# Quality Assurance Criteria

The quality assurance (QA) process ensures data entry complies with the QA criteria given in Table 1 before a UK PharmaScan record is approved. Records that do not comply with the QA criteria will be rejected along with details of why (see Appendix 1 for more information). Rejected records will need to be amended and re-submitted for further QA. Only data entry approved through QA is visible to horizon scanning organisations.

All records are also subjected to quality improvement (QI) checks to encourage high standards of data entry useful to horizon scanning organisations. The QI criteria are given in Table 2. The record owner of records that do not meet the QI criteria will be emailed with details and encouraged to make the necessary changes.

This document includes the following sections:

* Table 1 - Quality Assurance Criteria: These are the criteria the record must meet in order to be approved
* Table 2 - Quality Improvement Criteria: Additional criteria identified as useful to horizon scanning organisations
* Appendix 1: Quality Assurance – Regulatory section scenarios
* Appendix 2: Definitions of EU stage of development.

### Table 1. Quality Assurance Criteria

|  | **Field** | **QA Criterion** |
| --- | --- | --- |
| 1 | ALL fields | Information provided is factual and does not contain sales and marketing information. |
| 2 | ALL fields | The drug name is consistent throughout the record. |
| 3 | ALL fields | The correct data is in the correct field (e.g. dosing regimen data is not in the anticipated BNF class field). |
| 4 | ALL fields | External links to sales and marketing websites are not included. |
| **Indication** | | |
| 5 | ALL fields in the indication section | The indication section should refer to one indication only unless the company intends to include multiple indications within a single marketing authorisation application. In this case the company should include the text ‘*will apply for a single marketing authorisation’* in the **Proposed indication** field.  **For biosimilar records:**   * The record can have multiple indications listed; * The record can say ‘*as per reference product*’ in the **Proposed** **indication** field. |
| 6 | Proposed indication | It is not appropriate to complete this field by adding ‘*TBC*’ or ‘*Not finalised yet*’. |
| 7 | Proposed place in therapy | Should not contain phrases such as ‘*This drug has greater clinical effectiveness than X when used to treat Y’*. |
| **Details** | | |
| 8 | Is the drug being co-marketed? | If this reads Yes, then the **Co-marketing company** field should be completed.  The **Co-marketing company** should be different to originating company name.  If the Co-marketing company reads **Other**, the **Co-marketing company name** field should be completed. |
| **Clinical Trial Information** | | |
| 9 | ALL fields in Clinical Trial Information section | External links are accurate and not broken. |
| **Regulatory Information** | | |
| **MHRA status** | | |
| 10 | Estimated UK regulatory submission date | All records should have estimated date information until actual date information is available to replace it.  The date should be in the future.  If **MHRA regulatory procedure** reads **EU mutual recognition reliance procedure**, the date should be after the **Estimated International opinion date**. |
| 11 | Estimated UK licence date | All records should have estimated date information until actual date information is available to replace it.  The date should be in the future. |
| 12 | Estimated UK availability date | All records should have estimated date information until actual date information is available to replace it.  The date should be in the future. |
| 13 | Actual UK regulatory submission date | When completed, the date should be in the past.  If **MHRA regulatory procedure** reads **EU mutual recognition reliance procedure**, the date should be after the **Actual International opinion date**. |
| 14 | Actual UK licence date | When completed, the date should be in the past. |
| 15 | Actual UK availability date | When completed, the date should be in the past. |
| **International Status (IRP and pre-IRP EU)** | | |
| 16 | Estimated International regulatory submission date | If completed, the date should be in the future. |
| 17 | Estimated International licence date | If completed, the date should be in the future. |
| 18 | Actual International regulatory submission date | If completed, the date should be in the past. |
| 19 | Estimated International opinion date | If completed, the date should be in the future and the same or earlier than the **Estimated International licence date** and after the **Estimated International regulatory submission date**. |
| 20 | Actual International opinion date | If completed, the date should be in the past and the **Internationalopinion** field should read **Positive** or **Negative.**  If not completed, the **International opinion** field should read **Unknown.** |
| 21 | Actual International licence date | If completed, the date should be in the past. |
| **US status** | | |
| 22 | Response letter issued | If this reads **Yes,** then the **Date response letter issued** field should be completed. |
| **Orphan Drug / ATMP categorisation** | | |
| 23 | MHRA orphan drug status | If this reads **Yes,** then the **Date MHRA orphan drug status granted** and the **MHRA orphan status number** fields should be completed.  If this reads **No,** then the **Date MHRA orphan drug status granted** and the **MHRA orphan status number** fields should be blank. |
| 24 | Orphan drug status in EU | If this reads **Yes,** then the **Date EU orphan drug status granted** and the **EU orphan status number** fields should be completed.  If this reads **No,** then the **Date EU orphan drug status granted** and the **EU orphan status number** fields should be blank. |
| 25 | Classified as an Advanced Therapy Medicinal Product (ATMP) in EU? | This field can read Yes or No. It can also be left blank.  **If this reads Yes, then the ATMP classification and Date of recommendation on classification of ATMP fields should be completed.**  **If this reads No, then the ATMP classification and Date of recommendation on classification of ATMP fields should be blank.** |
|  |  |  |
| **MHRA / international regulator Withdrawal, Suspension of Discontinuation status** | | |
| 26 | Withdrawal reason / Reason for withdrawal | This field should be completed if there is a date in the **Withdrawal date** field. |
| 27 | Reason for suspension | This field should be completed if there is a date in the **If suspended, date of suspension** field. |
| 28 | Reason for discontinuation | This field should be completed if there is a date in the **If development is discontinued, date of discontinuation** field. |
| 29 | Other reason for archival | This field should be completed if there is a date in the **If other reason for archival, date of decision to archive** field. |
| **Cost and Budgets** | | |
| 31 | Is the drug likely to have a significant service impact? | If this reads **Yes**, further information should be added to the **Please specify** field. |

