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# The European Union proposal for regulating Artificial Intelligence and its application in Medical Robotics surgery

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**Abstract:** Time brings technological developments which serve multiple sciences conveniently with the purpose of improving and achieving better results. This holds true for the healthcare industry currently experiencing technological paraphernalia using artificial intelligence at its heart. This reality often leads the usual binary physician-patient relationship into a physician-robot-patient relationship, a scenario that requires a review of legal regulation while considering physicians' accountabilities.

Under this motto, the aim of this study is to understand how the legislative efforts carried out by the European Union, even if currently in the form of proposals, are consistent with respect to medical responsibilities in the context of medical activities led by artificial intelligence. In the event of harm to the patient, it is important to understand who is responsible and how the European Union intends to protect the injured party.

**Keywords:** robotic-doctor; artificial intelligence; robotic surgery.

## 1. Civil Liability and the Robotic-Doctor - Applications

Andre Dias Pereira contends that “the right to health is undergoing a great transformation! Something that mathematics is deeply involved with, in connection with genetics and bioinformatics, opening the field to gene therapy and personalized medicine”<sup>1</sup>.

It is undeniable that physicians are held responsible for the acts practiced in the exercise of their profession since immemorial times, in fact, surgeons who were considered imperfect and who did not follow the *legis artis*, or who acted inattentively or negligently, had to deal with penalties such as the amputation of their hands<sup>2 3</sup>.

Due to the intense technological developments that lead us to place ourselves in the 5.0 society, the responsibility of the physicians has changed and it is now faced with the need to make it compatible with such technological developments, namely with the existence of robotic-doctors.

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<sup>1</sup> *Our Translation.* PEREIRA, André Dias – O Médico-Robô e os Desafios para a Saúde: Entre o Algoritmo e a Empatia, *Gazeta Matemática – PT-Maths-In*, N189 (2919), PP. 30-34.

<sup>2</sup> Hamurabi Code, Article 218, “If a physician make a large incision with the operating knife, and kill him, or open a tumor with the operating knife, and cut out the eye, his hands shall be cut off”

<sup>3</sup> “(...) medical civil liability underwent constant transformation, from the probability of deportation and death penalty in Ancient Rome, to liability for guilt, when there was no respect for the basic rules determined by the Greeks; of the imputation of responsibility only when there was evidence of serious misconduct, indicated by the French (...)”. *Our translation.* DADALTO, Luciana; PIMENTEL, Willian - Responsabilidade Civil do Médico no Uso da Inteligência Artificial. *Revista Iberc*, V.2, N 3 (2019), PP. 1-20. P. 11.

Although, still far from this reality, there were and still are, jurisprudential disputes about how medical civil liability should be shaped, whether in the form of tortious liability<sup>4</sup> or contractual liability. Despite the jurisprudence leaning towards contractual liability, easing evidence to the injured/patient, it is urgent to sympathize with this desideratum given that medicine has an obligation of means in most of its interactions with the patient.

Regardless of how medical civil liability for damages caused to a patient is framed, the reality is that today this difficulty is exacerbated by the fact that we are no longer dealing with a simple physician-patient relationship, rather a physician-robot-patient relationship.

As mentioned already, technological development and medicine have always gone hand in hand in their discoveries and technology has always supported medicine in the search for better answers to the challenges it is constantly exposed to. From the combination of medical knowledge, technology, computing and robotics, the aforementioned robots arise to act in surgical procedures and to aid in medical diagnosis.

Artificial Intelligence (hereinafter AI) has indeed an evident application in healthcare. For example, the main task performed by a physician is the diagnosis and prescription of the best therapeutic strategy for a particular symptomatic condition.

However, the knowledge obtained by the physician is based on what he/she learned during the medical course and other studies that he/she carried out throughout his/her career as well as the experience he/she acquired in medical practice. Nevertheless, the physician will never sustain all the available knowledge, as this is humanly impossible, unlike a robotic-doctor equipped with AI which, while connected to the world wide web, is able to access countless data, medical literature, medication leaflets, clinical history of both the patient and others with similar symptoms. Also, the robotic-doctor can deliver this in less time and provide a more accurate diagnosis<sup>5</sup>. Regarding the robotic-doctor, Andrew McAfee, scientist, is convinced that “if it’s not already the world’s best diagnostician, it will be soon”<sup>6</sup>. Yet, nowadays, physicians who use AI are expected to use it as an aid to clinical decision-making, not as a substitute for the entire procedure. Therefore, it makes sense (for now!) that the physician is responsible for any damage that may occur.

