D3.2: Analysis of the legal and human rights requirements for Human Enhancement Technologies in and outside the EU

[WP3 – Human enhancement: ethical, legal and social analysis]

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Due date	29 March 2019
Delivery date	29 March 2019
Type	Report
Dissemination level	PU = Public

Keywords	Human enhancement, legal analysis, human rights, international laws, regional laws, national laws, regulation

The SIENNA project - *Stakeholder-informed ethics for new technologies with high socio-economic and human rights impact* - has received funding under the European Union's H2020 research and innovation programme under grant agreement No 741716.

Abstract

This report will help readers better understand the international, EU and selected countries' legal developments and approaches to specific legal issues and human rights challenges related to human enhancement. The report broadly discusses the legal issues and human rights challenges of human enhancement. It analyses relevant international, EU and regional laws and human rights standards. It summarises and compares the results of the country studies on law and human enhancement. It also discusses the adequacy of existing norms and standards and gaps and presents some recommendations that will be further developed in the forthcoming SIENNA work.

Document history

Version	Date	Description	Reason for change	Distribution
V1.0	4 February 2019	First Draft	Develop draft, comparative analysis and finalise	D3.2 contributors and reviewers
V2.0	29 March 2019	Comments	Address feedback and comments from partners and reviewers.	

Information in this report that may influence other SIENNA tasks

Linked task	Points of relevance
Task 5.6: Enhancement of the existing legal framework by networking with legislators and relevant committees about the three topics	Based on the results of Tasks 2.2, 3.2 and 4.2, task 5.6 will identify potential changes needed in the existing legal and human rights frameworks (i.e., international, EU and/or national) that might be necessary or desirable in order to create an environment in which the proposed codes of conduct could be implemented most effectively.
Task 6.2: Adapt and exploit methods developed in this project for legal analysis of emerging technologies in other domains	Task 6.2 will draw on the results included here (to analyse the possibilities for the general application of our approach for legal and human rights analysis, with reference to other types of future and emerging technologies).

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Executive summary

This report analyses legal and human rights requirements for Human Enhancement Technologies in and outside the EU. It implements the approach elaborated in the SIENNA methodological handbook.[1]

The basic normative presupposition[2] of this report is that the development and use of new technologies, including HETs, ought to remain consistent with fundamental rights and respect human dignity. Human rights are considered the touchstone for regulation and are treated as setting standards for other laws.

Given this fundamental idea, Chapter 1 of the report outlines the objectives, research questions and research methods, as well as the report's scope and limitations.

Chapter 2 summaries legal issues raised by HETs, including human rights implications, both supporting their use and limiting such uses due to concerns for human rights abuses. It is based on a literature review. In this chapter we first discuss legal issues raised by two broad categories of HETs: products and devices. We then turn to specific legal issues, such as: civil liability for HETs, including products liability and professional liability; issues related to property (ownership and patents); security and criminal liability issues; questions raised in the context of employment law, such as safe work practice, pressure to enhance and risk of discrimination; and issues related to family law, including children's rights, parental responsibility and authority. Finally, we offer a brief summary of other human rights challenges not explicitly covered in previous sections but that are relevant to all of the previously outlined issues, focusing on self-determination and autonomy.

Chapter 3 presents an overview of relevant international laws adopted by the UN and its specialized agencies (UNESCO and WIPO) and WTO. The selection of the legal sources analysed in Chapter 3 directly follows from the list of legal issues in Chapter 2. We analyse international human rights documents focusing on the prohibition of torture and cruel, inhuman and degrading treatment, the prohibition of arbitrary and unlawful interference with one's privacy, the right to health and the right to enjoy the benefits of scientific progress. We look at international standards on bioethics, guidelines on consumer protection, IP regulation and the international drug control regime. We conclude that international law provides an important point of reference for the regulation of HETs, as it addresses, directly or indirectly, many legal issues implicated by human enhancement. The impact of the development and use of HETs on human rights makes international human rights law a natural starting point for setting legal standards on HETs. We also note the tension between approaches adopted by international human rights law and the international drug control regime.

Chapter 4 presents an overview of regional human rights regimes and explores provisions that are relevant for the regulation of HETs. As designed in the SIENNA Handbook, this chapter looks at the Council of Europe (CoE), the Organization of American States and the African Union. It maps relevant sources of laws and specific provisions that are pertinent for the regulation of HETs. In this chapter, we conclude that in the case of CoE, human rights challenges raised by HETs will most likely be assessed through standards of the prohibition of torture and inhuman or degrading treatment and the right to respect for private and family life. The remaining two regional human rights regimes discussed in this Chapter have established other autonomous rights that may be particularly relevant for HETs, most notably the right to have one's physical, mental, and moral integrity respected.

[1] See SIENNA, *D1.1: The consortium's methodological handbook*, 30 April 2018.
[2] On "normative clarity" as a criterion to evaluate legal scholarship, see: Rubin, Edward L., "On beyond Truth: A Theory for Evaluating Legal Scholarship", *California Law Review*, Vol. 80, Issue 4, July 1992, pp. 915-917.

In Chapter 5 we present an analysis of relevant EU laws and human rights standards. We first map the EU laws against the legal issues outlined in Chapter 2. We then analyse selected EU legislation and assess the potential challenges arising from its application to HETs. We discuss the relevance of the EU law on medical devices, certain aspects of EU pharmaceutical legislation, and EU legislation on product safety and liability. As far as fundamental rights protection is concerned, we focus on protection of the right to bodily and mental integrity. We conclude that EU law provides a basis for the adoption of harmonization measures related to HETs. One of the key challenges is related to the fact that existing criteria for building risk profiles of new technologies may not be appropriate or satisfactory in the case of HETs.

Chapter 6 summarises and discusses results of country studies. It is based on twelve country reports prepared by SIENNA partners from the following countries: Brazil, China, France, Germany, Greece, the Netherlands, Poland, South Africa, Spain, Sweden, UK and USA. It provides an overview of legal developments relating to national-level legislation relevant to HETs and summarize main lines of inquiry relevant to HE pursued by national legal scholars. It compares legal responses to two groups of specific questions. The first group of questions is rooted in the debate on the distinction between therapy and enhancement. National partners were asked to examine how this demarcation is reflected in national laws by looking at the existing legal demarcations relevant to future regulation of HETs. The second group of questions focuses on the right to integrity. The purpose of this part of the study was to see whether national laws provide guidance or set limits to the types of interventions that are lawful.

Chapter 7 contains an elaboration of the following general conclusions. Surveys of the current legal landscape revealed that there is not yet much law that explicitly addresses HETs. Some law, especially medical law, is adjacent to HET law, and it has been or might be extended into the area of HETs. Other laws, for example product liability laws, apply to HETs by virtue of their general nature. The common thread that runs through different challenges posed by HETs is how to balance guarantees of individual autonomy with the need to ensure safety, while also remaining mindful of wider societal impacts of HETs. This assertion leads to two basic questions. First, whether and to what extent human rights norms are fit to meet this challenge. Second, if this is the time to adopt laws that provide explicitly for HETs. Existing human rights frameworks have accompanied many technological advancements and, as “living instruments”, they remain relevant for HETs. Legal orders analysed for the purposes of this report are consistent in the protection of rights that are at risk due to development and use of HETs. Development and proliferation of HETs reignites debates about the meaning and limits of some basic legal concepts. The interpretation of human rights in the context of HETs remains to be determined. In the future it may fall on domestic courts to decide whether a given claim should be satisfied as a matter of right. In general, the direction of human rights law rather consistently supports autonomy and self-determination. Within the human rights discourse there are, however, markers that seem less supportive of individual choice. This thread is related to a specific, conservative conceptualization of human dignity reflected, for example, in Art. 3 of the Charter of Fundamental Rights. This provision, based on the Oviedo Convention, is rooted in a vision of human dignity that functions to protect the intrinsic worth of the individual and the dignity of the human species as such, rather than individual choice. Other, more liberal, conceptualizations of dignity are, however, also possible. If human rights are to set standards for other laws, regulators need to be mindful of these different ideas of human dignity. As far as the second question is concerned, we conclude that before any laws are amended to accommodate HET (or HET laws are adopted), there is a need to revisit the model for risk/benefit analysis used in the case of new technologies, since the current model does not fully encompass potential (ethical and societal) risks and benefits. In addition to the above conclusions, Chapter 7 contains a list of measures that could help in ensuring that the rights and safety of any person participating in any kind of enhancement procedure are protected. These measures are based primarily on the analysis of national laws.

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List of acronyms/abbreviations

Abbreviation	Explanation
ACHR	American Convention on Human Rights/Pact of San Jose
ACHPR	African Charter on Human and People's Rights
AU	African Union
CJEU	Court of Justice of the Europan Union
CoE	Council of Europe
CRC	Convention on the Rights of the Child
CRPD	Convention on the Rghts of Persons with Disabilities
CS	Common specification
D	Deliverable
DBS	Deep Brain Stimulation
DoA	Description of Action
EC	European Commission
ECHR	European Convention on Human Rights
EctHR	European Court of Human Rights
ESC	European Social Charter
EU	European Union
FDA	Federal Drug Administration
GDPR	General Data Protection Regulation
HE	Human enhancement
HET	Human enhancement technology
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IDCR	International Drug Control Regime
MDD	Medical Devices Directive
OAS	Organization of American States
OAU	Organization of African Unity
STOA	Science and Technology Options Assessment
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UN	United Nations
UNESCO	United Nations Education Scientific and Cultural Organisation
VDPA	Vienna Declaration and Programme of Action
WHO	World Health Organization
WIPO	World Intellectual Property Organization

WTO	World Trade Organization

Table 1: List of acronyms/abbreviations

Glossary of terms

Term	Explanation
Human enhancement / human enhancement technology	A modification aimed at improving human performance and brought about by science-based and/or technology-based interventions in or on the human body (SIENNA D3.1, p.9)
Hard law	authoritative rules backed by coercive force exercised at the national level by a legitimately constituted (democratic) nation-state and constituted in the supranational context by binding commitments voluntarily entered into between sovereign states (typified by public international law[3]
Law	Encompasses both hard law and soft law (SIENNA D1.1, p.30)
Regulation	The intentional use of authority to affect behaviour of a different party according to set standards. Law is one of the institutions for purposively attempting to shape behaviour and social outcomes, but there may be other means, including the market, social norms, and technology itself. Regulation can also mean a species of hard law, e.g., a type of EU legal act with a direct effect defined by Article 288 of the Treaty on the Functioning of the European Union[4] or, in some instances, a legal act adopted at the national level.
Soft law	Normative, non-binding instruments emanating from law-making bodies including resolutions, recommendations, guidelines, communications, notices etc. (public, top-down instruments). The lack of binding force is the main feature distinguishing soft from hard law.[5]

Table 2: Glossary of terms

[3] Brownsword, Roger, Eloise Scotford and Karen Yeung, "Law, Regulation and Technology: The Field, Frame, and Focal Questions", in Roger Brownsword, Eloise Scotford and Karen Yeung (eds.), *The Oxford Handbook of Law, Regulation and Technology*, Oxford University Press, Oxford, 2017, pp. 3-40.

[4] According to this provision, "To exercise the Union's competences, the institutions shall adopt regulations, directives, decisions, recommendations and opinions. A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States. A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods. A decision shall be binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them. Recommendations and opinions shall have no binding force."

[5] Goncales, Maria Eduarda, and Maria Ines Gameiro, "Hard Law, Soft Law and Self-regulation: Seeking Better Governance for Science and Technology in the EU", Working paper, 2011. https://www.researchgate.net/publication/272351073_Hard_Law_Soft_Law_and_Self-regulation_Seeking_Better_Governance_for_Science_and_Technology_in_the_EU

1. Introduction

1.1 Objectives and research questions

The basic normative presupposition[6] of this report is that the development and use of new technologies, including HETs, ought to remain consistent with fundamental rights and respect human dignity. Throughout the report, human rights are considered the touchstone for regulation and are treated as setting standards for other laws.

The objectives of the SIENNA legal research have been pre-defined in the Description of Actions (DoA). Under this directive, SIENNA is expected to meet the following objectives in relation to HET[7]:

1. Map and study relevant norms from international and regional legal orders;
2. Explore how HET might affect the rights of individuals and groups;
3. Explore which human rights standards may be relevant to consider in establishing methods to avoid or alleviate negative impacts and encourage positive impacts of HETs;
4. Analyse selected EU and non-EU countries' legislation pertinent to HE;
5. Compare national laws against the international and regional norms and human rights standards;
6. Analyse the findings in terms of their regulatory-design characteristics.

Based on the objectives outlined above, the legal research carried out for the purpose of this report has been guided by the following questions:

- What are the international and regional laws relevant to human enhancement?
- Which rights of individuals (or groups) may potentially be affected by developments of human enhancement? Which human rights standards may be relevant to consider in establishing methods to avoid or alleviate negative impacts and encourage positive impacts of those developments?
- To what extent are the existing legal frameworks adequate to deal with challenges posed by developments of human enhancement?
- How might specific novel legal questions be solved in different jurisdictions according to different legal systems? What are the commonalities and differences between national legal systems with respect to those questions?
- What are the convergences, divergences and gaps between national and international legal orders for the three technologies? What are the possible ways to overcome the gaps?

1.2 Methods

The SIENNA Handbook (D1.1)[8] outlined the methods and approaches for analysing international, regional and national laws.

As far as method is concerned, a combination of doctrinal, functional and law-in-context methods, with preference for the former, has been used to address the research questions. The initial step

[6] On "normative clarity" as a criterion to evaluate legal scholarship, see: Rubin, Edward L., op. cit., July 1992, pp. 915-917.
[7] See SIENNA, *D1.1: The consortium's methodological handbook*, 30 April 2018.
[8] *Ibid*.

consisted of mapping the subject of our research by identifying the main legal issues, including human rights implications.

We then, using desktop research, studied relevant international norms and regional legal orders. We identified relevant organisations and mapped applicable international sources of hard and soft law. The selection of the legal sources was influenced by the identified legal issues. In the next phase we analysed EU law in light of the issues, accounting for distinct features of the EU legal system. We focused on the areas of law that raise HET-specific challenges. We analysed the extent to which addressing the identified legal issues lies within the competences of the EU. Afterwards, we conducted a comparative analysis of certain aspects of selected EU and non-EU countries' legislation pertinent to the area of human enhancement. The analysis was accompanied by an overview of national legal developments and a brief summary of the main lines of inquiry relevant to HE pursued by national legal scholars. We then conducted a cross-level comparison between national and international levels to identify convergences, divergences and gaps.

1.3 Scope and limitations

The scope of the report is pre-defined by the SIENNA project. It does not cover issues related to genetic enhancement, as these questions are addressed separately in Work Package 2 on genomics.

As far as practical limitations are concerned, due to time constraints it was not possible to carry out a comprehensive comparison between different national jurisdictions that would cover all legal issues and all areas of law. In order to address this challenge, in the case of country reports we have decided to limit the study to specific legal issues.[9]

The key substantive challenge was the lack of HET-specific laws. In such cases we built on general concepts, e.g. the right to integrity, and assessed their relevance to HETs. By analogy, we argued whether the same laws could apply in novel contexts, e.g. whether laws governing cosmetic surgery could provide a reference point or even a model for other cases of human enhancement.

1.4 Structure of the report

Chapter 2 outlines legal issues and human rights challenges of HETs. It is based on a literature review. Chapter 3 presents an overview of relevant international laws. Chapter 4 discusses regional human rights orders. In Chapter 5 an analysis of selected relevant EU laws is presented. Chapter 6 summarises and discusses results of country studies. It consists of an overview of national legal developments and legal scholarship. Chapter 7 presents a general analysis and discussion. It also presents some recommendations that will be further developed and operationalized in forthcoming SIENNA work. The guidelines for country studies, as well as country reports, are presented in the Annex.

2. Legal issues and human rights challenges of HET

Human enhancement technologies (HETs) entail a number of legal issues, including human rights implications, both supporting and limiting their use due to concerns for human rights abuses. This chapter reviews 35 articles and legal texts written by legal scholars and policymakers between 2008

[9] National partners carried out the national research within 0.6 person-months which amounts to ca. 12 working days.

and 2017[10] to identify the key legal issues raised by existing and emerging human enhancement technologies, including the numerous human rights challenges and opportunities presented by such technologies.

2.1 Regulating HETs: Devices and Drugs

One of the primary legal questions raised by HETs involves the level of regulation for pre-market approval that ought to govern these unique technologies. HETs that fall under existing regulatory regimes—or that might fall under such regimes in the future—can be categorized into two distinct categories: devices and drugs. Though these groups do not encompass all classes of HETs, both imaginable and currently existing, they represent a demarcation currently recognized by existing law[11] and largely adhered to by legal scholars. This section will therefore consider both categories in turn.

2.1.1 Regulating HE Devices

Currently, human enhancement devices do not fall under any specific existing regulatory regime beyond basic product safety requirements. For example, the European Medical Devices Directive (MDD)[12] distinguishes sharply between devices that are used for a medical purpose as opposed to those that are used by healthy individuals, drawing such a line based on how manufacturers market their devices. Thus, devices that are marketed for "diagnostic and/or therapeutic purposes"[13] are regulated under the MDD, whereas those marketed solely for enhancement purposes are excluded. [14]

The treatment/enhancement distinction, as applied to human enhancement devices, has been criticized by many scholars as arbitrary,[15] citing both the blurred line between health and illness and the inconsistencies that result from identical devices being used for different purposes.[16] The

[10] Some legislation referred to throughout the chapter dates from earlier than 2008 but is included in this review as it remains in effect today.

[11] The European Union and the United States, for example, both currently recognize this demarcation via their distinct regulations for medical devices and for drugs. The European Union regulates medical devices via the European Medical Devices Directive (93/42/EEC) and the United States regulates medical devices via the Federal Food Drug & Cosmetic Act (21 C.F.R. § 800-1299). (See Maslen, Hannah, "Toward an Ethical Framework for Regulating the Market for Cognitive Enhancement Devices", in Fabrice Jotterand and Velko Dubljević (eds.), *Cognitive Enhancement: Ethical and Policy Implications in International Perspectives*, Oxford University Press, New York, NY, 2016, pp. 275-292.) Both the European Union and the United States, along with almost every other country, regulate drugs through the international drug control regime. (See Bublitz, Jan-Christoph, "Drugs, Enhancements, and Rights: Ten Points for Lawmakers to Consider", in Fabrice Jotterand and Velko Dubljević (eds.), *Cognitive Enhancement: Ethical and Policy Implications in International Perspectives*, Oxford University Press, New York, NY, 2016, pp. 309-328.)

[12] European Parliament and the Council, Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993.

[13] *Ibid*., Article 1(2)(a).

[14] But see Annex XVI (European Parliament and the Council, Regulation 2017/745/EU of 5 April 2017 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, extending existing regulations to include specified HETs, to go into effect 26 May 2020.

[15] Still others criticize the distinction beyond its arbitrariness, arguing that the value judgments inherently contained within such views diminish the value of those whose natural capabilities fall below the thresholds set as standards, such as those with disabilities. (See, for example, Karpin, Isabel, and Roxanne Mykitiuk, "Going Out on a Limb: Prosthetics, Normalcy and Disputing the Therapy/Enhancement Distinction", *Medical Law Review*, Vol. 16, Issue 3, October 2008, pp. 413-436.)

