BIVDA
British In Vitro Diagnostics Association

CDTA Policy Consultation

CTDA.policy@ukhsa.gov.uk

18th October 2022

Dear Colleagues,

Please find herein, BIVDA's response to the Open consultation for Coronavirus Test Device Approvals (CTDA): call for evidence, published 6 September 2022.

BIVDA is the national industry association for the manufacturers and distributors of in vitro diagnostics (IVD) products in the UK. Representing over 97% of the industry, BIVDA has built an extensive network of relationships across Government, the NHS, public bodies and sister organisations to ensure the IVD sector remains at the forefront of the life science agenda.

Our 230+ members benefit from leading industry expertise, working parties and regulatory support to ensure member companies thrive no matter their size. BIVDA members remain a key asset to the UK economy and the growing HealthTech space – employing over 10,000 people in the UK, with a total industry turnover of approximately £1.4bn.

We are grateful to be given the opportunity to comment on such an important legislative review, and BIVDA would like to reiterate that we are available to assist in future activity and dialogue into the changing regulatory landscape for IVDs in the UK. BIVDA remain at the disposal of CDTA should you require any clarification in relation to our consultation response.

BIVDA would also like to take this opportunity to reinforce the importance of well-structured and clear legislation for regulation of medical devices in the UK.

Yours sincerely,

Helen Dent

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Introductory questions

1. Are you responding on behalf of an individual or an organisation?

An organisation.

BIVDA represents approximately 230 organisations within the IVD industry including start-up companies, SMEs, UK developers and manufacturers as well as subsidiaries of the global IVD corporations. This is approximately 97% of IVD companies operating in the UK. We also represent some distributors and other economic operators. Our response is submitted on behalf of this membership and reflects the general views of companies within the IVD sector.

2. What is the name of your organisation?

The British In Vitro Diagnostic Association (BIVDA).

3. In which country is your headquarters based?

UK.

4. On what date was your organisation established?

February 1992.

5. If your organisation is part of a group of companies, what is the name and location of the parent organisation?

NA.

6. If UK-based, select the nation or region your organisation is based in:

- Scotland
- Wales
- Northern Ireland

- North East of England
- North West of England
- Yorkshire and the Humber
- East Midlands
- West Midlands
- East of England
- **London**
- South East of England
- South West of England
- other (please state)

7. What is the nature of your organisation?

- manufacturer
- retailer
- distributor
- **trade association**
- other (please state)

8. Does your organisation manufacture COVID-19 detection tests? (If yes, specify the type of tests.)

No, but BIVDA represents around 90 organisations who manufacture products for COVID-19 detection.

9. Does your organisation distribute or sell COVID-19 detection tests? (If yes, specify if your organisation sells directly to the patient – for example, high street retailer.)

No, but BIVDA represents around 90 organisations who distribute or sell products for COVID-19 detection to both the NHS, private laboratories and direct to the consumer.

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10. Does your organisation currently sell COVID-19 detection tests on the UK market?

No, but BIVDA represents around 90 organisations who currently sell products for COVID-19 detection on the UK market.

11. Have you applied, or are you currently applying to have a test approved?

No, but every member company of BIVDA who sells, or manufactures COVID-19 detection tests have applied, or are currently applying to have a test approved.

12. Does your organisation manufacture or distribute other diagnostic tests (not COVID-19 detection tests)? (If yes, please specify.)

No, but around 75% of BIVDA's member companies manufacture and distribute other diagnostic tests. This covers almost all IVD tests on the market, as our membership is representative of approximately 97% of IVD organisations present on the UK market. The remaining 25% include regulatory or other ancillary industry companies like contract manufacturers and tooling providers.

13. If yes to the above questions, in which country are your tests manufactured? Have you manufactured elsewhere in the past?

BIVDA member companies manufacture across the globe with around 10 member companies manufacturing in the UK.

14. Is the production/sale/distribution of COVID-19 tests your main area of business? If not, what is?

No, BIVDA is a Trade Association representing companies producing, selling or distributing all IVD tests to the NHS and private UK market including those providing Covid-19 detection.

15. How many employees are in your organisation?

- 0 to 4
- **5 to 9**
- 10 to 19
- 20 to 49
- 50 to 99
- 100 to 249
- 250 or above

16. Can we contact you with follow-up questions?

Yes.

17. If you're happy to be contacted, what is your email address?

doris-ann@bivda.org.uk *(CEO)*

helen@bivda.org.uk *(COO)*

ashleigh@bivda.org.uk *(Regulatory Affairs Manager)*

18. Can we cite you directly in publications such as the evaluation or statutory review?

Yes.

Call for evidence questions

Below are several detailed questions to help guide your responses and highlight the evidence we are most interested in receiving.

The answers to these questions will more closely align with our analytical needs and the specific policy issues where we want to build our underlying understanding.

You do not need to answer all questions, but please answer questions which are relevant to you as fully as possible.

Any commercially sensitive data you use to support your responses will only be used for the purposes of understanding your experiences of CTDA and help us to effectively review this policy area.

