

## Economic and Legal on The Deploying of Medical and Healthcare Robotics: Case Study on a Comparison of the European Union (EU), South Africa, and Thailand

นโยบายทางเศรษฐกิจและกฎหมายในการใช้หุ่นยนต์ทางการแพทย์และการดูแลสุขภาพ: กรณีศึกษาการเปรียบเทียบระหว่างสหภาพยุโรป, แอฟริกาใต้และประเทศไทย

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### Abstract

Europe is well placed to benefit from the potential of Artificial Intelligence (AI). It produces industrial and professional service robots for healthcare and plays an important role in developing and using software applications for companies. Surprisingly, the African Region and Thailand, neither of which is traditionally associated with robotics technology, are making good progress in the use and development of robots in the field of medical service and healthcare by promoting investment in robotics innovation. However, there

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are still several unclear aspects to be addressed by policymakers in these two regions. Although medical robots have shown great potential in these two areas by contributing to various healing processes, many limitations to the application of the technology as such have emerged in terms of economic policy, legal frameworks, the risk to privacy, and moral responsibility. Apparently, the main barrier holding back these two communities from being the next generation of automotive developers in medical robots is that legislative and investment policies governing robot activities are produced and enforced by different organizations separately. This effectively discourages not only management policy but also related action to support robotics innovation. Even though experts are creating increasingly advanced robot technology, regulation of its development is still lagging behind. This article will inform the social sciences, ethics, law, and market policy to find a solution where robots and humans can work side by side, with an emphasize on the application of legal and economic regulations relating to this growth in automation to encourage the status of the robots, bringing them to the forefront of the socio-scientific platform by applying documentary and action research methodology. In order to achieve this goal, economic policymakers and legal regulators have to engage in these agendas together with producers to establish how law and market policy should react to medical robots appropriately.

**Keyword:** Medical Robotics, Healthcare Service, Legal and Economic Policy in Technology

## บทคัดย่อ

ยุโรปถือเป็นภูมิภาคที่ใช้ประโยชน์จากศักยภาพของปัญญาประดิษฐ์ (AI) ได้อย่างดี เมื่อจะเป็นการผลิตหุ่นยนต์ที่ให้บริการด้านการดูแลสุขภาพไม่ว่าจะเป็นในระดับอุตสาหกรรม หรือระดับมืออาชีพ รวมถึงการมีบทบาทสำคัญในการพัฒนาและใช้แอพพลิเคชั่นของฟ์แวร์ สำหรับบริษัทต่าง ๆ แต่น่าแปลกที่ภูมิภาคแօฟริกาและประเทศไทยซึ่งไม่ได้มีความเกี่ยวข้องกับเทคโนโลยีหุ่นยนต์กลับมีความก้าวหน้าที่ดีในการใช้และพัฒนาหุ่นยนต์ในด้านการบริการทางการแพทย์และการดูแลสุขภาพ อย่างไรก็ตาม ทั้งสองภูมิภาคนี้ยังคงมีประเด็นทางนโยบายที่ไม่ชัดเจนและควรได้รับการแก้ไขอย่างลายประการ เช่น แม้ว่าหุ่นยนต์ทางการแพทย์จะแสดงศักยภาพที่ดีโดยการมีส่วนในกระบวนการบำบัดต่าง ๆ แต่ก็มีข้อจำกัดหลายประการในการประยุกต์ใช้เทคโนโลยีดังกล่าว ข้อจำกัดดังกล่าว ได้แก่ นโยบายทางเศรษฐกิจ, ครอบของกฎหมาย, ความเสี่ยงต่อความเป็นส่วนตัว, และความรับผิดชอบทางศีลธรรม โดยอุปสรรคที่เห็นได้ชัด คือ นโยบายด้านกฎหมายและการลงทุนที่ควบคุมกิจกรรมเกี่ยวกับหุ่นยนต์ได้ถูกบัญญัติและถูกบังคับใช้โดยองค์กรต่าง ๆ แยกกัน สิ่งนี้จึงไม่เพียงแต่ส่งผลกระทบต่อการจัดการอย่างมีประสิทธิภาพ แต่ยังรวมถึงการดำเนินการที่เกี่ยวข้องเพื่อสนับสนุนวัตกรรมทางหุ่นยนต์ด้วยตั้งนี้ แม้ว่าผู้เชี่ยวชาญจะสร้างเทคโนโลยีหุ่นยนต์ขึ้นสูงขึ้นเรื่อย ๆ ไปเพียงใด แต่การออกกฎหมายยังคงล้าหลังอยู่ บทความนี้จึงมุ่งศึกษาในทางสังคมศาสตร์, จริยธรรม, กฎหมาย และนโยบายการตลาดเพื่อหาช่องทางในการให้มุขย์และหุ่นยนต์ทำงานร่วมกันได้โดยเน้นที่การประยุกต์ใช้กฎหมายและระเบียบททางเศรษฐกิจที่เกี่ยวข้องเพื่อส่งเสริมสถานะของหุ่นยนต์ และเพื่อนำหุ่นยนต์สู่แนวทางด้านสังคม-วิทยาศาสตร์ โดยเป็นการศึกษาโดยใช้ระเบียบวิธีวิจัยเชิงเอกสารและระเบียบวิธีวิจัยเชิงปฏิบัติ ดังนั้น เพื่อให้บรรลุเป้าหมายดังกล่าว ผู้กำหนดนโยบายทางเศรษฐกิจและหน่วยงานที่กำหนดกฎหมายต้องมีส่วนร่วมในเรื่องดังกล่าวร่วมกับผู้ผลิตเพื่อกำหนดว่ากฎหมายและนโยบายการตลาดควรเป็นอย่างไรเพื่อให้ตอบสนองต่อหุ่นยนต์ทางการแพทย์อย่างเหมาะสม

