

How is new innovation giving a much-needed boost to women's health and wellness?

The women's health and wellness industry has expanded exponentially over the last few years and it is expected that by 2027 it will be a \$65B industry. Driving this growth are innovative companies focused on developing technology specifically aimed at addressing women's health and wellbeing across a broad range of areas, including reproductive, sexual and mental health.

These companies are often aimed at bridging the gender gap in women's healthcare, resulting from, among other things, the underrepresentation of women in clinical trials and research and the design of healthcare systems .

While the issues presented by the gender gap are not new, they have become a focal point as a result of the intersection of a number of economic, demographic and market factors. There has been an increase in demand for products and services from women who are looking for optionality in their healthcare and demanding alternatives. This has coupled with a commercial awareness of both the size of the market, which includes more than half of the

global population, and the purchasing power of that market, with women directing 83% of all consumption in the United States.

As a result of this growing awareness and demand, venture capital investment has increased and in August 2021, following a \$110M series D funding round, Maven has become the first women's health startup to reach a valuation of over \$1M. Women's healthcare is also increasingly a focus of government attention; in 2021, the UK Department of Health and Social Care announced its intention to develop a new women's health strategy, requesting input from women to help create a set of priorities to put women back at the centre of their own health and wellbeing.

This shift in focus has intersected with a changing healthcare landscape increasingly concentrated on personalisation and digital healthcare solutions, exemplified by the growth and development of wearable technologies and the establishment of departments such as NHSX in 2019, with a remit to lead a digital and social care transformation of Britain's National Health Service.

This progression towards digital has been accelerated by the COVID-19 pandemic, which necessitated a move towards remote healthcare that could be provided through web-based applications, such as Zoom and FaceTime, during national lockdowns. The expansion of digital services has fuelled the growth of women's healthcare platforms and applications, which are often focused on the provision of remote healthcare, such as Peppy Health, which offers women immediate remote access to expert practitioners specialising in areas like fertility and menopause.

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One of the critical factors to consider in the continued expansion of the women's health and wellness industry is the legal and regulatory framework in which these technologies are being developed. There is no separate regulatory regime for female-focused technology and these developments therefore fall within regulatory frameworks applicable to remote access healthcare and medical technology more generally.

This raises the question of whether the existing legal and regulatory environment is able to achieve the right balance between ensuring that women receive products and services that are safe and fit for purpose, while also

eliminating unnecessary or disproportionate obstacles to continued innovation in an underserved space.

In the United States, the growth of remote access healthcare has faced regulatory obstacles resulting from restrictive and conflicting state laws in crucial areas. These restrictions have temporarily been waived as a result of the COVID-19 pandemic and the declaration of a public health emergency (“PHE”) in the United States beginning on 31 January 2020. The PHE declaration has been extended until 16 April 2022.

By law, PHEs are declared in 90-day increments and can be extended as many times as deemed necessary by the U.S. Department of Health & Human Services Secretary. This waiver has increased access to remote healthcare, which can now readily be provided to new and existing patients via third party applications, and has incentivised health care professionals participating in Medicare who are able to be reimbursed for remote services at the same rate as in-person visits.

Alongside state-wide relaxations, this has resulted in an increase in remote health utilisation in the United States to levels 38 times higher than before the pandemic. This has paved the way for female-focused companies in the remote healthcare space to continue to grow and broaden their audience. While the PHE is a temporary measure and it is unclear if more permanent relaxations of existing regulation will be put in place, it is evident that developments in this area will impact continued innovation and access in the women’s healthcare industry.

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Innovation in Great Britain faces different legal challenges as a result of regulations that do not clearly reflect the new application-based digital environment. For example, the Medicines and Healthcare products Regulatory Agency regulates technologies which are classified as a “medical device”, a term that is broad enough to cover web-based applications.

The regulatory framework maintains a distinction between regulated devices or software that is intended to provide a diagnosis, control conception and/or which is used to administer medication and unregulated applications intended

to monitor health and wellbeing or provide general advice.

However, new female-focused technologies may test the validity of these distinctions; for example, it is unclear whether an application that tracks a person's basal body temperature and is intended to facilitate conception will be subject to existing regulation as a medical device.

The above examples indicate some of the potential pitfalls in existing legal and regulatory regimes and how these interact with the development of technology centred on women's healthcare solutions. A continued focus by lawmakers and regulators on women's health strategies in connection with increased collaboration with innovators and investors will ensure that the potential of this nascent industry is maximised in the years to come.

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