Title: Validating COVID-19 tests in the private market **IA No:**	**Impact Assessment (IA)**
RPC Reference No:	**Date:** 28/06/2021
Lead department or agency: Department of Health and Social Care (DHSC)	**Stage:** Development/Options
Other departments or agencies:	**Source of intervention:** Domestic
	Type of measure: Secondary legislation
	Contact for enquiries: daniel.foster@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion: RED – Not Fit For Purpose

Cost of Preferred (or more likely) Option (in 2019 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£-99.3m	£-59.7m	£169.1m	Qualifying provision

What is the problem under consideration? Why is government action or intervention necessary?

Entry into the private SARS-CoV-2 (COVID-19) test product market is controlled by CE marking which is currently a self-declaration process for most of the COVID-19 test products on the UK market. The performance declaration made as part of CE marking is not required to be independently verified ahead of sale for such tests and there is no legally binding agreed process for establishing that performance. Further to this there is no minimum threshold for performance of a test product in terms of its ability to detect positives and negatives accurately. A significant number of tests have failed in independent validation to replicate their stated performance for their intended use. Government intervention is required to legislate and enforce standards of private COVID-19 test products to protect the interests of the public.

What are the policy objectives of the action or intervention and the intended effects?

The desired outcome is that all mature (antigen and molecular detection) COVID-19 testing technologies sold on the UK market and used in testing activities will meet a minimum standard of performance. This will be measured through analysis of test results reported to Public Health England (PHE), as legally required, only being products that have passed validation.

Increased confidence in the reliability of test products and easier comparability of their performance should drive increased take up of testing by employers and institutions. Increased volumes of private tests being reported; greater numbers of employers/bodies providing or requiring testing; and their general awareness of the validation programme will be key indicators of success.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 0: Do nothing.

Manufacturers will continue to self-certify COVID-19 tests against CE standards.

Option 1: Legislate market standards for COVID-19 tests.

On top of existing CE marking standards this would introduce a mandatory requirement for validation.

Option 2: Voluntary validation

A voluntary approach was initially considered where the same central validation programme would be created at a smaller scale with the same thresholds for performance for tests but on a purely voluntary basis.

Option 1 is preferred, requiring COVID-19 tests sold on the UK market to undergo validation. This was assessed as the only option where failure to apply and have a product scrutinised was not a better option for manufacturers.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Before 31.12.22

Is this measure likely to impact on international trade and investment?		Yes		
Are any of these organisations in scope?	**Micro** **Yes**	**Small** **Yes**	**Medium** **Yes**	**Large** **Yes**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: _____ Date: _____

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2020	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -132.8	**High:** -296.8	**Best Estimate:** -109.9

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	1.7	1	72.4	**678.1**
High	2.1		275.3	**2590.7**
Best Estimate	1.8		176.8	**1667.5**

Description and scale of key monetised costs by 'main affected groups'

Average annual costs to business are made up of c£6m for the validation programme (which will operate on a 100% passthrough basis, with a 55% fee reduction for SMEs) and c£165m in foregone profits for manufacturers either not applying for validation or whose products do not pass validation. As the UK COVID-19 diagnostic market shrinks, foregone profit falls year-on-year from c£650m in year 1 to c£35m in year 6.

Other key non-monetised costs by 'main affected groups'

Validation costs may be passed through to consumers in the form of increased prices, however this is likely to be a small amount.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0.0		57.6	**545.3**
High	0.0		242.3	**2293.9**
Best Estimate	0.0		164.5	**1557.6**

Description and scale of key monetised benefits by 'main affected groups'

Demand for test kits left unmet by the withdrawal of products failing validation, or those not presented for validation, is very likely to be fulfilled by the expansion of supply of products that do pass validation. The net result, rather than a complete loss of profit, will be a redirection of profit from manufacturers of lower-performing products to manufacturers of higher-performing products. The scale of this benefit mirrors the "profit foregone" cost. Following RPC published guidance[1] this recovery of profit is considered as indirect and so is involved in Present Value calculations but not the Equivalent Annual Net Direct Cost to Business (EANDCB).

Other key non-monetised benefits by 'main affected groups'

The validation programme will improve average test performance, increasing the successful detection of COVID-19 cases (reducing onward transmission and reducing the likelihood of future lockdowns and new variants) and decreasing false positives (reducing unnecessary self-isolation).

Key assumptions/sensitivities/risks	Discount rate	3.5

There is a low risk that validation will exclude so many products from the testing market that supply cannot meet demand, resulting in substantial price increases and lack of availability.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 187.2	**Benefits:** 0.0	**Net:** 187.2	845.5

[1] [1] RPC_case_histories_-_direct_and_indirect_impacts__March_2019__1_.pdf (publishing.service.gov.uk)

Summary

Problem under consideration and rationale for intervention

1. Validation of COVID-19 test devices for use in the NHS by the LVG[1] and TVG[2] established consistent gaps between manufacturers' claims (including field outcomes for selected products) in terms of test performance, even for well-performing devices.[3] This may lead to an increased risk of inaccurate test results when used for testing. Whilst the government has done extensive validation work to choose the most appropriate tests and understand their reliability for use in the NHS, only knowledge of the best performing tests is available in the private sector. Test kit/device selection based on manufacturer declared performance may be based on incomplete information, due to non-standardised data and evidence backing up performance claims. As a notifiable infectious disease this will also mean results collected may be unreliable when used in evaluating the progress in targeting COVID-19.

2. Entry to the market is currently 'controlled' by CE marking – a self-declaration process for the performance of this type of test kit/equipment. This performance is not independently verified ahead of sale. Regulation is also reactive rather than proactive, so tests are only removed from the market if problems are reported.

3. We have publicly consulted on the government's proposal to introduce mandatory validation for COVID-19 tests. 78% of respondents agreed that COVID-19 detection tests should be validated beyond the verification and assurance provided for CE marking. We are therefore confident there is support for the rationale for intervention.

4. DHSC proposes to legislate to introduce a mechanism independently and mandatorily to validate the self-certified performance of antigen and molecular detection tests for COVID-19 and ensure that to be sold on the UK market the products meet a minimum standard as used in the NHS. Those tests that do not pass validation will not be licensed for sale in the UK.

5. A greater role for private sector provision of asymptomatic testing is expected during 2021 subject to policy requirements. It is considered essential individuals are able privately to acquire dependable tests or testing services. For this reason, it is necessary to lay regulations to enforce and uphold existing quality standards as soon as possible.

Proposed measure

6. Option 1: Legislate market standards for COVID-19 tests.

7. On top of existing CE marking standards this would introduce a mandatory requirement for validation.

8. The validation process offering independent assessment of the performance a product is capable of minimising the cost to government by charging manufacturers for the service. Publishing the results of this process on a single gov.uk page will ensure that the data is accessible and comparable. This should maintain consumer faith in testing sufficiently

[1] Lateral Flow Device Validation Group
[2] Technical Validation Group
[3] To date, approximately 114 products have been through TVG the validation process and only 14 have been validated. This is similar for LFD validation, where 101 have gone through the validation process and only 20 validated.

that test outcomes will be used to inform their behaviours whether tests are government issued or not.

9. A mandatory approach, introducing minimum standards and compelling COVID-19 tests sold on the UK market to go through validation was assessed to be the only to sufficiently minimise gaming of the proposed system.