[16] Bockman, Collin R., "Cybernetic-Enhancement Technology and the Future of Disability Law", *Iowa Law Review*, Vol. 95, Issue 4, May 2010, pp. 1315-1340.

arbitrariness of such inconsistencies is compounded when recognizing the reality that devices marketed as medical are often likely to be used in non-medical settings (and vice versa).[17]

Regardless of their views on efficacy of the treatment/enhancement distinction, scholars have identified four distinct levels of regulation by which human enhancement devices could be governed: (1) no regulation (beyond existing product safety requirements; the status quo); (2) regulating through the existing legal regime (e.g. the Medical Devices Directive, with regulations less strict than, equally as strict as, or stricter than those currently in place for medical devices); (3) creating a new regulatory regime specifically for human enhancement devices; (4) banning them entirely.[18]

Most scholarly debate focuses on variations of the second and third options rather than favouring a complete ban[19] or, conversely, a complete lack of regulation. Both the second and third models (or any degree of regulation) involve a weighing of risks and benefits, ultimately considering whether consumer protection or consumer freedom should win out in cases where the relationship between such risks and benefits are unclear. Additional complications arise in conducting risk/benefit analyses in the context of HETs because, as Maslen et al. discuss,[20] benefits are more difficult to quantify in cases of enhancement than they are in medical situations, given the MDD's focus on effectiveness in calculating benefits. As Maslen explains, whereas medical devices "either succeed or fail in improving or maintaining health to a measurable degree… [cognitive enhancement devices] confer benefits that are more subjective."[21] While some argue that the subjectivity inherent in the benefits of human enhancement devices prohibits a traditional risk/benefit analysis,[22] Maslen maintains that the effectiveness of a given benefit *can* be measured; it is the *value* of such a benefit that is subjective and unique to any given individual. Thus, Maslen argues, benefits should be understood more broadly, and, in the case of human enhancement devices, "the requirement of strong evidence of benefit should… be relaxed."[23]

In applying this broader understanding of benefits, Maslen et al. have advocated for the second regulatory approach: extending the existing MDD to include cognitive enhancement devices, particularly through a positive list of specific devices[24] (rather than modifying the existing directive to include a new category of devices, which may be over inclusive). Specifically, they propose that experts determine the risks presented by any given device, and that both a low- and high-threshold for risk be determined, outside of which any devices would be completely unregulated and completely banned, respectively. For any devices presenting a moderate level of risk, Maslen argues, "given that all people will *value* these benefits to different degrees, … the risk benefit assessment should err on the side of

[17] *Ibid*., p. 1331.
[18] Maslen, Hannah, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu, op. cit., March 2014, pp. 68-93.
[19] Scholars cite concerns regarding unregulated, illicit use of human enhancement technologies as a primary reason for preferring regulation over total prohibition. See, for example, De Ridder, Dirk, Sven Vanneste and Farah Focquaert, "Outstanding questions concerning the regulation of cognitive enhancement devices", *Journal of Law and the Biosciences*, Vol. 1, Issue 3, September 2014, pp. 316-321.
[20] Note that Maslen's writings focus exclusively on *cognitive* enhancement devices, thus not explicitly applicable to a number of non-cognitive enhancers, such as devices that promise performance benefits rather than cognitive ones.
[21] Maslen, Hannah, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu, op. cit., March 2014, pp. 68-93.
[22] *Ibid*., p. 83.
[23] *Ibid*., p. 87.
[24] The European Union chose to adopt this approach in 2017 via Directive 2017/745/EU. See Annex XVI (*supra* note 17).

allowing consumers to decide whether the risks are worth taking."[25] In promoting this approach, Maslen gives more weight to consumer freedom than consumer safety, explaining that, because users of enhancement devices are not in medical need, they are less vulnerable to pressure to use such devices and therefore best suited to weighing the risks and benefits themselves. Manufacturers would be required to provide consumers with comprehensive information regarding the risks and benefits of their devices to enable users to make such decisions.[26]

Alternative approaches to Maslen's model have also been urged by scholars, including a more risk-averse approach advocated by Palmerini and an approach that regulates use proposed by De Ridder. Conversely to Maslen's conclusion, Palmerini argues when there is a medical need, interventions provide "clear advantages" that justify "that moderate or even substantial risks… be tolerated"[27]. However, "in the absence of such a qualified therapeutic function", as in the case of HETs, "only minimal risks should be considered acceptable, regardless of any subjective appreciation of the inherent benefits."[28] Thus, adequate warning labels are insufficient for regulating human enhancement devices; rather, "a common European stance, which would lay down the overarching principles and criteria to be respected" is required.[29] Palmerini also cites the need for clearer research guidelines as support for regulation of HETs, explaining that the lack of existing regulation in clinical trials is "insufficient both in adequately protecting the patients undergoing scientific tests, and in enabling them to benefit as much as possible from the therapeutic function of the tested devices."[30]

Alternatively, De Ridder et al. advocate for the regulation of enhancement devices through both product safety rules as well as regulations regarding the personal use of such devices, specifically in a manner similar to the regulation of the use of alcohol.[31] Citing primarily unknown safety risks, along with a lack of knowledge regarding the actual benefits of many such devices, the authors argue that regulation of devices alone is insufficient. Rather, "adequate regulation likely requires minimal professional oversight (e.g. a training session with a trained health care professional) before *personal* use should be allowed."[32]

Finally, other scholars have noted a need for considerations beyond merely the factors of consumer protection and consumer freedom that are weighed by risk/benefit analyses. Brownsword calls for two stages of scrutiny to be applied to any proposed regulatory regime: (1) whether a particular enhancement violates rights recognized by the community (e.g. x-ray vision as violation of privacy rights); (2) whether the enhancement proposed presents any threats to a community's ability to engage in "a moral way of life."[33] He concludes that "[o]nly if a proposal satisfies each limb of the test should it be given regulatory clearance."[34] Such human rights implications will be considered in greater detail in Section 2.7.

[25] Maslen, Hannah, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu, op. cit., March 2014, pp. 68-93.
[26] *Ibid*., p. 93.
[27] Palmerini, Erica, "A legal perspective on body implants for therapy and enhancement", *International Review of Law, Computers & Technology*, Vol. 29, Issue 2-3, 2015, pp. 226-244.
[28] *Ibid*., p. 233.
[29] *Ibid*.
[30] *Ibid*., p. 240.
[31] De Ridder, Dirk, Sven Vanneste and Farah Focquaert, op. cit., September 2014, pp. 316-321.
[32] *Ibid*., p. 321.
[33] Brownsword, Roger, "Regulating Human Enhancement: Things Can Only Get Better?", *Law, Innovation and Technology*, Vol. 1, Issue 1, 2009, pp. 125-152.
[34] *Ibid*.

In addressing concerns raised specifically by the regulation of human enhancement in children, Hagger and Johnson endorse Brownsword's approach while also articulating an emphasis on the autonomy of children in determining whether or not to enhance themselves.[35] Specifically, they argue that legally competent children, not their parents, should decide whether to use cognitive enhancements, and in the case of children who are not legally competent, they should be as fully involved in the decision-making process as possible. Others highlight the need for a special approach for children, given the unique importance of the development of the brain in children, as opposed to adults whose brains have fully developed.[36]

2.1.2 Regulating HE Drugs

Drugs currently used for enhancement are in most cases developed for medical purposes. As medical products, they are subject to pharmaceutical laws that entail clinical testing and pre-market approval procedures. Moreover, drugs used for human enhancement fall under the international drug control regime (IDCR). In the specific context of human enhancement drugs, a number of unique legal issues are implicated, especially related to whether the existing IDCR is an appropriate tool for regulating such drugs.

The IDCR has long been widely criticised by users, scientists, academics, and others as inflexible, arbitrary (citing, for example, the omission of alcohol and tobacco but the inclusion of less-addictive drugs like marijuana), and even harmful to public health.[37] As applied to human enhancement drugs, some scholars advance even harsher criticisms while others support its application to such non-medical uses of drugs.

Much like the regulatory regime for devices, the existing drug regime is founded on a balancing of risks and benefits, and in doing so, distinguishes between therapy and enhancement,[38] banning any use "other than [for] medical or scientific purposes."[39] In the context of applying the existing drug regime to cognitive enhancement drugs, Bublitz calls for a re-evaluation of the enhancement/treatment dichotomy, pointing out that "the categories of illness and health and, correspondingly, of treatment and enhancement [are] somewhat arbitrary cut-offs in a continuum of mental capacities and properties."[40] Moreover, Bublitz questions the analysis on which the distinction is based: because it distinguishes between treatment and enhancement, the cost/benefit analysis used by the IDCR only considers strictly medical benefits, thereby categorically excluding any non-"therapeutic or scientific" benefit—which constitute the *entirety* of benefits when it comes to human enhancement drugs.[41]

Bublitz thus finds the IDCR particularly troublesome, because of both its reliance on this clear distinction and the extreme consequences of such reliance: by drawing these harsh lines, the IDCR either totally permits or totally bans any given substance from the entire population. As an alternative to this strict dichotomy, Bublitz calls for a more nuanced approach, such as a prescriptive model, that

[35] Hagger, Lynn, and Gareth Hagger Johnson, "'Super Kids': Regulating the Use of Cognitive and Psychological Enhancement in Children", *Law, Innovation and Technology*, Vol. 3, Issue 1, 2011, pp. 137-166.
[36] Maslen, Hannah, Brian D. Earp, Roi Cohen Kadosh and Julian Savulescu, "Brain stimulation for treatment and enhancement in children: an ethical analysis", *Frontiers in Human Neuroscience*, Vol. 8, Article 953, 2014, pp. 1-5.
[37] Bublitz, Jan-Christoph, op. cit., 2016, pp. 309-328.
[38] Bublitz explains that in the specific context of drugs, enhancement falls under a broader category of 'nontherapeutic' use, which "unofficially, … is often indiscriminately termed 'recreational use' [and] includes consumption for leisure as well as enhancement." *Ibid*., p. 311.
[39] *Ibid*.
[40] *Ibid*., p. 316.
[41] *Ibid*., p. 317.

considers individual levels of usage and the threat of addiction or risk from their individual usage, noting that a majority of drug users do not cause a majority of the problems associated with drug use.[42] For such individuals, Bublitz believes that autonomy, along with a number of other human rights to be addressed below, requires that the IDCR be modified to allow access to cognitive enhancement drugs through a less restrictive model.

As an alternative to Bublitz's criticisms, Hall and Strang outline the justifications for the existing regime as applied to cognitive enhancers. They argue that regulating such drugs outside of the IDCR faces a number of barriers that may be insurmountable, such as reluctance of pharmaceutical companies to participate (given the existing markets for their medicinal products).[43] Moreover, "in the absence of good evidence about their safety and efficacy when used for [cognitive enhancement], prohibition is a precautionary response that is justified by the argument that it will minimize the risk of serious adverse health outcomes that could occur if these drugs were allowed to be used recreationally."[44]

Similar to cognitive enhancers, performance enhancement drugs are governed by the IDCR, though they raise some specific legal issues of their own. In the specific realm of sports doping, Posner advocates a law and economics approach over governmental regulation, explaining that because "the 'problem' of sports doping has only a minor public dimension" (namely, that doping can affect viewers' enjoyment of athletes' performances), "its solution can largely be left to the free market."[45] Moreover, the free market is well-equipped to address the problem, because, if viewers do care about the effects of doping on athletes, then "it is in the financial self-interest of the owners of professional [and amateur] sports teams… to prevent drug taking or other interventions that alter or obscure" such performances.[46]

Coleman and Coleman, however, criticize Posner's liberal approach for failing to properly account for a number of public harms caused by doping that they maintain are equally as significant as Posner's concern for market inefficiencies.[47] Among these harms are, for example, damage to athletes who choose not to use performance enhancement drugs; adverse health risks; and the harm to children who idolize professional athletes.[48] Thus, Coleman and Coleman's argument provides support for some form of regulation beyond Posner's unrestricted *laissez faire* recommendation.

2.2 Civil Liability for HETs: Product Liability and Professional Liability

Beyond regulatory regimes that determine which products are suitable to be placed on the market in the first place, HETs raise a number of legal issues once in the market, including who is responsible for harm that occurs as a result of their use. In this respect, HETs implicate issues of both product liability and professional liability, given that they include both products for personal use as well as services offered by medical or other professionals.

[42] *Ibid*.
[43] Hall, Wayne, and John Strang, "Challenges in regulating the use of stimulant drugs for cognitive enhancement in normal individuals", in Ruud ter Meulen, Ahmed Mohammed and Wayne Hall (eds.), *Rethinking Cognitive Enhancement*, Oxford University Press, Oxford, 2017, pp. 296-297.
[44] *Ibid.*, p. 299.
[45] Posner, Richard A., "In Defense of Prometheus: Some Ethical, Economic, and Regulatory Issues of Sports Doping", *Duke Law Journal*, Vol. 57, No. 6, April 2008, pp. 1725-1741.
[46] *Ibid.*, p. 1734.
[47] Coleman, Doriane Lambelet, and James E. Coleman Jr., "The Problem of Doping", *Duke Law Journal*, Vol. 57, No. 6, April 2008, pp. 1743-1794.
[48] *Ibid.*

2.2.1 Product Liability

In many countries, HETs that are products (as opposed to services, like cosmetic surgery) fall under existing product safety and liability rules, which set minimum safety requirements for products and determine who is responsible for injuries caused by defective products.[49] Legal scholars have noted, however, that HETs create new difficulties and uncertainties within these existing rules, given the complexities of many such products.

As Roosendaal notes, for example, one such possible complication results from difficulties in determining what constitutes a "defective" product in the context of HETs, specifically in human information and technology (ICT) implants, given that "damage" may take the form of no effect (when one was anticipated) or an effect that was not intended but also is not in itself harmful.[50] Moreover, once a product has been deemed defective, product liability law generally provides for its replacement, but this can be difficult, risky, or even impossible in the case of implants.[51] Finally, Roosendaal notes that products liability requires proof of causation, which might be especially difficult in cases of HETs given that they often include multiple complex components, including connections to databases and software. In the event of an injury, therefore, causation may be difficult to prove, "since several people may be involved in the development, manufacturing, programming, and implementation process."[52]

Additionally, Goold notes that under existing product liability schemes (in the United Kingdom, for example), producers bear the risk of harms that are knowable at the time of manufacturing, exempting them from harms resulting from unforeseeable risks.[53] Consumers, therefore, are left to bear such risks, which may be particularly high given the relative lack of knowledge regarding the effects of many HETs. Moreover, as Goold explains, existing product liability rules only serve to compensate victims after harms have occurred, rather than preventing them in the first place.[54] This can be particularly disconcerting because it allows manufacturers to build the cost of such harms into the cost of their products, thus passing the cost on to consumers rather than bearing the costs themselves. This may serve to prevent manufacturers from taking beneficial steps in reducing the harmfulness of their products, a fact that supports the calls by many academics and scholars for additional regulations for HETs.

2.2.2 Professional Liability

[49] For example, in the European Union, the General Product Safety Directive (European Parliament and the Council, Directive 2001/95/EC of 3 December 2001 on general product safety, OJ L 11, 15 January 2002) and the European Products Liability Directive (European Parliament and the Council, Directive 85/374/EEC of 25 July 1985 on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 7 August 1985) govern product safety and liability, respectively, and apply to HETs. (See Maslen, Hannah, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu, op. cit., March 2014, pp. 68-93, and Roosendaal, Arnold, "Carrying Implants and Carrying Risks; Human ICT Implants and Liability", in Mark N. Gasson, Eleni Kosta and Diana M. Bowman (eds.), *Human ICT Implants: Technical, Legal and Ethical Considerations*, Vol. 23 of Information Technology and Law, T.M.C. Asser Press, The Hague, 2012, pp. 69-79.)
[50] Roosendaal, Arnold, op. cit., 2012, pp. 69-79.
[51] *Ibid.*, p. 75.
[52] *Ibid.*
[53] Goold, Imogen, "The legal aspects of cognitive enhancement", in Ruud ter Meulen, Ahmed Mohammed and Wayne Hall (eds.), *Rethinking Cognitive Enhancement*, Oxford University Press, Oxford, 2017, pp. 250-273 (referring to the Consumer Protection Act of 1987 which implemented the Product Liability Directive 85/374/EEC).
[54] *Ibid.*

Given that many HETs, such as implants, require or involve procedures performed by professionals, HETs raise a number of unresolved questions regarding professional liability, particularly medical liability. First, some scholars argue that at least some HETs, such as cognitive enhancement devices (CEDs), ought to require administration or oversight by professionals, as such "experts may be better suited to safeguard the correct use of CEDs."[55] However, there is uncertainty as to whether doctors are even *allowed* to perform such procedures for enhancement rather than medical purposes.[56] Moreover, such a requirement would also entail determining which types of professionals fulfil the requirement, as well as what liability rules apply after having performed or overseen a human enhancement procedure.

Within existing medical liability rules, the legal implications for professionals are governed largely by national regulations.[57] Such national regulations primarily take the form of either strict liability or negligence, with no-fault serving as a third, less popular approach. In cases of negligence, determinations of liability require that a professional perform below the duty of care required of them. In cases of HETs, however, what that level of duty is may be uncertain because, as Roosendaal notes, there is no duty to achieve a result, "mean[ing] that the mere (careful) implantation [might be] sufficient to avoid liability, regardless of whether the implant has the intended effect."[58] Uncertainties also exist regarding what amount of information medical professionals would be required to give to their patients to release them from liability, given requirements for informed consent and the lack of clarity surrounding the exact effects of many HETs.[59]

A final complicating factor created by HETs regarding medical liability is that they have the possibility of altering the standard of care required by medical professionals. As Goold and Maslen explain, as enhancements, such as cognitive enhancers like modafinil that fight fatigue, become more widely used within the medical profession, the norm for doctors regarding what level of fatigue they can withstand, for example, may increase, thereby creating potential liability for doctors who choose *not* to use such drugs.[60] A corollary concern is also created by those who do choose to enhance themselves when injuries occur as a result of such enhancement, as it is uncertain whether they would (or should) be held to a higher standard of care.[61] Finally, Goold and Maslen note that there are arguments that medical professionals are morally obligated to use enhancements when doing so benefits their patients, though the authors ultimately conclude that, under existing law, such obligations are highly unlikely to be legally required.[62]

2.3 Property Law: Ownership and Patents

HETs implicate a number of legal questions regarding the ownership of devices or products that have become incorporated into the human body, such as implants. Palmerini argues that the existing legal framework is largely capable of resolving such questions of ownership, as the existing system addresses these issues in the context of treatment, and "an argument can be made, which has already proved to be successful in courts, that technological artefacts that function as therapeutic aids deserve the same treatment as body parts."[63] She clarifies, however, that this reasoning is limited only to

[55] De Ridder, Dirk, Sven Vanneste and Farah Focquaert, op. cit., September 2014, pp. 316-321.
[56] Roosendaal, Arnold, op. cit., 2012, pp. 69-79.
[57] *Ibid.*, p. 71.
[58] *Ibid.*, p. 72.
[59] *Ibid.*, p. 78.
[60] Goold, Imogen, and Hannah Maslen, "Must the Surgeon Take the Pill? Negligence Duty in the Context of Cognitive Enhancement", *The Modern Law Review*, Vol. 77, Issue 1, 2014, pp. 60-86.
[61] *Ibid.*
[62] *Ibid.*, p. 60.
[63] Palmerini, Erica, op. cit., 2015, pp. 226-244.

devices that "assist essential capabilities related to the fundamental rights to health or bodily integrity," as it is those rights that afford such protection.[64] Others argue for greater property rights over HETs, claiming that "technological products that serve a bodily function, [even when] not attached to the body, should be treated as body parts. As a consequence, they should be considered as market-inalienable things…, since a widely shared principle in the European community prohibits commercially exploiting the body and its detached parts."[65]

Beyond issues of ownership, HETs raise questions regarding the patentability of such technologies. Legal scholars anticipate potential opposition to the patenting of some HETs on ethical grounds, noting that a number of concerns arise from the fact that many HETs become part of individuals' bodies and are "strongly linked to [their] identities."[66] While in the United States patents for HETs likely face little legal opposition, given that "anything under the sun made by man" is patentable,[67] patents in Europe are governed by a more complex set of rules, including the European Patent Convention[68] and the Biotechnology Directive.[69] These complex rules create "uncertainty as to the role that ethical concerns should play within the patent system,"[70] thereby preventing any definitive answers regarding whether HETs are or should be patentable.

2.4 Security and Criminal Liability

HETs raise a number of security concerns that have the potential to implicate criminal liability. First, many HETs raise concerns about breaches and misuse of personal data, especially in the case of HETs that include AI or robotics components, such as wearables like smart watches and FitBits.[71] Because these devices transmit a great amount of personal information regarding the wearer, scholars have noted concerns regarding breaches of such information, especially sensitive medical data,[72] which could then be used maliciously to harm or manipulate users through, for example, advertisements targeted to consumer preferences.[73]

Beyond concerns over breaches of data, HETs raise additional cybersecurity concerns, such as denial-of-service attacks and unlawful access to implants, which can be especially troublesome given the close connection between HETs and the human body. As Gasson and Koops discuss, "all kinds of implants—passive RFID, medical devices such as pacemakers and DBS implants, bionic arms connected to the

[64] *Ibid.*, p. 241.
[65] *Ibid.*, p. 237.
[66] Schellekens, Maurice, and Petroula Vantsiouri, "Patentability of Human Enhancements", *Law, Innovation and Technology*, Vol. 5, Issue 2, 2013, pp. 190-213.
[67] *Diamond v. Chakrabarty*, 447 US 303 (1980).
[68] Convention on the Grant of European Patents of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act Revising the EPC of 29 November 2000.
[69] European Parliament and the Council, Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30.07.1998.
[70] Schellekens, Maurice, and Petroula Vantsiouri, "Patentability of Human Enhancements", *Law, Innovation and Technolog*y, Vol. 5, Issue 2, 2013, pp. 190-213, at pg. 192.
[71] Van Est, R. & J.B.A. Gerritsen, with the assistance of L. Kool, Human rights in the robot age: Challenges arising from the use of robotics, artificial intelligence, and virtual and augmented reality – Expert report written for the Committee on Culture, Science, Education and Media of the Parliamentary Assembly of the Council of Europe (PACE), Rathenau Instituut, The Hague, 2017.
[72] Palmerini, Erica, op. cit., 2015, pp. 226-244.
[73] Dupras, Charles, Linda J. Ger, Nakita Frater and Despoina Goniotaki, "Crossing mind barriers: A precautionary approach to neuroenhancement strategies", in Vincent Menuz, Johann Roduit, Daniel Roiz, Alexandre Erler and Natalia Stepanova (eds.), *Future-Human.Life*, Neohumanitas, Geneva, 2017.

nervous system and networked cognitive prostheses—may be open to such attacks."[74] While such attacks constitute more a novel application than a new type of crime, the link that HETs provide to the human body may cause "the consequences of attacks… [to be] far greater to human life and health than is the case with classic cybercrime."[75] Because of this, Gasson and Koops suggest that legislators revise or expand both substantive criminal provisions and criminal procedures to acknowledge "the qualitatively different consequences of attacks on human implants."[76] More broadly, this increased intersection between cybercrime and bodily integrity crimes calls for a re-evaluation of what criminal law views as an "attack," as it challenges traditional distinctions between things and human bodies and between physical and non-physical attacks.[77]

In addition to concerns regarding new types of cybercrime, HETs have prompted some scholars to call for the use of criminal sanctions for the misuse of HETs in particular contexts. Specifically, Maslen et al. suggest that criminal sanctions are appropriate in situations in which "untrained adults use CEDs on children without suitable supervision."[78] Thus, in the context of HETs, Maslen et. al propose favouring the protection of children, as well as other similarly vulnerable groups, over consumer choice because of the unique vulnerabilities inherent in such groups.