How can we define the robotic-doctor though? The robotic-doctor can be defined as a set of algorithms applied in software concatenated to perform medical activities, with self-learning ability derived from accumulating experiences while evolving with them, being able to act independently, deliberating autonomously.

Although today we are not faced with the possibility of a robotic-doctor proceeding autonomously and fully with a surgery - a situation prohibited by article 14 of the Proposal for a Regulation of the European Parliament and of the Council that establishes harmonized rules in the field of Artificial Intelligence (hereinafter PRIA)<sup>7</sup> -, the truth is that this is already technologically feasible.

Currently, these robotic-doctors equipped with machine learning have only acted without human mediation in surgeries on animals. However, surgical procedures assisted by robots occur in humans as long as they are mediated by a physician in hospitals around the world, especially in specialties such as thoracic surgery, urology, abdominal and neurosurgery, due to the need of millimeter intervention. These surgeries using robotic-surgeons offer benefits compared to the conventional approach, including lower risk of infection and blood loss, eliminating the surgeon’s natural tremor, and accessing complex places that are difficult to access by the human hand<sup>8</sup>.

<sup>4</sup> “Within the scope of the National Health Service (*portuguese*), there is no consensus in the doctrine and jurisprudence of the existence of a contractual relationship between the patient and the doctor or the hospital as a public entity, prevailing the thesis of non-contractual civil liability.”. *Our translation*. RODRIGUES, Abel - *A Responsabilidade por Ato Médico*, Braga: Nova Causa, 2020. ISBN 978-989-54812-4-8. P. 82.

<sup>5</sup> “The animals or decisions trees (...) that the textbooks illustrate, can be followed by artificial intelligence, with more fundamentals and, probably, more acuity than anyone else could”. *Our translations*. ANDRADE, Luís Gouveia - *Inteligência Artificial e Medicina: Haverá Lugar para o Factor Humano?* - Revista Portuguesa de Farmacoterapia. V. 10, N. 1 (2018), PP. 53-55, P. 54.

<sup>6</sup> “IBM’s supercomputer Watson may soon be world’s best doctor” - Economic Times [online]. 2014.[12.04.2022]available at <https://economic-times.indiatimes.com/magazines/panache/ibms-supercomputer-watson-may-soon-be-worlds-best-doctor/articleshow/34199362.cms>.

<sup>7</sup> Proposal COM(2021)206 of 21th april 2021.

<sup>8</sup> THAI, Mai Thanh [et. al.] - *Advanced Intelligent Systems for Surgical Robotics* [online]. 2020. [26.10.2021]. Available at <https://onlinelibrary.wiley.com/doi/full/10.1002/aisy.201900138>.

The use of the robotic-surgeons mainly translates into the use of an robotic arm that repeats the movements of the surgeon's hands outside the patient's body<sup>9</sup> allowing the surgery to be safer and more accurate. The robotic-surgeon's wrist has a swivel capacity superior to the biological surgeon's wrist, since it has the ability to rotate about its axis in a 360° angle, making the previously difficult or even inaccessible places now accessible. The robotic-surgeon operates with several instruments connected to a mechanical arm that contains a microcamera which expands the surgeon's vision and facilitates decision-making during the surgery, making it faster and more accurate. A scalpel among other necessary instruments adapted to a particular surgery also allows the same surgery to be carried out at kilometers of distance between the patient and the surgeon, referred to as telesurgery.

Although the current PRIA does not define intelligent autonomous robots, rather an artificial intelligence system, its definition was already advanced by the Parliament in the Resolution of 16 February 2017, which contains the recommendations to the Commission on Civil Law provisions on Robotics<sup>10</sup>, referring that intelligent autonomous robots are acknowledged based on the following categories: acquisition of autonomy through sensors and/or data exchange with their environment (interconnectivity) and the exchange and analysis of these data; self-learning through experience and interaction (optional criteria); minimal physical support; adaptation of their behavior and actions to the environment; and non-existence of life in the biological sense of the term.