10. Alternative options considered are described later in this IA.

Headline impacts

11. The direct costs to business of this policy are made up of £6m (annual equivalent) for the validation programme and £165m in foregone profits for manufacturers either not applying for validation or whose products do not pass validation.

12. As the UK COVID-19 diagnostic market shrinks, foregone profit falls year-on-year from £647m in year 1 to £35m in year 6.

13. Demand for test kits left unmet by the withdrawal of products failing validation, or those not presented for validation, is very likely to be fulfilled by the expansion of supply of products that do pass validation or to a lesser extent recovered through reinvestment in products (such that they subsequently successfully validate). The net result, rather than a complete loss of profit, will be a redirection of profit from manufacturers of lower-performing products to manufacturers of higher-performing products at a net cost of £1.3m (i.e. from reinvestment).

14. Residual costs arise to business from familiarisation (£0.1m) and transition costs (£40,000) and to the public sector from programme cost mitigation[4] (£5m) and communication costs (£1,000).

15. As legislation is being enacted through two separate SIs, the first validating performance claims through a desktop process and the second, for products successful at the first stage, validating through independent laboratory testing, we have appraised these two elements separately. The first SI accounts for:
    a. 99.8% of profit effects – this is based on experience of the TVG where the overwhelming majority of products failing validation did so at the desktop stage
    b. 20% of programme costs (and government mitigation costs[4])
    c. 88% of familiarisation and 99.8% of transition costs
    d. 50% of public sector communications costs

16. The policy will bring about direct improvements in the performance and reliability of COVID-19 tests. More specifically, reducing the number of false positive results and increasing the number of true negative results, removing unnecessary constraints on socioeconomic engagement, improving productivity and wellbeing of test participants.

17. Furthermore, improved test performance will reduce the number of false negative results and increase the number of true positive results, correctly identifying those carrying COVID-19, reducing onwards infections and improving wellbeing, long-term health, mortality and socioeconomic engagement.

[4] Ie the 55% reduction in programme costs offered to small and medium enterprises

Table 1 – Summary of 'best estimate' impacts, option 1

	Total				SI1		SI2		%SI1
	Annual	NPV	Impact on Business?	Direct Impact?	Annual	NPV	Annual	NPV	
Loss of profits	-£164.5m	-£1,557.6m	Yes	Yes	-£164.2m	-£1,555.0m	-£0.3m	-£2.6m	99.8%
Programme costs	-£5.9m	-£51.6m	Yes	Yes	-£1.2m	-£10.5m	-£4.7m	-£41.1m	20.3%
Familiarisation Costs	-£0.1m	-£1.4m	Yes	Yes	-£0.1m	-£1.2m	-£0.0m	-£0.2m	88.3%
Transition Costs	-£0.0m	-£0.4m	Yes	Yes	-£0.0m	-£0.3m	-£0.0m	-£0.0m	99.8%
Reinvestment Cost	-£1.3m	-£12.8m	Yes	No					
Recovery from reinvestment	£2.7m	£25.5m	Yes	No					
Recovery from expansion	£161.8m	£1,532.1m	Yes	No					
Public Sector Comms cost	-£0.0m	-£0.0m	No	No	-£0.0m	-£0.0m	-£0.0m	-£0.0m	50.0%
Government mitigation costs	-£5.0m	-£43.8m	No	No	-£1.0m	-£8.9m	-£4.0m	-£34.9m	20.3%
NPV		-£109.9m	-£66.1m	-£1,611.0m		-£1,575.3m		-£78.8m	99.8%
Annual	-£12.4m		-£7.4m	-£170.6m	£0.0m		-£12.4m		99.8%

Background and scope

18. Testing for COVID-19 has been at the heart of the government's response to the pandemic as the means not only to detect the virus but in aggregate to understand its prevalence and movement in the UK. The government has worked to pick the most appropriate and where possible best performing tests for government led testing. To do this it has conducted extensive validation of the performance of these test products, namely the ability to detect positive and negative cases accurately as well as other critical requirements like the biosafety of these products in a laboratory.

19. The reason it was necessary to do this is that entry into the market for COVID-19 test products is controlled by CE marking which is currently a self-declaration process for most of the COVID-19 test products on the UK market. The performance declaration made as a part of CE marking is not required to be independently verified ahead of sale for such tests and therefore there is no legally binding agreed process for establishing that performance. This means the evidence that one test product provides to prove its performance may be as follows, 20 positive samples all from highly infectious individuals and 80 negative samples. Another product applying the same evidence requirements may decide 150 positives samples from individuals from high to low infectiousness and 250 negative samples is necessary to prove the performance of their product.

20. The robustness and reliability of the claimed performance from the second dataset will be greater than the first and less likely to be inaccurate when the product is used in the laboratory or in the field.

21. Further to this, there is no minimum threshold for performance of a test product in terms of its ability to detect positives and negatives accurately.

22. The validation work conducted for government procurement found that a significant number of tests failed to match their claimed performance and a number of these test products deviated significantly from their claimed performance. Whilst the government can procure the test products that it wants and control which products it uses, this data and expertise is not easily available to the public and institutions when they are looking to find the right test to use.

23. There is already some demand for and use of private sector supplied tests, such as in media and travel industries. There is currently little guidance on which is the appropriate test to use. Most of the current demand for testing in the UK has been thus far met by free Government provision. However, we expect a growing role for the private sector, and it will be necessary for a robust and reliable market to ensure a continued supply of high-quality tests exists in the private market as a critical means of preventing transmission of the virus.

24. Therefore, government intervention is required to legislate and enforce standards for the most used COVID-19 test products to ensure that if a member of the public gets a test on the NHS or in a private setting that test will be equally as good. Our plan for the introduction of minimum performance standards, a centralised validation service to confirm tests meet these minimum standards and the publishing the results transparently on gov.uk will improve be key to addressing the problems identified in the market.

25. This proposed approach is in line with other legislative interventions to improve product standards for the benefit of health and consumer confidence. Examples include the Bread and Flour Regulations 1998 to fortify bread flour with four key nutrients and the Products Containing Meat etc. (England) Regulations 2014 setting minimum standards for meat products and providing consumer confidence on the quality of products they are purchasing.

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

Evidence gathered

26. Evidence gathered includes the following;

- Known DHSC models for programme costs given testing demand
- publicly available data from the national technical validation process for manufacturers of COVID-19 tests,
- Orion Market Research[14] on the UK COVID-19 diagnostic market
- Data and evidence gathered from interviews with suppliers and manufacturers of COVID-19 tests on the costs, transition and familiarisation costs, supply chain impacts and profit margins of different test types. In particular, several Small and Micro Businesses
- Discussions with experts, trade bodies and officials in across UK Government and the Devolved Administrations
- Commissioned research from Efficio UK to understand UK trade flows
- Data on the importation of COVID-19 Tests to the UK from UK Trade Info (HMRC data.)
- Public consultation on the validation policy (including 43 respondents)

27. In addition to highlighting where possible quantitative social impacts we note qualitative impacts of unreliable tests on public and professional trust in COVID-19 testing results and compliance with self-isolation. Fully quantifying the test performance benefits of this

proposed policy (e.g. the quantitative social impacts of inadequate tests allowed to remain on the market) is problematic due to uncertainty of future pandemic parameters, hence modelling would be unlikely to deliver confidence around central predictions of the impact of this legislation. The complexity of the modelling that would be needed (even with that caveat) would require resources beyond what is considered proportionate.

