Wearables in Taiwan: A New Regulatory Category?

by Po-Hsiang OU & Skye LIU

The market and possibilities for wearables continue to grow. Combining multiple technologies and applications, wearable devices have been revolutionizing our interactions with computers and changing the way we manage our bodies, health, and wellbeing. While wearables have been clearly creating a new category of consumer electronics, does the growth of this technology also need to trigger a special regulatory response, hence a "new regulatory category"?

In Taiwan, the question can be answered in the negative: no specific regulations for the time being. Regulatory uncertainties, however, remain as wearable technologies develop and move beyond simple fitness trackers. Eiger has previously analyzed the regulatory landscape of wearables in China. In this article, we will focus on developments in Taiwan, in particular two specific regulatory regimes: medical devices and data protection.

Wearables as medical devices?

Although wearables come into contact with our bodies and facilitate our wellness, they do not provide "treatment" and should not generally be defined as medical devices. The U.S. Food and Drug Administration (FDA), for example, has sought to draw a regulatory line between wearables and other medical devices that would be subject to premarket and postmarket regulatory controls under the U.S. Food, Drug, and Cosmetics Act (FD&C Act). According to a draft guidance published by the FDA[1], devices that are "intended for only general wellness use" and present "a very low risk to users' safety" would not be regulated by the FD&C Act. A "general wellness" product must be intended for the promotion of health or a healthy lifestyle (such as physical fitness or stress management), but

[1] FDA, "General Wellness: Policy for Low Risk Devices", Draft Guidance for Industry and Food and Drug Administration Staff. http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf

not for treatment or diagnosis (such as treating obesity or anxiety). The draft guidance also provides a negative list for defining whether a device is "low risk", such as being non-invasive and not using high-risk technologies that require device controls (e.g. the use of lasers, radiation or implants). In short, the draft guidance focuses on the *intention* of the device design and the *risk* of the device.

According to the previous stance of the Taiwan Food and Drug Administration (TFDA), it could be reasonable to consider that the Taiwan agency would take a similar regulatory approach. The boundary between "wellness" and "treatment/diagnosis", however, is not crystal clear. This will especially be the case as wearable technologies continue to develop and gradually enter into the area of preventive healthcare. The TFDA has not yet officially responded to the issue of wearables, but it has declared on various occasions that any product meeting the definition of medical devices under the Pharmaceutical Affairs Act (PAA) must comply with the Act's regulatory requirements. Products intended to diagnose diseases, monitor health conditions, or treat any kind of disorder would possibly fall into the definition of medical devices and would require premarket approval, including business licenses, quality standard inspections and product registration.

Some new wearable devices are indeed challenging the boundary between wellness and diagnosis/treatment. Neurofeedback wearables, for example, use electroencephalography (EEG) sensors that were previously only available in medical settings to analyze brain activities and to improve mental wellness. Although the risks of these wearables would generally be low, some studies suggest they should still be covered by medical device regulations[2]. Other wearables that transfer, store, or display data generated by medical devices could be defined as Medical Device Data Systems (MDDS) - such devices have been categorized as medical devices both in Taiwan and the U.S. While the U.S. FDA has issued a guidance loosening the regulatory control of MDDS[3], it remains unclear whether TFDA will follow this approach. In Taiwan, if a wearable is intended to collect, analyze, or communicate medical level data, it might still be categorized as a medical device and be subject to relevant controls. When in doubt, a business can make a formal inquiry to the TFDA to clarify the potential classification and relevant regulatory controls of a product.

In addition to the regulation of medical devices, wearables might also trigger a regulatory response in relation to Taiwan's privacy laws. Wearables promote a lifestyle that involves more intensive self-monitoring and tracking. While the use of wearables can improve the wellness of consumers, it also generates, collects, and analyzes a huge amount of personal data and thus raises concerns about privacy.

[2] Maslen et al., "The regulation of cognitive enhancement devices: extending the medical model" at Journal of Law and the Biosciences. http://jlb.oxfordjournals.org/content/1/1/68.full

[3] FDA MDDS Guidance: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm401996.pdf

Wearables and privacy

Taiwan's Personal Information Protection Act (PIPA), which came into force in October 2012, provides a structure for regulating the collection, processing, and use of personal data by government and non-government entities and individuals. The section in PIPA covering "sensitive personal information" - the type of which might be collected, processed, and/or used by wearables - did not, however, originally come into force with the rest of PIPA, only coming into force in an amended form in March 2016.

PIPA defines personal information or data as the name, date of birth, identification number, passport number, characteristics, fingerprints, marital status, family, education, occupation, medical records, medical treatment, genetic information, sexual life, health examinations, criminal records, contact information, financial conditions, social activities and other information *which may be used to identify a natural person, both directly and indirectly*. PIPA also identifies certain types of "sensitive personal information" that should not be collected, processed, or used subject to certain exceptions. This "sensitive personal information" would be information related to medical treatments, medical records, genetic information, sexual life, health examination details, and criminal records. (The Enforcement Rules of PIPA further define medical records, medical treatments, genetic information, sexual life, health examinations, and criminal records.)

Wearables could and most likely would be collecting, processing, and using personal information - information which may be used to identify a natural person, both directly and indirectly. Such devices and the companies offering them would then need to ensure PIPA compliance on notice, consent, collection, processing, and use. It would appear that such personal information most likely would not currently meet the definitions under the Enforcement Rules of PIPA for the various types of defined, sensitive personal information.

The takeaway for the manufacturers of wearables as well as those offering related software and applications would be that PIPA does not prevent the collection, processing, and use of personal information but it does provide requirements that must be met and restrictions that must be complied with. Viewed in this light, Taiwan's existing regulatory regime appears to offer a degree of certainty for the island's medical technology manufacturers. As wearables expand their functions to include a greater array of health-related data collection and monitoring, these firms can rest assured knowing that their efforts to capture this vast market should not be inhibited by unexpected acts of legislation. Given the importance of the technology sector to Taiwan's economy, a light touch on the part of the authorities will likely be the approach for the foreseeable future. It should be noted that the National Communications Commission can also assert jurisdiction over certain classes of wearables if they fall under the telecommunications regime, both for PIPA compliance and telecommunications compliance.

Summary

Wearables will continue to develop as a unique category of consumer lifestyle electronics while allowing consumers greater access to realtime information about themselves. This presents a great opportunity to create a healthy public without explicit and often expensive interventions from public health authorities while also presenting a number of possible challenges. As wearables become more a part of day-to-day life then so will concerns over how best to regulate them as well as to protect information being collected, processed, and used. Taiwan for the time being will allow wearables to navigate and ensure compliance with existing legislative and regulatory regimes.

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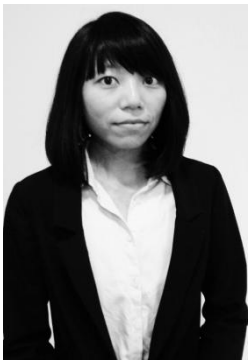

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