Department for Business, Energy & Industrial Strategy

Vaccines: approach to Indemnities

Summary

This paper invites Ministers to re-confirm their acceptance of potentially-broad Government indemnities for vaccine developers, in the light of updated analysis on the scale of the potential liabilities involved. This updated analysis shows a strongly-positive value for money case for entering into vaccine agreements, even with broad indemnity provisions.

Ministers are also invited to note that the draft AstraZeneca supply agreement, which is also for approval at this meeting, contains similarly-broad provisions on indemnities

Background

1. C-19 vaccines are being developed at a much faster pace than is typical, some of which are also using novel platform technologies. Whilst the vaccines will be subject to regulatory approval, given the timeframe, the vaccines will not be able to benefit from the longer and more extensive clinical trials that would usually be the norm in any vaccine development. Hence, many suppliers are asking for protection against liabilities, litigation and prosecution in the form of statutory immunity and/or government-backed indemnities.

2. In the US the Public Readiness and Emergency Preparedness (PREP) Act provides for wide ranging immunity from liability (except for wilful misconduct) arising from use/administration of products in response to declared public health emergencies. It authorises a US Treasury fund to provide compensation to eligible individuals for serious physical injuries or deaths directly caused by administration or use of a countermeasure covered by the Declaration. By virtue of this legislation manufacturers and distributors are exempt from liability, with the State solely liable for any claims of serious physical injury or death arising from the use of countermeasures.

   In our conversations to date, Pfizer/BioNTech, Janssen and GSK/Sanofi have already requested statutory immunity which the US offers and with which we have resisted. Statutory immunity to the extent requested by pharma companies would require passing primary legislation.

3. **Ministers have previously agreed binding indemnity terms in the context of negotiations with BioNTech/Pfizer**. Though we sought to limit the indemnity cover I&S

Irrelevant & Sensitive

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4. Offering broad-ranging indemnities, as Ministers have previously agreed in relation to Temporary RO brings with them a contingent liability and may expose HMG to levels of financial risk that are higher than normal. This is partly driven by the difficulty of quantifying the size of the risk. The VTF, DHSC, HMT, MHRA, PHE and the Government Actuary Department have worked together to provide a reliable best estimate of that financial exposure, as set out below. This is currently with HMT and we are awaiting comment. It should be noted that there are precedents for HMG offering indemnities – see Annex A.

Likely costs

5. Our current estimate is driven by three main factors: Exposure; Probability and average claim size – see Annex B. **It has reduced very significantly from the initial estimates at the time of the BioNTech/Pfizer negotiations, ranging from £75bn to £300bn.**

6. We now estimate for the contingent liability figure in a reasonable '**worst-case scenario' to be £1.7bn**. This figure uses data from the average pay-out from the narcolepsy side effect of the Pandemrix vaccine (the most severe side effect from the historical data) and the probability of a side effect with the same level of incidence as ITP from the MMR vaccine in children (the most commonly occurring severe side effect). We are therefore using the most extreme evidence we have available. In order for this worst-case scenario to be realised;
    a. A vaccine would have to have a new unexpected and undetected side effect similar to narcolepsy (the most severe side effect from available data) and, generate similar sized liability claims.
    b. That side effect would have to have a probability of occurring similar to a much less severe side effect such as Immune Thrombocytopenic Purpura (ITP) in children (the most common severe side effect from available data, which only occurred at this probability in children (who aren't being vaccinated) and not adults where it was rarer).

7. An alternative **'less worst-case scenario' would be £270m**, this would be a side effect with the same incidence and severity of Narcolepsy in adults. There is stronger evidence to support this, as it uses real world data from the most recent, most severe side effect from a vaccine, which did actually generate liability claims.

8. If the 'worst case scenario' of £1.7bn were to occur, a COVID-19 vaccine is still expected to have a strongly positive value for money (the net benefits of the entire vaccines programme, which include expected spend on vaccine candidates which ultimately are not successful, are estimated between £11bn - £231bn). It should be noted that it is entirely possible and indeed likely that a vaccine successful in trials has no side effects. Experts are unable to quantify the chance of an unknown severe reaction however, so we present the worst-case scenarios.

9. Based on the data available now, **the Value for Money case for respective agreements (resulting in a successful, deployed vaccine) would still be very strongly positive, even with significant increases to the potential cost of indemnities.** This document does not represent a final estimate. As more details about a successful vaccine emerge, we will update the maximum liability analysis based on any new evidence that emerges, however we cannot delay entering into binding agreements without risking early UK access to potential vaccine candidates.

10. Ministers should also be aware that the draft AstraZeneca supply agreement, which is also on the agenda for approval at this meeting, contains similar indemnity provisions to those in the previous BioNTech/Pfizer agreement. The draft AstraZeneca agreement would involv **Temporary RO** indemnity from HMG for losses arising from the vaccine, **Temporary RO**

Temporary Restriction Order

11. An Accounting Officer checklist has also been developed by BEIS / DHSC / HMT officials, which would be completed as part of the clearance process, ahead of agreeing the binding terms to respective agreements.

Additional considerations

12. Ministers are invited to note that DHSC is reviewing the UK Vaccine Damage Payments Act, which provides a statutory fund for persons who suffer severe disability caused by designated vaccines. Officials are considering options to expand the list of vaccines to include those for Covid-19 and review the eligibility criteria for the scheme. Ministers may also want to consider a separate compensation scheme for Covid-19 vaccines, for costs arising from litigation. There is ongoing work within DHSC and HMT on what such a scheme could look like. This may be an issue to decide upon in future months and years, once it becomes clearer what – if anything – we are compensating for. We'll provide further advice on the options in due course.