Stakeholder Engagement

28. We gathered a large amount of evidence through the public consultation survey, with evidence from 43 respondents including large and small manufacturers, chemists, retailers, trade associations, professional bodies, local authorities, universities and individual experts. Over 20 organisations from these sectors attended an industry roundtable, where we were able to gather further evidence from stakeholders on the potential impacts upon business.

29. Furthermore, we have also undertaken additional stakeholder engagement to gather evidence and test some of the assumptions underpinning this Impact Assessment. We reached out to over 30 external stakeholders and held interviews with manufacturers (including Small and Medium Enterprises and Small and Micro Businesses), retailers, trade associations and enforcement agencies.

Areas of uncertainty

30. Evidence has not been gathered to assess the specific social impacts of faulty tests (e.g. how are users' behaviour effected when told their test may be or was incorrect). These gaps have not been addressed.

31. While our expectation is that subsequent legislation will supersede this programme before it enters a second year, there is no end date specified in legislation itself. Therefore, in alignment with RPC appraisal period guidance[5], we cannot, at this point in time, justify moving away from the standard 10-year appraisal period.

32. Orion Market Research[14] forecasts the UK COVID-19 diagnostic market value until 2026. This IA uses this forecast and then extrapolates from 2026[6] to show 10-year business and market impacts with acknowledgement that these figures are highly speculative. The assumed lifecycle for a COVID-19 test is 1-3 years due to the risk that new COVID-19 variants and mutations render older tests obsolete or they are replaced by more innovative tests.

33. Stated (20%) profit margins for businesses producing COVID-19 tests have medium confidence. Many organisations are not willing to provide such commercially sensitive information. We have engaged 12 stakeholders including manufacturers, government officials with experience of the sector and trade associations to seek information on profit margins, with relatively few being willing to respond to these specific questions. Our profit assumptions and their basis are discussed further in paragraph 91.

34. We consider the approach we have taken to be proportionate to the impact of the legislation, which we anticipate being impacted within 12 months as the European Union

[5] https://www.gov.uk/government/publications/rpc-case-histories-appraisal-periods-september-2020
[6] Despite consistent decline between 2021 and 2026, we assume the market ceases to shrink from this point as it makes the analysis more conservative.

(EU) moves to introduce legislation[7] which will require all COVID-19 testing products to go through a more stringent regulatory regime including ongoing quality management. Whilst there is not a requirement to align with the EU process, manufacturers wishing to sell the same product in Europe will likely be applying this updated process and we have committed to reviewing the policy as this regulation develops.

Description of options considered

Option 0: Do nothing

35. Manufacturers will continue to self-certify COVID-19 tests against CE standards. There is no current legislative framework for removing tests from the market that fail independent validation. This is expected to affect consumer confidence in tests and the government's ability to utilise private testing in the COVID-19 response. Risks around false negatives to public health and local economies remain, similarly risks around false positives to local economies remain.

Option 1: Legislate market standards for COVID-19 tests.

36. On top of existing CE marking standards this would introduce a mandatory requirement for validation. The validation process would offer independent assessment of the performance a product is capable of and minimise the cost of this assurance to government by charging for the assessment to maximise the recovery of programme costs. The results of this process would be published on a gov.uk page to ensure that the data is accessible and comparable. This should reduce consumer confusion over tests and improve faith in testing sufficiently that test outcomes will be used to inform their behaviours whether tests are government issued or not, helping to address the secondary objective of the policy to make selecting the right test an easier process.

Option 2: Voluntary Validation

37. A voluntary approach was initially considered where the same central validation programme would be created at a smaller scale with the same thresholds for performance for tests but on a purely voluntary basis. This was discounted as it was assessed that there was insufficient incentive for manufacturers to apply to the process. As stated in earlier sections it is expected that the findings of a validation exercise to show a small drop off in stated performance for test products compared with their claimed performance.

38. Tests that did not subject themselves to this process would therefore be able to continue to claim their higher stated performance without independent contradiction. This clear disincentive to apply with few concrete benefits meant a non-legislative approach was discounted.

39. Whilst validation for government procurement was voluntary, there was a clear benefit of the, potentially significant, government contract at the end which compelled manufacturers to comply.

40. A mandatory approach, introducing minimum standards and requiring COVID-19 tests sold on the UK market to go through validation was assessed to be the only option where

[7] EUR-Lex - 02017R0746-20170505 - EN - EUR-Lex (europa.eu)

failure to apply and have a product scrutinised was not a better option for manufacturers.

41. 73% of respondents to this question in the public consultation agreed that mandatory validation of tests prior to their entry on to the market is best approach given the need to establish confidence in them and to re-open the economy. A strong majority of 88% of respondents also agreed that a legally backed and enforceable UK wide regime is the best approach.

42. 71% of respondents to this question also agreed that a mandatory validation process will not significantly reduce the supply of high quality COVID-19 detection tests. 79% of respondents to this question also agreed that the proposed mandatory validation process set out in the consultation document will increase the safety of COVID-19 tests and reduce the risks presented by poor quality tests.

43. A mandatory approach, introducing minimum standards and requiring COVID-19 tests sold on the UK market to go through validation was assessed to be the only option where failure to apply and have a product scrutinised was not a better option for manufacturers.

Approaches to validation

44. In addition to regulation options, there have also been considerations of alternative approaches to validation, and these options remain under review until fully implemented.

45. Option A: publishing a methodology and standards to be conducted by accredited laboratories.

46. This option offers greater speed to be set up as it minimises the effort needed to procure, stand up and kit out a central laboratory. It would also allow manufacturers to work with a laboratory potentially nearer to their own facilities. However, the lack of oversight and control of the process; the lack of ability to guarantee capacity to test all products believed to be on the market; and difficulties in compiling the outcomes of each test product meant that this approach was unlikely to be able to achieve the two main policy goals.

47. Option B: use existing validation capacity and processes as used for government procurement.

48. This again offered a quicker delivery timetable than the chosen option and reduced issues with control over the quality of the process. However, the facilities and resources used were provided on a voluntary basis and as such could not guarantee enough capacity to meet the potential demands of a mandatory validation programme. In addition, there were logistical challenges posed by the capacity of these laboratories to assess all the technology types in scope of the policy due to a lack of equipment and experience.

49. Option C: Procure an independent laboratory group to conduct the validation work on behalf of DHSC and review of findings by the DHSC.

50. This chosen option allowed for sufficient control over the process; the final decision to sit with DHSC; minimised coordination costs between the Department and the laboratory

group; and to guarantee that the laboratory had sufficient capacity and capability to complete the work on behalf of the department.

51. The principle negative impact here was in relation to the extra time taken to procure the laboratory to conduct the work which has meant a slower implementation of the policy.

Policy objective

52. The overarching objective is to ensure that any test for COVID-19 in the UK, whether provided by the government or by the private sector, meets a minimum standard of performance. This will ensure that people taking a test can rely on the result of that test being sufficiently accurate to inform their behaviour.
    Key indicators of success will be:
    a. Only the results of validated products being reported to PHE.
    b. Awareness of the thresholds and guidance amongst end users, manufacturers and distributors – either a survey or website hits
    c. Rate of take up by test manufactures
    d. Costs recovered from businesses as a result of applications vs. Cost of programme setup

53. In addition to this a sub-objective is to make it easier for those purchasing tests (e.g. for commercial purposes or for employers to test their staff) to have confidence that the test they have chosen is not only good enough but appropriate for the type of testing that they want to do. This will be achieved by publication of lists with the results of validation and providing further guidance on what that test product should be used for.
    Key indicators of success will be:
    a. Increased take-up of testing products provided in the private market due to increased confidence in their quality and improved clarity of guidance
    b. Key target stakeholders being aware the list exists
    c. Minimal feedback from key stakeholders that continue to struggle to identify an appropriate test to use.

