

## Regulation of Digital Health Technologies in the European Union

### *Intended versus Actual Use*<sup>\*</sup>

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The functionality of digital health technologies (DHTs), such as wearable devices and virtual assistants, is increasingly being used to make personal health and medical decisions. If manufacturers of DHTs are able to avoid regulation of their products as medical devices by marketing them as “lifestyle and well-being” devices, the potential harm caused to consumers who use DHTs beyond the manufacturer’s intended purpose will not be adequately addressed. This chapter argues the need for a framework to reclassify and regulate DHTs based on evidence of actual use.

This chapter focuses on how the classification rules and postmarket surveillance system provisions of the EU Medical Devices Regulation (MDR) need to anticipate and address the actual use of DHTs. To date, courts and regulators have not been consistent on the circumstances under which manufacturers are held responsible for known or encouraged “misuse” of their products. By defining a postmarket surveillance requirement for manufacturers of DHTs to acquire knowledge of the actual use of their products, informed regulatory decisions based on impact can be made. Actual use information can also help establish that the risk caused by a reasonably foreseeable misuse of DHTs was known to the manufacturer in a liability claim should consumers suffer harm from relying on statements or representations, made or implied, when using DHTs to self-manage their health. Moreover, if data generated by DHTs will be used to make regulatory decisions under the 2020 revision of the Good Clinical Practice, the MDR must proactively regulate technologies that have an actual impact on public health.

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## 8.1 INTRODUCTION

The functionality of digital health technologies (DHTs), such as wearable devices and virtual assistants, is being promoted as essential tools to empower people to take control and responsibility of their own health and wellness. Examples of wearable devices referred to in this chapter include devices that track health and fitness-related data such as heart rate, activity level, sleep cycles, caloric intake, and the like. An example of a virtual assistant includes Amazon Echo with its technology to analyze the user's voice to detect and determine "physical or emotional abnormality" and provide targeted content related to a particular medicine sold by a particular retailer to address the detected problem.<sup>1</sup>

There is significant literature on the potential benefits of DHTs in reducing costs and the burden on the health care system, for example, by providing patients with options to self-manage health from home.<sup>2</sup> DHTs are also attributed with the ability to help detect early warning signs of potentially serious health conditions, alerting users to irregularities, leading to investigations to detect illnesses that may otherwise have gone unnoticed with potentially tragic consequences.<sup>3</sup> While health care providers generally recognize DHTs as useful tools, there is also evidence that these very same technologies are increasingly being used by the public in a manner that potentially increases health care costs in the long run.<sup>4</sup> One study reported an increase in physician-"digitalchondriac" interaction where patients demand immediate attention from medical professionals based on troubling key health indicators detected by wearable devices, which may or may not be accurate.<sup>5</sup> On the other end of the spectrum, some patients elect to by-pass traditional health service structures and formalities and take medical and health decisions into their own hands at great risk to themselves instead of consulting a medical professional. Some doctors recount stories of patients taking prescription medication in response to an irregular reading from their wearable device without

<sup>1</sup> Issued US patent US10096319B1 entitled voice-based determination of physical and emotional characteristics of users, <https://patents.google.com/patent/US10096319B1/en>.

<sup>2</sup> See, e.g., Melinda Beeuwkes Buntin et al., The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results, 30 *Health Aff.* 464–71 (2011).

<sup>3</sup> See, e.g., Apple Watch Saves Man's Life after Warning Him of Heart Problems, *The Telegraph* (Jul. 16, 2019), [www.telegraph.co.uk/news/2019/07/16/apple-watch-saves-mans-life-warning-heart-problems/](http://www.telegraph.co.uk/news/2019/07/16/apple-watch-saves-mans-life-warning-heart-problems/); see also D.C. Ioannidis et al., Wearable Devices: Monitoring the Future?, *Oxford Med. Case Reps.* 492–4 (2019).