1. Impacts on business of CTDA

We invite manufacturers, suppliers, and retailers of COVID-19 tests to respond to the questions within this section. If you are not directly involved and are instead providing an estimate from an expert or academic perspective, please indicate this in your answer.

It is important that we understand as much as possible about the impact the legislation introducing mandatory validation for COVID-19 detection tests has had on cost or benefit to business so we can build upon its benefits while addressing the challenges it has raised.

1 (A) Profits

We want to collect detailed evidence of the gross profit margins over time of those involved in the supply of COVID-19 tests.

1. Please outline supported by evidence any changes in gross profit margins per device since July 2021, or since your application(s) for your test device(s) was submitted. Please explain what elements you are including in the cost of sales (for example, fixed costs, research and development spending, branding).

NA.

2. Please explain what elements you are including in the cost of sales (for example, fixed costs, research and development spending, branding).

NA.

1 (B) Costs

We want to collect detailed evidence of the costs involved in complying with the CTDA process and in supplying COVID-19 tests.

1. Please outline, supported by evidence, the total costs of applying for the CTDA process. Please show both the itemised cost and staff hours spent. Please identify the number of applications you have made and the outcome of each. Please include in your answer what activities you are including in the costs.

NA.

2. What is the average per unit production cost for COVID-19 tests?

NA.

3. What is the investment that companies make in meeting new regulations on average?

The investment is dependent on a number of variables but is almost certainly over £50,000. CPI, along with CDP and Innovate UK recently released grant funding for organisations who needed additional support with regulatory costs. This was up to a maximum of £30,000 per organisation. The grant was completely oversubscribed, and companies have reported this not fully covering the regulatory costs experienced. This would increase for organisations with more than one offering for the detection of Covid-19.

It is also important to note that due to the demand, the cost of regulatory professionals are now exceeding that of general medical devices for the first time in relation to salary and consultancy rates.

1 (C) Investment

We are interested in finding out how much it costs manufacturers to make improvements to their products, how often they revise tests and the associated costs in doing so.

1. Can you estimate how much it would cost, on average, to modify a COVID-19 detection test? Please support your answer with evidence.

NA.

2. Who would typically bear the cost of a reinvestment (for example, manufacturers in reduced profits or through cost cutting, equity holders in reduced dividends or further investment, or customers in prices)?

Ultimately, reinvestment would likely be felt within healthcare institutions themselves due to increased pricing.

3. How much would you estimate that it costs to bring a new product to market? Please outline:
   a. financial cost
   b. amount of time taken to bring a product to market

a. *Not quantifiable as a generic cost would have so many variables dependent of format of the product – few tests are performed without automation and for products sold as test kits for open systems this would require a lot of validation for each instrument system. Also dependent on risk class of the product under development.*
b. *At least 2 years.*

4. What are your investment plans for COVID-19 diagnostic devices?

The majority of manufacturers are now moving away from COVID-19 diagnostic devices as the supply demand has decreased. Instead, manufacturers are investing in utilising this technology for other indications.

1 (D) Future business planning

We invite manufacturers, suppliers, and retailers of COVID-19 tests to respond to the questions within this section.

Given the uncertain situation surrounding COVID-19, we are interested in understanding how businesses in the market for private COVID-19 testing devices and services are currently planning for the future.

1. Please set out your future business planning assumptions; what opportunities, dependencies or risks you may have identified and what horizon period you are planning.

Manufacturers are investing in utilising this technology for other indications. Manufacturers are considering whether the UK remains an attractive place to do business over markets in the rest of the world. The UK market is less than 3% of global IVD sales.

2. How is the uncertainty of future pandemics impacting your business planning decisions?

For example, external variables such as the potential for the emergence of new variants (or, if you are not a business, how do you predict these will impact these decisions?)

Companies will be cautious in investing heavily to address a pandemic response due to the experiences and significant costs that are not re-couped quickly, if at all. Some of our member companies have gone into liquidation due to the length of time it has taken to gain access to the market and secure procurement of their products.

1 (E) Product life cycle

We are interested in your assessment of your products' life cycles to gauge how often businesses must redevelop or update products to meet changing requirements.

1. What is the average life cycle for your product or products or a COVID-19 diagnostic device?

NA.

1 (F) COVID-19 epidemiology

COVID-19 is still an active public health issue and, as a result, we are interested in your thoughts on COVID-19 epidemiology and how you expect this will affect your business and the wider COVID-19 diagnostics market.

1. How do you expect new variants to impact the UK COVID-19 diagnostic market over the next 12 months?

New variants are expected to continue to appear but may potentially be identified later due to the reduction in the volume of testing.

2. What planning to replace or alter existing diagnostics devices do you conduct or think is appropriate for a manufacturer to conduct to ensure diagnostics remain effective at detecting new variants?

Organisations are continuing to analyse samples to identify new variants as quickly as possible and test their product to ensure it remains appropriate.

3. Are you expecting to withdraw any tests from the market due to new variants?

The costs of the CTDA process and the length of time taken to approve significant changes to incorporate potential new variants is likely to result in some companies not updating their products from the original formulation.

