Utrecht University

ARTIFICIAL INTELLIGENCE IN PHARMACEUTICAL PROMOTION AND MARKETING STRATEGIES: EXPLORING THE NEED FOR REGULATION IN THE EU

by

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Abstract

Background

Currently, the only types of AI systems in the healthcare industry that are considered 'high risk' and are subject to strict regulation, by the European Commission, are classified under 'medical devices'. This paper explores if AI systems used in pharmaceutical promotion and marketing strategies need to be bounded by the same regulations. AI in this domain is predominately used in two aspects: predictive analytics and omnichannel marketing. Public health concerns around these applications of AI and the digitalization and distribution of big data can be found in data collection methods, data quality, lack of AI-skilled professionals in companies, as well as targeted advertisements, and manipulative marketing. Sub-questions were devised to investigate stakeholder attitudes, perceived risks, and potential future provisions, in order to evaluate if AI in pharmaceutical marketing strategies should be further regulated.

Methods

Qualitative research methods were applied through semi-structured interviews using a sample size of 10 stakeholders. Each participant was presented with scenarios and questions that investigated the themes of the designed theoretical model. The collected data was thematically analysed using a combination of a deductive and inductive approach.

Results

The results were presented through the coding frequency for each theme that was recorded during the semi-structured interviews. Supporting and contradicting perspectives were highlighted through quotes and references of the interviewees.

Conclusion

The main findings of the research showed an overall call for change in the environment in which this AI system is used, either in areas of data privacy policy, education, or pharmaceutical transparency. It is proposed that policymakers consider these themes and identify that the precarious nature of AI used in pharmaceutical prediction and omnichannel marketing is a symptom of the inefficient data protection laws, low digital literacy amongst the public, and lack of transparency from pharmaceutical companies.

Artificial Intelligence in Pharmaceutical Promotion and Marketing Strategies: Exploring the Need for Regulation in the EU

Problem Statement

In April 2021, the European Commission put forth a regulatory proposal to certify that AI products in the European Single Market are safe, trustworthy, and protect the fundamental rights of Europeans. Its prospects include increasing protection and quality reliability in AI systems using a 'risks-based approach' (European Commission, 2021). According to this proposal, any AI that is classified as a 'medical device' in healthcare will be subject to greater regulation. In other words, every other AI within this sector can be used freely as they are considered risk-free (European Commission, 2021). This research project aims to explore the potential need for further regulation of one of these risk-free AI systems. The intention is to determine if AI applied in pharmaceutical promotion and marketing strategies should be considered 'high risk' and be subject to further regulations similar to the ones proposed for AI systems classified as 'medical devices'. There has been a surge in the debate around the implementation of AI systems in healthcare across social and scientific disciplines, especially regarding pharmaceutical promotion and marketing strategies. On a societal level, there is a public health concern around the ethics of digitalization and distribution of personal and electronic health records (EHR) due to the unclear nature of how data is collected, shared, and stored within and between companies (Salas-Vega et al., 2015). Whereas from a scientific perspective, using this type of online recorded data is essential to developing technology that helps further understand human behaviour and medicine (Günther et al., 2017). Authorizing pharmaceutical companies in healthcare to access this type of information, allows for accurate medical provisions and can help to discover potential trends that could lead to major medical advancements (Günther et al., 2017).

Overview of Existing Literature

Important Concepts

Artificial Intelligence, Big Data, and Machine Learning. The European Commission uses The High-Level Expert Group (HLEG) to define AI because of their key role in the implementation of the European AI Strategy. Their definition of AI can be described as follows:

> *Artificial intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (e.g., voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (e.g., advanced robots, autonomous cars, drones or Internet of Things applications).* (High-Level Expert Group, 2018)

The implementation of AI has become important to the advancement of major industries as a result of the exponential amount of big data[1] being stored online (Soni et al., 2020). Big data originates from internet users, monitoring devices, and activity logs. It can be collected from online platforms such as social media, meteorological monitors, and global position systems (GPS) (Tang et al., 2022). These large datasets allow organizations to forecast future dynamics and gain new and real-time insight (Tang et al., 2022). Machine Learning (ML), a subset of AI, solves and performs tasks through experience by drawing out patterns from raw information (Fox, 1986). The combination of ML and big data permits pharmaceutical industries to grow in

[1] Big data is usually distinguished by the 5V, i.e., Volume, Variety, Velocity, Value and Veracity (Tang et al., 2022). This refers to the volume of large-scale varied data which can be developed and processed at an inflated velocity (Günther et al., 2017).

areas such as productivity improvement, predictive analytics, product development, distribution, and product cost reduction (Fox, 1986).

European Commission's 'Risk-Based' Approach to Artificial Intelligence. The European Commission has devised a 'risk-based' approach using the Pyramid of Criticality to classify different types of AI systems (Appendix A). In this approach, AI systems can be classified as either 'unacceptable risk', 'high risk', 'limited risk', or 'minimal risk' (European Commission, 2021). Table 1 includes The European Commission's definition for each category and their criteria for AI systems.

Table 1

European Commission's Level of Risk Definition of AI Systems

Level of Risk	Criteria
Unacceptable Risk	Anything considered a clear threat to EU citizens will be banned: from social scoring by governments to toys using voice assistance that encourages dangerous behaviour of children.
High Risk	AI systems identified as high-risk include AI technology used in: **Critical infrastructures** (e.g., transport), that could put the life and health of citizens at risk; **Educational or vocational training,** that may determine the access to education and professional course of someone's life (e.g., scoring of exams); **Safety components of products** (e.g., AI application in robot-assisted surgery); **Employment, workers management and access to self-employment** (e.g., CV-sorting software for recruitment procedures);

	Essential private and public services (e.g., credit scoring denying citizens opportunity to obtain a loan); **Law enforcement that may interfere with people's fundamental rights** (e.g., evaluation of the reliability of evidence); **Migration, asylum, and border control management** (e.g., verification of authenticity of travel documents); **Administration of justice and democratic processes** (e.g., applying the law to a concrete set of facts). They will all be carefully assessed before being put on the market and throughout their lifecycle.
Limited Risk	AI systems such as chatbots are subject to minimal transparency obligations, intended to allow those interacting with the content to make informed decisions. The user can then decide to continue or step back from using the application.
Minimal Risk	Free use of applications such as AI-enabled video games or spam filters. The vast majority of AI systems falls into this category where the new rules do not intervene as these systems represent only minimal or no risk for citizens' rights or safety.

'High-risk' systems are constrained by rules before they are allowed to be placed on the market (European Commission, 2021). Figure 1 provides the detailed regulations that need to be enforced for these 'high risk' AI systems (European Commission, 2021).

Figure 1

New Rules for Providers of High-Risk AI Systems

Step 1	Step 2	Step 3	Step 4	
A high-risk AI system is developed	It needs to undergo the conformity assessment and comply with AI requirements For some systems a notified body is involved	Registration of stand-alone AI systems in an EU database	A declaration of conformity needs to be signed and the AI system should bear the CE marking. The system can be placed on the market	*If substantial changes happen in the AI system's lifecycle, go back to Step 2*

AI uses in Pharmaceutical Promotion and Marketing Strategies Pharmaceutical companies use AI in two areas of their promotion and marketing strategies: prediction and omnichannel marketing. Predictive AI systems anticipate outcomes based on collected data. In pharmaceutical marketing, predictive analysis usually carried out using an ML system, is a procedure that allows for insights to be gained into consumer and prescriber behaviour and permits the forecasting of specific drugs or medical needs (Berea, 2017). In the past, historical data was used to develop predictions and consumer desires however, now big data has enabled personal information such as demographic data, and medical data, like prescription and physician information, to be recorded, stored, and distributed in real-time (Yuan et al., 2019). As a result, pharmaceutical companies have adapted their marketing strategies using ML to analyse these new datasets. Omnichannel marketing uses AI systems in areas like rep-triggered email[2], mass mailing, paid advertisements, and social media, with the intention to maximize communication channels to engage with healthcare professionals (Viseven, 2021).

[2] Rep-triggered emails is a personalized communication tool that targets one individual (Viseven, 2021).

Benefits of using AI in Pharmaceutical Promotion and Marketing Strategies Pharmaceutical companies use ML-based analytics to play a key role in decision-making judgments in marketing because it can filter through large quantities of data and develop predictions (Bates, 2016). Having access to big data from social media profiles and EHR can lead to accurately identifying and predicting market trends, which enables pharmaceutical companies to efficiently meet the public's needs (PEX Network, 2015). The benefits that pharmaceutical companies experience because of this procedure include discovering optimal strategic directions to follow, frugal resource and budget allocation, development of advantageous shares, increasing revenue and profits in the market, identifying areas of value for maximizing growth, and increasing competitor differentiation (Bates, 2016). In terms of societal benefit, access to this type of data can lead to increased engagement with healthcare professionals, increased patient-level insights, increased consumer participation, and overall increased public health with personalized healthcare (Yuan & Zhao, 2018).

Potential risks of AI in Pharmaceutical Promotion and Marketing Strategies Since the interaction between big data and AI systems in pharmaceutical marketing is relatively new, there are knowledge gaps in the specific effects it can have on the population. Stakeholders such as HCPs and members of the public, have raised questions about the risks regarding data collection methods, data quality, lack of AI-skilled professionals, as well as targeted advertisements/manipulative marketing.

Data Collection Methods and Data Quality. Pharmaceutical companies have increasingly been using big data a source of information for marketing and promotional purposes (Ruckenstein & Schüll, 2017). Even though The European Commission has orchestrated a comprehensive ethical and legal baseline for data protection privacy in Europe through

frameworks and policies, there are gaps that allow for public risks to occur. Presently, pharmaceutical companies are able to benefit from collecting, sharing, or using personal information in their marketing designs using big data which originates from social media platforms and EHR (Ross et al., 2014). Under current data privacy laws in legal European policies like Europe's General Data Protection Regulation (GDPR) and other frameworks, if a 'data subject' has given explicit consent, companies, online platforms, and databases can share that personal information, including health-related details to partnered third parties, (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), 2016) like pharmaceutical companies. At the moment, individuals are coerced into allowing their data to be accessed by accepting the Terms of Service and user agreements in exchange for the utilization of the online platforms (Gerke et al., 2020). As a result, this eliminates the possibility for people to have autonomy over their personal information, thus allowing for pharmaceutical companies to disproportionally benefit from the shared information.

Additionally, statistics indicate that collecting information through online platforms and EHR is not necessarily representative of the overall public (Cesare et al., 2019). The European Union Agency for Fundamental Rights (FRA) has emphasized that there is still a digital divide amongst the European population. A study showed that 89% of European households had access to the internet in 2018, meaning that more than one in ten of households did not have connection (European Union Agency for Fundamental Rights, 2019). What is exemplified by this statistic is that a portion of the population is not even represented in the data that is collected from these resources. Populations like the elderly, individuals of low socioeconomic status, and ethnic minorities are a few examples of members of society that disproportionally have less access to

social media and even medical professionals, which consequently leads to recorded data misrepresenting them (Cesare et al., 2019). Relying on skewed datasets could have damaging outcomes by creating biased algorithms which can prompt medical disparities amongst different demographics, catering only to those who are already deemed advantageous, and less likely in need of medical resources (Davenport & Kalakota, 2019).