<sup>4</sup> See, e.g., Alex Matthews-King, Apple Watch and Fitbits Wrongly Sending Healthy People to Doctors Could Overwhelm NHS, Report Warns, *Independent*, [www.independent.co.uk/news/health/nhs-apple-watch-fitbits-ai-waiting-times-gp-misdiagnosis-a8749876.html](http://www.independent.co.uk/news/health/nhs-apple-watch-fitbits-ai-waiting-times-gp-misdiagnosis-a8749876.html); Artificial Intelligence in Healthcare, *Acad. Med. Royal Colls.*, [www.aomrc.org.uk/wp-content/uploads/2019/01/Artificial\\_intelligence\\_in\\_healthcare\\_0119.pdf](http://www.aomrc.org.uk/wp-content/uploads/2019/01/Artificial_intelligence_in_healthcare_0119.pdf).

<sup>5</sup> See, e.g., D. Lupton, The Digitally Engaged Patient: Self-monitoring and Self-Care in the Digital Health Era, 11 *Soc. Theory & Health* 256–70 (2013).

understanding or inquiring about the risk of taking a higher than recommended dosage of medication.<sup>6</sup>

DHTs have been setting off alarms for users to take note and control of their health, but there are also data and reports that suggest many of those alarms turn out to be false. As consumers increasingly engage in self-monitoring and self-care with the help of DHTs, health practitioners need to respond to patient confusion and anxiety created by data generated by DHTs.<sup>7</sup> Because the accuracy of DHTs can vary greatly with a margin of error as high as 25 percent across different devices,<sup>8</sup> health practitioners have the added burden of treating patients without medical training who nevertheless seek medical intervention for self-diagnosed illnesses derived from the internet by attributing symptoms detected by unreliable DHTs. The [next section](#) will examine the applicable regulatory framework in the European Union to better understand what oversight mechanisms are available to ensure the safety and efficacy of DHTs in view of evidence of how consumers actually use these devices to make personal health and medical decisions.

## 8.2 THE EU MEDICAL DEVICES REGULATION

Medical devices are recognized as essential to the health and wellbeing of European citizens and legislation is essential to ensure the safety and efficacy of medical devices for the protection of public health.<sup>9</sup> The new EU Medical Devices Regulation (MDR)<sup>10</sup> will come into force in May 2021, replacing the existing Medical Devices Directive (MDD).<sup>11</sup> The MDR attempts to modernize the MDD by introducing new concepts, definitions, and rules that may be applicable to DHTs. For example, the definition of a medical device in the MDR includes new qualifying language “prediction and prognosis of disease.”<sup>12</sup> In principle, this definition should capture the collection, monitoring, processing, and evaluation of physiological data associated with DHTs since they claim to be capable of potentially predicting or providing a prognosis of potential future disease identification from the data collected.

<sup>6</sup> See, e.g., K.J. Compton-Thweatt, Physicians or Facebook? The Effects of Do-It-Yourself Healthcare on Modern Society, *Integrated Studies* 171 (2018); A. Robeznieks, 4 Mistakes Your Patients Should Avoid With Wearables, AMA, [www.ama-assn.org/practice-management/digital/4-mistakes-your-patients-should-avoid-wearables](http://www.ama-assn.org/practice-management/digital/4-mistakes-your-patients-should-avoid-wearables).

<sup>7</sup> Lukasz Piwek et al., The Rise of Consumer Health Wearables: Promises and Barriers, 13 *PLoS Med.* (2016).

<sup>8</sup> M.A. Case et al., Accuracy of Smartphone Applications and Wearable Devices for Tracking Physical Activity Data, 313 *JAMA* 10–11 (2015).

<sup>9</sup> European Commission, New EU rules to ensure safety of medical devices, MEMO/17/848 (2017).

<sup>10</sup> Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, 2017 O.J. (L 117) 5,5 (EU).

<sup>11</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, 1993 O.J. (L 169) 12,7.

<sup>12</sup> Regulation 2017/745, *supra* note 10, at art. 2.

