

ETHICAL CONSIDERATIONS IN THE DEVELOPMENT AND USE OF MEDICAL TECHNOLOGY PRODUCTS

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Due to its direct impact on the health and well-being of patients, the medical technology industry must consider various ethical aspects in the development and commercialization of its products to ensure that these products are safe, effective, and promote the well-being of patients. The author identifies five critical aspects that should be addressed in the corporate social responsibility initiatives of medical technology companies.

Key words: medical technology; MedTech industry; corporate social responsibility; ethical aspects of medical technology; innovative medical products.

Medical Technology (MedTech) is a combination of technology and medical interventions. It is considered a fundamental component of health systems. New technologies applied to the medical sector have the potential to improve current standard of care by preventing, diagnosing, treating, and rehabilitating illnesses and diseases in a safe and effective way. MedTech companies are investing in Internet of Things, artificial intelligence, robotics, nanotechnologies, 3D-printing, and other advanced technologies to develop products that will positively contribute to global health. For example, in the last decades, robotics in the medical field have already transformed how surgeries are performed, providing better experience for patients, less invasive treatment and easier recovery.

In addition to the medical technology industry's core goal of saving lives and improving health, environmental and social considerations are an integral part of the industry's operations. Preserving a healthy environment and building socially responsible value chains are essential in keeping human beings in good health. Moreover, the medical technology industry is responsible for developing and commercializing products that directly impact patients' health and well-being, making it crucial to consider several ethical aspects in corporate social responsibility initiatives.

The list of reasons why ethics must be taken into account in the MedTech industry includes: the need for patient safety, the role of innovation, unequal access to the latest technology, the use of human subjects for testing, confidentiality and data protection issues.

Firstly, ethical aspects must be considered when it comes to MedTech products' safety, efficacy, and long-term implications. The MedTech industry

must ensure that their products are safe and effective, keeping the patient's best interest in mind.

Secondly, the MedTech industry is continuously developing new products and technologies that can revolutionize healthcare delivery and raise ethical questions. Innovative products and trends may raise ethical questions concerning the use of artificial intelligence, the integration of genetic data and technology, and other emerging trends.

Thirdly, the development and commercialization of the latest and modern MedTech products can benefit individuals, healthcare systems, and the entire population depending on a particular region. However, MedTech products can come with a high cost, leading to ethical considerations on access, affordability, and equitable distribution.

Fourthly, new and innovative medical products may need clinical trials involving human subjects for testing. These testing trials raise ethical concerns surrounding informed consent, protection of human subjects, and equitable distribution.

Fifthly, MedTech products involve the use of sensitive patient information, such as medical history, diagnostic images, and personal details. The collection, processing, sharing, and management of this data raise ethical issues on patient consent and data privacy.

It means that ethical considerations in the industry aim to safeguard patients, promoting the development and commercialization of safe and effective products that benefit individuals and the healthcare ecosystem as a whole.

The reasons listed above point to the ethical considerations that MedTech companies involved in product development and commercialization must address. Among them:

Informed consent. The development and commercialization of products that involve human subjects require obtaining informed consent from the participants. This means ensuring that they fully understand the risks, benefits, and implications of participating in the study. Informed consent is particularly important in MedTech products that involve invasive procedures, and patients should have a complete understanding of the product's indications, contraindications, and potential side effects.

Privacy and data protection. MedTech products that involve the use of sensitive personal data may raise privacy concerns. Recent data breaches related to MedTech highlight the need for data protection measures to prevent unauthorized access, sharing, or theft of sensitive data. Ethical challenges also arise regarding the use and ownership of patient data generated by medical devices.

Risk-benefit analysis. The risks and benefits of a MedTech product must be thoroughly evaluated and weighed against each other to ensure the products' safety, efficacy, and viability. Clinical trials play a crucial role in this process

to identify any potential side effects that could occur. The safety and efficacy of the product must be determined before it is available for commercial use.

Equity. Equity considerations in access to MedTech products are essential, particularly concerning developing countries. The production and commercialization of high-tech products can be an expensive venture, thus, can be out of reach of many low-income countries. The development of the product must take into account that the intended beneficiaries have access to them.

Ethical marketing and promotion. The MedTech industry must ensure that fair marketing practices are followed, particularly when dealing with vulnerable populations. Medical professionals and patients must receive clear and accurate information about the product's benefits, limitations, and safety profile.

Furthermore, these considerations vary depending on the social, cultural, economic, and regulatory landscape of a particular region or country. Here are some examples to illustrate this point.

The informed consent requirements for clinical trials can vary between countries. For example, in the United States, the Institutional Review Board is responsible for ensuring that research participants are fully informed before agreeing to participate [1]. In contrast, some developing countries may not have similar institutional review boards, making it challenging to ensure that participants understand the risks and benefits fully, which raises ethical concerns.

Access to MedTech products varies across countries, particularly in developing nations, where the products' cost may be out of reach for many. Thus, ethical considerations regarding equitable access and affordability differ accordingly. In contrast, in developed nations, access issues may relate to regulatory approval processes, which can be lengthy, expensive, and may cause innovative devices to be unavailable or significantly delayed.

Data privacy laws and regulations differ significantly between countries. For example, the European Union has implemented the General Data Protection Regulation (GDPR), which provides strict rules for the handling of sensitive personal information, including medical data [2]. In contrast, other countries, such as the United States, have less strict regulations, highlighting different privacy and data protection ethical considerations.

Regulatory authority rules and approval processes vary widely across countries. For example, the United States Food and Drug Administration (FDA) has strict processes to approve devices for use, including rigorous clinical trials [3]. Conversely, countries with less stringent regulatory approvals may raise ethical concerns regarding the safety and efficacy of medical devices, thereby posing a challenge to the development and regulation of MedTech products.

In summary, ethical considerations around informed consent, privacy, risk-benefit analysis, equity, and marketing and promotion play crucial roles in the development and commercialization of MedTech products. Health products

should be developed, marketed, and sold ethically, while keeping the interests of patients as top priority. As a final remark, it is also vital to mention that ethical aspects in the medical technology industry vary between countries, depending on a range of factors like culture, social, economic, regulatory, and technological differences. It is essential to recognize these divergences when considering developing and commercializing MedTech products.

References

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