Summary and preferred option with description of implementation plan

54. The preferred legislative option (1) will involve 2 Statutory Instruments (SI) laid under the Medicines and Medical Devices Act. Transitional arrangements will be necessary to help manage compliance for products already on the market by ensuring that the requirements come into force in stages. Initially by July 2021 we expect suppliers to be able to begin applications via a Gov.uk site and desktop reviews will begin. The first SI will not be in place until mid-July 2021.

55. The desktop review will allow time for feedback to applicants and re-application after adjustments where relevant. The second SI will be laid in Autumn 2021, this will build on the desktop review with additional laboratory based technical validations of the tests. Mandatory laboratory technical validation processed are expected to begin in late Autumn with outcome reporting following afterwards. There will again be a transition period but the length of this second period is still undergoing policy consideration and will incorporate lessons learned from the experience of the transition for business under the desktop review stage. After this point approvals and disapprovals will be possible and enforceable.

56. The SIs will make it a mandatory requirement for the COVID-19 tests sold on the UK market to pass or be in the process of passing the validation process to ensure that their performance meets minimum standards. The testing and removal of inadequate tests combined with the official approval of adequate tests is expected to reinforce public confidence in quality of testing. This base confidence in the product at the heart of testing can then be leveraged by further government policies to encourage private testing and individual behaviour change on receipt of COVID-19 test results.

57. The first SI will come into force before Summer recess in mid-July at the latest, subject to timing of the parliamentary debate. We recognise the need for time for the industry to comply with these extra requirements and therefore the obligation to have completed the stages of the validation process (application, desktop review, and following the second SI, laboratory review) will be staggered. The initial SI will require an application for validation to be made by 1st September 2021. This will ensure a test product can remain on the UK market (if the product is already available for sale) or permit the test product to be placed on the UK market from the application date onwards. Subsequently a test must have passed the desktop review process of validation before 31st October 2021 to remain on the UK market or before being placed on the market from that date onwards. A transition periods for the second SI are yet to be agreed.

58. DHSC will be the statutory body responsible for the validation process. Digital infrastructure (i.e. application portal) will be owned by DHSC. The application submission and desktop review portions of the validation process will be managed by DHSC. Technical validation services are intended to be contracted to a laboratory, though DHSC retains responsibility for outcome reporting.

59. The stated approach is matched to a tight timescale to meet a programme critical path that coincides with the government's plans to reduce restrictions and strengthen the economy and need for a stronger private market to allow those who wish to access tests to continue to do so as universal provision of free tests from the government for those without symptoms is scaled back.

Monetised and non-monetised costs and benefits of each option (including administrative burden)

Familiarisation and Transition Costs

60. There will be costs associated with familiarising and transitioning into this legislation.

61. Using the existing processes associated with validation as a guide, we have estimated the steps we expect manufacturers, retailers and consumers (business and individual) to undertake as a result of the new regulations, as well as the costs associated with them. These include assessing guidance documents, engaging with government officials, developing and disseminating information across their organisation as well as collating evidence for their application and the application processes. For manufacturers and retailers these have been informed by feedback from stakeholders.

62. At the desktop review stage, it is estimated that familiarisation costs will be between £1,067 and £1,600 per product (£1,333 best estimate). Transition costs are estimated to

be between £267 and £400 per product (£333 best estimate). Aggregating familiarisation costs by the number of products in circulation gives costs between £1.0m and £1.5m (£1.2m best estimate). Aggregating transition costs by the number of products in circulation gives costs between £250,000 and £370,000 (£311,000 best estimate).

63. At the technical review stage, it is estimated that familiarisation costs will be between £1,067 and £1,600 per product (£1,333 best estimate). Transition costs are estimated to be between £267 and £400 per product (£333 best estimate). Aggregating familiarisation costs by the number of tests reaching technical review stage gives costs between £0.2m and £0.4m (£0.4m also best estimate[12]). Aggregating transition costs by the number of tests reaching technical review stage gives costs between £40,000 and £100,000 (£55,000 best estimate).

64. Over both stages of the validation programme, familiarisation costs total between £1.4m and £1.7m (£1.4m also being the best estimate). Over both stages of the validation programme transition costs total between £0.3m and £0.4m (£0.4m also being the best estimate).

65. We will continue to engage with stakeholders as part of Monitoring and Evaluation to ensure we review familiarisation and transition costs in light of unintended costs not recognised.

66. Our assessment is that retailers should have fewer steps associated with familiarisation and transitioning to a new regulatory regime than manufacturers, with smaller costs associated with the overall process as a result. Consultation feedback indicated that purchasing practices for retailers meant stock was only held for a short period before being distributed and sold, making the transition period a sufficient “buffer” for all retailers to turn over stock purchased prior to the announcement of new standards. As such, on the basis of feedback to our consultation we have estimated zero cost to retailers for the SIs.

Annual programme costs

67. The cost of the programme will be passed through directly to manufacturers applying for validation. This cost depends on the number of devices that require validation in a given period and is higher for devices that progress further through the validation process (i.e. devices that progress to technical validation following desktop review).

68. A December 2020 review[8] into the size of the private testing market identified 496 devices in circulation that would be eligible for validation and had been introduced since the start of the pandemic, and a further 204 either still in development or awaiting CE marking. Extrapolating this figure to the present day gives a high-end estimate of 933 devices eligible for validation in the first year.

69. The LVG[1] and TVG[2] validated around 15% of devices presenting for validation, but there are strong grounds to believe that more will pass the process being established under this legislation:

[8] This involved collating data from the National Institute for Health Research Information Observation (NIHRIO) and the Medicines & Healthcare products Regulatory Agency (MHRA).

a. A key part of the LVG/TVG remit was to consider at desktop review the likelihood that a manufacturer would be able to deliver the volume of test devices demanded by government strategy, at a pace set by the development of the pandemic. As a consequence of this, a significant number of devices that were not validated, did not progress past the desktop review stage.
b. The minimum thresholds for sensitivity and specificity set by the LVG for lateral flow devices (i.e. the performance tested at technical review stage) were higher than is being considered under this legislation.

70. As such, we consider only those products that were not removed for commercial reasons as the basis for our central / best estimate pass rate (22%). We use 'corner' assumption about what outcome commercials *would* have seen (had they progressed through the process) to generate high and low assumptions:
    a. the highest possible pass rate assumes that all of the commercial exclusions would have passed both desktop and technical evaluations, giving a pass rate of 49%;
    b. the lowest possible pass rate assumes that all of the commercial exclusions fail either desktop or technical evaluations without affecting the balance *between* those two outcomes (i.e. the share of commercial exclusions failing at desktop vs technical evaluation is the same as for other products that failed one of those two stages). This gives a pass rate of 15%.

71. This effectively sets aside point 69b above: unfortunately there is no information from the TVG processes on which to base an adjustment to reflect this. This biases upwards our fail rate estimates and our estimates of impacts on business.