However, the MDR clearly states “software for general purposes, even when used in a health care setting, or software intended for lifestyle and well-being purposes is not considered a medical device.”<sup>13</sup> It is the intended purpose, as opposed to the technological features and capabilities of a device that determines whether a DHT will be regulated under the MDR. Intended purpose is defined as “the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.”<sup>14</sup> Because the regulatory framework can be challenging for many startups with limited resources, the ability to market the intended use of DHTs as health and wellness devices as opposed to a medical device that requires a higher degree of regulatory compliance is a pragmatic business decision, but at what potential cost to public health? Even for larger companies, Apple CEO Tim Cook stated that the regulatory process and degree of adherence required for the Apple Watch would prevent Apple from continuing to innovate and remain competitive in the medical product marketplace.<sup>15</sup>

In brief, the classification rules and procedures under the MDR are based on the potential risk a particular device poses to the user, having regard to the technical design and manufacture of the device.<sup>16</sup> Currently, a significant number of wearables are classified as Class I noninvasive devices.<sup>17</sup> However, under the MDR, the introduction of a more nuanced classification system and a more involved assessment procedure may increase the regulatory scrutiny of DHTs. For example, software intended to monitor physiological processes will be considered Class IIa, and software intended to monitor vital physiological parameters would be classified as Class IIb.<sup>18</sup> As the classification level increases, the applicable safety rules and conformity assessments also become stricter. However, the increased classification level applies only to “active devices intended for diagnosis and monitoring,” which again does not include DHTs that manufacturers self-declare as intended for “lifestyle and well-being purposes.”<sup>19</sup>

<sup>13</sup> *Id.* at p. 19.

<sup>14</sup> *Id.* at art. 2(12); see also Case C-329/16 *Syndicat national de l'industrie des technologies médicales (SNITEM), Philips France v. Premier ministre, Ministre des Affaires sociales et de la Santé Confédération paysanne and Others v. Premier ministre and Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt* [2017] ECLI:EU:C:2017:947; see also T. Minssen et al., *When Does Stand-Alone Software Qualify as a Medical Device in the European Union? – The CJEU's Decision in SNITEM and What It Implies for the Next Generation of Medical Devices*, 28 *Med. L. Rev.* 615–24 (2020).

<sup>15</sup> A. Heath, *Apple's Tim Cook Declares the End of the PC and Hints at New Medical Product*, *Telegraph*, [www.telegraph.co.uk/technology/2016/01/21/apples-tim-cook-declares-the-end-of-the-pc-and-hints-at-new-medi/](http://www.telegraph.co.uk/technology/2016/01/21/apples-tim-cook-declares-the-end-of-the-pc-and-hints-at-new-medi/).

<sup>16</sup> Regulation 2017/745, *supra* note 10, at p. 58, art. 51, Annex VIII.

<sup>17</sup> European Commission, DG for Communications Network, Content and Technology *Smart Wearables: Reflection and Orientation Paper* (2016).

<sup>18</sup> European Commission, *supra* note 9, at Annex VIII.

<sup>19</sup> *Id.*

While efforts continue to focus on what types of innovations fall into the definition of a medical device and within which classification level, this chapter focuses on how the public actually uses and interfaces with these products, regardless of the regulatory classification. There is increasing evidence to suggest that consumers use DHTs to help with medical care decision making despite the manufacturer's stated intent.<sup>20</sup> Although the MDR attempts to establish a contemporary legislative framework to ensure better protection of public health and safety, the point where DHTs "not intended for medical purposes" and the use of pharmaceuticals intersect, raises a myriad of legal, ethical, and policy implications. Pharmaceuticals, which are highly regulated, are reportedly being used by the public to make self-determined medication decisions based solely on information derived from DHTs,<sup>21</sup> which are not as well regulated under the MDR. Understandably, the regulatory framework should focus on technologies that pose the greatest risk to patients and their data security. However, as discussed in greater detail below, "misuse" of lower-risk devices beyond the manufacturer's intended use could raise significant public health risks not previously contemplated. Some DHTs proclaim medical benefits but disclaim that the device is intended for health and wellbeing purposes only.<sup>22</sup> If manufacturers of DHTs are able to avoid the higher regulatory burden associated with having their products classified as medical devices, the question is what legal framework exists to hold manufacturers responsible for known "misuse" of their products and whether consumer protection laws will provide adequate redress to the potential harm caused to consumers who nevertheless use DHTs beyond the manufacturer's stated purpose to make personal health and medical decisions.

