Response to DHSC Open Consultation: Changes to Human Medicine Regulations to support the rollout of COVID-19 Vaccines

Introduction

1. We are writing in response to the UK Government consultation in respect of the proposals to modify the Human Medicine Regulations 2012 ("the Regulations") in order to support the rollout of a COVID-19 vaccine.

2. This is a submission to the consultation on behalf of a group of specialists drawn from different disciplines setting out our views on the proposed changes.

3. Under the proposed modification of the Regulations, the envisaged scenario is that if there is a compelling case on public health grounds for using a vaccine before it is given a product licence, the Joint Committee on Vaccination and Immunisation may take the step of advising the UK government to use a tested, unlicensed vaccine/s against COVID-19.

4. This would be a highly unusual step to take, and we have concerns about any UK Government decision to resort to the supply of an unlicensed medicinal product in this manner and the public health messaging that is thereby relayed. This is particularly the case in respect of one or several vaccines which have been developed under a fast-track procedure, potentially based on innovative technology, and which is to be used on such a wide scale to the general population.

5. Such an approach is problematic in light of the critical issue of the acceptability of vaccines. Vaccines are biological and social technologies. To curb the spread of a disease at the population level, they have to stimulate an effective immune response and be taken up by a sufficient percentage of the population to interrupt transmission. Recent years have seen a rise of vaccine hesitancy around the world and the WHO has named vaccine hesitancy as one of the top 10 global health threats. A study published of vaccine hesitancy in 149 countries from 2015-2019 found low levels of vaccine confidence in Europe in comparison to other regions (Larson et al, 2020). Combined with the rise of disinformation campaigns and the early release of untested COVID-19 vaccines by other states, there is significant potential for lack of public trust

to undermine the uptake of a COVID-19 vaccine. Historical precedents like the 1976 swine flu campaign in the US, which was stopped after the detection of cases of Guillain Barré syndrome, show that fast-tracked licensing and vaccine rollouts can undermine trust not only in one vaccine but in the wider regulatory establishment licensing them.

6. It is also unclear how public opinion may be affected by the potential emergency licensing of multiple vaccine candidates with different safety, cost, and efficacy profiles. Between 1955 and 1961, the parallel development of two polio vaccine platforms (Salk - inactivated; Sabin - attenuated) with tests conducted on both sides of the Iron Curtain (Conis, 2015; Vargha, 2018) resulted in a degree of confusion and uncertainty. While Sabin's oral polio vaccines (OPV) remained in use in many low-income countries due to its low costs and mode of action, it was implicated in the spread of new vaccine-derived poliovirus (since 2012 its use has been phased out). Communicating why some people may have access to a safer but perhaps more expensive emergency vaccine and why others will not have such access could potentially pose a major public health and relations challenge in the likely event of multiple COVID-19 vaccine candidates being developed in parallel.

7. A third significant issue which regulators will face is to ensure high standards of vaccine manufacturing and public trust in resulting products. In 1955, trust in the safety of the Salk vaccine was negatively affected by the so-called Cutter incident when manufacturing and inspection failures on the part of the Cutter pharmaceutical company resulted in the spread of live virus. The unprecedented global scale of any COVID-19 rollout poses unique challenges in terms of guaranteeing safe manufacturing standards around the world. Depending on which vaccine candidate is licensed first, the UK government will likely have to rely on a mix of vaccine doses produced at home and imported from abroad. Creating trust in imports that have been licensed according to emergency rules will be challenging. Maintaining trust following likely reports of limited adverse events will be even more complicated and may depend on being able to hold individual companies to account.

8. Having an up to date vaccination status is a professional obligation for registered health care professionals, and employers or service providers may also require vaccination for certain groups of employees or service users. This means that COVID-19 vaccination may in practice become mandatory for some groups. This needs to be taken into account when considering the conditions for the rollout of such vaccines.

