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# The EU commission's risky choice for a non-risk based strategy on assessment of medical devices

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## ABSTRACT

### Keywords:

Apps  
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Regulation of medical devices has been one of the most notable regulatory initiatives of the European Union. The need to ensure that medical devices are of a high quality is self-evident in nature. This is demonstrated by the lack of willingness of both healthcare institutions and professionals to use medical devices that have not properly been certified. In determining which devices are medical devices and should therefore meet the requirements of the regulatory framework, both the current and the proposed frameworks foresee a central place for the concept of 'intended purpose'. This means that only those manufacturers that have explicitly stated that their device is to be used for a medical purpose should have to comply with the medical device framework. Unfortunately, however, this concept has become increasingly problematic given the rise in mHealth (mobile health) practices and 'appification' (shift to mobile devices) in particular, arguably posing potentially serious risks to human health in certain cases. This article discusses the problems that are created by the ever-increasing amount of 'well-being' apps and the fact that most will not be classed as medical devices. Despite apparently being aware of these problems, the EU Commission has opted to maintain its current approach in the newly proposed regulation, choosing not to employ other approaches as the FDA has for example done in opting to use a 'risk based case-by-case approach'.

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## 1. Introduction

The purchase and use of medical devices (at least in the legal sense of the term) was once something reserved mainly for

those involved in the management of medical institutions and the medical professionals that worked within them.<sup>1</sup> The producers of such devices more often than not were relatively well-resourced entities capable of complying with stringent regulatory regimes and the requirements posed by

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<sup>1</sup> M. Grennan, 'Price Discrimination and Bargaining: Empirical Evidence from Medical Devices', *American Economic Review*, 103 (1) (2013) pp. 145–177. As the authors discussed, the medical device market has traditionally been viewed in 'business-to-business terms'.  
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them.<sup>2</sup> Whilst there was a clear need to have a solid regulatory framework in place to prevent inappropriate objects (that did not meet sufficient standards) being used as medical devices, such a framework could operate in a context where only a small group of well-informed companies, institutions and individuals would ever seek to produce, market or purchase such devices. Such a framework did not need to be consumer friendly in the sense that other regulatory frameworks often need to be – in that such products would not usually be marketed directly to end consumers/patients themselves, but would work through intermediaries in the form of highly trained medical professionals and/or specialist institutions.<sup>3</sup> This dynamic arguably involved interactions between groups of relatively well informed actors and allowed potential risks to patient safety to be appreciated in the particular context at play.

The context in which medical devices operate has however begun to radically shift in recent times. Amongst the most important factors responsible for this shift has been the increasing development in mHealth in general and the phenomenon of ‘appification’ in particular.<sup>4</sup> This shift is introducing a sea change in the way that individuals interact with medical devices. Not only are patients ever more responsible for the day to day use of a particular medical device themselves, but they may even be active in selecting and purchasing them.<sup>5</sup> Though still only responsible for a small (but growing) fraction of medical care (even in the context of mHealth), smartphone applications or ‘apps’ are perhaps the most illustrative example of this transition.<sup>6</sup> Individuals can now select from an enormous variety

of available apps ranging from those that can be described as concerned with ‘well-being’ to those that perform roles classically associated with medical devices (e.g. the monitoring of symptoms, the diagnosis of disease and the administration of medicines).<sup>7</sup> Examples range from apps that may be used to plan a healthy lifestyle, taking into account dietary and exercise factors, to apps that may play a role in the management of chronic illnesses such as diabetes.<sup>8</sup>

The wide spectrum of mHealth apps that are now available has presented major challenges for the regulation of medical devices, particularly in terms of deciding which of these should be submitted to the requirements of the EU Medical Device Framework and which should not.<sup>9</sup> As this article discusses, the EU’s current approach (and its proposed new approach in the form of a new regulation) relies on the concept of ‘intended use’ in order to discern whether something is a medical device, and if so to what regulatory burden it should be subjected. This differs notably from the FDA’s ‘risk based’ approach (adopted in the US) and is concerning from a number of perspectives, including that of patient safety. Whilst either approach has problematic elements,<sup>10</sup> this paper will argue that in choosing to maintain the ‘intended use’ concept, the EU Commission has clearly opted to support what it perceives as a valuable area of innovation and growth (particularly in so called ‘well-being apps’, i.e. apps that are not intended to treat disease but to maintain physical and psychological health) at the expense of potential concerns regarding patient/consumer safety.