Although the vast majority of DHTs pose a very low risk of harm to consumers, there is increasing evidence that many of these devices are not as accurate as described or fail to work at all.<sup>23</sup> Without an oversight mechanism to detect and respond to the health risk arising from the actual use of low-risk devices beyond the manufacturer's stated intended use means many consumers could be adversely affected throughout the lifecycle of the product without recourse. To bring medical devices onto the EU market, the CE approval process is required to verify that a device meets all the regulatory requirements under the MDR. However, for Class I devices, the manufacturer is responsible for self-certification for the CE marking process.<sup>24</sup> Policy proposals related to permitting lower-risk devices to be brought to

<sup>20</sup> S.S. Bhuyan et al., *Use of Mobile Health Applications for Health-Seeking Behavior Among US Adults*, 40 *J. Med. Sys.* 153 (2016); see also Sean Day & Megan Zweig, *Beyond Wellness for the Healthy: Digital Health Consumer Adoption 2018*, Rock Health, <https://rockhealth.com/insights/beyond-wellness-for-the-healthy-digital-health-consumer-adoption-2018/>.

<sup>21</sup> Compton-Thweatt, *supra* note 6.

<sup>22</sup> See, e.g., Casey Erdmier et al., *Wearable Device Implications in the Healthcare Industry*, 40 *J. Med. Eng'g & Tech.* 141–8 (2016).

<sup>23</sup> See, e.g., B. Bent, *Investigating Sources of Inaccuracy in Wearable Optical Heart Rate Sensors*, 3 *NPJ Digit. Med.* 1–9 (2020).

<sup>24</sup> Regulation 2017/745, *supra* note 10, at Annex VIII.

market more efficiently on the condition that postmarketing data on safety and effectiveness is collected as part of mandatory renewal or reevaluation process has previously been considered.<sup>25</sup> While postmarket safety and efficacy data may be used to assess whether a DHT continues to qualify for a low-risk classification level, it falls short of providing an evidence-based reason to reclassify a DHT based on the potential risk arising from how consumers actually use these devices, regardless of their safety and efficacy profile.

### 8.3 INTENDED VERSUS ACTUAL USE

While DHTs are intended to modify behavior to improve health and wellness, an unintended consequence of the functionalities of these devices is that consumers are increasingly using them to make personal health and medical decisions.<sup>26</sup> DHTs offer to collect and monitor physiological data that medical devices do and can be used in combination with apps to interpret such data to provide medical advice. The line between DHTs and medical devices therefore increasingly becomes blurred, particularly to the consumer, as new devices and new improvements of well-established wearables allow the monitoring and assessing of a range of medical risk factors.<sup>27</sup> According to a recent survey, 71 percent of physicians say they use digital health data to inform their own personal health decisions,<sup>28</sup> and another survey found that consumers are increasingly using wearables to make critical health care decisions instead of monitoring physical activity and lifestyle.<sup>29</sup>

However, the majority of manufacturers provide no empirical evidence to support the effectiveness of their products, in part, because the applicable regulation does not require them to do so.<sup>30</sup> Recent reports indicate an increase in incidents of wearables sending otherwise healthy people to doctors due to incorrect and inaccurate readings.<sup>31</sup> Meanwhile, popular consumer devices continue to insist that their product, unless otherwise specified, is not a medical device and should not be held

<sup>25</sup> M.B. Hamel et al., FDA Regulation of Mobile Health Technologies, *N. Eng. J. Med.*, 371, 372 (2014).

<sup>26</sup> Compton-Thweatt, *supra* note 6; see also J. Dunn et al., Wearables and the Medical Revolution. 15 *Personalized Med* 429–48 (2018).

<sup>27</sup> Piwek et al., *supra* note 7.

<sup>28</sup> Stanford Medicine 2020 Health Trends Report, <http://med.stanford.edu/content/dam/sm/school/documents/Health-Trends-Report/Stanford%20Medicine%20Health%20Trends%20Report%202020.pdf>.

<sup>29</sup> Day & Zweig, *supra* note 20.

<sup>30</sup> Case et al., *supra* note 8; see also Sara Chodosh, “FDA approved” Medical Devices Don’t Actually Have to Do What They Promise, *Popular Science*, [www.popsci.com/fda-approved-medical-devices/](http://www.popsci.com/fda-approved-medical-devices/).