AI-Skilled Professionals. Currently, Europe is experiencing a shortage of AI-skilled professionals. In 2019, it was estimated that German firms would take an average of six months to fill each of their tech positions (Anderson et al., 2020). Compared to China, The United States (US) and the United Kingdom (UK), the EU is ranked last in the number of computer science bachelor and postgraduate degrees (masters and PhD combined) awarded (Anderson et al., 2020). This has a societal ripple effect on European businesses and companies, leaving them unable to close the skills gap to properly implement AI in their operations (Anderson et al., 2020). It has become a common practice for organizations, including pharmaceutical companies, to trust their AI without including experts and data scientists to oversee if their systems are properly functioning and protected (Anderson et al., 2020). Without the intervention of AI-skilled professionals, there is a lack of explainability and capability to identify bias in 'training data'[3] as well as skewed 'inferred labels'[4], leaving pharmaceutical companies dependent on inaccurate and potentially discriminatory data to revolve their promotion and marketing strategies around (European Union Agency for Fundamental Rights, 2019).

[3] 'Training data' refers to the datasets used in the development and creation of algorithms. It can include internet users, browsing history as well as advertisements that are clicked on. (European Union Agency for Fundamental Rights, 2019).

[4] 'Inferred labels' is the produced dataset from the algorithm which includes predictions, inferences, deduced actions, or out-put data (European Union Agency for Fundamental Rights, 2019).

Targeted Advertisements and Manipulative Marketing. Manz et al. (2014) found that pharmaceutical companies have the ability to use technology to their advantage to monitor physicians' social media profiles, online conversations among physicians, catalogue physicians' online profiles, and identify 'key opinion leaders' within social networks (Manz et al., 2014). AI systems used in omnichannel marketing allow for new pathways in collecting data which includes impacting physicians at the point of care during clinical decisions in regard to prescribing behaviour (Viseven, 2021). For example, IQVIA published a scenario describing how they developed an AI system to collect data originating from mass email campaigns to develop personal profiles and email approaches that targeted specific individual HCPs across Europe. (Yuan et al., 2019). They were able to develop the optimal subject line, message content, frequency, time of day, and day of the week that best fits each individual HCP and used this information to increase open and click rates (Yuan et al., 2019). However, HCPs may not be aware they are targets of such marketing procedures. Civaner (2020), investigated this problem and identified that without any regulations to limit pharmaceutical companies, a multitude of harmful issues could arise such as a lack of trust between patients and physicians, increased pharmaceutical costs, but most concerningly irrational, biased prescribing behaviour which aims to benefit the sales of pharmaceutical companies (Civaner, 2020).

Theoretical Framework

Upon evaluation, there are multiple components that need to be incorporated to establish ethical and risk-free AI in pharmaceutical promotion and marketing strategies. Two important frameworks around trustworthy AI were combined to develop an ethical and risk-free model. These frameworks are HLEG (2019) *Requirements of Trustworthy AI* and Floridi & Taddeo (2016) *Three Main Components of a Trustworthy AI*.

In 2019, HLEG published *Ethics Guidelines for Trustworthy AI* was presented to the European Commission to be established in future regulations. Within this publication, HLEG identified requirements that are necessary for trustworthy AI in the EU. Table 2 provides the list of all the requirements with a brief description of what they entail.

Table 2

Ethics Guidelines for Trustworthy AI [5]

Requirement	Description
Human Agency and Oversight	Including fundamental right, human agency, and human oversight
Technical Robustness and Safety	Including resilience to attack and security, fall back plan and general safety, accuracy, reliability and reproductivity
Privacy and Data Governance	Including respect for Privacy, quality and integrity of data, and access to data
Transparency	Including traceability, explaining and communication
Diversity, Non-Discrimination, and Fairness	Including the avoidance of unfair bias, accessibility and universal design, and stakeholder participation
Societal and Environmental Wellbeing	Including sustainability and environmental friendliness, social impact, society, and democracy
Accountability	Including auditability, minimisation, and reporting of negative impact, trade-offs and redress.

[5] Detailed explanation of each component found in Table 4 can be found in High-Level Expert Group. (2019). *Ethics Guidelines for Trustworthy AI*. https://ec.europa.eu/digital-

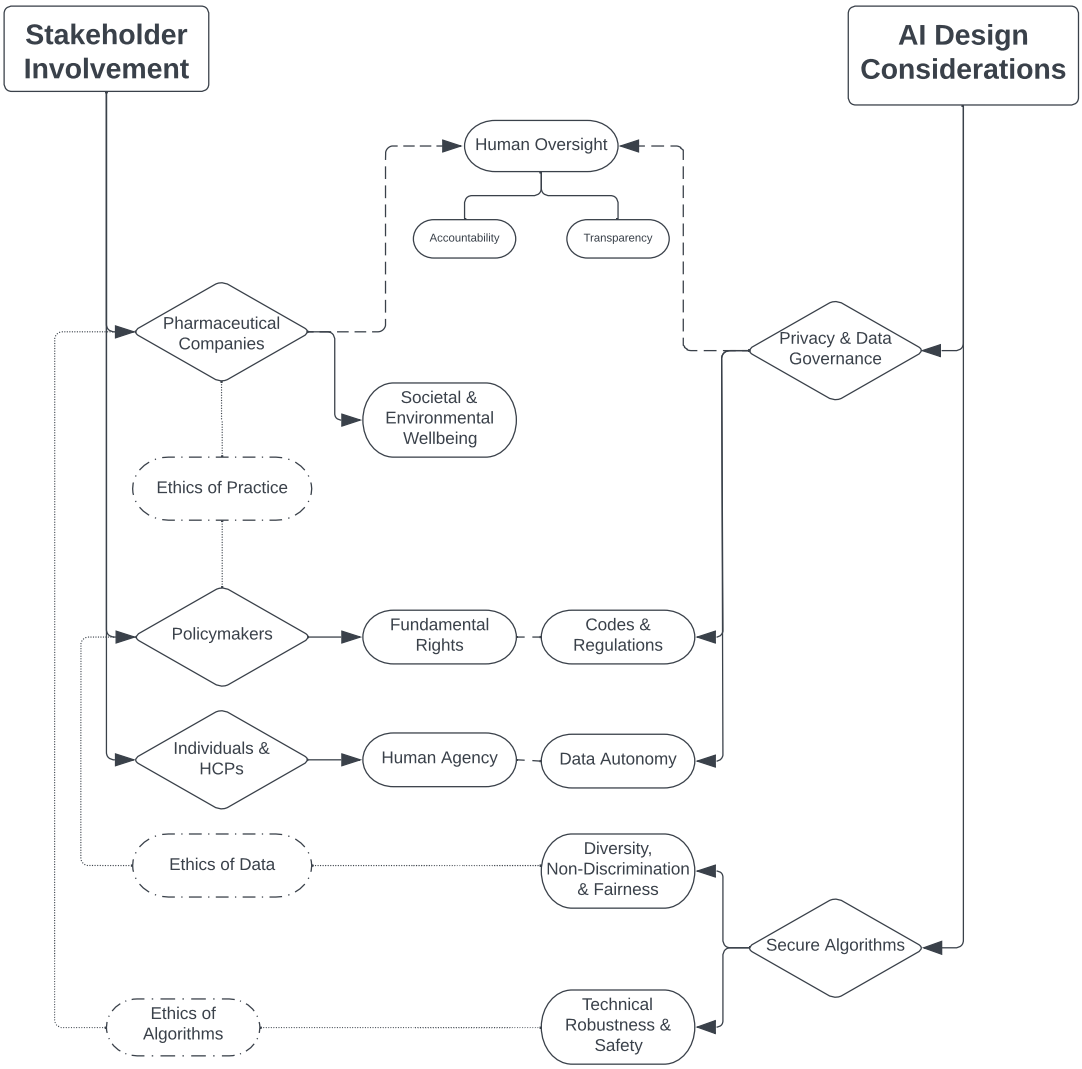
HLEG (2019) explains that different stakeholders play several roles in making sure that these requirements are properly implemented. For example, those who develop AI systems should be responsible for establishing as well as applying these requirements into the design and development process. Those who deploy the AI systems should be responsible for ensuring that the systems used, as well as products and services, are made available and meet the requirements established by the EU (High-Level Expert Group, 2019). Finally, the end-users and broader society need to be kept informed on how these requirements work and are established as well as have the ability to request that they be consistently upheld.

Floridi & Taddeo's (2016) *Three Main Components of a Trustworthy AI* focuses on three ethical considerations: ethics of data, ethics of algorithms, and ethics of practices. The ethics of data refers to the ethical problems that revolve around large quantities of data that are collected and analyzed for AI systems (Floridi & Taddeo, 2016). Questions around the risks of data mining, -linking, and -merging of large data sets are often raised and need to be addressed to have trustworthy AI (Kumar et al., 2020). The ethics of algorithms confronts the issues around understanding the complexity and autonomy of algorithms, especially in machine learning. It is necessary for designers and data scientists to have more responsibility and accountability around how the algorithm functions, as well as an understanding of the data that is collected (Kumar et al., 2020). Lastly, the ethics of practice pertains to questions around the responsibilities and the liabilities of organizations and people who oversee data processes, as well as policies to produce a framework that would re-enforce ethical practices (Kumar et al., 2020). Concepts like consent, user privacy and secondary use need to be employed to ensure that these practices are being followed (Floridi & Taddeo, 2016).

The developed theoretical model (Figure 2) considers important features from these frameworks as well as the roles of the relevant identified stakeholders which are crucial in applying ethical and risk-free AI application in pharmaceutical promotion and marketing strategies.

Figure 2

Ethical and Risk-Free AI in Pharmaceutical Promotion and Marketing Strategies Theoretical Model



The theoretical model includes two significant aspects: stakeholder involvement and important AI design considerations. Stakeholder involvement refers to the roles of

pharmaceutical companies, individuals & HCPs, and policymakers. Referring to concepts in the HLEG (2019) and Floridi & Taddeo (2016) frameworks, the position of pharmaceutical companies is defined by certifying that the AI used in their marketing strategies aims to protect and encourage wellbeing of society and the environment. They have the responsibility to ensure that their practice of AI in marketing is ethical and puts the protection of society at the forefront of their goals. Pharmaceutical companies should also be responsible for providing quality human oversight when applying AI in their marketing designs, especially in collecting personal information, predictive analysis, and omnichannel marketing strategies (High-Level Expert Group, 2019)

Policymakers' role as a stakeholder is to ensure that AI systems used in pharmaceutical promotion and marketing strategies protect the fundamental rights of individuals in society. Before the development of AI systems, policymakers need to establish a system that evaluates the potential risks each AI system imposes and its benefits to the public. Individual & HCPs' involvement can be found in the application of human agency when implementing ethical and risk-free AI in pharmaceutical promotion strategies. Human agency refers to individuals and HCPs having the autonomy over personal information that is collected and used for AI systems in pharmaceutical marketing. Giving the capacity of human agency to these stakeholders allows for the establishment of trust, not only towards the companies that use their data but in AI systems themselves, for maximum collaboration and transparency.