This autonomous ability to act *per se* raises questions of various kinds, namely ethical and legal issues. We must put into perspective the legal concerns, more specifically those related to civil liability for damages caused to a third party (patient) by a robotic-surgeon, since its self-learning capacity and AI endowment to accumulate experiences, learn from them and deliver improved behaviors, conjectures the possibility of an error. And from that same error, damages can arise. In the event of a surgical knife not moving at a certain moment to make an incision or the failure of certain elements of a surgical arm, are examples of ways to unexpectedly cause damage to the patient.

In fact, Rafaella Nogaroli<sup>11</sup>, draws attention to a scenario in telesurgery where there is a delay between the surgeon's movement and the robotic-surgeon's action caused, for example, by an interruption of internet services. In this regard, he contends the following: "imagine the scenario where a physician performs a myocardial revascularization telesurgery (...). During the procedure, the robotic arm makes an apparently unexpected movement and cuts the coronary artery." – *Quid iuris?* Should the physician be held accountable even if he had acted with all the prudence and diligence required and had the best knowledge and specialized robotic-surgeon training? Should the network service provider be held accountable?

## 2. The European Union's Artificial Intelligence regulation proposal and its *modus operandi* in robotic-surgery

After a long road of conjecture, on April 21 of 2021, the European Parliament and the Council introduced the PRIA which establishes rules for artificial intelligence and changes certain legislative acts of the European Union.

First, it must be noted that PRIA's future application eliminates the possibility of an error driven by the surgeon by lack of diligence or expertise. PRIA aims to regulate the damages caused by the robotic-surgical system itself, where this is not applicable, the general medical civil liability regime will always apply, namely in those cases where the damage to the patient is caused by an inappropriate robotic-doctor, previously selected by the surgeon, giving it an improper use or entering erroneous or false data about the problem to be solved.

<sup>9</sup> The surgical robot most used by hospitals around the world is called Da Vinci. "The Da Vinci robotic system is the latest evolution in minimally invasive surgery: equipped with high-definition 3D vision, Endowrist instruments and a simple and intuitive control system that allows the surgeon to perform delicate interventions, performing complex surgeries always with minimum intrusion guarantee. Born in the heart of Silicon Valley - from military patents - and developed by the Californian company Intuitive Surgical Inc., the da Vinci robot was launched in 1999. Since then, it has revolutionized robotic surgery in the United States and the rest of the world, allowing increasingly efficient results with the development of successive configurations." *Our translation*. [Online] [26.10.2021]. available at <https://www.excelenciarobotica.pt/pt/sistema-robotico-da-vinci/de-que-se-trata>.

<sup>10</sup> (2015/2103(INL))

<sup>11</sup> NEGOROLLI, Rafaella – Implicações ético-jurídicas na medicina robótica e inteligência artificial nas cirurgias e cuidados de saúde [online]. 2021. [12.04.2022]. Available at <https://academiamedica.com.br/blog/implicacoes-etico-juridicas-da-medicina-robotica-e-inteligencia-artificial-nas-cirurgias-e-cuidados-da-saude>.

PRIA reinforces what was already foreseen in the previous European Parliament resolution proposal, which includes recommendations to the Commission about the civil liability regime applicable to artificial intelligence (hereinafter PRRCIA) which establishes the need to ensure that all citizens who have suffered damage caused by systems equipped with AI or whose property damage is caused by them likewise benefit from the same level of protection in situations in which there is no intervention of this technology.

Once it is proven that an error was due to a deficient performance of an AI robot, the future EU legal framework on AI will apply. The question to be understood is how can the injured person prove the damage was caused by the robotic-surgeon? Those AI systems are configured as high risk and as such must be equipped with something similar to a black box that allows a concrete analysis of the actions or failures of both the system and the humanoid operator, in accordance with the requirement now provided in article 12 of the PRIA, which requires them to be equipped with the ability to record events and maintain records while the system is functioning. However, this requirement is complex as it requires technical and specialized knowledge from the holder of the burden of proof. To note that up until the moment when the damage was caused, the robotic-surgeon was exposed to several behavioral influencers throughout its whole life cycle. These concerns were previously addressed in the Report containing the Recommendations to the Commission about the civil liability regime applicable to AI, namely in article 4 when it refers to the objective responsibility for high-risk AI systems.

