# Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021

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| **Lead department** | Department of Health and Social Care |
| **Summary of proposal** | To introduce a mandatory validation requirement for Coronavirus test devices for sale in the private market |
| **Submission type** | Impact assessment (IA) – 25 May 2021 |
| **Legislation type** | Secondary legislation |
| **Implementation date** | July 2021 |
| **Policy stage** | Final |
| **RPC reference** | RPC-DHSC-5073(1) |
| **Opinion type** | Formal |
| **Date of issue** | 12 July 2021 |

## RPC opinion

| **Rating**[1] | **RPC opinion** |
|---|---|
| **Not fit for purpose** | After the Department's response to the RPC's initial review notice, the RPC still considers the calculation of the EANDCB not to be fit for purpose. This is due to the lack of evidence supporting some assumptions that are important in quantifying the EANDCB figure, such as the size of the import market of Coronavirus test devices and for the quantification of familiarisation and transition costs. |

## Business impact target assessment

| | **Department assessment** | **RPC validated** |
|---|---|---|
| **Classification** | Qualifying regulatory provision | Qualifying regulatory provision |
| **Equivalent annual net direct cost to business (EANDCB)** | £268.1 million (initial IA estimate)<br>£169.1 million (final IA estimate) | Unable to validate at this stage |
| **Business impact target (BIT) score** | £845.5 million | |
| **Business net present value** | -£59.7 million | |
| **Overall net present value** | -£99.3 million | |

[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'.

# RPC summary

| Category | Quality | RPC comments |
|---|---|---|
| EANDCB | **Red** | The RPC does not consider the assumption that all manufacturers of Coronavirus test devices are UK-based to be realistic and is, therefore, unable to validate the EANDCB figure as submitted. The assumption must be supported with data. The IA must also be improved through further explanation of how the familiarisation and transition costs of the proposal have been calculated. |
| Small and micro business assessment (SaMBA) | **Green** | The revised IA provides some explanation for why it would not be appropriate to exempt small and micro businesses (SMBs) and explains there will be mitigation in the form of an "*adjustment in fees*". However, the IA should explain how a reduction of 55 per cent of fees has been determined to be the most appropriate amount of mitigation. |
| Rationale and options | **Satisfactory** | 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 should explore further the incentives to participate in the voluntary option and consider whether it could be enhanced by government action. |
| Cost-benefit analysis | **Weak** | The revised IA discusses the information needed to quantify the benefits of the proposal to society and states that the construction of an epidemiological model required to interpret such information is not proportionate in this case. The IA should include evidence to support the assumption on the proportion of profit that is re-invested and discussion on the increase in accuracy of Coronavirus tests likely to occur as a result of the proposal. |
| Wider impacts | **Weak** | The revised IA considers the impact of the proposal on innovation and trade. It should be improved through providing information on the proportion of Coronavirus test devices that are imported into the UK and by discussing whether the proposal could have an impact on this figure. The IA would benefit from further discussion on the competition impacts as well as the acceptability of results for travellers' purposes. |
| Monitoring and evaluation plan | **Satisfactory** | The IA explains that the regulations will be formally evaluated no later than 31 December 2022 and details the impacts that will be monitored. |

# Response to initial review

As originally submitted, the IA was not fit for purpose, relating primarily to the EANDCB calculation but also with respect to the SaMBA.

The RPC's initial review identified the following issues with the original IA:

- It did not justify why costs associated with providing evidence for the validation programme, transition costs and familiarisation costs were not monetised.
- It did not consider whether part of the profit currently being earned through the sale of Coronavirus test devices is as a result of non-compliant activity with existing CE regulation.
- It did not appear to support its assertions on the pass rate of tests with evidence, nor justify why the central estimate is the most realistic.
- Further justification was needed to support the use of the 20 per cent profit margin for manufacturers.
- It did not consider the costs to businesses of preparing for, or complying with, inspections.
- Further consideration was needed on the implications of liability for retailers who sell test devices that have not passed independent validation.
- It did not explain how possible burdens on SMBs could be mitigated or discuss the possibility of disproportionate burdens from familiarisation costs due to most of the test market comprising of SMBs.

The Department has improved the IA through monetising the familiarisation and transition costs of the proposal, and by providing consideration for both profits earned through non-compliant activity and the costs to businesses in complying with inspections. The revised IA also now describes an "adjustment in fees" to mitigate the burden of the policy on small and medium enterprises (SMEs). However, while these points are discussed in further detail in the EANDCB and SaMBA sections below, the RPC is still unable to validate the EANDCB figure.