The second essential aspect in developing ethical and risk-free AI is AI design considerations. This includes topics such as privacy & data governance and secure algorithms, which references topics in the HLEG (2019) and Floridi & Taddeo's (2016) framework. The need to establish good privacy & data governance stems from the public's want for security and

transparency around their online personal information is collected and how it is used in pharmaceutical promotion and marketing strategies. AI systems need to guarantee that personal data is protected and kept private throughout its application and must utilize datasets that are free from socially constructed biases, inaccuracies, and errors. As can be seen in Figure 2, the implementation of Human Oversight, Fair Codes & Regulations, and providing data autonomy to individuals & HCPs, are all features that have been deemed necessary for ethical and risk-free AI and are heavily influenced by the involvement of each stakeholder group listed.

On the other side of AI design considerations, is the integration of secure algorithms. Having a secure algorithm means that the AI system needs to be diverse, non-discriminatory, and fair, and includes technical robustness and safety. Having diverse and non-discriminatory algorithms is important in avoiding AI bias and skewed results (High-Level Expert Group, 2019). When it comes to pharmaceutical companies, AI systems like ML used in promotion and marketing strategies need reliable and quality data that is representative of the public to produce accurate insights and models (Davenport & Kalakota, 2019). Social media platforms and even EHRs databases tend to not portray accurate, representational information about the public. Therefore, it is essential that extensive measures are taken in this area to ensure that the results produced by AI algorithms have no biases and can help address societal needs correctly. Having necessary protocols governed by people can allow for better security and less risk around personal data that is collected, stored, and utilized.

Lastly, technical robustness & safety is vital for the establishment of secure algorithms in ethical and risk-free AI. Technical robustness deals with the idea of establishing a preventative approach to AI systems to avoid potential risks and harms. AI systems are no exception to vulnerabilities like rival exploitation, corruption, and unintended application (High-Level Expert

Group, 2019). Without proper safety infrastructure, AI systems used in pharmaceutical marketing strategies can become highly sought out targets. Designing AI systems that incorporate high explainability around data processing, data management standards and risk disclosure can significantly aid in understanding potential risks as well as identifying future predicaments (Floridi & Taddeo, 2016).

Research Question

The overall aim of this research is to determine if AI systems used in pharmaceutical promotion and marketing strategies need stricter regulations to ensure the safety of European citizens' online personal data and protect their fundamental rights. Currently, is hypothesized that regulatory changes will need to be implemented accordingly to meet these standards. To further investigate this hypothesis, the following sub-questions have been devised: (1) What are the current stakeholder views and attitudes around AI in pharmaceutical promotion and marketing strategies? (2) What do stakeholders perceive to be potential societal risks in AI systems in pharmaceutical promotion and marketing strategies? (3) What do stakeholders consider to be necessary regulatory provisions for the future application of ethical and risk-free AI in pharmaceutical promotion and marketing strategies?

Methods

Study Design

For this research project, a qualitative design was selected since it provides primary insight onto the positions held by important stakeholders regarding the topic. The data was collected by conducting semi-structured interviews. The aim of the interviews was to highlight various outlooks as well as call attention to crucial opinions that would need to be considered for exploring the potential regulation of AI in pharmaceutical promotion and marketing strategies.

Study Sample

The participants intended for this research were stakeholders that are affected by and/or use AI in pharmaceutical promotion and marketing strategies. This included pharmaceutical companies, marketing companies, healthcare professionals, civil society stakeholders, and experts in areas like marketing, AI, and/or ethics. It was important to include participants who worked in each of these fields to gain maximum understanding of potential varying attitudes to develop an encompassing conclusion. Therefore, for this research study, a purposive sampling method was applied. This selection process allowed the researcher to obtain a sample of participants that had in-depth knowledge of the topic and contribute important information on the subject (Farrugia, 2019). The recruitment strategies involved a purposive sampling method, actively searching for and contacting individuals and organizations who possess the characteristics of the abovementioned stakeholders. The sample was collected through HAI's network of contacts and through individual online research on stakeholders in the field. Each organization and stakeholder were contacted either by direct email or through their official website page. From these contacts, snowball sampling was used as a technique to increase participant recruitment.

Data and Measurements

The participants recruited for the semi-structured interview were gathered from April 4th, 2022, to May 15th, 2022. An Interview Question Guide was developed (Appendix B) to provide the participants with the context of the research study. The context was built on two real scenarios published in an IQVIA white paper which demonstrated applications of AI in pharmaceutical promotion and marketing strategies (Appendix B). The rationale behind using

scenarios in the Interview Question Guide was to supply the participants with precise examples of how AI is applied in this environment and help them gain a deeper understanding of the research objective. The first scenario described how data collected originating from mass email campaigns was used to develop personal profiles and email approaches that targeted specific individual HCPs across Europe. The company was able to develop optimal subject line, message content, frequency, time of day, and day of week that best fits each individual HCP and used this information to increase open and click rates. In the second scenario, EMR and longitudinal prescription data (LRx) was collected to understand prescription behaviour in different regions. This data allowed the company to specifically target HCPs, track regional progress, predict future demands as well as identify the sources of business (Appendix B). These two scenarios were specifically chosen as they represented the two distinct methods in which AI is used in pharmaceutical promotion and marketing: prediction and omnichannel marketing.

From these scenarios, interview questions were developed to guide the participants in presenting their perspectives. The established theoretical model theorized what components would be necessary to establish risk-free AI in pharmaceutical promotion and marketing strategies. The questions and scenarios submitted to the participants were based on these themes in order to discover if their perspectives aligned with the theorized model and help answer the sub-research questions (Azungah, 2018).

The Interview Question Guide as well as a Participant Information Sheet (Appendix C) and Informed Consent Letter (Appendix D) were sent before the interview to the participant. Questions slightly varied based on their qualifications and background on the subject. Each

interview aimed to last for approximately 30 minutes and took place online either as a video or audio call. The interviews were recorded and transcribed for analysis.

Research Ethics Before recruiting participants, the Interview Question Guide, Participant Information Sheet, and the Informed Consent Letter were submitted to Utrecht University's Student Ethics Review & Registration Site (UU-SER) to gain ethical approval. The recruitment process was launched once the approval was established.

Data Analysis

Data Management To properly manage the collected qualitative data, the following course of action was taken. Firstly, the semi-structured interviews were conducted on Zoom, a video communications application. Each interview was then recorded on a mobile application called 'Voice Recorder'. The audio was then converted to mp3 files and stored according to the regulations of HAI. Afterwards, these files were uploaded to an online website called Otter.ai which develops speech-to-text transcription. To further increase the accuracy of the transcription of the interviews, each text was manually compared to the original audio recordings and was adjusted to eliminate any mistranslations.

Analysis The analysis used in this research study followed a similar process used by Azungah (2018) in analyzing qualitative data. It was first established that a thematic analysis was needed to be implemented to identify the important themes which would help answer the research question. This procedure included using a sequential method that combined a deductive and an inductive approach (Azungah, 2018). For deductive approach, pre-existing themes were originally deduced from the literature review to create the theoretical model as well as the interview questions. This framework acted as an initial coding guide for the interviews to be categorized in. On the other hand, an inductive approach required themes to be derived from the

collected data (Azungah, 2018). Elements of an inductive approach needed to additionally be applied as a new concept, found in the Topic List (Appendix E), were introduced in the interview data that were not previously identified in the theoretical model. Additionally, the computer program Atlas.ti was used to code the interview data using these two methods as well as to develop a visual code tree (Appendix F).

Results

Demographics of Participants

The recruitment processes included a total of 57 emails that were sent to members in each of the desired stakeholder groups. Of the 57 potential participants, 10 individuals consented to participation in the research study. The following individuals engaged in the research study: 3 Civil Society Stakeholders, 1 HCP, 1 HCP/Expert, and 5 Experts (Table 4).

Table 4

Participant Demographics

Participant Number	Stakeholder Field	Area of Expertise	Informant Code	Interview Mins
01	Civil Society Stakeholder		1CSS01	31
02	Civil Society Stakeholder		1CSS02	32
03	Civil Society Stakeholder		1CSS03	28
04	Healthcare Professional		2HCP01	0[6]
05	Healthcare Professional/Expert	Pharmaceuticals and Healthcare Marketing	2HCP02/3EX01	24

[6] The participant submitted written responses to the Interview Question Guide.

06	Expert	Health, Digital Rights, and Racial Justice	3EX02	52
07	Expert	Regulation of the Pharmaceutical Industry's Business Practices, Marketing, and Transparency	3EX03	36
08	Expert	Digital Healthcare	3EX04	33
09	Expert	Development of AI Algorithms and Psychological Effects of Interacting with Social AI systems on People's Perceptions and Behaviours	3EX05	31
10	Expert	Artificial Intelligence, Machine Learning and Data Science	3EX06	33

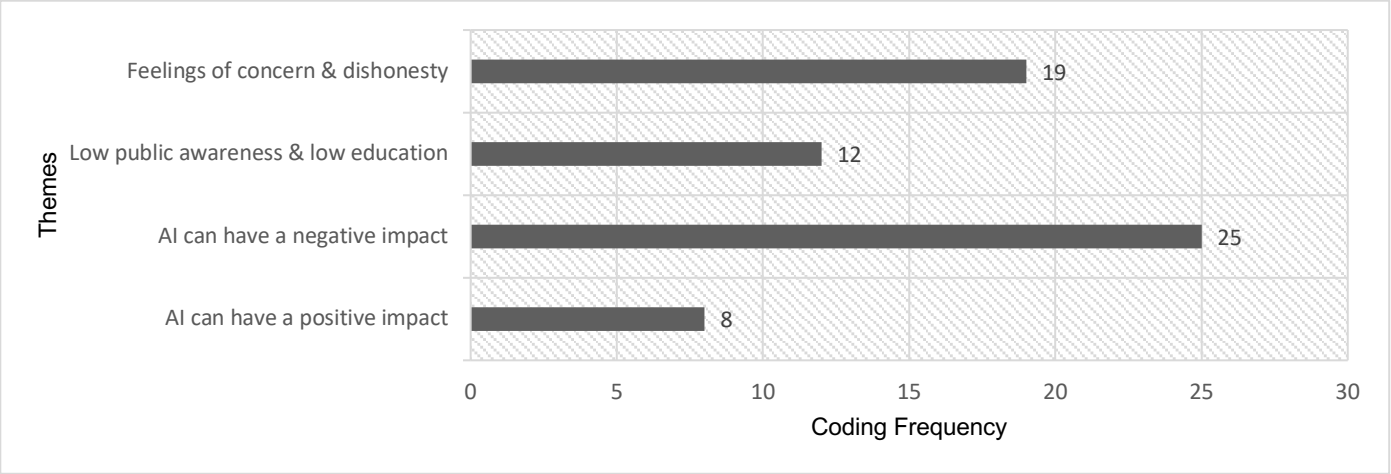
Key Findings[7]

Current Views and Attitudes After reading the provided scenarios, each participant was interviewed on their opinion regarding the use of AI in pharmaceutical promotion and marketing strategies. The results showed four main themes (Figure 3).

Figure 3

[7] Appendix G contains the number of interviews found per coding frequency.

