

**Quality Assurance Policy to support**

**the National Contract Procurement**

**of Licensed Medicines**

**Edition 4**

**August 2017**

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

Prepared by the NHS Pharmaceutical Quality Assurance Committee’s Procurement Sub-Committee

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| **Document History** | **Issue date and reason for change** |
| Edition 1 | QA and Risk Assessment of Licensed Medicines for the NHS Issued June 2004  QA Policy for Contract Procurement of Licensed Pharmaceuticals Issued June 2007 |
| Edition 2 | Issued April 2011 |
| Edition 3 | Draft only, not formally issued (Nov 2013) |
| Edition 4 | Issued August 2017, updated to add clarification of the QA support to the national procurement process for licensed medicines |

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1. **Purpose of this document**

The purpose of this national policy document is to:-

* define the arrangements for the quality assessment of licensed medicines in support of the national contracting process.
* define the roles and responsibilities of Regional Quality Assurance (QA) specialists in the contracting process for licensed medicines
* ensure equity and consistency of the quality and medication error potential assessment process and ongoing contract support
* to define the process for reporting the outcome of the quality and medication error potential assessments to contracting teams and purchasers to support risk based decision making.

# Scope of this document

The scope of this document is limited to the process of assessing the quality and medication error potential of licensed medicines in support of the **national contracting process** led by the DH Commercial Medicines Unit (CMU).

It does not cover assessing licensed indications, licensed routes of administration, or a comparison with product from any existing contract holder.

Off-contract purchases by individual Trusts are outside the scope of this policy.

The quality assessment of unlicensed medicines, medical devices and food supplements is also outside the scope of this policy. However, this policy identifies the arrangements necessary when a substitution for a contracted line is required and there is no alternative licensed medicine available.

1. **Governance and accountability**

Regional QA Specialists and their teams assess the quality and medication error potential of licensed medicines in support of the national contracting process.

This QA part of the overall assessment process results in each product being assigned a risk rating based soley on potential hazards identified, and medication errors that might be made, due to an issue with the packaging or labelling of a medicine.

This risk rating is communicated to pharmacy purchasing leads and to the CMU. Purchasers must decide whether or not they can accept/control the risks identified.

Regional QA Specialists can support this decision making process by the provision of further information as requested.

All QA staff performing these duties must be trained and signed off as competent by a Regional QA Specialist.

Attendance at the annual national training day is required.

Any dispute, including regarding the consistency of an assessment will be raised to the chair of the QA Committee Procurement sub-group for arbitration.

An annual meeting of QA assessors includes benchmarking activities to facilitate consistency in assessment of samples.

1. **Roles and responsibilities**

Regional QA Specialists and their teams are responsible for adhering to this policy whenever they are carrying out quality assessments of licensed medicines for contracts led by CMU.

The total arrangements for the national contracting process have been broken down into individual activities. The roles and responsibilities of QA specialists in this process are summarised in the table below, together with their inter - relationships with CMU, Regional Procurement Leads and individual NHS Trusts for each element of the process.

