck judgement, which the Court issued several years later, this does not apply to provisions that are equally binding for national and international products, and only constitute ‘selling arrangements’ and not requirements to be met by goods. In the course of its attempt to define guidelines when obstacles to the free movement of goods should be justified, the Court went further into detail in Cassis de Dijon. In this case, it pointed out that market impediments resulting from differences between national laws ‘must be accepted in so far as those provisions may be recognized as being necessary in order to satisfy mandatory requirements’.

2.2.2 Development of Case Law Concerning the Pharmaceutical Market

As pointed out above, the first question is always whether a measure taken by a Member State in conjunction with drug pricing, can impede the market or constitutes a measure having equivalent effect. The Court dealt with this question in Roussel v. The Netherlands, where it ruled on a change of national legislation concerning maximum prices of pharmaceuticals that prima facie applied to domestic as well as imported products, but had a greater impact on imported products. Although there was the presumption that price controls applying equally to imports and domestic drugs do not constitute a measure of equivalent effect, the Court ruled against the Dutch policy. If, as in this case, the legislation in fact applies to imports in a different way, and thus puts them at disadvantage, this constitutes an infringement of Article 34 (formerly Art 30).

In Belgium v. Commission, the Court stated again that pricing regulations for medicines do not constitute measures having equivalent effect, as long as they are equally applicable to national and international products. This jurisprudence shows that in general, the Court considers different pricing policies in the Member States as compatible with EU law.

Concerning the free movement of goods, this means that national pricing policies can have different systems and techniques to foster the sustainability of a healthcare system, as long as they do not hamper the internal market. For

35 Keck and Mithouard Joined Cases C-267/91 & C-268/91 [1993] E.C.R. I-6097, para. 16.
36 Cassis de Dijon, Case C-120/78, [1979] E.C.R. I-649, para. 8.
37 See P. Oliver and M.A. Jarvis, Free Movement of Goods in the European Community (London: Sweet & Maxwell, 2003) p. 199.
38 Roussel Laboratoria v. Netherlands, Case C-181/82 [1983] E.C.R I-3849, paras. 19-25.
39 Commission v. Belgium, Case C-249/88, [1991] E.C.R. I-1306, para. 15.
40 The Transparency Directive also implicitly accepts different systems, by laying out procedural requirements to make them more transparent.
example, if the maximum price is set at such a low level, that foreign products cannot compete with national products, as they have higher costs for transport and importation, and thus cannot be sold profitably in comparison to national products, this constitutes a measure having equivalent effect.\(^\text{41}\)

This also applies to the other side of the coin: when the minimum price is set at such a high level that foreign products cannot use discount and pricing strategies in order to increase their popularity and establish themselves successfully on the market, such a provision does not comply with EU law.\(^\text{42}\) In addition, price spirals and other pricing policies that dump pharmaceutical prices down to a certain level also do not fall under ‘selling arrangements’ anymore, and therefore need to be justifiable and proportionate – irrespective of whether they are equally applicable or not.\(^\text{43}\)

Whether a measure has an effect of equivalence directly leads to the question of whether the measure can be justified by the public health exception. Over the course of the years, the Court established a number of principles when answering these questions. In one of its early judgements concerning the pharmaceutical market, the Court held in the \textit{De Pejper} case, that national regulations do not fall within the exception ‘if the health and life of humans can [be] as effectively protected by measures which do not restrict intra-Community trade so much’.\(^\text{44}\) In particular, neither the lightening of bureaucratic burdens, nor the reduction of public expenditure can justify rules or practices, unless the burden or expenditures exceed reasonable limits.\(^\text{45}\) With these statements, the Court expressed the principle of proportionality, which applies to exceptions under Article 36.\(^\text{46}\)

In the same judgement however, the Court ruled that ‘health and the life of humans rank first among the property or interests protected by Article 30’ [now 36] and that it is up to the Member States, to decide what degree of protection they intend to assure.\(^\text{47}\) The Court’s cautious approach to matters of public health and its upholding of the right of Member States to take steps to guard against a public health risk led to the development of the precautionary

\(^\text{41}\) \textit{Roussel v. Netherlands}, C-181/82, para. 17; see also \textit{Commission v. Belgium}, C-249/88, para. 15.

\(^\text{42}\) See supra note 37, p. 203.

\(^\text{43}\) Ibid., p. 202.

\(^\text{44}\) \textit{Adriaan de Pejper}, Case C-104/75 [1976] E.C.R. I-613, para. 17.

\(^\text{45}\) Ibid., para. 18.

\(^\text{46}\) In the Case Duphar the Court dealt with the justification under Art. 36 and the precautionary principle again, see \textit{Duphar et al. v. Netherlands}, Case C-238/82, [1984] E.C.R. I-523.

\(^\text{47}\) \textit{Adriaan de Pejper}, Case C-104/75 [1976] E.C.R I-613, para. 15.
What Is Possible and What Is Not?

principle.48 This means that in case of possible risks, the absence of scientific proof for those risks should not lead to the postponement of measures with a view to preventing damages. Following this principle, evidence about prospective damages is not required before a measure is taken.49 This suggests that although Article 36 can only justify pharmaceutical pricing measures if there is a profound need, there must not be valid evidence that the lack of a measure will lead to health damages.

In the Germany v. Commission50 and Schuhmacher51 cases, the Court had to deal with national laws prohibiting the importation and purchase of prescription-only drugs in the pharmacies of other Member States. These rulings are of particular interest because the Court stated that justifications under Art. 36 have to be interpreted in light of the general principles of law and in particular in light of fundamental rights (see Art. 35 CFR explained above).

However, following the Court’s view, even those rights can be restricted if the restriction in fact corresponds to objectives of general interest pursued by the community and the restriction does not constitute an excessive interference that touches upon the very substance of the rights.52 Hence, Member States are allowed to control the importation of prescription-only drugs for the purposes of public health, but only ‘in such a way as to meet the requirements arising from the protection of fundamental rights [...]’.53 These findings on how fundamental rights interact with the free movement of goods also contributed to clarify the extent to which public health is prior to certain measures.

Furthermore, the Court held that the national government is responsible to adduce evidence to show that it would be impossible to meet public health requirements without impairing fundamental rights and the free movement of goods.54 This statement expresses what was already established through case law in other fields: The party alleging that a measure should constitute an exception from Article 34 as a mandatory requirement bears the burden of proving that the contentious measure is justified.55

Unfortunately, the Court did not address how far-reaching this evidence is supposed to be. Nevertheless, the CJEU (at that time) usually followed the

48 See supra note 37, at 256.
49 L. Antonopoulou and P. van Meurs, ‘The precautionary principle within European Union public health policy’, Health Policy 66(2) (2003) 179-197.
50 Commission v. Germany, Case C-62/90, [1992] E.C.R. I-2601.
51 Schumacher v. HZA Frankfurt, Case C-215/87, [1989] E.C.R I-617.
52 Commission v. Germany, supra note 50, para. 23.
53 Ibid., para. 24.
54 Ibid., para. 25.
55 See supra note 37, p. 221.
recommendations of international organisations (such as the WHO), and paid attention to the practices of other Member States and comparable third countries. After all, every Member State is still competent to decide on the level of protection of public health that it wishes to ensure, and conversely similar restrictions in another Member State do not necessarily lead to the justification of a measure.\footnote{Ibid., p. 259.}

The Court returned to the issue of how justifications can be proven in the first \textit{DocMorris} decision.\footnote{Deutscher Apothekerverband eV \textit{v. DocMorris NV}, Case C-332/01, [2003] E.C.R. I-14951.} After qualifying the prohibition of mail order trade as a measure having equivalent effect\footnote{Ibid. paras. 66-68 (referring to the \textit{Dassonville} and the \textit{Keck}-Formula).} it was required to assess whether this legislation could be justified in light of Article 36. Concerning the necessity to check the authenticity of prescriptions in an effective way the Court held that ‘without any other control [this] could increase the risk of prescriptions being abused or inappropriately used’. Thus, a prohibition on mail order sales was considered to be justified due to risks to public health.\footnote{Ibid., para. 119.} The Court did not ask for further evidence to underline this reasoning. This jurisdiction suggests that if justifying arguments that point towards an actual and substantial risk for public health are brought forward, the Court tends to stick to the precautionary principle and does not set a very high standard for the burden of proof.

Concerning the argument that medicines must be sold in pharmacies and not over the internet because of the fixed price level, the Court stated:

\begin{quote}
Although aims of a purely economic nature cannot justify restricting the fundamental freedom to provide services, it is not impossible that the risk of seriously undermining the financial balance of the social security system may constitute an overriding general-interest reason capable of justifying a restriction of that kind [...].\footnote{This statement confirmed the Courts former case law, see \textit{Decker v. Caisse de Maladie des Employés Privés}, Case C-120/95 [1998] E.C.R. I-831, para. 39.} Moreover, a national market for prescription medicines could be characterised by non-commercial factors, with the result that national legislation fixing the prices at which certain medicinal products are sold should, in so far as it forms an integral part of the national health system, be maintained.\footnote{Deutscher Apothekerverband eV \textit{v. DocMorris NV}, Case C-332/01, [2003] E.C.R. I-14951, para. 122.}
\end{quote}
These statements are of great importance regarding the conformity of national pricing policies. They clearly state that drug pricing regulations must comply with EU law under the condition of meeting the mentioned requirements. In this context however, the Court stated that there were no arguments put forward as to the fundamental necessity of these pricing measures for the health system in question. On one hand, this demonstrates that when it comes to pricing policies, the Court demands a substantial argumentation of the reasons why they are needed. On the other hand, however, the Court talks about ‘arguments’62 and not scientific evidence. This is central for the analysis below.

In *Apothekerkammer des Saarlandes et al* in 2007, the Court once again referred to the precautionary principle in conjunction with public health risks. In accordance with the jurisprudence discussed above it stated that Member States should always be able to take precautionary measures without having to wait until danger becomes fully apparent in cases where the existence or the extent of risks to human health are uncertain.63 In the course of its argumentation on the justification, the Court even names the financial balance of social security systems in conjunction with measures that are aimed at the prevention of public health risks.64

Summarising this case law, in general different national drug pricing mechanisms comply with Article 34 as long as they apply to imports and domestic products in the same non-discriminatory way and that price levels do not hinder access to the pharmaceutical market for foreign actors. If a measure constitutes an impediment of the market however, it can be justified under Article 36. This is not the case with measures of a financial or administrative nature, but can be the case when it comes to the balance of the social security system. According to the precautionary principle, the Court tends to set rather moderate requirements for the burden of proof if a measure seeks to prevent a substantial public health risk. Moreover, measures have to comply with the principle of proportionality and their justification needs to be interpreted in the light of fundamental rights, such as the right to health, which can be restricted as long as this happens for reasons of general interest and without substantially infringing upon that right.

62 Ibid., para. 123.
63 *Apothekerkammer des Saarlandes et al* (joined party: *DocMorris NV*) Cases C-171/07 & C-172/07, [2009] ECLI:EU:C:2007:311, para. 30.
64 Ibid., para. 34.
2.2.3 Recent Case Law

In a decision from 2016 that made waves in the legal world, the European Court of Justice once again dealt with a measure concerning the pricing of pharmaceuticals. In the Deutsche Parkinsonvereinigung case, the Court had to assess whether setting fixed prices for prescription-only medicinal products that are sold by pharmacies (the measure was applicable for resident pharmacies and pharmacies in other Member States) constitutes a measure having equivalent effect. Subsequently, it had to decide whether this measure could be justified under Article 36.

Concerning the first question, the Court held that a system of fixed sales prices has greater impact on foreign pharmacies, which is why it could ‘impede market access for products from other Member States more than it impedes such access for domestic products’. As outside pharmacies cannot use other methods than price competition in order to access the market, according to the Court, national pharmacies were less affected by the legislation, which is why the policy was qualified as a measure having equivalent effect.

In the view of some authors, the answer to this first question was already not 100 percent foreseeable, as the measure was obviously equally applicable and therefore could have been qualified as a certain selling arrangement. The second question however, especially introduced some new aspects to the jurisprudence on the justification of measures under Article 36. Even though the Court elaborated that guaranteeing a safe and high-quality supply of medication throughout Member States falls within the scope of Article 36 TFEU, legislation capable of restricting the free movement of goods can only be justified if it is appropriate and does not go beyond what is necessary.

As in former decisions, emphasis was placed on the importance of the evidence for the justification of the objectives pursued. In this context, the Court stated:

[... ] the court must examine objectively, through statistical or ad hoc data or by other means, whether it may reasonably be concluded from the evidence submitted by the Member State concerned that the means

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Deutsche Parkinsonvereinigung eV v. Zentrale zur Bekämpfung unlauteren Wettbewerbs eV, Case C-148/15, [2016] ECLI:EU:C:2016:776.
Ibid., para. 26.
Ibid., para. 27.
H.U. Oppenländer, ‘BGH: Arzneimittelpreisrecht gilt auch für ausländische versandapotheken’, GRUR-Prax 7(8) (2016) 184.
Deutsche Parkinsonvereinigung eV v. Zentrale zur Bekämpfung unlauteren Wettbewerbs eV, Case C-148/15, [2016] ECLI:EU:C:2016:776, para. 34.
chosen are appropriate for the attainment of the objectives pursued and whether it is possible to attain those objectives by measures that are less restrictive of the free movement of goods.\textsuperscript{70}

Since none of the evidence brought forward outlined how fixed prices for medicines could lead to a better geographical allocation of traditional pharmacies, the justification was rejected. Further, the Court pointed out in accordance with the General Advocate’s opinion,\textsuperscript{71} that regional pharmacies faced with competition from mail-order pharmacies from other Member States would be encouraged to improve such activities.\textsuperscript{72} When addressing the argument that patients in poor health conditions should not be required to carry out market analysis in order to determine where a certain medicine is available for the lowest price, the Court stated that ‘the existence of a genuine risk to human health must be measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research.’\textsuperscript{73}

3 Analysis

The analysis discusses the recent decision of the CJEU from a critical perspective in light of the former case law and written law. This discussion is followed by a demarcation of the scope that the increasingly stringent case law leaves for pricing policies in Member States.