Coding Frequency on Current Views and Attitude Participant Themes



The first theme that was frequently presented amongst the participants was the feeling of concern & dishonesty. This sentiment was usually affiliated with the lack of transparency that businesses, especially pharmaceutical companies provide for the public. One of the participants expressed this apprehensiveness by stating "*I think they are being devious using the data and not declaring how they are, say, customizing the marketing strategy using your personal online data. You are completely unaware of it. So, I think it's dishonest*" [1CSS01]. Additionally, a healthcare professional mentioned that even though they knew that their data was used in promotional marketing strategies, it was "*unclear the way in which they [pharmaceutical companies] can access personal data*" [2HCP01]. Experts identified this theme not only to be related to the evident lack of transparency from pharmaceutical companies, but also to the overall lack of awareness and low education within society regarding the functions of AI, and how they are used in convergence with big data for marketing purposes.

It was highlighted by the experts that digital literacy amongst the public is low and is not extensively understood in terms of how current technological applications are used by companies, especially in marketing. One expert illustrated this phenomenon by focusing on the

relationship between accessibility and data collection: "*Another aspect is that often the terms and conditions are lengthy, not necessarily accessible to most people. There are issues there as well around the accessibility of language and whether people know what they're signing up for*" [3EX02]. This combination of low public awareness of how personal information is collected online as well as low education in digital literacy has resulted in society being complicit in giving their data, rather than choosing to give their information.

The third and fourth themes that were raised, referred to the interviewee's general attitudes concerning the application of AI in this field, and if it could have a positive or negative effect on healthcare professionals, individuals, or society. On the one hand, these stakeholders predominately raised the issue of AI having the potential to negatively influence others. For example, an expert focused on how the application of AI systems in this context allows for greater effect due to its ability to collect, organize, and analyze data as well as recommend products to healthcare professionals at an easier and more consistent rate, resulting in pre-exiting problems like data bias to be amplified in the process.

> *I think that it's not like companies haven't been trying to influence healthcare professionals before, but I think what an AI enables is taking something that was a bit more arduous and difficult and it just allows that to be escalated at scale and very rapidly, so any issue that were present before then become scaled up and compounded with AI.* [3EX02]

The participants mostly deemed the implementation of AI to be negative, since there is a combined lack of transparency and knowledge regarding the administration of AI in data collection procedures, analysis, and omnichannel marketing methods. Having pharmaceutical

companies increase the efficiency of their marketing strategies by utilizing AI systems without explicit disclosure and explainability to the public and HCPs, has left most interviewees sensitive to the issue that there could be the possibility for ethical boundaries to be crossed.

Whilst the above belief was shown to be popular amongst some of the participants, important contradicting concepts were raised that either recognized the potential benefits of AI or the overestimation of its influential capabilities. One civil society stakeholder stated that AI had the capability to significantly assist in the identification of key health statistics within a population:

> *It could have a positive impact if you can identify illnesses, sicknesses, and people that need medication, and set up the proper methods to deliver them, and then push it up to the healthcare professional before they even meet them. That would be a good advantage.* [1CSS02]

A healthcare professional even emphasized that using AI for a *"personalised approach can be very convincing and surprising for hitting the mark of special interests"* [2HCP01]. This refers to the positive impact that AI and personalization of healthcare can have in understanding specific, and less well-known diseases. Furthermore, an expert in AI algorithms described that there can also be an over-amplification of the actual impact of AI in this context, as this procedure has been utilized before in pharmaceutical marketing strategies.

> *The benefit of machine learning and AI in these scenarios is highly overrated and overestimated. The amount of information that you can get from these types of campaigns in the first scenario [presented in the Interview Question Guide], and in the second scenario [presented in the Interview Question*

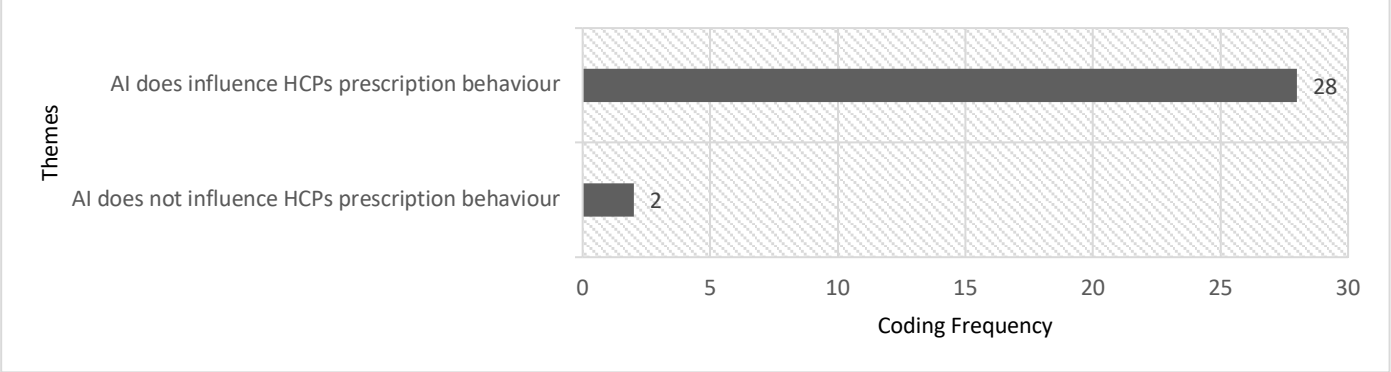
> *Guide], combining this longitudinal information with the electronic medical records, is a thing of the past. Therefore, I think it's marketing in itself to claim that there is a lot of information there, because in this case, there isn't. From a technical point of view, I don't think there is so much to be gained.* [3EX06]

Perceived Risks To understand if AI in pharmaceutical marketing and promotion plans need stricter regulations, it was crucial for the interviewees to deliberate on possible risks if they thought there were any, which could arise if current situations continued untouched.

Prescription Behaviour. As AI used in predictive analytics and omnichannel marketing are used to target healthcare professionals, questions around potential changes in prescription behaviour and the risks involved were repeatedly raised within the literature review. Therefore, each participant was asked if they believed this would be a possibility. Figure 4 shows the results of the participants' views.

Figure 4

Coding Frequency on Prescription Behaviour



As can be seen, there were 28 mentions throughout the interviews supporting the position that these applications of AI can influence HCPs prescription behaviours as opposed to 2 mentions

suggesting otherwise. One interviewee who has experience in exploring prescription behaviour of HCPs, explained why there would be an impact.

> *I really do believe that this [AI] will have an impact on prescription behaviour. We just performed a couple of investigations towards the prescription behavior of healthcare professionals. The prescription of new medicines is very difficult to predict or to explain. We saw that patient characteristic and practice characteristics were sometimes associated, but we couldn't explain the prescription of new medicine in general. Therefore, based on those investigations, we typically hypothesize, that it is mostly dependent on the attitudes of healthcare professionals including their beliefs and their perspectives. We know that the aim of marketing campaigns is to then target this aspect. If a pharmaceutical company can increase its marketing activities better than at this moment, I think it will influence healthcare professionals.* [2HCP02/3EX01]

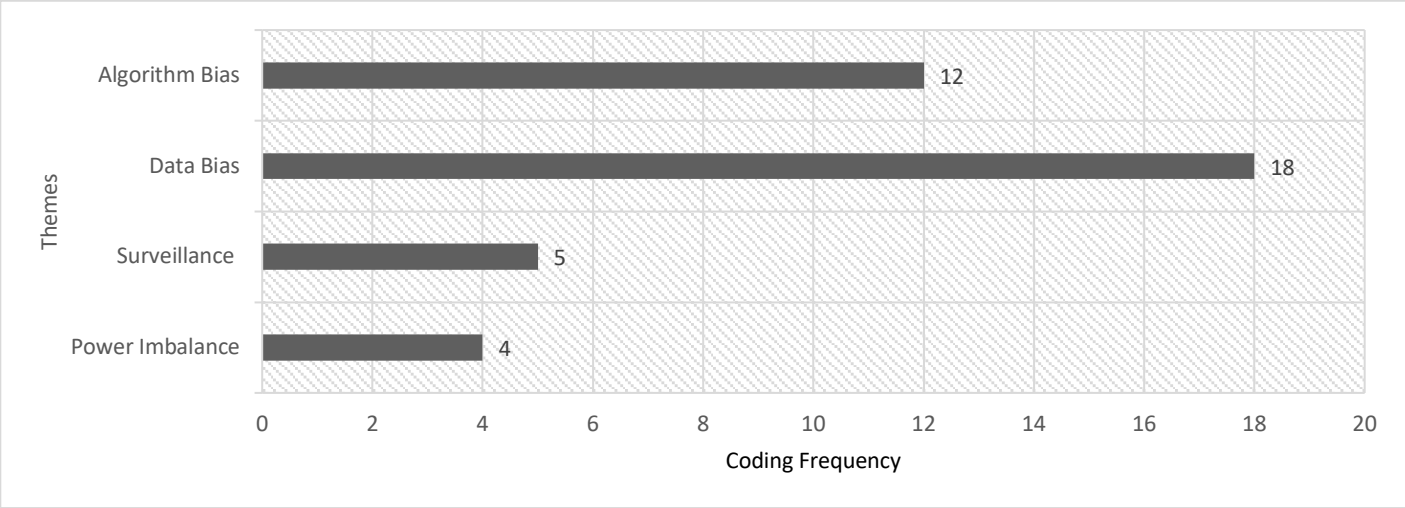
The other interviewees shared similar views, expressing that it would be unlikely that HCPs would be immune to this type of targeted marketing, especially when the strategies are personalized by AI systems to fit everyone individually. However, a compelling perspective, stated by a participant with expertise in pharmaceutical industry's business practices with regard to marketing and transparency, shared how other AI systems implemented by different actors or institutions could counteract the influence of the AI systems deployed by marketing and promotion plans. The expert alluded that there are separate AI systems *"that try to make sure that doctors prescribe drugs in an evidence-based, rational or in a cheaper way"* [3EX02]. With

the addition of these other systems trying to further influence HCPs, there is a possibility that all these systems interacting simultaneously could cancel each other out. Thus, not affecting prescription behaviour.

Biases, Surveillance, and Power Imbalance. Besides prescription behaviour, four themes were perceived to be potential risks (Figure 5).

Figure 5

Coding Frequency on Biases, Surveillance, and Power Imbalance



Biases The first two themes revolved around bias and its role in AI systems. Algorithm bias and data bias have been combined due to the proximity of their relationship in this context. As indicated in the results, these two concepts and their consequences were frequently focused on by participants as perceived risk. Since the collected data and developed algorithms play a crucial role in the predictive analysis, it was emphasized by expert interviewees that without proper inspection and implementation, the effect of skewed outcomes could be detrimental to society by increasing inequalities in areas such as drug production, accessibility, and affordability. As summarized by an expert:

> *When you try to make models based on the data from the past, the models will contain that bias. Then, when you then make decisions based on these models, the bias will propagate. So, you have to be careful about that. There have been examples that relate and are described in the literature.* [3EX06]

Another participant who specializes in health, digital rights, and racial justice reinforced this concept by stating that "*any algorithm that is taking data and then trying to use it to promote and influence decisions on products may, accidentally, have unknown consequences that increase different types of inequalities, like health, economic ratio, or other social inequalities"* [3EX02].