Finally, scholars note that HETs may have implications for criminal law by affecting the mental states of those who commit crimes, thereby changing one's capacity for purposes of criminal liability. For crimes that require intentionality, there is a possibility that HETs may make a criminal defendant more or less able to intend to commit a crime; however, as Goold notes, the current standard used is that of a sober, ordinary person. HETs, therefore, like alcohol, will likely not affect criminal responsibility even if they increase or decrease capacity.[79] Similarly, HETs have the potential to affect criminal proceedings and punishments, as they could be used both for treatment purposes and to increase an individual's competence, thereby making him or her competent to stand trial.[80]

2.5 Employment Law: safe work practices, pressure to enhance and risk of discrimination

HETs raise a number of issues in the area of employment law, ranging from concerns regarding safe work practices to pressures to enhance and the potential for discrimination. First, employees may feel pressures to enhance to remain competitive in the job market. Though anti-discrimination laws in many countries currently prohibit employers from selecting employees based on certain characteristics, it is unlikely that one's status as enhanced or not enhanced is currently included in these protected characteristics.[81] Thus, under such current laws, employers are not prohibited from making hiring decisions based upon one's enhancement or lack thereof.[82] Goold notes that this may be troubling because it has the potential to encourage unsafe work practices, particularly "if people experience pressure to enhance by taking potentially unsafe drugs or using unsafe techniques."[83]

[74] Gasson, Mark N., and Bert-Jaap Koops, "Attacking Human Implants: A New Generation of Cybercrime", *Law, Innovation and Technology*, Vol. 5, Issue 2, 2013, pp. 248-277.
[75] *Ibid.*, p. 276.
[76] *Ibid.*
[77] *Ibid.*, p. 277.
[78] Maslen, Hannah, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu, op. cit., March 2014, pp. 68-93.
[79] Goold, Imogen, op. cit., 2017, pp. 250-273.
[80] *Ibid.*, p. 258.
[81] Goold notes that in the United Kingdom, for example, the Equality Act (2010) "prevent employers from choosing one person over another on the basis of a 'protected characteristic,' namely age, disability, gender reassignment, race, religion or belief, sex, or sexual orientation." (*Ibid*., p. 263.)
[82] *Ibid.*
[83] *Ibid.*

Additionally, scholars note that HETs have the potential to create requirements that employees self-enhance, as is already the case in certain contexts (e.g. vaccinations for medical professionals).[84] Goold notes, however, that in the United Kingdom, for example, the existing legal framework provides some protection for employees against obligations to enhance by requiring employers to maintain safe workplaces.[85] Employees, therefore, would be protected from obligations to undertake risky enhancements that jeopardize their safety. This, however, does not guarantee that employees will be free from pressures or expectations by employers to enhance. Additionally, as previously discussed, HETs have the potential to indirectly require employees to enhance by changing the standard of reasonable care, such as in medical settings.[86]

2.6 Family Law: children's rights, parental responsibility and authority

A decision to give children enhancing drugs is likely to be made by parents. This raises questions about the lawfulness of non-therapeutic interventions (provided they do not cause significant harm), children's involvement in decision making and their autonomy. It has been suggested that it will be left to courts to decide whether parents are acting in a child's best interest.[87]

HETs also have indirect implications for family law through the process of child custody determinations in the context of divorce. Chandler has noted that, in the United States, refusals by parents to enhance their children, though not legally mandated, have been legally used against them in custodial disputes.[88] Chandler cites the examples of vaccinations and Ritalin for children with ADHD,[89] noting that in both cases, courts have viewed a parent's refusal to provide such enhancements as a negative indication of their parenting ability, using such decisions as (at least partial) justifications for awarding custody to the other parent. Chandler also hypothesizes that such decisions might be extended to other enhancements available to children, such as cochlear implants, as well as to new enhancements available in the future, notably neuroenhancers. Chandler notes that "it is possible that some might take the view that parents are neglecting their children if they refuse novel neurotherapies for their children in [the] future, if those therapies attain mainstream acceptance."[90] In this way, parents may feel pressure, extending even to coercion, to enhance their children, although the law does not explicitly punish them for failing to do so.

2.7 Human Rights Challenges

[84] *Ibid.*, p. 267.
[85] *Ibid.*
[86] *Ibid.*, p. 265.
[87] Hagger, Lynn, and Gareth Hagger Johnson, op. cit., 2011, pp. 137-166.
[88] Chandler, Jennifer A., "Autonomy and the Unintended Legal Consequences of Emerging Neurotherapies", *Neuroethics*, Vol. 6, Issue 2, August 2013, pp. 249-263.
[89] Although Chandler herself does not discuss it, it should be noted that the Ritalin illustration likely falls under the category of a medical *treatment* than a true application of an *enhancement*, as the cases cited are in the context of children who have been diagnosed with ADHD (rather than cases of parents giving their children Ritalin to improve their cognitive functioning to above-natural levels).
[90] Chandler, Jennifer A., op. cit., August 2013, pp. 249-263.

There are two key human issues[91] cited by scholars as implicated by HETs: self-determination and human dignity.[92] The principle of self-determination includes autonomy and the freedom of choice,[93] specifically "the right to determine what is done to one's body… [which] suggests a right to enhancement – at least for the body."[94] Scholars generally agree that "it follows from the principle of personal autonomy that … it has to be left to the individual to determine whether or not to make use of HET."[95] In the United States, Blitz argues, it is this freedom of "autonomy of the self," extending from the First Amendment's protection of freedom of speech, which protects the right to enhance.[96] The right to make enhancements to the body (e.g. through plastic surgery) is therefore largely protected by a fundamental right to self-determination.

The right to enhance the mind, however, is not explicitly included under the principle of self-determination. Because of this, scholars have called for the recognition of a new right: the right to cognitive liberty.[97] Bublitz argues that the law must recognize such a right of "cognitive liberty" (or "mental self-determination"), which "guarantees an individual's sovereignty over her mind and entails the permission to both use and refuse neuroenhancements."[98] As Bublitz explains, though such a right is not currently explicitly recognized, it is "among the implicit assumptions of any liberal democratic state… and can be inferred from general and widely-accepted ideas of the relation between the individual and the state, granting persons wide ranging liberties in self-regarding matters."[99]

Scholars are quick to note, however, that the right to self-determination (and the related proposed right to cognitive liberty), while inherently demanding recognition of a right to enhance, also necessarily confer restrictions on such a right. This is because self-determination and personal autonomy require that individuals have the option to *refuse* enhancement should they desire not to be enhanced. [100] Thus, "enhancement can be a right but never an obligation."[101] This is particularly important in arenas in which the pressure to enhance is high, such as the workplace. Not only may

[91] Ruggiu notes that these two rights are "in addition to the general theme of the protection of the individual good of health (the right to health)." While the right to health is relevant to discussions of HETs, it does not directly support or limit a right to enhance, as enhancements by definition exceed the realm of "health". (Ruggiu, Daniele, "A Rights-Based Model of Governance: The Case of Human Enhancement and the Role of Ethics in Europe", in Kornelia Konrad, Christopher Coenen, Anne Dijkstra, Colin Milburn and Harro van Lente (eds.), *Shaping Emerging Technologies: Governance, Innovation, Discourse*, IOS Press / AKA, Berlin, 2013, pp. 103-115.)

[92] While Ruggiu refers to human dignity itself as a right (supra note 91), other scholars view dignity as an inherent human quality that serves as the foundation for the recognition of other human rights. (For an in-depth discussion of this issue, see Bostrom, Nick, "Dignity and Enhancement", *Contemporary Readings in Law & Social Justice*, Vol. 1, No. 2, 2009, pp 84-115.)

[93] Ruggiu, Daniele, op. cit., 2013, pp. 103-115.

[94] Koops, Bert-Jaap, "Concerning 'Humans' and 'Human' Rights. Human Enhancement from the Perspective of Fundamental Rights", in Bert-Jaap Koops, Christoph H. Lüthy, Annemiek Nelis, Carla Sieburgh, J.P.M. Jansen and Monika S. Schmid (eds.), *Engineering the Human: Human Enhancement Between Fiction and Fascination*, Springer-Verlag, Berlin, 2013, pp. 165-182.

[95] European Parliament, Science and Technology Options Assessment, Directorate General for Internal Policies, Human Enhancement Study, Brussels, May 2009.

[96] Blitz, Marc Jonathan, "A Constitutional Right to Use Thought-Enhancing Technology", in Fabrice Jotterand and Velko Dubljević (eds.), *Cognitive Enhancement: Ethical and Policy Implications in International Perspectives*, Oxford University Press, New York, NY, 2016, pp. 293-308.

[97] Bublitz, Jan-Christoph, "My Mind Is Mine!? Cognitive Liberty as a Legal Concept", in Elisabeth Hildt and Andreas G. Franke (eds.), *Cognitive Enhancement: An Interdisciplinary Perspective*, Vol. 1 of *Trends in Augmentation of Human Enhancement*, Springer, Dordrecht, 2013, pp. 233-264.

[98] *Ibid.*, p. 233.

[99] *Ibid.*, p. 236.

[100] Bublitz, Jan-Christoph, op. cit., 2016, pp. 309-328.

[101] Ruggiu, Daniele, op. cit., 2013, pp. 103-115.

individuals feel pressure to enhance to stay competitive, but also "refusing cognitive augmentation might come to be regarded as irresponsible or controversial,"[102] such as in medical settings where doctors will be better able to serve their patients if they enhance. In such cases, the right to personal autonomy demands that individuals maintain a right to refuse modification.

Similar to self-determination, the principle of human dignity implies a right to autonomy and, according to Ruggiu, also requires "the protection of human nature, which belongs to every individual."[103] Bostrom explains that human enhancement can be both dignity-enhancing and dignity-threatening.[104] On the one hand, enhancements that boost motivation or increase the capacity for empathy and compassion have the potential to increase human dignity. On the other hand, however, enhancements can threaten human dignity when they decrease the ability to act authentically, thereby promoting a lack of autonomy.[105]

In addition to autonomy and dignity, the use of HETs is both supported and limited by the right to privacy and family life. As Goold explains, "the ECHR protects each person's right to respect for private and family life, and this includes protection against interference with an individual's bodily integrity."[106] Under this view, the right to privacy lends support both to an individual's right to enhance and not to enhance, by prohibiting government interference in both situations. The right to privacy regarding one's personal data, however, imposes restrictions on HETs, because such rights "imply that people are protected against intrusion into personal or sensitive information that is generated or stored in robotic applications."[107] Thus, although one may have a right to use HETs, such technologies may be limited in terms of what data they can collect and store.[108]

Human rights create additional restrictions on the right to enhance when the use of HETs invokes social justice concerns, such as the unequal distribution of wealth. Scholars note that an increased use of HETs will lead to unenhanced individuals being measured against those who are enhanced, "thus creating divisions within a society: people without enhanced capacities would be at risk of being seen as inferior and possessing fewer human rights."[109] Similarly, as HETs become more widely available, tolerance for those who choose not to use such technologies may decrease, resulting in increased discrimination against not only the unenhanced but also people with disabilities.[110] Moreover, because of the often-significant costs associated with HETs, wealthy individuals will have greater access to the benefits of enhancement, and the resulting unequal distribution of enhanced capacities will perpetuate and worsen wealth disparities.[111]

Beyond whether individuals have the right to enhance, and which restrictions accompany such a right, human rights are implicated by HETs when considering what happens after a person has been enhanced. "The question is whether this post-human body, electively manipulated with recourse to

[102] Palmerini, Erica, op. cit., 2015, pp. 226-244.
[103] Koops, Bert-Jaap, op. cit., 2013, pp. 165-182.
[104] Bostrom, Nick, op. cit., 2009, pp. 84-115.
[105] *Ibid.*
[106] Goold, Imogen, op. cit., 2017, pp. 250-273.
[107] Koops, Bert-Jaap, A. Di Carlo, L. Nocco, V. Casamassima and E. Stradella (2013), "Robotic Technologies and Fundamental Rights: Robotics challenging the European Constitutional Framework", *International Journal of Technoethics*, Vol. 4, No. 2, 2013, pp. 15-35.
[108] *Ibid.*
[109] Bateman, Simone, Jean Gayon, Sylvie Allouche, Jérôme Goffette and Michela Marzano (eds.), *Inquiring into Human Enhancement: Interdisciplinary and International Perspectives*, Vol. 14 of Health Technology and Society, Palgrave Macmillan, Basingstoke, 2015.
[110] Bockman, Collin R., op. cit., May 2010, pp. 1315-1340.
[111] Dupras, Charles, Linda J. Ger, Nakita Frater and Despoina Goniotaki, op. cit., 2017.

artificial devices, should [be] afford[ed] all the guarantees of an organic body."[112] Koops argues that "fundamental rights will in the future [] be given to enhanced humans who derive from human beings and—in the longer term and to a certain degree—to androids and robots that function in society in a way comparable to natural or legal persons."[113] While discussion and debate will be required to determine the scope and content of such rights as applied to androids and other robots, Koops predicts that "their claim to fundamental rights… will not be disputed."[114] This is because he views the purpose of human rights as "protect[ing] citizens from abuse of power and safeguard[ing] their lives and development opportunities," a rationale that can apply to androids and other robots, as well.[115] Koops anticipates this extension of human rights to androids because, he theorizes, as human-like robots perform more and more human tasks, it will become beneficial to society to afford them some level of protection.[116]

3. International laws including human rights standards

This section presents an overview of relevant international laws, including human rights law, that may be applicable to HET in light of the legal issues and challenges outlined in the previous chapter.

3.1 Relevant international organizations and sources of law

The UN has been considered "a natural starting point for setting standards on human enhancement and defining the nature of human dignity and human destiny".[117] The UN's scope includes promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion, as well as being a centre for harmonising the actions of nations in the attainment of these common ends. [118] Besides the United Nations, relevant organisations under the purview of this research include UN specialized agencies: United Nations Educational, Scientific and Cultural Organization and WIPO. The purpose of UNESCO is to contribute to peace and security by promoting collaboration among the nations through education, science and culture in order to further universal respect for justice, for the rule of law and for human rights and fundamental freedoms. The World Intellectual Property Organization is relevant in light of the challenges related to ownership and patents outlined in section 2.3. For the same reason we look at acts adopted by the World Trade Organizations.

Legal actors	Sources of law
UN	Universal Declaration of Human Rights International Covenant on Civil and Political Rights, International Covenant on Economic, Social and Cultural Rights Convention on the Rights of Persons with Disabilities Convention on the Rights of the Child Single Convention on Narcotic Drugs Convention on Psychotropic Substances Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances UN Guidelines for Consumer Protection Principles for Older Persons

[112] Palmerini, Erica, op. cit., 2015, pp. 226-244.
[113] Koops, Bert-Jaap, op. cit., 2013, pp. 165-182.
[114] *Ibid.*, p. 180.
[115] *Ibid.*, p. 179.
[116] *Ibid.*
[117] Al-Rodhan, Nayef R.F., *Politics of Emerging Strategic Technologies*, New York, Palgrave Macmillan, 2011, p. 245.
[118] UN Charter, Article 2(7). http://www.un.org/en/charter-united-nations/

UNESCO	Declaration on Bioethics and Human Rights
WIPO	Patent Cooperation Treaty Model Law for Developing Countries on Marks, Trade Names, and Acts of Unfair Competition
WTO	Agreement on Trade-Related Aspects of Intellectual Property Rights

Table 3: International legal actors and sources of law

The table below maps the clusters of issues identified in Chapter 2 to international laws[119] to better understand whether such provisions exist and are adequate and to understand the gaps and challenges. While none of the documents mention "human enhancement" (as they are technology-neutral), their wide and universal scope encompasses the issues identified.

Legal issue	**Treaty that may apply (with examples)**
Regulating human enhancement devices	• UN Guidelines for Consumer Protection
Regulating human enhancement drugs	• Single Convention on Narcotic Drugs • Convention on Psychotropic Substances • Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances
Civil liability for human enhancement technologies: product liability	• UN Guidelines for Consumer Protection
Civil liability for human enhancement technologies: professional liability	Not covered
Security and criminal liability	• Universal Declaration of Human Rights (no arbitrary interference with privacy) • International Covenant on Civil and Political Rights (no arbitrary or unlawful interference with privacy) • Convention on the Right of People with Disabilities (respect for privacy of person with disabilities) • Convention on the Rights of the Child (children's privacy)
Property law: ownership and patents	• Patent Cooperation Treaty • Model Law for Developing Countries on Marks, Trade Names, and Acts of Unfair Competition • Agreement on Trade-Related Aspects of Intellectual Property Rights
Employment law: pressure to enhance and risk of discrimination	• International Covenant on Economic, Social and Cultural Rights (rights to safe and healthy working conditions, right to fair wages and equal remuneration for work of equal value without distinction of any kind)
Family law: parental responsibility and authority	• Convention on the Rights of the Child (principle of the best interest of the child, the views of the child should be given due weight in accordance with the age and maturity of the child, no arbitrary or unlawful interference with child's privacy)
Human rights challenges[120]	• Universal Declaration of Human Rights • International Covenant on Civil and Political Rights (protection of dignity, prohibition of torture and cruel, inhuman or degrading treatment, prohibition of arbitrary or unlawful interference with privacy)

[119] We looked at the key treaties, including the core international human rights instruments; this is not an exhaustive analysis.
[120] We are mindful that most, if not all, of the above issues may be viewed as human rights issues.

Legal issue	Treaty that may apply (with examples)
	• International Covenant on Economic, Social and Cultural Rights (protection of dignity, right to health, right to enjoy the benefits of scientific progress and its applications) • Convention on the Rights of Persons with Disabilities (state obligation to undertake and promote research and development of new technologies suitable for persons with disabilities)

Table 4: Legal issues and international treaties that may apply

3.2 Analysis of existing legal standards

The United Nations System

International human rights documents

International human rights instruments that are broadly relevant to HETs include: Universal Declaration of Human Rights, International Covenant on Civil and Political Rights, International Covenant on Economic, Social and Cultural Rights, the Convention on the Rights of Persons with Disabilities, and the Convention on the Rights of the Child. All human rights instruments are technology-neutral. The applicability of the provisions outlined below to HETs remains to be determined. International human rights instruments unequivocally protect human dignity,[121] which is conceived as a "hidden concept, the architrave, of the whole of human rights, being implied in several rights and freedoms" [122] and, as outlined in section 2.7, is a key normative reference point in the legal discussion on the regulation of HETs.

Article 5 UDHR and Article 7 ICCPR prohibit torture and cruel, inhuman or degrading treatment or punishment. In particular, they entail a prohibition of conducting medical or scientific experimentation without free consent. According to Article 12 UDHR and Article 17 ICCPR, no one shall be subject to arbitrary or unlawful interference with their privacy. Neither of the General Comments[123] to both of the ICCPR provisions make any mention of technology, or refer to the possibility of violation of these rights by scientific or technical means. It is, however, highly likely that compulsory enhancement, depending on the degree of invasiveness, would infringe one or both of these two Articles. Provisions guaranteeing the protection of privacy are broadly relevant to cybersecurity concerns raised by HETs, such as breaches of data, denial-of-service attacks and unlawful access to implants (section 2.4).

[121] Human dignity is a value commonly recognized in international human rights instruments. It is included in preambles of human rights instruments (e.g. UDHR, ICCPR, ICESCR), or in a specific provision as a right afforded to individuals or as a value to be protected (e.g. Article 1; Article 22 in connection with social security UDHR; Article 10 in connection with deprivation of liberty ICCPR).
[122] Ruggiu, Daniele, op. cit., 2013, p. 107.
[123] A General Comment provides guidelines on how to interpret the normative content of a concrete right and the related State obligations. The document is produced by a committee responsible for the monitoring of a given standard-setting instrument.

The relevant provisions of ICESCR include Article 12, which recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (right to health).[124] General Comment 14[125] on the right to health notes that:

> "In drafting article 12 of the Covenant, the Third Committee of the United Nations General Assembly did not adopt the definition of health contained in the preamble to the Constitution of WHO, which conceptualizes health as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.'"

Authors of the comment highlight, however, that the right to health is not confined to right to health care, but embraces a wide range of socio-economic factors. The right to health contains the following elements: availability, accessibility, acceptability and quality. The condition of acceptability means that:

> "all health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned."

The condition of quality implies that "health facilities, goods and services must also be scientifically and medically appropriate and of good quality. This requires, *inter alia*, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation."

The right to health contains both freedoms and entitlements. Such freedoms include the "right to control one's health and body and the right to be free from interference". The right to health is therefore closely related to principle of autonomy, the freedom of choice and limits thereof, as well as standards of safety, quality and care which are of key relevance for the regulation of HETs. The actual scope of the right to health falls, however, within the broad discretion of the State, which decides how to allocate limited resources.