Furthermore, the future Regulation (PRIA) scope will include localized AI suppliers and users, or suppliers and users who implement localized systems whose final results are in the EU territory, whether of public or private nature following the article 2 from the AI regulation. It will only not be applicable to those who use AI for private and non-professional purposes, according to the combined interpretation of article 2º and article 3º, 4º and also Wherea 59.

### **2.1. The Graduation of Risk**

PRIA puts forward a proposal for grading possible risk<sup>12</sup>s driven by AI with the aim to achieve security and trust: unacceptable, high, limited and minimal. The use of a risk-based legislative framework was considered a better option than applying generalized regulation to all AI systems, with risk types and threats being based on a case-by-case approach. AI applications that can be used in assisted surgery are classified as high risk, since their failure or anomaly puts people's health at risk and such assessment is not based solely on the function for which the AI system was designed but of its specific purpose and the modalities for which that system may be used. This categorization, in addition to taking into account the functions to be performed, possible and specific modalities of the application of AI technology, the level of dependence of the operator in relation to the results obtained and the irreversibility of the damages<sup>13</sup>, lists such systems in Annex III of the PRIA<sup>14</sup>. The latter can be expanded and updated in accordance with the provisions of article 7.º of the same legal diploma<sup>15</sup>.

Based on article 6º of the PRIA "classification rules for high-risk AI systems", it's possible to infer that robotic-surgeons are classified as a high-risk artificial intelligence system, not only because of the possible risks but also because they are covered by the Union harmonization legislation listed in Annex II of the PRIA, given the Regulation (EU) 2017/745 of the European Parliament and of the Council as of 5 April 2017 about medical devices.

These systems equipped with AI must be equipped with human-machine interface tools so that the robotic-surgeon's actions are supervised effectively, providing them with a "stop" button or a similar tool as anticipated in article 14. This regulation aims to ensure that signs of anomalies, possible dysfunctions and unexpected performance can be detected and resolved in the shortest possible time avoiding further damage.

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<sup>12</sup> "Using a risk-based framework was considered a better option than blanket regulation of all AI systems. The types of risks and threats should be based on a sector-by-sector and case-by-case approach." At point 3. results of ex-post evaluations, stakeholder consultations and impact assessments 3.1. stakeholder consultation of Explanatory Memorandum of PRIA, P.9.

<sup>13</sup> Wherea 32 of PRIA.

<sup>14</sup> Provided that one or both situations provided for in Article 6.º, subparagraph a) and b) are completed and cumulatively included in the list of harmonized legislation of the European Union, provided for in Annex II to the same Regulation.

<sup>15</sup> Attached (Annex III) to the PRIA is a list of uses of AI which the Commission currently describes (now) as high risk, and the Commission is empowered to adopt acts aimed at updating the list in Annex III, adding AI systems that should be listed as high risk (Article 7, n. 1).



However, it is important to understand the types of damage that can be caused by the robotic-doctor: the robotic-doctor can cause damage simply because it has a defect that prevents its use by the user who has contracted the product or service; the robotic-doctor may misdiagnose; the robotic-doctor can present a correct diagnosis yet an inadequate treatment. As for the person who may suffer the damage, it can lead to damaging a contracting party such as the hospital, clinic, medical insurance company (legal person) or to the physician in a biological sense who uses the robotic-doctor to provide services or provide it to a third person or the robotic-doctor generates harm to the patient.

PRIA sets different requirements and strict obligations for the producers and suppliers of these AI systems, such as: assessment of their conformity before placing them on the market or in service; development of detailed technical documentation; provision of information to its users; synchronous reporting of serious incidents of any malfunction to the competent authority<sup>16</sup>. In order to keep that list up-to-date, a continuous and systematic system must be implemented, documented and executed, maintained throughout the life cycle of a high-risk AI system, such as a detailed biography of that system (*see article 9°, 11° and 12° of the Proposal*). The testing regime itself is covered by the PRIA whereas the tests “shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.” (n° 7, article 9°).

Likewise, the provision of an entity is anticipated in each state-member responsible to establish and implement the procedures necessary for the assessment as well as the designation and notification of conformity assessment bodies and their supervision (article 30°). The same holds true for the creation of an European Union database on autonomous high-risk artificial intelligence systems meaning the systems which are not incorporated into products have their own identity (article 60°).