Surveillance The theme of surveillance was a perceived risk that was referenced by participants during their interviews. It relates to the concerns around the lack of transparency from pharmaceutical companies in terms of disclosure of their motivations and methods of marketing strategies. The general attitudes of the participants can be reflected by the following comment of an interviewee which calls attention to the apprehensiveness around the situation:

> *It depends on the level of detail of the data [that has been collected] and whether it has been taken from the professional activity of the healthcare professional, or if it's some personal information that is independent or semi-independent. Because if it is, then it's much more problematic. I think it depends on the detail, the context and the breadth of the data that's been taken. Ultimately, I also think it depends on the purpose of the collection of this data. Is it for manipulation? Or is it for surveillance? In this case, it would be more problematic. I think that there are problems involved here, and those problems*

> *relate to the fact that the AI applied has some imperative to it. Meaning that there is an imperative to collect as much data as possible from the public and from healthcare professionals, which is not necessarily known.* [3EX03]

Participants generally expressed that, the stakeholders whose information is being selected for these AI systems desire to understand the parameters in which their data is being collected, shared, stored, and used. It was clear that to some extent the public is willing to provide their information for companies with the ability to select where this information is being distributed without being surveyed constantly on their online activities

Power Imbalance The last perceived risk, which was discussed during the interviews, was the evident power imbalance that occurs between the stakeholders. According to some of the interviewees, pharmaceutical companies have an advantage over HCPs and individuals when it comes to the disproportional ability to influence.

> *The third problem I see has to do with the growing of power asymmetries, as more and more pharmaceutical companies know about doctors and patients. Doctors and the patients don't necessarily know about the pharmaceutical companies or the marketers, which as a result, creates a power asymmetry. Currently, pharmaceutical companies are the ones who are in power. This is because they are the ones who have the information which can then be used to make other people behave in the way that they want for commercial profit maximization. I think that's the issue here, the manipulation of power asymmetry.* [3EX03]

Additionally, a comparable contrast was recognized between the current power asymmetry of pharmaceutical companies and society and previous colonial appropriation.

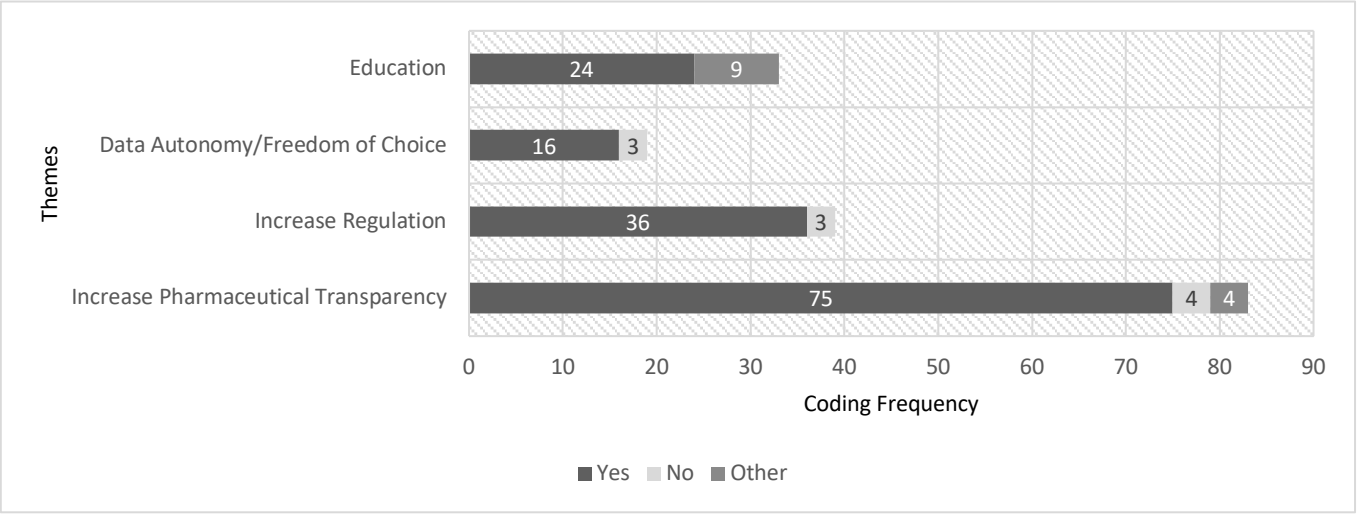
> *There is an issue with the power dynamic which we are subject to. If we want to access apps, then we must agree to their terms and conditions. Quite an interesting parallel can be drawn to data colonialism. This term recognizes that there are these greater or bigger powers that design the systems and implement digital tools. And because they have something that we want to buy into, we are giving up our own resources, which at the moment, one of the biggest kind of resources growing in value; that is data.* [3EX02]

This comparison suggests that, as social relations continue to develop on online platforms, the pre-existing power inequalities found in the offline social systems have equally shifted to be adapted to this territory. The aim of these authoritarian powers is to gain control over data and give grounds to justify it does *"what it does as an advance in scientific knowledge, personalized marketing, or rational management, just as historic colonialism claimed a civilizing mission."* (Couldry & Mejias, 2019)

Future Provisions and Regulatory Changes Throughout each interview, participants proposed or highlighted elements that they believed to be imperative for the future safe application of AI in pharmaceutical marketing. Figure 6 shows the themes that were described by the participants.

Figure 6

Coding Frequency on Future Provisions and Regulatory Changes



Overwhelmingly, participants urged for pharmaceutical companies to be more transparent predominantly on their data collection methods and marketing strategies especially if they are using AI systems. Understandably, the interviewees expressed concern regarding the practices of data surveillance originating from their online profiles and EHRs, as well as the true motivations behind the promotional activities the pharmaceutical companies are pushing. As one respondent emphasized:

> *I think it's important for things to be transparent in terms of what kind of data is being collected and used and what's being done with the data. For example, cleaning and feature selection for the AI, what models they're using, and then follow up studies about the influence of the promotion.* [1CSS03]

Furthermore, they mentioned the importance of education, not only for the public, and HCPs in terms of digital literacy and marketing procedures but for the companies who are implementing these systems. Experts reiterated this concept by indicating that *"there needs to be systems, or mechanisms through which this is explained to people, in terms of how these things are used, and what type of information is being collected, and how different types of information are being*

combined" [3EX03] which ultimately aims for the public and HCPs to have data autonomy over their own personal information. Another interviewee added by providing evidence on how they are currently seeing these changes in their own field of work:

> *We see there are some new types of health care professionals for example, practice nurses, nurse practitioners, and physicians, who are quite trained during their education in identifying marketing, activities, etc., and being critical in when they read information.* [2HCP02/3EX01]

Increasing education in these aspects could potentially eliminate risks such as data and algorithm bias. Thereby increasing the public's knowledge of the collection and distribution of their data, so that they can make more informed digital decisions, properly implement privacy parameters online and identify marketing strategies. Specifically, it could additionally increase awareness for HCPs regarding targeted marketing strategies.

However, despite the strong desire by these interviewees to implement such changes, in terms of increasing transparency and education, it was frequently expressed that this desire may not be applicable to or wanted by the rest of the population. As mentioned by a few experts:

> *But the question is, who wants the awareness of this? Because the healthcare professionals don't have an interest if it benefits them. The pharmaceutical industry doesn't have an interest if it benefits them. So, the question is, who will be interested in this transparency?* [3EX04]

> *The problem is that people do not always care that much. I think even if you make them aware of the risks, they will still, if it's convenient, just share their*

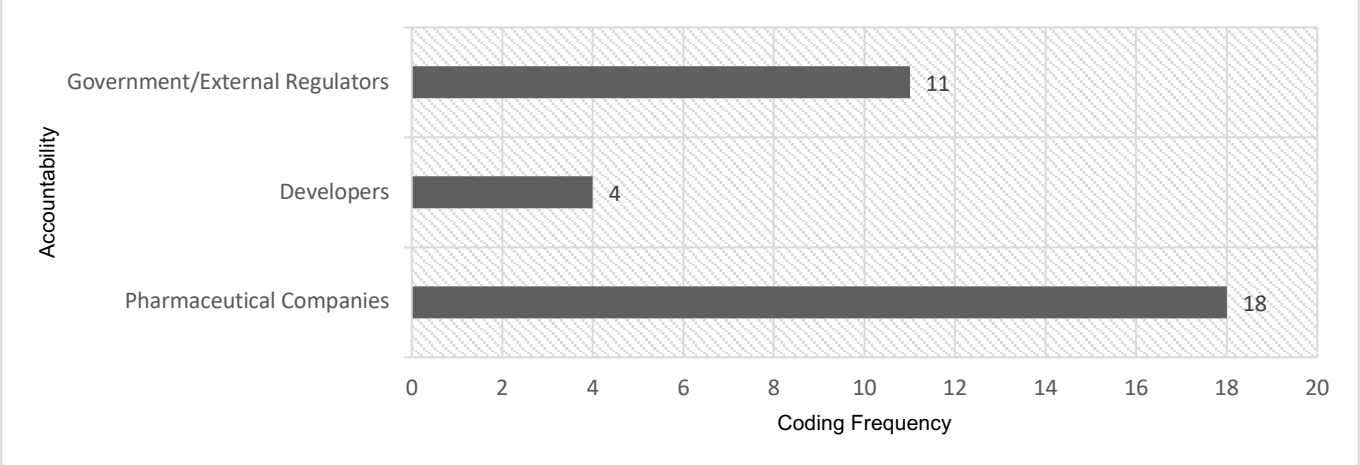
> *data. So that it's really challenging to educate people and really make them understand what AI does and how it works.* [3EX05]

Both professional and personal social interactions in society have transferred to online platforms, increasing the reliability of the digital sphere. For every online platform, privacy terms and conditions are required to be accepted. Without accepting these terms, individuals are unable to use the platform. As a result, users are forced to allow the collection and distribution of their data to gain access to online platforms. Consequently, individuals have become desensitized on the terms they are agreeing to and accept that their data is being collected and utilized by companies. Therefore, pharmaceutical companies have an advantage when collecting individual data from members of society, including HCPs.

Accountability. As required by HLEG's *Ethics Guidelines for Trustworthy AI*, it is required for accountability to be instituted to allow for maximum trustworthiness of an AI. Figure 7 demonstrates the coding frequency by which participants determined who should be held accountable and responsible for ensuring the AI used in pharmaceutical promotion and marketing strategies is safe and risk-free.

Figure 7

Coding Frequency on Accountability



The findings show that the interviewees favoured both pharmaceutical companies and the government/external regulators to be mainly held accountable, with an emphasis on pharmaceutical companies. The argument held by most participants was that:

> *The people that are using it [AI] are responsible, and if something happens, they should be made responsible. Of course, there are other actors that responsibility falls on. Regulators and governments to have appropriate safeguards and appropriate rules and property laws in place to make sure that these things don't happen. And if they happen, that the people that that are responsible are brought to court. But ultimately, I mean, the responsibility lies with the people that uses this technology, like any other technology.* [3EX03]

As society continues to digitally immerse itself on online platforms, people want the reassurance that companies who implement AI in their strategies are held accountable as well as the government provides them with sufficient protection around the distribution and utilization of their data.

Discussion

Summary of Findings

The expectation of this research study was to identify the different perspectives of each stakeholder group regarding the use of AI and its application in pharmaceutical promotion and marketing strategies for potential future regulation. The main findings of the research showed an overall call for change in the current environment in which this AI system is used, either in areas of data privacy policy, education, or pharmaceutical transparency. In general, participants' views aligned with the developed theoretical framework. They expressed that one or more of these

areas needed to be changed, as they play a role in negatively contributing to risks such as prescription behaviour, data and algorithm biases, surveillance, and power imbalances within the EU. However, it should be noted that perspectives differed in terms of the level of influence these areas could impact society if they were changed. For example, some participants strongly believed that increasing education and transparency would be essential for future provisions as it would increase accountability and reduce societal risks. On the other hand, other interviewees mentioned that increasing education and transparency would be ineffective because of the lack of concern or motivation from the general public.