3.1 Critical Analysis of the Deutsche Parkinsonvereinigung C-148/15 Decision

3.1.1 Qualification as a Measure Having Equivalent Effect

In the recent Deutsche Parkinsonvereinigung case, the Court used a modified variant of the Dassonville formula for its definition of a drug pricing policy as a measure of equivalence. Remarkably, it did not stick to the procedure laid out in the cases above. First, it adopted a strong market access approach that stresses the effect on foreign economic operators, which is also mirrored in the Court’s use of language. It departed considerably from the initial formulation

\textsuperscript{70} Ibid., para. 36.

\textsuperscript{71} Opinion of Advocate General Szpunar, Deutsche Parkinsonvereinigung, C-148/15, paras. 52-54.

\textsuperscript{72} Deutsche Parkinsonvereinigung eV v. Zentrale zur Bekämpfung unlauteren Wettbewerbs eV, Case C-148/15, [2016] ECLI:EU:C:2016:77, para. 40.

\textsuperscript{73} Ibid., para. 42.
of the Dassonville-formula.\textsuperscript{74} Second, it seems that the Keck-formula and the question of whether this measure could only constitute a certain selling arrangement is not addressed at all.\textsuperscript{75} This lack of attention to former case law was deemed fairly striking in the legal community, considering that even the Advocate General, whose opinion was followed by the Court in many respects, had at least discussed this possibility.\textsuperscript{76}

However, reading between the lines, the statement that the sale of national medicinal products and those coming from other Member States are not affected in the same way could be considered as an implicit reference to this case law.\textsuperscript{77} In addition, the German Bundesgerichtshof that had had to answer this question before considered the policy as a certain selling arrangement.\textsuperscript{78} With regard to the importance of this qualification under the former case law, it would have been desirable for the legal security of drug pricing measures, if the Court had further elaborated this aspect. Since the Court took the specific configuration of the German legislation into account in his decision, the fact that he did not address the topic of certain selling arrangements explicitly further raises insecurities that Member States have to face when trying to enact EU law-conforming pricing measures.

3.1.2 Justification under Article 36 TFEU

As stated above, the major principle of the internal market is that the free movement of goods only allows a small number of exceptions under certain mandatory requirements laid down in Article 36 TFEU.\textsuperscript{79} The article itself does not specify how justifications under this provision can be proven in a proceeding. The background analysis of the case law, however, shows the recognition of public health as a maxim of high value in the EU legal system, which is also

\begin{itemize}
    \item \textsuperscript{74} See S. López Artetxe, ‘Is Health Really the First Thing in Life?’, Legal Issues of Economic Integration 44(3) (2017) 315-322, who argues that the Courts ‘far-reaching” variant of the Dassonville formula strongly emphasises and is satisfied with the effect of the measure on foreign economic operators.
    \item \textsuperscript{75} See Kai P. Purnhagen, ‘Keck is dead, long live Keck? – How the CJEU Tries to Avoid a Sunday Trading Saga 2.o’, Wageningen Working Papers in Law and Governance 1 (2018) 5-11. He points out that the Court did not make a differentiated examination of the formulas but rather used a ‘unitary approach’.
    \item \textsuperscript{76} Supra note 74, p. 318.
    \item \textsuperscript{77} According to one view, represented in scholarly literature this formulation intends to say that the measure in question does not constitute a certain selling arrangement, see I. Bach, ‘Zu Risiken und Nebenwirkungen – Der EuGH kippt die Arzneimittelpreisbindung’, GPR 14(1) (2017) 8-12.
    \item \textsuperscript{78} See the judgement of the BGH (2014) – I ZR 79/10, online at https://openjur.de/u/685825.html, retrieved 12 February 2019.
\end{itemize}
covered by the fundamental rights of EU citizens. Nevertheless, the burden of proof constitutes a considerable hurdle.

On the basis of the principle-exception model of the Treaty, the burden of proof to justify a measure rests on the party raising it.79 Former case law clearly demonstrates a tendency towards strict interpretation of Article 36.80 In the DocMorris case, however, the Court did not ask for further evidence for a justification that concerned the safety of medicine supply and that sought to prevent an actual and potential public health risk.81 It only required ‘bring forward arguments’. In light of this status quo, the decision in Deutsche Parkinsonveriegung marks a significant paradigm shift. Even though the Court highlighted the possibility of the justification of market impediments by public health objectives, it set very high standards for this endeavour.

The demand for scientific evidence and ad hoc data therefore constitutes a substantial increase in the extent of the burden of proof. This becomes especially clear when comparing the language of the Court in this recent decision to former ones. While it was only in 2009 that the discretion of the Member States and their argumentation was held higher than general counter-arguments,82 the Court now insists on an examination of evidence that must take place ‘objectively, through statistical or ad hoc data or by other means’.83 Taking into account that public health issues usually also touch on fundamental rights, this is a high bar for the State willing to defend its measure.

Some authors even argue that Article 35 of the Charter of Fundamental Rights (CFR) can potentially lead to another shift of the burden of proof when the justification of an ‘impeding’ measure is based on public health objectives.84 Even though this thesis might be quite far-reaching, literature on Article 35 CFR shows that this provision contains a restraining order for all EU measures that could constitute a risk for the high level of public health protection.85 In this context, Article 35 CFR can be interpreted in such a way that measures ensuring a high level of public health as well as the Member States’ competences to

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79 See supra note 37, p. 256.
80 See the Cases of Commission v. Germany, Case C-62/90, [1992] E.C.R. I-2601, para. 25; and Deutscher Apothekerverband eV v. DocMorris NV, Case C-332/01, [2003] E.C.R. I-14951, para. 124.
81 Ibid., para. 119.
82 Apothekerkammer des Saarlandes et al. (joined party: DocMorris NV) Cases C-171/07 & C-172/07, [2009] ECLI:EU:C:2009:31, para. 30.
83 Deutsche Parkinsonvereinigung eV v. Zentrale zur Bekämpfung unlauteren Wettbewerbs eV, Case C-148/15, [2016] ECLI:EU:C:2016:776, para. 36.
84 See supra note 78, p. 10.
85 Gregor Ribarov, ‘Artikel 35 GRC’, in: M. Holoubek and G. Lienbacher (eds.), Charter der Grundrechte der Europäischen Union: GRC-Kommentar (Vienna: Manz, 2014) pp. 467-474.
organise and supply health services must be respected by Union actions by all means. The logical consequence of this interpretation would be that national policies that seek to maintain public health standards have to be measured with a different scale.

Furthermore, Article 35 CFR not only obliges the EU, but also its Member States. According to prior cases, they had to stick to the precautionary principle within their margin of discretion. It was also only in Apothekerkammer des Saarlandes when the Court returned to this principle in its argumentation without demanding scientific evidence for the justification of the measures taken. In this case, the CJEU even rejected the Commissions counter-arguments with the remark that it was not proven that other measures were less of an impediment for the free movement than the one in question.

This raises the next problematic aspect of the latest case. While demanding high standards for evidence and increasing the burden of proof that rests on a Member State, the Court’s own assumptions and arguments seem to be exempt from these requirements. The Court e.g., does not provide any evidence for its thesis that internet pharmacies need price competition to establish themselves on the German market. Considering that under German law nearly the entire price of pharmaceuticals is reimbursed by the social health insurance system, the final price of a medicine might not be of such great importance after all. Social security law often stipulates a complex regulatory system where not only the price, but a variety of different factors play a role for the decisions on whether a medicine is reimbursed or not. Therefore, doubts with respect to this thesis are equally justified as they are with respect to the arguments of the justification under Article 36.

3.2 Defining the Remaining Scope for Drug Pricing Policies

3.2.1 The Transparency Directive

As the examination of the background information shows, there is only one piece of written legislation on the level of secondary law that affects the national margin for pricing decisions to a certain extent: the Transparency Directive. This Directive constitutes a central yardstick for the compliance with EU Law.

86 Apothekerkammer des Saarlandes et al (joined party: DocMorris NV) Cases C-171/07 & C-172/07, [2009] ECLI:EU:C:2007:311, para. 30.
87 Ibid., paras. 53-55.
88 See supra note 77, p. 10.
89 Ibid.
However, its provisions contain only procedural requirements; the focus of the analysis therefore lies on the free movement of goods.

3.2.2 The Scope of Market Impediments and Measures that Have Equivalent Effect

Most of the questions raised when defining the legal frame for drug pricing mechanisms in the context of the free movement of goods are linked closely to a certain step of the procedure before the European Court of Justice. The following considerations therefore address the different aspects in the chronological order in which the Court generally addresses these questions.

First, one must define whether a certain measure constitutes an impediment for the market. In general, policies that do not apply to foreign and domestic products in the same way as in the Roussel case constitute an infringement of the internal market. However, Member States are generally allowed to enact equally applicable pricing measures. In this context, the aspect of access to foreign markets plays a central role. Maximum prices cannot be set at such a high level that it prevents price competition, and in turn, the possibility for foreign products to establish themselves on the market. In addition, minimum prices can also constitute an aggravating factor when it comes to market access.

Taking these recent decisions into account, there is little likeliness that a drug pricing measure is qualified as a certain selling arrangement, and the importance of this test step has devolved to the question of justification. Pricing policies enacted by the Member States therefore now face the employment of a wide market access test, making it almost impossible not to be qualified as a measure having equivalent effect. In the event that a national measure is challenged before the CJEU, it must be proven that the measure is not only equally applicable, but also that it does not restrict access to a national market in any way.

1.1.1. The Scope of Mandatory Requirements under Article 36 TFEU

As most of the measures might not pass this first hurdle, further attention must be paid to the next step of the procedure – the question of whether a

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90 These requirements can also impact national healthcare systems to a certain extent. See e.g. Commission v. Austria, Case C-1100/00 [2001], E.C.R I-7545; and A. Menarini Industrie Farmaceutiche Rianite et al joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 [2009], E.C.R. I-2495.

91 Roussel, C-181/82, paras. 19-25.

92 See supra note 75, p. 5.

93 See supra note 1, p. 510.
measure constitutes an objective that is ‘protected’ by Article 36 TFEU, and can therefore be justified. Pricing policies for drugs are very common among the Member States, and often constitute a central factor for the efficiency of healthcare systems. These measures can pursue different objectives.

For instance, in the recent Deutsche Parkinsonvereinigung case, they sought to ensure a safe and nationwide provision of medicines. Although different aims are usually closely linked to each other, the major goal of pricing mechanisms is the financial sustainability of the healthcare systems, rather than the safety of the population or the prevention of substantial public health risks. When addressing the definition of a scope for pricing policies, this fact has to be kept in mind. In this recent case, according to the German government the goal of fixed prices was deemed mainly of a non-budgetary nature, and yet the Court still set the standards for the justification so high, that they could scarcely be met. Consequently, this raises the question of whether price controls that pursue financial objectives can ever be justified under Article 36 on the mandatory requirements.

In the setting out of the case law on pharmaceutical prices above, we can see that the Court certainly does not tend towards interpreting exceptions for the internal market very generously, especially not in recent years. This tendency might be due to the fact that Article 36 TFEU is directed at eventualities of a non-economic kind. Therefore, measures such as the promotion of employment or investment, lowering the inflation rate, and cost containment are not covered by this provision of the Treaty.

When considering this telos of the primary law and the Court’s view expressed in the DocMorris case, it appears that pricing mechanisms can only constitute a mandatory requirement if they prevent a serious undermining of the financial balance of the social security system, and this system forms an integral part of the national health system. In short, this means that financial objectives behind pricing measures have to amount to a significant public health interest in order to qualify as a reason for justification.

In addition, justifications for a restriction of the free movement of goods have to comply with the principle of proportionality and measures therefore have to be appropriate for securing such an objective. Furthermore, the next step must examine whether the restriction goes beyond of what is necessary.

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94 SWD (2018) 42 final on the Strengthening of HTA, supra note 7, p. 15.
95 See supra note 37, p. 204.
96 Ibid., p. 235.
97 Deutscher Apothekerverband eV v. DocMorris NV, Case C-332/01, [2003] E.C.R. I-14951, para. 122.
for attaining that objective, meaning that there must not be any alternatives, which would be less of an impediment and would enable the objective to be attained just as effectively.98

3.2.3 The Scope of the Burden of Proof
The strict requirements for the burden of proof are a major issue in the case law on the drug pricing policies of the CJEU. Even though by law the EU does not have the competence to interfere with the public health systems of Member States, their margin of discretion has been considerably restricted. Not only has the importance of the precautionary principle faded in favour of the free movement of goods, it also became clear that the burden of proof rests solely on the Member State introducing a measure and moreover, it has a far-reaching extent.

On one hand, Member States enacting pricing measures have to provide extensive research data about how the measure can help achieve the public health goal pursued. In addition, it is probable that the mandatory requirement, meaning a substantial risk for the financial sustainability of the public health system, as well as the proportionality of a measure, have to be proven in this manner. Arguments based on the precautionary principle that are not backed-up with ad hoc data or other objective criteria (that is inherent to this principle), are now likely to fall under what the CJEU considered ‘general conjecture’.99 On the other hand, in its recent case the Court entitled itself to counter these arguments without having to prove its view with any evidence. This narrows the remaining scope to measures that are based on scientifically rigorous studies that have to be carried out before introducing a new policy.

