



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

Edition 6

October 2023

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* (edition 1 - March 2003), which was based on the recommendations of *MLX275*. This document has been updated and the most recent version was issued in 2020.

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.

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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.

Although all the resources above are several years old the principles remain current and relevant.

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 2011 and 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. End users should review the identified risks as part of their local change management process and implement any appropriate risk mitigation measures.

POLICY

1. Purpose

The purpose of this policy is to define the process, roles and responsibilities for undertaking and reporting graphic design for safety assessments for branded and generic licensed medicines by the Specialist Pharmacy Service Quality Assurance (SPS QA) team in support of NHS England licensed medicines contracts led by the Commercial Medicines Unit (CMU).

The purpose of the assessments is to

- inform the CMU tender process, the suppliers' future bids and the final CMU contracting decision
- alert end users to in-use safety issues, and to support development and implementation of local risk mitigation measures.

2. Scope

The scope of this policy is limited to the assessment of medicines with a UK marketing authorisation undertaken in support of the national medicines contracting process led by the CMU.

- The assessment score to inform the purchasing decision is based on the graphic design only of the primary and secondary packaging and any printed overwraps. It does not include evaluation of licensed indications, licensed routes of administration, the presence/absence of excipients of known effect or any other product features (e.g. "sugar free", presence of child resistant cap).
- The assessment narrative may include comment on any of the above characteristics where information comes to the attention of the assessor, but this is recorded for end user information only.

The assessment of unlicensed medicines and medical devices is out of scope of this policy.

3. Policy Statement

3.1. Assessment overview

- 3.1.1. For a complete assessment to be made it is necessary for the graphic design of all printed packaging to be seen. Graphic design may be assessed from:
- Artwork of primary packaging, secondary packaging and any printed overwraps, or
 - Photographs of primary packaging, secondary packaging and any printed overwraps, or
 - A combination of artwork and photographs of the primary and secondary packaging and any printed overwraps

The artwork and/or photos must show all of the printed packaging for primary and secondary containers, including any printed overwraps to enable an assessment to be made.

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3.1.2. Medicines are then assigned a score (refer to 3.3) to inform the CMU adjudication process.

3.1.3. A narrative assessment is made to:

- further inform the adjudication process
- enable “in use” risks to be communicated to end users

3.2. Assessment criteria

3.2.1. All medicines must conform to the fixed gateway criteria listed in Appendix 1 Non-compliance on any single point will result in a Critical Score (refer to 3.3).

3.2.2. Medicine packaging should comply to best practice for labelling and packaging to ensure that medicines can be used safely by all patients, the public and healthcare professionals alike. Good practice principles set out in:

- Best practice guidance on the labelling and packaging of medicines (MHRA December 2020) (see section 4)
- Promoting safer use of injectable medicines (NPSA Alert 20, March 2007) (see section 4)
- Design for patient safety: A guide to the graphic design of medication packaging (NPSA 0463A 2008) (see section 4)
- Design for patient safety: A guide to labelling and packaging of injectable medicines (NPSA 2008) ISBN: 978-1-906624-02-6 (see section 4)

If unacceptable patient safety risks are identified for which risk mitigation measures are likely to be impracticable or insufficiently effective a critical score will be assigned to the medicine.

See section 3.3.2 for scoring definitions.

3.3. Assessment process

3.3.1. The medicine is assessed by one assessor with reference to the criteria in 3.2 above.

3.3.2. A score is assigned, and a narrative assessment recorded where indicated.

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Score	Definition	Narrative assessment
Critical	Unacceptable risk to patient safety for which risk mitigation measures are likely to be impracticable or insufficiently effective (see 3.2.1 and 3.2.2). This product should not be put onto contract.	Yes
Major	Major risk to patient safety or non-compliances with general good practice principles (see 3.2.2 above) where additional local risk mitigation measures may be required	Yes
Other	One or more non-compliances with general good practice principles (see 3.2.2 above) where additional local risk mitigation measures may be required	Yes
No comment	No non-compliances with general good practice principles (see 3.2.2 above) that require additional local risk mitigation measures	No
Incomplete/incorrect submission	Offered product does not meet the specification, or the documentation or images are insufficient or inadequate to permit the assessment to be completed.	No
Not an UK licensed medicine	Any product offered that is not a UK licensed medicine e.g. medical devices.	No

- 3.3.3. Medicines assigned a Critical score are reported to the SPS QA hub team and referred for peer review by a minimum of two additional SPS QA assessors.

The peer review group will review the assessment to confirm whether the medicine does not conform to one or more of the fixed gateway criteria, or whether there is an unacceptable patient safety risk for which risk mitigation measures are likely to be impracticable or insufficiently effective.

A file note is retained by the SPS QA Hub identifying the peer group and the outcome of discussion.

- 3.3.4. All assessments are recorded on the SPS Graphic Design Assessment Record.

3.4. Governance arrangements

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

4. References

1. 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>

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



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



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



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5. 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
Edition 6	Clarification of purpose and scope of assessments and revised fixed gateway criteria and scoring	October 2023

Appendix 1 – Fixed Gateway Criteria

Ref No.	Applicable to	Criteria N.B "Packaging" is defined as "all primary and secondary packaging, and any printed overwraps"	A Critical (Fail) score will be given if... Refer also to exceptions, and examples, if given.	Exceptions
1	All	All packaging must be labelled in English	English is absent from packaging.	Multi-language packaging provided one language is English.
2	All	All critical information (name, form, strength, route of administration) must be present on all packaging.	Critical information is absent from packaging.	Route labelling is not required on blister packaging for tablets and capsules to be administered orally
3	All	Wherever the proprietary name of the medicine appears the generic name (or, where applicable, the co-name) must be present on the same face of the packaging. NB: For the purposes of this policy, the generic name is defined as the NPSCode name.	The generic name (or, where applicable, the co-name) is absent from, or incomplete on, the packaging.	None
4	All	Chemical symbols may only be used in addition to full generic names.	Chemical symbols are used instead of full generic names.	None
5	All	The strength is expressed according to the generic name. If both the salt and base are included on the packaging, it must be clear which is related to the dose.	The strength is not expressed according to the generic name. If both the salt and base are included on the packaging, there is ambiguity about which is related to the dose.	None
6	Injectable medicines in liquid form	Wherever strength is expressed on the packaging the total quantity per total volume appears on the same face.	The total quantity per total volume is not expressed on the same face of the packaging wherever the strength is expressed.	- For multi-dose containers e.g. insulin - Where the total volume is 1mL - Where the strength is expressed as a ratio or %, where the total volume is also clearly stated. - Prefilled syringes where the total volume is to be administered
7	All	Strengths are expressed using units of measurement.	Strength is expressed without units of measurement.	Strengths expressed as % and ratios.
8	All	Micrograms and nanograms are spelled out in full, and the symbol μ is never used.	Micrograms is abbreviated to mcg or μ g, or nanograms is abbreviated to ng.	The abbreviation mcg may be used if necessary for space reasons on small primary packaging labels, provided it is expressed in full on secondary packaging
9	All	Decimal points are only used where necessary to express fractions of whole units.	There are trailing zeros (zeros after the decimal point).	Trailing zeros within text, and where they are unlikely to be mistakenly used for calculations, may be acceptable but should be avoided.
10	All	Decimal points are always shown as "full stops".	Commas are used instead of decimal points.	None
11	All	Only positive statements about injectable routes and methods of administration may appear on the packaging.	Negative statements about injectable routes or methods of administration appear on the packaging.	None
12	Products listed in Doc 4b, Section 7	Primary container must not be overlabelled	Primary container is overlabelled	None