<sup>31</sup> Matthews-King, *supra* note 4; see also Dora Allday & Stephen Matthews, Fitbits Are Putting a Strain On Doctors “Because the Exercise Trackers Are Incorrectly Telling Wearers They Are ILL,” *Daily Mail*, [www.dailymail.co.uk/health/article-6639305/Hypochondriacs-rely-data-Fitbits-piling-extra-pressure-NHS.html](http://www.dailymail.co.uk/health/article-6639305/Hypochondriacs-rely-data-Fitbits-piling-extra-pressure-NHS.html); Emily Clarkson, Is Your Fitness Tracker Helping or Hurting Your Health?, *The Manifest*, <https://themanifest.com/app-development/fitness-tracker-helping-hurting-health>.

to such a standard<sup>32</sup> despite marketing their devices as being able to “help improve wellness, disease management and prevention.”<sup>33</sup> Experts agree that wearable devices cannot be expected to give medical grade accuracy, nor should consumers demand such high scientific quality from DHTs. However, as users become increasingly more reliant on DHTs that may provide a false sense of security on one spectrum to misguided self-diagnosis on the other, the need for legal solutions and regulatory oversight has been called for to address issues of consumer harm and accountability.<sup>34</sup>

To avoid liability, manufacturers typically rely on disclaimers even though it is known that users tend to ignore such information.<sup>35</sup> Legal measures are available to address direct-to-consumer marketing practices relating to fraudulent or misleading advertising. For example, in the 2018 dispute against Fitbit’s Purepulse heart rate tracker for being grossly inaccurate, alleging false advertising, common law fraud, and breach of implied warranty among other claims, the court allowed the class action to proceed, stating that “[g]iven the magnitude of the aberrant heart rate readings and multiple allegations that the devices under-report heart rate, [plaintiff] has plausibly alleged an ‘unreasonable safety hazard’ that may arise when users rely on Fitbit heart rate readings during exercise.”<sup>36</sup> Similarly, the FDA also monitors medical product communications to make sure they are consistent with the product’s regulatory authorization.<sup>37</sup> However, the FDA has stated that it will only oversee “medical devices whose functionality could pose a risk to patient safety if the [device] were to not function as intended.”<sup>38</sup> More specifically, the FDA stated that it does not intend to regulate general wellness products.<sup>39</sup> In other words, if the manufacturer’s stated intention is for DHTs to be used for “life-style and well-being”

<sup>32</sup> See, e.g., Important Safety and Product Information, Fitbit, [www.fitbit.com/dk/legal/safety-instructions](http://www.fitbit.com/dk/legal/safety-instructions).

<sup>33</sup> See, e.g., Fitbit Launches Fitbit Care, A Powerful New Enterprise Health Platform for Wellness and Prevention and Disease Management, Fitbit, <https://investor.fitbit.com/press-releases/press-release-details/2018/Fitbit-Launches-Fitbit-Care-A-Powerful-New-Enterprise-Health-Platform-for-Wellness-and-Prevention-and-Disease-Management/default.aspx>.

<sup>34</sup> See, e.g., M. Schukat et al., Unintended Consequences of Wearable Sensor Use in Healthcare, 25 Y. B. Med. Informatics 73–86 (2016); see also A.B. Cohen & K. Safavi, The Oversell and Undersell of Digital Health, Health Aff. Blog 442, 443 (2019) and Jenny McGrath, Lack of Regulation Means Wearables Aren’t Held Accountable for Health Claims, Digit. Trends, [www.digitaltrends.com/wearables/wearable-devices-leading-to-over-diagnosis/](http://www.digitaltrends.com/wearables/wearable-devices-leading-to-over-diagnosis/).

<sup>35</sup> Akshay et al., Wearable Healthcare Technology – the Regulatory Perspective, 4 Int’l J. Drug Reg. Aff. 1–5 (2016).

<sup>36</sup> McLellan v. Fitbit, Inc., Case No. 16-cv-36, (N.D. Cal. 2018).

<sup>37</sup> US Food & Drug Admin., Medical Product Communications That Are Consistent with the FDA-Required Labeling – Questions and Answers Guidance for Industry (2018).

<sup>38</sup> See US Food and Drug Admin., Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff, [www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf).

