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Health self-testing kit crackdown: Tougher regulations set to remove harmful products from the UK high street following *BMJ* studies

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Tougher oversight of popular health self-testing kits sold on the high street, including a clampdown on "misleading or unsubstantiated claims" is being planned by the UK's medicines and devices regulator.

It follows research and a major investigation published in *The BMJ*,[1 2] which found that many high street health tests-including for serious diseases like cancer-are unsafe for patients.

This work also found that most self-test manufacturers either refused or ignored requests to provide reports of the studies supporting their claims.

Self-testing has become increasingly popular, with a growing range of tests available directly to consumers without the need for medical involvement. The UK self-test market is projected to generate £660m in revenue by 2030.

Many health tests are sold in major retailers such as Tesco and Superdrug at prices ranging from £1.89 to £39.99.

But the ease with which manufacturers get these products on the shelves in the UK could soon change.

The Medicines and Healthcare Products Regulatory Agency (MHRA) has published new draft regulatory requirements for medical devices and in vitro diagnostic devices entering the UK market.[3]

The changes will make it illegal to mislead patients over the tests "purpose, safety, or performance."

This includes "suggesting the device has a function or property which it does not have or which cannot be established from available evidence," and "failing to inform of any risk associated" with the device.

Proposed regulation covers the labelling, packaging, and any marketing related to the device and suggests that manufacturers will be required to share the evidence behind their marketing claims.

Self-tests will also attract a higher risk classification-meaning those tests that could lead to a critical diagnosis, such as HIV or cancer, will have more stringent evidence requirements to meet before they can be marketed.

Jon Deeks, professor of biostatistics at the University of Birmingham and corresponding author of *The BMJ* studies, welcomed the plan.

"Now there is an opportunity for consumers and consumer organisations to challenge misleading clinical claims-whilst manufacturers will still not legally need to share reports of their clinical studies, they will be challenged if they do not," he said.

"There is no reason for manufacturers not to share the evidence backing up claims on day one."

Clare Davenport, clinical associate professor at the University of Birmingham and coauthor of the studies, added that, although the proposals were a "springboard" for action, the real test will be in the implementation.

"It is good news from a regulatory perspective, but how it is translated will be key," she said.

"The draft says patients must not be misled over the 'intended purpose of the test.' What is meant by 'intended purpose'? What information would help the consumer decide whether the test is for them?

"Will a PSA [prostate specific antigen] test labelled as a 'prostate health' test rather than as a 'prostate cancer' test be regulated in different ways?"

An MHRA spokesperson said that the authority took concerns about the self-test market seriously and that the regulations were designed to "elevate" the standard of self-tests.

This included measures "for intended purpose statements to be objective, harmonised classification rules, greater quality requirements, preventing misleading or unsubstantiated claims, standards for labelling requirements and instructions for use, unique device identifiers, mandatory data requirements for registration that will be publicly searchable and electronic instructions for use."

Research published in *The BMJ* last year by researchers at the University of Birmingham reviewed 30 self-tests sold within a short radius of the campus.[1]

The tests assessed 20 biomarkers for 19 different conditions, but many failed to provide consumers with basic information such as who should take the test, how results should be interpreted and what action to take afterwards.

At the point of purchase, test packages also failed to show who should be using them and how to interpret results.

More than half the tests were found to go against current evidence based guidance: for example, the NHS states that PSA screening should be done only after discussing the complexity of the meaning of the test result-and not simply bought and used as a simple test.[4]

Responding to the changes, Bernie Croal, president of the Royal College of Pathologists, told *The BMJ* that it was too early to tell what effect the changes might have.

"As a profession, we are still deeply concerned about the unregulated expansion of direct-to-consumer testing," he said.

"There is potential to make good testing available to the public, but it needs to be done safely.

"There is awareness of the money to be made in this field, and the market is exploding. It impacts us because the public picks up the test, goes to the GP, and even phones laboratories to ask what this means.

"For the patient, it leads to stress, anxiety, and in some cases unnecessary referrals to secondary care."

Other changes in the MHRA proposals

- Give swifter access to the UK market to medical devices already approved by regulators in Australia, Canada, and the US
- Require healthcare organisations that implant medical devices to give patients implant cards that provide information about the device that was implanted, improving ability to manage adverse events and transparency for patients
- Make unique device identifiers compulsory to enable precise identification and traceability of devices throughout their lifecycle.

A consultation on the MHRA's proposed changes is running until 19 June 2026. https://www.gov.uk/government/calls-for-evidence/pre-market-medical-devices-regulation-stakeholder-impact-survey

1 Davenport C, Richter A, Hillier B, etal. Direct-to-consumer self-tests sold in the UK in 2023: cross sectional review of information on intended use, instructions for use, and post-test decision making. *BMJ* 2025;390:e085546. pmid: 40701637. doi: 10.1136/bmj-2025-085546

2 Coombes R, Boytchev H, Iacobucci G. How safe are health tests on UK supermarket shelves? *BMJ* 2025;390:. pmid: 40701650. doi: 10.1136/bmj.r1503

3 Medicines and Healthcare products Regulatory Agency. MHRA invites views on proposed changes to medical device regulation. 11 May 2026. https://www.gov.uk/government/news/mhra-invites-views-on-proposed-changes-to-medical-device-regulation

4 Watson J, McCartney M. The pitfalls of diagnostic self-tests. *BMJ* 2025;390:. pmid: 40701648. doi: 10.1136/bmj.r1476