

techUK Position Statement: Consumer Wearable Health Technology

Executive Summary

Consumer wearables, including smartwatches, rings and other sensors that people typically choose and own themselves, track signals such as heart rate, blood pressure, sleep and movement. They offer a significant opportunity to detect chronic disease earlier and help people live independently for longer. In line with the Government's ambitions on prevention and neighbourhood health, they can help shift care from hospital to home, supporting NHS, community and social care services to work together around the person. Realising that opportunity depends on data that health and care professionals can trust and act on, that is: filtered, integrated into existing systems and linked to a clear next step, rather than adding to the workload of an already stretched workforce.

Many consumer wearables combine general fitness and lifestyle features with features that can inform health and care. This statement focuses on the second group: those that can help detect, monitor or manage a health condition. It sets out the common ground reached through a series of techUK engagements with the wearables community on how they should be regulated, evidenced and adopted. It makes four asks: an accreditation route within the regulatory reform led by the MHRA, a clear route into the NHS and social care, baseline clinical data standards, and a dedicated conversation on funding.

The Opportunity

Wearables are now widely used, often bought for fitness and lifestyle reasons, and their features can flag conditions that often go unnoticed, such as atrial fibrillation¹, sometimes even before a person notices a problem. For people with long-term conditions such as diabetes, they can also support management between appointments. Continuous monitoring can spot meaningful change as it happens, rather than in a single clinical snapshot, supporting the shift from hospital to community and from sickness to prevention at the heart of the 10 Year Health Plan, which aims to make wearables standard in preventative, chronic and post-acute NHS treatment by 2035.² It can also help social care and community teams notice gradual change, such as declining mobility, to support falls prevention and independent living. The ambition is not to replace clinical devices or treatment decisions, but to strengthen prevention and remote monitoring so that clinical teams can focus their time where it is needed.

The NHS and the DHSC have shown real enthusiasm for this potential, and industry wants to work with them to match this fast-moving market with a clear plan for delivery. That means clearer routes for pilot and validation studies, clear ownership of wearables policy across NHS and DHSC teams, and a consistent path from evidence to adoption across the NHS and local government.

Our Position

Wearables need a voluntary accreditation route of their own, sitting between wellness products and medical devices. Under current UK rules, consumer wearable features that monitor general fitness or wellbeing are not usually classed as medical devices and so sit outside medical-device regulation,³ even though some features in the same devices, such as

ECG, are already regulated as medical devices. This produces inconsistent outcomes in practice: near-identical features can end up classified differently depending on a manufacturer's stated intended use, and divergence between UK and EU routes to market adds further uncertainty. A proportionate, purpose-built accreditation route would let useful monitoring and screening features reach people faster while still being held to real, published accuracy and reliability standards. It would also bring more devices into a genuinely trusted category than today's choice between full certification or no regulation at all allows. For many manufacturers, taking a device through full medical-device certification simply is not proportionate to its overall risk profile, yet the device would meet a dedicated accreditation bar suited to its intended use. This is not about lowering the bar, it is about designing regulation that is proportionate to the actual risk involved. Accreditation would stay voluntary, incentivised by recognition in regulation and procurement.

The MHRA's draft Medical Devices (Amendment) Regulations 2026, published in May 2026,⁴ aim for proportionate requirements and include accelerated routes for devices already approved in Australia, Canada and the USA. techUK sees these reforms as the right vehicle for a wearables route, rather than asking Government to build a separate system.

Regulation should build trust. Any accreditation route should be governed by real, published accuracy and reliability criteria, developed jointly by industry, the MHRA, NICE and recognised standards bodies, so that clinicians and other health and care professionals, including community and social care teams, have a reliable, agreed way to judge whether a device's readings can be trusted. But even fully validated data is of little use if it cannot be worked into a clinical workflow: for example, a GP cannot realistically review a thousand blood pressure readings in a ten-minute appointment, so wearable data needs to be pre-processed and integrated directly into the clinical systems health and care teams already use, such as GP clinical systems and electronic patient records, rather than delivered as a raw, unfiltered stream. It also needs to be actionable rather than simply flagged: an alert is only useful if the data behind it points to a clear next step in the person's pathway, rather than adding an unresolved signal to a clinician's workload.

Evidence should be built around specific conditions and care pathways, not broad wellbeing claims, and matched by adoption. The strongest evidence, and the kind that will ultimately support commissioning, comes from testing wearables against a clearly defined condition and care pathway, such as atrial fibrillation detection, sleep apnoea screening, hypertension monitoring or falls prevention in older adults. At present, evidence and adoption are waiting on each other: manufacturers are wary of investing in evidence without confidence that the NHS and local authorities will adopt their products, and commissioners are reluctant to commit before the evidence exists. A staged approach would break the cycle, showing first that a device is accurate, then that it performs in real-world use, then that it benefits the people using them, and drawing on NICE's existing real-world evidence framework⁵ rather than creating a new one.