However, referring back to the research question *does AI in pharmaceutical promotion and marketing strategies need to be further regulated,* the response would be, *yes*. Because of the current environment in which the AI functions in, the utilization of this AI system in pharmaceutical promotion and marketing strategies can pose more risks than benefits to society. As it currently remains, not enough environmental provisions are implemented within the EU to ensure that HCPs' prescription behaviour will not be negatively influenced, data and algorithm biases will not disproportionally affect part of the population, and online surveillance and power imbalances will not occur.

Strengths and Limitations

Strengths To ensure that credibility was present throughout the study, the method of 'involved informants' was used to confirm that the findings were accurate and representative (Anderson et al., 2014). Supervisors from both the internship as well as the university were consulted to confirm that the procedures used to collect, analyse, and present the data were appropriate. Additionally, the methods of dependability were then applied through peer-debriefing and scrutiny as a strategy to establish trust (Anderson et al., 2014). Lastly, the transferability of the

research to support future investigations, and studies, can be highlighted by the extensive literature review and the variety of perspectives of stakeholders that were expressed (Anderson et al., 2014). Overall, the quality of the information provided by the participants was informative and enlightening. Each participant was knowledgeable in their relative field which added depth and perspective to the topics explored. The nature and flexibility of the semi-structured interviews provided for genuine responses of the interviewees to be elicited. As a result, participants raised concepts that were not necessarily mentioned in the initial literature review but were relevant and crucial to understanding current attitudes, perceived risks, and future provisions.

Limitations The first limitation of this research was found during the background literature review phase. Since the US allows direct-to-consumer pharmaceutical marketing strategies, the majority of studies and reports investigate this aspect which cannot be generalized to European pharmaceutical AI strategies[8]. The second challenge of this study ensued during the recruitment process in finding diverse participants. Not only was the number of participants low, but the participant sample was disproportionally represented. Due to the combination of time constraints as well as the low positive response rates, important stakeholders such as pharmaceutical companies and healthcare professionals were either scarcely or not involved in the data collection. Consequently, their perspectives were not made apparent during the results and are therefore absent in the conclusion. This circumstance led to the reduction of the confirmability and low participant sample representativeness of the study. It is highly suggested in future research that members of pharmaceutical companies and HCPs are to be investigated to gain a more inclusive scope of perspectives and it is encouraged that further research including these

[8] Reference Baeten, R. (2009). EU pharmaceutical policies : direct-to-consumer advertising. In *Social develop*

components are incorporated before any recommendations for changes to the current policies are made.

Conclusion and Future Implications

The implementation of AI within the healthcare industry has immensely accelerated over the course of the past few decades. Considering how popular and widespread the application of AI is used in different areas of the field, it is important to highlight that, the rate at which this tool is used is disproportional to the research on the benefits and risks it can have on the public. It is proposed that policymakers consider these themes and identify that the precarious nature of AI used pharmaceutical prediction and omnichannel marketing is a symptom of the current environment. The results have demonstrated that the insufficient data protection laws, low digital literacy amongst the public, and lack of transparency from pharmaceutical companies, contribute to the risks involved. If this AI were to be classified as 'high risk' according to EU Commission's *Artificial Intelligence Act Chapter 2 Articles 9-15 and Chapter 3 Article 16-29* then these environmental areas of concern raised by the stakeholder participants would be addressed, thus resulting in the minimization of the risk for the public.

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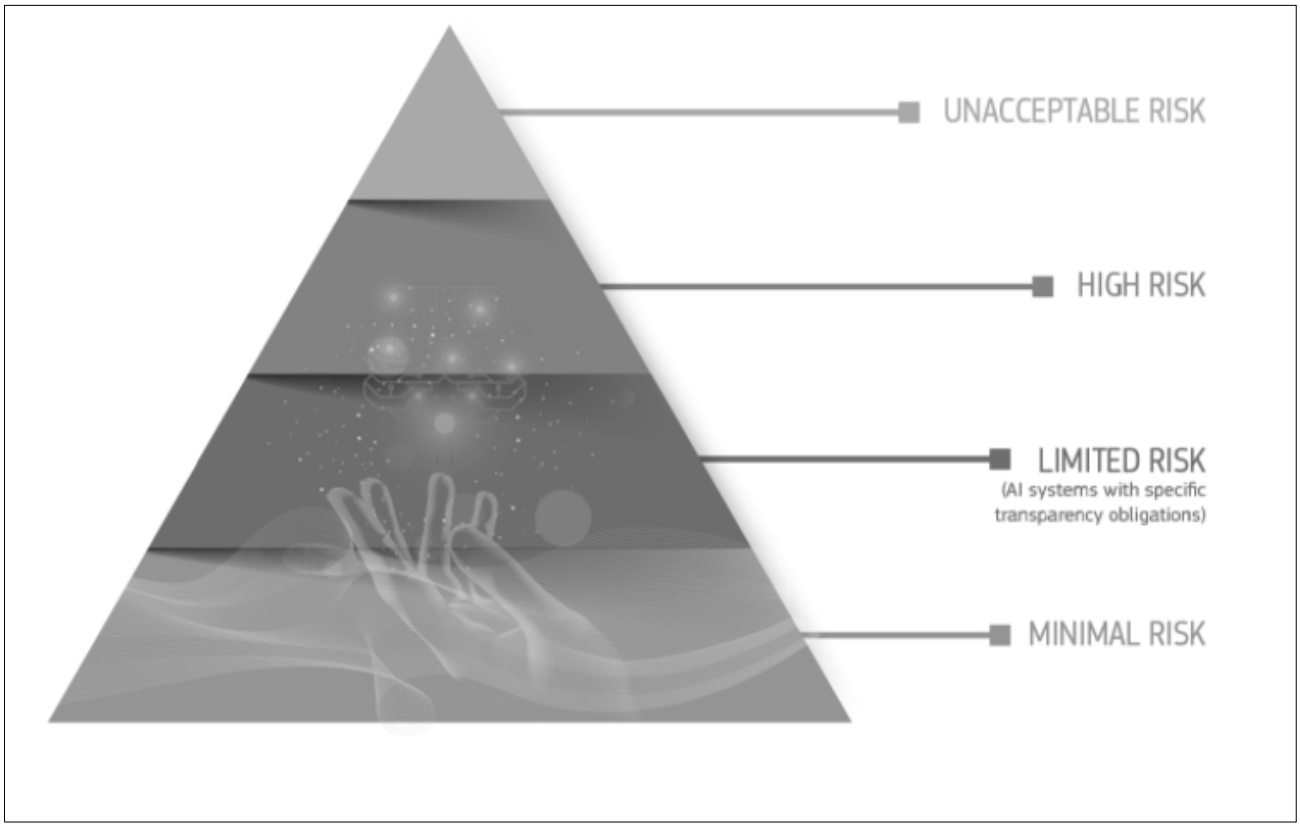
Appendix A

European Commission's 'Risk-based' approach using the Pyramid of Criticality



Appendix B

Interview Question Guide

INTERVIEW QUESTION GUIDE

Title of the proposed research project: ARTIFICIAL INTELLIGENCE IN PHARMACEUTICAL PROMOTION AND MARKETING STRATEGIES: EXPLORING THE NEED FOR REGULATION IN THE EU

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Introduction
In the European Union, the GDPR, the Charter of Fundamental Rights of the European Union and the EU regulation, Document I21134: Advertising Medicinal Products for Human Use, have limited the ability for pharmaceutical companies to market directly to consumers. As a result, these companies have focused their efforts on influencing healthcare professionals (HCPs) by using AI systems and personal digital information in their marketing efforts. The two cases presented below are real examples published in a whitepaper from a company called IQIVA on how AI systems have been implemented by pharmaceutical companies in their promotion and marketing strategies by a third party. These scenarios aim to help participants understand the topics that will be discussed during the interview.

Interview Scenarios

Scenario 1
Digital Engagement Across the EU *700 Campaigns + 50,000 HCPs +100 Behavioural Attributes*
Email and digital channels play an important role in commercial healthcare professionals' engagement, with many companies setting up complex operational customer relationship management systems to gather healthcare professionals' opt-ins and optimize communications. And while mass emails are popular because the cost per send is so low, to generate real business value from these campaigns, the messages have to be personalized. In 2018, this EU based pharmaceutical company leveraged AI & machine learning to achieve that customization. For this client, the analytics team employed machine learning algorithms to analyze 700 campaigns impacting 50k healthcare professionals across the EU. They used this information to predict healthcare professional response to digital campaigns and optimize execution of: Subject lines, Message content, Frequency, Time of day, Day of the week Armed with data-driven insights, the commercial team customized their email approach down to the individual healthcare professional, defining the optimal content, frequency, and time-and-day to increase open and click rates.'

Scenario 2
Tracking Multi-Indication Production *EMR and LRx data deliver depth and breadth of knowledge*
When a product is approved for multiple indications, understanding the specific condition an healthcare professional prescribed the product for can contribute to successful brand management. However, many brand performance data assets only report total prescriptions over time and can't track at an indication level. In 2018, a global healthcare company deployed an AI & machine learning solution to understand how their brand performed across different indications and against their competition. The analytics team built an algorithm that combined two sets of patient data, pulling from the strengths of each: • EMR data provided knowledge about indication and treatment on a local scale. • Longitudinal prescription data (LRx) provided regional insights and trends across the entire country. With this combined set of data, the algorithm predicted why the drug was being prescribed for particular patient profiles. These brand performance driver insights included the source of business (new, switch, repeat) at an indication level. With this knowledge, the commercial teams accurately targeted healthcare professionals with messaging for the disease they were most likely to treat, tracked indications over time based on region and specialty, identified, and addressed gaps in performance with enhanced resource planning, and better predicted future demands.

Interview Questions

Questions around Data Privacy and Security used in AI Systems

In scenario 1, the data that was collected originated from mass email campaigns to develop personal profiles and email approaches that target specific individual HCPs across Europe. The pharmaceutical company was able to develop optimal subject line, message content, frequency, time of day, and day of week that best fits each individual HCP and used this information to increase open and click rates. In the second scenario, EMR and LRx data was collected to understand prescription behaviour in various regions. This data allowed the company to specifically target HCPs, track regional progress, predict future demands as well as identify the sources of business.

*Questions for **All** **Participants***

(a) After reading these scenarios, were you aware that pharmaceutical companies in the EU use AI technologies and collect and use personal data for marketing purposes? ***(Question only for civil society participants and HCPs)***

(b) Based on your opinion, what is your perspective on pharmaceutical companies collecting and using personal online data from HCPs and the public for their AI systems to create targeted emails to HCPs?

(c) Do you believe the 'personalization' approach pharmaceutical companies are taking, like targeted emails, could have impacts either on HCPs or individuals? Do you believe that this could also have an impact on society and general public safety?