Use of the temporary authorisation procedure

9. The use of the temporary authorisation procedure under Regulation 174 of the Regulations, rather than seeking to license the vaccine through ordinary market authorisation route, has the potential to undermine public confidence in a COVID-19 vaccine. As noted above, there is already considerable public sensitivity vis-à-vis the development of such an emergency vaccine. It is our view that the use of the temporary authorisation procedure of an unlicensed product, coupled with the accompanying immunity from liability of manufacturers and others (see below) has the potential to undermine public trust, which is a very precious commodity in the current pandemic. That may affect the ultimate take up of the vaccine. It is our view that strong preference should be given for the ordinary market authorisation route which, even though it may require greater time for the full clinical trial to be undertaken, and the usual authorisation to be completed, will be more likely to attract public confidence and acceptability of the resultant vaccine.

Civil liability and immunity

10. The provisions of the Regulations regarding civil liability also raise issues in respect of the acceptability of vaccines.

11. It is indeed correct that the current Article 5(3) of Directive 2001/83 requires Member States to lay down provisions so that marketing authorisation holders, manufacturers and health professionals are not subject to civil or administrative liability for any consequences resulting from the use of an unauthorised medicinal product, or from the use of a product otherwise than in accordance with its authorisation, when such use is by the licensing authority in response to (among other things) the spread of pathogens. This has been transposed into UK law by virtue of Regulation 345(3) of the Regulations.

12. We are of the view that there are reasons to question whether such an immunity is advisable in the current circumstances.

13. The immunity in Regulation 345 is not absolute. As noted in the consultation document, Regulation 345 does not provide complete immunity from civil liability. Regulation 345(4) thus provides for a carve-out in terms of product liability under the Consumer Protection Act 1987 (hereinafter "CPA."). It is thus stated that there is no immunity in relation to a claim under section 2 of the CPA.

14. A consequence of this is that there is in effect a channelling of liability towards the cause of action under the Consumer Protection Act. The specific regime applicable to clinical trials of medicinal products which would normally apply to the period before a medical product is granted a licence in the UK, is inapplicable in the current circumstances given the temporary authorisation. The immunity under Regulation 345(3) moreover results in an exclusion of claims under the orthodox common law causes of action of contract, tort and breach of statutory duty. It is uncertain at this stage whether the statutory compensation scheme under the Vaccine Damage Payments Act 1979 would be applicable or not (as COVID-19 would need to be added as a specified disease in respect of the scheme). We note also that that there is no statutory exception in case of intentionally caused harm or egregious fault as is often the case for statutory immunities,[1] albeit it is proposed in the consultation that the immunity should not apply where the supply is materially inconsistent with the terms of the licensing authority's approval (see further below).

15. As a result, great emphasis is placed upon the product liability regime pursuant to the Consumer Protection Act 1987. Restrictions on time and space prevent us from reviewing this regime in detail here. Two points will however be made. First, liability under these provisions requires proof by the claimant that the product was defective, that damage was sustained by the claimant, and that this damage was caused by defect. Making out these elements can often be challenging, and that may be particularly difficult where the product in question is a medicine. Secondly, it is also to be noted that the success rate of actions under the CPA has not been high, particularly in group actions concerning medicines and medical devices where claims have failed on defect and causation grounds. The development risks defence under the CPA (which does not require a finding of negligence) may still pose significant problems for a claimant as it enables a manufacturer to rely on the fact that the objective state of scientific and technical knowledge, at the time the vaccine was put into circulation, was not such as to enable the

[1] See for example in the financial services sector : Sch 1, s 19(1) of the Financial Services and Markets Act 2000 (as originally enacted); Banking Act 1987, s 1(4).

existence of the defect to be discovered. Indeed, the current position as regards medicines has been subject to criticism in the recently published *Report of the Independent Medicines and Medical Devices Safety Review* led by Baroness Cumberlege:[2]

> *To date, litigation has not served the patient groups we have met well. In the future a more equitable way to deliver redress that truly works for patients must be developed. Even the best pre-market testing will not capture all adverse events that may occur in real world treatment with pharmaceuticals and medical devices. Individuals may be harmed by new products in ways that were not foreseen during development and testing. We must establish an effective redress mechanism for those who suffer avoidable harm or unforeseen drug or device injury.*