72. Without there being a central register of test products that would meet the entry criteria, judgements had to be made about the number of products presenting for validation and the proportion progressing through each stage. Best, worst and base numbers were used with direction from experts who have managed the applications of test products undergoing validation for government procurement.

73. Working backwards from this, we assume that in most cases manufacturers will be well-positioned to anticipate the performance of their products at validation and will not expose themselves to needless expense of a product unlikely to pass. In the most likely scenario we therefore assume that 60% of devices on the market will be presented for validation, 13pp[9] of which progress at desktop review and 13pp[9] of which are validated under the technical review. These proportions are all based on the experiences of the TVG.

74. Under the worst-case scenario, we assume that 100% of devices present for validation, 15% of which progress at desktop review and 15% of which are validated in the technical review. Under the best-case scenario we assume that 80% of devices present for validation, 39pp of which progress at desktop review and 39pp[10] of which are validated in the technical review.

75. We will assess data as part of Monitoring and Evaluation to ensure we review pass and failure rates.

[9] Percentage points
[10] Percentage points

76. To redress the tendency of appraisers to be overly optimistic, adjustments have been made to the programme costs. With limited precedent of this type of appraisal, we have used the upper bound for optimism bias estimates (41%) recommended for project outsourcing, detailed in table 4 of the Green Book supplementary guidance[11].

77. On this basis, programme costs will be between £10.7m and £20.1m in year 1, with £10.7m the most likely estimate.[12]

78. Assuming emergence of new strains of COVID and a developing legislative environment restricting the lifespan of a testing kit to 2 years (1/3 years in worst/best cases) implies 50% (100%/33%) of devices will be replaced each year and so need to undergo validation again, giving programme costs in subsequent years between £5.4m and £11.3m, with £5.4m being the most likely estimate.

79. The 10-year NPV[13] for total programme costs is -£52m (-£52m to -£71m)[12].

Annual loss of profits

80. Current regulations require tests obtain a CE marking to be sold on the UK market. This is a self-declared standard for almost all COVID-19 testing products on the market that allows significant latitude for manufacturers to set the contexts in which their products meet those standards (for example of sensitivity and specificity). As such, even products that fail to uphold those standards in independent testing would be unlikely to lose their CE marking (presuming that if control of the testing context reverted to manufacturers, those claims would be demonstrated). As such these products are compliant with the current legislative standard, and so any loss of profit arising from the introduction of a new standard constitutes a direct cost to business, both where products fail to meet that standard and where they are not presented for validation (the latter presumed to be a signal of a manufacturer's expectation that the product would not pass, were it presented). Any recovery of profits resulting from reinvestment in products, or the expansion of supply of products that *do* meet the new standard, is considered indirect (as is the cost of that reinvestment).**Error! Bookmark not defined.**

81. Manufacturers whose devices do not pass the validation process may:
    a. Withdraw the product from the market, forsaking any profits they otherwise expected the product to attract.
    b. Reinvest in the product in order for it to 'pass' validation – reinvestment costs and the resulting recovery of profits are indirect costs and benefits (respectively).

    The TVG process identified reinvestment taking place in only a small minority (1.6%) of cases where products failed validation. Our best estimate assumes that the same proportion of 'failing' manufacturers will reinvest under these SIs, with a high (worst case) assumption of 10% and low (best case) of 0%.

82. While ostensible a positive response, reinvestment is characterised in this analysis as representing a higher cost means to recovering otherwise lost profits than the expansion

[11] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/191507/Optimism_bias.pdf
[12] Because the best-case assumptions assume a high proportion of tests meeting validation standards, they also entail higher volumes of tests *presenting* for validation, and so attract higher programme costs than under the most-likely assumptions
[13] Base year for prices & discounting is 2021

of supply of products that are successfully validated. Those manufacturers who do reinvest in products are assumed to commit 50% of expected profits on average. This follows from an assumption of rationality: reinvestment can be presumed to cost more than £0 and less than the total of expected profit recovery (since no manufacturer could be expected to commit more to recovery than they expected to gain from it) and if the distribution of costs between these two extremes is symmetrical then average will be 50% of expected profits.

83. As suggested above, demand for test kits left unmet by the withdrawal of products failing (or not presented for) validation is very likely to be fulfilled by the expansion of supply of products that do pass validation. The net result, rather than a complete loss of profit, will be a redirection of profit from manufacturers of lower-performing products to manufacturers of higher-performing products. This recovery of profit is an indirect benefit and is described under the benefits section of this IA.

84. There will also be implications for the supply chains associated with tests that are not presented for validation or fail the process. These impacts are difficult to quantify due to complex and globalised nature of diagnostics supply chains and the relationships between suppliers and manufacturers being widely variable. Diagnostics supply chains will also vary according to technology types (e.g. PCR tests require additional steps to account for sample collection and processing often being separated by additional logistics as well as additional processing steps). In some cases, products could be withdrawn from the UK market but continue to be manufactured and sold elsewhere, whilst in others, the test could cease to be manufactured completely. There are a range of implications that could occur as a result, though these will be highly context specific to the manufacturer, situation and suppliers involved.

85. This complexity has supressed consultation responses: those stakeholders who did engage were not able to present any real-world examples on which we could base an assessment of the scale or likelihood of these impacts, and when considering hypothetical scenarios, postulated a very wide range of highly nuanced outcomes.

86. Given the significant complexity and difficulty in obtaining real-world examples of supply chain implications and the scale of analysis that would be needed to accurately monetise these impacts, we have taken the decision that not to monetise this at this stage, but will address in our monitoring and evaluation what market impacts have arisen throughout the supply chain.

87. Analysis from Orion Market Research[14] values the UK's PCR and antigen COVID-19 diagnostic market at £3.7bn in 2021, falling year-on-year to £0.2bn in 2026. Annex 2 details the forecasted annual market value from 2021 to 2026, alongside additional analysis by DHSC to provide an extrapolation of this trend to 2030 and an assessment of profits for the market as a whole. While we could reasonably presume a continuation of market decline between 2026 and 2030, we have assumed a flat progression from 2026 in order to make our analysis more conservative; on this basis our estimates are particularly likely to overstate losses for the period 2026-2030.

[14] UK COVID-19 Diagnostics Market: Analysis Report, Share, Trends and Overview 2021-2027, published 2021-28-04

88. The development of a completely new suite of diagnostics in 2020 in line with their use during the pandemic has seen substantial growth in 2020/2021, however, assessments by Orion Market Research propose that is likely to decrease over time.

89. Their assessments are in line with current widely held assumptions on the impact of the pandemic declining over time, but COVID-19 remaining an endemic disease in the UK. This is likely to involve the overall prevalence of and burden of disease caused by COVID-19 reducing over time due to an increased proportion of the vaccinated individuals and improved treatment options. This view that we cannot eliminate but will learn to live with COVID-19 is shared across government[15] and academic communities[16]. DHSC estimates that there will be an ongoing need for COVID-19 diagnostics, particularly for clinical settings, but that the current population level of testing that is justified for a novel disease is unsustainable in the long term. The growth we have seen in this sector will, in time, present opportunities for many companies to diversify into diagnostics for other conditions or diseases, but this is an area of significant uncertainty.

90. This policy specifically focuses on the private COVID-19 test product market, which is a section of the overall market. The extent of this section of the market depends on future policy framework. A growing role is expected for the private sector in the provision of COVID-19 testing during 2021, subject to policy requirements. Acknowledging this, the profit loss section of this IA considers the overall market to ensure the policy impact is not underestimated.

