Specialist Pharmacy Service

NHS

Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines

Edition 5.1

September 2022

The first stop for professional medicines advice

INTRODUCTION

Background

The Department of Health Document, *An Organisation With a Memory* (2000), identified targets to reduce the number of serious errors in the use of prescribed drugs by 40 per cent by 2005 and to reduce death or paralysis caused by maladministered spinal injections to zero by the end of 2001.

The Department of Health report, *Building a Safer NHS for Patients* (2001), recommended that safety was built into purchasing policy within the NHS.

In 2001, the Committee on Safety of Medicines established a working group to review the packaging and labelling of medicines following a death related to a spinal injection of vincristine. The findings were published in *MLX275, Recommendations for the Labelling and Packaging of Medicines* (Aug 2001).

In 2003, MHRA and NPSA worked collaboratively to publish the guidance document, *Best Practice on the Labelling and Packaging of Medicines* (edition1 - March 2003), which was based on the recommendations of MLX275.

In 2004, the NHS Pharmaceutical Quality Assurance Committee published the document, *Quality Assurance and Risk Assessment of Licensed Medicines for the NHS to support Contracting of Medicines in the NHS (edition 1)* in collaboration with NHS Purchasing and Supply Agency (PASA) and regional procurement pharmacists. This document described a risk assessment process to help evaluate the medication error potential of medicines associated with their packaging and labelling. It was developed against the principles of MLX275 and the MHRA best practice guidance and used by NHS Regional Quality Assurance Pharmacists to inform and advise the contract adjudication process.

Design for Safety

In 2006, The NPSA and the Helen Hamlyn Research Centre jointly published the guidance document, *Design for patient safety: A guide to the graphic design of medication packaging* (see Section 5). The guide demonstrates how graphic design on medicines packaging can enhance patient safety and details best practice based on user testing, taking views from patients, pharmaceutical Industry personnel, NHS agencies, nurses and pharmacists. The scope of this guidance was primary and secondary packaging of medicines in blister packs.

In 2007, the NPSA published *Promoting safer use of injectable medicines (NPSA Alert 20)* (see Section 5), which reported that they received 59,000 reports of patient safety incidents involving medicines between January 2005 and June 2007. Approximately a third of those incidents involving injectable medicines accounted for 25 per cent of all medication incidents, and 58 per cent of the most serious incidents (i.e. those that resulted in death or serious harm to patients). It also reported that approximately a third of medication errors were linked to confusion over packaging and labelling.

Recommended actions included the “use of purchasing for safety policies” and that procurement groups should procure injectable medicines that have design features that make them safer to use in practice.

Following on from this alert, in 2008 The NPSA and Helen Hamlyn Research Centre published a second guidance document, *Design for patient safety: A guide to labelling and packaging of injectable medicines* (see Section 5). This guide provided guidance to the pharmaceutical industry for primary and secondary packaging of injectable medicines.

The two NPSA design for safety guides are aimed at packaging designers and pharmaceutical companies manufacturing but have also been adopted as the key reference documents to support the safe procurement of medicines within NHS because they describe best practice for the packaging and labelling of medicines for safety.

Purchasing for Safety

Purchasing for safety is a fundamental principle underpinning the procurement of medicines that is embedded into the central contracting process for generic medicines in the NHS. Purchasing for safety plays an important role in mitigating the risks of medication errors, especially in preventing selection errors associated with “look alike, sound alike” (LASA) medicines.

The NHS Pharmaceutical Quality Assurance Committee first developed a risk assessment tool in 2004 (Quality Assurance and Risk Assessment of Licensed Medicines for the NHS) to evaluate the potential for medication errors associated with the packaging and labelling of generic medicines. This was supplemented with a policy in 2007 (QA Policy for Contract Procurement of Licensed Pharmaceuticals). These two documents were combined in 2011and describe the arrangements for how NHS regional quality assurance specialists support the contracting process.

The risk assessment process evaluates the packaging and labelling of medicines against MHRA and NPSA design for safety guidance documents:

- *Best practice on the labelling and packaging of medicines*
- *Design for patient safety: A guide to the graphic design of medication packaging*
- *Design for patient safety: A guide to labelling and packaging of injectable medicines*

The risk assessment informs both the adjudication process and supports the communication of identified risks to end users and suppliers.

This version has been revised to reflect the following:

- The updated governance arrangements for the QA assessment process following the NHS Specialist Pharmacy Service (SPS) transformation and consolidation of the Regional QA services in England
- Clarification of fixed gateway specification criteria relating to packaging and labelling requirements

POLICY

1. Purpose

The purpose of this policy is to define the process, roles and responsibilities for undertaking and reporting packaging and labelling for safety quality assessments for licensed medicines in support of NHS England licensed medicines contracts led by the Commercial Medicines Unit (CMU). The assessments inform purchasing decisions made by CMU and identify potential 'in use' risks to end users of the medicines.

