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Procurement of Covid-19 vaccines: why were legal liabilities transferred to the public sector?

Covid-19 Vaccine Legal Research Group

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The recent release of the Covid-19 vaccine supply contract between the European Commission and Astra Zeneca has caused a political and media storm about vaccine production logistics and supply issues. A lesser noticed but controversial issue revealed by the contract is that of where ultimate liabilities should lie, which has potentially far-reaching consequences for the public purse. Many commercial contracts include so-called indemnity clauses whereby one party contractually agrees to cover liabilities incurred by the other. The European Commission accepted in Article 14 of the agreement an extremely broad indemnity of the manufacturer covering almost any and every defect imaginable whether that be the vaccine's inherent characteristics, manufacturing / distribution, and storage issues, labelling errors or even

problems due to administration of the vaccine. This is a potentially significant burden to place on the state, and ultimately taxpayers.[1]

On a cursory analysis, the position of anyone suffering an adverse effect of the vaccine is not changed, as they may still bring a legal claim. Indeed, from one perspective, it could be seen as simply a matter of shifting liabilities between equally deep-pocketed defendants, the manufacturer, and the public purse. In that sense, the position would seem to be compatible with the letter of the 1985 European Product Liability Directive, implemented across Europe to ensure compensation for defective products. On closer scrutiny, however, doubts do arise. Such legal provisions are designed to have a disciplining or deterrent impact, inciting producers to strive for higher standards in producing products.[2] Such a preventive effect would inevitably be dulled by the wholescale transfer of liabilities to third parties. Is this approach really compatible with the spirit of provisions that were explicitly designed to establish "a fair apportionment of the risks inherent in modern technological production"? Insurance might have a similar effect, but insurance companies will often be astute to monitor risks and require measures to reduce their exposure.[3]

There might also be concerns about the impact on public attitudes to vaccines if it is revealed that the producer is so reticent to stand by the quality of that product. At a time when public trust is in short supply, it is appropriate to question why such across-the-board legal safeguards have been accorded to healthcare producers, particularly given that substantial public funds have been expended to subsidise the research and clinical trial phase. Already in 2011, after the H1N1 vaccine saga, very critical reports were made about the procurement process,[4] including by the European institutions.[5] There is a danger that history is again repeating itself, even though Astra Zeneca has committed to provide the vaccines at cost price during an (unspecified period) of the current pandemic.

Why would the authorities consent to sign a supply contract on such unfavourable terms? The European Commission had substantial purchasing and political power and also past experience of procurement pitfalls. There was undoubtedly a pressing need to ensure supply of a potentially life-saving product (within very challenging circumstances) and the commercial balance may have in practice shifted to the supplier rather than purchaser. However, it is unlikely that the nature of that pressure could be the basis for challenging any indemnity.

Perhaps, the potentially indemnifying party proceeded on the assumption that any litigation risks in this area are rather low, given the difficulties injured parties face in bringing successful

[1] It is also unclear due to redaction of the contract what (if any) exceptions are provided for: as a minimum carve-outs should be included for wilful misconduct / gross negligence by the product manufacturer.

[2] On this, see opinion of Advocate General Bot in *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt - Die Gesundheitskasse* (Case C-503/13, 504/13) [2015] 3 CMLR 173 (CJEU) §38. AG Bot refers to the "preventive function" of the Directive, noting also that the producer is "in the best position to minimise [the risk] and to prevent damage at the lowest cost."

[3] See discussion in D.Fairgrieve and R.Goldberg, *Product Liability* (3rd edn, OUP, 2020) para 7.21.

[4] See e.g. Assemblée parlementaire du Conseil de l'Europe, *La gestion de la pandémie H1N1 : nécessité de plus de transparence*, Document 12283, 7 June 2010.

[5] European Parliament, *Rapport sur l'évaluation de la gestion en 2009-2010 de la grippe H1N1 en Europe*, 9 February 2011.

claims against healthcare producers.[6] Indeed it is arguably neutral on the public purse whether an indemnity is given, or the cost of insurance is factored into the price. Due to the deterrence and acceptability arguments mentioned above, we believe it beneficial to keep the liability with the producer.

More fundamentally, the barriers for any injured party seeking to recover court-awarded damages remain. It is to be hoped that there are no serious permanent side effects from the vaccine. However, the problematic current position underlines the need for a well-resourced compensation fund to be established to ensure that anyone suffering serious adverse effects receives adequate and fair compensation.[7] The COVAX / WHO / GAVI no-fault compensation scheme has recently been rolled out across the 92 countries of operation,[8] and surely is it not impossible for UK and European authorities to follow that lead either at a national or supranational level.

[6] See further D.Fairgrieve, P.Feldschreiber, G.Howells and M.Pilgerstorfer, "Products in a Pandemic : Liability for Medical Products and the Fight against Covid-19" (2020) European Journal of Risk Regulation 1. Note also that the European Product Liability Directive is currently under review.

[7] Certain authors of this article have argued in favour of a bespoke COVID-19 vaccine compensation scheme, see D.Fairgrieve, S.Holm, G.Howells, C.Kirchhelle, S.Vanderslott, 'In favour of a bespoke COVID-19 vaccines compensation scheme", The Lancet Infectious Diseases, 3 February 2021.

[8] See further www.covaxclaims.com. For a comparative view of national schemes, see S.Halabi, A.Heinrich, and S.Omer, "No-Fault Compensation for Vaccine Injury" The New England Journal of Medicine, 28 October 2020; E.Rajneri, J-S.Borghetti, D.Fairgrieve and P.Rott, "Remedies for Damage Caused by Vaccines: A Comparative Study of Four European Legal Systems" (2018) European Review of Private Law 57. For national views, see P.Rott, "Compensation for Vaccination Damage under German Social Security Law" (2019) Vol 16 No 1 Otago Law Review 199; E. Rajneri, "Il vaccino contro il covid-19. La normativa speciale e il meccanismo di distribuzione dei rischi e dei benefici", in Contratto e Impresa, 2021, forthcoming.