4 Conclusion
Whether price regulations are indispensable to reach certain public health goals, or whether the resulting market impediments have a counterproductive effect, may be open to interpretation.100 The CJEU’s demand that this debate should not be conducted using hollow phrases is therefore generally plausible. The relationship of the internal market law and the free movement of goods

98 See e.g. Apothekerkammer des Saarlandes et al. (joined party: DocMorris NV) Cases C-171/07 & C-172/07, [2009] ECLI:EU:C:2007:311, paras. 29 and 52.
99 Deutsche Parkinsonvereinigung eV v. Zentrale zur Bekämpfung unlauteren Wettbewerbs eV, Case C-148/15, [2016] ECLI:EU:C:2016:776, para. 42.
100 See supra note 77, p. 10.
with public health risks has always been an area of tension, as the wide-rang-
ing case law addressed above shows. Thus, arguments and evidence to prove
public health risks have always been of importance.\textsuperscript{101} Therefore, the \textit{Deutsche Parkinsonvereinigung} case was not as surprising as some authors may suggest.\textsuperscript{102}

The margin of discretion however, is – without a doubt – restricted by the re-
quirement of scientific evidence for the justification of market-impeding mea-

\textsuperscript{103} This might be justified to a certain extent, but it cannot be stressed
enough that the Court should not exceed its competences. Considering the
Treaty provisions and earlier rulings, we must not forget that the competence
for the organisation and the financing of healthcare systems lies with the
Member States. Even in questions that touch upon internal market issues, a
certain margin of discretion should be left to them.\textsuperscript{104} Especially in the field of
innovative and high-priced medicines, Member States need a certain political
and legal range to be able to tackle these new phenomena. In order to leave
scope for weighing, a return to yardsticks such as transparency and fair market
access,\textsuperscript{105} as well as the precautionary principle and principle of proportion-
ality would be desirable.

Therefore, applying double standards to the burden of proof, as the Court
did in the recent decision, is definitely not a step in the right direction. The
pursuit of avoiding ‘gut decisions’ in sensitive areas of public health such as
pharmaceutical pricing should be consistent while giving flexibility to the
Member States. Furthermore, one must not forget that the EU only has limited
competence in the field of public health. Future decisions will show if the CJEU
will continue to follow the path it chose in \textit{Deutsche Parkinsonvereinigung}, or
if it returns to a more precautionary approach, leaving a broader scope for
which drug pricing mechanisms in the Member States are possible and which
are not.

\textsuperscript{101} See e.g. the Case of the \textit{Scotch Whisky Association} where the Court stated the central
role scientific evidence plays for the justification under Article 36 TFEU. \textit{Scotch Whisky
Association et al v. Scotland}, Case C-333/14, [2015] ECLI:EU:C:2015:845.
\textsuperscript{102} See supra note 74, p. 317. López Artetxe even describes the stringent requirements of the
decision as ‘disequilibrium’ in comparison to former decisions resulting from unforeseen
‘weighing exercises’ of the judges.
\textsuperscript{103} See supra note 77, p. 10.
\textsuperscript{104} Ibid.
\textsuperscript{105} See the recitals of the Transparency Directive.
News & Views

The Legal Framework for the Fight against Female Circumcision: From Cultural Indulgence to Human Rights Violations. The French Example

Catherine Le Bris
CNRS Researcher, Institut des Sciences juridique et philosophique de la Sorbonne, University of Paris 1 Panthéon-Sorbonne – CNRS, Paris, France

Abstract

The harmful consequences of female circumcision for women’s health have been demonstrated and are regularly recalled by the World Health Organisation. Whereas in the past, the cultural dimension of the practice was emphasised, which result in impunity or absence of guilt, it is now considered by the United Nations as a violation of human rights, especially of the right to health. In 2012, the General Assembly asked States for a total ban on the practice. Despite the consensus on the punishability of female circumcision, its enforcement diverges, in particular in Western Europe. France is considered as a model in this area, that’s why this study focuses on it. Yet, under French law, there is no special legislation criminalising the practice: female circumcision is punishable on grounds of mutilation. However, the French success is not complete: the prevention of such acts could be improved.

1 Centre National de la Recherche Scientifique (CNRS: National Centre for Scientific Research).
Keywords

female circumcision – female genital mutilation – right to health – human rights –
criminal law – custom – cultural practice – asylum

1 Introduction

In February 2016, UNICEF estimated that some 200 million women and girls had suffered female circumcision in 30 countries, with up to a quarter of them being under the age of 15. According to the most recent figures, there were 53,000 circumcised adult women living in France as at 2004.

The first female circumcision cases emerged in France during the 1970s, following the arrival of migrants practising that rite and the Soninke community in particular. The first criminal trial took place a short time later, in 1979, when a 3 year-old girl named Doua died following her circumcision. That judicial response was initially taken very badly by the Malian community concerned, which viewed the prosecutions as an assault on its cultural identity. Female circumcision is a rite of passage for the Soninke. It is claimed that the practice contributes to a differentiation between the sexes and promotes fertility; it is intended to remove any vestige of masculinity in women and young girls.

Contrary to received thinking, female circumcision is not specific to the Muslim community: it is also practised by East African Christians, and indeed has been since the times before Islam. Female circumcision is therefore more...
a cultural than a religious rite, even if the two aspects are all too often inexorably linked. Furthermore, genital mutilation (hereinafter FGM) has historically been practised in Europe, not for ritualistic reasons but rather on hygiene or therapeutic grounds. Thus, in the 19th century, some doctors recommended its use in treating pathologies such as epilepsy and hysteria. Nowadays, however, the harmful consequences of female circumcision for women’s health have been very clearly demonstrated and are regularly recalled by the World Health Organisation. During the excision itself, girls and women experience pain and bleeding; they are exposed to risks of fatal haemorrhaging and subsequent infections. Later, there can be complications when giving birth. Lastly, and above all, the practice leaves psychological scars.

In this context, the fight against female circumcision has intensified and become universal. Whereas in the past the cultural dimension of the practice was emphasised, which resulted in impunity or absence of guilt, it is now considered by the United Nations as a violation of human rights, especially of the right to health (Section 2). Despite the consensus on the punishability of female circumcision, its enforcement diverges, in particular in Western Europe. France is considered as a model in this area: it has the highest number of prosecutions for genital mutilation in all of Europe; that is why this study focuses on it. However, under French law, there is no special legislation criminalising the practice: female circumcision is punishable on grounds of mutilation (Section 3). Yet in France the customary nature of female circumcision, while often argued, does not allow defendants to evade criminal penalties (Section 4). Furthermore, French law strives to protect potential victims

8 On this matter, see K. Monahan, ‘Cultural Beliefs, Human Rights Violations, and Female Genital Cutting’, Journal of Immigrant & Refugee Studies 5(3) (2007) 21-35, https://www.tandfonline.com/doi/abs/10.1300/J500v05n03_02, retrieved 19 December 2018.
9 See K.G. Fisaha, ‘Female Genital Mutilation: A Violation of Human Rights’, Journal of Political Sciences and Public Affairs 4(2) (2016) 198; on this matter, see also McGee, supra note 6, p. 145.
10 See B.D. Williams-Breault, ‘Eradicating female genital mutilation/cutting: Human rights-based approaches of legislation, education, and community empowerment’, Health and Human Rights Journal (14 August 2018), https://www.hhrjournal.org/2018/08/eradicating-female-genital-mutilation-cutting-human-rights-based-approaches-of-legislation-education-and-community-empowerment/, retrieved 2 December 2018.
11 See R. Kool and S. Wahedi, ‘Criminal enforcement in the area of female genital mutilation in France, England and the Netherlands: A comparative law perspective’, International Law Research 3(1) (2014), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2433554, retrieved 19 December 2018.
of female circumcision, particularly by granting them asylum. However, the French success is not complete: the prevention of such acts could be improved (Section 5).

2 The Universalisation of the Fight against Female Circumcision

Given the risks that it presents to women's health, female circumcision is routinely condemned by the international community,\textsuperscript{14} and particularly by the United Nations General Assembly.\textsuperscript{15} However, whereas in the 1980s, female circumcision was framed only as a health problem,\textsuperscript{16} it is now considered furthermore as a human rights matter. Indeed, the previous strategy failed to motivate large-scale behaviour change:

In circumcising communities, people are often already aware of many, if not most, of the potential adverse health outcomes but feel that the risk is worth taking in light of the social and cultural importance of the practice.\textsuperscript{17}

In addition, from a scientific point of view, it is quite difficult to establish a laundry list of adverse health outcomes. That is why female circumcision has been characterised as a violation of human rights.\textsuperscript{18} On this basis, in 2012, the

\textsuperscript{14} See for example United Nations, Economic and Social Council, \textit{Ending Female Genitale Mutilation, Report of the Secretary-General} (UN Doc. E/CN.6/2012/8).
\textsuperscript{15} See for example UN General Assembly (hereafter UNGA), ‘Girls’, Resolution 64/145 of 1 March 2010 (UN Doc. A/RES/64/145).
\textsuperscript{16} See for example B. Essén and C. Jensen Wilken, ‘How to deal with female circumcision as a health issue in the Nordic countries’, \textit{Acta Obstetricia et Gynecologica Scandinavica} 82 (2003) 683-686.
\textsuperscript{17} B. Duncan, ‘From health to human rights: Female genital cutting and the politics of intervention’, \textit{American Anthropologist New Series} 110(2) (June 2008) 226.
\textsuperscript{18} On this matter, see F.A. Althaus, ‘Female circumcision: Rite of passage or violation of rights?’, \textit{International Family Planning Perspectives} 23(3) (1997) 130-133; M.R. Coffey, ‘From comparison to paradox to the dichotomous nature of international human rights and feminist perspectives of female circumcision as a violation of the human rights of women,’ \textit{Depaul International Law Journal} 4 (2000) 1-15; H. Kalev Dahan, ‘Cultural rights or human rights: the case of female genital mutilation’, \textit{Sex Roles} 51(5-6) (September 2004) 339-348; C. Fernandez-Romano, ‘The banning of female circumcision: cultural imperialism or a triumph for women’s rights?’, \textit{Temple International and Comparative Law Journal} 13(1) (Spring 1999) 137-162; Fisaha, \textit{supra} note 10; A.A. Oba, ‘Female circumcision as female genital mutilation: human rights or cultural imperialism?’, \textit{Global Jurist} 8(3), https://doi.org/10.2202/1934-2640.1286, retrieved 19 December 2018; E. Grande, ‘Hegemonic human
General Assembly asked States for a total ban on the practice, including where it is performed at medical centres; States are requested to intensify global efforts for the elimination of female genital mutilations.\textsuperscript{19}

There are numerous international legal instruments underpinning the ban on female circumcision.\textsuperscript{20} First, female circumcision is considered as a breach of the rights of women. The Declaration on the Elimination of Violence against Women – a ‘soft law’ instrument –, expressly states that the concept of violence includes genital mutilation and any other traditional practices of that nature.\textsuperscript{21} Female circumcision is also contrary to the Convention on the Elimination of All Forms of Discrimination against Women. In accordance with the latter treaty, which France ratified in 1983 and which therefore has binding force there, States must take all measures necessary with a view to achieving the elimination of customary practices which are based on stereotyped roles for men and women or on the idea of the inferiority or the superiority of either of the sexes.\textsuperscript{22} Admittedly, the Convention does not make explicit reference to female circumcision but the Committee monitoring its application takes the view that the practice falls within the scope thereof.\textsuperscript{23}

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\textsuperscript{19} UNGA, ‘Intensifying global efforts for the elimination of female genital mutilations’, Resolution 67/146 of 20 December 2012 (UN Doc. A/RES/67/146); see specifically para. 2 of the Preamble and para. 4 of the Resolution. See also UNGA, ‘Traditional or customary practices affecting the health of women and girls’, Resolution 53/117 of 9 December 1998 (UN Doc. A/RES/53/117); and UNGA, ‘Intensifying global efforts for the elimination of female genital mutilations’, Resolution 71/168 of 19 December 2016 (UN Doc. A/RES/71/168).

\textsuperscript{20} See R. Khosla, J. Banerjee, D. Chou, L. Say and S.T. Fried, ‘Gender equality and human rights approaches to female genital mutilation: A review of international human rights norms and standards’, Reproductive Health 14(59) (2017), https://reproductive-health-journal.biomedcentral.com(track/pdf/10.1186/s12978-017-0322-5, retrieved 19 December 2018.

\textsuperscript{21} See Article 2 of the Declaration, adopted by UNGA Resolution 48/104 of 20 December 1993.

\textsuperscript{22} Article 5 of the Convention on the Elimination of All Forms of Discrimination against Women. Convention adopted by UNGA Resolution 34/180 of 18 December 1979.