**คำสำคัญ:** หุ่นยนต์ทางการแพทย์, บริการด้านการดูแลสุขภาพ, กฎหมายและนโยบายทางเศรษฐกิจด้านเทคโนโลยี

## 1. Introduction

With increasing rates of longevity and low fertility in most parts of the world, ageing population and questions around the quality of life have become a global issue. Continued progress in robotics technology and medical innovations will bring ongoing improvement to people's quality of life. From robot-assisted surgery to robotic nurses to in-home rehabilitation and eldercare robots, the possibilities and benefits seem endless. However, robots are difficult to place within existing regulatory frameworks and will cause regulatory turbulence. The use of robots in healthcare represents an exciting opportunity to help a large number of people. Nevertheless, many interesting law and policy issues arise surrounding the use of robotics systems, especially the idea of healthcare being performed by robots utilizing artificial intelligence (AI) someday.

Europe is well placed to benefit from the potential of AI, not only as a user but also as a creator and producer of this technology. Both the African Region and Thailand, neither of which is traditionally associated with robotic technology, are making good progress in the use and development of robots in the field of medical service and healthcare by promoting investment in robotics innovation. The stage is to bring a better quality of life to patients in remote areas, including Thailand and South Africa.

The purpose of this article is to briefly address the legal and economic regulation of this growth in automation from the perspective of AI in the healthcare setting, using 5G and the Internet of things as a tool to reflect the intention to promote the status of robots, bringing them to the forefront on the socio-scientific platform, which could come to prominence through implementation in the South African and Thai context. This study aims to present (1) robotics in healthcare, (2) international and regional approaches, (3) the economic contribution to healthcare robotics in the European Union (EU), South Africa, and Thailand, and (4) legal policy and the practical applications of healthcare robotics.

## 2. Robotics in healthcare

In the current digital revolution, computing and machines can perform some non-routine tasks that had been hitherto reserved for humans<sup>1</sup>. The disruption caused by the Fourth Industrial Revolution appears particularly palpable in developed countries, yet there are also growing signs of the phenomenon in the developing world. While there are exciting advances in healthcare robotics, it is important to carefully consider the definitions and stakeholders inherent to the sphere of healthcare robotics in connection with the effectiveness of robots.

The Oxford English Dictionary defines AI as “the theory and development of computer systems able to perform tasks normally requiring human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages” According to The Organization for Economic Co-operation and Development (OECD)<sup>2</sup> and United Nations Conference on Trade and Development (UNCTAD)<sup>3</sup>, AI is defined as the ability of machines and systems to acquire and apply knowledge and to display intelligent behavior. This includes a variety of cognitive tasks, demonstrating an ability to move, and manipulate objects accordingly. Intelligent systems use a combination of big data analytics, cloud computing, machine- to- machine communication and the Internet of Things (IoT) to operate and learn. Today, AI is becoming increasingly sophisticated at doing human tasks, more efficiently, more quickly, yet at a lower cost. AI and related technologies are increasingly prevalent in business and society and are beginning to be applied to healthcare.

AI and robotics are not the same things. Robotics is a branch of technology that deals with physical robots. Robots are programmable machines that are usually able to carry out a series of actions autonomously, or semi-autonomously. AI is a branch of computer science which involves developing computer programs to complete tasks that would otherwise require human intelligence. AI is used in several ways. Often, AI is used to control robots. The AI

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<sup>1</sup> Erik Brynjolfsson and Andrew McAfee, *Race Against the Machine* (Lexington: Digital Frontier Press, 2011).

<sup>2</sup> OECD, *OECD Science, Technology and Innovation Outlook 2016* (Paris: OECD Publishing, 2016).

<sup>3</sup> UNCTAD, *Information Economy Report 2017: Digitalization, Trade, and Development* (Geneva: United Nation Publication, 2017).

algorithms are only part of the larger robotic system, which also includes sensors, actuators, and non-AI programming. This is the reason why the two fields are almost entirely separate.