2. Scope

The scope of this policy is limited to the assessment of the packaging and labelling of licensed medicines by the Specialist Pharmacy Service in support of the national medicines contracting process led by the Commercial Medicines Unit (CMU).

The assessment does not include evaluation of licensed indications, licensed routes of administration, the presence/absence of excipients of known effect or other product features unless specifically stated in the product descriptor.

The assessment of unlicensed medicines, re-packaged and overlabelled GB-licensed packs, Medical Devices and food supplements is out of scope of this policy.

3. Policy Statement

3.1. Assessment overview

3.1.1. Medicines are assessed from:

- artwork
- photographs
- Summary of Product Characteristics (SmPC)
- Patient Information Leaflet (PIL)

For a complete assessment to be made it is necessary for a complete set of images and documents to be available (see appendix 1).

3.1.2. Medicines are then assigned a score (High, Medium, Low or No Score – refer to 3.3 below) and uploaded to PharmaQC to inform the CMU adjudication process.

3.1.3. It is sometimes possible for a High score to be assigned based on artwork only, if the reason for the High score is already evident from the artwork.

3.1.4. In exceptional circumstances, assessors may agree to receipt of a physical sample. This will be agreed on a case-by-case basis.

3.2. Assessment criteria

3.2.1. All medicines must

3.2.1.1. fully match the NPC descriptor against which they are offered (e.g. co-name medicines must be labelled with the co-name, not individual drug names); medicines requiring specific features (e.g. licensed route; prohibited excipients; scored tablets; container type) must have that feature. *Non-compliance will result in a No Score (refer to 3.3).*

3.2.1.2. conform to the fixed gateway criteria listed in Appendix 2. *Non-compliance will result in a High Score (refer to 3.3).*

3.2.1.3. In addition, the medicines must

- be clearly labelled, with the critical information prominent and readable. The critical information is the generic name (NPCode name) of the medicine, the strength of the medicine, the form of the medicine, the route of administration, and posology and warnings.
- be adequately differentiated from other medicines in the range (same molecule) and other Look Alike/Sound Alike medicines from the same manufacturer. Packaging and labelling (primary and secondary) will be considered poorly differentiated if there is no judicious use of colour or differentiation in text size or layout to emphasise the key differences in critical information. This applies to all primary and secondary packaging, and any printed overwraps
- include sufficient, clearly presented technical information on the packaging or in the PIL to direct the intended user to prepare and administer the medicine safely

Non-compliance with any of the above will result in a High score (refer to 3.3).

3.2.2. For pre-labelled packs, the pre-label element must be incorporated into the carton artwork. Packs overlabelled with a separate label will be given No Score. The pre-label wording should either be in accordance with the pre-label specifications for each pre-labelled line, if included in the tender specification, or in accordance with the PIL and BNF warnings if there is no specified pre-label. *Non-compliance will result in a High score (refer to 3.3).*

3.2.3. Medicines should also comply with the general good practice principles set out in

- Best practice guidance on the labelling and packaging of medicines (MHRA December 2020) (see section 5 below)
- Promoting safer use of injectable medicines (NPSA Alert 20, March 2007) (see section 5 below)
- Design for patient safety: A guide to the graphic design of medication packaging (NPSA 0463A 2008) (see section 5 below)
- Design for patient safety: A guide to labelling and packaging of injectable medicines (NPSA 2008) ISBN: 978-1-906624-02-6 (see section 5 below)

See section 3.3.1 for consequence of non-compliance

3.3. Assessment process

Refer also to diagram (fig. 1).

3.3.1. The medicine is assessed by one SPS QA assessor with reference to the criteria in 3.2 above and assign a score

No Score – Offered product does not meet the descriptor, or the documentation or images are insufficient or inadequate to permit the assessment to be completed.

High – Significant risk to patient safety or any of the grounds in section 3.2 above which expressly state they result in a High score
Medium – One or more non-compliances with general good practice principles (see 3.2.3 above) where additional local risk mitigation measures may be required
Low risk – No non-compliances with general good practice principles (see 3.2.3 above) that require additional local risk mitigation measures
Artwork only – partial assessment from artwork where the score is inconclusive or may change following receipt of photographs. An Artwork only score may be qualified with a narrative "likely low" or "likely medium"; medicines that can already be identified as High are assigned a High score.

3.3.2. Medicines assigned a High score, including from artwork, are reported to the SPSQA hub team and referred for peer review by a minimum of two additional SPS QA assessors. A file note is retained by the SPS QA Hub identifying the peer group and the discussion.