\textsuperscript{23} See UN Committee on the Elimination of Discrimination against Women, Female circumcision, General Recommendation no 14 (ninth session, 1990) and UN Committee on the Elimination of Discrimination against Women, Violence against women, General
belief cannot validly be argued in the face of a practice that violates gender equality.\textsuperscript{24}

Female circumcision is also considered as a breach of the fundamental rights of the child. Young girls are protected as minors against it: ‘Traditional practices prejudicial to the health of children’ must be abolished according to the terms of the Convention on the Rights of the Child.\textsuperscript{25} The Committee on the Rights of the Child does not hesitate in regularly reminding those States that are especially concerned of their obligation.\textsuperscript{26}

In Europe, the fight against female circumcision entered a new phase in 2011 with the adoption of the Council of Europe’s Istanbul Convention on preventing and combating violence against women and domestic violence.\textsuperscript{27} This treaty, to which France has been a party since 2014, also recalls that female genital mutilation constitutes ‘a serious violation of the human rights of women and girls’ and ‘a major obstacle to the achievement of equality’ between the sexes.\textsuperscript{28} Moreover, it extends the scope of the repression of FGM by providing that States establish as a criminal offence not only the practice itself but also the act of inciting or forcing a women or girl to undergo such an act, or even the act of furnishing her with the means of doing so.\textsuperscript{29} Echoing the Convention,\textsuperscript{30} the Parliamentary Assembly of the Council of Europe requested, in 2013, that member States establish their extraterritorial jurisdiction in cases of FGM performed overseas.\textsuperscript{31}

It would be a mistake, however, to think that the condemnation of female circumcision was confined to Europe. It can also be seen in Africa: FGM is a ‘harmful practice’ which must be eradicated, according to the terms of the

\begin{footnotesize}
\begin{enumerate}
\item In this sense, see in particular: \textit{Interim Report of the Special Rapporteur on Freedom of Religion or Belief}, 7 August 2013, para. 37 et seq. and para. 43 (UN Doc A/68/290).
\item Article 24 (3), International Convention on the Rights of the Child, adopted by UNGA Resolution 44/25 of 20 November 1989. France ratified the Convention on 7 August 1990.
\item See in particular, UN Committee on the Rights of the Child, \textit{Concluding Observations on Senegal}, 2016, specifically para. 42 (UN Doc CRC/C/SEN/CO/3-5); UN Committee on the Rights of the Child, \textit{Concluding Observations on Togo}, 1997, para. 24 (UN Doc CRC/C/15/Add.83); UN Committee on the Rights of the Child, \textit{Concluding Observation on the Sudan}, 1993, para. 13 (UN Doc CRC/C/15/Add.10).
\item Council of Europe Convention on Preventing and Combating Violence against Women and Domestic Violence, Istanbul, 11 May 2011.
\item See the Preamble to the Convention.
\item Article 38 of the Convention.
\item See Article 44 of the Convention
\item See Resolution 1952 adopted 1 October 2013 by the Assembly at its 31st session, para. 7.5.
\end{enumerate}
\end{footnotesize}
Maputo Protocol to the African Charter on Human and Peoples’ Rights.\(^\text{32}\) In the same vein, ‘State Parties […] shall take all appropriate measures to eliminate harmful social and cultural practices affecting the welfare, dignity, normal growth and development of the child’ and in particular those that are ‘prejudicial to the health or life of the child’, in accordance with the African Charter on the Rights and Welfare of the Child.\(^\text{33}\) The approach taken to female circumcision as a human rights violation now tends to generate consensus within international and regional bodies.

As these legal texts show, ‘attempts to divorce health and human rights concepts have been unsuccessful’.\(^\text{34}\) The alliance persists: female circumcision is considered as a violation of the right to health and bodily integrity. According to the Committee on Economic, Social and Cultural Rights in its General Comment on the right to the highest attainable standard of health, ‘there is a need to adopt effective and appropriate measures to abolish harmful traditional practices affecting the health of children, particularly girls, including (…) female genital mutilation’.\(^\text{35}\) In addition, States have to ‘prevent third parties from coercing women to undergo traditional practices, e.g. female genital mutilation’.\(^\text{36}\) More recently, the Committee went further in its General Comment on the right to sexual and reproductive health.\(^\text{37}\) It asserted that:

States parties have a core obligation to ensure, at the very least, minimum essential levels of satisfaction of the right to sexual and reproductive health; ‘the core obligations include at least (…) to enact and enforce the legal prohibition of harmful practices and gender-based violence, including female genital mutilation.

It specified that ‘violations of the obligation to protect occur when a State fails to take effective steps to prevent third parties from undermining the enjoyment of the right to sexual and reproductive health. This includes the failure

\(^{32}\) See Article 5 of the Protocol to the African Charter on Human and Peoples’ Rights on the Rights of Women 2003.

\(^{33}\) Article 21 of the African Charter on the Rights and Welfare of the Child 1990.

\(^{34}\) B. Duncan, ‘From health to human rights: Female genital cutting and the politics of intervention’, American Anthropologist New Series 110(2) (2008) 226.

\(^{35}\) United Nations Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), 11 August 2000 (UN Doc. E/C.12/2000/4).

\(^{36}\) CESCR, supra note 35.

\(^{37}\) CESCR, General Comment No. 22 (2016) on the Right to Sexual and Reproductive Health (article 12 of the International Covenant on Economic, Social and Cultural Rights), 2 May 2016, (UN Doc. E/C.12/GC/22).
to prohibit and take measures to prevent all forms of violence and coercion committed by private individuals and entities, including (...) harmful practices such as female genital mutilation; Besides, ‘it is also important to undertake preventive, promotional and remedial action to shield all individuals from the harmful practices and norms and gender-based violence that deny them their full sexual and reproductive health, such as female genital mutilation’.

3 Punishing Female Circumcision as Mutilation

In France, the human body is protected and considered as inviolate. Consequently, ‘no mutilating intervention can be undertaken without serious medical grounds’. In such a context, female circumcision is considered as damage; the victim is entitled to compensation. Furthermore, female circumcision performed by one parent without the knowledge of the other may constitute grounds for the withdrawal of rights of access and accommodation.

However, female circumcision is not just a tort under civil law; it is also a criminal offence. Nevertheless, it is not the subject of special legislation: it is apprehended through general legislation such as the law governing violations of the physical or mental integrity of the person. By contrast, female circumcision is explicitly criminalised in other States. This is the case for some African countries such as Senegal, which punishes the violation of ‘the integrity of the genital organ of a person of the female sex by the partial or total ablation of one or several of its parts, by infibulation, anaesthetisation or by any other means’; this is also the case for some European countries such as Belgium, which criminalises the act of ‘performing, facilitating or encouraging any form of mutilation of the genital organs of a person of the female sex, without or without the consent of the latter’.

38 Article R4127-41 of the French Public Health Code; see also Article 16-3 of the French Civil Code.

39 In this sense, see F. Messner, P.H. Prelot and J.M. Woehrling, Droit français des religions (Paris: LexisNexis, 2013, 2e edition) p. 868.

40 Messner et al., supra note 39. Regarding the risk of female circumcision, see e.g., Douai Court of Appeal (chamber 7), Decision of 19 October 2006, No. 05/03743, Juris-Data n° 2006-336693.

41 See Article 222-1 et seq of the French Penal Code.

42 Article 299 bis of the Senegalese Penal Code (Law No. 99-05 of 29 January 1999).

43 See Article 409 of the Belgian Penal Code.
In France, the issue of creating a specific criminal offence also arose but the idea faltered and would now appear to have been dismissed entirely.\textsuperscript{44} Such an incrimination is seen as contrary to the French republican spirit to realise one shared identity: in France, particular attention is drawn to universalism, yet ‘the introduction of a specific penal provision would differentiate between citizens and thus might lead to discrimination and stigmatisation of minority groups’.\textsuperscript{45}

However, the creation of such a criminal offence would be justified nonetheless. Trials for female circumcision concern a cultural norm: it is the rite itself that is put on trial, more than it is the person.\textsuperscript{46} From that perspective, the adoption of a law – ‘the expression of the general will’\textsuperscript{47} and therefore the result of a democratic process – would appear to be the best way of establishing a ban on female circumcision. A specific criminal offence would send out a strong signal against FGM on a social level even where the offence can, in strictly legal terms, be punished on the basis of other offences. Furthermore, special legislation would fulfil a practical purpose insofar as it would serve to take better account of the different types of female genital mutilation as categorised by the World Health Organisation (WHO). Indeed, The WHO identifies different types of mutilation:

- **Type I**: Partial or total removal of the clitoris and/or the prepuce: clitoridectomy;
- **Type II**: Partial or total removal of the clitoris and the labia minora, with or without excision of the labia majora: excision;
- **Type III**: Narrowing of the vaginal orifice with creation of a covering seal by cutting and positioning the labia minora and/or the labia majora, with or without excision of the clitoris: infibulation;
- **Type IV**: All other harmful procedures to the female genitalia for non-medical purposes: scarification, stretching for instance.\textsuperscript{48}

\textsuperscript{44} See CNCDH, \textit{Avis du 28 novembre 2013 sur les mutilations sexuelles féminines} (Opinion of 28 November 2013 on female genital mutilation): ‘There is no specific legal classification for acts of genital mutilation under French law. Such a classification is not desirable insofar as female genital mutilation is an indisputable infringement of physical integrity, sanctioned by the Penal Code.’

\textsuperscript{45} Kool and Wahedi, \textit{supra} note 13.

\textsuperscript{46} G. Giudicelli-Delage, ‘Excision et droit pénal’, \textit{Droit et Cultures} 20 (1990) 207-208.

\textsuperscript{47} Article 6 of the French Declaration of the Rights of Man and of the Citizen, 1789.

\textsuperscript{48} For further information, see http://www.who.int/reproductivehealth/topics/fgm/overview/en/ (as at 22/11/2018). See also McGee, \textit{supra} note 6, p. 134; and Williams-Breault, \textit{supra} note 12.
Pending such a law – were such a law to see the light of day – in France female circumcision is primarily described as ‘violences ayant entraîné une mutilation’ (assault resulting in mutilation), and on that basis falls within the scope of Article 222-9 of the Penal Code. It is worth noting that when, after some hesitation, the practice was first described thus, the case concerned non-ritual circumcision: a French mother of Breton origin, in a fit of lunacy, had mutilated her daughter’s genitals. The choice made in the case to hand down such an unprecedented classification was not without significance. French judges had initially expressed qualms in imposing a criminal standard on a cultural norm; the case concerned presented an opportunity to publicise female circumcision without stigmatising its perpetrators, who are so often foreign nationals.

Assault resulting in mutilation is a misdemeanour offence carrying a sentence of 10 years’ imprisonment. However, where the offence is committed against a minor aged 15 or under (which is often the case in female circumcision matters), it becomes a crime and is then punishable by 15 years’ imprisonment. Furthermore, where the offence is committed by an ascendant, the sentence rises to 20 years. In a scenario where the assault has also resulted in the death of the young girl, female circumcision is punishable under Article 222-7 of the Penal Code (‘violences ayant entraîné la mort sans intention de la donner’ – acts of violence causing an unintended death), which carries a sentence of 30 years’ imprisonment.

Moreover, a criminal conviction for mutilation constitutes grounds for withdrawing a residence permit and for not issuing such a permit. Such a criminal conviction may also constitute a reason for deprivation of French residence permit.

49 Court of Cassation (Criminal Chamber), Decision of 20 August 1983, No. 83-92.616, Bulletin criminel, n° 229.
50 In this sense, CNCDH, supra note 4, p. 10.
51 Art. 222-10 of the French Penal Code.
52 Ibid.
53 Art. 222-8 of the French Penal Code: ‘The penalty incurred is increased to thirty years’ criminal imprisonment where the offence defined under article 222-7 is committed against a minor under the age of fifteen years by a legitimate, natural or adoptive ascendant or by any other person having authority over the minor.’
54 Article R311-14 of the Code of Entry and Residence of Aliens and the Right to Asylum (Code de l’entrée et du séjour des étrangers et du droit d’asile, hereafter CESEDA): ‘Where a foreign national who holds a residence permit is convicted of having committed against a minor under the age of fifteen years the offence defined at Article 222-9 of the Penal Code or of having been an accomplice to the same.’
55 Art. L314-5 CESEDA: ‘A residence permit may not be issued (...) to a foreign national convicted of having committed against a minor under the age of fifteen years the offence defined at Article 222-9 of the Penal Code or of having been an accomplice to the same.’
nationality;\footnote{Council of State (Conseil d’Etat, hereafter CE), decision of 22 February 2008, No. 303709.} bearing in mind that it would apply only to those perpetrators of female circumcision who have acquired French nationality by naturalisation, the latter measure is controversial insofar as it is likely to generate inequality between French nationals.

\section{Rejecting the “Culture” and “Custom” Arguments}

The punishment of female circumcision is first and foremost an issue of culture. Consequently, during criminal trials, the issue of whether the concept of ancestral custom, even religious requirements, would allow a perpetrator to avoid any punishment. Indeed, when questioned, defendants state that ‘our ancestors did it, our parents did it and we cannot do otherwise’.\footnote{See J.P. M’Barga, ‘Excision et migrants de France. 1. Excision, fonction et conséquence de sa répression en milieu migrant en France’, in: E. Rude-Antoine (ed.), \textit{L’Immigration face aux Lois de la République} (Paris: Karthala, 1992) p. 170.} While the argument is often raised by counsel, it has not however been welcomed by the courts. In the 1980s, one investigation chamber pointed out that ‘whilst it is true that, in their original tribal setting, circumcising young girls may be viewed by the accused as a duty that is more customary than religious – as it is widely recognised that not all Muslim women are subjected to this mutilation – the same cannot be said for Garges-lès-Gonesse and the country where they lived for a number of years’.\footnote{Baradji case in 1988, cited in: D. Vernier, ‘Le traitement pénal de l’excision en France: historique’, \textit{Droit et Cultures} 20 (1990) 195-196. For more detail on the consideration given to custom in FGM cases, see: C. Le Bris, ‘La contribution du droit à la construction d’un “vivre ensemble”: entre valeurs partagées et diversité culturelle’, \textit{Droit et Société} 9(1) (2016) p. 82 et s.}

The cultural diversity argument has thus gradually waned as the arsenal of legal measures against female circumcision has strengthened. In 2013, in order to take account of the Council of Europe Convention on preventing and combating violence against women and domestic violence recently signed by France,\footnote{France signed this Convention on 11 May 2011 before ratifying it on 4 July 2014.} a law was passed criminalising ‘the act of making offers or promises to a minor, or offering them any gifts, presents or advantages whatsoever, or using pressure or constraints of any nature whatsoever against them, in order for said minor to submit to genital mutilation’ when – and herein lays the innovation – said mutilation has yet to be carried out.\footnote{Article 227-24-1, para. 1, Penal Code.} In the same vein, acts of direct incitement of others, by one or other of the means mentioned above, ‘to
perform genital mutilation on the person of a minor, where said mutilation is not carried out' now constitutes a criminal offence.61 Prior to this law, in order for such acts to be punishable, the mutilation had to have been carried out, i.e. an advance from word to deed. From that perspective, the legislation strengthens existing protection62 by instituting a preventive criminal offence.63

Where a young girl has already been circumcised, French law also reveals a genuine concern for protecting the victim. Thus, where in principle the limitation period in France is 3 years for misdemeanours and 10 years for crimes and said period begins to run from the time when the offence is committed, in mutilation cases – and particularly those involving genital mutilation – the limitation period is 20 years and only begins to run from the time when the victim reaches legal majority.64 Although they were minors at the time when the offence was committed, women have until they are 38 to file a complaint.