The revised IA also shows a decrease of approximately £100 million in the EANDCB figure when compared to the original submission. This adjustment appears to be as a result of a reassessment of the Coronavirus test device market size over the appraisal period. The IA assumes that vaccination will reduce demand for tests. This assumption would benefit from further support. In summary, the substantial reassessment demonstrates the high sensitivity of the proposal's EANDCB estimate.

In addition to the red-rated points in the initial review notice, the RPC identified other areas for improvement. The revised IA has addressed some of these sufficiently, but other areas still require improvement, as noted below.

# Summary of proposal

The proposal is to introduce a mandatory validation requirement for Coronavirus test devices to be sold in the private market. The IA explains that currently Coronavirus

test products sold in the private market are controlled by CE marking, which is a self-declaration process.

The proposed policy would require that, in addition to the CE marking, antigen and molecular detection tests for Coronavirus be approved by government prior to being sold in the private market. The approval would be based on independent validation of the self-certified performance of these products, undertaken by government-approved laboratories. The IA explains that the 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.

The policy is designed to ensure that products to be sold on the UK market meet a minimum standard as used in the NHS, in order to maintain public confidence in testing and reduce the incidence of incorrect test results. Products that do not receive validation will not be licensed for sale in the UK.

**Summary of impacts**
The impacts of the proposal include direct impacts on business associated with the validation programme, transition costs, familiarisation costs and loss in profit for the manufacturers. The IA also includes the indirect impact on some businesses that benefit from others leaving the market. In addition to these impacts on business, the IA also discusses impacts on the public sector and consumers.

# EANDCB

The RPC considers the calculation of the EANDCB to be not fit for purpose for the following reasons.

**Businesses operating in the UK**
The revised IA explains that "*we have treated all losses and benefits as if arising to UK-based manufacturers*" and states that this will likely over-estimate the EANDCB figure (Paragraph 125). As the IA acknowledges, impacts on firms that do not operate in the UK should not be included in the calculation of the EANDCB figure.

The revised IA goes on to explain that it estimates between 8 and 80 per cent of manufacturers are UK based. The IA must use a reasonable estimate for the number of firms operating in the UK impacted by the measure and justify this, using evidence and RPC guidance[2] to assist where appropriate. This must include an estimate for the volume of tests placed on the UK market that are manufactured in the UK or that are directly and effectively subject to these regulations. Due to the potentially large proportion of the test market that operates outside of the UK and the potentially large impact on the EANDCB, the RPC does not consider it is able to validate the EANDCB figure without a more accurate estimate.

[2] https://www.gov.uk/government/publications/rpc-guidance-issues-around-defining-a-business-january-2020

**Non-monetised impacts**

In its initial review notice, the RPC stated that the IA must monetise familiarisation costs, transition costs and costs associated with undertaking the validation programme, or justify why it is not proportionate to do so. The revised IA provides estimates for these costs at both the desktop and technical review stages. However, the IA must explain how these figures have been determined and justify the selection of the best estimate within the ranges. Further, if wage costs have been used in the calculation of these figures, the IA must discuss whether non-wage uplifts have been applied.

The IA explains that Local Authority Trading Standards units will focus on retailers to ensure that unvalidated tests are not sold on shop shelves (paragraph 127) and that retailers will be liable if found selling test devices that have not passed independent validation (paragraph 131). However, the IA estimates that retailers will not incur any costs from familiarising themselves with the proposal, from preparing for investigations or otherwise, despite the need for suppliers to undertake due diligence on their supply chains.

The IA must justify this assumption further, discussing the time required for retailers to familiarise themselves with the legislation and the number of retailers that are likely to be in scope of the proposal. The IA must also consider how Coronavirus test devices sold online will be monitored and how enforcement will be carried out online.

**Evidence to support assumptions**

The calculation of the EANDCB figure relies on several assumptions, which do not appear to be supported by evidence in the IA. For example, that 60 per cent of devices on the market will be presented for validation (paragraph 73) or that the life cycle of Coronavirus test devices is between one and three years due to Coronavirus variants (paragraph 32). The IA must provide evidence explaining why these are the Department's best estimates, taking into consideration that there have been a number of variants since the outbreak of the pandemic 18 months ago.

The IA must also justify its extrapolation of the size of the private testing market. The RPC considers it unlikely that this assumption is accurate without further information about the market dynamics and in particular the impact of government provision of free test kits.

In its initial review, the RPC stated that the Department must provide evidence to support the assumption that the profit margin of businesses in the market is 20 per cent. The revised IA contains annex 3, which details the response from stakeholders. However, it should also discuss the possible limitations of the dataset in more detail and define its use of the term "*profit margin*", explaining if it includes fixed costs, R&D spending or considers how products are branded. Within this context the IA should describe the structure of the market, discussing if free public provision of Coronavirus test devices has an effect on profit margins and the pass on of costs to consumers.