Under Article 15, para. 1 (b), States shall recognize the right of everyone to "enjoy the benefits of scientific progress and its applications"[126]. According to Article 15, para. 2, States should take the steps necessary to achieve the full realization of this right, including "conservation, the development and the diffusion of science". What constitutes "benefits" continues to be a point of contention. Historically, the notion of "benefits" has tended to focus on cultural participation in the progress of science, whether through support for research programs or establishing means of disseminating and sharing the outcomes of scientific research. The UN Special Rapporteur in the field of cultural rights noted that "[t]he terms 'benefits' of science and 'scientific progress' convey the idea of a positive impact on the well-being of people and the realization of their human rights".[127] The right to benefits of scientific progress remains largely underdeveloped, though greater debate and attention has been given in the recent years. As of yet no general comment on Article 15, para 1(b) has been elaborated,

[124] The right to health is also recognized, *inter alia*, in article 5(e)(iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 1965, in Articles 11.1(f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women of 1979 and in Article 24 of the Convention on the Rights of the Child of 1989. Several regional human rights instruments also recognize the right to health. See the following chapter..

[125] CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), 11 August 2011.

[126] The right to share in scientific advancement and its benefits is also recognized in Article 27 (1) of the UDHR.

[127] Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed: The right to enjoy the benefits of scientific progress and its applications, 2012, section III.A.24.

however,[128] and the scope of the rights, as well as the entitlements and obligations they entail, is yet to be determined.

As regards CRPD, besides protecting privacy (Article 22) and the right to health (Article 25), Article 4 prescribes steps that should ensure full realization of all rights and freedoms for all persons with disabilities without discrimination. The steps that States should take include, among others, undertaking and promoting research and development of new technologies, including information and communications technologies, mobility aids, devices and assistive technologies, suitable for persons with disabilities, giving priority to technologies at an affordable cost. States should also promote the availability and use of such technologies.

CRC includes the principle of the best interest of the child (Article 3). According to Article 12, the views of the child should be given due weight in accordance with the age and maturity of the child. CRC also protects children's privacy (Article 16).

International standards on bioethics

The UNESCO Declaration on Bioethics and Human Rights concerns ethical issues related to "medicine, life sciences and associated technologies as applied to human beings". The challenges raised by HE are bioethical in nature for the simple reason that HE concerns changes on or in the human body.[129] Several principles from the Declaration should be accounted for in the regulation of HE. In particular, States have an obligation to protect privacy of persons and confidentiality of their personal data (Art. 9). In view of the security challenges related to HETs, the need to protect confidentiality of data related to and produced by the human body has particular importance. Moreover, the promotion of health and social development should be a central purpose of governments (Art. 14). The same provision recalls that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being and that progress in science and technology should advance, among others, improvement of living conditions and the environment. In addition, States should guarantee the sharing of benefits resulting from any scientific research, as well as its application with society as a whole and within the international community (Art. 15). Benefits may take the form of access to quality health care; the provision of new diagnostic and therapeutic modalities or products stemming from research; or support for health services.

Consumer protection

The only internationally-agreed-upon legal instrument that addresses consumer protection and product safety is the UN Guidelines for Consumer Protection adopted in 1985. The latest revision took place in 2015. The guidelines are non-binding. As far as product safety is concerned, Section V.B refers to physical safety and section V.D to standards for the safety and quality of consumer goods and services. It is noteworthy that the guidelines should apply both to domestically-produced goods and services and to imports. According to guideline 16, "Member States should adopt or encourage the adoption of appropriate measures, including legal systems, safety regulations, national or international standards, voluntary standards and the maintenance of safety records to ensure that products are safe for either intended or normally foreseeable use". Guideline 35 sets out that "Member States should encourage and ensure the availability of facilities to test and certify the safety, quality and performance

[128] The work on a general comment is pending. See https://www.ohchr.org/EN/HRBodies/CESCR/Pages/Discussion2018.aspx

[129] For the purpose of the Declaration, bioethics has been defined in the explanatory memorandum as "a systematic, pluralistic and interdisciplinary field of study involving the theoretical and practical moral issues raised by medicine and life sciences as applied to human beings and humanity's relationship with the biosphere." See: http://unesdoc.unesco.org/images/0013/001390/139024e.pdf

of essential consumer goods and services." UN Guidelines are, since 2017, accompanied by a Manual on Consumer Protection that contains a chapter on general rules on product safety and liability. In 2018, the UN published a note on consumer product safety. The note highlights that the definition excludes pharmaceuticals and health-care products, as they are governed by specific rules and regulations and are supervised by sector-specific government authorities.

Intellectual Property regulation

Patent law contains different exclusions[130] regarding what constitutes patentable subject matter.[131] As far as the relevant documents adopted by the World Intellectual Property Organisation are concerned (i.e. the Patent Cooperation Treaty and the Model Law for Developing Countries on Marks, Trade Names) and the Acts of Unfair Competition are concerned, the most relevant exclusion for HET concerns "methods of treatment". Broadly speaking, the aim of this exclusion is to insulate from market mechanisms activities that are not regarded as economic. It has been aptly noted that "the purpose of the limitation is… merely to keep patent law from interfering directly with what the doctor actually does to the patient."[132] Rule 39.1 of the PCT specifies that a designated International Search Authority is not obliged to search[133] an international application if its subject matter falls within any of the six categories, including "methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods". According to Article 112, para. 1(3)(iv) of the Model law for developing countries,[134] methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practised on the human or animal body, shall be excluded from patent protection. These provisions do not apply to products for use in any of those methods.

International Drug Control Regime

The international legal framework of the global drug regime consists of three treaties:

- the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol;
- the Convention on Psychotropic Substances, 1971; and
- the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

The aim of the IDCR is to limit, i.e. prevent and combat, production and supply of narcotic drugs (1961 treaty) and psychotropic substances (1971) to medical or scientific purposes. All other purposes are considered illegitimate. In order to achieve its purposes, the IDCR implements prohibitive control measures. The rationale behind the adoption of the treaties is straightforward, as noted in their preambles: Narcotic drug substances cause harm to the health and welfare of mankind, and addiction

[130] The term "patent eligibility" denotes limitations in terms of the kind of "subject matter" that would qualify for patent protection. This question is different from and often precedes the question of whether the said subject matter meets the "patentability' criteria". WIPO, Standing Committee on the Law of Patents, Experts Study on Exclusions from patentability and Exceptions and Limitations to Patentees' Rights, 2010, https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=141352

[131] "Exclusion" set limits to the domain of patentability; common examples include exclusions of abstract theories, discoveries or methods of treatment. "Exceptions" mean limitations of patentees' rights, e.g. compulsory licensing. *Ibid.*

[132] Basheer, Shamnad, Shashwat Purohit and Prashant Reddy, "Patent exclusions that promote public health objectives", WIPO, 2010, p. 6.

[133] The objective of the international search is to discover relevant prior art. (see art. 15 PCT). "Prior art" refers to documents that describe the invention in whole or in part. See: https://www.iusmentis.com/patents/priorart/

[134] World Intellectual Property Organization, WIPO Model Law for Developing Countries on Inventions, Geneva, 1979.

constitutes a serious evil for the individual as well as a social and economic danger to mankind. The UN has a duty to prevent and combat this evil.

Similarly, in the case of psychotropic substances, the starting point is concern for the health and welfare of mankind, as well as the social problems resulting from the abuse of these substances. The aim is to prevent and combat abuse. It is clear that public health—and not human rights—are the goal of drug policy. Human rights are explicitly mentioned only once in the three treaties: in Article 14(2) of the 1988 Convention.

The IDCR framework is based on the distinction between medical and non-medical uses. The treaties, however, do not define "medical purpose". The Preamble to the Single Convention strongly suggests that, at least in the case of narcotic drugs, it means relief of pain and suffering. Medical properties of a substance are assessed by WHO (WHO Expert Committee on Drug Dependence) from a public health perspective. WHO makes recommendations to the Commission on the Narcotic Drugs on the classification of substances.

The WHO lexicon[135] provides more than one definition of "abuse". "Psychoactive substance abuse" may be defined as: "a maladaptive pattern of use indicated by… continued use despite knowledge of having a persistent or recurrent social, occupational, psychological or physical problem that is caused or exacerbated by the use or by recurrent use in situations in which it is physically hazardous". Abuse has also referred to non-medical or unsanctioned patterns of use. Because of its ambiguity, the term is generally not used in ICD-10; "harmful use" and "hazardous use" are the equivalent terms in WHO usage. They usually are limited to effects on health and not to social consequences. The lexicon provides the following definition of "recreational use": "use of a drug, usually an illicit drug, in sociable or relaxing circumstance, by implication without dependence or other problems".

World Trade Organisation

Articles 27(2) and (3) of the Agreement on Trade-Related Aspects of Intellectual Property Rights signed by members of the World Trade Organisation contain explicit exclusions from patentability for morality and methods of treatment. Articles 27(2) provides that: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law." Article 27(3)(a) adds that members may also exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

3.3 Discussion

International law provides an important point of reference for the regulation of HETs as it addresses, directly or indirectly, many legal issues implicated by human enhancement.

In the case of product safety and liability, the UN consumer guidelines are non-binding and of a very general nature. Similarly, relevant international standards on bioethics take the form of a declaration that lays down general rules that should be taken into consideration in the regulation of all technologies applied to human beings, including HETs. As far as patent law is concerned, exclusions

[135] World Health Organization, Lexicon of drugs and alcohol terms, Geneva, 1994. http://apps.who.int/iris/bitstream/handle/10665/39461/9241544686_eng.pdf;jsessionid=7723B312544A0D4AADCA6F85889A8A91?sequence=1

contained in international treaties related to "methods of treatment" add an interesting legal ingredient to the debate about the therapy versus enhancement distinction.

The impact of the development and use of HETs on human rights makes international human rights law a natural starting point for setting legal standards for HETs. The fact that the protection of individual freedom constitutes a cornerstone of international human rights law speaks in favour of adopting a liberal approach that would guarantee a freedom to enhance, while the prohibition of inhuman or degrading treatment is a strong argument supporting a ban on any mandatory enhancement. As far as the right to health is concerned, the state is entitled to deny access to the required treatment if it is decided that provision of such treatment falls outside the bounds of its available resources. The relevance of the right to enjoy the benefits of scientific advances, which has been referred to as arguably the least known human right,[136] still remains unclear; nevertheless, uncertainties about safety and unforeseen impacts of HETs speak in favour of adopting a cautious approach as far as a state's obligations to respect, protect, and fulfil the right to science are concerned. That being said, it is clear that states should promote the development of technologies suitable for people with disabilities. Moreover, according to the United Nations Principles for Older Persons,[137] the elderly should have access to health care to help them maintain or *regain the optimum level* of *physical, mental and emotional well-being* and to prevent or delay the onset of illness. As technologies aimed at assisting people with disabilities or older people become more advanced, they may surpass ordinary human functions and pose new legal challenges related to the need to re-evaluate the legal notion of a "vulnerable group".

Finally, it is important to note that although the exact scope and nature of states' human rights obligations in relation to HETs is not entirely clear, international human rights law has been generally interpreted as favouring the freedom to enhance.[138] The international law on drug control, on the other hand, adopts a highly prohibitive approach. These two highly divergent approaches give rise to insurmountable difficulties. This point will be taken up in the final chapter of this report.

4. Regional human rights regimes

This section presents an overview of regional human rights regimes and explores provisions that are relevant for the regulation of HETs.

4.1 Relevant international organizations and sources of law

As prescribed by the SIENNA Handbook, this chapter looks at the Council of Europe, the Organization of American States and the African Union.[139] The Council of Europe was established to promote democracy and protect human rights and the rule of law in Europe. The African Union's objectives include promoting and protecting human and peoples' rights in accordance with the African Charter on Human and Peoples' Rights and other relevant human rights instruments. In the case of OAS, although Article 2 of its Charter that establishes the organization's essential purposes does not include promoting or protecting human rights, general competences have been relied upon to pursue a human

[136] Boggio, Andrea and Cesare PR Romano, "Freedom of Research and the Right to Science: From Theory to Advocacy" in Simona Giordano, John Harris and Lucio Piccirillo (eds), *The Freedom of Scientific Research: Bridging the Gap between Science and Society*, Manchester University Press, 2018, p. 1. Preprint version available at https://digitalcommons.bryant.edu/cgi/viewcontent.cgi?article=1089&context=histss_jou
[137] https://www.ohchr.org/en/professionalinterest/pages/olderpersons.aspx
[138] See section 2.7.
[139] SIENNA Handbook, op.cit, section 4.4.

rights agenda in that region. The relevant sources of law and specific provisions are listed in the table below.

Regional human rights organization	**Sources of law (with examples)**
Council of Europe	Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention of Human Rights) • Prohibition of torture and inhuman or degrading treatment (Art. 3) • The right to respect for private and family life (Art. 8) European Social Charter • Protection of children and young persons (Art. 7, Art. 17) • The right to protection of health (Art. 11) • The right to independence, social integration and participation in the life of the community of people with disabilities (Art. 15) • The right to social protection of the elderly (Art. 23) The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine • Primacy of the human being over the sole interest of science or society (Art. 2) • Any intervention in the health field must be carried out in accordance with professional obligations and standards (Article 4) • Prohibition of financial gain from the human body and its parts (Article 21) • Right to fair compensation according (Art 24) Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data • Security measures (Art. 7)
Organization of American States	American Declaration of the Rights and Duties of Man • The right to personal security (Art. I) • Right to protection against abusive attacks upon private life (Art. V) • Right to preservation of health and the right to take part in the benefits that result from intellectual progress especially scientific discoveries (Art. XIII) American Convention on Human Rights • The right to have one's physical, mental, and moral integrity respected (Art. 5.1) • Prohibition of torture or to cruel, inhuman, or degrading punishment or treatment (Art. 5.2) • Right to recognition of dignity (Art. 11.1) and the right to private life (Art. 11.2) • Rights of the child (Art. 19) Additional Protocol to the American Convention on Human Rights in the area of Economic, Social and Cultural rights • The right to health, understood to mean the enjoyment of the highest level of physical, mental and social well-being (Art. 10.1) • The right to enjoy the benefits of scientific and technological progress (Art. 14.1. b), and freedom indispensable for scientific research (Art. 14.3). • The right of every child to the protection that their status as a minor requires from his family, society and the state (Art. 16) • The right to special protection in old age (Art. 17.a) Inter-American Convention on the Elimination of all Forms of Discrimination Against Persons with Disabilities • States should cooperate in the development of means related to rehabilitation, and integration into society of persons with disabilities (Art. 5) Inter-American Convention on Protecting the Human Rights of Older Persons • The right to a comprehensive system of care that protects and promotes health (Art. 12)
African Union	African Charter on Human and Peoples' Rights

Regional human rights organization	Sources of law (with examples)
	• Protection of inviolability of human beings, right to life and personal integrity (Art. 4) • The right to the respect of the dignity inherent in a human being, prohibition of exploitation and degradation of man and prohibition of cruel, inhuman or degrading treatment (Art. 5) • The right to enjoy the best attainable state of physical and mental health (Art. 16) • The aged and the disabled shall also have the right to special measures of protection in keeping with their physical or moral needs (Art. 18.4) Protocol to the African Charter on Human and Peoples' Rights on the Rights of Older Persons • The right of access to health care facilities that meet their specific needs (Art. 15) Protocol to the African Charter on Human and Peoples' Rights on the Rights of Persons with Disabilities • Right to barrier free access, states should facilitate development of mobility aides, assistive devices and technologies (Art. 15) African Charter on the Rights and Welfare of the Child • Right to health (Art. 14) • Right to privacy (Art. 10) • Principle of the best interest of the child, the views of the child should be heard (Art. 4) African Union Convention on Cyber Security and Personal Data • States should adopt legislation and/or regulatory measures against cybercrime (Art. 29)

Table 5: Regional human rights instruments and relevant sources of law

4.2 Analysis of existing legal standards

4.2.1 Council of Europe

As it is in the case of the ICCPR, ECHR provisions particularly relevant for assessing the impact of scientific and technological advances on human rights include the prohibition of torture and inhuman or degrading treatment and the right to respect for private and family life. The scopes of both rights are subject to evolution. ECHR is technology-neutral but in line with the doctrine that the Convention is a living instrument it should be interpreted in the light of present-day conditions. The definition of torture, inhuman or degrading treatment is subject to an ongoing reassessment in the light of the present-day conditions and the changing values of democratic societies.[140] Private life is a broad concept that is not susceptible to an exhaustive definition and that covers different aspects of the physical and moral integrity of the person.[141] It encompasses, *inter alia*, aspects of an individual's physical and social identity, including the rights to personal autonomy, personal development and to establish and develop relationships with other human beings and the outside world.

ECHR guarantees that no one can be forced to undergo a physical intervention without consent. It follows that no one can be forced to enhance. Moreover, the European Court of Human Rights has

[140] European Court of Human Rights, *Selmouni* v. *France*, No. 25803/94, 28 July 1999, para. 101. European Court of Human Rights pointed out that "certain acts which were classified in the past as "inhuman and degrading treatment" as opposed to "torture" could be classified differently in future". The Court took the view that "the increasingly high standard being required in the area of the protection of human rights and fundamental liberties correspondingly and inevitably requires greater firmness in assessing breaches of the fundamental values of democratic societies."

[141] European Court of Human Rights, *Pretty v. United Kingdom*, No. 2346/02, 29 April 2002, para. 61.

ruled that the ability to conduct one's life in a manner of one's own choosing may also include the opportunity to pursue activities perceived to be of a physically or morally harmful or dangerous nature for the individual concerned.[142] In fact, the has Court noted that "[t]he extent to which a State can use compulsory powers or the criminal law to protect people from the consequences of their chosen lifestyle has long been a topic of moral and jurisprudential discussion, the fact that the interference is often viewed as trespassing on the private and personal sphere adding to the vigour of the debate." This could at least imply that the Convention does not exclude the protection of the freedom to enhance.

The European Social Charter protects the right of every individual to benefit from any measures enabling them to enjoy the highest possible standard of health. ESC recognizes that special protection should be granted to children, people with disabilities and the elderly, who should remain full members of society for as long as possible.

The aim of the Convention on Human Rights and Biomedicine is to guarantee everyone's rights and fundamental freedoms and, in particular, their integrity, and to secure the dignity and identity of human beings with regard to the application of biology and medicine. The Convention confirms the principle of free and informed consent and the need to protect private life and the right to information. In the context of HE, of particular relevance are Articles 1 and 2 of the Convention. According to Art. 1, parties to the Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. Article 2 lays down the principle of primacy of the human being over the sole interest of science or society. According to this provision, "the interests and welfare of the human being shall prevail over the sole interest of society or science". An Explanatory Report[143] highlights that the whole Convention is inspired by the principle of the primacy of the human being, and all its articles must be interpreted in this light. The Convention stipulates that any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards (Art. 4). It prohibits financial gain from the human body and its parts (Art. 21). The Convention states that any person who has suffered undue damage resulting from an intervention is entitled to fair compensation (Art. 24).

Finally, in light of concerns about data breaches and the security of HETs that transmit personal information regarding the carrier, it is important to recall Article 7 of Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data that obliges member states to provide that the data controller, and, where applicable the processor, takes appropriate security measures against risks such as accidental or unauthorised access to, destruction, loss, use, modification or disclosure of personal data. This provision lays down an obligation to notify the competent supervisory authority of data breaches that may seriously interfere with the rights and fundamental freedoms of data subjects.

4.2.2 Organization of American States

The American Declaration of the Rights and Duties of Man guarantees the right to personal security (Art. I), to the protection against abusive attacks upon private life (Art. V), to preservation of health to the extent permitted by public and community resources, and the right to take part in the benefits that result from intellectual progress, especially scientific discoveries (Art. XIII).

[142] *Ibid.*
[143] Council of Europe, Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 4 April 1997.

The American Convention on Human Rights protects the right to have one's physical, mental, and moral integrity respected. It prohibits torture and cruel, inhuman, or degrading punishment or treatment. It protects dignity and the right to private life.

The Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights includes the right to health. It also embraces the right to enjoy the benefits of scientific and technological progress and the freedom indispensable for scientific research. It asserts the right of every child to the protection that his status as a minor requires from his family, society and the State, as well as the right to special protection in old age, which is reflected in the State Parties' obligation to provide (progressively) specialized medical care for elderly individuals who are unable to provide for themselves. The right of the elderly, *inter alia*, to a comprehensive system of care that protects and promotes health, is protected by Inter-American Convention on Protecting the Human Rights of Older Persons.

According to the Inter-American Convention on the Elimination of All Forms of Discrimination Against Persons with Disabilities, State parties to the Convention should cooperate in scientific and technological research, as well as the development of other means and resources related to, *inter alia*, the treatment, rehabilitation, and integration into society of persons with disabilities (Art. 5).

4.2.3 African Union

The African Charter on Human and Peoples' Rights (ACHPR) not only contains the prohibition of exploitation and degradation of man and the prohibition of cruel, inhuman or degrading treatment, but also explicitly protects the inviolability of human beings and their personal integrity. ACHRP recognises certain economic, social and cultural rights, including the right to enjoy the best attainable state of physical and mental health. It affords special protection to the elderly and people with disabilities who have the right to special measures of protection in keeping with their physical or mental needs.