2. Analysis of the wider market

In this section, we are seeking evidence regarding the wider market.

This will enable us to set the evidence of the experience of individual players in the broader context. It will also provide evidence of consumer experience. It will help us develop analysis of the likely shape of the market going forward and in turn analyse the best type of regulation to protect consumers going forward.

2 (A) Interaction with universal free testing

To meet the public health risk of the pandemic the UK provided free tests to all citizens on request.

We recognise that the universal testing offer (UTO) was a major intervention in the market and it distorted demand and supply of tests into the market. We are keen to understand the impact this had on consumers, retailers, suppliers, and manufacturers.

1. Please describe how the UTO affected your business. What changes did the ending of the UTO have on your business?

The government buying COVID-19 tests universally distorted the UK market significantly by only procuring for an extended period of time, the first mover products and the products that were given EUA derogation. Whilst the processes and activities elsewhere in the market for validation and framework contracts and dynamic purchasing systems were introducing competition and access to market in theory, the repeated direct awards and extended contracts resulting from Article 32 (Public Contracts Regulations) awards during the early period of the pandemic meant that the majority of suppliers had no access to this programme, and the procurements were disproportionately made to a very small number of companies. During the UTO, products were in a higher demand and therefore higher supply. This resulted in increased revenue for any suppliers who were supplying into the UTO and the testing at hospitals did also increase revenues for suppliers who were not providing into the UTO.

However, for those companies whose routine testing in hospitals and community had reduced significantly, those revenues are still recovering. Now that these tests are associated with a cost and are no longer mandatory, revenue has decreased substantially for Covid-19 detection.

The communication from government to industry was unclear throughout the introduction of the regulation, as whilst it appeared that the suppliers were providing products for evaluation, there were elements of the validation that resembled parts of a procurement process, and this could be viewed as distorting the market through a theoretically scientific process. There was insufficient reassurance or adjustment to the process when this became apparent, therefore giving a small number of suppliers significant competitive advantage due to the process and approvals being

updated ad-hoc. Not allowing suppliers who had not submitted for national procurement to "catch up" in terms of validation requirements in advance of approvals has meant that these suppliers lost their customers and revenue to suppliers who had a head start in a particular format.

Because of the national procurements undertaken at the outset of the pandemic, the specifications and requirements for the CTDA regulation were structured in a way that suited the suppliers of the early awards through Test and Trace. This introduced a rigid and inflexible data structure for assessors to use to assess data provided by applicants which was not in the same format as products assessed previously.

By introducing a protocol, this further benefitted certain suppliers at the expense of others who had already benefitted under the UTO. Commercially it allowed those suppliers to gain additional supply contracts and usage as the CTDA process cut off supply routes in a disproportionate manner for the majority of suppliers who did not apply or get awarded for the national UTO procurements. This was despite following explicit early guidance from government to the effect that suppliers who did not wish to supply via Test and Trace would be able to continue to supply to the NHS providing they met the regulatory requirements, which of course at this time was under the UK Medical Device Regulations (2002) and therefore the associated regulatory data and market requirements.

Adjusting a defined and mature regulatory requirement in a mature IVD market in only 3-6 months showed significant misunderstanding of the nature of IVD manufacturing and regulatory requirements, including their ability to meet different and disproportionate criteria compared to other international regimes which was derived from a specific and bespoke experience of particular favoured suppliers of the UK through the roll out of the UTO.

BIVDA has commissioned an independent report provisionally titled "Diagnostics Procurement in the COVID-19 Pandemic: Lessons Learned and Recommendations for the Future" by Dr. Luke Butler (Public Procurement Research Group, University of Nottingham) which will be available in the future to UKHSA. Certain preliminary findings from that report (in progress) have been included in, or otherwise informed, part of this consultation response.

2 (B) Understanding the market

We invite stakeholders involved in the manufacture, distribution or retail of COVID-19 or other diagnostic tests, academics, and experts in the diagnostics industry to respond to the questions within this section.

We are interested in understanding more about the size, structure, and investment within the COVID-19 diagnostics market. Please support your answer with evidence.

1. The size, volume and value of the COVID-19 test market.

The UK Covid-19 test market was non-existent at the end of 2019.

The BIVDA Market Audit captured revenues from participant companies of £217m for Coronavirus testing in 2020, of which £83m were from PCR reagents, £23m from antigen and antibody laboratory

tests and £106m from Rapid tests (i.e. Lateral Flow Tests, or LFTs). In addition, an increase of £14.5m was spent on transport media, which was due to purchases of swab kits for PCR testing.

The BIVDA Market Audit captures an estimated 95% of total UK IVD market revenues, including all major suppliers into the NHS. Correcting for the additional 5% gives an estimate for total Coronavirus testing revenues of £244m in 2021. This figure does not include direct government purchases e.g. from Innova for LFTs for home testing reported in the press to be worth £2.8bn.

