

## **Open letter to the General Pharmaceutical Council (GPhC)**

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General Pharmaceutical Council  
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22<sup>nd</sup> July 2020

Dear Mr Rudkin,

### **Pharmadoctor supported Antibody Testing Service in Community Pharmacy**

I am writing to you in response to the communication sent out from the GPhC to pharmacists 21<sup>st</sup> July stating that they *“do not regard it as appropriate for community pharmacy to be selling and recommending rapid antibody test kits”*.

In addition to being the UK’s leading provider of clinical service packages to community pharmacy, Pharmadoctor is also the distributor for a small high-tech company based in Belfast which manufactures a highly reliable cassette-based rapid COVID-19 antibody test; ideally suited to being administered by community pharmacists and other healthcare professionals such as pharmacy technicians.

To support pharmacies, Pharmadoctor has also developed a suite of Antibody Testing Service support documents which are currently being used by more than 500 pharmacies to deliver a professional, clinically robust and popular testing service in community pharmacy.

Since launching the service in June, it is proven that there is high demand for a COVID-19 antibody testing service in community pharmacy. However our client pharmacies are currently being hampered from providing such a service because of the current GPhC advice which is anchored on the following PHE guidance:

<https://www.gov.uk/government/publications/covid-19-rapid-tests-for-use-in-community-pharmacies-or-at-home/covid-19-rapid-tests-for-use-in-community-pharmacies-or-at-home>.

This PHE advice has remained unchanged since 25<sup>th</sup> March and which we believe is now out-of-date and inappropriate since it takes no account of recent developments. The PHE advice also takes a one-size-fits-all approach, conflating a number of very different sorts of tests and testing procedures. As a result, the use of reliable rapid antibody tests is being stifled to the detriment of healthcare professionals and the public. The guidance is arguably also anti-competitive.

PHE's advice says:

'The current view by PHE is that use of products that give a very rapid result is **not** advised:

1. some of these products look for virus while others look for the body's immune response to the virus. Such tests are very rapid and can work on a range of specimens including serum, plasma or finger-prick whole blood
2. there is little information on the accuracy of these rapid point of care tests, or on how a patient's antibody response develops or changes during COVID-19 infection. It is not known whether either a positive or negative result is reliable
3. currently there is no published evidence about the suitability of these rapid point of care tests for diagnosing COVID-19 infection in a community setting'

When we look at the PHE advice, it does not really seem to be relevant to the tests we are supplying to pharmacy, nor the antibody testing service being provided in hundreds of UK pharmacies.

In response to each of the PHE points above:

1. (i) The test being supplied by Pharmadoctor does not look for the virus but rather looks for the presence of antibodies in whole blood following infection with the COVID-19 virus.  
(ii) We fully accept the uncertainties about the evolution of immune response. However, these uncertainties apply equally to the lab-based antibody tests which have been "validated" by PHE.
2. The antibody tests which Pharmadoctor is supplying are showing to be highly sensitive and specific at identifying COVID-19 IgG antibodies, with results comparable to the lab-based antibody tests which have been validated by PHE and are on open sale. For their supply to the public not to be allowed is therefore discriminatory.  
Furthermore, we have offered our tests to PHE for validation, however they have yet to take up our offer. We believe a potential reason for this is that our current output (manufacturing a maximum of 4,000 tests a day) is too small for use in a national testing programme. Pharmadoctor would be happy to meet the costs of PHE validating its antibody tests.
3. This third point above does not relate to the tests being supplied by Pharmadoctor. The tests Pharmadoctor is supplying are 'antibody' tests, not 'antigen' tests, meaning that they detect the presence of antibodies following COVID-19 infection. They are not intended for the 'diagnosis of COVID-19' as suggested in PHE's advice above.

Finally, the first paragraph of the guidance conflates tests being taken at home with those that are administered by pharmacists. We can appreciate that there may be problems with the former. However, the antibody tests that Pharmadoctor have been supplying are strictly for administration and evaluation by pharmacists/pharmacy technicians and we give them guidance on how to explain to customers the limitations of the test.

Pharmadoctor appreciates PHE's concern that the public do not (yet) understand that the presence of COVID-19 antibodies is not a guarantee of immunity to the virus. However, as trusted healthcare professionals, surely community pharmacists are best placed to communicate this by providing a professional antibody testing service to members of the public who want to know their antibody status. As you will see from the service support documents attached, it is made very clear by pharmacists carrying out the testing service that a positive result does not infer immunity and that people using the service should continue following government advice in relation to social distancing and isolating if required to do so.

Feedback from people using the service is that they simply want peace of mind that they have had COVID and that their bodies were able to successfully fight off the virus.

Having successfully supplied over 70,000 antibody tests (at cost) to healthcare professionals all across the UK and listened to people's feedback, Pharmadoctor believes that this is a service which is greatly sought after by members of the public and that community pharmacy is best placed to continue providing a low cost and reliable antibody testing service alongside the companies that are supplying the rather different, far more expensive and inconvenient lab-based antibody tests which have been "validated" by PHE.

Pharmadoctor wrote to PHE in May asking them to update and correct their advice so as to make clear that antibody tests that meet appropriate accuracy standards may be administered by qualified pharmacists; thus acknowledging the value of community pharmacy in providing much sought after antibody testing services to meet public demand.

Appropriate guidance from both PHE and the GPhC might make clear that such tests should meet certain accuracy standards as regards sensitivity and specificity (comparable to those which have been accepted for the Roche and Abbott tests, thus allowing for a level playing field) and that they should only be administered by healthcare professionals trained to provide appropriate guidance as per their CE certification.

For more information relating to the antibody tests and testing service framework being supplied by Pharmadoctor, please see our [FAQs](#) and the accompanying service support documents.

Finally, I would welcome the opportunity for an open dialogue with the GPhC so that we can constructively discuss the testing service being provided by UK pharmacies and alleviate any concerns.

I look forward to hearing from you.

Yours sincerely,

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