Data should stay in the person's control. People should decide if, when and with whom their wearable data is shared. It should reach health and care services through a clear, person-facing integration point, not a patchwork of device-specific platforms. The NHS App may be part of that picture, but should sit alongside, not replace, established condition-specific platforms that already work well within their pathways. Handling should reflect purpose: for direct care, data must be identifiable so the right professional can act on it, shared with the person's knowledge and control; for research and population planning, it should be de-identified to protect privacy while retaining enough detail to stay useful.

techUK's Policy Asks

techUK is calling on stakeholders to:

Ask 1: Secure a defined, wearables-specific accreditation route within the MHRA's ongoing regulatory reform, sitting between wellness and full medical-device regulation.

As the MHRA takes forward its 2026 draft regulations,⁴ it should work with industry to set specific, published criteria for wearable features within them, rather than capturing them incidentally or leaving them to a later exercise.

Within this, the MHRA should create a bespoke "trusted wearables" accreditation route, developed jointly as set out above and owned by regulators and standards bodies rather than the NHS alone. It could work as follows:

- Criteria are scoped condition by condition, for example atrial fibrillation detection, sleep apnoea screening or fall-risk monitoring in older adults, and include evidence that devices perform reliably across the people who will use them.
- The route builds on existing conformity assessment, international standards and manufacturers' existing evidence, accepting it where it meets the published criteria, so nothing is tested twice.
- Where equivalent evidence does not exist, manufacturers run a validation study against the published criteria and submit the results to a review committee.
- Review costs are kept proportionate, so the route stays open to smaller manufacturers.
- Devices that meet the criteria are recognised by the MHRA, and in NHS and local government procurement, as suitable for health and care use, without the multi-year process for full medical devices.

Ask 2: Give wearables a clear route into the NHS and social care, starting with practical near-term steps.

This is how the 10 Year Health Plan's commitment to make wearables standard in NHS treatment by 2035 can be delivered.² In the near term, DHSC and NHS England, working with local government, should name a clear, published owner of wearables policy, so manufacturers know who to approach rather than navigating informal channels. Wearables should also be explicitly recognised within existing NHS and National Institute for Health and Care Research (NIHR) innovation funding, such as NIHR's Invention for Innovation programme,⁶ rather than requiring a new mechanism. They should also:

- publish a clear route for manufacturers to propose pilot and validation studies to Trusts, integrated care boards and local authorities, built on existing programmes;
- publish practical guidance on how a consumer wearable pilot concludes, so manufacturers and Trusts know what happens once initial engagement ends;
- clarify who holds clinical responsibility, and for which decisions, when wearable data and alerts cross organisational boundaries; and
- ensure that accredited devices are not asked to repeat safety and effectiveness assessment in NHS and local government procurement, and that the route aligns with the Digital Technology Assessment Criteria (DTAC),⁷ which cover the software elements of devices, so evidence is not requested twice.

Ask 3: Mandate baseline clinical data standards for any wearable data that becomes part of a person's formal health and care record, while keeping wider interoperability voluntary and person-directed.

Whenever wearable data enters a person's formal health and care record, whether or not the device has been accredited, DHSC and NHS England should require it to be mapped to a recognised clinical coding standard, and to relevant medicines and medical device data, so it can be safely interpreted alongside the rest of that record. The trigger is the data entering the record, not the setting in which the wearable is used. They should also make clear who is responsible for that mapping, whether the manufacturer, a platform provider or the organisation bringing the data into the record, rather than leaving it to be negotiated system by system.

Beyond this coding requirement, wider interoperability and data sharing should remain voluntary. Over time, people should be able to choose to share their wearable data with the NHS through one clear route, rather than a separate connection for each device. Setting clear national expectations for standard data formats now would let manufacturers build once, instead of rebuilding for every system.

Ask 4: Open a dedicated conversation on how wearables could be funded.

Industry has no single agreed view on the right funding or reimbursement model for wearables, and this statement does not prescribe one. A structured conversation between Government, NHS England, local government, NICE and industry is needed to work through the options once a pathway's clinical and economic case is established, recognising that costs and benefits fall across NHS and social care budgets.

Get Involved

techUK members working in consumer wearables and adjacent digital health fields are welcome to contribute to this work. To get involved, or for more information, please contact the techUK Health & Social Care programme team.

References

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