In 2021 these figures were £146m for PCR reagents, £171m for LFTs, £17m for laboratory antigen/antibody tests and £15.7m for transport media, totalling £266m, or using the 95% correction factor an estimated £280m on all forms of Coronavirus testing. Again, this does not include direct government contracts for LFTs for home testing.

The 12 months to the end of June 2022 (the most recent Market Audit period) saw revenues for PCR reagents reach £146m, Rapid Tests £171m and laboratory antigen and antibody tests £17m. Transport media declined to £3.5m giving a total of £337.5m or estimate of £355m using the 95% factor.

The pandemic provided a shocking challenge to market supply, both to rapidly develop, validate and ramp up manufacturing volumes for Covid-19 tests, but also to adjust volumes for other tests which were required to help monitor and differentiate clinical conditions of patients (e.g. clotting tests) and to shut down many elective tests which laboratories suddenly stopped performing during lockdown. Individual companies had very different experiences according to their business focus and specialities.

	2020	*2021*	*July 21– June 22*
PCR	*£83m*	*£146m*	*£140m*
LFT	*£106m*	*£171m*	*£154m*
Laboratory	*£23m*	*£17m*	*£14m*
Swabs	*£14.5m*	*£15.7m*	*£0.75m*
TOTAL	*£227m*	*£350m*	*£308*
Estimate for 100% of the market	*£238m*	*£368m*	*£325m*

Table: UK market revenues for Coronavirus test supplies and consumables

BIVDA do not collect information on unit pricing or volumes of tests, as this would transgress European Competition Law. As an order of magnitude estimate, using a price per PCR reagents at £8 and per LFT at £3, there were 17m PCR tests in 2021 and 50m LFTs.

2. What the supply chains look like and consist of.

Manufacturers in various global regions, economic operators (including importers and distributors), and UK Responsible Persons where the manufacturer is not UK-based.

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2 (C) Market predictions

To understand the mindset many companies operating in the UK diagnostic devices market will be acting under, we are interested in collecting economic predictions for the next 2 years. This will enable us to understand the thinking behind business decisions in this sector.

1. Please set out, with evidence, the levels of growth you expect to see in the diagnostic devices markets in the UK and internationally, particularly for COVID-19 devices.

The diagnostic industry has been growing rapidly for a number of years, even before the pandemic. It is a field that is constantly driving new growth and is likely to continue to progress as new innovative tests are identified and produced. Additionally, we expect that increasingly tests will be needed to allow drug prescription and to monitor efficacy of treatment.

The BIVDA Market Audit summary report for 2019 showed the total UK IVD market had undergone a compound annual growth rate (CAGR) of 5.4% in the previous 13 years. This growth was variable between technologies, with high-volume routine chemistry testing becoming cheaper in real terms due to development of increasingly efficient automated systems, hence revenue growth was small despite significant volume increases. These growth rates were reflected in other developed countries, as evidenced in the Global Diagnostic Market Survey reports produced by MedTech Europe, with a greater reduction and recovery from 2011 outside of the UK. Overall, the UK spends approximately half to two thirds per capita on IVDs compared with Germany, France, Italy, Belgium and Spain, despite having caught up a little in the last decade.

If the Coronavirus pandemic fades into insignificance, and there is no new emergency of such a size, the IVD industry will probably return to previous growth rates with the new constraint of economic austerity that seems likely to be coming perhaps reducing revenue growth to a few percent. Innovations will have an impact, but it will be a bold political decision to significantly increase expenditure even where benefits to the health economy may be realised.

2. Do you expect there to be similar levels of demand for testing in the private market if another pandemic (other than COVID-19) were to emerge?

Yes.

This depends on the nature of the infective agent – Coronavirus is detectable by PCR before it is symptomatic, so transmission can be limited by testing contacts, and isolation measures taken. The initial infectivity and pathogenicity of Covid-19 meant that lives could be saved, and the health service kept from being overwhelmed only by rapid deployment of testing and isolation.

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Consumer behaviour

The key issue in the early COVID-19 diagnostic devices market was the information asymmetry between sellers and consumers. The information provided was often not reflective of actual performance, confusing and not comparable with other products. Policy objectives included addressing this issue, protecting test users from poor quality tests and improving consumer confidence.

We are interested in your experiences of changing consumer behaviour and how CTDA has informed and affected this. We would like to collect evidence regarding how consumers reacted to the pandemic in terms of purchasing COVID-19 diagnostic tests or testing services, and the extent to which the CTDA market intervention have impacted the consumer experience.

1. If you have procured or purchased tests for your organisation, did you use the CTDA register to inform your decision?

No; we did not use the CTDA register to inform our decision, but our provider is on the register.

2. Are there any improvements to the register you can suggest?

Transparency of who is progressing through the process. Changes to products not having to go through new applications at extra costs, more than just an excel spreadsheet.

The process of approvals onto the register significantly improved from the introduction to present, however a fail-fast methodology with an FOC resubmission would be better for the process flow rather than attempting to keep suppliers in the process with numerous clarifications, the adoption of verbal communications during the early stages is welcomed and appears to be beneficial for suppliers and the CTDA assessors.