<sup>39</sup> US Food and Drug Admin., General Wellness: Policy for Low Risk Devices, [www.fda.gov/media/90652/download](http://www.fda.gov/media/90652/download).

purposes, then any use by the public outside the intended use falls outside the scope of the FDA regulatory framework.

Courts and policy makers seem to support the consumer demand for reliability of DHTs.<sup>40</sup> However, courts have not always been consistent on the circumstances under which manufacturers are held responsible for known or encouraged “misuse” of their products.<sup>41</sup> Nor have they provided clear or predictable guidance on what constitutes reasonably foreseeable misuse that manufacturers should have known that their product is being used for a purpose for which it is not intended.<sup>42</sup> Because of the legal duty to anticipate and take precautions against unintended but reasonably foreseeable use of products, manufacturers have always been expected to be apprised of the potential “misuses” of their products. Generally, under the reasonable foreseeability standard, manufacturers can be held liable for injuries caused by a product even if the consumer fails to use the product as intended, but the consumer must show the actual use rendered the product defective, which was known or should have been known to the manufacturer.<sup>43</sup> In practice, it can be difficult to determine what unintended uses and what harms arising from such unintended uses are reasonably foreseeable, with some responsibility of prudence being placed on the consumer.<sup>44</sup> It would likely be difficult to establish legal liability under the consumer protection framework for harms arising from the known use of DHTs by consumers who rely on these devices to make medical and health decisions instead of using them for health and wellness purposes only.

There is an opportunity for the MDR to implement a reclassification framework based on evidence of actual use to provide better regulatory oversight, especially as the functionality of DHTs continues to expand their focus toward health care by detecting and measuring an increasing number of physiological parameters associated with health conditions. Manufacturers should not be able to circumvent and avoid higher regulatory burdens by being willfully blind to the increasing evidence of consumers who feel empowered by promotional statements or representations made or implied that they can use DHTs as a means to take control of and responsibility for their own health and wellness.<sup>45</sup> However, according to the Court of Justice of the European Union “[where] a product is not conceived by its manufacturer to be used for medical purposes, its certification as a medical device

<sup>40</sup> See European Commission, *Assessing the Impact of Digital Transformation of Health Services* (2018); see also World Health Org., *Draft global strategy on digital health 2020–4* (2019).

<sup>41</sup> See, e.g., E. Timmerman & B. Reid, *The Doctrine of Invited Misuse: A Societal Response to Marketing Promotion*, 4 *J. Macromarketing* 40–8 (1984).

<sup>42</sup> W.L. Trombetta & T.L. Wilson, *Foreseeability of Misuse and Abnormal Use of Products by the Consumer*, 39 *J. Marketing* 48–55 (1975).

<sup>43</sup> *Id.*

<sup>44</sup> *Infra note 45.*

<sup>45</sup> Clarkson, *supra note 31*; see also Brian Fung, *Is Your Fitbit Wrong? One Woman Argued Hers Was – and Almost Ended Up in a Legal No-Man’s Land*, *Washington Post*, [www.washingtonpost.com/technology/2018/08/02/is-your-fitbit-wrong-one-woman-argued-it-was-almost-ended-up-legal-no-mans-land/](http://www.washingtonpost.com/technology/2018/08/02/is-your-fitbit-wrong-one-woman-argued-it-was-almost-ended-up-legal-no-mans-land/).



cannot be required.”<sup>46</sup> In other words, how a device is actually used should have no bearing on how the device is regulated if the stated intention of the manufacturer is that the product is not a medical device. Nevertheless, the postmarket surveillance (PMS) requirement under the MDR may be used to require manufacturers to proactively understand how their products are being used by the public to better align regulatory purposes with public health objectives.