This concern for protecting victims who are minors is all the more striking as this may be against their will. Thus, if a young girl refuses to bring a civil action for damages when a prosecution has already been set in motion (e.g. because she finds it difficult to face her relatives in such a context), an anti-FGM association can exercise those civil-party rights on the girl's behalf without her agreement.65 In the same vein, doctors are not bound by medical confidentiality in genital mutilation cases involving 'a minor or a person unable to protect themselves owing to their age or physical or mental disability'.66 This provision is essential insofar as healthcare professions are often called upon to play a

61 Article 227-24-1, para. 2, Penal Code.
62 For greater detail on this issue, see M. Benillouche, ‘L’interdiction des mutilations sexuelles: entre confirmation et révolution ...’, Revue des Droits Fondamentaux 6 (2014), http://www.revueclf.com/personnes-famille/linterdiction-des-mutilations-sexuelles-entre-confirmation-et-revolution-article/, retrieved 18 December 2018.
63 See S. Grunvald, ‘La répression des mutilations sexuelles féminines: une mise à distance de principe de la diversité culturelle, Brèves remarques à propos de l’avis de la CNCDH du 28 novembre 2013’, Archives de Politique Criminelle 36 (2014) 84.
64 See Article 7 of the French Criminal Procedure Code: ‘The limitation period for the prosecution of the felonies set out in article 706-47 when committed against minors is twenty years, and only starts to run from their coming of age’.
65 See Articles 2-3 of the French Criminal Procedure Code: ‘Any association lawfully registered for at least five years on the date of offence proposing through its constitution to protect or assist children in danger or victims of any form of abuse may exercise the rights granted to the civil party in respect of torture and acts of barbarity, acts of violence and sexual aggressions committed against minors and the offence of endangering minors punished by articles (…) 222-1 to 222-18-1 (…) of the Penal Code, where the public prosecution has been initiated by the public prosecutor or by the injured party’.
66 See Article 226-14 of the French Penal Code.
frontline role in identifying victims of female circumcision.\textsuperscript{67} In practice, ‘despite the fact that not all PMI doctors are willing to report, a larger degree of cooperation between doctors and criminal authorities exists than elsewhere’.\textsuperscript{68}

This policy of punishing female genital mutilation can be seen in cases where female circumcision is performed overseas but is nevertheless punished by French courts. While criminal law applies in theory only on French territory, it can exceptionally take on an extraterritorial dimension. This is the case for instance of FGM which, if performed on a minor who is habitually resident in France, can be sanctioned by the relevant French authorities.\textsuperscript{69} Introduced in 2006,\textsuperscript{70} this option is of real benefit as, while in the 1990s female circumcision was mainly performed on French soil, it is currently performed for the most part during a visit to the parents’ home country, although it sometimes takes place elsewhere without the parents’ knowledge.\textsuperscript{71} In order to prevent such situations occurring, parents may instigate opposition proceedings (before the Prefect)\textsuperscript{72} and apply for an order prohibiting the removal of their child from the territory (before the \textit{juge aux affaires familiales} (Family Court))\textsuperscript{73} or, if the child is the subject of educational assistance measures, before the \textit{juge des enfants} (children’s court).\textsuperscript{74}

While the principle banning female circumcision is clearly established in the French legal order, the perpetrators of this practice are, additionally, \textit{effectively} liable to criminal prosecution. France brings the highest number of prosecutions for genital mutilation in all of Europe.\textsuperscript{75} In 2007, 29 criminal trials took place in France, while in Italy, for 2009 the figure stood at just two (bearing in mind that the number of victims of FGM is significantly lower in France:

\begin{itemize}
\item \textsuperscript{67} In this sense, see \textit{CNCDH}, Opinion of 28 November 2013, cited above.
\item \textsuperscript{68} Kool and Wahedi, \textit{supra} note 13.
\item \textsuperscript{69} See Article 222-16-2 of the Penal Code: ‘In the event that the offences provided at Articles 222-8, 222-10 or 222-12 are committed overseas against a minor habitually resident on French territory, French law shall apply by derogation to the provisions of Article 113-7. Where a misdemeanour is concerned, the provisions of the second sentence of Article 113-8 shall not apply’.
\item \textsuperscript{70} See Article 14 of Law No. 2006-399 of 4 April 2006.
\item \textsuperscript{71} In this sense, see \textit{CNCDH}, Opinion of 28 November 2013, cited above.
\item \textsuperscript{72} See Article 2, 111, 3° of Decree No. 2010-569 of 28 May 2010 on the database of wanted persons.
\item \textsuperscript{73} See Article 373-2-6 of the French Civil Code.
\item \textsuperscript{74} See Article 375-7 of the French Civil Code.
\item \textsuperscript{75} See European Institute for Gender Equality, \textit{Female Genital Mutilation in the European Union and Croatia: Report}, 2013, Belgium, European Union, p. 45, http://eige.europa.eu/sites/default/files/documents/eige-report-fgm-in-the-eu-and-croatia.pdf, retrieved 19 December 2018.
\end{itemize}
35,000 according to recent estimates). For these reasons, a success status is internationally awarded to France. This French ‘success’ can be explained in different ways. First, care providers working in infant and youth health care (Protection Maternelle et Infantile, hereafter: PMI) play a key role: the parents are obliged to have their children undergo medical examinations until the age of six; an examination of the genitals is part hereof and this also applies to immigrants. In addition, ‘for them the fact that PMI offers freely available health care, something they otherwise would not be able to afford, also plays a role’.

Moreover, as stated above, a doctor, discovering a genital mutilation during a medical check, is under the obligation to denounce it and associations are entitled to join as a party during a preliminary judicial investigation. Finally, the organisation of French criminal investigation and more specifically the prominent presence of the investigating judge can also explain the French success:

When the police are on the track of a cutter, they call in an investigating judge, who has wide, independent investigative powers. In combination with PMI’s readiness to provide information in connection with the report, building a criminal case [is] relatively easy.

Nonetheless, it must be acknowledged that French courts have displayed a degree of leniency in sentencing. The cultural background of the accused and the wish not to disrupt family life are stated as reasons for these relatively light sentences. For a long time, sentences were often suspended. They are currently a little more severe but they remain relatively lenient if we consider them in the light of the classification of the offence, namely mutilation.

Thus in France, a couple of Guinean origin, parents to 4 girls who had been circumcised, were convicted of ‘complicity in assault resulting in the mutilation of a minor under the age of 15 by an ascendant’ in June 2012. The parents faced up to 20 years’ imprisonment; the Assize Court at La Nièvre ultimately sentenced them to two years’ imprisonment for the father and 18 months’ imprisonment for the mother. The difficulty lies in the fact that this kind of trial

76 For these figures, see the Communication from the Commission to the European Parliament and the Council, Towards the Elimination of Female Genital Mutilation, (COM/2013/0833).
77 See Kool and Wahedi, supra note 13.
78 Ibid.
79 Ibid.
80 In this sense, R. Libchaber, ‘Circoncision, pluralisme et droits de l’homme’, Recueil Dalloz, 31(7524) (13 septembre 2012) 2044 et seq.
81 See Agence France-Presse (AFP), ‘Excision: 2 ans et 18 mois de prison’, 01/06/2012.
gives the sense that it is not an individual on trial, but an entire community and a rite.

In this respect, the idea of creating a specific criminal offence remains relevant. Female circumcision is not a relic of the past: according to France’s Commission nationale consultative des droits de l’homme (CNCDH – National Consultative Commission on Human Rights), it no longer concerns ‘populations from sub-Saharan Africa only; they have become more widespread and affect a variety of populations’. Furthermore, the target has changed: adolescent girls ‘become a high-risk population’: taken out of school from the age of 11-12, they are forced back to their parents’ country and then circumcised.82 Faced with the continued existence of this practice, its cultural dimension is held at a distance.83

In its 2013 report, the CNCDH stated forcefully that ‘no right to be different, no respect for a cultural identity can legitimise violations of the integrity of the person, which are criminal offences’. From the Commission’s point of view, ‘the legitimate consideration of respect for other cultures cannot induce a relativism that would prevent female sexual mutilation from being understood in terms of violation of the fundamental rights of women’.84 The terminological development is a reflection of that change: the CNCDH recommends the use of the term ‘mutilation sexuelle féminine’ (female sexual mutilation) rather than ‘excision’ or ‘mutilation génitale’ (genital mutilation).85

5 Conclusion

The French success in the area of the fight against FGM is closely linked to criminal policy. In recent years, punishment has intensified under the influence of international law and of the universalisation of the total ban of female circumcision. However, ‘the nationwide familiarity with the punishability of FGM that was generated by the criminal cases has not opened up the issue any further, nor intensified the combat thereof’. Punishing female circumcision is not enough in any assumption, if only because such punishment generally

82 See CNCDH, supra note 44.
83 In this sense, Grunvald, supra note 63.
84 See CNCDH, supra note 44.
85 CNCDH, ibid. Article 227-24-1 of the French Penal Code uses the notion of ‘sexual mutilation’ and not ‘female sexual mutilation’; the omission of the adjective is such as to create confusion: thus worded, the article can apply to FGM and male circumcision: on this issue, see Benillouche, supra note 62.
arises when the ban has been breached. With this in mind, it is supplemented on two levels, by protection and prevention.

As regards protection, in France, refugee status may be granted to girls arriving from a State where they face the threat of sexual mutilation, but also to girls born in France who run the risk of being circumcised if they were to their parents’ country of origin.86 Girls threatened with female circumcision constitute, according to the Conseil d’Etat, a ‘social group’ within the meaning of the Geneva Convention: likely to be persecuted owing to their membership of that group, they are granted asylum in France if they cannot get appropriate protection in their country of origin. According to a study conducted by the United Nations High Commission for Refugees in 2012, France is the European country that receives the greatest number of female asylum seekers from countries where genital mutilation is performed.87

As regards the parents of a girl threatened with female circumcision, the Conseil d’Etat considered in 2013 that insofar as they themselves did not personally face the risk of persecution, they could not be granted refugee status in light of the stipulations of the Geneva Convention.88 In that context, the parents were admittedly likely to obtain a temporary residence permit on the grounds of private and family life, but that was a more precarious status that that of refugee.89 However, the Law of 29 July 2015 on reforming the right to asylum90 brought an end to that paradox, providing that the parents of a

86 See CE (Assembly), decisions of 21 December 2012, No. 332492; No. 332491; No. 332607. On those decisions, see G. Cholet, ‘Droit d’asile: Le Conseil d’Etat aux prises avec les mutilations génitales féminines’, Lettre ‘Actualités Droits-Libertés’ du CREDOF, 18 February 2013. See also CE, 30 December 2014, No. 367428.
87 See European Institute for Gender Equality, supra note 75, p. 25 and 26: ‘A recently published statistical study using this method is the UNHCR study on ‘Female Genital Mutilation and Asylum in the European Union’ (UNHCR, 2012), which calculated estimates of the prevalence of FGM among female asylum seekers in the EU, disaggregating data by the applicants’ countries of origin and their countries of asylum. According to this study, the EU Member States with the highest number of female asylum applicants originating from FGM-practising countries were, in 2011, France (4,210), Italy (3,095), Sweden (2,610), the United Kingdom (2,410), Belgium (1,930), Germany (1,720) and the Netherlands (1,545) (UNHCR, 2012). Compared to 2008, these figures increased in all but two (the Netherlands and Sweden) countries’.
88 See CE, Opinion of 20 November 2013, No. 368676. On this issue, see C. Brice-Delajoux, ‘Quel statut pour les parents des fillettes reconnues réfugiées du fait d’un risque d’excision?’, Lettre ‘Actualités Droits-Libertés’ du CREDOF, 27 December 2013.
89 Refugees are issued 10-year residence permits while the duration of the ‘private and family life’ permit was then one year maximum (since the Law of 7 March 2016 on the rights of foreign nationals in France, multi-annual permits can now, in certain conditions, be issued on the basis of private and family life).
90 Law n° 2015-925 of 29 July 2015 on reforming the right to asylum.
refugee child (unmarried) can now a benefit in their own right of the same residence permit as their child, i.e. a ten-year residence permit.91