*(stages in the process that are performed by other groups of staff are shown in italics)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Activity** | **QA** | **CMU** | **Procurement** | **Trust** |
| *Specifying products required for contract* | X | Y | Y | Y |
| *Creation of NPC codes* | X | Y | X | X |
| *Initiation of the tender process and receipt of submissions from suppliers* | X | Y | X | X |
| *Communication with suppliers at all stages of the process. This includes requests for substitutions and pack changes during a contract.* | X | Y | X | X |
| Liaison with CMU to select samples requiring assessment based on tender returns and according to agreed criteria | NW region | Y | X | X |
| *Preparation of a sample allocation spreadsheet for QA staff to allocate samples, and notification of individual QA assessors of products they have been allocated to assess* | X | Y | X | X |
| Allocation of samples (products submitted at tender, substitutions, pack changes during a contract) to QA assessors | NW region | X | X | X |
| Receipt and assessment of samples | All | X | X | X |
| Confirmation to CMU that any extended stability data that has been provided relates to the reconstituted product. | London region | X | X | X |
| Assigning a PQA score and adding this with comments to PharmaQC in a timely manner and using the agreed criteria (as given in the Guidance to Performing a PQA document) | All | X | X | X |
| *Preparation and circulation of summary documents for adjudication* | X | Y | X | X |
| Review pre-adjudication documents provided by CMU | All | Y | Y | Y |
| Participation at regional/national adjudications | All/London region | Y | Y | Y |
| *Awarding of contracts* | X | Y | X | X |
| *Purchasing products in line with contracts awarded where possible* | X | X | X | Y |
| Follow-up of lines awarded where PQA not done or incomplete at adjudication date | All | Y | Y | X |
| Accept/reject products assessed post adjudication (eg. where PQA completed after the adjudication, or of substitutions or pack changes during a contract) | X | Y | Y | X |
| *Preparation of a summary of products awarded with a High/Medium/Low risk PQA with potential acceptability issues for some users. This is sent to QA staff for the preparation of Safe Medication Bulletins (SMBs)* | X | Y | X | X |
| Preparation of Safe Medication Bulletins for products awarded but having a High/Medium/Low risk with potential acceptability issues as appropriate. This includes extra bulletins produced following the start of a contract, for substitutions or pack changes as appropriate | NW region | X | X | X |
| Distribution of SMBs within each region as appropriate | All | X | X | X |
| *Interpretation of Safe Medication Bulletins issued and the implementation of appropriate risk management measures at a local level* | X | X | X | Y |
| *Providing information as requested by Regional Procurement Leads, CMU, QA staff in relation to contract products* | X | X | X | Y |
| *Feeding back to Regional Procurement Leads/CMU/QA Specialists any issues relating to product acceptability issues or product defects* | X | X | X | Y |
| Responding to quality related queries from Trusts, CMU, Regional Procurement Leads or suppliers for products on contract | All | X | X | X |
| *Responding to any queries from Trusts, CMU, QA staff or suppliers relating to contract products* | X | X | Y | X |
| Logging defect reports concerning contract products and forwarding to the national database for collation (AIC) | All, and South West region collates | X | X | X |

The full roles/responsibilities of the Regional Procurement Pharmacists/Specialists, the CMU, individual Trusts, the regional and national adjudication groups, and PMSG are outside the scope of this policy.



Text in green boxes represents QA involvement in specific stages of the overall process

1. **Policy statements**

**5a) Sample selection and allocation**

QA input (team as nominated by the NHS Pharmaceutical QA Committee) is required for all tenders except when a quality assessment is not required. See decision tree below.

Samples are:-

* selected according to joint agreement between the CMU and the QA team designated by the NHS Pharmaceutical QA Committee
* then allocated, usually the following day, to regional QA assessors by this designated QA team

Samples are selected in accordance with the following principles:-



NB. Not all tendered products are PQA assessed.

**5b) Sample assessment and addition of comments and PQA score to**

**PharmaQC**

Pharmaceutical Quality Assessments (PQA) are undertaken in line with this policy document, and associated PQA Tool (Appendix 1), procedures and Medicine Quality Assessment Guidelines (MQAGs).

Decisions required as part of this process that are based on professional judgement are covered in separate MQAG documents.

QA assessors meet annually to review MQAG documents, which may then be updated according to regulatory influences and perceived good practice issues. This facilitates:-

* maintenance of competency and a consistent approach by the QA assessors
* continual improvement of the process

Analysis or other testing of products may be undertaken at the discretion of the QA assessor

This may include

eg. concerns identified about the appearance of a medicine,

medicines requiring reconstitution/dilution may be reconstituted/diluted to confirm

accuracy with the instructions in the package insert and appearance of product once

prepared

orodispersible tablets may undergo disintegration testing

Future improvements to the process may involve early engagement with specific clinical groups, including UKMi, as appropriate.