In the context of medical and healthcare robotics, technological developments in the fields of robotics and AI can provide countless opportunities for addressing many challenges. The use of robots in healthcare represents an opportunity to help a large number of people. Robots can enable people with cognitive, sensory, and motor impairments, help people who are ill or injured, support caregivers, and aid the clinical workforce. The development of robotic technology for healthcare purposes can be sorted into three domains: medical, assistive, and rehabilitation robotics. The medical robotics domain includes robotic systems that provide support in performing medical processes related to healing (surgery) and care (diagnosis). The domain associated with assistive robotics covers systems that provide assistance in task-related healthcare processes, either to carers or to patients, as well as in care facilities (involving logistic tasks, surveillance, bed transfers, etc). Lastly, the rehabilitation robotics domain covers a range of different forms of post-operative or post-injury care, where direct physical interaction with a robotic system will either enhance recovery or act as a replacement for lost functions.

Robots have been deployed to assist the logistics of health and social care in various ways. Applications include hospital and care-home environments and comprise specific solutions addressing relatively well-defined problems. Thus, there are many stakeholders in the use of robotics technology in healthcare. It is important to note that all the stakeholder groups are critical to the success and deployment of robotics in healthcare and should be included in decision-making whenever possible.

### **3. International and regional approaches**

This section examines the emerging regional regulatory and policy landscape surrounding artificial intelligence in healthcare robotics.

#### **3.1 Europe**

The Council of Europe and the European Union (EU) share the same fundamental values – human rights, democracy, and the rule of law – but are

separate entities and perform differently. The EU is the Council of Europe's most important institutional partner at both political and technical levels.

On 4 December 2018, the European Commission for the Efficiency of Justice of the Council of Europe (CoE) adopted the European Ethical Charter on the Use of Artificial Intelligence in Judicial Systems and Their Environment (European Ethical Charter)<sup>4</sup>. The European Ethical Charter sets out five ethical principles and is intended to serve as a guideline for policymakers, legislators, and justice professionals when dealing with AI. The principles that should be observed are as follows: 1) Respect for fundamental rights during the design and implementation of AI, 2) Nondiscrimination, 3) Quality and security when processing judicial decisions and data, 4) Transparency, impartiality, and fairness, and 5) "Under user control"<sup>5</sup>

### **3.2 Asia and the Pacific**

The Economic and Social Commission for Asia and the Pacific (ESCAP)<sup>6</sup> serves as the United Nations' regional hub promoting cooperation among countries to achieve inclusive and sustainable development. The Commission's strategic focus is to deliver the 2030 Agenda for Sustainable Development, which it does by reinforcing and deepening regional cooperation and integration to advance connectivity, financial cooperation, and market integration. ESCAP's research and analysis coupled with its policy advisory services, capacity building, and technical assistance to support countries' sustainable and inclusive development ambitions in the following ways: 1) conduct research on frontier technology, 2) support its members to develop appropriate policies by supporting knowledge-sharing between the growing expertise in the region, and 3) provide a link between the regional and the global to share knowledge on the emerging movement on frontier technology in the region.

### **3.3 Africa**

International organizations supporting governments through policy analysis, dialogue, and multilateral commitments are the African Development

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<sup>4</sup> an international organization focused on human rights comprising forty-seven European countries.

<sup>5</sup> CEPEJ, *European Ethical Charter on the Use of Artificial Intelligence in Judicial Systems and Their Environment*, (Strasbourg: Council of Europe, 2019).

<sup>6</sup> The largest regional intergovernmental platform with 53 member States and 9 associate members.

Bank (ADB) and The Organization for Economic Cooperation and Development (OECD)

ADB has partnered with Microsoft to launch the Coding for Employment Programme, with the goal of preparing African youth for tomorrow's jobs while unleashing the next generation of African digital innovators<sup>7</sup>.

OECD is reviewing the economic and social impacts of AI technologies and applications, as well as the implications for policy. The organization has launched an Expert Group on AI in Society for multi-stakeholder discussions to scope principles that will foster trust in and adoption of AI and is actively conducting consultations to take stock of existing principles and best practices. The OECD is planning to launch a policy observatory in 2019 to ensure the beneficial use of AI.

Pulse Lab Kampala (Pulse Lab) in Uganda is the leading innovation lab in Africa, and the third lab of the United Nations' Global Pulse network. It works through partnerships and in alliance with the Ugandan government to support the UN Country Team and the Government of Uganda to achieve the Global Goals for Sustainable Development. Pulse Lab brings together data scientists, data engineers, partnership specialists, academics, and technical experts to generate high impact data analysis tools to address development challenges.

International organizations are eager to include AI-related topics in their agendas, work-plans, and research topics. While these discussions may seem detached from the national regulatory processes, they promise to be powerful platforms able to shape norms and set acceptable parameters for national policymakers looking for guidance. They provide forums for sharing experiences and best practices which enable governments to approach issues from a shared basis of understanding, reach consistent outcomes, and reduce the risk of irreconcilable positions on important issues. For AI, such cohesion on key issues will ensure that the technology is used for the benefit of humanity. It is also important to define what these systems should contain and how the development process is structured. Moreover, issues of human agency and bias must also be considered when creating the algorithms.

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<sup>7</sup> The programme will be launching in Côte d'Ivoire, Kenya, Nigeria, Rwanda, and Senegal. In addition, it will establish 130 Centres of Excellence across Africa to help bridge the skills gap.

