COVID-19 – Greater clarity on what therapeutic innovation is required

Professor Whitty, the Chief Medical Officer of the UK government, provided an indication of the benchmark of success they are seeking for innovations to treat COVID-19. It was in a response to a question from a journalist during the UK Government daily briefing about the likely duration of long lock-down measures.

Professor Whitty responded by moving the reference point for release of restrictions from time to the scientific progress needed to catalyse such a change. He stated the need for "A vaccine, and there are a variety of ways they can be deployed ... and/or, highly effective drugs so that people stop dying of this disease even if they catch it, or which can prevent this disease in vulnerable people.

"Until we have those – and the probability of having those any time in the next calendar year are incredibly small, and I think we should be realistic about that – we're going to have to rely on other social measures.."

This is the type of response we have come to expect from Professor Whitty as he seeks to manage public expectation and preserve orderly adherence to social restrictions.

Innovation Success Criteria - COVID-19 vs standard therapeutics

This creates a subtle shift in the benchmark of success for therapeutic innovation in terms of COVID-19. Either they provide the necessary impact to release the social restrictions or they don't. This differs from the standard criteria that determine pharmaceutical or biotechnological product success. Typically this includes regulatory assessment of risk/benefit, whether government health agencies or health insurers will pay the proposed price for the associated benefit all which is debated against a backdrop of data from trials in comparison to best in class products and placebo. Whereas there is no change to the regulatory regime, the Government has linked the criteria defining success in COVID-19 therapy to those attributes needed to remove social distancing.

What does this mean for vaccines and anti-virals in development?

For a vaccine this could mean effective inoculation of the vulnerable and/or vaccinating the masses to ensure the majority are no longer able to spread SARS-CoV2. Such a vaccination route to 'herd immunity' reduces the likelihood of large numbers of the vulnerable being infected in a timeframe likely to stretch health resources beyond capacity. Other forms of therapeutic innovation he mentioned focus on preventing the escalation of severe COVID-19 in the high-risk population.

The scientific realities of such benchmarks for success are fairly profound. For example, does a vaccine instill immunity that ensures sufficient proportion of those inoculated are no longer contagious? How long does such immunity last? Given the high incidence of dysregulated immune systems in those vulnerable to severe COVID-19, will vaccines and anti-viral prevent the excessive inflammatory response in this vulnerable population? Will COVID-19 vaccinations remain effective if the virus mutates and the new strains are similarly immune provocative?

For therapeutic innovations, the inferred benchmark is whether the proposed therapy prevents the pathology of severe COVID-19 which leads to hospitalisation and fatality? As any immunologist will tell you, the sheer complexity of the immune system means such innovation is no simple task.

Speed of testing vs likelihood of success

As public and private money is committed to COVID-19 research and development there is an understandable emphasis on repurposed drugs and other innovations that can be used in patients quickly. However, a key question must be whether, under objective assessment, do such speedy solutions have a scientific rational that will realistically deliver the necessary therapeutic impact now clarified by the government? If the big economic prize is the release of all forms of social restriction, then the scientific advance needed to unlock this has been clarified. Against this benchmark prioritising solutions on the basis they are quickly able to enter testing in patient may prove a false economy. Critical to the prize of properly unlocking society and the economy is a rational cold assessment of whether the science of a given therapy is capable of delivering the impact needed.