Wearables and healthcare: regulatory strategies

‘Wearables” (smart wristbands, watches, rings and patches) are measuring aspects of users’ lives ever more accurately and subtly. They can collect millions of data points a day about a wearer’s health.

The market for these products cuts across both the consumer and medical device sectors. Some products are intended for the ‘wellness’ market and not for use in a clinical setting. Others are regulated as medical devices for use in a clinical setting and so subject to a greater regulatory burden.

Whether or not products are intended to perform a medical function, manufacturers and suppliers of wearables should assess how best to place their products on the market, whilst avoiding regulatory and liability risks.

This infographic sets out some tips to consider, covering regulatory issues affecting software, the use of wearables in decentralised clinical trials, advertising and approaches to mitigating the risk of personal injury litigation.

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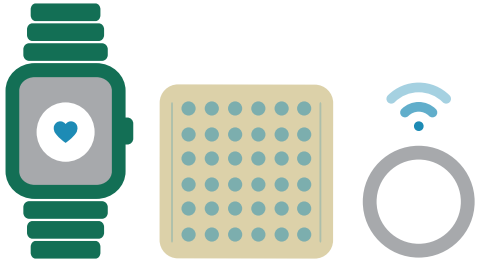

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Why is it important?

The wearables market has its origins in the fit tech industry but as the software has become more sophisticated, the application of these devices has expanded. Whilst new opportunities abound for developers to produce ever more exciting technology for both the wellness and medical markets, manufacturers may face challenges when moving from consumer products into the much more tightly regulated medical device sector. Manufacturers need to determine whether or not a product is regulated as a medical device.

What's the risk?

- Manufacturers need to get it right when determining how a product is to be regulated: is the wearable a consumer product or a medical device?
- Regulators may investigate a wearable that performs a clinical function but has been placed incorrectly on the market as a consumer product.
- A breach of regulations can lead to penalties, including fines or custodial sentences, as well as adverse publicity. There can also be a financial cost to addressing compliance issues reactively instead of proactively as part of a product's development.

Mitigation strategy

- Keep in mind that regulations and guidance from regulators will change over time as the law catches up with the market. A product that was not classified as a medical device when first launched could become subject to medical regulations in future. This is particularly relevant to software, where regulators have issued detailed guidance to help manufacturers determine if their products are regulated as medical devices.
- Remember that later iterations of a product could be caught by medical device regulations, even if earlier models were not. As a product becomes more sophisticated it may enable a user to gather increasingly critical data on their health and act on it. This increases the risk that a product will be deemed to be a medical device.
- Weigh up the pros and cons of positioning a wearable as a consumer product or a medical device. Whilst medical devices are subject to a greater regulatory burden, in some cases there could be a commercial advantage in demonstrating to the public that a product has undergone greater scrutiny before being placed on the market to address particular health concerns.

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Why is it important?

Traditionally, clinical trials take place at a trial centre, where participants are monitored on site and the performance of the medical product is documented. There is a high level of interaction between trial clinicians and the participants. There would be no need to recruit technologically skilled participants as they would not require training on using devices.

However, some elements of a clinical trial can instead be decentralised. Wearable devices play an important role in making this possible via collecting health information from the patient in their home, for review by clinicians. Depending on the type of trial, the patient themselves may also need to interpret data generated by the wearable device.

What's the risk?

- Patients do not have 24/7 access to clinical staff. This means that there is limited human oversight of patients. Patients may therefore not receive medical attention as quickly as needed in the event of side effects. This creates a risk that patients may suffer an avoidable injury or worsening of their condition.
- Patients are not specialists in generating and collecting data. The point of a clinical trial is to obtain data on the product's efficacy but the process of collecting the data could be prejudiced by unsophisticated trial participants.
- Whilst regulators have issued guidance, there are no steadfast regulations determining how decentralised clinical trials should be run. Therefore, added care is needed to set up and operate the trial in case of concern raised by regulators or trial participants.

Mitigation strategy

- Stress-test the equipment and processes used for data generation and collection. There should be a plan to address potential weaknesses or failures of equipment. Trial participants and service providers should be trained in how to use digital tools to ensure proper data collection.
- Anticipate what safety concerns, and adverse events, may arise during the trial and set out actions for how they will be notified to clinicians or patients and where immediate medical attention may be needed.
- Assess whether a decentralised clinical trial is appropriate or whether a traditional, hospital based trial is preferable. This assessment should take into account factors such as the risk profile of the participants, the benefits of gathering data in a home setting, ensuring commitment to the trial from participants over the long term and the reliability of the data collected. Consideration should also be given to whether the amount of data collected will have an impact on the capacity of investigators to fulfil their responsibilities.