(d) As can be seen in these two scenarios, pharmaceutical companies use targeted advertising to gain insight into prescribing behaviours and use AI systems to contact HCPs online as much as possible. Do you believe that with the additional influence of AI systems this will affect prescription behaviour? If so, how?

(e) Do you think it is important for pharmaceutical companies to be transparent about their use of data and AI systems in their promotion and marketing strategies towards HCPs and citizens? If so, what would recommend as important information to be open to the public?

(f) Currently, within the healthcare sector, the EU Commission has only identified AI systems in medical devices to be 'high risk' and in need for stricter regulations. This means that every other AI in the sector is considered 'minimal risk' with no regulations in their application. After reading these scenarios and how pharmaceutical companies use AI in areas like collecting data and creating targeted advertisements in their promotion and marketing strategies, in your opinion, do you believe that it is necessary for stricter regulations to be implemented for these AI systems.

Questions around Human Agency & Oversight, Cybersecurity Risks and AI Bias

In general, it has been identified that AI systems lack human agency & oversight due to the complex and complicated nature of its fundamental functions. As a result, users of AI systems are unable to identify issues that may arise when using these systems, like cybersecurity breaches and AI bias. As presented in Scenario 1 and Scenario 2, AI is heavily relied on to make important decisions like, knowing what products to recommend, and to predict future demands.

*Questions for **All** **Participants***

(a) Previous research has suggested that to establish risk-free AI there needs to be an increase in human agency & oversight at every step of the process, especially regarding data collection for AI systems. Do you believe that individuals and HCPs should have full autonomy over personal information that is collected and used for AI in pharmaceutical marketing? Why or why not?

(b) Should pharmaceutical companies explain the risks, risk mitigation measures as well as the societal impact around AI systems applied in promotion and marketing strategies like patient outcomes and public health indicators? Why or why not?

*Questions for **Pharmaceutical and Marketing Companies and Civil Society Participants***

(a) To what extent is there currently are pharmaceutical companies transparent to the public around how AI functions in terms of how personal data is stored, used, and to whom it is accessible to?

(b) Like every technology and software system, AI can also be prone to cyber security risks and breaches, who do you believe should be responsible in ensuring the safety of the AI is properly functioning and risk free?

*Questions for **Pharmaceutical and Marketing Companies Participants***

(c) Oftentimes, AI systems can be complex in nature. As a result, it is difficult for the users within pharmaceutical companies to understand and interpret the outcome data. Do you believe that this is an issue that needs to be addressed?

(d) Do you believe that human agency plays a role in mitigating the complexity of AI application in pharmaceutical promotion and marketing? If so, how would you increase human agency to ensure that AI systems are well understood when applied in these strategies?

(e) Pharmaceutical companies use AI not only for recommendation but as well for predictive analysis as presented in Scenario 2. However, AI systems in these instances can be biased when the input information given is skewed or not representative depending on where the data was collected. As a result, the predicted outcomes that are generated from the AI can be partisan and disproportionally affect unrepresented members of the population such as minority groups. What are the current methods that are being used in limiting and reducing AI bias in pharmaceutical promotion and marketing strategies? Do you believe there should be changes in the application of these methods? If so, what kind of changes?

Appendix C

Participant Information Sheet

PARTICIPANT INFORMATION SHEET

Title of the proposed research project: ARTIFICIAL INTELLIGENCE IN PHARMACEUTICAL PROMOTION AND MARKETING STRATEGIES: EXPLORING THE NEED FOR REGULATION IN THE EU

Dear participant,

We would like to extend an invitation for you to participate in a student research study. The details of the study will be described below and will be further explained by the research team. Additionally, any questions that may arise will be answered to provide more clarity on the topic and participation requirements. We thank you for your time and involvement.

Study background
In April 2021, the European Commission put forth a regulatory proposal to certify that Artificial Intelligence (AI) products in the European Single Market are safe, trustworthy, and protect the fundamental rights of Europeans. Its prospects include increasing protection and quality reliability in AI systems using a 'risks-based approach'. However, within the health sector, the only AI systems that are classified as 'high risk' and require stricter regulations are AI systems that are categorized as medical devices. The objective of this research project is to investigate the need for regulations of other health-related AI systems. Specifically, the purpose is to identify potential risks that may arise around the uses of AI in pharmaceutical promotions and marketing strategies if kept unregulated. The intention is to determine if this use of AI should be considered 'high risk' and be subject to further regulations like AI systems classified as medical devices.

Research team
The researchers involved in this study includes Laura Sandor (Research Intern) and Janneke van Oirschot (MSc., Research Officer). Please contact these researchers if you have any questions regarding the study.

Data collection
The research project is comprised of two aspects, literature review in semi-structured interviews.

The semi-structured interview: during this interview, we would like to discuss the topic of AI and its risks in pharmaceutical promotion and marketing strategies. This semi-structured interview will be led by a set of already developed questions which will be completed either through video call or over the phone. The interview will be recorded and transcribed afterwards to be analyzed for the research. The interview aims to about 20-30 minutes in total. No compensation or reimbursement will be granted for your participation.

Benefits
Investigating the uses of AI in pharmaceutical promotion and marketing is important in the future of AI regulation in the European Union. Understanding different perspectives on this subject allows for accurate evaluations to be considered in future regulations.

Risks/discomforts
There are no known or anticipated risks associated with participation in this research project. If any questions or concerns on this topic need to be raised, it is urged that the investigators listed above are contacted. If participants at any point feel as a question during the interview makes them feel uncomfortable, they are free not to answer the question.

Alternatives
Your participation in this research project is voluntary. You have the right to end your participation at any moment, without citing a reason after agreeing to participate. Withdrawing from the research project will not lead to any consequences. Even if you choose not to participate in the interview, you may receive the results of the research project.

Offer to answer questions
You are given the opportunity to ask questions about the research. Questions may be asked before, during or after the interview. If you have any further questions or complaints about this study, you may contact the researchers listed at the top of the informed consent form.

Participants rights
The researchers recognize the participant's rights and freedoms. The participant will be treated equally and with dignity. The participant will be under no pressure to participate and will not experience any negative consequence if they decide to refuse engagement in the interview. The participant has the right to receive information regarding the research to make better and knowledgeable decision. Additionally, the participant can ask questions with the guarantee of an answer. If the participant agrees to the terms of participation, they will be asked to sign and date the informed consent form. A copy of the signed and dated consent form will be sent to the participant.

Confidentiality
Regarding the use of your data, the following conditions apply:

- Your data will be used for scientific purposes, including publication. Only the researchers have access to the data.
- Your data will be handled and stored confidentially. This means that your data cannot be traced back to you. Specifically, the researcher will use a code number instead of your name to save your data. Further, you won't be able to be identified in any publication.
- After publication, only the data that is necessary for the verification of the study results will be kept and stored safely for a minimum of 10 years and deleted once it is no longer needed.
- You have the right to withhold any responses you have provided from subsequent analysis. This means we will not use your data for this or any follow-up research, nor will we share it anonymously for open science purposes. You can decide to withdraw your data until the study results are accepted for publication.

Yours sincerely,

Laura Sandor and Janneke van Oirschot

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Appendix D

Informed Consent Form

INFORMED CONSENT FORM

Title of the proposed research project: ARTIFICIAL INTELLIGENCE IN PHARMACEUTICAL PROMOTION AND MARKETING STRATEGIES: EXPLORING THE NEED FOR REGULATION IN THE EU

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Introduction
Thank you for taking part in this research project about the use of Artificial Intelligence in pharmaceutical promotion and marketing strategies. Below is a description of the research procedures and an explanation of your rights as a research participant. You are asked to read this information carefully. You will receive a copy of this form should you agree to proceed under the terms stated.

General information
In April 2021, the European Commission put forth a regulatory proposal to certify that Artificial Intelligence (AI) products in the European Single Market are safe, trustworthy, and protect the fundamental rights of Europeans. Its prospects include increasing protection and quality reliability in AI systems using a 'risks-based approach'. However, within the health sector, the only AI systems that are classified as 'high risk' and require stricter regulations are AI systems that are categorized as medical devices.

The objective of this research project is to investigate the need for regulations of other health-related AI systems. Specifically, the purpose is to identify potential risks that may arise around the uses of AI in pharmaceutical promotions and marketing strategies if kept unregulated. The intention is to determine if this use of AI should be considered 'high risk' and be subject to further regulations like AI systems classified as medical devices.

This research is funded by The European AI Fund. The researchers declare no conflicts of interest in the conducting of this research study.

Procedure
This research project consists of only interviews. You may participate in the interview or decline participation.

The interview, if you choose to participate, will involve investigating your perspective around AI systems used in pharmaceutical promotion and marketing strategies. Your participation will last for approximately 30 minutes and will take place online either as a video or audio call and will be recorded and transcribed for analysis. The interview is semi-structured and will include prepared questions as a template for discussion. You will receive no reimbursement or compensation for your participation in this research project.

Participants
The participants intended for this research are any stakeholders that are affected by and/or are using AI in pharmaceutical promotion and marketing strategies. This includes pharmaceutical companies, marketing companies, healthcare professionals, civil society stakeholders and experts in AI and ethics.

Risks/discomforts
There are no known or anticipated risks associated with participation in this research project. If any questions or concerns on this topic need to be raised, it is urged that the investigators listed above are contacted. If participants at any point feel as a question during the interview makes them feel uncomfortable, they are free not to answer the question.

Benefits
Investigating the uses of AI in pharmaceutical promotion and marketing is important in the future of AI regulation in the European Union. Understanding different perspectives on this subject allows for accurate evaluations to be considered in future regulations.

Alternatives
Your participation in this research project is voluntary. You have the right to end your participation at any moment, without citing a reason after agreeing to participate. Withdrawing from the research project will not lead to any consequences. Even if you choose not to participate in the interview, you may receive the results of the research project.

Offer to answer questions
You are given the opportunity to ask questions about the research. Questions may be asked before, during or after the interview. If you have any further questions or complaints about this study, you may contact the researchers listed at the top of the informed consent form.

Participants rights
The researchers recognize the participant's rights and freedoms. The participant will be treated equally and with dignity. The participant will be under no pressure to participate and will not experience any negative consequence if they decide to refuse engagement in the interview. The participant has the right to receive information regarding the research to make better and knowledgeable decision. Additionally, the participant can ask questions with the guarantee of an answer. If the participant agrees to the terms of participation, they will be asked to sign and date the informed consent form. A copy of the signed and dated consent form will be sent to the participant.

Confidentiality
Regarding the use of your data, the following conditions apply:

- Your data will be used for scientific purposes, including publication. Only the researchers have access to the data.
- Your data will be handled and stored confidentially. This means that your data cannot be traced back to you. Specifically, the researcher will use a code number instead of your name to save your data. Further, you won't be able to be identified in any publication.
- After publication, only the data that is necessary for the verification of the study results will be kept and stored safely for a minimum of 10 years and deleted once it is no longer needed.
- You have the right to withhold any responses you have provided from subsequent analysis. This means we will not use your data for this or any follow-up research, nor will we share it anonymously for open science purposes. You can decide to withdraw your data until the study results are accepted for publication.

Statement of Consent

..... has given to me all the details of what is going to be done, the risks, the benefits involved as well as my rights regarding this study. I am consenting that my decision to participate in this study will not affect me in any negative aspect. I am conscious that I have the right to withdraw at any time during my participation. I understand that my identify will be concealed when using my information in this research. I understand that by signing this form, I do not waive any legal right to merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Signature of Participant

Participant's Name .....