16. In light of the foregoing, the route to compensation in case of harm deriving from a COVID-19 vaccine/s under the Regulations is likely to be a challenging one. We are concerned that this might be seen by the public as being unjustifiably restrictive in respect of those impacted by adverse events / side effects of the products in question. This has the potential of undermining public confidence in the COVID-19 vaccine process, which would almost inevitably impact on the take up of any vaccine/s and thus impede its effectiveness. This would be an unfortunate position, and would actually be counter-productive in terms of the overall public health objectives for the roll out process of a COVID-19 vaccine.

17. The final issue is whether, having taken account of these considerations, if the immunity contained in Regulation 345 is nonetheless maintained (contrary to the considerations set out above), there are justifications for the extension of the immunity to pharmaceutical companies which are responsible for placing unlicensed products on the market on the same footing as manufacturers of unlicensed products and the same footing as marketing authorisation holders of products which the licensing authority recommends are used otherwise than in accordance with their authorisation. Our view is that such an approach has some justification in the sense that liability of the supplier under the CPA regime mentioned above is subsidiary, with the primary liability being attached to the producer, and thus it would make sense for the supplier not to be in a less favourable position in respect of liability in tort or contract.

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[2] *The Report of the Independent Medicines and Medical Devices Safety Review* (2020), Appendix 3, para 7, page 213.

When the Protection is lost

18. It is indicated in the consultation that the immunity contained in Regulation 345 should not apply where the supply is materially inconsistent with the terms of the licensing authority's approval, and that legal recourse is thus possible in such circumstances. This position is reflected in draft Regulation 174A(3)(b).

19. In our view, the proposed approach to this issue in the draft regulations is problematic. First, the application of a nuanced objective test to the question of whether the protection of the immunity should be forfeited or not seems extremely complex. It should be noted that even if an immunity is removed for a technical or minor breach, any claimant will still need to make out the elements of a standard cause of action, such as the tort of negligence. For a claim in negligence, the claimant will in effect need to show negligence of the defendant manufacturer / supplier - not at all easy to make out in terms of mere technical breach. Moreover, causation would surely be difficult to prove when there is a "breach of a technical requirement with a relatively inconsequential effect." In our view, it would be simpler for the immunity to be removed if the supply does not "materially comply" with the licensing authority's recommendation.

20. If however, despite the aforementioned, an objective test is adopted, we would express a preference for the simplest approach (ie reference solely to a "reasonable person") and for it to be left to the courts to determine whether any specific knowledge is imputed to the "reasonable person" (the courts are well-used to doing this in other areas of the law).

21. Second, Regulation 174A(3)(b) sets out that "any risk of death or personal injury that is wholly or partly attributable to that breach is such that a reasonable person [with an interest in placing medicinal products on the market] would regard the breach as sufficiently serious to justify the licencing authority setting aside the recommendation or requirement." The relevance of the latter part of this test (underlined) is uncertain as it is not the recommendation that is in doubt, but the rather the supply which is inconsistent with the terms of the licensing authority's approval.

Compensation for Vaccine Damage

22. In light of the restricted avenues to compensation, we consider that there are strong arguments in favour of the creation of a bespoke regime for compensation for those who suffer injury caused by a COVID-19 vaccine. This is justified by the particular circumstances of the current pandemic, including the expedited regulatory process, the use of novel vaccine technology, potential mandatory nature of the vaccine for some persons, and the imperative need to reinforce public trust in COVID-19 vaccine and ensure high take up of any such vaccine/s.

23. Such a bespoke compensation scheme should be designed to provide adequate redress for the loss caused, going beyond that which is provide by the current vaccine damage scheme under the Vaccine Damage Payments Act 1979. Such a bespoke scheme for harm caused by COVID-19 vaccines would be in line with the no-fault redress schemes recommended by the aforementioned *Report of the Independent Medicines and Medical Devices Safety Review*, and could thus fall within the purview of the proposed Redress Agency.

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