#### **4. The Economic contribution to healthcare robotics in the European Union (EU), South Africa, and Thailand**

The technology sector (AI) is being deployed in sectors such as transportation, financial services, health care, and the media because AI technologies may have a disruptive impact on the region's economies and its workers. AI solutions can enable new kinds of preventive and remote health care; they may also improve diagnoses and speed the development of new drugs. Adaptive learning algorithms could play a role in delivering individualized and virtual education. But most of the region will need to build foundational digital infrastructure and data ecosystems to realize these types of opportunities.

This section reviews the key challenges faced by public and private organizations striving to make healthcare robotics a reality for all citizens and businesses, to bring about the application of healthcare robotics, and to maximize the impact of investments at the EU and national levels in Thailand and South Africa, and to foster synergies and cooperation across the world.

##### **4.1 The European Union (EU)**

The EU is well placed to benefit from the potential of AI and make the most of opportunities offered by AI to address the new challenges. The EU aims to lead the way in developing and using AI for the good of all. On 19 April 2016, the European Commission launched the first industry-related initiative of the Digital Single Market package. Building on and complementing the various national initiatives for digitizing industry, such as Industry 4.0 and Smart Industry, the Commission will take action in line with five main pillars<sup>8</sup>. These include the use of policy instruments and financial support, the coordination and legislative powers to trigger further public and private investments in all industrial sectors, and the creation of framework conditions for the digital industrial revolution.

To benefit from digital transformation, all the economic sectors in Europe are building Digital Innovation Hubs (DIH) to help companies improve their processes, products, and services through the use of digital technologies. Small and Medium Sized Enterprises (SMEs), in particular, are integrating digital technologies. All DIH should provide support to SMEs to understand and adopt

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<sup>8</sup> The European platform for national initiatives on digitizing industry, digital innovations for all: Digital Innovation Hubs, strengthening leadership through partnerships and industrial platforms, a regulatory framework for the digital age, preparing Europeans for the digital future.

AI, and it will be important for at least one innovation hub per Member State to have a high degree of specialization in AI. SMEs and start-ups will need access to finance in order to adapt their processes or to innovate using AI. Building on the forthcoming pilot investment fund of €100 million in AI and blockchain, the Commission plans to further scale up access to finance in AI under InvestEU. AI is mentioned explicitly among the areas eligible to use the InvestEU guarantee. However, the Commission will work with Member States to ensure that at least one digital innovation hub per Member State has a high degree of specialization in AI. Digital Innovation Hubs can be supported under the Digital Europe Programme.

#### 4.2 Thailand

As technology becomes more intelligent, manageable, and diverse, automation and robotics will play a bigger role in generating and creating value. Thailand is already a significant market for industrial robots. In 2017, it was the third-largest market in ASEAN and, by 2018, it was estimated to have become the 2<sup>nd</sup> largest. Recognizing the importance of automation and robotics, the Thai government has implemented various measures to promote the growth of these key industries. The use of industrial robots in the country is therefore expected to continue growing. Thailand has established a strong supply chain in the automation and robotics industries. The majority of firms in these industries are in the business of System Integration (SI) and mechanical brain & software development. This represents massive opportunities for foreign companies to invest in parts and components manufacturing<sup>9</sup>.

According to the Thailand 4.0 vision, the country plans to leverage its reputation and excellence in medical services, medical devices, and strengthen its position as the regional medical hub. The nation is making good progress in the development and use of robotics in the field of medicine and promoting investment in robotics technology, including medical robots. Medical robots have been used in Thailand in many areas, including surgery, diagnosis, rehabilitation, and services.<sup>10</sup>

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<sup>9</sup> The Thailand Board of Investment, “Thailand’s automation and robotics,” [https://www.boi.go.th/upload/content/automation\\_5a4fa9cec04d6.pdf](https://www.boi.go.th/upload/content/automation_5a4fa9cec04d6.pdf). accessed January 13, 2020.

<sup>10</sup> For example, in 2017, Ramathibodi Hospital successfully performed the first robot-assisted brain surgery in Asia., see Chulalongkorn University Intellectual Property Institute, Intellectual Property

Many public and private organizations have been working closely together to drive medical innovation to promote medical robotics. The Ministry of Science and Technology, the Ministry of Public Health, and the Ministry of Education have jointly set up a committee with key responsibility to promote medical and health-related innovations. More importantly, being a targeted future industry, the robotics industry has received full government support. Many public organizations have been set up to promote research and development as well as human resources training.

The Thailand Board of Investment (BOI) has offered a wide range of investment promotion incentives. Recognizing the importance of automation and robotics, BOI offers a wide range of tax and non-tax incentives for eligible activities that meet national development objectives. On the investment in relevant activities in targeted locations, BOI has been providing additional incentives for investment in the EEC. Promoted zones for specific industries related to automation and robotics include the Eastern Economic Corridor of Innovation (EECi) and Digital Park Thailand (EECd). Eligible activities located in these zones may receive additional incentives.

