

Private COVID-19 Testing Validation Consultation

DHSC

**Chartered Trading Standards Institute
Response**

May 2021

About The Chartered Trading Standards Institute

The Chartered Trading Standards Institute (CTSI) is the professional membership association for trading standards in the UK. Founded in 1881, we represent the interests of trading standards officers and their colleagues working in the UK.

At CTSI and through the trading standards profession we aim to promote good trading practices and to protect consumers. We strive to foster a strong vibrant economy by safeguarding the health, safety and wellbeing of citizens through empowering consumers, encouraging honest business, and targeting rogue practices.

We provide information, guidance and evidence based policy advice to support local and national stakeholders including central and devolved governments.

Following a Government reorganisation of the consumer landscape, CTSI are responsible for business advice and education in the area of trading standards and consumer protection legislation. To this end, we have developed the [Business Companion website](#) to deliver clear guidance to businesses on how to meet their legal and regulatory obligations.

CTSI are also responsible for the [Consumer Codes Approval Scheme](#) which facilitates high principles of assisted self regulation through strict codes of trading practice. This ensures consumers can have confidence when they buy from members of an approved scheme and also raises the standards of trading of all businesses that operate under the relevant sector's approved code.

CTSI is also a key member of the [Consumer Protection Partnership](#), set up by central government to bring about better coordination, intelligence sharing and identification of future consumer issues within the consumer protection arena.

We run training and development events for both the trading standards profession and a growing number of external organisations. We also provide accredited courses on regulations and enforcement.

A key concern for CTSI is diminishing resources. UK local authority trading standards services enforce over 250 pieces of legislation in a wide variety of areas vital to UK consumers, businesses and the economy. Since 2009 trading standards services have suffered an average reduction of 46% in their budgets and staff numbers have fallen by 53% in that same period.

This response is submitted by The Chartered Trading Standards Institute (CTSI) with input from CTSI Lead Officer in Fair Trading, Sylvia Rook. Should you have any queries or wish to discuss the response please do not hesitate to contact Laura Kane, CTSI Policy Executive laurak@tsi.org.uk.

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Consultation Purpose

Overarching policy objective

The consultation sets out that a key part of the government's approach to managing COVID-19 in the long term is to facilitate and empower a thriving private sector market for COVID-19 detection tests to supplement and support NHS testing. This will support the safeguarding of public health in the long term. The government is keen to create and grow a private testing market where businesses and members of the public can trust and use the private tests they procure safely. The 2 key objectives are:

- to ensure tests' performance (sensitivity and specificity) can be relied upon by NHS Test and Trace and test users, to facilitate a robust private market
- to grow the size of the private sector market, so a greater range of tests are available to individuals and organisations.

These objectives support the government's overarching objective of safeguarding public health.

The problem the government is aiming to solve

Consumers need to know that COVID-19 tests they buy are of satisfactory quality. This requires tests with sensitivity that is high enough to apply in 'real world' settings that provide accurate results and avoid spreading the virus.

Excluding self-test kits, there is currently no legal requirement available for independent validation of COVID-19 tests performance. Entry to the market is controlled by CE marking which is currently a self-declaration process for the performance of this type of test kit or equipment. This means performance is not independently verified ahead of sale.

CTSI Response

General Observations

CTSI welcome the opportunity to respond to this consultation on behalf of Trading Standards. We wish to note that there appears to be a separate consultation by DHSC on enforcing persistent breaches of minimum standards by testing laboratories. We understood that it was initially DHSC's view that this should be enforced by Trading Standards, but it later transpired that the powers were given only to district and unitary councils. This meant that enforcement could not be carried out by Trading Standards.

We consider that there is potential for substantial confusion on these issues and it would be beneficial if DHSC could ensure that communications on both the tests and testing are communicated together with clarity as to where the powers for each lie. We would also be grateful to receive notification of any consultation relevant to Trading Standards as we were made aware of this consultation by a third party and as such our time to compile a response was limited. Our consultation response is limited to the questions around enforcement. Please find these questions and answers set out below.

Relevant Questions and CTSI Responses

Do you agree or disagree that the range of enforcement powers set out above is appropriate and proportionate as a first line response for breaches of regulation that may arise?

We agree that these appear to be a good range of sanctions, however, these are not “enforcement powers” as mentioned in the question. We would consider it imperative that the powers for enforcement officers are made clear.

We would point to the enforcement strategy used by Trading Standards (TS) with regard to unsafe products which could be used as a reference here. TS use a Product Safety Database (PSD) operated by the Office of Product Safety and Standards (OPSS). Whilst these tests are medical products, and TS will liaise with the MHRA, it would be useful if the PSD could be used for intelligence/enforcement purposes. This would aid in preventing duplicitous enforcement by TS and other authorities. We would envisage that the PSD could be helpful to matters related to product recalls also.

We note that the Medicines and Medical Devices Regulations are considered to be Safety Regulations for the purposes of enforcement, and this should also be made clear in this legislation.

We also note that the monetary penalties (fixed penalty notices) are considered to be a ‘debt to the Secretary of State’. We are unsure of the practicalities of this provision and seek clarification on how this would work for the enforcement officers.

Do you suggest any other additional powers are required to investigate suspected offences?

Trading Standards Officers would require all of the powers afforded to officers under Schedule 5 of the Consumer Rights Act 2015 (which superseded the majority of powers in the Consumer Protection Act 1987 under which the Medical Devices Regulations 2002 are made). These include:

- Powers in relation to the production of information
- Power to purchase products
- Power to observe carrying on of business etc
- Power to enter premises without warrant
- Power to inspect products etc
- Power to test equipment
- Power to require the production of documents
- Power to seize and detain goods
- Power to seize documents required as evidence
- Power to break open container etc
- Power to enter premises with warrant
- Entry to premises under warrant
- Power to require assistance from person on premises

We would like to emphasise that without these powers, we envisage enforcement to be extremely difficult.

Do you agree or disagree that MHRA and local authority Trading Standards are the correct enforcement authorities?

Yes, we agree and MHRA is the most appropriate agency with expertise in the regulation of medical devices.

We also agree that TS would be an appropriate enforcement authority as long as TS are properly equipped with the appropriate powers via Local Weights & Measures Authorities. This would ensure that TS departments at all tiers in local government can carry out enforcement.

Do you agree or disagree that the failure to comply with the enforcement notices should be a criminal offence?

Yes, we agree, as if it were not a criminal offence, this may dilute the strength of the enforcement notice. Enforcement notices are tools TS use to engage with businesses to get them to take timely actions or provide a comprehensive response. TS would then consider this information alongside their respective Enforcement Policy and determine what action may be needed to protect the public/consumers from unsafe and/or non-effective medical devices.

It would also be helpful if the failure to comply with a fixed penalty notice were also a criminal offence, to encourage immediate payment, as opposed to just being a civil debt.