As regards the prevention aspect,92 while many years after the first criminal prosecutions for female circumcision, the practice has become an established one, it is because the existing punishment does not suffice and persuasion remains the key. From that perspective, two preventive measures would appear to be essential. Firstly, insofar as female circumcision is most often performed in the parents’ country of origin, co-operation between those countries and France remains fundamental.93 Secondly, while it seems necessary to ‘make women seen and heard on matters of female sexual mutilation’,94 it is equally important increasingly to involve men in prevention measures: according to the findings of the Excision et handicap inquiry published in 2009 by the Institut national d’études démographiques (National Institute for Demographic Studies), men play a major role in the decision to have their daughters circumcised.95 Female circumcision is not, in fact ‘women’s business’ and ‘while men are habitually held responsible for instituting the practice and for its continued existence’, a distinction must be made between patriarchal power and men’s individual situations in order to understand that the facts are ‘more complex and contradictory’. Some in fact do not hesitate in ‘standing against the old ways in order to give rights to their daughters’.96

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91 See Article L314-11, 8°, CESEDA.
92 On this matter, see M. Kwoka, ‘Female Genital Surgeries: Rethinking the Role of International Human Rights Law’, Human Rights Law Commentary, 2007, Vol. 3, https://www.nottingham.ac.uk/hrlc/documents/publications/hracommentary2007/femalegenitalsurgeries.pdf, retrieved 19 December 2018.
93 In this sense, see A. Andro, M. Lesclingand and D. Pourette, Volet Qualitatif du Projet Excision et Handicap (ExH) – Comment Orienter la Prévention de l’Excision chez les Filles et Jeunes Filles d’Origine Africaine Vivant en France: Une étude des Déterminants Sociaux et Familiaux du Phénomène, 2009, p. 73, https://www.ined.fr/fichier/s_rubrique/269/volet_qualitatif_de_exh_rapport_final.fr.pdf, retrieved 19 May 2018: ‘Interviews also demonstrate the need to have an understanding of the fight against female genital mutilation that is shared by countries of the North and the South. Migrants generally keep in touch with their families in the various countries of origin and across borders, the families are attentive and sensitive to the changes at work. Anti-FGM programmes in the countries of origin resonate with migrants in Europe when the denunciation of those practices in the countries of Europe is reflected in public opinion in the countries of origin’.
94 See CNCDH, Opinion of 28 November 2013, cited above.
95 See Andro et al., supra note 93, p. 73; see also, Williams-Breault, supra note 12.
96 Couchard, supra note 5, p. 115.
Selected Legislation and Jurisprudence

European Court of Human Rights

ECHR 2019/6 Case of Milićević v. Montenegro, 6 November 2018, no. 27821/16 (Second Section)

The Facts

In February 2013 an individual, X, attacked the applicant, born in 1966, inside his coffee bar with a hammer. He was taken to hospital with a head injury. X was arrested, prosecuted for violent behaviour against the applicant, and ordered to have mandatory psychiatric treatment in a hospital. At the same time he was found guilty of stabbing another man, VJ, causing him light bodily injuries, four months before the attack on the applicant.

The applicant instituted civil proceedings for compensation, submitting that he had reported X to the police for threatening him a few days before the attack, and that he had already attacked others. The courts ruled against him in 2015, finding that the police had acted as required and that the State was not liable for any damage.

During the proceedings, it transpired that X suffered from schizophrenia and was a long-term psychiatric patient. The courts noted that he had a history of violent behaviour, which included attacking his neighbours and setting his

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1 These summaries are based on the provisional text of the judgements of the European Court of Human Rights. These judgments are still subject to editorial revision before their reproduction in Reports of Judgments and Decisions. For the full provisional text, see: www.echr.coe.int.
A policeman also confirmed in court that he “knew that X always carried a knife” and that the police had often received complaints about him.

X was allowed to start outpatient treatment in November 2015. Since April 2016 he has been having regular monthly check-ups with a specialist.

The Law

**Alleged Violation of Article 8 of the Convention**

The applicant complained under Article 2 (right to life) that by failing to undertake necessary measures, the State had failed to prevent an attack on him by a mentally ill person, a risk of which the police had been aware. The Court considers that the complaint falls to be examined under Article 8 (right to respect for private life).

While the essential object of Article 8 is to protect the individual against arbitrary interference by the public authorities, there may in addition be positive obligations inherent in effective respect for private life, which may involve the adoption of measures in the sphere of relations between individuals. The Court will therefore examine whether the respondent State, in handling the applicant’s case, has been in breach of its positive obligation under Article 8.

The Court appreciates that the competent bodies did intervene after X had attacked the applicant: he was arrested, prosecuted and ordered to undergo mandatory inpatient psychiatric treatment. It is also clear that as of 18 April 2016 he was medically monitored on a regular basis. The Court cannot, however, overlook the fact that it was the domestic authorities’ inactivity and failure to ensure that the applicant was protected after X had threatened him, or to ensure that X was duly provided with psychiatric treatment after he had stabbed V.J., which led to his threat against the applicant materialising. It was only after the applicant had been attacked by X that the State intervened. In this connection, the Court reiterates that the domestic authorities were under a duty to take reasonable preventive measures where they “knew or ought to have known at the time of the existence of a real and immediate risk” to the life or bodily integrity of an identifiable individual.

It is undisputed in the present case that the applicant had notified the police that X had threatened him. Although the threat in itself may not have sounded too ominous, it was coupled with a few other facts. Firstly, less than four months prior to threatening and attacking the applicant, X had left the hospital even though the doctor in charge had considered that he needed to
continue hospital treatment. Secondly, at the time when the applicant complained to the police about X's threats, the police were well aware that X had already attacked others, given that they had often received reports to that effect. The latest such attack had been six days after he had left the hospital contrary to the doctor's recommendation, when he had stabbed V.J. for no reason, inflicting light bodily injuries on him. There is no evidence in the case file that after that attack and before attacking the applicant, X had been taken to any medical centre for an assessment as to whether he represented a danger to others. Although an indictment had been issued against him in that regard, it was not processed until after the attack against the applicant, when the two indictments were processed jointly. Thirdly, the police, on their own admission, also knew that X always carried a knife or some other similar weapon. Nevertheless, the only measure undertaken by the domestic authorities was by the police, who kept an eye open for X around the neighbourhood.

The Court thus notes that: (a) the authorities were aware of the fact that X was a long-term psychiatric patient, that he had a history of violent behaviour, which included attacking his neighbours, setting his flat on fire, and causing a flood in a neighbour's flat, and that he always carried a knife or some other similar weapon; they were also aware of X's previous criminal record and that during those proceedings the domestic courts had established a causal link between X's mental state and the offences he had committed; (b) four months prior to attacking the applicant X had left the hospital of his own will and contrary to the doctor's recommendation; (c) a few days after he had left the hospital he had stabbed V.J. without any reason; (d) there is no evidence that X was medically checked after attacking V.J. in order to ensure that he was taking his medication, which indicates a lack of cooperation between the police and the medical services; (e) the indictment for that attack had been issued but it had not been processed for more than three months, that is until after X attacked the applicant; and (f) the authorities were aware of X's threatening the applicant as the latter reported it to the police. The Court considers that in these circumstances the authorities ought to have been aware of the real and imminent risk of violence against the applicant.

The Court finds that the lack of sufficient measures taken by the authorities in reaction to X's behaviour amounted to a breach of the State's positive obligations under Article 8 of the Convention to secure respect for the applicant's private life.

For these reasons, the Court, unanimously, holds that there has been a violation of Article 8 of the Convention.
The Facts

The applicant, born in 1977, has been serving a life sentence in prison since 2008. In November 2010 and October 2011, he was taken to hospital for medical examinations. After a risk assessment, the prison authorities decided that he had to wear handcuffs and ankle cuffs. He stated that prison officers remained in the examination room with him, that they could overhear his conversation with medical staff and that he had not been allowed to wear his own clothes.

He was also taken to visit his seriously ill newborn daughter in hospital in January 2012, which included the same security measures. He states that he was prevented from touching his child and the officers remained with him all the time, being able to overhear his conversation with his daughter’s doctors.

The applicant complained about the security arrangements for the visits but in January 2013 the administrative court dismissed his complaint in full. His appeal was rejected.

The Law

Alleged Violation of Articles 3 and 8 of the Convention as Regards the Security Requirements of Hospital Visits for Medical Examination of the Applicant

The applicant complained that the conditions resulting from the security requirements of his hospital visits had violated his rights under the Articles 3 (prohibition of inhuman or degrading treatment) and 8 (right to respect for private and family life).

The Court notes that in situations which concern the medical treatment of prisoners, the State authorities have, on the one hand, an obligation to provide detainees with the requisite medical assistance to secure their health and well-being. On the other hand, the States have an obligation under Article 1 of the Convention to secure to everyone within their jurisdiction the rights and freedoms defined in the Convention and that this, taken together with Article 3, requires States to take measures designed to ensure that individuals are not subjected to torture or inhuman or degrading treatment or punishment, including such ill-treatment administered by private individuals.
The Court acknowledges that there might be situations where a prisoner has to be taken to a medical facility outside prison to receive such treatment which the prison itself does not or cannot provide. However, such situations may inevitably entail a risk of the prisoner absconding or posing danger either to themselves or anyone else (for example medical personnel or other patients). The Court is also mindful of the fact that medical staff in ordinary public hospitals cannot be expected to have the same level of preparedness and training as prison officers to deal with possible risks posed by prisoners’ unpredictable or violent behaviour. It is in that light that the obligation of securing to everyone the rights and freedoms defined in the Convention must be underlined. The State authorities must be particularly vigilant when they have sufficient prior knowledge about the possible danger the prisoner might pose (for example previous attempts of escaping or violent behaviour).

In the present case, the Court notes first that the use of prison clothing, the use of handcuffs and ankle cuffs and the requirement to observe the applicant throughout his visits had a basis in domestic law. There is no dispute that such measures served the legitimate aim of preventing him escaping or harming and posing a danger to other people. In the context of Article 8, they can thus be seen to have had the aim of ensuring public safety and protecting the rights and freedoms of others.

The Court will assess next, for the purposes of both Articles 3 and 8, whether the combined use of security measures can be reasonably considered necessary in the light of the above-mentioned objectives. The Court will lay particular emphasis on whether the application of such measures was adapted to the needs of the situation and took into account the specific personality of the applicant.

The Court notes that when authorising the applicant’s visits to the hospitals and drawing up the escort plans, the prison authorities took into account his criminal history – observing that his crimes had become more serious over time – as well as his behaviour in prison. They provided a thorough risk profile, stressing that the applicant did not respect to the prison regime, and was aggressive and capable of attacking others as well as of self-harm. The risk of escaping when escorted outside prison was also highlighted. Against that background, the prison director decided that the applicant had to wear handcuffs and ankle cuffs during the visits and had to be accompanied. The Government submitted further corroborating information, according to which the applicant could be considered to be impulsive, manipulative and violent.

The Court finds that the prison authorities, who were in daily contact with the applicant and who were well aware of the risk he might pose, decided to order the use of above-mentioned security measures after careful
consideration and gave sound reasons for their decisions. The applicant did not challenge the relevant risk assessment, but argued that since he had never tried to escape, less restrictive measures could have been used. However, the aim of the security measures was not only to avoid a possible escape, but also to avoid potential harm to other people as well as to the applicant himself. Against that background, the Court finds that the security measures were directly linked to the applicant’s specific behaviour and, as such, did not exceed what could be reasonably considered necessary.

Furthermore, the Court notes that in the instant case no health-related reasons could be ascertained that would cast doubt on the use of measures of restraint – the applicant was a young man without any particular health concerns – that could have rendered the use of cuffing excessive or contraindicated. Although the handcuffs and ankle cuffs left pressure marks, abrasions and redness on the applicant’s skin, it cannot be concluded from this that excessive force was used when applying them.

The Court is mindful of the confidentiality concern and the distress caused by the presence of the prison officers during the hospital visits. Prisoners have, in the context of the right to private life, the right to medical confidentiality, which should not be encroached upon unless it is necessary in the specific circumstances of the case. Although there is no dispute in the present case that the prison officers accompanied the applicant during the visits, including during his examinations, the parties disagree as to whether there was a screen between the prison officers and the applicant during his medical examinations and whether the prison officers were able to overhear his conversations with the doctors. However, the Court does not find it necessary to determine the exact details of the applicant’s visits to hospitals as it considers that – given the particular circumstances of the instant case – the interference with the applicant’s private life can be considered justified for the same reasons as already indicated above.

In conclusion, the Court finds that the application of those measures did not exceed what could reasonably be considered necessary and thus did not lead to a violation of Article 3. The Court also considers that such measures were necessary for ensuring public safety and protecting the rights and freedoms of others. Accordingly, there has been no violation of 8 of the Convention.

*Alleged Violation of Articles 6 and 8 of the Convention as Regards Certain Aspects of the Applicant’s Visit to See His Daughter*

The applicant complained that the circumstances of his visit to a hospital to see his seriously ill daughter had violated his rights under Article 8 and added, relying on Article 6 § 1 (right to a fair hearing by a tribunal), that this matter
had not been addressed by the domestic courts. The Court considers that the complaint raised by the applicant under Article 6 § 1 is closely linked to his complaint under Article 8 and may accordingly be examined as part of the latter complaint in view of the State’s positive obligations in the sphere of private and family life.

Even though the applicant clearly raised his complaint about the circumstances of the visit to see his daughter in hospital before the domestic courts and the administrative court and the court of appeal also referred to such a complaint in the “facts and proceedings” parts of their respective judgments, neither of the courts addressed this issue on the merits.