#### 8.4 POSTMARKET SURVEILLANCE (PMS) UNDER THE MDR

Under the MDR, the PMS system is a proactive procedure where manufacturers act in cooperation with other economic actors to collect, review, and report on experiences of devices on the market with the aim of identifying any need for corrective or preventative measures.<sup>47</sup> One of the new features of the MDR is the concept of a PMS plan that requires manufacturers to define the process of collecting, assessing, and investigating incidents and market-related experiences reported by health care professionals, patients, and users on events related to a medical device.<sup>48</sup> According to the MDR, the PMS plan “shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.”<sup>49</sup> Because of a growing demand to adopt a more proactive as opposed to the current passive reactive approach to PMS,<sup>50</sup> the implementation of the PMS plan under the MDR may be an avenue to address the concerns associated with the actual use of DHTs beyond the manufacturer’s stated intended use. The ability to identify risks and take corrective measures in a timely manner is vital for any regulatory framework. Clear guidance on the implementation of the PMS plan is essential to improve the delivery of health care to consumers through the help of DHTs.

Arguably, the PMS plan can be interpreted to include an obligation to collect postmarketing data on consumer use of DHTs as part of a mandatory reevaluation process to assess the appropriate classification level and regulatory compliance the DHT must adhere to in order to continue to remain on the market. By defining a PMS requirement for manufacturers of DHTs to acquire knowledge of actual use of their products in order to maintain their lower classification status, informed regulatory decisions based on data and evidence can be made. Actual use information can also help establish that the risk caused by a reasonably foreseeable misuse of

<sup>46</sup> Case C-219/11 *Brain Products GmbH v. Biosemi VOF and Others*.

<sup>47</sup> Regulation 2017/745, *supra* note 10, at art. 2(60).

<sup>48</sup> *Id.* at arts. 83–6, Annex III.

<sup>49</sup> *Id.* at § 1.1 of Annex III.

<sup>50</sup> See, e.g., Josep Pane et al., *Evaluating the Safety Profile of Non-active Implantable Medical Devices Compared with Medicines*, 40 *Drug Safety* 37, 37–47 (2017).

DHTs was known to the manufacturer in a liability claim should consumers suffer harm from relying on statements or representations, made or implied, when using DHTs to self-manage their health.

However, the MDR is not particularly clear on the extent of the PMS obligation, stating that the PMS plan should be “proportionate to the risk class and appropriate for the type of device.”<sup>51</sup> For Class I devices, a PMS report based on the PMS plan shall be “updated when necessary and made available to the competent authority upon request,”<sup>52</sup> and there is no clarification of how often information should be collected. The elements and type of information that shall be collected for the PMS plan include adverse events, data on nonserious incidents and undesirable side effects, safety updates, trend reporting, relevant specialist or technical literature, and feedback and complaints from users.<sup>53</sup> Although information about actual use is not specifically mentioned, it may be captured under trend reporting, which is intended to include incidents “that could have a significant impact on the benefit analysis . . . which may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.”<sup>54</sup> The reclassification of devices is contemplated for reasons of public health based on new scientific evidence or based on information that becomes available in the course of vigilance and market surveillance.<sup>55</sup> Evidence of actual use collected as part of the PMS plan can therefore be used as grounds for reclassification to anticipate and address the actual use of DHTs. However, even with the ability to reclassify, the classification rules and definition of noninvasive versus active devices based on intended use renders this process a vicious cycle. Furthermore, the reclassification of devices based on PMS requires a request to the commission by a Member State and consultation with the Medical Device Coordination Group,<sup>56</sup> making the process bureaucratically cumbersome and unlikely to be used in practice. Without clearer implementation guidelines and a better alignment of the PMS objectives with the classification rules, the PMS plan could become a toothless oversight mechanism.

PMS allows for continuous vigilance, not only to ensure quality, safety, and efficacy of the devices but to ensure the appropriate level of regulatory adherence based on how a device is actually being used. With the rapid proliferation and advancement of DHTs, it will require a collaborative effort between manufacturers, regulators, health care providers, and consumers to strike the right balance between the appropriate regulatory burden and the benefit that DHTs promise to bring to the public health system. DHTs could prove to be a good secondary diagnostic tool with

<sup>51</sup> Regulation 2017/745, *supra* note 10, at art. 83(1).

<sup>52</sup> *Id.* at art. 85.

<sup>53</sup> *Id.* at Annex III.

<sup>54</sup> *Id.* at art. 88.

<sup>55</sup> *Id.* at art. 51(3).