## SaMBA

The RPC's initial review stated that the IA must set out the disproportionate burdens on SMBs and discuss how these will be mitigated. The revised IA contains a description of an adjustment in fees for small and medium enterprises which represents a reduction of 55 per cent for the fees associated at the desktop validation stage (paragraph 140). However, the IA does not explain how the 55 per cent reduction in fees for these businesses was determined and how far it is expected to mitigate or remove the disproportionate burden on SMBs.

Further, whilst the IA describes the proportion of the market that is comprised of SMBs, it must also demonstrate the proportion of total costs likely to fall on SMBs.

## Rationale and options

In response to the initial review, the Department has provided evidence on the public support for intervention explaining that "*78% of respondents agreed that COVID-19 tests should be validated beyond the verification and assurance provided for CE marking*".

The IA should be improved through further explanation on what the current CE validation involves and explain more clearly whether the proposal aims to prevent dishonest behaviour and/or to create a process to validate all Coronavirus test devices to the same standard. The IA should discuss the possibility that if the concern is dishonest behaviour, then under the preferred option, firms could game the validation process by selectively sending tests to be assessed and therefore, whether without monitoring of the manufacturing process the minimum standard for Coronavirus test devices may not be achieved.

Further to this, the IA's rationale could be improved through explaining why improving the CE process to make it more consistent across manufacturers would not meet the objectives of the proposal. The IA should also endeavour to support comments on the accuracy of laboratory or field tests by using statistics, referencing the trade-off between Type one and Type two errors and by discussing the number of false positives or false negatives that the Department would deem acceptable.

The revised IA also contains further discussion on why the voluntary option is not appropriate. However, the IA states that "*there was insufficient incentive for manufacturers to apply to the process*". In order to show that a voluntary option has been properly considered before being discounted, the IA should explore this further and consider if the Department could assist in providing an incentive to encourage manufactures to participate in the voluntary scheme and if voluntary certification, perhaps in the form of a kite mark, could become a key factor of consumption choices as has become the case in other markets.

## Cost-benefit analysis

The IA states in paragraph 116 that qualitative benefits centre partly on "*instilling public confidence in privately available tests and subsequent behaviours associated*

*with this*". The IA could usefully expand on this to discuss the extent to which the proportion of tests providing the correct results is expected to increase as a result of the proposal and to include consideration that there will still be false positives/ negatives.

The revised IA also states that "*those manufacturers who do reinvest in products are assumed to commit 50 per cent of expected profits*" (paragraph 82). The IA continues by explaining that this is taken as a midpoint assumption and assumes that the distribution of costs between extremes is symmetrical. The IA should provide evidence to support this assumption or to explain why it is appropriate to assume that the distribution of costs is symmetrical.

The RPC welcomes the fact that the revised IA considers indirect impacts such as the effect on the supply chain of Coronavirus test devices. However, the IA should do more to monetise the enforcement costs of the proposal or justify further why it is not proportionate to do so. The IA explains that the judgment of the organisations responsible for enforcement is that the "true" impact is close to £0 but it should explain in relation to expected number of enforcement cases why this estimate is likely to be accurate and whether enforcement for online retailers will be treated differently.

# Wider impacts

The RPC's initial review stated that the IA should provide more detail on the expected impacts on trade. The revised IA explains that the proposal would constitute a technical barrier to trade with businesses outside the UK, but also when discussing the common routes into the UK for Coronavirus test devices that "*we do not anticipate changes to these trade flows as a result of these regulations*". The IA should attempt to provide an estimate for the proportion of tests imported to the UK and discuss whether this number is likely to change after the introduction of the validation process.

In response to the comments in the RPC's initial review notice, the revised IA explains that the risk of the proposal providing a barrier to innovation is limited as the scope of the legislation covers existing mature technology (antigen and molecular detection tests).

The revised IA contains limited discussion of the impact of the proposal on competition. It should be improved through providing further evidence and analysis on competition in the different testing markets that use the same technologies and the concentration within the different parts of the supply chain, quantifying figures or explaining why it is not proportionate to do so.

# Monitoring and evaluation plan

The RPC commends the Department for its commitment in the IA to assess certain impacts of the proposal as part of its monitoring and evaluation plan, such as trade flows and data on test performance, to compare with the estimates made in the IA. The IA should explain how the Department intends to demonstrate the quality of the

correlation between test results with public health consequences when evaluating the policy.

**Regulatory Policy Committee**

For further information, please contact regulatoryenquiries@rpc.gov.uk. Follow us on Twitter @RPC_Gov_UK, LinkedIn or consult our website www.gov.uk/rpc.