3. What trends in consumer confidence in COVID-19 diagnostic devices have you observed?

More understanding for laypersons on diagnostic tests, and terms associated with diagnostics such as sensitivity and specificity.

The initial criticism of the value of LFTs by some political interests was not helpful, however, over time, the public came to depend on these tests to determine their behaviour, and to accept that a positive result was very highly likely to be genuine, whereas a negative result could be early in the disease process. PCR has generally been accepted as highly reliable and accurate.

4. To what extent do you believe consumer behaviour regarding illness and diagnostics has changed due to the pandemic?

Individuals are more vigilance and more likely to take illness seriously (i.e. not coming into an office with a cold).

5. Outside of medical diagnostics over the next 10 years, what activities, business areas or types of consumers will make regular use of COVID-19 testing?

Healthcare providers, insurance providers, sport, entertainment and social events.

6. Are you working with other businesses and, if so, do these businesses want to test staff or customers (or both) in the absence of government requirements to do so?

No; it is no longer a priority now that the UK is "living with Covid".

3. International regulation and trade flows

3 (A) International regulatory environment

We are interested in how the CTDA experience compared to other international jurisdictions. We are particularly interested in the impact of regulation and the application journey when compared to regulation in the US, Canada, Australia, and South Korea.[footnote 1]

1. What comparisons can you make between CTDA and other regulatory regimes internationally? Please include views on levels of scientific rigour, fees and if they met in their countries the 5 objectives of CTDA. Please support your answer with evidence.

Other jurisdictions are significantly easier to enter for COVID-19 products and have less burdensome systems. They also tend to have clearer guidance.

The UK has long been seen as centre of excellence in high quality regulation which first and foremost protects consumers. This reputation has extended to many British goods sold internationally which have a reputation for high quality.

We have received feedback that suggests in many parts of the world a test that has been seen to pass British regulatory standards will be seen as a trustworthy product and as such could act as an

incentive to consumers particularly when coupled with the register information available online. This additional regulation doesn't give any additional benefit to what the UK regulatory framework had previously.

2. Would you see passing the UK's validation for COVID-19 tests as a helpful marketing tool for selling in other international markets?

No. . This additional regulation doesn't give any additional benefit to what the UK regulatory framework had previously.

3 (B) Trade flows

Trade in diagnostic devices expanded massively over the pandemic.

The UK and other developed markets experienced large influxes of test devices particularly from manufacturers based in the far east. In addition, there were many new entrants to the market. Understanding these aspects and the impact that regulation had on these flows will be important to the evaluation.

We are interested in understanding more about the flow of COVID-19 test products in, out and around the UK.

1. Where in the UK do you import to, and where do you import from?

NA.

2. Where in the UK do you export from, and where do you export to?

NA.

4. CTDA application and administration

The CTDA was rapidly set up within DHSC as the body able to deliver a regulatory regime in the timings dictated by the pandemic. This required quickly standing up both an operational team and scientific advisors. In addition, a portal had to be designed and developed to receive applications.

It was important to ensure that the evidence received from companies was of a sufficiently high quality to make a decision.

Though we recognised the higher level of rigour CTDA required compared to the EU regulations, a large number of companies in a scientific focused sector were unable to provide evidence of the quality required.

To support industry and manufacturers, rather than reject these applications, scientific advisors have provided extensive support to help these applications meet the evidential standards required. This has impacted the speed of applications through the process.

4 (A) CTDA application process

CTDA was designed as a scientifically rigorous yet efficient process. However, we recognise some elements on evidence standards were novel and challenging to some in industry to adapt to. We would like to hear about your experiences when applying through CTDA. This includes the evidence you prepared for the application and your communication with officials.

1. We invite stakeholders involved in submitting an application for COVID-19 tests to provide their experiences of the CTDA application process. Please provide as much detail as you can, including when you made an application and when you received your decision.

The logic and rationale behind implementing the CTDA process was sound, in that a more rigorous process was needed for these products in comparison to the regulatory requirements of standard diagnostic tests (UK Medical Device Regulations 2002) to protect non-scientific users and the public.

We do not believe the scope should have included sales to the NHS Pathology Service who have the expertise to assess products independently.

Additionally, the process was made more difficult by constant changes to what exactly was required. This made it very costly and time consuming for organisations. Along with this, it was difficult to get answers to queries.

4 (B) CTDA administration

The CTDA has been administered since inception by the UK Health Security Agency (UKHSA) (and its predecessor NHS Test and Trace). It has used an online portal to receive applications and fees payment. A team of operational staff manages the applications through the system and supports the scientific advisors in their work.

2. Please provide any other experience supported by evidence of the performance of the CTDA scheme not covered by the previous section. Please include experience of complaints or re-review process in this answer.

BIVDA members have identified the following issues:

(1) It was not clearly understood why a CTDA process additional to MHRA regulation and other requirements was necessary: it was described as a "bureaucratic response" to a problem which had not been fully explained.

(2) It was not clear why both TVG validation and the CTDA process were necessary.

