

12th September 2016

Dear Independent Prescriber,

1 - I am writing to advise you of an issue concerning Pharmacist Independent Prescribing which has recently come to our attention.

2 - We have embarked upon an organisation wide review of all relevant legislation and Regulations and compliance therewith as part of our continuing improvement strategy.

3 - The primary legislation pertaining to our organisation is the Pharmacy (Northern Ireland) 1976 Order (the Order). In 2004 powers were added to the Order under Article 5 to permit the making of Regulations to annotate the Register to identify, amongst other things, qualification or specialisms. Shortly thereafter amending Regulations were introduced for Supplementary Prescribers (SP), permitting the use of the annotation "SP".

4 - In 2006 the concept of Independent Prescribing (IP) was introduced and the then DHSSPS, working with us and other bodies, developed a Pharmacist IP qualification, and those qualifications were accredited by this organisation in early 2007 and re-accredited when required.

5 - Since 2007 we have been accepting applications for Pharmacist IP, checking eligibility against length of time on the Register, possession of an accredited qualification and charging a fee of £25 before granting Pharmacist IP designation.

6 - As part of the review referred to in paragraph 2 above we have established that unlike the arrangements for Pharmacist SP, no specific Regulations were ever made or approved in relation to Pharmacist IP annotations. In 2012 much of the Medicines Act was transposed to the Human Medicines Regulations and a new requirement to ensure the pharmacist "***is noted in the relevant register as qualified to order drugs, medicines and appliances as a pharmacist independent prescriber***" was also introduced without any specific power being granted to permit "noting" in the Register.

7 –It is clear that the policy intent since 2007 was for the Pharmaceutical Society NI to exercise the powers necessary to permit the annotation for Pharmacist Independent Prescribing and that the action taken in providing designations to date is consistent with the accepted requirements around experience and relevant qualification, albeit in the absence of specific Regulations .

8 – Our legal advisors have, however, stated that the current position is not beyond challenge and it would be preferable to have a specific Regulation for both the annotation and "notation" in relation to IPs.

9 – In the interim the Department of Health has advised that its view is that specific Regulations are required and confirmed its intention to work with us to approve specific Regulations, which will address both matters. Council has both approved draft Regulations for consultation and instructed the Registrar to add the note specified in paragraph 6 against all current IPs entry in the Register. The Department of Health has also confirmed that it

does not intend to seek to invalidate any accreditations currently in place in the absence of specific Regulations.

10 – In relation to fees it is noted that a fee of £25 was charged in the absence of a specific power, Council does not propose to refund any fees previously paid, having obtained legal advice, in particular because the costs of course development and accreditation, and the costs of administration and any CPD or fitness to practise matters arising out of annotated registration, should properly be met by those annotated.

11 – As an interim measure we have met with the Pharmacists' Defence Association (PDA), National Pharmacy Association (NPA) Insurers and Numark Insurance in their capacity as indemnity providers and they have provided assurances to us that this situation would not invalidate any current indemnity arrangements provided by them. We have also met with the pharmacy leads in the Health Trusts and we understand that they plan to contact all staff with regard to this matter.

12 – If you are indemnified by one of the above bodies or employed by a Health Trust you do not need to take any action as a consequence of the circumstances we have set out in this letter, we will shortly be consulting upon Regulations which will provide a more robust basis for current and future annotations, and we will notify you directly when the process is complete

13 If you hold indemnity arrangements not listed you should contact your provider to ensure that your cover is unaffected – if your provider requires more information they should be directed to the Chief Executive, trevor.patterson@psni.org.uk.

14 – Council regrets that this situation has arisen but is committed to ensuring that it is at all times compliant with legislation and regulation, and to openness when issues are discovered. Council is also supportive of the Department of Health's recent decision to modernise pharmacy regulation in NI and will work with the Department to ensure that the modernised legislation is fit for purpose in the current context.

Yours Sincerely

A handwritten signature in black ink, appearing to read 'Jim Livingstone', written in a cursive style.

Dr Jim Livingstone, President PSNI