91. Advice submitted to DHSC's consultation suggested typical profit margins in the diagnostic market of around 20% (10% - 30%) detailed in

[15] https://www.gov.uk/government/speeches/pm-statement-at-coronavirus-press-conference-14-june-2021
[16] https://www.nature.com/articles/d41586-021-00396-2

92. Annex 3 – Stakeholder feedback on profit margins in the UK COVID-19 Diagnostic Market. This gives annual profits of around £372m - £1,120m (£745m best estimate) in 2021, falling year-on-year to £20m-£60m (£40m best estimate) in 2026 as the market shrinks. Annex 2 details the annual profits from 2021 to 2026 based upon Orion Market Research[14] forecasted market value.

93. While our expectation is that subsequent legislation will supersede this programme before it enters a second year, there is no end date specified in legislation itself. Therefore, in alignment with RPC appraisal period guidance[5], we cannot, at this point in time, justify moving away from the standard 10-year appraisal period.

94. With Orion Market Research[14] forecasting to 2026, this IA then extrapolates from 2026 to show 10-year business and market impacts with acknowledgement that these figures are highly speculative.

95. Taking the failure and withdrawal assumptions outlined in paragraph 74 gives profit losses of £226m - £953m (£647m best estimate) in 2021, falling year-on-year to £12m-£51m (£35m best estimate) in 2026.

96. The 10-year NPV[13] for profit losses is -£0.5bn to -£2.3bn (-£1.6bn best estimate).

97. With firms withdrawing from the market, it is also important to consider the impact on market power and supply of products.

98. Taking an extremely conservative 496 as the number of devices presenting for validation (those identified in a December 2020 review to be eligible for validation at the time) and applying a worst-case 15% validation rate, there would still remain 60 products in the market. So, even in a worst-case scenario, the market would not be sufficiently concentrated to generate serious competition concerns. Therefore, we have no reason to believe consumers would face a rise in the price of private COVID-19 tests through concentrated market power.

99. Advice from industry suggests that sunk costs represent a substantial part of the overall cost of test products: marginal costs of producing kits themselves are very low; therefore the expansion of one supplier's business to accommodate the contraction of another's is probable and could reduce average costs overall, even where the expanding business is delivering a higher quality product.

Price rise on consumers

100. Whilst not monetised in this IA, it is important to consider the impact on consumers of recovering the costs of the programme from business, where in particular validation costs may be passed on to consumers in the form of increased prices of tests. It is unclear how far an increase in the price of tests might lead to a contraction in demand from consumers, and the degree to which this could be offset by an expansion relating to improved quality (and consumer confidence).

101. The extent of both these effects depends on how much of the programme cost (and the cost of any reinvestment) is passed on to consumers, as well as the price elasticity demand for private COVID-19 tests.

102. Therefore, onward impacts on the likelihood of breaking chains of transmission, prevalence, hospitalisations, deaths and restrictions are challenging to analyse.

103. Price rises will still place an additional burden on consumers, particularly those from lower socio-economic backgrounds where the private test market becomes disproportionately more unaffordable.

104. However, adding a worst-case £20m of programme costs into a £3.7bn market (year 1) and assuming this is passed onto consumers suggests prices rise by around 0.5%.

105. Additionally, greater regulatory control via this policy could protect vulnerable people who may be less able to defend themselves from unscrupulous sellers, particularly if a low/high quality market emerges with no or little control.

106. In the absence of this proposed legislation it is likely there would be inequality in the access to better performing tests on the private market.

107. An Equalities Impact Assessment has been conducted alongside this IA to capture distributional and equality impacts of the proposed policy.

108. We will assess market data as part of Monitoring and Evaluation to ensure we review whether this regulation does in fact change prices of tests on the private market.

Total costs

109. Across programme costs and profit loss, plus familiarisation and transition costs the direct policy NPV[13] totals -£0.6bn to -£2.4bn (-£1.6bn best estimate).

Profit gain (indirect) benefit

110. Data from TVG suggests 2% of products enter the validation process a second time after being unsuccessful. It is anticipated that these cases will have reinvested in their product in order to meet validation requirements. There is no independent data on the amount that businesses will reinvest in their product. Further, stakeholders are unable to foresee the outcome of their product in the validation programme and therefore have not been able to provide a cost for this upon consultation.

111. This results in a situation where reinvesting firms recover lost profit at a cost of reinvestment. Demand for test kits left unmet by the withdrawal of products failing validation, or those not presented for validation, is very likely to be fulfilled by the expansion of supply of products that do pass validation. The net result, rather than a complete loss of profit, will be a redirection of profit from manufacturers of lower-performing products to manufacturers of higher-performing products.

112. Following RPC published guidance on direct and indirect impacts**Error! Bookmark not defined.**, this recovery of profit is considered as indirect so is included in Present Value calculations but not the Equivalent Annual Net Direct Cost to Business (EANDCB).

Performance benefits

113. The exclusion from the market of lower performing devices by definition improves average performance. Specifically, this will:
    a. Reduce the number of false positive results / increase the number of true negative results for individuals not carrying COVID-19 at the point of testing.
        i. By removing constraints on social/economic engagement (i.e. removing the need to self-isolate), reducing false positives will increase the productivity and wellbeing of test participants.
        ii. It will also reduce cost pressures on the test and trace system, and the need for contacts to self-isolate (therefore also improving their productivity and wellbeing).
    b. Reduce the number of false negative results / increase the number of true positive results for individuals who are carrying COVID-19 at the point of testing.
        i. By correctly identifying more individuals who are carrying COVID-19, this will reduce the spread of the virus through self-isolation and contact-tracing of carriers, which by reducing onward infections improves wellbeing, long-term health, mortality and social and economic participation of prevented onward infections.
        ii. This will also marginally reduce the likelihood of future disruption to business resulting from high prevalence of the virus and marginally slow the emergence of new strains of the virus.

114. While nascent models exist to describe the r-reduction implications of improved test performance, attempts to monetise these effects have so far been extremely limited and are highly dependent on input assumptions around factors like current virus prevalence and the demographics of the test participants. As such, we describe these effects in qualitative terms only.

115. In order to quantify (with a view to monetising) these effects we would need:
    a. A clear view of the distribution of standards of tests in use in a counterfactual world – we can reasonably expect to build a picture of tests presenting for validation through the implementation of the first SI, but have no access to this information at present
    b. An assessment in the resulting improvement in average sensitivity and specificity
    c. An assessment of the use cases in which each of those different types of tests is deployed, consumers' behavioural response particularly in terms of isolation, contact reporting and contact isolation
    d. Assumptions about the future prevalence and infectiousness of dominant strains of COVID-19 and coverage and resistance imparted by vaccines (and consequent health implications for individuals who contract COVID)
    e. Assumptions about the policy response in the counterfactual in
    f. Access to a cost-benefit framework robustly to evaluate these impacts
    g. Access to an epidemiological model to identify likely caseloads on the basis of those input assessments and assumptions

116. The construction of an epidemiological model is a months-long endeavour requiring the attention of teams of data scientists at costs beyond what is considered proportionate for this IA, and given uncertainty around the input assumptions (to which it would be highly sensitive) would be unlikely to deliver confidence around central predictions of

the impact of this legislation. For this reason, we are also unable to consider the break-even point, at which the returns from this legislation could be expected to outweigh its costs.