(3) The programme itself was vastly under-resourced.

(4) There should have been more notice at the start before it was introduced i.e. the transitional arrangements were not realistic (suppliers given limited time to apply)

(5) The Government did not deliver on the "extensive guidance" that it said would be developed to provide clarity, including on the proposed verification process for tests where robust performance evidence already exists.

(6) There needed to be "less unwarranted exemptions". The DHSC were exempt from the CTDA process and continued to supply lateral flow tests that had not completed the process, which does not seem to present a level playing field.

(7) In contrast to the EUA process, there does not appear to be any published policy guidance in respect exemption.

(8) There has been poor quality communication with suppliers e.g. mainly via email submission. There was also ineffective feedback. The FDA by contrast arranges pre-submission meetings to understand the process, expectations in respect of it and to help clarify areas where tests may be different. The absence of any engagement from the CTDA to suppliers other than emails informing suppliers that they will be informed when a decision has been reached was considered an "obvious error" and that communication and verbal dialogue would have improved the efficiency of the process.

(9) Another significant issue concerned delays and inconsistency in this regard e.g. two applications being submitted on the same day but with differing timeframes on outcomes. The 4-week indication was vastly under achieved with applications taking up to six months

(10) Sensitivity and specificity requirements were potentially set too high and not necessarily appropriate for clinical decisions.

(11) Diagnostics criteria for comparator assays were too restrictive.

(12) The number of samples required was unnecessarily high considering the difficulty sourcing samples for evaluation at short notice.

(13) No example documents were provided.

(14) The process was not able to effectively manage changes in assays which came onto the market whilst CTDA approval was ongoing. There was a lack of process for improved versions of approved assays which was slowing down access to newer technology in the NHS.

(15) There were also issues regarding the format of required information. The CDTA team did not have a set format for data prior to the deadline for application and stated that this would not affect supplier's applications. This is clearly not the case and was misleading.

(16) The excel file which has been created for PCR tests does not align with requirements for rapid tests therefore several sections are marked as Not applicable. There is not enough space to provide comments which means it is not possible to add more information and give context to studies performed and the results. This has then led to several emails between the reviewer and customer thus extending approval lead times unnecessarily

(17) The performance characteristic template was not suitable for non-PCR assays.

(18) Basic questions concerning their application were asked many months after submission; on occasion, the data already provided has been asked to be provided again.

(19) There have been issues in respect of the consistency in requirements that were applied by different reviewers.

(20) Finally, the payment system experienced problems in processing.

5. CTDA objectives

During the pandemic there was high demand for COVID-19 diagnostics and there was an influx of new entrants to the market with a broad range of tests they were placing on the market. Existing EU regulation, including third-party conformity assessment, had failed to prevent poor quality COVID-19 tests entering the market.

This created a confusing marketplace for consumers and risked undermining attempts to combat the pandemic. CTDA was established with 5 overarching objectives to address this market failure and associated public health risk.

These objectives are set out below:

- reduce false negative and false positive test rates to help manage the spread of the disease, reduce incidences of unnecessary self-isolation and contact tracing
- correct the market failure, particularly the information asymmetry that prevented consumers from understanding or being able to compare test devices
- ensure all tests on the UK market were of the same standards as those used in the NHS, so that they can contribute to empowering people to manage their own health and combat the pandemic
- increased reliability of test products and easier comparability of their performance should drive increased take-up of testing by employers and institutions
- increased consumer confidence in test and subsequently, increased volumes of private tests being reported

1. Do you consider that these objectives remain the appropriate ones for validation of COVID-19 test devices?

Yes.

2. For each of the above we would welcome your thoughts on whether you think these objectives have been met, how they have been met and whether you can propose any better or less onerous ways of achieving them. Please support your answers with evidence.

No – the system was fundamentally flawed when certain products were exempted from it if they were already procured or in use by DHSC.

The timeframe allowed for the review of the products on the market has proved to be wholly insufficient, the approach had a significant distortive effect on the market and the implementation of the policy did not properly assess the availability of products on the market and how the legislated timescales could impact on this. Insufficient assessment was made of the processes needed to meet the requirements. The implementation has obviously been challenging for the CTDA team and the impact on competition not considered fully and there must be a clear demarcation between validating products technically and their considered availability for procurement. The requirement that inclusion on the annex to the protocol only applying to tests that have undergone validation for public sector procurement or supply for Test and Trace contracts had the effect of significantly curtailing access for many suppliers of tests. With regards to procurement, the vast majority of suppliers had been supplying the NHS through NHS Supply Chain Framework and the PHE Microbiology Framework, neither of which required a validation to be undertaken by TVG (which looks to be the list of products from which the temporary protocol was derived). The NHS was responsible for verification and validation within their statutory remit, and additional legislation for the NHS was burdensome and not required.

The guidance on the government website stated that a test or developer did not need to submit through the triage process for TVG and could sell to the laboratories provided they had the relevant regulatory approvals (at the time). The length of time the helpdesk took to respond to suppliers is unsatisfactory, and time was not of the essence when considering suppliers' queries.