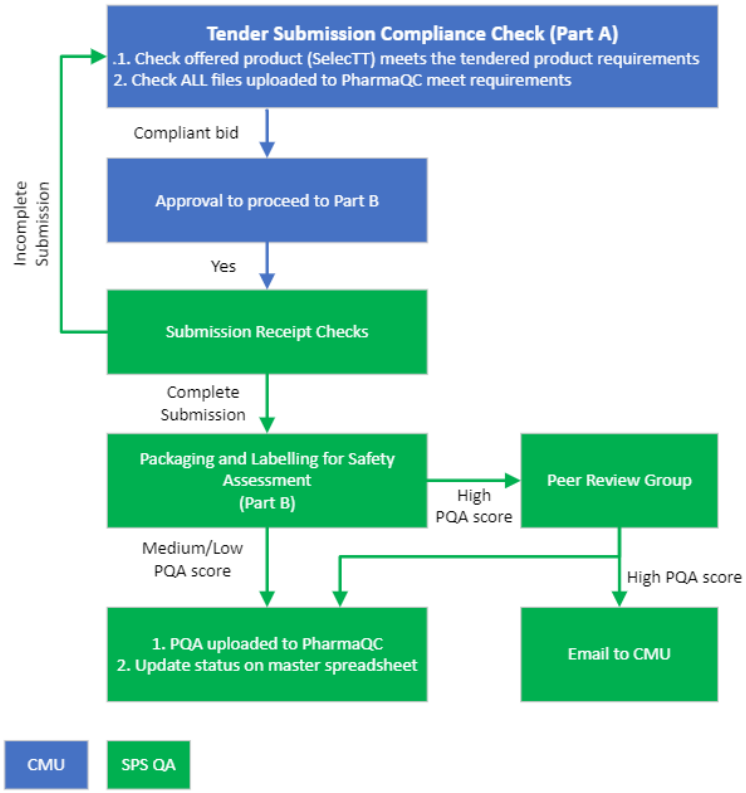
If the peer review concludes there is a significant risk to patient safety this results in a High score.

3.3.3. All assessments are recorded on PharmaQC. In addition to the assessment observations, assessors may also add comments under "PAI" (Potential Acceptability Issues) which may be of interest to Trusts (e.g. presence of excipients of known effect, compatibility with vial/bag adaptors).

3.3.4. The completion of the assessment is communicated to CMU

- High scores are notified by the Hub directly to CMU by email to **samples@cmu.nhs.uk**
- All other scores are entered onto the tender-specific electronic assessment communication spreadsheet.

Fig.1



3.4. Governance arrangements

3.4.1. The Quality Assurance Hub lead pharmacist is responsible for the assessment service.
3.4.2. Assessments are performed by suitably trained SPS QA personnel.
3.4.3. Assessors are trained and competence is assessed and maintained by the SPS Quality Assurance Hub.
3.4.4. Disputes are directed to the Quality Assurance Hub lead pharmacist or deputy in the first instance, with escalation to the Head of SPS.

4. Appendices

Appendix 1 – Requirements for artwork, photographs and documentation to permit a complete assessment


Appendix 1 –
Requirements for ar

Appendix 2 – Fixed gateway assessment criteria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5. References

1. Promoting safer use of injectable medicines (NPSA Alert 20, March 2007)


NRLS-0434-Injectabl
e-medicines-PSA-20

2. Design for patient safety: A guide to the graphic design of medication packaging (NPSA 0463A 2008)


NPSA-0463A-Design
-for-patient-safety-

3. Design for patient safety: A guide to labelling and packaging of injectable medicines (NPSA (NRLS 0592) 2008) ISBN: 978-1-906624-02-6 [3]


NRLS-0592-guide-t
o-labell_medicines-(

4. Best practice guidance on the labelling and packaging of medicines (MHRA December 2020)

https://www.gov.uk/government/publications/best-practice-in-the-labelling-and-packaging-of-medicines

6. Document History

Document History	Reason for change	Issue date
Edition 1	QA and Risk Assessment of Licensed Medicines for the NHS QA Policy for Contract Procurement of Licensed Pharmaceuticals	June 2004 June 2007
Edition 2	Update to consolidate above two documents	April 2011
Edition 3	Draft only, not formally issued	Nov 2013
Edition 4	Updated to add clarification of the QA support to the national procurement process for licensed medicines	August 2017
Edition 5	Scope narrowed to detailing the policy for undertaking packaging and labelling for safety quality assessments for licensed medicines by SPS QA.	July 2022.
Edition 5.1	Added introduction and reference to Design for patient safety: A guide to the graphic design of medication packaging (NPSA 0463A 2008)	September 2022