117. Further qualitative benefits centre on overcoming information asymmetry and instilling public confidence in privately available tests and subsequent behaviours associated with this. No matter how a test is provided to an individual, through government led or private provision, it is necessary that the public have (well-founded) confidence in the tests they are using.

118. During the consultation, we found that many stakeholders also commented on the benefits in making the market more equitable for manufacturers. That is by ensuring strong performing products were not undercut by lower performing products purporting high or equally high performance.

119. The benefits outlined here are contingent on the behaviour of individuals. Testing must be accompanied by the following of government guidelines, but with compliance with self-isolation requirements as measured by the ONS currently standing at 92%[17] it is not unreasonable to assume that this will remain high.

120. The lack of a mechanism to enforce minimum standards for testing products, or ensure that manufacturers' claims are delivered in live environments, risks undermining consumer confidence in COVID-19 tests and supressing use of the technology, either disengaging from social and economic activity or engaging on an 'at risk' basis. Poorer average test quality will result in more false negative results (increasing onward transmission and the likelihood of future lockdowns and the emergence of new variants) and more false positive results (increasing unnecessary self-isolation).

121. We will assess data on test performance as part of Monitoring and Evaluation to capture the impact of this regulation on test standards.

Potential implications for innovation and trade

122. A key theme drawn from the public consultation was that respondents had concerns about the potential impacts upon innovation in COVID-19 diagnostics. However, the scope of the legislation intentionally covers existing mature technology (antigen and molecular detection tests), and therefore we have assessed that the risk that this regulation will present a barrier to innovation is limited. Wholly novel technologies that do not use these processes are not in scope of these regulations, though could use the Target Product Profiles as a baseline to align to. Taken together, we do not anticipate that these regulations serve as a significant barrier to innovative new COVID-19 test technology, improved tests using existing technologies or existing antibody tests which obtain CE marking and seek to enter the UK market.

123. The regulations have also been framed to provide clear standards for those wishing to innovate on or improve existing antigen and molecular detection technologies, ensuring current and future tests of these types are of high quality.

[17] Coronavirus and self-isolation after being in contact with a positive case in England, extracted from www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/coronavirusandselfisolationafterbeingincontactwithapositivecaseinengland/latest on 2021-05-19

124. The measures outlined in this IA will apply equally to both foreign and domestic products/manufacturers, with no expectation of a disproportionate impact on either. This would constitute a technical barrier to trade to businesses outside of the UK, which represent the majority of the market, with only a small number of UK based firms. Officials at the World Trade Organisation and Department for International Trade have been notified of these measures and the implications for international businesses.

125. Assessments of the importation of COVID-19 tests (or where not directly available Medical Devices and Clinical Consumables as a category that would include COVID-19 diagnostics) into the UK has shown that the majority of these devices will enter the UK via the channel ports for goods from the EU, or through air freight into England for goods from the Rest of the World. These represent the most common routes for these products given the timelines for delivery and their origin. We do not anticipate changes to these trade flows as a result of these regulations but will assess this as part of the monitoring and evaluation of these regulations.

126. Our consultation[18] has been unable conclusively to establish the proportion of test manufacturers based in the UK vs based abroad, with estimates of the UK base ranging from 8% to 80% by market revenue. In practice, the geographical base of test manufacturers does not affect our estimate of the impact of the legislation, simply whether those impacts are attributed to UK manufacturers (in which case they will feature in the EANDCB) or non-UK manufacturers (in which case they will arise as trade impacts). As such, we have treated all losses and benefits as if arising to UK-based manufacturers, and so are likely to have overstated the EANDCB (which captures the costs of this legislation [programme costs and loss of profits] but not its benefits [profit recovery]) and understated the impacts on trade (which would have captured programme costs but where profit impacts would have been more muted, given they would cover both losses and recovery).

127. We will assess data on trade flows as part of Monitoring and Evaluation to understand any unanticipated impact on trade.

Enforcement

128. This legislation will use the existing enforcement mechanism for medical devices. In practice, this will involve a combination of intelligence led enforcement by the MHRA, focused on the manufacturers of non-compliant test products, while work by Local Authority Trading Standards units will focus on retailers, and will ensure unvalidated tests are not on shop shelves. These enforcement process will use existing regulatory powers and pathways already in place and will primarily focus on activities that involve non-compliant devices. Officials in the respective agencies declined to provide additional costing for enforcement activity that will be undertaken by MHRA or Trading Standards as part of the course of their business on the basis that these can be absorbed by existing budgets. In principle the introduction of the proposed requirements for test products means that there is likely to be an increase in activity, with implications for resources within these organisations; in practice, the judgement of those

[18] Including stakeholder engagement, assessment of location of product development in the December 2020 review and Orion market research

organisations is that the “true” impact of this is (close to) £0.

129. There will be no costs to businesses in terms of preparing for investigations: in principle these only happen where there are instances of non-compliant or counterfeit devices are reported. Following feedback from MHRA, their assessment is that the risk of investigations involving companies with compliant devices and disruption to businesses as a result, is very low (partly as a consequence of initial intelligence-gathering exercises by MHRA) with estimated associated activity likely to involve a small quantity of administration in the few instances (c1%[19]) in which this may occur. The investigations they have undertaken for COVID-19 tests have only involved non-complaint devices, with no disturbance to businesses with compliant devices on that basis.

130. There may be costs associated with investigations including administration costs related to correspondence with agencies undertaking investigatory or enforcement actions, the physical seizure of non-compliant devices, requirements to take down or alter marketing materials or in certain instances the removal of certain non-compliant products from sale. The costs associated with these activities have not been monetised due to the complex and context specific nature of each enforcement, but all investigations made are subject to assessment, risk assessment and a consideration of health and product safety at their core.

131. We will assess data on MHRA investigations as part of Monitoring and Evaluation to keep review whether any compliant business faces enforcement costs.

Education

132. Manufacturers and third parties will need educating about this policy as retailers will be liable if found selling tests that have not passed independent validation once the transition period ends in 2021.

133. We will be contacting key stakeholders in advance to help disseminate knowledge of the policy and regulations across the system, as well as gain support for the new policy. In addition, we will work closely with key stakeholders to ensure they support us privately but also make public comment to highlight the benefits of this new policy for consumers specifically.

134. As the secondary legislation is laid in the House and through its passage DHSC press office will produce a Gov.uk press notice to be issued to all national media alongside any potential Written Ministerial Statement or laying in the House of Commons Library. This will also include publication of the consultation response and new regulations on Gov.uk.

135. Alongside published products, DHSC communications officials will work with supportive consumer journalists and digital colleagues to ensure digital content is created to highlight the benefits of this to consumers who will want to understand which testing products have been validated. A full communications handling plan has been developed outlining handling in further detail, with a total cost of £13,000.

[19] This figure relates o MHRA activities not relating to COVID-19 test devices; activities in relation to COVID-19 test devices have all been in relation to non-compliant devices

Direct costs and benefits to business calculations

136. As discussed above

Risks and assumptions

137. As discussed above

Impact on small and micro businesses

138. The policy intent is to impose a minimum floor for COVID-19 testing in order to maintain public confidence in tests and compliance with their role in government strategy to control the prevalence of COVID-19. Exemption of any size of manufacturer would undermine the policy objective and so has not been considered for SMBs. The Private COVID-19 Testing Validation Consultation which ran from 8th April 2021 to 5th May 2021 has provided feedback that has prompted consideration of a reduced charge for small and medium enterprises for the programme of work.

