CLAIM NO: CO/771/2019
R (GOOD LAW PROJECT LIMITED) v SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

CLAIMANT'S REPLY DATED 11 MARCH 2019 TO THE SGOD

1. **Ultra vires**: Reg. 9 is clearly not in furtherance of Arts.70/71 of the 2001 Directive as permitted by s.2(2)(b) of the 1972 Act. These Arts. require D to specify "*dangerous*" medicinal products as prescription-only unless, under Art.71(4), D finds it appropriate not to do so, exceptionally. However, under Arts. 1(19) and 70/71, prescription-only products may only be issued by a professional person qualified to do so: in the UK, doctors and the other appropriate practitioners referred to in Reg.214 of the 2012 Regs (and not pharmacists).

2. Reg.9 authorises pharmacists – *unqualified* persons for the purposes of the domestic regime – to sell/supply medicines that are prescription-only medicines. The effect of this is that: (a) Reg. 9 is actually in breach of Arts. 1(19) and 70/71; and, (b) further and/or alternatively, Reg. 9 does not deal with matters arising out of or related to any obligation in the 2001 Directive. Insofar as Reg.9 creates a mechanism that removes doctors etc. from the treatment process, and provides for prescription-only medicines to be sold/supplied to patients by pharmacists on the advice of D, it does something completely different than what the 2001 Directive encompasses and therefore cannot fall within s.2(2)(b): see *USA v Nolan* [2015] UKSC 63, [2016] AC 463, §61.

3. Contrary to the SGOD at §40-42, a patient who attends a pharmacy with a prescription for medicine A, but who is sold medicine B, is sold medicine that is not of the nature/quality specified in the prescription and that sale is "*in pursuance of a prescription",* contrary to ss64, 67 Medicines Act 1968: whether the reason for the pharmacist's conduct is an SSP, a free-standing exercise of judgment by them or simply an error. There would not be a sale, or an SSP, if there was not a prescription and the offence is any sale or supply that varies from the prescription.

4. **Consultation, PSED and NHSA**: D admits that he did not undertake a "*formal assessment of the duties under the NHSA" [D/SGExh/9/48]*, that he only undertook a "*short impact assessment" [D/SGExh/9/47]* and that he failed to undertake the 12-week public consultation that he would normally undertake in this type of case *[SGOD/60]*. D claims that this is the type of case where consultation and impact assessment may occur in stages. But he is unable to point to any plans to do that and a major function of the SSP is to enable D to deal *swiftly* with emergencies. Accordingly, proper advance assessment of the *principle* of SSP, and how it might work best in an emergency, was vital. Nor was there any/pressing need for Reg. 9: it was expressly not linked to Brexit *[D/SGExh/10/57]* and, in any event, Brexit day has been known for the last 2 years.

5. Further, and on the s.31 point, if D acted lawfully, the status quo would continue: in the event of a shortage, the patient's doctor/other clinical professional, would prescribe alternative treatment taking into account any advice from D about what was available and might be suitable. The purpose of Reg. 9 and the SSP is to save the cost of GP time *[D/SGExh/9/47]* and *D/SGExh/9/52]*. The saving is hypothetical and relatively small. Set against that, Reg. 9 offers patients *no* benefits but exposes them to risks that D has almost entirely failed to assess, flowing from a new, un-tested and still largely un-explained process (as to the detail), that takes drugs from the manufacturer to the patient via the government and a pharmacist, dispensing with the professional and patient-centred expertise of doctors/other clinical professionals.

6. The lack of proper patient involvement and the wholly inadequate consultation process were procedurally unfair on patients, and contrary to past practice and the fundamental principle of patient involvement on which the NHS is based. The test is fairness in the eyes of the Court, and lawful compliance with the NHSA; not rationality, as D suggests.

7. It is now clear that, behind the scenes, a belated and half-hearted attempt was made to discharge the PSED. That attempt was undermined by a failure seriously to involve patients and patients' groups. The "*short impact assessment*" relied on *[D/SGExh/9/52]* contains, in the light of C's evidence, a wholly inadequate understanding of the nature, range and intensity of the risks posed by the SSP process. Further, whilst some information relevant to the PSED was communicated to D, the manifold risks were not and the advice tendered was ultimately no more than the type of "*Panglossian"* sentiment deprecated in *Domb v Hammersmith & Fulham LBC* [2009] EWCA Civ 941, §79: "*Our assessment is that there is no detrimental impact on particular protected groups…the protocol should have a positive impact on anyone taking medicines….This benefits all patients, including those with protected characteristics" [D/SGExh/9/56].*

8. **Standing**: C has standing on a Brexit-related matter of general public importance. If necessary, he is lent standing by the patient-related charities that support these proceedings but are unable to bring them, and by the 1200 (and counting) crowd-funders, many of whose messages left on the crowdjustice.com website indicate that they or a loved one are at risk from an SSP.

9. **In conclusion**: C emphasises the risks to patient safety; the fact that there **is** no need/urgent need, for the SSP regime; and that on D's own case its only benefit is to save the cost of GP time. In the short term, D can take practical steps to ensure continuity of medical supplies and issue guidance to "*appropriate practitioners*" about alternatives (or even directions) if a shortage arises; in the longer term Parliament can legislate or D can consult/risk assess properly.

STEPHEN KNAFLER QC and **YAASER VANDERMAN** on the 11 March 2019