Thailand will need to prioritize building up backbone infrastructure to capture healthcare robotics opportunities, but if policymakers and businesses prioritize the opportunities associated with these trends, the results could indeed be transformative. Thailand could be poised to make major strides in economic development and to expand the possibilities for what integration can achieve.

### 4.3 South Africa

In South Africa, with a population of more than 58 million people, companies find themselves encumbered by legacy technologies and systems, business models, and corporate structures, as well as sunk investments in antiquated infrastructure. Indeed, like many workers in other countries, South Africans are concerned that AI will eliminate their jobs and worsen income inequality even more.

Health systems in South Africa face several structural challenges. National medical systems often suffer from shortages of qualified healthcare professionals

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Innovation Driven Enterprise, (Bangkok: Chulalongkorn University Intellectual Property Institute, 2017), 49.; SensibleTAB and SensibleSTEP, for example, were developed by a local company to help patients with arm and leg injuries perform practice movements aided by the robots.

and supplies, resulting in divergent outcomes for patients depending on the facilities and services they need. In addition to accessibility barriers and rural-urban disparities, lack of awareness on health issues can be an obstacle to seeking care, receiving more effective treatments, and to more effective public health policies. Even when facilities and staff are available, affordability can put necessary services out of reach of patients. AI can help plug these gaps and enhance outcomes. Large corporations and startups alike are developing AI-focused healthcare solutions for these challenges.

South Africa need to emphasize education and training, especially for people who are disproportionately affected in terms of employment and income. It will also need to develop a code of ethics for AI, create adaptive, self-improving regulation to keep pace with technological change, and integrate human intelligence with machine intelligence by reconstructing work modalities to take advantage of the respective strengths of each.

## **5. Legal policy and the practical applications of healthcare robotics**

From discussions of AI in healthcare robotic, the possibilities for AI in the practice of healthcare and medical research seem endless. Nevertheless, the ethical, legal, and social issues associated with its implementation in South Africa and Thailand have not yet been adequately addressed. While Europe is well-positioned to exercise global leadership in building alliances around shared values and promoting the use of AI, the EU's work on AI has already influenced international discussions. This section introduces the legal policy and practical applications of healthcare robotics in Europe, South Africa, and Thailand to understanding the effects and consequences of the systems.

### **5.1 Europe**

Europe will continue to lead progress in the algorithmic foundations of AI. However, there is a need to build an ecosystem that can support the development and uptake of AI across the EU economic and public administration because the use of AI brings both opportunities and risks. The main legal issues related to the use of healthcare robotics concern:

#### **5.1.1 Data Protection**

The creation of a Digital Single Market, including the free flow of data across borders, is a key driver for the uptake of healthcare robotics.

Healthcare robotics becomes a part of people's lives. However, the use of robots enable a large amounts of personal sensitive data acquisition and healthcare information repetitive provision easier. A number of existing and planned EU regulations have quite a significant impact on the use of AI technologies. The General Data Protection Regulation (GDPR) that came into effect on 25 May 2018 addresses individuals' freedom to control their personal data.

### **5.1.2 Liability Regulations**

For SMEs and start-ups, legal certainty with respect to liabilities issues is a key for access to financing because AI projects have to pass a due diligence process undertaken by private financers, which includes oversight of regulatory compliance with respect to contingent liabilities. However, establishing liability rules for existing and prospective AI algorithms is a difficult problem to address and solve. One has to take into due consideration the wide variety of stakeholders involved and the lack of interpretability of many kinds of AI learning systems. Another related and widely debated issue is whether or not AI systems can be deemed to be subjects of law. The EC has conducted evaluations of the Product Liability Directive<sup>11</sup> and the Machinery Directive<sup>12</sup>. However, some experts highlight that the legal framework related to AI-enabled decision-making might require the development of specific regulations because of the difficulty of predicting the exact future behavior of many complex AI systems and the emerging behavior of interacting AI systems.

### **5.1.3 Fundamental Rights of AI Systems**

The EU Treaties<sup>13</sup> and the Charter of Fundamental Rights of the European Union<sup>14</sup> provide a general guarantee of fundamental rights protection. The development and/or use of AI systems may, thus, potentially lead to a compromised fundamental rights protection. Healthcare robotics can enable and hamper fundamental rights in equal measure. However, it can also have a

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<sup>11</sup> Directive 85/ 374/ EEC of 25 July 1985 on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products.

<sup>12</sup> Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC.

<sup>13</sup> These rights are reflected in Articles 2 and 3 of the Treaty on European Union, and in the Charter of Fundamental Rights of the EU.

<sup>14</sup> Other legal instruments reflect and provide further specification of these commitments, such as the Council of Europe's European Social Charter or specific legislation.

negative effect on fundamental rights. In situations where such risks exist, a fundamental rights impact assessment should be undertaken. For example, the impact assessment for rights and freedoms of the individuals - the deployment of AI systems will most likely meet at least one of the criteria set in Article 35(3) GDPR<sup>15</sup>. This should be done prior to the system's development and include an evaluation of whether those risks can be reduced or justified as is necessary in a democratic society in order to respect the rights and freedoms of others.

