Validating COVID-19 tests in the private market

Lead department	Department of Health and Social Care
Summary of measure	Mandatory validation requirements for COVID-19 test devices for sale in the private market.
Submission type	Impact assessment (IA) – 26 October 2021
Legislation type	Secondary legislation
Implementation date	2021
Policy stage	Final
RPC reference	RPC-DHSC-5073(2)
Opinion type	Formal
Date of issue	07 December 2021

RPC opinion

Rating[1]	RPC opinion
Fit for purpose	The Department first published an IA on 20 July 2021, on which the RPC issued and published an opinion[2] which was rated as not fit for purpose based on the calculation of the equivalent annual net direct cost to business (EANDCB). The first stage (desktop validation) of the measure was introduced in legislation on 28 July 2021. The Department has now submitted the next iteration of the IA in anticipation of the passage of legislation to introduce the second stage (laboratory validation) of the measure. The IA provides a clear rationale for intervention. It is well researched and draws upon a range of sources, such as consultations and commissioned research, to inform the assumptions used in the cost-benefit analysis. However, the IA may contextualise the analysis further by illustrating the acceptable levels for producing false results and how this compares to government-procured devices or other forms of available testing. The IA apportions the impacts to non-UK businesses and correctly excludes these from the calculation of the equivalent annual net cost to business and net present value. The IA could have provided more on any insights from the implementation of the first stage earlier this year.

[1] The RPC opinion rating is based only on the robustness of the EANDCB and quality of the SaMBA, as set out in the Better Regulation Framework. The RPC rating is fit for purpose or not fit for purpose.
[2] The RPC opinion on DHSC's Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 can be found here.

Business impact target assessment

	Department assessment	RPC validated
Classification	Qualifying provision	Qualifying regulatory provision - IN
EANDCB	£56.7 million[3]	£56.7 million *(2019 prices, 2020 pv)*
Business impact target (BIT) score	£283.7 million	£283.5 million
Business net present value	-£23.3 million	
Overall net present value	-£50.0 million	

[3] In the previous the iteration of the IA, the Department's initial estimate for the EANDCB was £159.1 million, however, the RPC was unable to validate this figure.

RPC summary

Category	Quality	RPC comments
EANDCB	**Green**	The EANDCB calculation is fit for purpose. The IA monetises the direct costs to business including familiarisation and transition costs, programme costs and profit losses.
Small and micro business assessment (SaMBA)	**Green**	The IA explains why it is not possible to exempt small and micro businesses (SMBs) and notes and explains the use of the 55 per cent reduction of fees as a mitigation for SMBs.
Rationale and options	**Good**	The IA identifies research to support the need for government intervention and provides evidence of public support for validation beyond the CE marking. The IA discusses a range of options including voluntary validation; however, on these, the IA explains why they are discounted for further appraisal.
Cost-benefit analysis	**Good**	The IA clearly sets out the data and evidence used in the analysis; this has helped to inform the assumptions used in the analysis. The IA considers the indirect impacts on the measure, such as the benefits of businesses picking up profits from devices withdrawn from the market.
Wider impacts	**Satisfactory**	The IA considers the measure's impact on innovation, non-UK business and trade as well as the UK internal market. The IA also uses research into international comparators to analyse any competition impacts. However, this could be improved by considering how the measure may remove anti-competitive distortions that result from price competition where the quality of devices varies. The IA may also consider the measure's wider impacts on industries such as travel.
Monitoring and evaluation plan	**Weak**	The IA explains that the first stage of regulations will be formally evaluated no later than 31 December 2022. The IA should confirm whether similar commitments will be made for the second stage. The IA outlines the themes that will be evaluated and how these will be monitored but it could more to relate these to the IA's key success indicators.

Summary of measure

The measure introduces a mandatory validation requirement for COVID-19 test devices that are to be sold in the private market in order to maintain public confidence and reduce the incidence of incorrect test results. The IA explains that the current demand for testing in the UK has been met by free government provision. The role of private market testing is expected to grow, with additional demand for private sector supplied tests in the media, creative industries, sport and travel sectors. At present, such devices are controlled by CE marking, which is a self-declaration process.

The measure requires that, in addition to CE marking, antigen and molecular detection tests for COVID-19 are approved by the government and meet a minimum standard of performance prior to being sold. The approval would be based on independent validation by the UK Health Security Agency (UKHSA) of self-certified performance of these products.

The IA explains that the measure is being enacted through two separate statutory instruments: the first validates performance claims through a desktop process and came into force on 28 July 2021; and the second, for products successful at the first stage, validation through independent laboratory testing, is planned to be brought forward in late 2021.

The Department previously submitted the first iteration of the IA in July 2021 for RPC scrutiny. This was rated as not fit for purpose as the RPC was unable to validate the EANDCB. The RPC commends the Department for addressing the comments raised in that opinion in this IA.

The Department anticipates the measure to have an overall net present value (NPV) of -£50 million over a 10-year appraisal period. The monetised costs include familiarisation and transition costs for manufacturers and retailers, programme costs, loss of profits and costs to government to partly subsidise the costs paid by SMBs for validation. The monetised benefits include gained profits of well-performing products and profit recovery from re-investment.