Once an assessment has been carried out, a PQA score is allocated by the QA assessor.

Potential PQA score may be:-

High risk

Medium risk

Low risk

Artwork only

No score

Any of the above could also have PAIs (potential acceptability issues for users)

* High risk – the QA Committee recommends that products given a High risk PQA score are not awarded to contract unless there are extenuating circumstances. This decision is made and reasons for award documented by the adjudication committee. Risk reduction measures may need to be implemented locally, and risk reduction measures are communicated via the networks
* Medium risk - indicates that potential issues have been identified with the product but that these may be acceptable to some users. Risk reduction measures may need to be implemented locally, and it is recommended that risk reduction measures are communicated via the networks
* Low risk - indicates that either no or only very minor issues have been identified with a product. It is recommended that these products can be awarded to contracts without communication of specific risk reduction measures.
* Any of the above but also with PAIs
* Artwork only (where an assessment has been done on artwork only and a sample has not been seen so the assessment is incomplete)
* No score (see below)

Medicines that do not hold a UK/EMA licence eg. CE marked devices, food supplements, are assessed only for error potential associated with the packaging/labelling and potential user acceptability issues.

A “no score” is assigned and comments made in the PQA comments section to clearly indicate that the product is not a licensed medicine.

The assessment result goes to the adjudication committee to inform a purchasing decision. It is the responsibility of the adjudication committee to accept/reject risks highlighted in the PQA assessment.

Risk reduction measures possible at that time may not be the same for future tenders.

NB. Confirmation, or otherwise, is made to the CMU that any extended stability data, uploaded to PharmaQC by suppliers, relates to the reconstituted/further diluted product.

No assessment of the quality of the data, or compliance with the NHS Pharmaceutical QA Committee document “Standard Protocol for deriving and assessment of stability”, is made at national level.

Suppliers are asked to provide robust extended stability data for at least 7 days (where stability allows) for injectable products likely to be used in aseptic units, including all cytotoxic injectable medicines. Data should be for the specific manufactured line provided by that supplier (or rationale given if extrapolated from another product), and in line with the NHS Pharmaceutical Quality Assurance Committee document “Standard Protocol for deriving and assessment of stability, part 1, aseptic preparations”.

It is the responsibility of users to ensure that any extended stability data they use is of appropriate quality and meets the needs of their patients.

**5c) Adjudications**

Regional QA Specialists and their teams participate in their own regional contract adjudications.

Participation in the national adjudication is undertaken at the direction of the chair of the QA Committee Procurement subgroup.

Participation in any adjudication includes highlighting risks identified with tendered medicines to the adjudication panel.

**5d) Preparation of Safe Medication Bulletins (SMB)**

Safe Medication Bulletins communicate risks identified and risk reduction suggestions.

Products awarded a High or Medium risk PQA score (with/without Potential Acceptability Issues (PAIs) may be included in the Safe Medication Bulletin for that contract.

Items for the bulletin are chosen by considering the total number of products involved and the following:-

* All products awarded with a High risk PQA score must go on the bulletin even if they are the current contract line

These products would be described as having a perceived High risk of an error occurring due to the packaging/labelling

* Awarded products with a Medium risk PQA score may be included in the bulletin if they are new to contract/at the discretion of NW Regional QA/QA Leads.

These products may be

* included in the main bulletin if a photograph/image is helpful in showing the risks identified
* included in an appendix to the main bulletin in cases where a photograph/image is not required to show the risks identified
* Awarded products with a Low risk PQA score but with PAIs may be included in the bulletin/appendix to the bulletin at the discretion of NW Regional QA/QA Leads.