Regulation to support AI's trustworthiness already exists today (product safety legislation and liability frameworks). As we consider that regulation may need to be revised, adapted or introduced, both as a safeguard and as an enabler, this will be raised in our second deliverable, consisting of AI Policy and Investment Recommendations.

## 5.2 Thailand

Thailand is considered to be the medical hub of Asia due to its high standards and quality of services, together with its highly professional medical personnel combined with lower prices than other countries. According to the 2016 Medical Tourism Index (MTI), which measures and compares the consumer perception of medical tourism among leading destinations, conducted by the International Health Care Research Center (IHRC), Thailand is ranked 18th overall and 2nd among ASEAN countries after Singapore and is also ranked 6th globally in the category of "medical tourism industry with the best health care system".

Given the growth in wellness and medical services, Medical and Public health were included as one of the goals of Thailand's 20-Year National Strategy (2018-2037) to promote good health in Thai people, as well as to promote Thailand as a Medical Hub internationally. In addition, Thailand has also drawn a health, wellness, and Bio-Med roadmap for Thailand 4.0<sup>16</sup>, as well as medical infrastructure development to push Thailand to become an ASEAN Medical Hub by 2025. While public and private hospitals also put their efforts into raising their medical potential by increasing imports of medical devices and the use of AI

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<sup>15</sup> European data protection supervisor, "Opinion 4/2020 EDPS Opinion on the European Commission's White Paper on Artificial Intelligence: A European approach to excellence and trust," [https://edps.europa.eu/sites/edp/files/publication/20-06-19\\_opinion\\_ai\\_white\\_paper\\_en.pdf](https://edps.europa.eu/sites/edp/files/publication/20-06-19_opinion_ai_white_paper_en.pdf) accessed January 4, 2019.

<sup>16</sup> The current Thai economic model, a value-based and innovation-driven economic paradigm.

technology, most of Thailand's medical treatment and healthcare robotics industry lacks the development of its own technology and innovation.

In addition, Thailand 4.0 indicated Affluent Medical and Wellness Tourism as one of the top five target industrial groups (5 First S-Curve), which is a group of industries where Thailand retains expertise and profound knowledge and therefore has well-founded potential for further development, to increase its efficiency in the use of production factors, to add value, and to be able to compete at an international level. Thailand also indicated the Medical Hub as one of the five new industrial group targets (5 New S-Curve) to enhance product and technology capacity to a higher level for future competitiveness. Yet, there is no direct policy nor an expressed strategy on medical treatment and healthcare robotics. Nevertheless, a strategy for medical treatment and healthcare robotics can be found implicitly in the 10-year Strategic Plan to Develop Thailand as an International Medical Hub (2017-2026).

Regarding the 10-year strategy for the Medical Hub and the 12th National Economic and Social Development Plan on healthcare robotics, Thailand cannot produce medical devices that require highly complex innovation or technology; Thailand, therefore, has to import them. The fact that Thailand also lacks interconnection data on demand and supply means entrepreneurs are not able to make an effective production plan. As a result, the 20-year National Strategy plan on public health recognizes that medical devices are one of the areas of medical technology that need to be administrated.

Nowadays, technology is an important part of human life, including medical treatment and healthcare. In this light, the Ministry of Public Health set up the eHealth Strategy 2017-2026 to serve as a framework for driving digital technology, acting as a mechanism for the development of the national health system. This, therefore, shows an active effort by the government to take advantage of digital technology in the Thai healthcare system. Nevertheless, there are still several issues that need to be addressed explicitly.

### **5.2.1 Legal Issues**

The obstruction of the development of medical treatment and healthcare robotics in the medical and wellness service sector is the structure of, or approach to, legislation. The main problems related to government action. Thailand needs to facilitate private sectors in the related commercial areas. Some

specific issues that need to be dealt with urgently derive from many causes, such as outdated legislation: inflexible laws unable to keep up with technological change. Solving these problems will support the services provided, add value to the business, and level up and develop medical enterprises in Thailand as a whole.

Major problems in urgent need of solution are discussed below:

### 1) The Liability Principle for Autonomous and Artificially Intelligent Robots in Medical Treatment and Healthcare Sectors

In the future, autonomous and artificially intelligent robots (hereafter “smart robots”) could operate autonomously of any human supervisory control. The legal problem then arises as to who will be liable for the damage these robots cause. Under current Thai liability law, robots cannot be liable for the damage they have caused, which lies with the owner, supervisor, or manufacturer. The principle of strict liability in product liability law<sup>17</sup> also proves difficult to apply to the liability of smart robots. To hold smart robots liable, there must be a causal relationship between the legally unsafe product (the smart robots) and the damages or injury the product has caused; therefore, if smart robots cause damage or injury that does not derive from a manufacturing defect or design defect, this strict liability cannot be invoked.

As yet, there are no legal issues with regard to surgical robots since it can be considered a tool for surgeons, so it is possible to invoke the liability principle in relation to the surgeon and the strict liability of the robot. Nevertheless, with the use of smart robots in the future, there should be some revision in the law.