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Why is it important?

The ability for members of the public to track and act on their own health data has put an end to the old paternalistic approach where people relied exclusively on a medical professional for their care. Manufacturers have ever increasing opportunities to meet the public's demand for products that make access to health data a part of everyday life. In responding to demand, care should be taken when promoting wearables, for both the consumer and healthcare markets.

In the UK, advertising is generally governed by the UK's independent advertising regulator, the Advertising Standards Authority (ASA). The ASA enforces codes relating to non-broadcast ads and promotions, including claims made on websites (the CAP Code) and broadcast ads on TV and radio (the BCAP Code). Specific chapters of the Codes relate to advertising medical devices (as well as other healthcare products and services, including medicines). In the event of persistent non-compliance, the ASA may refer advertisers to Trading Standards, or the Competition and Markets Authority may decide to investigate. Furthermore, where ads for wearables could be seen to be making medical claims for unlicensed products, the UK's healthcare regulator, the Medicines and Healthcare products Regulatory Agency (the MHRA), may get involved.

What's the risk?

- A manufacturer or supplier of wearable health-related devices could fall foul of the CAP Code or BCAP Code in any number of ways, including by exaggerating a product's capabilities where the claims cannot be substantiated by suitable documentary evidence, discouraging essential treatment for medical conditions or acting irresponsibly towards consumers.
- Breaches of the CAP Codes or BCAP Code may lead to adverse adjudications by the ASA which publicly "name and shame" non-compliant advertisers. In some cases, these adjudications are picked up by the press, leading to reputational damage.
- For repeat offenders, Trading Standards and/or the Competition and Markets Authority may take action under laws which prohibit misleading actions, omissions or aggressive commercial practices. The maximum penalties are unlimited fines and up to two years' imprisonment.
- It can be a fine line between making a wellness-related claim and a medical claim, with the latter being reserved for medicines and devices that are appropriately licensed, for instance by the MHRA in the UK. Phrases such as "cure", "restore", "prevent", "avoid", "fight" or "heal" are likely to be considered as medical claims.

Mitigation strategy

- Avoid misleading consumers, including in descriptions of features and the outcomes that can be achieved by a product; for example, regarding the potential for diagnosing a clinical condition or the impact of a product on a user's health.
- Guard against making suggestions that a consumer should self-diagnose minor ailments or avoid seeking professional help.
- Ensure that advertising and promotions are in keeping with the intended purpose of a product's CE or UKCA mark. This will help to ensure that advertising avoids misleading the public by promoting the product in line with the clinical data supporting statements about its performance.

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Why is it important?

Wearables create a shift in the balance of responsibility between clinicians, patients and consumers. Individuals can now obtain ever increasing amounts of data about their health. This increases the risk of regulatory investigations or litigation by members of the public alleging that reliance on the products caused them to suffer an injury.

What's the risk?

- A lack of robust testing of a product. Manufacturers may struggle to defend themselves from personal injury litigation if they cannot refer to testing demonstrating the product's efficacy and how the development process took into account an assessment of the risks of injury and how best to mitigate them.
- Positioning products for use by an unrealistically broad a section of the public. Wearable products that are designed for use by a generic "person" may not necessarily be effective for all demographics. This may not become apparent until the products have been on the market and used by large numbers of people.
- Inflating consumer expectations to unrealistic levels. Where a manufacturer makes claims that cannot be supported by the product's actual performance, consumers are more likely to consider litigation if their expectations are not met.

Mitigation strategy

- Consider the limits of a product's performance and reflect that assessment in the literature, packaging and advertising that accompanies a product.
- Accompany products with appropriate warnings, such as that the wearable is not a substitute for seeking clinical advice or that there are limits to what can be done with the data gathered by the wearable.
- Ensure that data have been collected and robustly tested that supports claims made about the performance of the product. Armed with this data, manufacturers will be able to address concerns from regulators or consumers regarding the pre-market assessment of a product's performance and safety. Such data can also support countering any negative PR.

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