

Pharmaceutical Society NI Response to DHSC Consultation on its proposals to amend the Medicines Act 1968 and Human Medicines Regulations 2012 regarding Pharmacy Supervision

- 1. Proposal 1 is to amend the Medicines Act 1968 and Human Medicines Regulations 2012 to enable pharmacists (should they wish) to authorise a registered pharmacy technician to carry out, or supervise another person to carry out, the preparation, assembly, dispensing, sale and supply of prescription-only medicines and pharmacy medicines.**

Do you agree or disagree with proposal 1?

Agree X

Neither agree or disagree

Disagree

If you have any additional information to support your answer, please provide details.

We acknowledge that the proposals will not apply in Northern Ireland until Pharmacy Technicians are registered and the aim of the Government to apply this legislation as soon as possible thereafter. We also acknowledge that the details of the authorisation process will be a matter for the Pharmaceutical Society NI (the Society) in Northern Ireland to be determined through the Society's rules, regulations and standards.

Within this framework, we do in principle agree with the proposals which have the support of the Chief Pharmaceutical Officer, the Supervision Practice Group and local government.

We do however have concerns about the range of the new term 'authorisation' in the proposal which states,

'...an authorisation given to a pharmacy technician can be expressed in either specific or general terms (for example, relating to particular transactions or orders for medicines, or in general terms, potentially covering a range of prescriptions or categories of medicines). An authorisation can be given orally or in writing, may be subject to conditions or restrictions and may be varied or withdrawn by the pharmacist by whom it is given. In giving authorisation, a

pharmacist must have due regard to patient safety and failure to comply with that requirement may lead to professional fitness to practice proceedings.'

We believe that this proposed process required a more robust structure to ensure a consistency of practice and safeguards which would include such matters as:

- Authorisation must be clearly defined in the proposed regulations and in any relevant guidance and procedures. A glossary of all terms including Responsible Pharmacist, should be included in the regulations.
- There must be mutual agreement of the transfer of authority between the pharmacist and technician as both will be accountable as regulated professionals. This authorisation must be the subject of review and can be terminated if either party believes that the responsibilities are outside their competence.
- There must be a clear record maintained of the authorisation for accountability purposes and as a reference.
- The transfer can only be authorised by the Responsible Pharmacists who satisfy themselves of the competence of the technicians for the authorised tasks.

2. **Proposal 2 will enable a pharmacist to authorise any member of the pharmacy team to hand out checked and bagged prescriptions to patients or patient representatives. This is to align 'bricks and mortar' pharmacy premises with current practice for home delivery, locker box and other delivery services.**

Do you agree or disagree with proposal 2?

Agree X

Neither agree or disagree

Disagree

If you have any additional information to support your answer, please provide details. (optional)

We note that these proposals will apply to Northern Ireland.

We recognise that the proposed changes are to bring into line practice in Community Pharmacies with other current practice including delivery services.

As the pharmacy regulator in Northern Ireland, we will ensure that guidance ensures that both pharmacists and all pharmacy team members clearly understand what is and what isn't permitted by the transfer of authority.

- 3. Proposal 3 is to allow a registered pharmacy technician to be responsible for a hospital aseptic facility in the same way that a pharmacist is under the current law.**

Do you agree or disagree with proposal 3?

Agree

Neither agree or disagree

Disagree X

If you have any additional information to support your answer, please provide details.

As pharmacy technicians are not a regulated profession in Northern Ireland, this provision will only apply in Great Britain. We acknowledge the aim of the DHSC to apply this legislation in Northern Ireland once possible.

We acknowledge that hospital aseptic facilities are already strictly governed by Standard Operating Procedures, and that pharmacy technicians within hospital pharmacy teams are very experienced in this service.

The Society would caution against any proposal which removes the day-to-day oversight of the pharmacy process leaving the Chief Pharmacists (who may be responsible for several pharmacy services in separate locations) to be responsible for ensuring the safe and effective running of this pharmacy service and urge that the DHSC rethink this proposal to ensure that the medicines expertise of pharmacists is always available as required.

- 4. 'At or from'**

We propose that Regulation 220 of the Human Medicines Regulations 2012 is brought into line with the changes already made to other legislation concerning the supply of medicines 'at or from' a registered pharmacy premises. This is to better reflect current practice, particularly in the provision of delivery services from a registered premises.

Do you agree or disagree with this proposal?

Agree x

Neither agree or disagree

Disagree

If you have any additional information to support your answer, please provide details.

We note that this will apply to Northern Ireland. We are content that this is a straightforward alignment of current legislation which reflects current practice for example, in delivery services.

Legislative barriers

- 5 Do you think there any other barriers to modernising pharmaceutical practice in government legislation that we should consult on removing in the future?**

Yes ☒ **X**

No ☐

Don't know ☐

If you have any further information to inform the consultation-stage impact assessment on the costs and benefits of each option, please provide it here.

There are many issues to be addressed on the modernisation of pharmacy in Northern Ireland, however, these are being systematically addressed through partnership with the Department of Health and local government.

Impact assessment

- 6 Question**

If you have any further information to inform the consultation-stage impact assessment on the costs and benefits of each option, please provide it here.

No comments.

Draft statutory instrument

- 7 Question**

If you have any further comments on any aspect of the draft statutory instrument, please provide it here.

The areas of applicability of the measures to Northern Ireland should be made clear in the statutory instrument. This is of particular relevance to UK wide institutions and UK wide pharmacy companies.

All terms used in the statutory instrument should be clearly defined.

Consideration should be given to an additional Northern Ireland consultation covering the areas not yet applicable when the process of the registration of technicians is complete to ensure the compatibility of the current proposed legislation with the final technician registration and responsibility structure and relevant legislation.