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Private COVID-19 testing validation
Royal Pharmaceutical Society response

1.Should COVID-19 detection tests be validated beyond the verification and assurance provided for CE marking?

Yes. The CE marking is not sufficient to ensure that tests meet the same quality standards. Having an additional validation process will ensure the quality threshold is met.

2. Do you agree or disagree that independently validating COVID-19 detection tests is the right approach to reduce the number of false results from tests and assure consumers that the tests they buy meet minimum quality criteria (such as specificity and sensitivity thresholds)?

Yes, we agree. Further asymptomatic testing across a range of settings is key as part of the roadmap to opening up society. Independent validation will make sure tests from both the private market and public market are of equal quality and that the test product is of sufficient quality and accuracy and can be used to make decisions on isolation etc. There have been failure rates already seen with some tests going through validation for test and trace and it is currently hard to compare performance data across different tests. An independent validation process will address these issues

The accuracy of tests needs to improve so the number of false negatives and false positive reduces, especially when people are undertaking the tests in their own homes. Even specificity at a 1:1000 false positive rate, at 5million tests a week will lead to 5000 people falsely isolating as mass testing is rolled out.

3. Do you agree or disagree that a legally backed and enforceable UK-wide regime is the best approach?

Yes, we agree. Having a legally enforceable system across the UK will ensure that all tests on the market meet the minimum threshold and safety and accuracy requirements.

4. Do you agree or disagree that categorising COVID-19 test performance measures as part of the validation process will ensure more standardised, comprehensive data on test performance measures from private companies?

Yes, we agree. It will be useful to have performance measures so individuals can compare different tests.

5. Do you agree or disagree that a mandatory validation of tests prior to their entry on to the market is best approach given the urgent need to quickly establish confidence in them as a step to reopening the economy?

Yes, we agree. However, for tests that are already on the market there needs to be a period of time for them to go through the validation process and they should remain available to purchase and be used until they can undergo the validation tests. During this time, they could be labelled to say they are not yet validated and may provide varying results.

6. Do you agree or disagree a mandatory validation scheme will not significantly reduce the supply of high quality COVID-19 detection tests?

Yes, we agree. The cost of the validation testing may deter some smaller companies to produce tests but the overall supply should remain high. In addition, if tests get a reputation for being unreliable, people will stop purchasing them so in the long run, it would be counterproductive for testing manufacturers not to have their tests validated. The assurance around quality and accuracy is more important.

7. Do you agree or disagree a government-run validation process will increase the likelihood of the UK being seen as a favourable place in which to carry out research relating to COVID-19 tests, develop COVID-19 tests and manufacture or supply COVID-19 tests.

We neither agree nor disagree.

8. Do you agree or disagree that the Department of Health and Social Care is the appropriate delivery body to provide UK-wide validation?

Yes, we agree. The consultation document outlines the reasons as to why the DHSC should take on this role and we agree with the arguments put forward for this, subject to the agreement of the devolved administrations in Scotland and Wales.

9. Do you agree or disagree 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?

Yes, we agree. All test will be required to meet the same thresholds and the validation process must be used on existing tests, both used by NHS and privately, as well as new ones. Tests that do not meet the criteria should not be available to purchase on the UK market.

10. Do you agree or disagree that a desktop review followed by a laboratory testing is the most effective way to validate tests?

Yes, we agree. For those tests that do not pass the desktop review, this means that the manufacturer only pays for this initial part of the validation process.

11. How much time do you think is reasonable to complete an application to validation? Please explain.

Timescales should be short as we need high volumes of tests on the market and there needs to be a commitment on the time between application and validation confirmed or denied. We would suggest a maximum of 12 weeks.

12. Do you have any further comments you would like to make about your expectations around the validation process or user experience?

The testing process should not stifle innovation so some areas, such as the development of breath tests, may need to be kept out of scope currently.

13. Do you agree or disagree that the costs of the validation process and associated running costs should be covered through fees rather than subsidised by the taxpayer?

Yes, we agree. It seems fair that the manufacturers of the tests should pay for the validation process for their product. This cost can be reflected in the purchase price.

14. Do you think that the proposed fee between £55,000 and £75,000 per test for the total cost of the validation service is reasonable?

15. Can you name other national or international diagnostic testing validation services that require payment, and what the cost is of those services?

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

Yes, we agree. These enforcement powers appear proportionate and will deter the sale of unvalidated tests.

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

Consideration needs to be given to the purchase of tests online that potentially have not undergone UK validation I.e. purchased from other countries.

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

Yes, we agree. These organisations already have procedures in place that can deal with enforcement processes.

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

Yes, we agree. This will deter any manufacturers from selling tests that have not undergone the validation process. However, clarity around the process needs to be easily understandable and well communicated.

20. Do you feel the proposed regulations are fair for businesses?

The regulations should be clear to understand. We believe it is fair that business minimise the chances of less reliable tests being sold and discrediting the whole product range. It protects the interests of business as well as the public.

21. Do you have any additional comments to add to the response?

Guidance needs to be developed and issued to employers so that they understand to only use tests that have been validated.

There needs to be an ongoing process of assurance to ensure batch safety and continued reliability of tests.

We recommend that COVID-19 tests are only sold from regulated healthcare sites, so that the relevant advice is given to the person purchasing the test in terms of actions that need to be taken in line with the result of the test.

Whilst profiteering is out of scope of this consultation, the issue does need to be addressed.

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