EANDCB

The Department's EANDCB is fit for purpose. It is based on familiarisation and transition costs to manufacturers and retailers, costs of the validation programme and the profit losses of devices withdrawn from the market. The IA apportions the costs to UK-based businesses based on market research, which indicates that 33 per cent of test volumes were manufactured by UK-based businesses. Costs to non-UK businesses are correctly omitted from the calculation of the EANDCB and NPV. The IA uses the project market valuation, profit margins and the expected pass and failure rates of devices to calculate the UK-based profit loss associated with those devices withdrawn from the market as a consequence of the measure.

The Department should clarify any labelling requirements necessary for the measure and if so, provide details of the impacts.

SaMBA

The IA bases their assessment on businesses with fewer than 100 employees, explains why these businesses are not exempt from the measure and provides an overview of the large proportion (94 per cent) involved in the manufacture and wholesale supply of pharmaceutical goods and preparations. The IA uses consultation results that indicate the measure's costs are considered a barrier by small and medium-sized enterprises (SMEs); it therefore proposes to mitigate the burden on these businesses. The IA describes, as consideration of mitigation, an adjustment in fees for SMEs representing a 55 percent reduction in the fees at both validation stages. The IA confirms that engagement with SMEs has proven positive for this action.

The IA could have benefitted from providing data from the implementation of the first stage to indicate how many of the 146 devices that have applied for validation to-date have benefited from the reduction in fees for SMEs.

Rationale and options

The IA clearly identifies the rationale for intervention, outlining the current CE marking system and citing the need to address the persistent information asymmetry problem. This is supported with evidence from two rounds of consultations, which shows public support for the measure. The IA discusses three alternatives to the preferred option: voluntary validation, third party conformity assessment and government monopoly. However, these are discounted for further appraisal.

Cost-benefit analysis

The IA clearly sets out the evidence, data and the methodology used in the analysis.

The RPC commends the Department for using a range of evidence and data including consultations and a call for evidence, market research on the UK COVID-19 diagnostic market and commissioned research conducted by the Universities of Cambridge and Sussex. These support the assumptions used in the cost-benefit analysis.

The IA tests the sensitivity of the analysis to the assumptions by constructing low and high scenarios. This includes the annual churn of products needed due to the risk that new COVID-19 variants and mutations render older tests obsolete or they are replaced by more innovative tests. Further sensitivity analysis could be conducted on important variables such as the proportion of products that enter for validation a second time and those firms that reinvest 50 per cent of expected profits on average to ensure that products pass validation.

The IA identifies several indirect impacts of the measure. These include indirect benefits when better-performing products pick up lost profit from withdrawn products as well as profit recovery as a consequence of reinvestment. The IA also provides an assessment of the performance benefits such as reducing the number of inaccurate results; however, these are not monetised.

As the validation costs are passed on to manufacturers and are correctly included in the EANDCB, the IA also considers the enforcement costs to the public sector, noting that there is no difference in the approach to online and high street retailers, based on engagement with two stakeholders. The IA monetises the average cost of an investigation and assumes a reducing profile of annual investigations based on the shrinking market valuation of the COVID-19 diagnostic market, based on the results of the commissioned research. The IA also notes the assumption of the COVID-19 pandemic declining over time but remaining an endemic disease in the UK.

Wider impacts

The IA considers the impacts of the measure on innovation, non-UK business and trade.

It asserts that the risk of the measure providing a barrier to innovation is limited, because the scope of the legislation covers existing mature technology (antigen and molecular detection tests).

Based on test volumes, the IA estimates that two thirds of the UK COVID-19 diagnostic market is currently supplied by non-UK based firms, notably via imports from China, the USA and Germany. The IA notes that although “the regulation would constitute a technical barrier to trade”, these firms are not disproportionately affected as the regulations would apply equally to UK and non-UK based firms. Using the same methodology, the IA calculates the total net present value of costs to non-UK businesses to be -£1.1 billion; however, this is correctly excluded from the EANDCB and overall NPV. Although the IA notes difficulties in fully assessing the impacts on trade due to the multiple factors affecting trade in devices, the RPC commends the Department for including trade flows as part of its monitoring and evaluation plan.

The IA highlights the findings of a research project that provides insights into the impact of regulation on competition in the COVID-19 test device market, exploring four international comparators with pre-market authorisation. It concludes that the measure would still support a significant degree of competition. Although presenting a worst-case scenario where 10 products remain (as a result of a 15 per cent validation rate), the IA could interrogate further the impacts that would arise if the measure indirectly reduced the number or range of suppliers but also how this may remove anti-competitive distortions arising from price competition where the quality

of testing devices varies.[4] The IA may also consider the measure's wider impacts on industries such as travel and venues, from which a significant increase in private market testing has been derived or may benefit from better-performing tests.

Monitoring and evaluation plan

The IA notes the statutory commitment to evaluate the regulatory regime noted in the SI for the implementation of the first stage no later than 31 December 2022. The Department should clarify if a similar commitment will be made for the second stage. Ahead of this, the Department also plans to review the regulations in May 2022 to assess the effectiveness of the UK's approach as further international comparators emerge.

The IA also considers the evaluation themes - such as supply, test performance and affordability - and outlines the qualitative and quantitative methods by which they will be monitored. The RPC commends the commitment to monitor areas such as test performance, trade flows and supply chains, and to compare the results with estimates made in this IA. However, the Department should include further detail on the frequency of the data collection and how these relate to the policy objective and key success indicators outlined in paragraphs 79 to 82.

Regulatory Policy Committee

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[44] Further guidance is available in the *RPC case histories guidance on competition assessments* here.