<sup>56</sup> *Id.* at art. 51.

its ability to constantly monitor and collect data and provide detailed longitudinal data to monitor progress and understand patterns.<sup>57</sup> A deeper understanding of patients through their health data is one of the keys to improving health, especially in managing chronic conditions that are primarily driven by leading an unhealthy lifestyle.<sup>58</sup> As the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use continues to consider revisions to the Good Clinical Practice (GCP) to enable the use of real-world evidence, such as patient data derived from or influenced by consumer use of DHTs, reliable oversight and regulation of DHTs become even more pressing to ensure the data are reliable and appropriately collected and interpreted to serve as evidence for informing future regulatory decisions. The underlying presumption that data derived from DHTs can be transformed into meaningful real-world evidence to be used for the intent contemplated by the GCP is that the data is reliable and that there is a relationship between the use of the DHT and the clinical relevance of the data.<sup>59</sup> A PMS system that is aligned with the classification rules to adapt regulatory oversight of DHTs based on actual use and actual impact on consumer health will better support the use of real-world evidence or data derived from DHTs for the purposes of the GCP. The interpretation of the PMS plan to include a proactive requirement on manufacturers to self-report and be informed of not only the safety and efficacy of their products but also how their products are being used will help users and regulators make more informed decisions. This requirement also aligns with the EU responsible research and innovation policy objectives to ensure the innovation process is interactive, transparent, and responsive to public interests and concerns.<sup>60</sup> The PMS plan may be resource intensive; however, innovation will still be encouraged by allowing manufacturers to continue to benefit from easier access to the market without imposing a higher regulatory burden at the outset. Furthermore, the collection of actual use information may constitute know-how that can be used to facilitate follow-on innovation and ultimately increase competition. A risk-based regulatory framework that promotes innovation, protects patient safety, and avoids overregulation of DHTs can be achieved if the clear objectives and a robust structure are defined for the PMS system.

## 8.5 CONCLUSION

With the introduction of the PMS plan in the MDR, industry, regulators, health care professionals, and consumers have the opportunity to work together to define

<sup>57</sup> Piwek et al., *supra* note 7.

<sup>58</sup> Dinesh Puppala, Regulatory Standpoint: Wearables and Healthcare, Hopkins Biotech Network, <https://hopkinsbio.org/biotechnology/regulatory-standpoint-wearables-healthcare/>.

<sup>59</sup> Determining Real-World Data's Fitness for Use and the Role of Reliability, Duke-Margolis Center for Health Policy.

<sup>60</sup> H. Yu, Redefining Responsible Research and Innovation for the Advancement of Biobanking and Biomedical Research, 3 *J. L. & Biosciences* 611–35 (2016).

oversight parameters and mechanisms to realize the potential of DHTs as a health care tool. If consumer DHTs are being advertised as providing medical grade results<sup>61</sup> and therefore being used by consumers as a medical device, the MDR needs to provide adaptive mechanisms to respond to how DHTs are actually used. Leveraging the PMS plan to require manufacturers to proactively monitor, collect, and report on the actual use of DHTs by consumers in order to continue to qualify for classification and regulation as a lower-risk device will convey accountability and provide an evidence-based oversight mechanism within the MDR to garner public trust. Interpreting the PMS plan to require manufacturers to report on how their products are actually used as part of a mandatory reevaluation process to continually assess the classification of the device, regardless of the device's safety and efficacy profile, will ensure greater consumer protection. To achieve this, the MDR must provide clearer implementation guidelines that better align PMS obligations with the classification rules applicable to DHTs. As advocated by some medical professionals, if medical decisions will be made from information generated by DHTs, then such DHTs will require proportionate regulatory oversight.<sup>62</sup>

<sup>61</sup> See, e.g., KardiaMobile, which advertises to be “the most clinically-validated personal EKG in the world. Now a medical-grade EKG can become part of your daily routine. Enjoy peace of mind,” [www.alivecor.com/kardiamobile](http://www.alivecor.com/kardiamobile). Kardia is FDA cleared. See <https://alivecor.zendesk.com/hc/en-us/articles/115015799808-Is-Kardia-FDA-cleared-and-CE-marked>.

<sup>62</sup> Kenneth R. Foster & John Torous, The Opportunity and Obstacles for Smartwatches and Wearable Sensors, 10 *IEEE Pulse* 22, 22–5 (2019).