139. Analysis of the ONS' UK Business Workbook[20] suggests that:
    a. 93% of businesses involved in the manufacture of basic pharmaceutical products are micro[21] or small[22] (76% and 17% respectively)
    b. 85% of businesses involved in the manufacture of pharmaceutical preparations are micro or small (68% and 16% respectively)
    c. 95% of businesses involved in the wholesale of pharmaceutical goods are micro or small (72% and 24% respectively)
    d. Across all three groups, 94% of businesses are micro or small (71% and 22% respectively)
    e. Across all businesses, 99% of businesses are micro or small (90% and 10% respectively)

140. On this basis, businesses affected by this legislation are 5% less likely to be SMBs than businesses overall. Further, SMBs affected are disproportionately likely to be small than micro.

141. During the public consultation, small and micro businesses and trade associations highlighted that a high fee could present a barrier for SMEs entering the market. For the purposes of the first stage (desktop validation) there is an adjustment in fees to account for the differential impact on small and micro businesses. Where a company meets the definition of a small or medium-sized enterprise (under 250 employees) this represents a reduction of 55% for the fees associated with this stage. At present the fee schedule for the second laboratory validation stage (to follow through an additional SI in Autumn 2021) has not been finalised, but will feature a similar proportional reduction (assumed also to be 55% for the purpose of this IA) for small or medium-sized enterprises.

142. In real terms, this reduces the per-product cost for both stages from £25,000 to £11,000. The response we have had from engagement with small and medium sized enterprise with regards to this pricing adjustment has been very positive in terms of mitigating any disproportionate impacts that the cost of validation could have on SMEs.

[20] www.ons.gov.uk/businessindustryandtrade/business/activitysizeandlocation/datasets/ukbusinessactivitysizeandlocation
[21] 0-9 employees
[22] 10-99 employees

143. Taking an average number of products per business of 1 for SMEs and 3 for larger entities,[23] and assuming that employee numbers are commensurate with revenues, validation fees represent around 7% of 2021's revenues from COVID-19 test products[14] for a micro business, 0.6% of revenues for a small business and around 0.2% for a medium or large entity. The reduction in fees takes this down to 3.3% for micro businesses and 0.3% for small businesses, at a cost to government of around 46% of programme costs (NPV £43.8m over the appraisal period). Achieving parity between micro, small and other businesses would require a 98%/74% subsidy of programme costs for micro/small businesses (respectively) at a cost to government of 77% of programme costs (NPV £73.3m).

Monitoring and Evaluation

144. Introducing a regulatory regime is a strong intervention to the market, it is required to address the public health priority caused by the COVID-19 pandemic. We recognise the fast-paced approach to regulation we are taking is unique as is the underlining cause of this particular market failure. However, we also recognise that the policy the market conditions may evolve rapidly. As such we intend to keep the regulatory regime under continuous review and engage with stakeholders to ensure its efficiency and effectiveness.

145. Though this regulatory regime is focused on COVID-19 related tests, COVID-19 will not be the last pandemic or other serious public health issue that requires rapid market intervention. As such it will be important to retain the learning from this regime functioning to apply to future regimes.

146. To this end we have committed in the regulation itself to formally evaluate the regulatory regime set out in the first SI in a report published no later than 31 December 2022. This evaluation will then be published in a report for parliament. Given the drastic change in the market should occur relatively quickly the outcomes of the intervention should also become apparent more quickly. As such our current planning is look to review in May 2022 particularly as we are aware international partners will be bringing in their own regulations at this time they will provide useful counterpoints to assess the effectiveness of our approach.

147. To assess the ex post costs and benefits of the policy in an evaluation, there are certain impacts we would want to monitor in order to be robust in this assessment. The main themes to this evaluation will be supply; test performance; affordability; wider impacts; enforcement; and unintended consequences:
    a. Supply – to understand how the number of products in the market is impacted by the policy we will monitor the number of products applying for validation compared to what we expect; as well as engaging with stakeholders to review whether familiarisation and transition costs in this IA remain accurate. Furthermore, we will monitor the number of products passing and failing at each stage and for what reason, as well as the number that reapply.
    b. Test performance – to understand the impact on test performance we will compare the difference in performance of tests on the UK market before and after the policy comes into force. This will provide evidence to assess whether this regulation is effective in achieving the policy objective.

[23] Based on consultation responses and market research.

c. Affordability – carrying out market research will allow us to better understand the impact of the policy on affordability by monitoring changes in unit cost of producing tests and any corresponding price rises on consumers.
d. Wider impacts – engage with the both the upstream and downstream supply chain to recognise the impact of the policy on raw material providers, distributors and retailers. Additionally, compare the nationality of products in the market compared to our current assessment to understand the impact on trade flows.
e. Enforcement – monitor the number of investigations carried out by MHRA and the outcome, to ensure we are not imposing unnecessary burden to compliant business.
f. Unintended consequences – we will also engage with stakeholders to understand any unintended consequences of the policy that haven't been anticipated in this impact assessment.

Annex 1 – Programme costs (option 1)

	Best	Worst	Likely
Tests in circulation	933	933	933
Apply for validation	746	933	560
Pass to technical	368	139	124
Digital Infrastructure	£0.9m	£0.9m	£0.9m
Laboratory Capability	£5.5m	£4.3m	£4.3m
Samples Provision	£13.8m	£5.5m	£5.0m
Resources	£1.4m	£1.4m	£1.4m
Sub Total	£21.7m	£12.2m	£11.6m
VAT + commission	£4.6m	£2.6m	£2.5m
Grand Total (incl. VAT)	£26.3m	£14.8m	£14.1m
Unit charge	£35,000	£16,000	£25,000

Annex 2 – Annual UK COVID-19 diagnostic market valuation, profits and loss of profits (option 1).

Year	Market valuation	Profits			Loss of profits		
		Best	Worst	Likely	Best	Worst	Likely
2021	£3.7bn	£372m	£1,117m	£745m	£226m	£953m	£647m
2022	£2.2bn	£223m	£670m	£446m	£136m	£571m	£388m
2023	£1.4bn	£137m	£410m	£273m	£83m	£350m	£237m
2024	£0.8bn	£75m	£225m	£150m	£46m	£192m	£130m
2025	£0.4bn	£40m	£120m	£80m	£24m	£103m	£70m
2026	£0.2bn	£20m	£60m	£40m	£12m	£51m	£35m
2027	£0.2bn	£20m	£60m	£40m	£12m	£51m	£35m
2028	£0.2bn	£20m	£60m	£40m	£12m	£51m	£35m
2029	£0.2bn	£20m	£60m	£40m	£12m	£51m	£35m
2030	£0.2bn	£20m	£60m	£40m	£12m	£51m	£35m
Average annual		**£95m**	**£284m**	**£189m**	**£58m**	**£242m**	**£165m**
NPV		**£0.9bn**	**£2.7bn**	**£1.8bn**	**£0.5bn**	**£2.3bn**	**£1.6bn**

Annex 3 – Stakeholder feedback on profit margins in the UK COVID-19 Diagnostic Market (anonymised due to commercial sensitivity)

Stakeholder	Profit Margin
Stakeholder 1	20%
Stakeholder 2	20%
Stakeholder 3	30+%
Stakeholder 4	10%-25%
Stakeholder 5	11%