

Dear Sir,

We would like to introduce DANAI (Dermatology Aesthetics Nurses Association Ireland).

Our mission statement is that by 2020 we will have enhanced our reputation as the leading Professional Association in the area of Dermatology and aesthetics sector supporting nurses who are delivering high quality services to the public in an ethical way by providing education and training, advocacy and support for our membership in collaboration with our stakeholders.

In previous correspondence, we were advised by a HPRC compliance officer:

“As the HPRC has no role in the regulation of healthcare professionals we cannot provide advice on clinical practice.”

As a consequence, we have met with the governing body for nurses in Ireland, the NMBI. Please find letter attached which issued as a result of our engagement with NMBI.

NMBI have confirmed to us that once a nurse is working within her scope of practice and code of professional conduct, which includes adhering to legislation and local guidelines, there is no issue with the administering of botulinum toxin A (“Botox”) by our members.

We feel there may be confusion in relation to Registered General Nurse and Nurse Prescribers. As both have different qualifications they have different set of “rules” as outlined in the letter from the NMBI.

In relation to administration of toxin, a nurse prescriber can prescribe a licensed medicine that is “off label”. If there is not another nurse present, she is also to allowed administer that medicine.

A Registered General Nurse can administer Botox if it is prescribed by a Doctor or a nurse prescriber.

This is our very clear understanding from our regulatory and governing body.

In relation to supply, one of your compliance officers has stated:

“All aspects of relevant medicines legislation must be taken into consideration for each different medicinal product and each supply route etc.

I would have serious concerns regarding this supply as under normal operations at a health service provider where nurse prescribing exists, there is never a need for a nurse to order, or be in direct receipt of

medicinal products themselves if they are in-line with the legislative requirements outlined below.

Relevant legislation from the prescription and control of supply regulations, SI 540 of 2003, as amended, is outlined below.”

It appears that medicinal products can be ordered by a nurse who is employed by a health service provider (as defined in the legislation) to the premises she works from e.g. practice nurses. A nurse prescriber can open an account in her name, when a script is required a nurse prescriber can write the required script, and the medicine can then be dispensed to the place that the nurse prescriber is employed. Once a nurse or nurse prescriber is working within her scope of practice and code of professional conduct, she is adhering to Irish nursing legislation.

In relation to Botox specifically, it appears your position that a nurse prescriber is not entitled to receive Botox, Dysport or Azzalure under Irish legislation (using these as examples only but there may be others). Nurses also cannot prescribe unlicensed/exempt medicines.

This would seem to conflict with the legislative provisions.

Furthermore, Botox and Azzalure are not unlicensed. A nurse prescriber can prescribe “*off label*”.

According to our governing body, NMBI, there is no rationale for Botox to be differentiated from other drugs.

As a consequence of the above we do not understand the HPRA position or rationale in respect of Botox, Dysport or Azzalure.

In relation to the SPC we have contacted the companies who manufacture Botox and Azzalure, and spoke to the departments who wrote the SPC for their product. These engagements have confirmed to us that the word “*physician*” can be defined to include a nurse or not to include a nurse.

The manufacturers did not choose to exclude nurses from their definition of physician. This would appear to be a decision made by the HPRA. Nurses in the United Kingdom and Northern Ireland have been administering botox for years and nurse prescribers have been prescribing it for years.

In relation to storage of Botox, in previous correspondence you advised:

“In relation to legislation and interpretation of ‘holding of medicines’, we advise that you contact the NMBI or the PSI (Pharmaceutical Society of Ireland), as this area is outside the remit of the Health Product Regulatory Authority (HPRA)”.

The NMBI have confirmed to us that they have no issue with medicines been stored on premises, when the nurse is acting within her scope of practice.

It also seems to us that a Nurse Prescriber is in a position to open an account with a supplier in her own name, once she is operating within her role as employee of a health service provider.

DANAI and our members are all concerned to ensure that proper practice, procedure and protocols are adhered to and that there is clarity and consistency. At present we are concerned that the HPRA is interpreting legislation very differently to other regulatory and governing bodies, which has the potential to expose our members to investigation and possible sanction, when it would appear that our members are acting within the statutory framework which the Oireachtas has provided. If that legislative framework is in some way deficient, that is a matter for the Oireachtas to legislate for, and not for agencies to attempt to remedy and deficit, perceived or otherwise.

We would be grateful if you could consider and we would appreciate if you could revert within 4 weeks from the date of this letter.

Yours sincerely,

DANAI