It was the role of the domestic courts, in view of the positive obligations arising from Article 8, not only to pay due regard to the private and family life considerations arising from the applicant’s complaint, but also to elucidate the relevant facts necessary to reach a decision and to give reasons when dismissing complaint.

Given that the applicant’s complaint was dismissed without any reasons being given for such a decision, the Court concludes that the domestic courts’ handling of the applicant’s complaint fell short of the State’s positive obligation. Accordingly, it finds that there has been a violation of Article 8 of the Convention.

For these reasons, the Court, unanimously, holds that there has been no violation of Articles 3 and 8 of the Convention concerning the security measures during the applicant’s visits to hospital and that there has been a violation of the State’s positive obligation under Article 8 of the Convention concerning the applicant’s visit to see his daughter in hospital.

**ECHR 2019/8 Case of Ilneher v. Germany, 4 December 2018, nos. 10211/12 and 27505 (Grand Chamber)**

**The Facts**

The applicant, born in 1978, is currently detained in a centre for persons in preventive detention on the premises of Straubing Prison (Germany). He has been in preventive detention since 2008, when he finished a ten-year juvenile sentence for having murdered, at the age of 19, a woman in 1997 while she was out jogging. The crime was sexually motivated. His detention was subsequently
extended by court orders, based upon psychiatric assessments which revealed a high risk that he could commit similar serious crimes of a sexual and violent nature if released.

On 4 May 2011, the Federal Constitutional Court granted the applicant’s constitutional complaint and quashed the order for his subsequently extended preventive detention and remitted the case to the regional court. On 6 May 2011, the regional court, however, once again ordered his provisional preventive detention. The applicant was mainly detained in the preventive detention wing of Straubing Prison.

After a series of appeals the courts ultimately found that his preventive detention had been necessary, as a comprehensive assessment of the applicant, his offence and his development during the enforcement of the sentence revealed that there was a high risk that he could commit serious crimes of a violent and sexual nature, similar to the one he had been found guilty of, if released. The applicant’s appeals against the preventive detention order to the Federal Court of Justice and the Federal Constitutional Court were dismissed.

Since 20 June 2013, the applicant has been detained in a newly-built preventive detention centre at Straubing Prison. He took up one-to-one psychotherapy from June 2015 until June 2017. The proceedings for review of his provisional preventive detention lasted in total 11 months and one day over three levels of jurisdiction, of which eight months and 22 days were before the Federal Constitutional Court.

The Law

This summary is restricted to the issues raised under Article 5 § 1 of the Convention.

**Alleged Violation of Article 5 § 1 of the Convention**

The applicant complained that his “retrospectively” ordered preventive detention executed on the basis of the regional court’s 3 August 2012 judgment from 20 June 2013 onwards in the Straubing preventive detention centre had been in breach of his right to liberty, as provided in Article 5 § 1.

**Grounds for the Deprivation of Liberty**

The Court will examine whether the applicant’s detention can be justified as detention of a person of unsound mind for the purposes of Article 5 § 1 (e). This requires that, at the relevant time of the decision ordering his preventive
detention on 3 August 2012, the applicant was reliably shown to be of unsound mind, that is, a true mental disorder must have been established before a competent authority on the basis of objective medical expertise.

The Court observes that the regional court, which had consulted two external psychiatric experts, was convinced that the applicant suffered from a sexual preference disorder, namely sexual sadism, as described by the relevant tool for the classification of diseases, the International Statistical Classification of Diseases and Related Health Problems in its current version (ICD-10). The court was satisfied that the applicant has had fantasies of sexual violence entailing attacks on the neck and the strangulation of women and masturbation on their inanimate bodies. That sexual sadism was of a serious nature and had affected the applicant’s development since his adolescence. The mental disorder had caused and been manifested in his brutal offence and still persisted. The applicant therefore suffered from a mental disorder for the purposes of the Therapy Detention Act.

The Court reminds that the notion of “persons of unsound mind” (“aliéné” in the French version) in Article 5 § 1 (e) of the Convention might be more restrictive than the notion of “mental disorder” (“psychische Störung”) referred to in the Therapy Detention Act. However, the Convention does not require that the notions used in domestic law, and in particular the notion of mental disorder for the purposes of the Therapy Detention Act, be defined or interpreted in the same manner as terms used in the Convention. What is decisive is whether the domestic courts have established a disorder which can be said to amount to a true mental disorder as defined by this Court’s case-law. In this context, the Court again stresses the need to interpret the permissible grounds for deprivation of liberty narrowly.

In the present case, the domestic courts, as detailed above, found the applicant to suffer from a form of sexual sadism which must be considered as being of a serious nature. The applicant’s condition necessitated comprehensive therapy, to be provided either in the preventive detention centre or in a psychiatric hospital. The Court is therefore satisfied that the condition with which the applicant was diagnosed amounted to a true mental disorder for the purposes of Article 5 § 1 (e). Furthermore, the Court is satisfied that the regional court’s finding, confirmed on appeal, was based on objective medical expertise.

As to whether the domestic courts “established” that the applicant suffered from a true mental disorder for the purposes of Article 5 § 1 (e), the Court notes that the regional court, in the impugned judgment of 3 August 2012, thoroughly scrutinised the findings made in the reports of the two psychiatric experts.
it had consulted, as well as the findings of numerous medical experts who had previously examined the applicant since his arrest following his offence, and decided on that basis that the applicant suffered from sexual sadism.

The Court does not overlook in this context the fact that the regional court concluded that the applicant suffered from this serious mental disorder, whereas the trial court had not considered that the applicant had suffered from a severe mental disorder and had therefore found that he had acted with full criminal responsibility when committing his offence in 1997. This does not, however, suffice to cast any doubt on the establishment of the facts by the domestic courts concerning the applicant’s mental condition.

Finally, the validity of the applicant’s continued confinement depended upon the persistence of his mental disorder. In accordance with the German Criminal Code, the domestic courts could order the continuation of his preventive detention in the subsequent periodical judicial review proceedings only if, and as long as, there was a high risk that he would reoffend as a result of that disorder if released. Nothing in the file indicates that this risk had ceased to exist during the period of time at issue in the present case.

The Court therefore concludes that the applicant was a person of unsound mind for the purposes of Article 5 § 1 (e).

“Lawful” Detention “in Accordance with a Procedure Prescribed by Law”

As for the lawfulness of the applicant’s detention, the Court notes that the detention was ordered in a judgment of the regional court of 3 August 2012, and confirmed on appeal, under the Juvenile Courts Act, read in conjunction with the Federal Constitutional Court’s judgment of 4 May 2011.

The lawfulness of the applicant’s detention under Article 5 § 1 (e) further requires the detention to have been effected in an appropriate institution for mental-health patients. During the period from 20 June 2013 until 18 September 2014, the applicant was detained in the newly-established Straubing preventive detention centre.

The Court notes that there had been a change in the medical and therapeutic care provided for him in that centre, compared to the conditions prevailing in Straubing Prison. The Court observes that a total of 71 members of staff are in charge of a maximum of 84 detainees in the Straubing preventive detention centre. In particular, one psychiatrist, seven psychologists, one physician and four nurses are entrusted with providing medical and therapeutic treatment.

A broad range of treatment is provided for persons suffering from mental disorders, such as treatment programmes for violent or sexual offenders, individual therapy tailored to the detainee’s needs, group social therapy and individual social pedagogical support, if necessary involving external therapists.
The applicant was offered, in particular one-to-one or group social therapy, an intensive treatment programme for sexual offenders and therapy administered by an external psychiatrist.

The Court takes note of the applicant’s argument that, despite these elements, the preventive detention centre was not an appropriate institution for mental health patients as the majority of the persons placed in the centre had not been found to suffer from a mental disorder. However, as mentioned above, the applicant is being provided with an individualised therapy programme tailored to his needs and his mental condition. The Court is satisfied that the applicant was offered the therapeutic environment appropriate for a person remanded as a mental health patient and was thus detained in an institution suitable for the purposes of Article 5 § 1 (e).

Given that in the circumstances of the instant case the domestic courts, with the help of expert advice, established a considerable danger for the individuals concerned of becoming the victims of one of the most serious offences punishable under the German Criminal Code, the Court is satisfied that the applicant’s deprivation of liberty had also been shown to have been necessary in the circumstances.

For these reasons, the Court holds, by fifteen votes to two, that there has been no violation of Article 5 § 1 of the Convention.

*Dissenting opinion* of Judge Pinto de Albuquerque joined by Judge Dedov stating that “the retrospective conversion of a time-limited punitive security measure into a potentially life-long pseudo-medical confinement measure imposed on convicted offenders with *ex nunc* established ‘mental disorders’ is an historically and dogmatically unreasonable, let us say it, abusive interpretation that not only goes beyond the nature and purpose of the measure of preventive detention, but circumvents the prohibition of *nulla poena sine lege praevia* guaranteed in a State governed by the rule of law.”

**ECHR 2019/9 Case of X v. the former Yugoslav Republic of Macedonia, 17 January 2019, no. 29683/16 (First Section)**

**The Facts**

At birth (in 1987) the applicant, X, was registered as a girl, with a clearly female name. From an early age X became aware that he was male rather than female. In 2010 X went to a specialist clinic in Belgrade, where a psychologist
and sexologist diagnosed him with “transsexuality”. X started taking hormones to increase his testosterone levels, as recommended by the clinic. In June 2011 X applied for a change of his first and family name. The Ministry of the Interior allowed that application, registering X under a clearly male forename and issued X with a new identity card. However, the sex/gender marker and numerical personal code remained the same, identifying X as a female. In July 2011 X requested to have the sex/gender marker and the numerical personal code on his birth certificate corrected to indicate that he was male. However, the Ministry of Justice (“the Ministry”) dismissed X’s application on the grounds that there was no official document showing the applicant had changed gender.

X appealed to the Ministry, alleging that there was no statutory provision that regulated the matter. Sex reassignment surgery was unavailable in his home country and unjustified in his case. Furthermore, such a requirement would subject him to unwanted medical treatment and sterilisation. He argued that he had already been diagnosed as transsexual, which was sufficient to obtain legal gender recognition. In October 2011 the Ministry dismissed the appeal, but in February 2013 the administrative court quashed the Ministry’s decision.

In June 2013 X underwent a double mastectomy (breast removal) and continued his hormone therapy. In the resumed proceedings, the authorities instructed the Forensic Institute to examine X and it found that he should be provided with a document attesting to his new sex.

However, in December 2014 the Ministry again dismissed his request to alter the sex/gender marker in the birth register, as it had still not obtained “evidence of an actual change of sex”. Fresh proceedings before the administrative court are still ongoing. X submitted reports from 2012 and 2016 showing that the protracted procedure on the legal recognition of his gender identity has had negative consequences on his mental health and life.

The Law

**Alleged Violation of Article 8 of the Convention**

The applicant complained under Article 8 (right to respect for private and family life) of the lack of a regulatory framework for the legal recognition of his gender identity and about the requirement, which had no basis in domestic law, that he undergo genital surgery as a precondition for having his (male) gender identity recognised.
Preliminary Remarks: Whether the Case Concerns Interference or a Positive Obligation

The Court considers that the primary question to be determined is whether or not the respondent State failed to comply with its positive obligation to put in place an effective and accessible procedure, with clearly defined conditions securing the applicant’s right to respect for his private life. The answer to that question would be determinative for the other aspect of the applicant’s complaint – namely that he was allegedly compelled to undergo complete gender reassignment surgery in order to have his sex/gender marker changed in the birth register. This is so given the fact that that aspect concerns a specific requirement which allegedly was imposed by the authorities to be fulfilled by the applicant, as a pre-operative transsexual who has undergone partial surgery.

Compliance with the State's Positive Obligation

The Court notes that there is no provision in the domestic law that explicitly allows the alteration of a person's sex/gender marker in the civil status register, unlike the right to have a person's personal name changed. Furthermore, the legislation does not impose any terms and conditions to be fulfilled and procedures to be followed. Similarly, no provision clearly specifies the body that has jurisdiction to decide such a request (unlike a request for a change of a personal name).

The Court observes that the registry refused on two occasions to change the applicant’s sex/gender marker in the birth register from a female to a male one owing to the absence of documentary evidence attesting to his altered sex. However, the registry did not specify the nature of that evidence. The administrative court referred to that omission in remitting the case for reconsideration. The Court attaches weight to the fact that the Government did not present any evidence that those issues, including the procedure for obtaining the relevant evidence were regulated by law or that there was established judicial practice regarding the matter. In so far as it may be inferred from the Government's submissions that a judicial declaration by the administrative court acknowledging the applicant’s new gender identity could be relied upon by the registry in making the change sought, it is to be noted that that court did not decide on the applicant’s case on the merits, even though it had examined it on two occasions. Lastly, it is not without relevance that the registry, in its last decision of 28 February 2018 – namely six and a half years after the applicant had initiated the impugned proceedings – declared that it did not have the authority to decide on the applicant’s claim.
All the above is sufficient for the Court to conclude that the current regulatory framework in the respondent State on legal gender recognition leaves a number of important questions unanswered. Among them is the existence and nature of any requirement that a claimant needs to fulfil in order to have the sex/gender marker in the official records changed. Furthermore, the Court was not presented with any evidence that there was any (let alone settled) jurisprudence specifying any such requirement. The applicant argued that he had been compelled to undergo complete gender reassignment surgery in order to have the sex/gender marker changed in the birth register. Assuming that the early findings of the administrative authorities may have pointed to such a conclusion, the Court observes that no definitive position was taken on the matter. It is to be noted that the applicant’s claim to be granted a new male sex/gender marker was not finally dismissed, and the impugned proceedings are still pending. Accordingly, any conclusion as to whether the applicant, as a pre-operative transsexual who has undergone partial surgery, will be allowed to have his preferred gender legally recognised would veer precariously close to speculation.

