

Standards and Guidance Review Programme – Council Highlight Report

FOR NOTING

This paper provides Council with an update on key workstreams within the Standards and Guidance Review Programme.

Action Required by Council

Council is asked to note progress on the Prescription Collection and Delivery guidance, Pharmacist Prescribers Standards, and the Standards and Guidance Review Framework.

David McCann

Head of Regulatory Strategy

07 September 2026

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1. Draft Guidance for Prescription Collection and Delivery in NI:

During this reporting period, the final draft of the Guidance for Prescription Collection and Delivery in Northern Ireland was completed following public consultation in November 2025 and subsequent consideration by the Expert Advisory Group (EAG).

Consultation responses highlighted the need for greater clarity in relation to governance and accountability arrangements, automated collection units, controlled drugs, patient consent, accessibility, safeguarding and the use of technology. In response, the guidance has been revised to address these areas.

The revised guidance sets clearer expectations in relation to governance, risk management and patient safety and includes additional provisions relating to automated collection units, home delivery services and higher-risk medicines.

The Consultation Outcomes Report and Phase 2 Equality Impact Assessment are being finalised in preparation for Council consideration.

Before the guidance can proceed to approval, it will undergo an internal regulatory enforceability review to assess whether the proposed requirements are sufficiently clear, proportionate and capable of supporting regulatory decision-making. Any amendments arising from this review will be incorporated before the guidance proceeds to the final approval stages.

As a result, the programme will extend beyond its original anticipated publication date. A revised publication timeframe will be established following completion of the remaining review and approval stages.

Next Steps

- Complete the internal regulatory enforceability review.
- Finalise the Consultation Outcomes Report and Phase 2 Equality Impact Assessment.
- Obtain SMT and Council approval.
- Publication and implementation.
- Withdrawal of the 2016 supplementary guidance.

2. Draft Standards for Pharmacist Prescribers in NI

During this reporting period, the pharmacist prescribing standards programme reached a significant milestone with the completion of the public consultation phase. Consultation responses demonstrated broad support for the proposed standards and provided valuable feedback on a number of areas where further clarification and supporting guidance would assist implementation.

Following analysis of the consultation responses, the Standards for Pharmacist Prescribers in Northern Ireland have been revised and are being presented to the Expert Advisory Group (EAG) for endorsement. An endorsement paper and amendment schedule have been shared to support consideration of the consultation findings, the changes made in response to stakeholder feedback and the recommendations arising from the consultation process.

Consultation feedback also highlighted a number of areas where registrants and stakeholders considered additional guidance would be beneficial, particularly in relation to prescribing competence and scope of practice, prescribing in remote and online care settings, and the prescribing of higher-risk medicines. In response, draft supporting materials have been developed to complement the standards and support their application in practice.

The consultation process identified a need for supplementary guidance in a number of areas. As a result, the programme now includes the development, review and approval of both standards and supporting guidance.

Subject to EAG endorsement of the revised standards and the proposed approach to supporting guidance, detailed review of the draft guidance materials will be undertaken through specialist EAG subgroups before returning to the full EAG for sign-off.

Following completion of the EAG review process, the standards and supporting guidance will undergo an internal regulatory enforceability review to assess whether the proposed requirements are sufficiently clear, proportionate and capable of supporting regulatory decision-making. Any amendments arising from this review will be incorporated before the package proceeds to the final approval stages.

Publication will be dependent on completion of the remaining review and assurance stages, including EAG consideration, subgroup review and internal regulatory enforceability assessment. A revised publication timeframe will be established once the scope of any further amendments arising from these stages is known.

Next Steps

- Finalise the Consultation Outcomes Report.
- Finalise the Phase 2 Equality Impact Assessment.
- EAG consideration of the revised Standards for Pharmacist Prescribers and proposed approach to supporting guidance.

- Detailed review of draft supporting guidance through specialist EAG subgroups.
- Final EAG sign-off of the standards and supporting guidance package.
- Internal regulatory enforceability review.
- Final approval process.
- Publication and implementation of the standards and supporting guidance.

3. Consultation Responses

The Society has not responded to any consultations within this reporting period.

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7 September 2026