The rights of older persons and people with disabilities are further elaborated in protocols to the ACHPR. The rights of the child, e.g. their right to privacy and the right to health, are protected by the African Charter on the Rights and Welfare of the Child. According to the Charter, the best interest of the child should be the primary consideration in all actions concerning the child undertaken by any person or authority.

The African Union Convention on Cyber Security and Personal Data stipulates that States should adopt legislation and/or regulatory measures against cybercrime, including offences that affect the confidentiality and integrity of information and communication technology systems.

In 1996 the Assembly of Heads of State and Government adopted a Resolution on Bioethics that confirmed the inviolability of the human body and of the genetic heritage of the human species, as well as the prohibition of subjecting the human body and its components, particularly human genes and the sequences thereof, to commercial and property rights purposes. The Declaration recalls the right of the individual to the benefits of scientific progress, as well as application thereof as guaranteed by the ICCPR.

4.3 Discussion

While all regional human rights regimes are committed to dynamic interpretation of the substantive provisions of human rights treaties, each treaty has its own specific rights provisions that need to be

interpreted by courts and commissions.[144] In the case of the ECHR, human rights challenges raised by HETs will most likely be assessed through standards of the prohibition of torture and inhuman or degrading treatment and the right to respect for private and family life. In addition, an important guiding role will undoubtedly be played by principles laid down in the Convention on Human Rights and Biomedicine. Principles set forth in this document, e.g. the right to fair compensation or that any intervention in the health field must be carried out in accordance with relevant professional obligations and standards, should guide the adoption of any European regulation of HETs.

The remaining two regional human rights regimes discussed in this Chapter have established other autonomous rights that may be particularly relevant for HETs. Specifically, the American Convention on Human Rights protects the right to have one's physical, mental, and moral integrity respected. It has been considered an important contribution to international human rights law:

> "Whereas other treaties only listed prohibited forms of conduct, Article 5 was innovative for general human rights treaties because, in addition to its other components, it established an autonomous *right*: 'Every person has the right to have his physical, mental, and moral integrity respected.'" [145]

Following the American example, personal integrity has been recognized by the African Charter on Human and Peoples' Rights, as well as the European Union Charter of Fundamental Rights, which will be discussed in the next Chapter. Within the CoE, integrity is explicitly protected by the Convention on Human Rights and Biomedicine. Regional organisations adopted legal instruments that protect vulnerable groups including children, people with disabilities and the elderly. American human rights regimes recognize the right to enjoy the benefits of scientific research.

In all three regional human rights regimes, the right to (the protection of) health is recognized. In the case of the African and African systems, the right to health is protected in the main human rights instruments that protect civil and political rights, which indicates a link between different "generations" of human rights and their interconnectedness.

5. EU legislation

This chapter presents an analysis of relevant EU laws and human rights standards. It first presents an overview of the laws, then examines in more detail the laws that address HET-specific issues.

5.1 Relevant sources of law

EU law does not address the issue of human enhancement explicitly. Still, a number of legal issues implicated by HET that have been identified in Chapter 2 fall within the remit of existing EU law and is regulated at the EU level. These, most notably, are related to:

Legal issue	Relevant EU legislation (examples)
Regulating human enhancement devices	Directive 93/42/EEC of the European Parliament and the Council of 14 June 1993 concerning medical devices

[144] Çalı, Başak; Rask Madsen, Mikael; Viljoen, Frans, "Comparative regional human rights regimes: Defining research agenda", *International Journal of Constitutional Law*, Vol. 16 Issue 1, 2018
[145] Antkowiak, Thomas, and Alejandro Gonza, *The American Convention on Human Rights*, New York, Oxford University Press, 2017, p. 22.

Legal issue	Relevant EU legislation (examples)
	Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
Regulating human enhancement drugs	Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use Directive 2001/20/EC OF the European Parliament and of the Council of 4 April 2001 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 (Consolidated version : 07/08/2009) Council Directive 89/105/EEC, of 21 December 1988, relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004
Civil liability for human enhancement technologies: products liability	European Parliament and the Council, Directive 85/374/EEC of 25 July 1985 on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products
Civil liability for human enhancement technologies: professional liability	Not covered[146]
Security and criminal liability	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 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 (General Data Protection Regulation)

[146] As far as liability for services is concerned, the Services Directive (Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market) encourages the development of European standards in order to improve compatibility between services, information to the recipient and the quality of service provision. Regulation 1025/2012 (Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council) provides a legal basis for their development.

Legal issue	Relevant EU legislation (examples)
	Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union Regulation (EU) No 526/2013 of the European Parliament and of the Council of 21 May 2013 concerning the European Union Agency for Network and Information Security (ENISA) and repealing Regulation (EC) No 460/2004 Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)
Property law: ownership and patents	TFEU Article 118 EU Charter of Fundamental Rights Article 17(2) Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection
Employment law: pressure to enhance and risk of discrimination	TEU Article 3(3) TFEU Article 9, 107(3)(a), Articles 145-166 EU Charter of Fundamental Rights (Art. 31 Fair and just working condition) Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation (Employment Equality Directive) Regulation (EU) No 1304/2013 of the European Parliament and of the Council of 17 December 2013 on the European Social Fund and repealing Council Regulation (EC) No 1081/2006
Family law: parental responsibility and authority	TEU Article 3(3) EU Charter of Fundamental Rights (Art. 24 Rights of the child)
Human rights challenges	TEU Articles 2, 3(3) EU Charter of Fundamental Rights

Table 6: Legal issues and relevant EU laws

The following sections take a closer look at selected EU legislation and assess the potential challenges arising from its application to HETs.

5.2 Human enhancement devices and the EU law on medical devices

The European Medical Devices Directive (MDD)[147] distinguishes sharply between devices that are used for a medical purpose as opposed to those that are used by healthy individuals, drawing such a line based on how manufacturers market their devices. Thus, devices that are marketed for "diagnostic

[147] European Parliament and the Council, Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993.

and/or therapeutic purposes"[148] are regulated under the MDD, whereas those marketed solely for enhancement purposes are excluded.

Via the new Medical Devices Regulation,[149] the EU chose to extend the legal regime applicable to medical devices to cover some groups of products for which a manufacturer claims only an aesthetic or other non-medical purpose, but which are similar to medical devices in terms of functioning and risk profile. Groups of products without an intended medical purpose have been listed in Annex XVI and include:

1. Contact lenses or other items intended to be introduced into or onto the eye.

2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.

3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.

4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

5. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.

6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

The new regulation will apply to those groups of products without an intended medical purpose listed in Annex XVI from the date of application of implementing acts, i.e. common specifications (CSs). CSs will be adopted where no harmonised standards exist, where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns. They will concern general safety and performance requirements, technical documentation, clinical evaluation and post-market clinical follow-up or requirements regarding clinical investigation. In the case of devices listed in Annex XVI, common specifications for each of the groups of products will address at least the application of risk management and, where necessary, clinical evaluation regarding safety. CS will apply from six months after the date of their entry into force or from 26 May 2020, whichever is later. Manufacturers of products listed in Annex XVI will have to comply with the relevant CS for those products unless they can duly justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent thereto. Devices with both a medical and a non-medical intended purpose shall fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose.

The EC will be empowered to adopt delegated acts to amend the list in Annex XVI, by adding new groups of products, in order to protect the health and safety of users or other persons or other aspects

[148] *Ibid.,* Article 1(2)(a).
[149] European Parliament and the Council, Regulation 2017/745/EU of 5 April 2017 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), OJ L 117, 5.5.2017, to go into effect 26 May 2020.

of public health on account of the similarity between a device with an intended medical purpose and a product without an intended medical purpose in respect of their characteristics and risks.

5.3 Human enhancement products

Many products with a potential for enhancement are developed for medical purposes and therefore are subject to requirements on clinical testing and pre-market approval laid down in the EU pharmaceutical legislation for medical products. Medicinal products are extensively regulated in EU legislation.[150] EU legislation does not, however, regulate the way they are used in medical practice.

According to the Directive on the Community code relating to medicinal products for human use,[151] it is prohibited to market medicinal products without a marketing authorisation. A medicinal product is defined as:

> (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
>
> (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

The decision to grant or refuse a marketing authorisation is based on an assessment (by the competent authorities) of the quality, safety and efficacy of the medicinal product, and of the risk/benefit ratio. This assessment is conducted on the basis of chemical-pharmaceutical, clinical and preclinical data submitted to the authorities. In general, the assessment of the risk/benefit ratio focuses on a specific condition in a specific subpopulation, investigated in clinical trials.[152] Regulation for the approval of drugs does not consider risks such as ethical or human rights risks, e.g. impact on equality and fairness. Thus, the observations outlined in the 2009 STOA report[153] remain valid. The authors of the STOA report remarked:

> "Aspects considered by [the procedure for approval of drugs] (…) are mainly the efficacy and safety of medicines. Questions and problems associated with enhancement drugs which go beyond health-related aspects dealt with in clinical trials and drug approval procedures are not covered. Regulations deal with a trade-off between risks and side effects of a drug and its benefit for the treated patients. Non-medical enhancement purposes, ethical questions and possible societal side effects related to a respective use of a medicine are not the subject of the approval procedure."[154]

When a medicinal product is placed on the market, physicians may prescribe it off-label. The General Court noted that: "[i]n the EU, off-label prescribing is not prohibited, or even regulated by law. There

[150] Medicinal products are extensively regulated in the EU legislation, see: https://ec.europa.eu/health/documents/eudralex/vol-1_en
[151] European Parliament and the Council, Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001.
[152] Weda, M., Study on off-label use of medicinal products in the European Union, European Union, 2017.
[153] Science and Technology Options Assessment, Human Enhancement. Study, Brussels, 2009.
[154] *Ibid.*, p. 136.

is no provision [in EU law] which prevents doctors from prescribing a medicinal product for therapeutic indications other than those for which a marketing authorisation has been granted."[155]

5.4 EU legislation on product safety and liability

Product safety and liability are two closely linked and complementary legal frameworks. Both have been considered pillars of the EU internal market: "[t]he EU approach to the internal market is based on common safety rules, underpinned by provisions on product liability, while the regime for contractual or extra-contractual liability are left to national law".[156] In the European Union, the General Product Safety Directive[157] and the European Products Liability Directive[158] govern product safety and liability, respectively.

All HETs, including those with connectivity features, as any products placed on the market of the EU, must meet the health and safety requirements laid down in the applicable EU safety legislation. Under EU safety legislation, the manufacturer is always responsible for ensuring that a product meets the requirements of the relevant EU legislation, even if there is mandatory third-party conformity assessment.[159]

At the EU level, product liability was introduced by the Product Liability Directive. It has been in force since 1985 and "has accompanied many technological innovations"[160]. In 2018 the Commission carried out an evaluation of the directive. It assessed the continued relevance of some of the basic concepts around which the Directive was conceived[161].

For the purpose of assessing the relevance of the directive for emerging HETs, it is important to recall that the Directive applies only to producers and not to service providers that may use products that are found to be defective.[162] HETs create new difficulties and uncertainties within these existing rules, given the complexities and specificities of many such products. As far as the notion of defectiveness is concerned, as pointed out by Roosendaal,[163] it may be difficult to conclude what constitutes a "defective" product given that damage may take the form of no effect (when one was anticipated) or

[155] General Court, case T-452/14 *Laboratories CTRS v. Commission*.
[156] European Commission Staff, Working Document on liability for emerging digital technologies, COM (2018) 237 final, Brussels, 25.4.2018, https://ec.europa.eu/digital-single-market/en/news/european-commission-staff-working-document-liability-emerging-digital-technologies, p. 4.
[157] European Parliament and the Council, Directive 2001/95/EC of 3 December 2001 on general product safety, OJ L 11, 15 January 2002.
[158] European Parliament and the Council, Directive 85/374/EEC of 25 July 1985 on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 7 August 1985.
[159] Since enhancement is a feature rather than a product itself, besides the general product safety legislation, EU product safety rules as laid down in the harmonised EU product safety rules may apply, e.g. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery provides health and safety requirements for robots.
[160] European Commission Staff, Working Document on liability for emerging digital technologies, COM (2018) 237 final, Brussels, 2018, p. 17.
[161] Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Application of the Council Directive on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products (85/374/EEC).
[162] Court of Justice of the European Union, *Case 495/10*, Judgment of 21 December 2011,. CJEU also ruled that the Directive applies to products used while providing services but it does not cover the liability of the service provider (c-52/00).
[163] Roosendaal, Arnold, op. cit., 2012, pp. 69-79.

an effect that was not intended but also is not in itself harmful. Moreover, at present damages are limited to physical or material damages, while the use of HET may give rise to infringement of fundamental right, e.g. mental integrity or privacy, without physical damage.

Another problematic concept is burden of proof. The Liability Directive established a strict liability regime, i.e. the injured person is not required to prove fault by the producer. Instead, he or she must prove the defect in the product, damage, and the causal link between the defect and the damage. Roosendaal noted that proof of causation might be especially difficult in cases of HETs given that they often include multiple complex components, including connections to databases and software. In the event of an injury, therefore, causation may be difficult to prove, "since several people may be involved in the development, manufacturing, programming, and implementation process."[164] In this context, it is important to recall the CJEU ruling in a case concerning an allegedly defective vaccine in which CJEU concluded that the causal relationship between the defect and damage may be established by different types of specific evidence, medical or otherwise.[165] CJEU cautioned that national courts must be satisfied that the evidence is sufficiently serious, specific and consistent to determine that the existence of a defect in the product is the most plausible explanation as to the cause of the disease or damage. This means that in cases of scientific uncertainty the claimant can attempt to use other factors, e.g. proximity of time and lack of family history of a disease, to convince the court to find a link between the defect and damage.

Under the existing products liability scheme, producers bear the risk of harms that are knowable at the time of manufacturing, exempting them from harms resulting from unforeseeable risks.[166] The Liability Directive excludes liability for damage caused by a defect if the state of scientific and technical knowledge at the time when the producer put the product into circulation was not such as to enable the existence of the defect to be discovered (Art. 7).

Consumers, therefore, are left to bear such risks, which may be particularly high given the relative lack of knowledge regarding the effects of many HETs. Moreover, as Goold explains, existing products liability rules only serve to compensate victims after harms have occurred, rather than preventing them in the first place.[167] This can be particularly disconcerting because it allows manufacturers to build the cost of such harms into the cost of their products, thus passing the cost on to consumers rather than bearing the costs themselves. This may serve to prevent manufacturers from taking beneficial steps in reducing the harmfulness of their products. Member states may, however, maintain in their legislation or provide by new legislation that this exonerating circumstance is not admitted. For example, the state of art defence does not apply to any product in Finland, and it applies only to particular products and/or in particular circumstances in France, Germany and Spain.[168]

5.5 Fundamental rights

5.5.1 Introduction

TEU states in Article 2 that the Union is "founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities." Human rights at the EU level are guaranteed by the EU Charter of

[164] *Ibid.*
[165] Court of Justice of the European Union, *Case C-621/15*, 21 June 2017.
[166] Goold, Imogen, op. cit., 2017, pp. 250-273 (referring to the Consumer Protection Act of 1987, which implemented the Product Liability Directive 85/374/EEC).
[167] *Ibid*.
[168] Fondazione Rosselli, Analysis of the Economic Impact of the Development Risk Clause as provided by Directive 85/374/EEC on Liability for Defective Products, 2004, p. 28.

Fundamental Rights. The Charter protects human dignity as a fundamental right as well as the basis for all fundamental rights. Other provisions of the Charter particularly important for the regulation of the development and use of HET include: right to integrity of the person (Art. 3), respect for private and family life (Art. 7), protection of personal data (Art. 8), and freedom of scientific research (Art. 13). The EU Charter of Fundamental Rights applies to EU institutions and bodies in line with the principle of subsidiarity and to the Member States when they are implementing Union law. The next sections discuss in more detail the scope and meaning of the right to bodily and mental integrity as a normative anchor point for the regulation of HET.

5.5.2 Right to bodily and mental integrity

Physical and mental integrity at the EU level are guaranteed in Article 3 of the Charter. Article 3(1) is general in character – it does not relate the concept of integrity to any particular area of life. According to this provision, "[e]veryone has the right to respect for his or her physical and mental integrity". Article 3(2) provides for integrity specifically in the fields of medicine and biology. It follows that:

> "In the fields of medicine and biology, the following must be respected in particular:
> (a) the free and informed consent of the person concerned, according to the procedures laid down by law;
> (b) the prohibition of eugenic practices, in particular those aiming at the selection of persons;
> (c) the prohibition on making the human body and its parts as such a source of financial gain;
> (d) the prohibition of the reproductive cloning of human beings."

The protection of physical and mental integrity by the Charter is based on a provision of the CoE Bioethics Convention. In Case C-377-98 Netherlands v. European Parliament and Council, referred to in the text of Explanatory Note on Article 3, the CJEU highlighted that it has power "in its review of the compatibility of acts of the institutions with the general principles of Community law, to ensure that the fundamental right to human dignity and integrity is observed". It has been pointed out that although the relevance of the right to physical and mental integrity for areas of EU competence may not be obvious at first sight, at least in the area of health, the exercise of EU competence creates a need to "integrate concerns related to the right to physical and mental integrity".[169]

Article 3 of the EU Charter, which protects the right to integrity, has been referred to as a "double edged sword"[170]:

> "[T]he three prohibitions contained in Article 3(2) though formulated as if they were designed to shape and strengthen the individual right to physical and mental integrity in the areas of medicine and biology, in fact not only outlaw certain activities in the name of protecting individual integrity, but at the same time put limitations on the exercise of the individual right to integrity in order to serve an objective vision of human dignity … This tension becomes clearest in the context of Article 3(2)c, the prohibition of making the human body and its parts the source of financial gain. It seems that the general prohibition … aims less at the protection of the integrity of the individual … than at condemning the commodification of the human body as an infringement of human dignity, regardless of whether the individual concerned has given free and informed consent."

[169] Michalowski, Sabine, "Article 3 – Right to the Integrity of the Person" in: Steve Peers, Tamara Hervey, Jeff Kenner, Angela Ward (eds.), *The EU Charter of Fundamental Rights,* Hart Publishing, Oxford, 2014, p. 41.
[170] *Ibid*., p. 58.

5.6 Discussion

A number of legal issues implicated by HETs outlined in Chapter 2 fall within the remit of existing EU laws. According to the authors of the 2009 STOA report, the impact of human enhancement on matters that have relevance at the EU level demands a political response from the EU and the member states. According to the authors: "before implementing any human enhancement policy…, the EU would first have to perform a thorough inventory of existing regulations to determine which regulations need to be altered or even replaced and where entirely new regulations need to be drafted."[171] This Chapter, building on the work done by other scholars, has been a humble and non-exhaustive step in that direction.

The 2009 STOA report outlined five possible policy options that the EU could take vis-à-vis HETs:

- a total ban on any technology that alters "human nature";
- a laissez-faire approach;
- a reasoned pro-enhancement approach;
- a reasoned restrictive approach; and
- a systematic case-by-case approach.

The new Medical Devices Regulation with its Annex XVI would suggest that the EU has opted for the case-by-case approach. The diversity of HETs speaks in its favour. In a systemic case-by-case approach, a normative perspective on HE is taken into account whenever a technology or science-based intervention aimed at improvement of individual human performance is proposed. As it is explained, this approach does not require a large regulatory system. Specific regulations that fit within a general framework are drawn up in a deliberative and flexible process as new technologies appear. For devices with no medical purpose listed in Annex XVI, this process should take place before the adoption of CSs.

Within the EU the central role in the regulation of new technologies remains to be played by internal market law, as new technologies in principle fall within the free movement of goods.[172] Art. 114 TFEU provides a basis for the adoption of harmonization measures related to HETs. In fact, the adoption of a number of existing measures that are now relevant for HETs (e.g. General Product Safety Directive, the Clinical Trials Regulation, Medical Devices Regulation) have been based on Article 114 of the TFEU (or Art 95 EC Treaty).[173] EU legislation does not regulate the way products or devices are used in practice. It does not have impact on administration of (enhancement) drugs or use of (enhancement) devices.

The organisation, delivery and financing of health services and medical care falls within the competences of the member states. Moreover, while EU laws establish liability for producers of defective products, the liability of service providers does not fall within its the scope. These issues are

[171] Smits, M., *STOA Workshop in the European Parliament: A European Approach to Human Enhancement*, Rathenau Institute, Den Haag, 2009. http://ernaehrungsdenkwerkstatt.de/fileadmin/user_upload/EDWText/TextElemente/Gesundheit_Ernaehrung-Status/Enhancement_Human_STOA_Workshop_2009.pdf

[172] Flear, Mark L., "Regulating New Technologies: EU Internal Market Law, Risk, and Socio- Technical Order", in Marise Cremora (ed.), *New Technologies and EU Law*, Oxford University Press, 2017, p. 80.

[173] While the choice of this legal basis for the adoption of EU measures relevant to public health has been questioned, CJEU concluded that "the Community legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made." CJEU, *C-380/03*, 12 December 2006, para. 39.

regulated by national legislation. Within existing medical liability rules, the legal implications for professionals are governed largely by national regulations (with some exceptions, e.g. the rules of good clinical practices that are set by European legislation). As far as liability for services is concerned, the Services Directive[174] encourages the development of European standards in order to improve compatibility between services, information to the recipient and the quality of service provision. [175]

Bearing in mind uncertainties about the effects of HETs on human health, doubts may arise whether HET-related measures, adopted on the basis of Art. 114 TFEU, respect Art. 168 TFEU, which creates an obligation to ensure the protection of human health in the definition and implementation of all EU policies and activities.