Section 2 will look at the medical device framework and the important role it plays in the protection of patients. Section 3 looks at the role the concept of ‘intended use’ plays in the current directive, a concept that will remain in the proposed new Medical Device Regulation. Section 4 analyses the effect that the rise of mHealth and ‘appification’ in particular have had on medical devices, focusing on the problems that such an evolution creates for the EU’s existing and proposed medical device framework. Section 5 will contrast the EU’s approach with the ‘risk based’ approach taken by the FDA in the US.

<sup>2</sup> A. Kaplan and D. Williams, ‘Medical Device Regulatory Landscape: The Imperative of Finding Balance’, *Circulation: Cardiovascular Interventions*, 5, (2012) pp. 2–5. “When technology with potential to address a significant market need demonstrates proof of concept, it is often acquired by large established device manufacturers who leverage their manufacturing, clinical development, and marketing expertise as well as provide the large capital required for further development.”

<sup>3</sup> L. Burns, *The Business of Healthcare Innovation* (Cambridge: 2012). p. 11.

<sup>4</sup> The author has, with others, written several papers on issues related to the increasing use of ‘apps’ in mHealth. See in particular P. Quinn, A. Habbig, E. Mantovani and P. De Hert, ‘The Data Protection and Medical Device Frameworks? Obstacles to the Deployment of mHealth across Europe?’, *European Journal of Health Law*, 20 (2) (2013) pp. 185–204. E. Mantovani and P. Quinn, ‘mHealth and data protection – the letter and the spirit of consent legal requirements’, *International Review of Law, Computers & Technology*, (2013). <http://dx.doi.org/10.1080/13600869.13602013.13801581>.

<sup>5</sup> M. Bradway, E. Arsand and A. Grottlund, ‘Mobile Health: empowering patients and driving change’, *Trends in Endocrinology and Metabolism*, 26 (3) (2015) pp. 114–117.

<sup>6</sup> S. Stoyanov, L. Hides, D. Kavanagh, O. Zelenko, D. Tjondronegoro and M. Mani, ‘Mobile App Rating Scale: A New Tool for Assessing the Quality of Health Mobile Apps’, *JMIR mHealth uHealth*, 3 (1) (2015) pp. [doi:10.2196/mhealth.3422](https://doi.org/10.2196/mhealth.3422); O. Franko and O. Tirrel, ‘Smartphone App Use Among Medical Providers in ACGME Training Programs’, *Journal of Medical Systems*, 36, (2011) pp. 3135–3139; F. Gravenhorst, A. Muaremi, J. Bardram, A. Grunerbl, O. Mayora, G. Wurzer, M. Frost, V. Osman, B. Arnrich, P. Lukowicz and G. Troster, ‘Mobile phones as medical devices in mental disorder treatment: an overview’, *Personal and Ubiquitous Computing*, [doi:10.1007/s00779-014-0829-5](https://doi.org/10.1007/s00779-014-0829-5), (2014).

## 2. Medical devices and the need for regulation

### 2.1. An expectation of protection

The idea that the products that we purchase and use in our day-to-day lives should be regulated in order to ensure that

<sup>7</sup> As Section 3 will discuss, these aspects are related to the official definition of what can constitute a medical device as found within the European Medical Device Framework.

<sup>8</sup> The US Federal Food and Drug Administration provides a wide range of examples on its website. See: <http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368744.htm>.

<sup>9</sup> In a 2014 green paper on mHealth the EU Commission estimated that there were already 100,000 apps available related to mHealth. See: European Commission. Green paper on mobile health (‘m-health’). Brussels, 10 April 2014. <https://ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth> (24 June 2015).

<sup>10</sup> D. Kramer, S. Xu and A. Kesselhiem, ‘Regulation of Medical Devices in the United States and European Union’, *New England Journal of Medicine*, 366 (9) (2012) pp. 848–855.

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