Vaccine Diplomacy: A Shot in the Arm?

The EU's response to its vaccine crisis has shown the organisation at its worst. Brexit has given the UK the freedom the pursue a more effective vaccine strategy. Rather than stooping to the EU's vaccine nationalism, we should be generous in using our advantage to help others, writes ***Nigel Moore****.*

The EU in need is *not* a friend indeed. In the past week we have witnessed increasingly bizarre and threatening jabbering coming from senior figures in the European Commission to cover up their failings over vaccinations.

Vaccine nationalism; threatening supplies to the UK and raids of production facilities; seizing documents; unrealistic claims about contract conditions – none of this is helpful. Yet helping out the EU with supplies of UK-sourced and regulated vaccines could be a shot in the arm all round if provided as a generous gesture of goodwill and not seen as caving in to EU bullying.

The EU Commission's vaccine approval problem

The elephant in the room for any supplies of vaccine to the EU is approval and regulation by the European Medicines Agency (EMA). Some idea of the overall process is provided by these slides produced by the EMA, whilst their website is a veritable Aladdin's Cave of regulatory intricacy and subtlety. This is not bureaucracy for its own sake, but a comprehensive and therefore complex approach to ensuring safety of the public. Regulation thus covers not only initial assessment and

authorisation, but continuing surveillance and testing of every batch of vaccine produced.

Production of a novel vaccine using an EU-domiciled supply chain for the EU market is not just a commercial issue, but perhaps more importantly, a regulatory one as well. A domestic supply chain obvious grants easier access to regulators, greater familiarity with their requirements and ways of working, and more straightforward regulatory sign-off of each phase and manufactured batches.

The EMA's own processes are thus likely to frustrate panicky attempts by the European Commission to quickly divert vaccine batches from one intended market (the UK) to another (the EU), where those vaccines have not satisfied all the regulatory steps.

Alternatively, the EU Commission could choose to manipulate or ignore inconvenient sections of the EMA's regulation of vaccines. Given the EU's current panic and blame shifting game, this may indeed happen.

Why mutual recognition makes sense

A much more sensible approach would be for the EU to adopt mutual recognition of mandatory regulation of vaccines. Thus, the EU and EMA could accept a UK-produced vaccine that is regulated by the UK's Medicines and Healthcare products Regulatory Agency (MHRA). This would help get novel vaccines quickly into the EU from multiple UK sources, saving some duplication of efforts. This needn't be replacing the EMA's processes, but rather providing expeditious MHRA input into them.

Mutual recognition, though, very much goes against the EU's grain. The EU works to harmonised or common mandatory standards and assessment. Mutual recognition tends to apply

only within the Single Market where mandatory standards and assessment have not been harmonised.

But these are not normal times. Mutual recognition could help get flexibility and speed to novel vaccine deployment across the EU (and UK) where most needed to save lives. If the EU accepts this, then they may also be given to accept some flexibility on treatment of the UK (or more accurately, mainland Britain) as a third country outside the Single Market. The EU imposes numerous non-tariff barriers including official controls on third countries exporting to the Single Market. Given the unprecedented impact of Covid on both economic and daily life, bitterness and economic hardship created now by perceived official intransigence is a wound in EU-UK relations which will likely take a long time to heal.

Brexit has given the UK the freedom to be generous

The UK Government's vision for vaccine development is set out in its report *UK Vaccine Taskforce 2020: Achievements and Future Strategy.* Brexit has removed an EU dead hand, allowing critical infrastructure to be created, expanded and strengthened to adequately satisfy projected demand and prepare for future exigencies.

This includes reserving all production capacity with Wockhardt (AstraZeneca's UK vaccine supply partner) for exclusive use for the next 18 months. This somewhat nullifies the EU's spurious contractual claims regarding AstraZeneca. AZ has obligations to work to 'reasonable best efforts' in numerous places in its contract with the European Commission. Neither AstraZeneca nor Wockhardt are required to divert British Government contracted vaccines to the EU.

So, unlike the EU, we can afford some leeway to be flexible and compassionate in the expeditious supply of vaccines to others less fortunate or plain incompetent. Such a gesture

would illustrate in a practical way our altruism, business acumen and trustworthiness, potentially ‘building bridges’ to future mutually beneficial co-operation.

While EU Health Commissioner Stella Kyriakides and EU President Ursula von der Leyen continue jabbering, let’s get jabbing.