It has been convincingly argued that internal market law is particularly concerned with the regulation of technological risk.[176] In the case of HETs, the regulatory challenge is significant due to scientific uncertainties related to the lack of research data, since enhancement results are not investigated, as well as the fact that the existing criteria for building risk profiles of new technologies may not be appropriate or satisfactory. According to Flear, Art. 114 TFEU, which, as mentioned, provides the primary legal basis for the adoption of EU regulatory measures on new technologies:

> "reduces the scope of permissible EU risk regulation within the internal market. Article 114 essentially provides the foundation for the narrowing of technological risk to product safety matters and render this as the dominant frame for the legislative instruments eventually adopted by the EU legislature (as well as the supplementary techniques)."[177]

This approach may fail to encompass specific risks and benefits entailed by HETs, e.g. the ethical and societal risks or benefits beyond medical ones.

Finally, it has been pointed out that one of central problems for internal market law is the potential for disparate national attempts to regulate the risks of new technologies.[178] In this context it is important to recall that according to CJEU: "the health and life of humans rank foremost among the assets or interests protected by [Art. 36 TFEU]" and "it is for the Member States, within limits imposed by the Treaty, to decide what degree of protection they wish to assure".[179] In cases of scientific uncertainties, as is the case for HETs, member states may decide what measures are appropriate and adopt precautionary approaches. This may lead to substantial differences between domestic legislation.

6. Analysis of country reports

[174] European Parliament and the Council, Directive 2006/123/EC of 12 December 2006 on services in the internal market, OJ L 376, 27.12.2006.
[175] Regulation 1025/2012 (Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance) provides a legal basis for their development.
[176] Flear, Mark L., op. cit., 2017, p. 76.
[177] Flear, Mark L., op. cit., 2017, p. 95.
[178] Flear, Mark L., op. cit., 2017, p. 83.
[179] Court of Justice of the European Union, *C-322/01*, 11 December 2003, para. 103.

This section is based on twelve country reports prepared by SIENNA partners from the following countries: Brazil, China, France, Germany, Greece, the Netherlands, Poland, South Africa, Spain, Sweden, UK and USA. Its aim is two-fold. First, it is to provide an overview of legal developments relating to national-level legislation relevant to HETs and to summarize the main lines of inquiry relevant to HE pursued by national legal scholars. (Partners were asked to consider last five to ten years.) Second, it is to compare legal responses to two groups of specific questions (see Guidelines in the Annex). The first group of questions is rooted in the debate on the distinction between therapy and enhancement. National partners were asked to examine how this demarcation is reflected in national laws by looking at the existing legal demarcations relevant to future regulation of HETs. The aim was to see the extent to which they are fixed and whether and how they may encompass the category of HET. The second group of questions focuses on the right to integrity. The purpose of this part of the study was to see whether national laws provide guidance and set limits to the types of interventions that are lawful. In the analysis of national laws we focused on certain types of human enhancement, particularly non-therapeutic (medical) procedures as a proxy for other future human enhancement procedures. We examined requirements regarding e.g. consent and limits to autonomy. In addition, we looked at whether the national law, including case-law, and national legal doctrine provide some indications on the status and protection granted to the augmented or modified body.

6.1 Legal developments and national legal scholarship

6.1.1 Legal developments

In the countries included in the study, there have been no attempts or plans to adopt new legislation or set up new regulatory bodies in an explicit and direct response to developments or increased use of human enhancement technologies, nor have there been attempts to regulate how HETs are designed, set up, commissioned or used. Nevertheless, domestic legislation ostensibly affects the legal status of HE. The relevant laws include (the list is not exhaustive):

- Pharmaceutical legislation
- Laws on medical devices
- Product safety legislation
- Data protection legislation
- Anti-narcotic legislation
- Anti-doping legislation
- Health-care legislation
- Bioethics legislation
- Laws on cosmetic surgery (in countries where there are specific laws related to cosmetic surgery, e.g. China)

In the case of two countries included in the study, national parliaments published reports touching on issues directly related to HE: the German Bundestag published a report on neuroenhancement,[180] and the French National Assembly showed some concern for HET-related issues in the report related to the review of the bioethics law.[181] Both reports were published in 2018.

The following examples of legal developments that, although not labelled “enhancement”, are relevant for HET have been identified:

[180] Germany, Deutscher Bundestag, *Informationen zu Neuroenhancement*, 2018. https://www.bundestag.de/blob/572364/c62698c6de2b0c74477a44cc24a83c97/wd-9-060-18-pdf-data.pdf
[181] France, National Ethics Consultative Committee for Life and Health sciences, *Bioéthique Etats généraux. Rapport de synthèse du Comité Consultatif National d’Ethique. Opinions du comité citoyen*, CCNE, 2018.

- amendments to laws on psycho-active substances
    - In Poland, in response to some tragic events involving the use of new psychoactive substances (so called "designer drugs", pl. "dopalacze"), the Act on counteracting drug addiction[182] has been amended to facilitate inclusion of new substances and extend the legal regime applicable to narcotic drugs to cover those substances.
    - In the UK, the Psychoactive Substances Act 2016[183] was adopted to create a blanket ban on the production, distribution, sale and supply of psychoactive substances, which are defined as any substance that is capable of producing a psychoactive effect in a person who consumes it and is not an exempted substance. Exempted substances are alcohol, tobacco, medicines and controlled drugs, caffeine and foodstuffs such as nutmeg and chocolate. The law makes it an offence to produce, supply, offer to supply, possess with intent to supply, import, export, or possess in a custodial institution, psychoactive substances and provides for civil sanctions to enable the police and local authorities to adopt a graded response to the production, supply, etc. of psychoactive substances.
- developments related to anti-doping
    - In Brazil, the Federal Medical Council issued in May 2018 a booklet[184] containing information concerning the health risks associated with the use of drugs and supplements for the purpose of physical enhancement.
- developments related to laws on cosmetic surgery
    - In Sweden in 2015, a law regulating cosmetic surgery was proposed but never adopted. The main points of the proposal included introducing a license obligation for businesses conducting aesthetic treatments that pose significant health risks, limiting certain treatments to specific occupational groups, naming IVO as the competent regulatory body, imposing a national register of licensed businesses and a national, web-based information service with independent information on body treatments.[185] The Swedish government has commissioned a new investigation about regulating aesthetic treatments..
    - In the UK, the Cosmetic Surgery (Standards of Practice) Bill 2016-17[186] was introduced to make provisions for the training, qualifications and certification of medical practitioners conducting cosmetic surgical procedures; to establish a code of practice for the provision of information to patients on the options and risks in relation to such procedures; to create provisions about permissible treatments and the advertising of such treatments; and for connected purposes. The Bill was expected to have its second reading debate on 12 May 2017; however, as a General Election was called and Parliament dissolved from 3 May 2017, the Bill fell and no further action was taken. A new bill has been introduced in the House of Lords, the Cosmetic Surgery (Standards) Bill [HL] 2017-19, which aims to make provisions to include medical practitioners specialising in cosmetic surgery in the Specialist Register for medical practitioners. Its first reading was held on 12 July 2017 (second reading yet to be scheduled).

[182] Poland, Ustawa o przeciwdziałaniu narkomanii (Act on counteracting drug addiction), 29 July 2005.
[183] UK, Psychoactive Substances Act, 28 January 2016.
[184] Brazil, Conselho Federal de Medicina, Atletas e médicos ganham guia elaborado por entidades médicas e esportivas e que ajuda a prevenir casos de doping", 11 May 2018. https://portal.cfm.org.br/index.php?option=com_content&view=article&id=27628:2018-05-11-11-41-54&catid=3
[185] Sweden, SOU 2015:100, "Kroppsbehandlingar. Åtgärder för ett stärkt konsumentskydd", 2015.
[186] UK, Cosmetic Surgery (Standards of Practice) Bill 2016-17. https://services.parliament.uk/bills/2016-17/cosmeticsurgerystandardsofpractice.html

- In 2016 China amendments to Order no. 19 of Ministry of Health of the People's Republic of China, Management Methods of Medical Cosmetology Services effective from May 1, 2002 have been enacted.[187]

- changes in the regulation of medical devices
  - In the US, the 21st Century Cures Act, signed into law on December 13, 2016,[188] was enacted "to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently." In doing so, the Act includes amendments to the Federal Food, Drug, and Cosmetics Act (FDCA), which defines the powers of the Food and Drug Administration (FDA), the regulatory body responsible for regulating the sale of drugs and medical devices in the United States. Relevant to HETs, the Act amended the definition of "device" in the FDCA to exclude certain devices from the FDA's purview, namely those "that include a software function that is intended … for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition." According to the FDA, these devices are being excluded because "premarket review is not necessary to provide a reasonable assurance of safety and effectiveness."[189] Additionally, their exclusion "will decrease regulatory burdens on the device industry and eliminate private costs and expenditures"[190] in an effort to "help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently." In doing so, the Act ostensibly allows manufacturers to develop and sell (some) devices—those which include such a nonmedical software function—for enhancement purposes without having to meet FDA standards for safety and efficacy.
- other issues
  - In Brazil there is currently a Bill with a proposal for the prohibition of microchip implants for the purpose of human identification or GPS location. As of October 2018, this Bill has not been enacted into law.[191]

6.1.2 Legal scholarship

National partners were asked to assess through a literature search academic articles that have appeared in the past ten years that address legal aspects of human enhancement. On the basis of the search they were asked to provide a brief review of the academic legal discourse on human enhancement that covers the themes and topics discussed. The following list of search terms was suggested:

Search terms
1. Human enhancement

[187] China, National Health Commission of the People's Republic of China, Management Methods of Medical Cosmetology Services, 19 January 2016.
[188] US, Food and Drug Administration, Regulatory Information, Laws Enforced by FDA, Selected Amendments to the FD&C Act: 21st Century Cures Act, 13 December 2016. https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothefdcact/21stcenturycuresact/default.htm
[189] US, Gottlieb, Scott, "How FDA Plans to Help Consumers Capitalize on Advances in Science", U.S. Food and Drug Administration, 7 July 2017. https://blogs.fda.gov/fdavoice/index.php/2017/07/how-fda-plans-to-help-consumers-capitalize-on-advances-in-science/
[190] Gottlieb, Scott, op. cit., 2017.
[191] Brazil, Projeto de Lei No. 6489, 2016. http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=2117288

2.	Non-therapeutic human enhancement
3.	(Human) Enhancement technologies
4.	Non-therapeutic services
5.	Non-therapeutic medical services
6.	Non-medical health devices
7.	Lifestyle medical services

Table 7: Search terms

The search was restricted to academic journal articles, books and book chapters with a strong focus on legal issues. After carrying out the search, some authors of the national reports concluded that, while "human enhancement" is a popular topic in the academic debate on ethics, it is much less common among legal scholars. That has been the case in France and Germany. Still, "human enhancement" has been explicitly discussed by legal scholars in several countries, including these two, as well as the US, UK and Greece. Moreover, certain categories of enhancements, most notably cosmetic surgery[192] and doping[193], as well as cognitive-[194] and neuro- enhancement,[195] have attracted more attention from legal scholars.

Legal scholars discuss whether human enhancement should be regulated and, if so, on what grounds. For example, scholars consider such questions as whether the purpose of regulation should be limited to protecting health and safety, or whether it should also aim at protecting morality.[196] A wide spectrum of regulatory approaches is present, ranging from a very conservative stance advocating criminalization of enhancement,[197] to a laissez-faire attitude arguing that existing legal structures are capable of managing the concerns raised by HET.[198] Arguments on both sides of the spectrum tend to be normatively grounded. Legal scholars refer to principles of dignity,[199] autonomy,[200] issues of fairness

[192] UK, Latham, Melanie, "If It Ain't Broke, Don't Fix It?': Scandals, 'Risk', And Cosmetic Surgery Regulation in the UK and France", *Medical Law Review*, Volume 22, Issue 3, 1 September 2014, pp. 384–408; UK, Wicks, Elizabeth, *The State and the Body: Legal Regulation of Bodily Autonomy*, Bloomsbury Publishing, 2016; South Africa, Verwey, Hanneke, *Wish-fulfilling medicine: legal and bioethical perspectives with reference to the practice of cosmetic surgery*, Diss. University of Pretoria, 2013.
[193] Greece, Takis, Vidalis, "Enhancement", in Sakkoulas (ed.), *Biolaw, the human face*, Athens-Thessaloniki, 2007, pp. 239-260; US, Posner, Richard A., op. cit., 2008, pp. 1725-1741; Coleman, Doriane Lambelet, and James E. Coleman Jr., op cit.,2008, pp. 1743-1794.
[194] UK, Goold, I., op. cit., 2017, pp. 250-273.
[195] Germany, Lindner, J.F., "Neuro-Enhancement als Grundrechtsproblem", MedR, 2010, pp. 463 ff.; Gärditz, F., "Pharmakologisches Neuro-Enhancement als Rechtsproblem", *PharmR*, 2011, p. 46.
[196] USA, Lamkin, Matt, "Regulating Identity: Medical Regulation as Social Control", *Brigham Young University Law Review*, 2016, p. 501.
[197] France, Damien Roets, "Réprimer pénalement les interventions biotechniques à finalité transhumaniste?" dans Xavier Labbée (ed.), *L'homme augmenté face au droit*, Villeneuve d'Ascq, Presses Universitaires du Septentrion, 2015, p. 135. "menaces sur l'espèce humaine (…) constituant autant d'atteintes à des valeurs essentielles de nos sociétés démocratiques (la liberté et l'égalité).
[198] US, Wexler, Anna, "A pragmatic analysis of the regulation of consumer transcranial direct current stimulation (TDCS) devices in the United States", *Journal of Law and the Biosciences*, October 2015.
[199] China, Yongmou, Liu and Chen Xiangyu,. "The ethical debate on cognitive enhancement", *Zhejiang social science*, No. 5, 2018.
[200] UK, Wicks, Elizabeth, op. cit., 2016.

and access,[201] as well as the need to protect specific groups and their rights, including children[202] and workers, who should be protected against indirect and direct coercion.[203]

The issue of whether and how to regulate HE is related to the question of the legal status of the (augmented) human body and prosthetics,[204] and the limits of the legitimate role of the state in regulating the body.

Scholars also discuss the obligations and rights of medical professionals and the adequacy of current medical standards in the context of non-therapeutic procedures. Is the use of enhancing techniques for non-therapeutic purposes compatible with responsible medical conduct? What are potential consequences for the physician-patient relationship?[205] The treatment and enhancement debate urged some scholars to ponder the question of the limits of healthcare.[206]

The issue of a legal definition of health has been discussed by legal scholars in some countries. For example, in Greece, two interpretations have been supported. The first one adopts the definition of health provided by the WHO.[207] The second one adopts a narrow definition and provides that health is the state where all organs of the human organism function normally.[208] Legal theory seems to support the negative definition of health as more functional.[209] In the German legal scholarship debate, the leading opinion is that it is not necessary, or rather not helpful, to include the WHO definition in German law. The main criticism is that this definition is based on subjective criteria.[210]

[201] US, Greely, Henry T., "Of Nails and Hammers: Human Biological Enhancement and U.S. Policy Tools", in Julian Savulescu, Ruud ter Meulen and Guy Kahane (eds.), *Enhancing Human Capacities*, Blackwell Publishing Ltd, 2011.
[202] Sweden, Garland, J, "The Rights of Children in Biomedicine: Challenges posed by scientific advances and uncertainties", 2017; UK, Goold, I., & Maslen, H., "Responsibility Enhancement and the Law of Negligence", in Jens Clausen and Neil Levy (eds.), *Handbook of Neuroethics*, 2015, pp. 1363-1380.
[203] US, Greely, Henry T., op. cit., 2011.
[204] France, Pascal Labbée, "L'homme augmenté à l'épreuve de la distinction des personnes et des choses", indans Xavier Labbée (ed.), *L'homme augmenté face au droit*, Villeneuve d'Ascq, Presses Universitaires du Septentrion, 2015, p. 44.; UK, Karpin, Isabel, and Roxanne Mykitiuk, "Going out on a limb: prosthetics, normalcy and disputing the therapy/enhancement distinction", *Medical Law Review*, Vol. 16, Issue 3, 1 October 2008, pp. 413–436.
[205] This question is discussed e.g. in Lindner, J.F., "Neuro-Enhancement als Grundrechtsproblem", Medizinrecht Volume 28, Issue 7, 2010.
[206] Sweden, Johnsson, L-Å, "Måste patienten skylla sig själv? Om medicinska insatser, särskilt i hälso- och sjukvårdens utmarker", Ny Juridik 1:16 s. 75, 2016.
[207] World Health Organization, "Mission", http://www.who.int/about/mission/en/. Greek legal theorists who adopt the wide interpretation include Kremalis, Kostas, *The Right to the Protection of Health*, Sakkoulas, Athens, 1987, p. 56; Katrougalos, George, *The Social State of the Post-industrial Era*, Sakkoulas, Athens, 2004, p. 702.
[208] Greece, Paparrigopoulou, Patrina, *The Public Law of Health*, Nomiki Vivliothikki, Athens, 2009, p. 34;, Petros, Tsantilas, *European and International Law of Health*, Sakkoulas, Athens, 2008, p. 21; Anthopoulos, Charalambos, "The protection of health as a fundamental right", *The Constitution*, Vol. 4, 1993, p. 753; Chrysogonos, Konstantinos, *Civil and Social Rights*, 3rd edition, Nomiki Vivliothiki, Athens, 2006, p. 514.
[209] Greede, Chrysogonos, Konstantinos, op. cit.,2006, p. 549; Vlahopoulos, Spyros, *Fundamental Rights. Civil, Social and Political Rights*, Nomiki Vivliothiki, Athens, 2016, p. 515.
[210] For this debate see e.g. Germany, Laufs, A., *Handbuch des Arztrechts*, Beck, 2010 and Bundesärztekammer, *Gesundheits- und sozialpolitische Vorstellungen der deutschen Ärzteschaft*, 1986.

The adequacy and usefulness of the treatment versus enhancement division for regulatory purposes[211] and its impact on consent, information duty,[212] and issues of liability[213] have drawn the attention of legal scholars. Relatedly, scholars have addressed the question of the legality of enhancement procedures.[214]

Finally, in the US, HE scholarship has been discussed in the context of the military,[215] while some Spanish scholars have considered the question of the impact of enhancement on criminal justice, asking whether enhancement is a way to reduce crime.[216]

6.2 Comparative analysis and discussion of specific legal questions

6.2.1 Terminology and legal demarcations

A key, though not unproblematic, distinction used in the ethical debate on HE is a distinction between "therapy" and "enhancement".[217] The search of domestic legislation revealed that the term "human enhancement" does not appear in legal texts. This does not, however, mean that the debate lacks a legal dimension. Terminology used in domestic laws that allows the therapy versus enhancement debate to be embedded in the legal context consists, among others, of the following terms and distinctions:

- health
- medical vs. non-medical act, device, product
- health care measure vs. non-health care measure
- medical character vs. medical aim
- therapeutic vs. non-therapeutic aim/purpose/intent

These notions are commonly used in domestic laws and/or legal doctrine and therefore should be accounted for in the discussion on the regulation of HE.

The notion of "health"

In the vast majority of studied jurisdictions (Poland, Sweden, Germany, Greece, France, the Netherlands, UK, China, Brazil, USA), domestic legislation contains no definition of "health". One

[211] Greece, Panagiotou, A., "Enhancement, medical liability, and the reforms needed in the Greek legal framework, an initial theoretical approach", *Archives of Hellenic Medicine*, Vol. 33, Issue 5, 2016, pp. 688-698; UK, Karpin, Isabel, and Roxanne Mykitiuk, op. cit., 2008, pp. 413-436.
[212] Greece, Bottis M., "Informed Consent in Plastic Cosmetic Surgery", *Applications of Civil Law and Civil Procedure*, Vol. 3, 2015, pp. 194-204.
[213] See, for example, Poland, Fiutak, Agnieszka, *Odpowiedzialność karna za wykonanie zabiegu leczniczego bez zgody pacjenta*, Wolters Kluwer Polska, 2016; Greece, Panagiotou, A., op. cit., 2016, pp. 688-698.
[214] See, for example, Poland, M. Filar, "Odpowiedzialność karna związana z nieterapeutycznymi czynnościami lekarskimi", Prawo i Medycyna, No. 5, 2000.; Poland, Daniluk, P., "Pozaustawowe nieterapeutyczne (*nielecznicze) czynności* lekarskie"; Państwo i Prawo, No. 1, 2006; Poland, Dukiet-Nagórska, Teresa, Autonomia pacjenta a polskie prawo karne, Wolters Kluwer Polska, 2008; Greece, Takis, Vidalis, op. cit.,2007, pp. 239-260.
[215] US, Parasidis, Efthimios, "Emerging Military Technologies: Balancing Medical Ethics and National Security", *Case Western Reserve Journal of International Law*, Vol. 47, 2015, p. 167; Greely, Henry T., "The social effects of advances in neuroscience: legal problems, legal perspectives", in Judy Illes (ed.), *Neuroethics: Defining the issues in theory, practice, and policy*, Oxford University Press, 2005.
[216] Spain, Sánchez Vilanova, María, *¿Neuroimputabilidad? Una mirada interdiciplinar a la responsabilidad y tratamiento jurídico-penal de los trastornos de la personalidad desde los avances de la neurociencia*, Universidad de Valencia, Valencia, 2017.
[217] For more information on the key demarcations, see the SIENNA D3.1 State- of-the-art Review: Human enhancement.

identified exception is Spain,[218] where in the sexual and reproductive health act a broad definition of "health" has been adopted. According to this definition, health is the state of physical, mental and social complete wellness and not only the absence of complaint or illness. In South Africa, the preamble of the Mental Health Care Act recognizes that "health is a state of physical, mental and social well-being"[219] and thus also incorporates the WHO conception of health.