At present, all Thai laws regarding medical treatment and healthcare services<sup>18</sup> only allow qualified and certified medical practitioners to perform certified operations. Therefore, smart robots are not allowed to perform any operation under these terms. Hence, the law must be revised to allow smart robots to perform medical operations. Accordingly, professional standards for operations performed by smart robots as well as questions of liability must also be addressed.

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<sup>17</sup> Product Liability Act, B.E. 2551.

<sup>18</sup> For example: Health Facility Act, B.E. 2541, Healing Arts Practices Act B.E. 2542, Emergency Medical Act B.E. 2551, Dental Profession Act, B.E. 2537, Medical Profession Act, B.E. 2525.

## 2) National Electronic Health Records

New legislation should also be enacted to establish and regulate the National Electronic Health Record System (hereinafter “NEHRS”). National health information will enable the promotion and growth of healthcare business sectors as well as the improvement of medical treatment due to medical and healthcare data transfer and the continuity of patient care, ensuring better and safer medical treatment for the patient. This will also help patients to be stress and anxiety-free when requesting medical data, whichever medical institutions patients choose to go to, or to which they later have to be transferred. As a result, medical institutions will also be in competition to provide better services, and thus benefit all service recipients.

In addition, in order to prepare for and support the use of telemedicine and telehealth systems, information on medical practitioners should also be included in the NEHRS. The system should also allow service recipients to be able to check the qualifications of medical practitioners.

Thailand has a law on Digital Government<sup>19</sup> regulating the application of digital technology in public management, including information linkage and sharing among governmental organs. This should enable information linkage between public medical institutions in the future.

## 3) Roboethics

The regulation of the application of ethics and morals in the smart robot system is probably the most difficult and sensitive measures. The law should oblige smart robot designers, engineers, and manufacturers to ensure that there will be no discrimination based on nationality, racial or ethnic origin, religion, or belief. At a core principle, smart robots should take into consideration patients’ safety, rights, and privacy regarding their information. Among others, Isaac Asimov’s the Three Laws of Robotics<sup>20</sup> and the Zeroth law<sup>21</sup> should also be taken into consideration.

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<sup>19</sup> Digital Government Administration and Services Act B.E. 2562.

<sup>20</sup> (1) A robot may not injure a human being or, through inaction, allow a human being to come to harm; (2) a robot must obey the orders given it by human beings except where such orders would conflict with the First Law; (3) A robot must protect its own existence as long as such protection does not conflict with the First or Second Laws.

<sup>21</sup> A robot may not harm humanity, or, by inaction, allow humanity to come to harm.

#### 4) Economic Issues

In this section, the authors would like to propose some related economic and commercial measures through which the Ministry of Commerce (MOC) should proceed to support and promote the Thailand Medical Treatment and Healthcare Robotic Services.

1. Establish an institution to support and improve medical treatment and health service businesses under the supervision of the MOC

One of the common problems facing entrepreneurs is an adaptation to the new rules and regulations, which is a regulatory risk that affects business continuity. For example, when new rules and regulations enter into force, additional investment may be necessary in order to comply with the rules. Without government support, a business may not be able to continue.

There are many cases in the healthcare business sector where it is difficult to add more value to a business or introduce innovation to services. In such cases, if entrepreneurs possess a certain level of potential, they may be able to improve their services with support from the government.

There are also numerous government organs involved in conducting medical and healthcare business, which makes it more difficult for private sectors to proceed. There is no government body that acts as a coordinator among the different organs to facilitate procedures.

In the light of the above-mentioned problems, the MOC should establish an institution to support and improve medical treatment and health service business under its supervision to assist entrepreneurs in adapting to new regulations and gaining access to finance, as well as facilitating capacity building to expand their business. It will also act as a focal point for coordination between government organs, especially the MOC and the Ministry of Public Health. The establishment of such an institution would not only improve quality control in medical treatment and the healthcare business, not to mention consumer protection, but it would also improve growth in these business sectors.

The institution could be established under section 31 of the Government Administration Act, B.E. 2534. The status of the institution would be equal to that of a division in the Department of Business Development in the MOC.

## 2. A Regulatory Sandbox or a Pilot Project in medical treatment and healthcare business

One of the legal problems of the medical treatment and healthcare business is inflexibility and its one-size-fits-all nature. As a result, there are many cases where State governance under the current law matches neither the context nor the potential of each area. For example, in the field of tourism, where there is high growth potential in medical and healthcare business, the one-size-fits-all Thai Investment Promotion Act, which does not take into account the differences among areas nor envisages any tax measures, is not likely to attract investors to invest more in this area rather than others.

Hence, there must be a regulatory sandbox or an area for a pilot project to allow private sectors to conduct their business under a flexible form of regulation that matches the context and potential of the area. Nevertheless, since there are numerous relevant governmental organs, the MOC would need to play an important role as coordinator of the relevant government bodies in order to design the appropriate regulations for the target area. The MOC can assign this role to the Institution mentioned above at first issue.

