1. Following a brief examination of the Terminally Ill Adults (End of Life) Bill (colloquially referred to as the "assisted dying bill"), two fundamental issues are apparent which will be of concern to pharmacists and the pharmacy sector, and more widely in respect of the process by which the drugs would reach the doctor providing them.

Conscience Clause

2. First, the "conscience clause" at s.23 seemingly would not apply to the sale or supply from a pharmacy of the drug(s) used for ending a patient's life. s.23(1) provides that "*No registered medical practitioner or other health professional is under any duty (whether arising from any contract, statute or otherwise) to participate in the provision of assistance in accordance with this Act.*"

3. A sale or supply from a pharmacy would at least arguably not be "*in accordance with this Act*" or within the meaning of "*the provision of assistance*".

4. The proposed Act is silent on the sale or supply of the drug(s) involved to the doctor providing them to the patient.

5. s.28(1)(a) allows (but does not require) the Secretary of State to make regulations about the "dispensing" of approved substances, but "dispensing" is not defined and may be taken (if interpreted by the courts) not to encompass sale or supply from a pharmacy.

6. "*Provision of assistance*" is not defined in the bill, but may be taken (if interpreted by the courts) to have the specific meaning outlined in s.18 - which does not relate to sale or supply from a pharmacy.

7. Further, the word "*participate*" in a similar conscience clause exercisable in respect of abortions was given a narrow construction by the Supreme Court in *Greater Glasgow Health Board (Appellant) v Doogan and another (Respondents) (Scotland)* [2014] UKSC 68 (see at [38]). The effect of this was that only direct, hands-on involvement in the process amounted to participation, and so people who were carrying out ancillary activities could not utilize the clause. Applying this to the clause proposed in the assisted dying bill, it would at least arguably mean that it did not extend to those whose involvement was restricted to selling or supplying the drug to the doctor. This would mean that those *participating* in the "provision of assistance" would only be those with direct, hands-on involvement, and only such individuals could not be placed under a duty to participate.

8. The Act itself at least arguably would not prevent pharmacists being placed under a duty to supply drugs used for ending a patient's life, upon receiving a lawful request to do so. This could be, for example, a regulatory duty, or a contractual duty imposed by an employer.

Legal Mechanism and Vehicle for Sale or Supply to the Doctor

9. A further issue is that it is not clear what if any thought has been given as to whether a drug used for ending a patient's life would or should be intended to be manufactured, sold or supplied in accordance with the Human Medicines Regulations 2012 (with or without further restrictions), and if so whether it could come within the current definition of "medicinal product" in reg. 2, or (for example) be granted a marketing authorization (consider e.g. reg. 58(4)(b)). The bill does not seek to modify the Human Medicines Regulations in any way. The definition of medicinal product in reg. 2 includes substances used with a view to "*modifying a physiological function*".

10. It may be argued that the drugs used for assisted dying have the effect of "modifying a physiological function" until the patient dies, but this would I think be interpreting that regulation out of context - the drug would ultimately result in the complete cessation of all physiological functions, not merely the modification of one. The regulation does not appear to conceive of this, which is understandable because the Human Medicines Regulations as a whole were drafted without provision for euthanasia. It would fundamentally change our understanding of the meaning of a "medicine" if a drug used to end life came within the definition in reg. 2.

11. In *R v Chapman* [2017] EWCA Crim 1743 at [11] and [20]-[23], the Court of Appeal considered the genesis of the Human Medicines Regulations and adopted the decision of the European Court of Justice in *Criminal Proceedings against D* [2014] P.T.S.R 1217 (see joined Cases C-358/13 and C-181/14, *Markus D. And G.* [2014] ECLI:EU:C:2014:2060). This judgment held at [38] that "*the term 'medicinal product'… must be interpreted as not covering substances whose effects merely modify physiological functions and which are not such as to entail immediate or long term beneficial effects for human health.*"

12. Status as a medicinal product, then, depends on the purpose for which the drug is ultimately to be used.

13. Reg. 58(4) provides that the licensing authority can only grant a marketing authorization if it thinks that "*the positive therapeutic effects of the product outweigh the risks to the health of patients or of the public associated with the product.*" It is difficult to see how this would be met, and this requirement serves to demonstrate the functions that a medicinal product was conceived to have at the time the regulations were drafted.

14. Various question arise, including:
    a) What drug(s) would be used?
    b) What is the intended mechanism and legal vehicle by which the drug(s) would be sold or supplied to the doctor who is providing them to the patient pursuant to s.18(3)? Could this vary depending on the specific drug used?

c) If it is the case that the drug to be used is not a medicinal product because of the purpose for which it is to be used, does this affect the legal vehicle(s) available for selling or supplying to the doctor who is providing them to the patient?
d) Would a supply by a pharmacist to such a doctor be authorized under the Misuse of Drugs Regulations 2001 (reg. 9, assuming that a (schedule 3) 5,5 disubstituted barbituric acid was used)? How would the quality and efficacy of the drug be guaranteed? Again, would this depend on the specific drug(s) used? If a *supply* but not a *sale* were authorized, could any money change hands in connection with the supply?
e) Could an order under s.105 of the Medicines Act 1968 overcome these problems?

15. A proposed change to the law such as that in the assisted dying bill would warrant, before a draft was first laid before parliament, an extensive public consultation on the circumstances in which the drug(s) to be used would be, for example, manufactured, sold or supplied, and the legal provisions which would apply. Whilst two issues in particular have been examined above, there are others; such a proposal naturally raises many issues which need to be considered.

16. Link to the bill: https://publications.parliament.uk/pa/bills/cbill/59-01/0012/240012.pdf