In some cases, the challenge of formulating a definition of health has been pointed out by courts or in the course of preparatory legislative work. The Polish Constitutional Court has ruled that "the content of the right to health protection is not some abstract 'state of health' of an individual". [220] The "state of health" is in fact, according to the Court, "undefinable". The "right to health" means rather "the possibility to use the health care system, functionally focused on combating and preventing diseases, injuries and disabilities". The Court ruled that Article 68 of the Constitution, according to which "everyone shall have the right to have his health protected", does not allow for the construction of a material (substantive) definition of the term "health protection". In particular, based on the constitutional provisions, it is impossible to precisely specify the types or categories of benefits falling within the scope of the law guaranteed by Article 68.

In the US, in *United States v. Vuitch* the Supreme Court provided some guidance as it was faced with the question of whether the use of the word "health" in a state statute was unconstitutionally vague.[221] The statute in question prohibited abortions except when necessary to protect the health of the mother. The Court was specifically faced with the question of whether "health" includes mental health. In upholding the lower court's decision, which determined that "health" does include mental health, the Court stated:

> "We see no reason why this interpretation of the statute should not be followed. Certainly this construction accords with the general usage and modern understanding of the word 'health,' which includes psychological as well as physical well-being. Indeed Webster's Dictionary, in accord with that common usage, properly defines health as the 'state of being . . . sound in body [or] mind.'"[222]

The Court also clarified that "whether a particular operation is necessary for a patient's physical or mental health is a judgment that physicians are obviously called upon to make routinely whenever surgery is considered."[223] Thus, the Court has applied a broad definition of health that allows for differentiations on a case-by-case basis.

In Sweden, in the course of preparatory legislative works, it has been stated that health is difficult to define due to several reasons.[224] For example, the view of what is healthy and unhealthy can be defined in relation to each individual as well as an entire population. The meaning of the term is constantly changing and varies between different social groups and ages. Health is thereby a relative concept

[218] Spain, Ley Orgánica 2/2010 de salud sexual y reproductiva y de interrupción voluntaria del embarazo (Sexual and Reproduction Health and Voluntary Pregnancy Interruption Act), 3 March 2010. https://www.boe.es/buscar/pdf/2010/BOE-A-2010-3514-consolidado.pdf
[219] South Africa, Mental Health Care Act, 2002.
[220] Poland, Judgement of the Constitutional Tribunal, *Case no. K 14/03*, 7 January 2004.
[221] The US Supreme Court has previously ruled that statutes can be "void for vagueness", explaining that statutory terminology that is insufficiently clear fails to properly inform citizens of what is required to conform with the law, thus violating the Constitution's requirement for due process. (See, e.g. US, Supreme Court, *Papachristou v. Jacksonville*, 1972).
[222] US, Supreme Court, *United States v. Vuitch*, 1971.
[223] *Ibid.*
[224] Sweden, Prop. 1982/83 Om samordningsfrågor inom det socialpolitiska bidragssystemet, 1982, pp. 112-113.

depending on aspects such as financial resources, the development of science, various social and environmental conditions, etc.

Enhancement services and goods (products and devices)

In order to better understand the legal context relevant for the (future) regulation of HE, it proves helpful to draw a broad distinction between enhancement services (procedures, act, actions) and enhancement technologies (devices and products).

Services

In the case of services, the most relevant terms to consider, besides the basic notion of "health", are "medical activity" (or a "medical act") and "health service". The notions of a "medical" or "health care" service are used across studied jurisdictions to refer to an activity performed by medical (health care) professionals using means and methods of a medical nature that have an impact on the human body. These are typically activities aimed at the prevention of disease or the preservation, saving or restoring of health. Therapeutic medical activities are medical activities that are taken to save human health or life and to reduce suffering. Non-therapeutic medical activities are, to the contrary, all those medical activities that do not directly lead to saving health or human life or reducing the suffering of the person they concern. One example of this type of medical activity is medical research. Non-therapeutic activities include actions aimed at improving physical or mental well-being. These include cosmetic interventions (surgical or non-surgical) for aesthetic purposes. It is not always clear if those activities should be classified as medical or health-care services. The classification proves to be at times problematic and may be based on different criteria and dependent upon the context. This should be a source of concern, because classification of a service as medical or non-medical may have significant legal consequences for the level of protection enjoyed by the person undergoing the procedure.

In the case of Poland, for example, the relevant criterion for classifying a service as medical is who the person performing the service is. If a procedure is carried out by a medical professional, the service constitutes a "medical service" (term considered synonymous to the notion of "health service"), regardless of whether its aim is therapeutic or non-therapeutic. In other words, the term "medical" refers to the character of the service, and not necessarily its purpose. In Sweden, on the other hand, the relevant criterion for a service to be classified as "health care" is the purpose of the measure, i.e. it is a measure that medically prevents, investigates and treats diseases and injuries. In addition, the measure should require medical competence, i.e. it should need to be performed by a health care professional.[225] Consequently, non-therapeutic HE interventions should *not* classify as "health care". This approach has been confirmed in a case where the court was faced with the question of whether non-therapeutic cosmetic surgery constitutes health care and therefore should be exempted from VAT. The Swedish court followed the ECJ judgment[226] where it was stated that aesthetic interventions should only be covered by the concept of health care insofar as they are performed for the purpose of treating or providing care for persons suffering from ailments, injuries or congenital malformations in need of aesthetic surgery. Interventions carried out for purely aesthetic reasons cannot be regarded as health care treatments that are exempted from VAT. Furthermore, the purely subjective perception of the person who undergoes an aesthetic intervention is not in itself decisive in the assessment of whether the intervention has a therapeutic purpose. Since that is a medical assessment, it must be based on findings of a medical nature that are made by a person qualified for that purpose. It has been reported that a similar approach was adopted by the French tax office.

[225] This condition has been laid down in preparatory works.
[226] Court of Justice of the European Union, C-91/12, *Skatteverket v. PCF Clinic AB*, 21 March 2013.

At the same time, both in Sweden and France, opposing views also exist on this topic. In Sweden, in the context of insurance, there were cases in which a non-therapeutic intervention was considered by courts to constitute health care when performed by a health care professional. Similarly, in France, in relation to compensation, the court assessed that acts of plastic surgery could be recognised as medical acts and could therefore benefit from compensations in the case of negligence on the part of the practitioner.

The second category of enhancement services are procedures performed on the human body by non-medical professionals. In the reviewed countries there are no separate pieces of legislation that comprehensively regulate all non-medical procedures aimed at the modification of the human body. This does not, however, mean that they are left unregulated.

Products and devices

In the case of medical products and devices that could be used for enhancement purposes, in the EU member states' relevant domestic laws are, to a significant degree, a result of implementing EU pharmaceutical legislation and EU legislation on medical devices. The criteria used for classifying products or devices as medical are:

- the claim (the intention) of the manufacturer in the case of devices;
- how the product is presented in the case of medical products;

The new Medical Devices Regulation extends the legal regime for medical devices to select devices that have no medical purpose. It remains to be seen how these provisions will be implemented by member states.

Similar criteria for classifying goods as medical have been adopted beyond the EU. For example, the current position in South African law is that a substance constitutes a medicine if the sellers of the medicine *purport* that it is to be used for a therapeutic purpose or if it is widely used for a therapeutic purpose (in the absence of the sellers advancing any claim to that effect). "Therapeutic purpose" is, accordingly, to be understood to include curative, preventative and diagnostic procedures in addition to curative treatments. Recent case law might be understood to have further broadened the concept of "therapeutic purpose" to include enhancements to physical or cognitive performance. In the US, devices are "medical," and therefore subject to FDA regulations, when they are "*intended* for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals."[227] The FDA clarifies that if a product is either "labelled *or* used in a manner that meets this definition", then it will be considered a medical device.

6.2.2 Issues related to bodily and mental integrity

As human enhancement occurs via interventions in or on the human body, the "strategic role" in building a possible "normative anchor point" for future developments in HE has been given to the right to bodily integrity.[228] The right to bodily integrity is protected at constitutional and/or statutory levels.

[227] US, Food and Drug Administration, "Classify Your Device". https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm

[228] Ruggiu, Daniele, "Implementing a responsible, research and innovation framework for human enhancement according to human rights: the right to bodily integrity and the rise of 'enhanced societies'", *Law, Innovation and Technology*, published online 27 March 2018.

The right to integrity is explicitly guaranteed, for example, in German, Greek, Spanish and South African constitutions. In cases where the right is not explicitly recognized in a constitution, as is the case in Poland or Sweden, for example, it is inferred from other constitutionally protected rights. In Poland, the need to protect the integrity (both physical and mental) is inferred from the constitutional guarantees of the inherent and inalienable dignity of the person and the guarantees of personal inviolability. Swedish law also does not explicitly guarantee a right to physical and mental integrity of the person. However, variations of such a right are recognised by the Instrument of Government (one of the fundamental documents that form the constitution of Sweden), which prohibits the death penalty. It is there also stated, under the heading "bodily integrity and freedom of movement", that everyone is protected against forced bodily intervention from the public.

The right to bodily integrity is related to the principle of autonomy and the value of informed consent. The right to bodily integrity has a two-fold nature. On one hand, it entails protection against forced bodily intervention. This aspect of the right is expressed by the prohibition of scientific experimentation, including medical experimentation, without voluntary consent. The second aspect of the right entails a right (on reaching an age of understanding) to make decisions about one's own body. Both aspects of this right are related to the value of consent. Non-therapeutic procedures due to the lack of a therapeutic purpose may be considered an assault on the body.

No enhancement procedure should be performed without the consent of a person undergoing the procedure.[229] As far as the scope of information that needs to be provided to a person undergoing a procedure, the reviewed domestic laws tend not to differentiate between therapeutic and non-therapeutic medical acts. One identified exception is Greece, where under Art. 11, para. 3 of the Code of Medical Ethics, the obligation to inform the patient is augmented when the procedure in question is cosmetic. In some cases, e.g. in Poland, it has been established in the case law that for non-therapeutic procedures, requirements concerning informed consent shall be more rigorous than in the case of procedures with a therapeutic aim. In Poland the question about the scope of information has been addressed by the Supreme Court specifically in the context of surgeries for aesthetic purposes. The Court held that: the requirement of obtaining a patient's consent to undergo surgery only for aesthetic purposes (improvement of appearance) is preserved only if the patient is sufficiently informed about specific - that is, any (more or less) predictable - effects of an intervention.[230] In addition, in the case of procedures carried out for aesthetic purposes, patients cannot relinquish their right to information. Similarly, in France the fact that there is no therapeutic necessity leads to stronger requirements in terms of the information that the practitioner must provide to the patient. Jurisprudence points to the need for a very large amount of information for the patient in cases of a medical or surgical intervention that is to be conducted for an aesthetic purpose. Due to the fact that there is no "medical necessity", there is even more importance given to the information to be provided to the patient in order to ensure their informed consent.

In all countries included in the research, domestic laws set limits to what an adult person able to provide informed consent can actually consent to. The common criteria used to establish those limits are:

- degree of physical invasiveness (violence), and
- its social acceptability.

In the case of the second criterion, the line tends to be set by general clauses in contract law and thus may not always be sharp. As a general rule, a contract may be deemed invalid, if it violates social

https://www.tandfonline.com/doi/abs/10.1080/17579961.2018.1452177

[229] Unless we are dealing with a minor or a person who cannot give consent. In these cases, the question is whether enhancement should be allowed at all.

[230] Poland, Supreme Court, *Case no. II CR 280/80*, 5 September 1980.

norms. Different general clauses are used by domestic laws to address this issue and limit the freedom of contract. Contracts may be deemed invalid if they violate, e.g., rules of social coexistence, principles of community life, (public) morality, good practices, or good customs.

In the case of non-therapeutic medical acts, limits to consent are set by what the medical professional is permitted to do. In some countries, performance of HE procedures by medical professionals is prohibited according to the letter of the law, although the observed practice sometimes deviates from the wording of the provisions. For example, in Brazil physicians are not allowed to perform non-therapeutic procedures on the body of a patient, as the medical profession itself is defined in terms of its capacity to promote the "treatment" and "rehabilitation" of individuals. In France doctors are prohibited from engaging in medical acts that have no therapeutic purposes, which has been confirmed by a report of the National Assembly that specifies that doctors should not engage in procedures that do not address situations of suffering or distress.

The law may criminalize interventions on the human body, even if they are performed with consent, if they exceed a certain degree of severity. For example, in Greece, the rule in criminal law is that one may consent only to simple bodily injury; anything more severe than a simple bodily injury may not be legalized through the consent of the person consenting to being harmed. According to the Swedish criminal law, a person may not concede to grave abuse. In Poland, a doctor cannot undertake activities that are cosmetic in nature, even if the patient has consented to them, if they cause the patient serious injury. Despite the letter of the law, however, non-therapeutic services that *do* involve a serious and irreversible intervention in the human body may be considered legal due to the social setting and the fact that they are socially acceptable. This happens most notably in the case of surgical cosmetic interventions.

Another example of the lack of clarity with regard to the limits on non-therapeutic procedures that can be performed is evident in the case of DIY (do-it-yourself) human enhancement – where human enhancement and augmentation is or might be carried out privately, and where the reach of the law might not extend due to the lack of visibility of such actions. The law protects a person against harms caused to her or him by another (e.g., trespass to person, negligence, bodily injury or assault), but it is still not very clear whether or how the law should treat someone who has self-enhanced to their own detriment or perceived benefit.

Domestic law in the countries included in our research provides little guidance on how risks and benefits of non-therapeutic procedures should be weighed and/or what is the acceptable level of risk. In some cases, it is stated that the risk may only me minimal, or that benefits must outweigh the risks, but no concrete indicators are referenced. The question of benefits is related to that of possible redress in the event that something goes not as planned. This in turns raises the question of whether contracts for enhancement procedures entail obligations of results or of means. This question has not been addressed in all searches, but the limited data available related to cosmetic surgery shows that there might be different approaches. For example, in Brazil when a patient sues a cosmetic surgeon who has failed to deliver the agreed result, the Superior Court of Justice has ruled that, indeed, the cosmetic surgeon has an obligation of result, for the expectation of the result is precisely what motivates the patient to contract the services of a cosmetic surgeon, and not the cure or treatment of a disease. At the same time, according to a resolution passed by the Federal Medical Council, plastic surgeons, like other surgeons, do not have civil liability for the results of the surgeries they perform.

6.2.3 Status of the augmented or modified body

As far as the status of the augmented or modified body is concerned, some indications can be drawn from case law and legal doctrine. In the US, the Supreme Court has ruled that police officers cannot

search the data of a cell phone seized incident to an arrest without a warrant.[231] Drawing on due process rights protected by the Fourth Amendment of the US Constitution, the Court found that the privacy interests of arrestees outweigh any government interest in obtaining data from cell phones. Notably, the Court stated that "modern cell phones … are now such a pervasive and insistent part of daily life that the proverbial visitor from Mars might conclude they were an important feature of human anatomy."[232] Though this statement is dicta and therefore does not itself constitute binding law, it offers insight into the Court's views regarding the right to privacy in the context of new technologies—if such a right extends to the data on cell phones, then technologies that are even more intimately connected with an individual's body would presumably be likewise protected by the right to privacy. Importantly, however, the ruling is limited to situations involving government action because the case specifically involved the privacy of arrestees as protected by the Fourth Amendment. Thus, the right to privacy may not protect HETs in other contexts, such as civil litigation between two private actors.

In a recent criminal case in Poland,[233] the appellant claimed that the court of the first instance failed to establish whether a denture fixed permanently on the first and third teeth of victim's upper jaw was a so-called "internal prosthesis" or an "external prosthesis", which was supposedly key to determining whether damage to the prosthesis should be classified as "a violation of body function" or "health disorder", or as a crime against property. The Court, however, did not address this issue.

In the Netherlands, the UK and France, legal issues implicated by the augmented or modified body have been discussed by legal scholars. In the Netherlands, scholars made a distinction between objects that are temporarily placed in the human body and objects that are placed there permanently. In the case of the latter, the doctrine argues that these objects become a part of the human body and merge with the human body.[234] The patient therefore has the right to self-determination regarding these objects.[235]

In the UK, Quigley and Ayihongbe argue that "the law is ill-equipped to deal with challenges raised by the linking of the organic, biological person with synthetic, inorganic parts and devices".[236] They further suggest that what the shape of the law remains to be explored and debated.[237] It could be argued that overall, an augmented or modified body would enjoy protection and guarantees afforded to a human body (e.g., personal injury protection) and may benefit from specific protections afforded to its parts (e.g., patent or copyright protection, protection from illegal interference with wireless communications, product liability protection for prosthesis),[238] though this has not been exactly fully tested in the courts. If a substance or device is integrated into the human body, then it obtains the same status as the body.[239] As Barfield and Williams suggest, As far as the question of ownership is concerned, there is no legislation dealing with the ownership of, for example, implanted medical devices. Quigley and Ayihongbe note that "the specific question of the property status of medical devices once implanted into or integrated with the body has not been tested in the courts".[240]

[231] US, Supreme Court, *Riley v. California*, 2014.
[232] *Ibid.*
[233] Poland, Regional Court in Poznań, *Case no. IV Ka 340/15*, 29 April 2015.
[234] Netherlands, Leenen, H.J.J., *Handboek Gezondheidsrecht*, Den Haag, 2017, p. 85.
[235] *Ibid*.
[236] UK, Quigley, Muireann, and Semande Ayihongbe, "Everyday Cyborgs: On Integrated Persons and Integrated Goods", *Medical law review*, Vol. 26, Issue 2, 2018, pp. 276-308.
[237] *Ibid.*
[238] UK, Barfield, Woodrow, and Alexander Williams, "Law, Cyborgs, and Technologically Enhanced Brains", *Philosophies,* Vol. 2, Issue 1, 2017, p. 6.
[239] From a consumer law perspective, however, such elements could be considered defective products.
[240] UK, Quigley and Ayihongbe, op. cit., 2018, p. 288.

In France, a key terminological distinction in the legal debate related to the regulation of HETs that has relevance to the protection of the augmented body is the status of the person and his/her body. While the "person" is the subject of rights, the body is an object of rights. However, as it "envelops" the person, the body is not like any object.[241] As Pascal Labbée puts it, the 1994 bioethics law has made the body a "sacred" object.[242] This sacredness reflects the notion of "human dignity" that is present in art. 16 of the Civil code and leads to an obligation to protect it.[243] It is on the basis of this definition of the person and the body that Labbée then defines the status of the implant. For this, Labbée relies upon a legal distinction between the "person by nature" ("personne par nature") and the "person by destination" ("personne par destination"). This distinction was established thirty years ago by the tribunal of Lille. The implant becomes a "person by nature" and will be regulated by the regime of the person and the human body to which it is incorporated.[244] On the contrary, removable prostheses have been qualified by the Lille tribunal as "person by destination". As such, the removable instrument is considered as the person insofar as it is associated with him or her.[245] Labbée specifies that, if the instrument is separated from his or her owner, then it becomes again an object in the legal sense of the term. As such, for instance, a denture that is taken away while still in the mouth of the person will be considered an offence against a person; on the contrary, a denture that is stolen while removed from the mouth will be considered a property-related offence.[246] According to Labbée, it is urgent to define, within the regime of things, the status of enhancing prostheses.[247] According to him, insofar as the purpose of these prostheses is to satisfy individual or collective desires to be the best, then they should not receive any particular status.[248] An additional proof of the fact that prostheses belong to property law is the fact that they have a cost, contrary to organs, which can only be donated.[249]

6.3 Final remarks

As far as the domestic law in the studied countries is concerned, neither "human enhancement" nor "enhancement procedures" are recognised per se. Some specific procedures that might be considered "enhancement procedures", most notably cosmetic interventions or doping, are regulated by law, even though the term "enhancement" is not used.

The point that the division between therapy and enhancement is problematic manifests itself also in the domestic legal context. The fact that a clear demarcation between treatment and enhancement or medical and non-medical uses is at times challenging to maintain may give rise to "grey zones" where it is unclear which legal provisions should apply. The issue is further complicated by the evolving and differentiated understandings of the very concept of health.

The legality of enhancement procedures is not entirely clear-cut, as there is no blanket or overarching regulation that is applicable given the varying nature of such procedures. Enhancement is legally permitted insofar as it is not prohibited. The law provides limited guidance on specific aspects of enhancement procedures (e.g. informed consent, assessment of risk). This role is often taken up by courts on a case-by-case basis.