The government should work with the National regulator and National Regulatory framework post leaving the European Union to ensure that all products on the IVD market are satisfactory and aligned internationally rather than introducing separate and onerous legislation specific to one jurisdiction.

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Closing questions

1. Are you aware of any research that would be useful to this evaluation? Please provide as much detail as you can and any links, journal numbers and so on.

NA.

2. Please provide any evidence you think would be useful to this analysis not covered in the preceding questions.

NA.

Next steps

We will collate and analyse the responses we receive to this call for evidence, and we will use this to develop our analysis of the CTDA policy. When we are satisfied that we have collected the best evidence possible, we will submit our findings to the Regulatory Policy Committee for their review.

This analysis will feed into the wider policy review of the CTDA process which will be published by 31 December 2022.

Thank you for responding to this call for evidence.

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Annexe A: Guidance document

CTDA call for evidence - guidance

This document will accompany the main call for evidence questions and provide additional guidance on how to answer each question and what you may wish to consider in your answers.

Considering the following points and questions in your responses will ensure we can collect comprehensive views to allow us to fully evaluate the policy based on your perspective.

You do not need to answer those questions which are not applicable to you, but please provide detailed responses and supporting evidence for the questions you do respond to.

Please see below further guidance on the key questions we would like you to answer.

Profit and costs

In addition to the main questions on profit and costs, please also consider the following questions regarding profit, loss, and costs:

- losses incurred because a product failed to meet CTDA standards
    - total cost
    - hours lost
- losses incurred because a product was not put forward for CTDA validation
    - total cost
    - hours lost
- costs incurred due to reinvestment in a product to achieve successful validation
    - total loss
    - hours lost
- total increase in profits since the implementation of CTDA in July 2021
- gains in profit after successful CTDA applications
    - total gain
- gains in profits as a result of reinvestment in a product
    - total gain
- total increase or decrease in costs directly related to compliance with CTDA regulations since July 2021
- estimated compliance costs
    - cost per hour

- How were any losses incurred to the business absorbed (for example, higher costs passed onto consumers, cuts in dividends and so on)?
- What are your import costs?
- Have you incurred any additional costs because of data collection related to the CTDA application? What are these?

Are there any other areas not covered above where you have experienced direct or indirect losses or gains to profits as a result of the CTDA process?

Estimate your profit margins from the choices below:

- negative gross profit margin
- 0% to 10%
- 11% to 20%
- 21% to 30%
- 31% to 40%
- 41% to 50%
- 51% to 60%
- 61% to 70%
- 71% to 80%
- 81% to 90%
- 91% to 100%

Polymerase chain reaction (PCR)

- current gross profit margin
- target gross profit margin

Lateral flow devices

- current gross profit margin
- target gross profit margin

Other (please specify):

- current gross profit margin
- target gross profit margin
- In calculating the gross profit margin above, what elements have you included in the cost of sales (for example, fixed costs, research and development spending, branding)?
- What proportion of devices currently available on the market would you anticipate presenting to the scheme for validation, rather than being excluded from the market?
- How this would vary by:
    - technology type
    - country of origin
    - size of revenue

Investment

In addition to the main questions on investments, please also consider:

1. What would be the most likely scenario if a COVID-19 test product failed validation?
    - product is discontinued; exit the market
    - redesign and resubmit for validation
    - seek alternative international markets
    - other (please specify)
2. How this would vary by:
    - technology type
    - country of origin
    - size of revenue

Future business planning

We are interested in any future business planning you have undertaken to gauge the trajectory of the COVID-19 diagnostics market. In addition to the main questions on future business planning, please also consider:

- What horizon period are you currently planning for within your business planning?
    - 0 to 6 months
    - 7 months to 1 year
    - 1 to 2 years

- 2 to 3 years
- 3 to 5 years
- 5 to 10 years
- more than 10 years

- What opportunities have you identified over the next year within the COVID-19 private testing market?
  - Do you expect the market for COVID-19 private testing to grow or shrink? By how much (%)?
  - Are there any dependencies or risks attached to this? Where possible, please break this down by technology type (for example, PCR demand vs lateral flow device demand)
  - Do you plan to increase investment into COVID-19 test products over the next few years?
  - If you currently only produce COVID-19 tests, will you continue to exclusively sell into the COVID-19 testing market, or do you have plans to expand into the wider diagnostics market?
  - Do you expect pandemics, such as COVID-19, to become more common occurrences? If yes, has this increased or decreased your desire to retain resources in the diagnostics market?
  - Before bringing a COVID-19 testing device or service to market in the UK, for how long in years and months have you been involved in the diagnostic testing sector?
    - years
    - months

Interaction with universal free testing

In addition to the main questions on interactions with the universal testing offer, please also consider:

- How has the end of the UTO (free tests offered to the public by the government) impacted your businesses profitability and business planning decisions?
- How is the uncertainty of future pandemics impacting your business planning decisions? For example, external variables such as the potential for the emergence of new variants (or, if you are not a business, how do you predict these will impact these decisions?). Do you expect there to be similar levels of demand for testing in the private market if another pandemic (other than COVID-19) were to emerge?