The Court finds that the circumstances of the case reveal legislative gaps and serious deficiencies that leave the applicant in a situation of distressing uncertainty vis-à-vis his private life and the recognition of his identity. The Court concludes that the current legal framework in the respondent State does not provide “quick, transparent and accessible procedures” for changing on birth certificates the registered sex of transgender people.

For these reasons the Court holds, by five votes to two, that there has been a violation of Article 8 of the Convention on account of the lack of a regulatory framework ensuring the right to respect for the applicant’s private life.

*Dissenting opinion* of Judges Pejchal and Wojtyczek, defending the view that the applicant’s request to have the sex marker modified has not been examined within a reasonable time because of procedural mistakes made by the domestic authorities in application of the existing rules, not because of problems with the interpretation or the content of any legal provisions.

*Joseph Dute*

Professor of Health Law, Faculty of Law, Radboud University, Nijmegen,
The Netherlands
Selected Legislation and Jurisprudence

European Court of Justice

2019/2, Novartis Farma SpA v. Agenzia Italiana de Farmaco (AIFA) e.a. 29AB, 21 November 2018 (case C-29/17)

General Context

The European Court of Justice has delivered this judgement after it had received a request for a preliminary ruling. It is about the question whether national measures, which lay down the conditions under which the national healthcare insurance system, for financial reasons, reimburses Avastin re-packaged in order to be administered to patients for the treatment of ophthalmological indications not covered by its MA, frustrate the effectiveness of Dir. 89/105 and of Dir. 2001/83.

The Facts

The request has been made in the context of proceedings between Novartis Farma SpA, on the one hand, and the Agenzia Italiana del Farmaco (AIFA) (Italian Medicines Agency) (‘the AIFA’), Roche Italia SpA and the Consiglio Superiore di Sanità (Federal Board of Health, Italy) (‘the CSS’), on the other, concerning the entry of a medicinal product, used off-label for the treatment of eye diseases, onto the list of medicinal products reimbursed by the Servizio Sanitario Nazionale (National Health Service, Italy) (‘the SSN’).

Lucentis and Avastin are biotechnological products subject to the marketing authorisation (MA) centralised procedure laid down in Reg. No 726/2004. The MA for Avastin, granted in 2005, covers cancer treatments exclusively, and is held by a company belonging to the Roche pharmaceutical group.
The MA for Lucentis was granted in 2007. It relates to the treatment of eye disease, in particular, age-related macular degeneration. A company belonging to the pharmaceutical group Novartis, to which Novartis Farma belongs, holds that MA. From the explanations of the referring court, it follows that those medicinal products differ both structurally and pharmacologically, as well as in terms of their packaging and unit price. Although based on the same technology, these medicinal products have different active ingredients, ‘ranibizumab’ for Lucentis, and ‘bevacizumab’ for Avastin.

Avastin is often prescribed for treating ophthalmological diseases that are not mentioned in the MA. Avastin must then be extracted from its original vial and divided into single-use 0.1 ml syringes for intravitreal injection. When used for ophthalmologic purposes, the repackaged Avastin costs the SSN EUR 82 per dose and Lucentis EUR 902.

By decision No 24823 of 27 February 2014, the Autorità Garante della Concorrenza e del Mercato (Authority responsible for competition compliance and enforcement of market rules, Italy) fined Roche and Novartis for infringement of competition law. In an action brought against that decision, the Consiglio di Stato (Council of State, Italy) referred questions to the Court of Justice for a preliminary ruling, to which the Court replied in its judgment of 23 January 2018, F. Hoffmann-La Roche and Others (C-179/16, EU:C:2018:25).

On 15 April 2014, the CSS issued an opinion on the use of Avastin in ophthalmology, which states that the preparation of that medicinal product for intravitreal use is a ‘sterile magistral pharmaceutical preparation’. In keeping with that opinion of the CSS, the AIFA entered the use of Avastin for the treatment of age-related macular degeneration onto the list of reimbursable medicinal products pursuant to Art. 1(4)bis of Decree-Law No 536/96.

Novartis Farma challenged the opinion of the CSS of 15 April 2014 brought an action before the Tribunale amministrativo regionale per il Lazio (Regional Administrative Court, Lazio, Italy). Following the decision to dismiss that action, Novartis Farma appealed against that decision before the Consiglio di Stato (Council of State). In those proceedings, it submitted that for the SSN to allow reimbursement of the ophthalmologic use of Avastin laid down in Art. 1(4)bis of Decree-Law No 536/96 is incompatible with EU pharmaceutical law.

In those circumstances, the Consiglio di Stato decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling.
Considerations Made by the Court

By its questions, the referring court wishes to ascertain whether the national measure, which lay down the conditions under which the national healthcare insurance system, for financial reasons, reimburses Avastin repackaged in order to be administered to patients for the treatment of ophthalmological indications not covered by its MA, frustrate the effectiveness of Dir. 89/105 and of Dir. 2001/83 and the powers conferred on the European Union under the centralised procedure introduced by Reg. No 726/2004.

The organisation and management of health services and the allocation of the resources are the responsibility of the Member States. Art. 4(3) of Dir. 2001/83 and the second paragraph of Art. 1 of Reg. No 726/2004 state that the provisions of those instruments do not affect the powers of Member States’ authorities as regards setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes on the basis of health, economic and social conditions.

Nonetheless, in exercising those powers Member States must comply with EU law. In addition, the EU rules on pharmaceutical products prohibit neither the off-label prescription of a medicinal product nor its repackaging for such use but do require that they comply with the conditions laid down in those rules.

In order to ascertain whether national measures are precluded by the conditions laid down in the EU rules, the second question referred on the contours of the scope of Dir. 2001/83 must be considered and then, the first, fourth and third questions referred for a preliminary ruling.

By its second question, the referring court asks, whether Art. 3(1) of Dir. 2001/83 must be interpreted as meaning that Avastin, after being repackaged according to the conditions laid down by the national measures, falls within the scope of that directive.

In the case in the main proceedings, the application of Dir. 2001/83 to Avastin has not been called into question. By contrast, the referring court asks whether the transformations which that medicinal product undergoes when

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1 Judgment of 2 April 2009, A. Menarini Industrie Farmaceutiche Riiunite and Others, C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07, EU:C:2009:217, paras. 19 and 20.

2 Judgment of 23 January 2018, F. Hoffmann-La Roche and Others, C-179/16, EU:C:2018:25, para. 59.
being repackaged for the purposes of its use in treating eye diseases not covered by the terms of its MA, in circumstances in conformity with the national measures the legality of which is challenged, may fall within the scope of Ar. 3(1) of that directive and therefore take Avastin thus modified outside of the scope of the directive.

In accordance with the essential aims of Dir. 2001/83, inter alia, to safeguard public health, recital 35 thereof states that the directive aims ‘to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the [European Union] through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions’. As the Advocate General stated in point 63 of his Opinion, that objective would be defeated if a repackaging process undertaken after a medicinal product had been placed on the market could have the effect of excluding that product from the scope of Directive 2001/83 within which it had until then fallen.

The answer to the second question is therefore that Art. 3(1) of Dir. 2001/83 must be interpreted as meaning that Avastin, after being repackaged according to the conditions laid down by the national measures at issue in the main proceedings, falls within the scope of that directive.

By its first question, the referring court asks whether Art. 6 of Dir. 2001/83 must be interpreted as precluding national measures which determine the conditions under which Avastin may be repackaged in order to be used for the treatment of ophthalmological indications not covered by its MA and, if so, whether Art. 5 of that directive must be interpreted as allowing such measures to be justified as a derogation.

As has mentioned above, the EU rules on pharmaceutical products prohibit neither the off-label prescription of a medicinal product nor its repackaging for such use, but do require that they comply with the conditions laid down in those rules.

Those conditions include the requirement of holding an MA and manufacturing authorisation. In a case similar to that at issue in the main proceedings the Court held that the repackaging of Avastin for off-label use in the treatment of eye diseases did not require a new MA, provided that that process does not result in any modification of the medicinal product, and that it is carried out solely on the basis of individual prescriptions making provision for that process.3 The reasoning behind that decision is that, contrary to the facts of the

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3 Judgment of 11 April 2013, Novartis Pharma, C-535/11, EU:C:2013:226, para. 42.
case which gave rise to the judgment of 19 September 2002, Aventis (C-433/00, EU:C:2002:510), the process of repackaging Avastin takes place prior to that medicinal product being placed on the market, after a doctor has prescribed its use in such conditions for a patient through an individual prescription.

The Court thus stated that the drawing off of liquid medicinal products from the original vials, and the transfer into ready-to-use syringes of the portions so drawn off, without any modifications of those products, is in reality analogous to actions which, in the absence of another undertaking's activities, could otherwise be, or have been, carried out, under their responsibility, by doctors prescribing the treatment or by pharmacies themselves in their dispensaries, or else in hospitals (judgment of 11 April 2013, Novartis Pharma, C-535/11, EU:C:2013:226, paragraphs 42 and 43).

Subject to factual findings to be made by the referring court, the repackaging of Avastin under the conditions laid down in the national measures at issue in the main proceedings, does not therefore require an MA to be obtained in so far as that process is prescribed by a doctor by means of an individual prescription and undertaken by pharmacists for that medicinal product to be administered in hospitals.

As the Advocate General stated in point 79 of his Opinion, despite the fact that it may be found before the referring court that the pharmacies authorised to divide up and repackage Avastin under the national measures do not hold the authorisation required under Art. 40(1) of Dir. 2001/83, those pharmacies could nevertheless fall within the exception under the second subparagraph of Art. 40(2) of that directive. Subject to findings of fact to be made by the referring court, it must be held that if it is found that, in accordance with the national measures at issue in the main proceedings, Avastin is, on the basis of an individual prescription, repackaged to be used off-label for the treatment of eye diseases, by a pharmacy lawfully authorised to that effect, for that medicinal product to be administered in hospitals, such a process falls within the exception of the directive and does not require manufacturing authorisation.

Since the process of repackaging Avastin covered by the decisions of the AIFA at issue in the main proceedings does not require an MA under Art. 6 of Dir. 2001/83 or manufacturing authorisation, within the meaning of Art. 40 of that directive, it is not necessary to answer the first question in so far as it concerns the interpretation of Article 5 of the directive.

Hence, the answer to the first question is that Art. 6 of Dir. 2001/83 must be interpreted as not precluding national measures which lay down the conditions under which Avastin may be repackaged in order to be used for the treatment of ophthalmological indications not covered by its MA.
By its fourth question, the referring court asks whether Art. 1(3) of Dir. 89/105, according to which nothing in that directive is to permit the marketing of a medicinal product in respect of which the MA provided for in Art. 6 of Dir. 2001/83 has not been issued, must be interpreted as precluding national measures such as those at issue in the main proceedings.

Given the answer to the first question, there is no need to answer the fourth question.

By its third question, the referring court asks whether Arts. 3, 25 and 26 of Reg. No 726/2004 must be interpreted as precluding a national measure that authorises the AIFA to monitor medicinal products such as Avastin, whose off-label use is reimbursed by the SSN, and, where relevant, introduce measures necessary to safeguard patient safety, on the grounds that that measure encroaches on the exclusive powers of the EMA in respect of medicinal products subject to the centralised procedure.

Reg. No 726/2004 confers exclusive responsibility for evaluating applications for an MA under the centralised procedure on the EMA. However, as mentioned above, repackaging Avastin under the conditions set by national measures does not require an MA to be obtained. Accordingly, those measures cannot undermine the exclusive powers conferred on the EMA in evaluating applications for MA under the centralised procedure any more than Art. 1(4) bis of Decree-Law No 536/96.

As regards the pharmacovigilance system for medicinal products placed on the EU market, that system also covers any use of a medicinal product outside the terms of its. As regards medicinal products covered by the centralised procedure, Chapter 3 of Title II of Regulation No 726/2004, in particular Articles 25 and 26 thereof, introduces pharmacovigilance mechanisms bringing together the national competent authorities and the EMA, the latter of which ensures their coordination. Those articles do not preclude a national measure that authorises the AIFA to activate the appropriate monitoring mechanisms to safeguard patient safety and to take the necessary decisions in good time, provided that their implementation furthers or reinforces the pharmacovigilance system introduced by Reg. No 726/2004.

Therefore, the answer to the third question is that Arts. 3, 25 and 26 of Reg. No 726/2004 must be interpreted as not precluding a national measure which authorises the AIFA to monitor medicinal products such as Avastin the
off-label use of which is reimbursed by the SSN and, where relevant, to introduce measures necessary to safeguard patient safety.

An Baeyens
European Commission, DG Internal Market, Industry, Entrepreneurship and SMEs, Brussels, Belgium

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4 EU Official. The information contained in this contribution is not binding for the European Commission and does not present an official position of the European Commission.
Announcement

The Seventh Conference of the European Association of Health Law Conference will be held on 25-27 September 2019 in Toulouse, France, under the auspices of the Secretary of the Council, Mr. Thorbjørn Jagland. The conference is entitled: “Innovation and Healthcare. New Challenges for Europe”.

The main topics will be: access to health care and innovation, e-health and data protection, empowerment and involvement of patients in innovative healthcare, innovative healthcare and patient rights, innovative health products and research, innovative medicine, intellectual property, links with ethics and law in innovative healthcare, etc.

Interest-groups are welcome to organise a workshop.

Online registration and abstract submission was launched in October 2018, the deadline is 15 May 2019.

Conference website: https://eahl2019.sciencesconf.org/.
Contact: aduguet@club-internet.fr.
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