This AI legislative harmonization is supplemented by the Regulation of the European Parliament and of the Council regarding machinery products (hereinafter PRRMachines), which appears in the hands of the European Commission and some Members of Parliament after the evaluation of the Directive 2006/42/EC of the European Parliament and the Council as of 17 May 2006. It's considered that it does not “sufficiently cover the new risks arising from emerging technologies”, leading to a transfer of this Directive to the 21st century, already in the form of regulation, however. Hence, PRMachines establishes the requirements and rules for the design and manufacture of machines and their components and accessories, allowing them to be made available on the market or entering into service and also laying down the rules on their free movement within the European Union.

With the expected approval of PRMachines, producers, suppliers, distributors, importers, among other machinery and equipment agents from article 2° of that diploma, acknowledge their obligations and requirements enabling the viability of the AI devices (article 17° and following.), the rules to adopt the CE brand (article 20°), the required compliance assessment (article 21° and following.) among other issues of extreme relevance.

## **2.2. The liability of the robotic-surgeon operator**

The European Union understood the need to approach the civil liability regime in a uniform way requiring the revision of the producer liability's Directive. This need to amend the regime had already been defended<sup>17</sup>, reinforcing the fact that many of the damages caused may not be based on a defect, rather on an erroneous evolution of the algorithm as well as the fact that the regime does not compensate material damages driven by the “defect”<sup>18</sup>.

It should also be mentioned that the RCIA anticipates the duality of responsibilities: subjective and objective, depending on whether or not we are faced with a high-risk AI system. It defends that different degrees of autonomy should imply different levels of control as a justification to apply different civil liability regimes.

<sup>16</sup> Article 30.° of PRIA.

<sup>17</sup> MAIA, Ana Rita - A Responsabilidade Civil na Era da Inteligência Artificial – Qual o Caminho?. [Em linha]. [online]. 2020. *Julgar Online*, (2021). [26-10-2021] PP. 1-44. Available at <http://julgar.pt/a-responsabilidade-civil-na-era-da-inteligencia-artificial-qual-o-caminho/>. P. 18.

<sup>18</sup> José Alberto González clears who are the third spatially close, referring: “(...) the damage caused by the defective stove hold the producer responsible not only to the buyer but also to the relatives who live with him; the damage caused by the defective motor vehicle shall hold the manufacturer liable to its owner, but also to the persons transported therein.”. *Our translation*. GONZÁLEZ, José Alberto - *Direito da Responsabilidade Civil*, Lisboa: Quid Juris – Sociedade Editora. 2017. ISBN 978-972-724-774-5. P. 457. Vide também a este propósito CALVÃO DA SILVA, João - *Compra e Venda de Coisas Defeituosas (Conformidade e Segurança)*. 5.ª ed. Coimbra: Almedina, 2008. ISBN 978-972-40-3475-1, pp. 215 e ss..

It is now urgent to question how does the proposal provide for holding an employee liability of the possible damage that has occurred under technology? The PRRCIA maintains in its tenth Wherea that the “The liability of the operator under this Regulation is based on the fact that he or she exercises a degree of control over a risk connected with the operation and functioning of an AI-system, which is comparable to an owner of a car.”

Responsibility becomes a liability when dealing with damages that go beyond the normal risk of living. When this holds true and there is a viable legal basis, it makes sense that there is a demanded compensation to the injured party. To note that PRRCIA accepts the inevitability of risk associated with the creation of new AI systems, as the Wherea 2 states: “in the beginning of a new product or service life cycle, after being tested, there is a degree of risk”.

Under this motto, article 4° of the PRRCIA anticipates that “the *objective responsibility for high-risk AI-systems*” and “the operator of a high-risk AI-system shall be strictly liable for any harm or damage that was caused by a physical or virtual activity, device or process driven by that AI-system”, meaning the AI system operators cannot be exempted from accountabilities, claiming that they acted with due diligence or that the damage was caused by a device or an autonomous process based on the AI system.<sup>19</sup> <sup>20</sup>Unless, they can prove otherwise with compelling events.