Research in the market

We would welcome any research you may be aware of that would be useful in our analysis of the UK private market for tests:

- Are you aware of any research which you believe accurately represents the volume of tests available on the private market in the UK? Please provide the title and source, and a brief summary.
- Are you aware of any research which highlights good management of supply chains to deliver COVID-19 test products to the UK market? Please provide the title, a source, and a brief summary.
- Are you aware of any research that best represents the size of the UK's diagnostics market, or market for COVID-19 tests?

Yes. The BIVDA Market Audit captures an estimated 95% of total UK IVD market revenues, including all major suppliers into the NHS. Correcting for the additional 5% gives an estimate for total Coronavirus testing revenues of £244m in 2021. This report is proprietary to BIVDA.

- Are you aware of any research that estimates the value of the UK diagnostics market, or market for COVID-19 tests?

Yes. The BIVDA Market Audit captures an estimated 95% of total UK IVD market revenues, including all major suppliers into the NHS. Correcting for the additional 5% gives an estimate for total Coronavirus testing revenues of £244m in 2021. This report is proprietary to BIVDA.

International regulation and trade flows

In addition to the main questions on international regulation and trade flows, please also consider:

- How effective at addressing information asymmetry in the market is CTDA compared to other regulatory regimes internationally?

Poor

- How effective at addressing the public health risk of inaccurate results is CTDA compared to other regulatory regimes internationally?

Poor

- How do CTDA application fees compare to other regulatory regimes internationally?

Not Comparable

- Are you aware of any other regulatory regimes internationally offering a small and medium enterprise (SME) discount? If so, how is an SME defined? And what are the discounts rates?

Not comparable

- How quick is it to get a CTDA decision compared to other regulatory regimes internationally?

Not comparable

- Which countries do you import or export COVID-19 products from or to?

NA

- What affects your decision to import COVID-19 products from a particular country?

NA

- What affects your decision to export COVID-19 products to a particular country?

Cost, market access and ease of doing business for the vast majority of BIVDA member companies

- If you are manufacturing in the UK, where are your manufacturing centres?

NA

- Have you considered shifting your business out of the UK? If so, why?

Member companies continually assess the profitability of manufacturing in the UK. Cost, market access and ease of doing business are the main drivers for the vast majority of BIVDA member companies.

Consumer behaviour

In addition to the main questions on consumer behaviour, please also consider:

- Was the information on the CTDA register useful?

A member of the public would probably not be sufficiently capable to understand any more than a product's inclusion.

- Did you find it easy to compare the information between different tests on the register?

As above.

- Is there any information absent from the register you would have found useful in informing purchasing decisions?

No.

Product life cycle

We are interested in your assessment of your products' life cycles to gauge how often businesses must redevelop or update products to meet changing requirements:

- What is the average life cycle for your product or products or a COVID-19 diagnostic device?

Variable.

- How would this vary by technology type? For instance, how long would a device last for before manufacturers decide to update or make substantive changes to their product (for example due to innovation, market competition or new variants)?

Dependant on demand and fitness for purpose, also the cost to update a product vs the return on investment.

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COVID-19 epidemiology

COVID-19 is still an active public health issue and, as a result, we are interested in your thoughts on COVID-19 epidemiology and how you expect this will affect your business and the wider COVID-19 diagnostics market:

- How do you expect new variants to impact the UK COVID-19 diagnostic market over the next 12 months?
- What planning to replace or alter existing diagnostics devices do you conduct or think is appropriate for a manufacturer to conduct to ensure diagnostics remain effective at detecting new variants?
- Are you expecting to withdraw any tests from the market due to new variants?

BIVDA expects that some manufacturers won't update products due to the excessive investment compared to demand.

CTDA application process

We are aware that changes to regulatory processes can be challenging for businesses to navigate. We are therefore interested in your experiences of the CTDA application process.

Please consider the following in your responses:

- Have you been involved in applying for validation for a coronavirus test device?
    - yes
    - no
- When did you submit your application?
- When did you receive a decision on your application?
- Did you supply all evidence required with your initial application, or did you need to submit additional evidence?
    - all required evidence was submitted initially
    - additional evidence had to be submitted
    - application is still live, and I have had no requests for additional evidence
    - application is still live and additional evidence has been requested

- What, if any, challenges did you face when first making the application and during the validation process?
- If you sought a re-review what were your grounds for doing so?
- If you sought a re-review what was the outcome of the process?
- If you sought a re-review how was the process handled?
- Did you face any challenges after successfully passing validation?
- How were you supported through the process by UKHSA?
- How would you rate your experience of applying for validation? (This question is on a scale of one to 10 with 1 being very poor and 10 being very positive)
- Have you found the guidance clear and accessible?
    - yes
    - no
    - I don't know
- Have you found the online portal easy to use?
    - yes
    - no
    - I don't know

If you have any suggestions for improvement, please identify these here (max 250 words).