The institution, under the supervision of the MOC, should act as a central organization to coordinate between the Ministry of Public Health, the Ministry of Finance, and the BOI to regulate measures regarding medical treatment and healthcare enterprises at a specific promotion location. The measures should cover investment promotion measures, access to funding sources, tax measures, and import tariff rate reduction. The measures should be designed to reflect the scope of authority that each body has.

Nevertheless, in many cases, the law does not give government organs discretion to regulate specific rules, or make exceptions to the general rules. Therefore, it is necessary to enact a new law to allow the use of a regulatory sandbox specifically for medical treatment and healthcare business.

### 5.3 South Africa

Currently, South Africa does not have a legal framework in place for the regulation of AI. Nevertheless, statutory measures have been introduced to achieve health-related demands, and to bring about health reform, as explained below.

### **5.3.1 The National Health Act and the National Health Amendment**

South Africa is one of the best-known examples of how human rights matter to health, and this is a country where an explicit codified right to health has prompted health reforms<sup>22</sup>.

The primary purpose of the National Health Act is to “provide a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws... with regard to health services...”<sup>23</sup> In its preamble, the National Health Act recognizes “the socio-economic injustices, imbalances, and inequities of health services of the past and the need to improve the quality of life of all citizens” and acknowledges Section 27 (2) of the Constitution, which establishes that the State must take “reasonable legislative and other measures within its available resources to achieve the progressive realization of the right of the people of South Africa to have access to health care services”.

### **5.3.2 The Health Professions Council of South Africa’s guidelines**

The Health Professions Council of South Africa (HPCSA) is a statutory body, created pursuant to powers granted in terms of the Health Professions Act. The Council, which is mandated by the South African government to provide regulations, guides health care professions in South Africa in aspects pertaining to the ethical behavior and conduct of health professionals and in “fostering compliance with health care standards”. The HPCSA has developed a series of ethical rules and guidelines, which have been set out in booklets regulating, for instance, good ethical practice relating to, for instance, confidentiality and the protection of information. The regulatory mandate of the HPCSA affects healthcare practitioners in both state and privately-owned health care institutions, and its primary purpose is to protect patients against abuse or maltreatment by health care practitioners, while affording guidance. With regard to the regulation of e-Health and telemedicine, the HPCSA has recently published draft guidelines governing the ethical practice of telemedicine in South Africa.

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<sup>22</sup> Jerome A. Singh, Michelle Govender, and Edward Mills, ‘Do human rights matter to health?’ *Lancet*, 307, 9586 (2007), 521-527.

<sup>23</sup> The National Health Act No. 61 of 2003 and the National Health Amendment Act No. 12 of 2013.

### 5.3.3 The Protection of Personal Information Act (POPI)

Since many matters raised above overlap with the issues around the use of data, what the current laws on data protection provided in this regard should be considered. The Protection of Personal Information Act (POPI) No. 4 of 2013<sup>24</sup>, in section 71(1), specifically states that a data subject “may not be subject to a decision which results in legal consequences for him, her or it, or which affects him, her or it to a substantial degree, which is based solely on the basis of the automated processing of personal information intended to provide a profile of such person, including his or her performance at work, or his, her or its creditworthiness, reliability, location, health, personal preferences or conduct.” This essentially means that a person or institution (data subject) may not be subjected to an automated decision based on a personality profile, unless (and in accordance with 71(2) of POPI) the automated decision-making is allowed for the purposes of concluding a contract, provided the request of the data subject in terms of the contract has been met, or appropriate measures have been taken to protect the data subject’s lawful interests, or, the decision is governed by a code of conduct in which appropriate measures are laid down for protecting the lawful interests of data subjects. In addition, uncertainty as to who is actually in control when the use of AI in healthcare is contemplated is a reality. This would then have implications for a patient’s legal recourse should a private healthcare practitioner, the State or the creator of the AI device be held liable for an AI error, if one occurs. Furthermore, regulatory policies and guidelines would have to be updated in terms of the Health Professions Council of South Africa and other similar statutory councils. Moreover, some relevant laws would require amending, and perhaps even new laws enacted, to address the legal intermission in this regard.

## 6. Conclusion

There is no denying that AI, as the driving force behind the Fourth Industrial Revolution, will have a positive impact on the future of medicine, especially in developing world settings where resources are scarce. Global health care expenditures continue to escalate, shining a light on the need for health

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<sup>24</sup> South Africa. Protection of Personal Information Act No. 4 of 2013.

systems to reduce costs and increase efficiency, although cost-containment efforts combined with faster economic growth should maintain the share of GDP devoted to health care. To rise to this challenge, South Africa and Thailand will need to recalibrate their economies and workforces for the digital age, developing an environment in which humans and machines work together. This will drive demand and consumption within the economy, and boosting growth. Nevertheless, the excitement around AI must be balanced with broader ethical, legal, and social concerns that should be addressed and incorporated into a concise governance framework. In Europe, the aims are to promote Europe's innovation capacity in the area of AI and support the development and uptake of ethical and trustworthy AI across the EU economy. This means that in order to benefit from the opportunities of AI, the necessary industrial and technological capacities must be developed and reinforced, as set out in the accompanying European strategy for data.

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