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[241] France, P. Labbée, op. cit, p. 44.
[242] *Ibid.*
[243] *Ibid.*
[244] *Ibid.*, p. 46.
[245] *Ibid.*
[246] *Ibid.*, pp. 46-47.
[247] *Ibid.*, p. 48.
[248] *Ibid.*
[249] France, C. Aludaat-Dujardin, "Médecin ou mécanicien? Une approche cybernétique de la pratique médicale en Droit", Lille, 2015, p. 70.

In general, in light of the analysis carried out in this report, it could be argued that as physical invasiveness and complexity of the enhancement become greater, the easier (i.e. more legitimate, proportionate and necessary) it is to justify limiting individual autonomy.

As far as the status and protection granted to the augmented or modified body are concerned, a tendency could be observed to treat technologies that are intimately and permanently connected with physical bodies as their parts. This is particularly the case with regard to implants, and in some circumstances, e.g. the need to protect privacy, this approach may be extended to other devices. It is, however, too early to draw any-far reaching conclusions, as data gathered in this report is very limited.

7. Conclusions

7.1 The challenge for legal regulation

Law, by shaping conditions for the development and marketing of new technologies, plays a leading role in their regulation.[250] The survey of the legal landscape, including international, EU and national law, revealed that there is not yet much law that explicitly addresses HETs. Some law, especially medical law and EU law on medical devices and drugs, is adjacent to HET law and it might be extended into the area of HETs. Other laws, for example product liability laws, apply to HETs by virtue of their general nature.

The common thread that runs through the different legal challenges posed by HETs outlined in Chapter 2 is the need to balance guarantees of individual autonomy with the need to ensure safety, while remaining mindful of the wider societal impacts of HETs. This assertion leads to two questions. First, whether and to what extent human rights norms are fit to address this challenge. Second, if this is the time to adopt laws that provide explicitly for HETs. These questions are referred to below.

7.2 Relevance of human rights

HETs are not developed in a legal void, but rather in the environment of elaborate, co-dependent and interacting legal frameworks. The table below summarizes whether different levels of legal regulation address the issues raised by HETs outlined in Chapter 2.

	1. International legal order (including human right instruments)	**2. Regional human rights regimes**	**3. EU law**	**4. National law**
Regulating enhancement devices			√	√
Regulating enhancement products	√ (IDCR)		√ (pharmaceutical legislation)	√ (both aspects: pharmaceutical law and drug control)
Products liability	√ (UN Guidelines for Consumer Protection)		√	√
Professional liability				√

[250] Flear, Mark L., op.cit., p. 74.

	1. International legal order (including human right instruments)	2. Regional human rights regimes	3. EU law	4. National law
Property law: ownership and patents	√	√ (i.e. right to property)[251]	√	√
Security and criminal liability	√ (i.e. protection of privacy)	√ (i.e. protection of privacy and personal data)	√ (i.e. protection of privacy and data protection)	√ (i.e. protection of privacy and data protection, criminal law)
Employment law: safe work practice/ pressure to enhance and risk of discrimination	√	√	√	√
Family law: children's rights, parental responsibility and authority	√	√	√	√
Human rights challenges	√	√	√	√

Table 8: Legal issues vis-à-vis legal orders

Some fields in the first and second column have not been marked. However, the basic normative presupposition guiding the legal research conducted in the SIENNA project—namely that where laws might touch and concern access to and use of HETs, then they should be compatible with human rights norms—would suggest that *all* of the issues listed have a human rights dimension and can be encompassed by general human rights norms. Indeed, human rights instruments are relevant to all issues outlined in Chapter 2, because all regulatory challenges can be situated in a framework of common overarching principles that constitute the sphere of rights and freedoms.[252] As a "common thread defined by concerns about the protection of important values",[253] human rights encompass a wide variety of issues and different legal sub-fields. Due to their normative structure, human rights can help foster the coherence of regulation.[254] Human rights norms can be looked to in order to challenge other laws that fail to protect the individual.

Legal orders analysed for the purposes of this report are consistent in the protection of rights that are at risk due to development and use of HETs. The right to health, prohibition of degrading or inhuman treatment, the right to privacy and the right to (bodily and mental) integrity are commonly protected

[251] At the regional level, there are different organizations that address IP issues raised by HETs (i.e. patentability of the methods of treatment, exemptions from patentability on social or ethical grounds), e.g. European Patent Organization, African Regional Intellectual Property Organization. The analysis of legal instruments adopted by these organizations has however been beyond the scope of this report.

[252] Leenes, Ronald, Erica Palmerini, Bert-Jaap Koops, Andrea Bertolini, Pericle Salvini, Federico Lucivero, "Regulatory challenges of robotics: some guidelines for addressing legal and ethical issues", *Law, Innovation and Technology*, Vol. 9, Issue 1, 2017, pp. 1-44.

[253] Palmerini, Erica, "The interplay between law and technology, or the RoboLaw project in context", in Erica Palmerini and Elettra Stradella (eds.), *Law and Technology. The Challenge of Regulating Technological Development*, Pisa University Press, Pisa, 2013, p. 23.

[254] Ruggiu, Daniele, "Temporal Perspectives of the Nanotechnological Challenge to Regulation: How Human Rights Can Contribute to the Present and Future of Nanotechnologies", *Nanotechnologies*, Vol. 7, Issue 3, December 2013, p. 207.

across jurisdictions, although the right to integrity has not been recognised as a separate right at the global level. It is indisputable trite that HETs and their use ought to remain consistent with those rights and respect human dignity.

Existing human rights frameworks have accompanied many technological advancements and, as "living instruments", they remain relevant for HETs. Nevertheless, the development and proliferation of HETs reignite debates about the meaning of some basic concepts such as human dignity or the limits of individual autonomy. It would be naïve to expect that these debates will be resolved with the arrival of HETs; however, the new setting provided by HETs is a breath of fresh air and in some cases may be a tipping point. The debate on the regulation of enhancement drugs revives, for instance, the discussion on the difficulty, or even the impossibility, of reconciling international human rights law and the international law on drug control. It sheds more light on the disconnect between those regimes.[255] All arguments speaking in favour of freedom to enhance add to the already heavy criticism towards the IDCR.

As far as specific human rights are concerned, their exact scope and limits in the context of HETs will have to be determined. While the right to health is guaranteed across international, regional and national legal orders, it may or may not encompass or be extended to cover acts with an enhancement purpose, depending on what conception of health is explicitly or implicitly adopted by the domestic law or policy. In the future it may be up domestic courts to decide whether or not a given claim should be satisfied as a matter of right. Similarly, it is yet unclear if the freedom to enhance, as an expression of individual autonomy and the right to bodily integrity, would be protected under provisions on the right to privacy. In Europe, for instance, the concept of "private life", referred to in Article 8 ECHR, is understood as encompassing aspects of an individual's physical and social identity, including the right to personal autonomy and personal development. Private life is a concept that includes both the physical and moral integrity of the person. If the freedom to enhance is protected by Article 8 of the ECHR—an open question that will have to be tested by courts—it could be interfered with only in accordance with the law and if doing so is necessary in a democratic society in the interests of "national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others" (Article 8 par. 2) Any infringement on the right to privacy must also be proportionate. Bearing in mind the limits to what an adult person able to give informed consent can consent to (as established by national laws, discussed in the previous chapter), it would likely be considered proportionate to limit autonomy if the enhancement exceeded a certain degree of physical invasiveness or was considered socially unacceptable. Finally, the international and regional human rights regimes guarantee that no one can be forced to undergo a physical intervention without consent. Governments, however, may, under strict conditions, infringe upon the right to bodily integrity. Some examples common across jurisdictions include laws prohibiting the use of drugs, laws prohibiting euthanasia, laws requiring the use of seatbelts and helmets, and forced blood tests. It is, however, highly unlikely that compulsory enhancement would be considered compatible with human rights. Due to the novelty of various HETs, many resulting legal questions will have to be decided by courts, on a case by case basis, weighing the corresponding risks and benefits. Responses to the same questions may be different in different legal cultures. In the course of adaptation, elaboration and operationalization of human rights in different legal orders may give different meanings to the same concepts. It may be expected that, since there are no established human rights standards on enhancement, and because enhancement raises many ethical issues, states will enjoy a wide margin of appreciation in deciding those questions, even within the same regional human rights regimes.

[255] See, e.g., Lines, R., *Drug Control and Human Rights in International Law*, Cambridge University Press, 2017.

EU regulatory activities related to HETs will require reaching a consensus among member states on some of the ethical and human rights challenges. The right to bodily and mental integrity guaranteed in the EU Charter should play a guiding role in reaching that agreement. It is well-suited for that task as it is, in fact, a cluster of rights, covering different aspects of the right to privacy, the prohibition of torture and the right to health. Moreover, at least in the case of the EU member states included in the SIENNA research, it is explicitly or implicitly recognized by domestic laws.

In general, the direction of human rights law rather consistently supports autonomy and self-determination. Within the human rights discourse there are, however, markers that seem less supportive of individual choice. This thread is related to a specific, conservative conceptualization of human dignity reflected in Art. 3 of the Charter of Fundamental Rights. As it stands now, Article 3 reflects a particular vision of human dignity that overrides individual autonomy: "the function of dignity is to protect the intrinsic worth of the individual (whether she likes it or not) and, possibly more importantly, the dignity of the human species as such, rather than empower the autonomous person's claim that their choices be respected."[256] Other, more liberal, conceptualizations of dignity are, however, possible.

While the conservative idea of human dignity seems incompatible with the ideas of autonomy and self-determination, it might still affect the interpretation and development of human rights norms in the context of HETs. If human rights are to set standards for other laws, regulators must be mindful of these varying ideas of human dignity.

7.3 Rethinking the risk/benefit assessment

At all stages of the innovation cycle, regulatory interventions must be tailored to the perceived risk profile presented by a particular technology.[257] If the development of HETs leads to the adoption of new laws, such laws should, as far as possible, be evidence-based; however, scientific uncertainty and the lack of knowledge and data about the potential impacts of HETs create challenges for regulation. In order to overcome them, funding may be required for research into the safety and efficacy of enhancers, as well as for epidemiological studies of the broader effects of long-term use.[258] Currently, due to scientific uncertainty, a cautious approach is justified. While "cautious" should not be synonymous with "overtly prohibitive", users should at least be informed of potential risks and uncertainties.

Existing procedures for trials and market approval may be inadequate for enhancement uses. While existing law covers possible medical risks of HETs if they are developed in a medical context, HETs are not investigated for enhancement effects. Current requirements entail assessment of medical benefits and risks, but do not demand the assessment of ethical questions and societal effects related to non-therapeutic uses. The challenge is, thus, to establish a model of risk/ benefit analysis that would encompass the different societal and ethical impacts entailed by HE, and fit the risk profile of HETs. Such a model ought to be one that protects users without unnecessarily limiting their autonomy. A better, more nuanced understanding of risks and benefits is particularly important bearing in mind, as

[256] Michalowski, Sabine, "Article 3 – Right to the Integrity of the Person" in Steve Peers, Tamara Hervey, Jeff Kenner, Angela Ward (eds.), *The EU Charter of Fundamental Rights,* Hart Publishing, Oxford, 2014, pp. 82-103.
[257] Brownsword, Roger, *Rights, Regulation and the Technological Revolution*, 2008, p. 107.
[258] See Oxford Martin, https://www.oxfordmartin.ox.ac.uk/downloads/briefings/200806-FHI-enhancement-e.pdf.

Maslen et al. discuss,[259] that benefits are more difficult to quantify in cases of enhancement than they are in medical situations. [260]

7.4 Ensuring safety of procedures and avoiding "grey zones"

In order to protect the rights of a person participating in any kind of enhancement procedure, regulators should avoid creating "grey zones" where it is unclear which standards of care apply and where accountability gaps may occur. The analysis of national laws suggests that the adoption of the following safety measures might be considered:

- HE services should be carried out by an authorized person that has been appropriately trained and can be held accountable; such persons should be required to have measures in place to provide sufficient financial coverage for their potential liability; they should gather information from the client about their health and suitability for the procedure;
- HE services should be performed in a technically-correct way, according to professional standards and safety requirements; the expected benefits of any HE service should outweigh the risks; the procedure should not put one's life in imminent danger or cause a serious injury;
- A person undergoing a procedure should obtain clear, accurate information about the risks, possible adverse outcomes and possible complications that could arise from the procedure;
- A person should not be permitted to give up their right to information; informed consent must be obtained. An additional measure to consider is a requirement of a time lapse between providing information about the procedure and the procedure itself;
- As far as advertising is concerned, interventions should not be trivialised; there should be no aggressive inducement.

The implementation of these measures may require development of a classification for different types of enhancement procedures based on the following criteria:

- invasiveness
- complexity
- permanence or reversibility
- health risks
- societal acceptability.

Other steps would consist of:

- setting up licensing/authorisation bodies and monitoring mechanisms;
- establishing ethics codes, professional guidelines, industry standards and operational procedures;
- establishing or developing criteria to assess and quantify the risks and benefits of HE, which is key to ensure recourse to adequate redress in the event of something going wrong.

[259] Note that Maslen's writings focus exclusively on *cognitive* enhancement devices, thus not explicitly applicable to a number of non-cognitive enhancers, such as devices that promise performance benefits rather than cognitive ones.

[260] A similar recommendation about drug approval has been made by experts at the Future of Humanity Institute, according to whom the disease-focused regulatory framework for drug approval should be expanded into a "health- or wellbeing focused framework, in order to facilitate the development and use of safer cognitive enhancement of healthy adults. This would fit with current trends towards patient choice, and reduce medicalization and grey markets." See Oxford Martin, https://www.oxfordmartin.ox.ac.uk/downloads/briefings/200806-FHI-enhancement-e.pdf.

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9. Annexes

Annex 1 Guidelines for country studies

SIENNA
Work package 3: Human enhancement
Task 3.2

"Guidelines for conducting studies of domestic laws in Work-package 3: Human enhancement[261] technologies"

Version as of 7 June 2018
Zuzanna Warso, Helsinki Foundation for Human Rights

1. Introduction

National studies carried out in Task 3.2 shall consist two main parts.[262] Part I will provide a brief discussion of relevant legal developments and a summary of relevant legal scholarship. Part II will address specific legal questions (listed in sections 3.2 and 3.3 below).

2. Part I: legal developments and the analysis of national legal scholarship.

Please address the following questions concerning legal developments (consider last 5 to 10 years). Following the steps outlined in 2.2, provide a summary of relevant national legal scholarship. Please list sources, databases as well as search terms that you use (in your national language and an English translation, in case of doubt about the translation please explain briefly the source or nature of your doubts).

2.1. Legal developments (1-2 pages)

1. *Have there been attempts or plans to adopt at national level new legislation or set up new regulatory bodies in response to new development and/or increased use of human enhancement technologies.[263] Have there been/are there attempts to regulate[264] how HETs are designed, set up, commissioned or used?*

2. *Have developments of HETs led to amendments in constitutional or human rights and/or legislation bearing on constitutional or human rights (for example the right to privacy, the right to bodily or mental integrity)? Please identify judgments of the highest national courts (constitutional or supreme courts) that address developments of HET.*

2.2. Legal scholarship:

Please assess through a literature search academic articles that have appeared in the past 10 years that address legal aspects of human enhancement. On the basis of the search, please provide references to 15 (max.) publications and a brief review of the academic legal discourse on human enhancement that covers the themes/topics discussed. The search should be restricted to academic

[261] By "human enhancement" we understood a "modification aimed at improving human performance and brought about by science-based and/or technology-based interventions in or on the human body".
[262] For a detailed structure of the report, please see the reference report on Polish law.
[263] For what is meant by "new developments and/or increased use of human enhancement technologies", please consult the SIENNA State-of-the-art Review document. To give an example, we are, for instance, interested in the following phenomena currently occurring:
- the proliferation of cognitive enhancement devices and their easy availability,
- the use of drugs for cognitive enhancement (including administration of the drugs to children),
- recent development of CRISPR-Cas systems,
- the need to protect the augmented body (including technology ON the human body).

We are also interested in the development concerning the more common and established ("traditional") types of enhancement (e.g. the issues of age limit in cosmetic surgery or the problem of doping) as long as they fit the definition of HET.
[264] This could be both to restrict or advance the development or use of such applications.

journal articles, books and book chapters written in the national language with a strong focus on legal issues.
Suggested list of search terms:

Search terms
1. Human enhancement
2. Non-therapeutic human enhancement[265]
3. (Human) Enhancement technologies
4. Non-therapeutic services
5. Non-therapeutic medical services (sic!)
6. Non-medical health devices
7. Lifestyle medical services

3. Part II: Specific issues

3.1. Background information

- World Health Organisation offers a broad definition of the state of "health". According to WHO: "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."[266]
- One of the key demarcations in the debate on HET is that between "treatment" and "enhancement" (for more information on the key demarcations see the SIENNA State- of-the-art Review). It has been repeatedly argued that the demarcation between treatment and enhancement seems increasingly challenging to maintain. Still, in spite of the challenges, according to some scholars "the state creates sharp boundaries for the purpose of making laws and enacting policy. For example, a distinction between treatment and enhancement is implicit as a marker of which interventions should be made accessible through the health care system or reimbursed by health insurance."[267]
- The classification of a service or a device as therapeutic or non-therapeutic or as medical or non-medical may have significant legal consequences concerning, for example: informed consent, liability, or how the acceptable level of risk is established.
- Benefits become increasingly harder to quantify and assess as they move beyond the sorts of benefits that enable individuals to pursue the standard range of activities most people wish to pursue. Some scholars say that weighing the risks and benefits of a product which does not have a medical purpose is different than for medical products. The consequence of the variation in the value that different people attach to enhancement is that a regulatory system should err on the side of leaving room for users to attach their own values to the potential benefits. According to H. Maslen, where there is room for disagreement about how to quantify a benefit in relation to risks, regulation should err on the side of consumer freedom.[268]
- Two sorts of arguments can be found in literature regarding the acceptable level of risk in the case of non-medical devices or services. The first one is that which is made in the case of enhancement research: "as medical need falls, the potential benefits of participating in

[265] See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:306E:0426:0429:EN:PDF.
[266] Preamble to the Constitution of WHO as adopted by the International Health Conference, New York, 19 June - 22 July 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of WHO, no. 2, p. 100) and entered into force on 7 April 1948. The definition has not been amended since 1948.
[267] Maslen, Hannah, op. cit., 2016, p. 279.
[268] *Ibid*.

research must increasingly outweigh any risks in order for the study to be ethical".[269] But a different approach is also possible, namely: as medical need falls consumer freedom to assess the reasonableness of risks for themselves should rise.[270]

- As human enhancement occurs via interventions in or on the human body, the "strategic role" in building a possible "normative anchor point" for future developments in HE has been given to the right to bodily integrity.[271]

3.2. Terminology and legal demarcations

Please address the following questions based on the analysis of the laws in force, case-law and legal scholarship:

1. *Does the domestic law in your country provide a legal definition of "health" or the state of "health"? If yes, please quote the relevant source. Has the question of the definition of "health" been addressed in the case law?*
2. *What are the basic legal terms and demarcations used nationally that should be taken into consideration in the discussion on the regulation of HET?[272] Please consider the following dichotomies: medical v. non-medical, treatment v. enhancement, therapeutic v. non-therapeutic, natural v. non-natural. Are there any other potentially relevant legal demarcations or distinctions? Please provide a list of terms in the national language and an English translation (in case of doubt, please briefly explain the nature or source of doubts).*
3. *What criteria are used to classify services, devices and products according to those categories?*

3.3. Right to integrity of the person, legal permissibility of non-therapeutic services on the human body, limits to the permissibility; specific legal requirements.

Please address the following questions based on the analysis of the laws in force, case-law and legal scholarship:

1. *Does the domestic law recognize the right to (physical and/or mental) integrity of the person? If yes, please provide a relevant citation. What are the limits to this right? Please provide examples. What criteria and values are considered to set those limits?*
2. *How is the legality of enhancement procedures (understood as non-therapeutic interventions in the human body) established?*
3. *Are there limits to what non-therapeutic procedures can be performed on a human body? What criteria are used to establish those limits? What is the role of consent? Does the national law, case-law or legal doctrine provide any guidance on how risks and benefits of non-therapeutic procedures should be weighed and/or what is the acceptable level of risk in those cases?*
4. *Is there a legal requirement for informed consent in the case of all non-therapeutic procedures? If yes, are requirements concerning informed consent more or less rigorous than in the case of procedures with a therapeutic aim?*
5. *Has the question of the protection afforded to the augmented or modified body (e.g. body with prosthetics) been addressed nationally? Is the augmented or modified body afforded the same protection and guarantees as an organic body? Are there issues regarding ownership?*

[269] Maslen, Hannah, op. cit., 2016, p. 284.
[270] Maslen, Hannah, op. cit., 2016, p. 286.
[271] Ruggiu, Daniele, op. cit.,2018.
https://www.tandfonline.com/doi/abs/10.1080/17579961.2018.1452177
[272] Please consult the SIENNA State of the Art deliverable concerning the main relevant demarcations in the field of HET.

Annex 2 List of country studies[273]

1. Brazil
2. China
3. France
4. Germany
5. Greece
6. Netherlands
7. Poland
8. South
9. Spain
10. Sweden
11. UK
12. USA

[273] Country studies are available at: www.sienna-project.eu