Date (DD/MM/YY) .....

Signature of Researcher

Researcher's Name .....

Date (DD/MM/YY) .....

Appendix E

Topic List

AI Design Considerations

Privacy & Data Governance

- 1.1 Codes & Regulations
  - 1.1.1 Need More Regulations
  - 1.1.2 Need Third-Party Regulators
  - 1.1.3 No Further Regulations Needed
- 1.2 Data Autonomy
  - 1.2.1 Freedom of Choice
  - 1.2.2 Need Data Autonomy
  - 1.2.3 No Need for Data Autonomy

Secure Algorithms

- 2.1 Developer Accountability
- 2.2 Diversity, Non-Discrimination & Fairness
  - 2.2.1 Algorithm Bias
  - 2.2.2 Data Bias
- 2.3 Technical Robustness & Safety
  - 2.3.1 Quantified Risks

Stakeholder Involvement

Individuals & HCPs

- 3.1 Human Agency
  - 3.1.1 Feelings of Concern & Dishonesty
  - 3.1.2 HCPs Accountability
  - 3.1.3 General Public Awareness
  - 3.1.4 Public Indifference

Pharmaceutical Companies

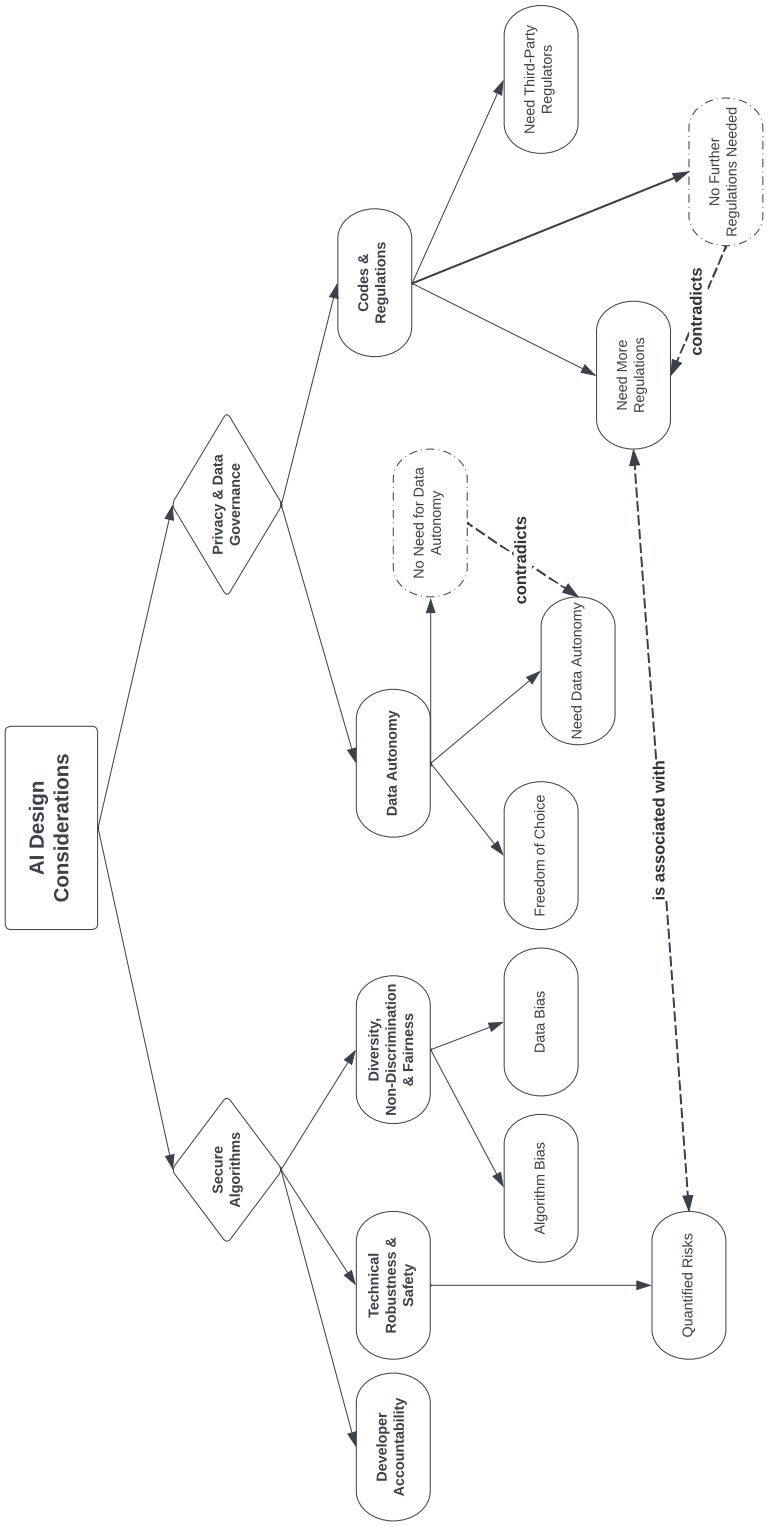
- 3.2 Human Oversight
  - 3.2.1 Pharmaceutical Accountability
  - 3.2.2 Need for Pharmaceutical Transparency
  - 3.2.3 No Need for Pharmaceutical Transparency
  - 3.2.4 Transparency is not the only Solution
- 3.3 Societal & Environmental Wellbeing
  - 3.3.1 AI has Negative Impact
  - 3.3.2 AI has Positive Impact
  - 3.3.3 AI Influences People & Society
  - 3.3.4 Power Imbalance
  - 3.3.5 AI Influences Prescription Behaviour
  - 3.3.6 AI does not Influence Prescription Behaviour

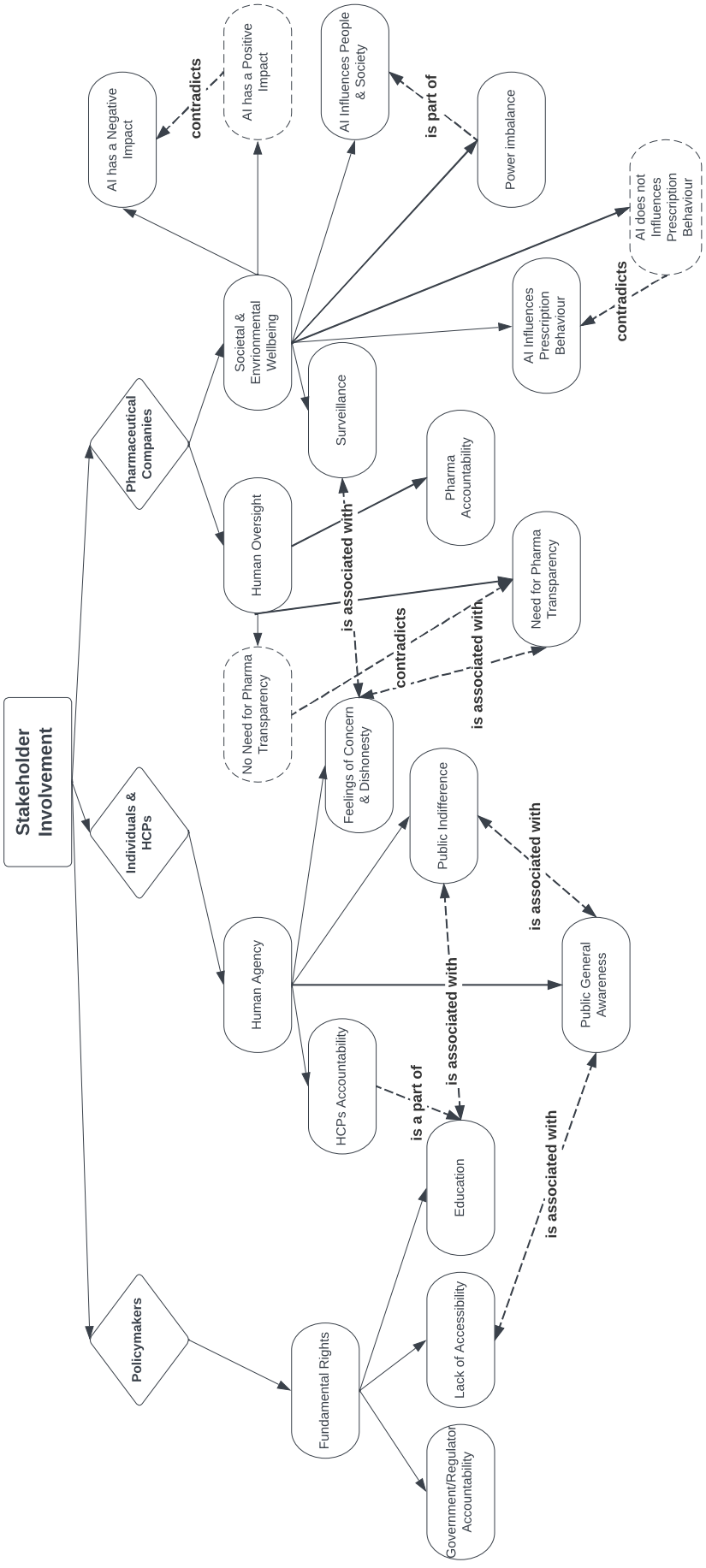
Policymakers

- 4.1 Fundamental Rights
  - 4.1.1 Education
  - 4.1.2 Government/Regulators Accountability
  - 4.1.3 Lack of Accessibility

Appendix F

Code Trees




Stakeholder Involvement
Pharmaceutical Companies
Individuals & HCPs
Policymakers
Societal & Envrionmental Wellbeing
Human Oversight
Human Agency
Fundamental Rights
AI has a Negative Impact
AI has a Positive Impact
contradicts
AI Influences People & Society
is part of
Power imbalance
AI does not Influences Prescription Behaviour
AI Influences Prescription Behaviour
contradicts
Surveillance
Pharma Accountability
No Need for Pharma Transparency
is associated with
contradicts
Need for Pharma Transparency
is associated with
Feelings of Concern & Dishonesty
Public Indifference
is associated with
Public General Awareness
HCPs Accountability
is a part of
is associated with
Education
Lack of Accessibility
is associated with
Government/Regulator Accountability

Appendix G

Number of Participant Interviews vs. Coding Frequency

Section	Theme	Coding Frequency	Number of Participant Interviews
Current Views and Attitudes	Feelings of concern & dishonesty	19	7
	Low public awareness & low education	12	7
	AI can have negative impact	25	8
	AI can have positive impact	8	5
Perceived Risks	AI does influence HCPs prescription behaviour	28	8
	AI does not influence HCPs prescription behaviour	2	1
	Algorithm Bias	12	7
	Data Bias	18	8
	Surveillance	5	1
	Power Imbalance	4	2
Future Provisions and Regulatory Changes	Need Education	26	8
	Education is not the only Solution	9	2
	Need Data	16	9

	Autonomy/Freedom of Choice		
	No Need for Data Autonomy/Freedom of Choice	3	3
	Increase Regulation is Needed	36	8
	No Increase in Regulation is Needed	3	3
	Increase in Pharmaceutical Transparency	75	9
	Do not Need Increase in Pharmaceutical Transparency	4	3
	Pharmaceutical Transparency is not the only Solution	4	3