Therefore, there is a need to question who is the *operator of the robotic-surgeon*? is it the surgeon, the nurse, the developers? In article 3°, subparagraph d), PRRCIA defines that “operator” as a *frontend* operator (or final operator) and *backend* operator (or initial operator), covered by the paragraphs e) and f) in the same article. Hence, from the analysis of these concepts, it’s possible to say that the surgeon will always fit into the frontend operator designation given he/she uses a degree of control of the risk and benefits from the functionalities of the AI system as well as the other healthcare professionals who perform a degree of control of the risk such as the nurses, radiologists, among others. On the other hand, in article n° 3, subparagraph 8), PRIA defines operator as “(...) the provider, the user, the authorized representative, the importer and the distributor”. From these legal expressions, the take away is that if there is an objective liability of the operator, this responsibility will be shared between the *frontend* and *backend* operators. In the event of an operator being simultaneously the producer of an AI system, the Regulation to be approved on the basis of the PRRCIA will prevail over the Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products<sup>21</sup> in accordance with article 11° of the PRRCIA.

However, in cases of telemedicine in which the robotic-surgeon is operating miles away from the surgeon and, although he is considered an operator, the one who is next to the patient, will he/she also be considered an operator for accountability following the provisions of article 14° of the PRIA? It seems the answer is yes, given there will be shared responsibility between the two *frontend* operators as they both have shared accountabilities. Hence, the operator who is close to the patient will have the same ability to continue the surgery, every time the remote surgeon or the surgeon *in loco* releases any malfunction.

As Filipe Medon alludes<sup>22</sup>, “the definition of an operator goes through two basic elements: benefit and control”. The latter, also in article 3° of the PRRCIA, is defined as “any action an operator performs which influences the functioning of an AI system and, therefore, the extent to which the operator exposes third parties to the potential risks associated with the surgery and operation of the AI system (...)”.

The limitation of objective responsibility for the purposes of the PRIA is small, and the agent is held accountable only in cases of major force, in accordance with article 4° of the PRRCIA. However, doctrine states commonly “it was caused by major force” for indefinite and indeterminate reasons which can only be cataloged only on a case-by-case list.

<sup>19</sup> It’s contained in article 3°, subparagraph d) and f) of the PRRCIA the definition of operator.

<sup>20</sup> “(...) given the need for fair distribution of risks and benefits, the producer should not be allowed to avoid his responsibility by relying on the risk of development. (...) “it cannot be said that it was not, according to the state of science and technique, possible to predict that an injury would occur.” MOREIRA, Sonia - Considerations on Artificial Intelligence and Civil Liability: The Case of Autonomous Vehicles. In CARVALHO, Maria Miguel - *E.Tec Yearbook Yearbook – Artificial Intelligence & Robots*, Braga, Jusgov, 2020. ISSN 2184-707X. PP. 111-127. PP. 69-91. P. 86th

<sup>21</sup> Directive 85/374CEE.

<sup>22</sup> MEDON, Filipe - *Damage Caused by artificial intelligence and the complete repair put to the test: why should the Substitute for PL 21 of 2020 be changed urgently?*. [Online]. 2021. [12.04.2022]. Available at <https://www.migalhas.com.br/columa/migalhas-de-responsabilidade-civil/351200/danos-causados-por-inteligencia-artificial-e-a-reparacao-posta-a-prova>.



It is extremely important to stress that *the frontend operator* of high-risk AI systems should ensure that all operations are covered by appropriate liability insurance to the amounts and size of the compensation provided in articles 5° and 6° of the RCIA, an issue which leads us to question whether the current medical liability insurance will cover these surgeries or not.

Regarding the responsibilities of the operator of other AI systems, meaning all os the systems not high-risk, a subjective responsibility is applicable with presumed guilt, under article 8° and following of the PRRCIA.

### **3. Brief Conclusions**

In conclusion, in the event of a damage caused by a robotic-surgeon, the civil liability must be held by the AI systems' operator e.g., a medical technician, surgeon, nurse, paramedic, among others (when there are other operators), meaning the responsibility will be shared without prejudice of the eventual right of return. The liability will be objective given that the AI systems applied to healthcare are considered high-risk. Finally, the aim was to give a response to how a user can identify the *per se* AI system as being high-risk? The answer to this question is provided by PRIA via a mandatory AI system registry, article 51° annex VIII as well as the obligation of the producer to be accountable for the whole AI system's life cycle.