The content of SMBs gives:-

* Product name, strength, form and pack size
* PQA score
* PQA comments
* Suggested possible risk reduction measures
* Regions to which the award applies
* Reason for award

Suggested possible risk reduction measures may be covered by:-

|  |  |
| --- | --- |
| **Potential risk identified** | **Possible risk reduction measures** |
| Risk of incorrect selection  Eg. similarity with other products | Segregate where possible/ensure not on contract at same time as other products with which may be confused |
| Difficulty in product identification/selection  Eg. generic name not clear | Inform staff so they are aware what the product looks like |
| Risk of incorrect administration  Eg. requirement for further dilution not clear,  route of administration not clear | Inform staff/provision of information according to local use |
| Risk of incorrect storage/handling  Eg. requirement for fridge storage not clear,  no cytotoxic warning on packaging | Inform staff/apply extra labels (eg. fridge stickers) |
| Risk of difficulty in dose calculation  Eg. mg/ml not clear, complex calculations needed | Inform staff/provision of information according to local use |
| Product not suitable for certain patient groups  Eg. contains alcohol | Ensure relevant staff aware and purchase alternative where required |

Finished SMBs are circulated to all relevant NHS networks via the Regional QA Leads.

NB. Information in the SMB is confidential within the NHS and must not be circulated outside the NHS (emails circulated as “confidential”). Also, it is applicable only to the contract in question. Circulation to other NHS staff may lead to confusion and inappropriate actions if unaware of the very specific purpose of the SMB and why it contains the information it does.

# 5e) Substitutions and Pack Changes

Substitutions or pack changes made during the life of a contract, or pack changes made where a product is not currently on contract but an updated assessment is deemed appropriate, may be requested.

The need for a sample assessment should be determined as per decision tree in Section 6b).

Assessments are undertaken as per policy and procedures for sample allocation, receipt, assessment and addition of comments and PQA score to PharmaQC.

Subsequent supply of any different product from that originally awarded on a contract must be subject to approval by a Regional QA Lead and a Regional Procurement Pharmacist, on behalf of Trusts, before any supply is made unless the product has only been given a Low risk or Low risk PQA score with PAI score. In this case the substitution is authorised directly by CMU.

However, occasionally, for certain critical products, a licence holder may receive permission from the MHRA to import a non-UK licensed pack from that licence holder.

In this case an assessment is still required. This might be a product licensed under a batch specific variation and hence legally a UK licensed product, but an assessment is still required. Alternatively, this may be an unlicensed medicine assessment rather than a PQA assessment as for UK licensed packs.

Samples are allocated to a QA team to assess as an unlicensed medicine via the QA Committee.

Non – UK licensed packs that are not in English should be overlabelled in accordance with the NHS Pharmaceutical QA Committee document “National Requirements for the Overlabelling of Foreign (non-English language) Imported Medicines Unlicensed in the UK”

**5f) QA engagement with Companies**

QA assessors may engage with Companies to influence changes being made to the packaging and labelling of some medicines.

Suppliers are able to obtain feedback from the CMU regarding the PQA assessments of their products. PQA comments should therefore be clear, and indicate what the risk is that has been identified.

Suppliers may then ask for further QA assistance/comments on how to improve the packaging/labelling/acceptability issues of their products in order to obtain a lower risk PQA score.

This process is mediated via the CMU.

Alternatively, QA assessors may contact Suppliers directly following an incident or “near miss” involving a specific product where the likely cause may be attributable to the packaging/labelling/user issues.

This engagement with a Supplier may be with a view to the Supplier changing the packaging/labelling etc to reduce the risk of further incidents.

**5g) Executive decisions**

Executive decisions may be made by a representative of the National Pharmaceutical QA Committee Procurement Sub-group and a representative of PMSG

Samples may not be available for PQA assessment before adjudication. If artwork is available, an “Artwork only” assessment may have been done in the absence of a physical sample.

An “Artwork only” assessment is an incomplete assessment, but according to the product and any issues identified from the artwork, the national adjudication committee may decide to award the product.

**Appendix 1**

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