### Table 2. Quality Improvement Criteria

|  | **Field** | **Quality Improvement Criterion** |
| --- | --- | --- |
| **Indication** | | |
| 1 | Final indication | Should not be present until available in UK. |
| 2 | Is paediatric | Value should match the **Proposed indication**. |
| **Details** | | |
| 3 | Mode of action | Should include the pharmacological class. |
| 4 | Route | Value should match that given in the **Formulation** field.  e.g. if Formulation is tablet, Route should be enteral. |
| 5 | BNF chapter | The relevant BNF chapter should be selected from the drop-down list. You can suggest a chapter to the record owner. |
| 6 | Disease state | The most specific option should be chosen from the drop-down list. |
| **Regulatory Information** | | |
| 7 | Current EU stage of development | If an International Recognition Procedure with a non-European reference regulator is selected in the MHRA regulatory procedure field, the regulatory information in the International Status (IRP and pre-IRP EU) subsection will relate to that non-European reference regulator.  In such cases, the selected Current EU stage of development will describe any additional regulatory activity happening within the EU and the EU stage does not need to match the regulatory information in the International Status (IRP and pre-IRP EU) subsection.  If “International Recognition Procedure – European Union as reference regulator” or a pre-IRP EU reliance procedure is selected in the MHRA regulatory procedure field, the regulatory information in the International Status (IRP and pre-IRP EU) subsection will relate to regulatory activity within the EU.  In these cases, the EU Stage should match the rest of the regulatory information in the International Status (IRP and pre-IRP EU) subsection. See definitions in [**Appendix 2**](#_Appendix_2_–).   * If the record indicates that a regulatory dossier has been filed, the stage of development should be **Pre-registration;** * If the record indicates that a CHMP opinion has been given, the stage of development should be **CHMP Opinion;** * If the record gives an Actual licence date the stage of development should be **Licenced in member state** or **Approved in EU;** * If the record gives an Actual UK availability date the stage of development should be **Available in UK.**   **NB:** Technologies following an EU decentralised **Regulatory procedure** may vary from this logic. |
| 8 | EU Regulatory procedure | The **EU** **regulatory procedure** should be identified from the drop-down list provided. Only request this field to be completed if there is other EU regulatory data entered into the record. |
| **Cost and Budgets** | | |
| 9 | UK patient population notes | The source should be provided for any figures given in the **UK patient population range** field. They can state if the figures are from company information. |
| 10 | Estimated eligible patient population | The source should be provided for any figures given in this field. They can state if the figures are from company information. |

### Appendix 1: Quality Assurance - Regulatory section scenarios

The User Group agreed there are key fields in the Regulatory Information section which (if completed and meet the QA criteria) should be approved via QA and published so Horizon Scanning Organisations have access to the most up to date regulatory information, even if the record fails QA on other fields.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Fails QA on regulatory fields (see list below)** | **Fails QA on any other field** | **Approve/Reject decision** |
| **New OR updated record WITH new information in Regulatory Information section** | No | No | Approve |
| No | Yes | Approve and email |
| Yes | Yes | Reject |
| Yes | No | Reject |
| **Updated record WITHOUT new information in Regulatory Information section** | No | No | Approve |
| No | Yes | Reject |
| Yes | Yes | Reject |
| Yes | No | Reject |

1. If any of the following fields in the Regulatory Information section do not meet the QA criteria, the record should be **rejected**.

* Estimated UK regulatory submission date
* Estimated UK licence date
* Estimated UK availability date
* Actual UK regulatory submission date
* Actual UK licence date
* Actual UK availability date
* Reason for withdrawal
* Reason for suspension
* Reason for discontinuation
* Other reason for archival

1. If a **new** record meets all QA criteria in relation to the regulatory fields listed above but does not meet other QA criteria and/or does not meet the quality improvement criteria, the record should be **approved** and the record owner emailed.
2. If any of the regulatory fields listed above have been **updated** and meets all QA criteria in relation to those fields but does not meet other QA criteria and/or does not meet the quality improvement criteria, the record is **approved** and the record owner emailed.
3. If none of the regulatory fields listed above have been updated but does not meet other QA criteria, the record is **rejected**.

### Appendix 2 – Definitions of EU stages of development

**Phase I:** The product is the subject of a Phase I clinical trial but no Phase II or III trial has yet been started.

**Phase II:** The product is the subject of a Phase II clinical trial but no Phase III trial has yet been started.

**Phase III:** The product is the subject of a Phase III clinical trial (possibly in parallel with a continuing Phase II trial) but no regulatory application has been made in the EU or a member state.

**Pre-registration:** A regulatory dossier has been filed with the European Medicines Agency, the MHRA or the national regulatory body of another member state, but a CHMP Opinion has not been issued and no marketing authorisation has been granted. Must be selected if a regulatory dossier has been submitted, even if Phase II or Phase III trials are ongoing.

**CHMP Opinion:** For products following the EU Centralised route, the Committee for Human Medicinal Products of the EMA has issued an Opinion on the product (positive or negative), but the EMA has not yet granted a marketing authorisation.

**Licenced in member state:** The product has received a marketing authorisation from the MHRA or the regulatory body of another member state, but has not yet been granted a marketing authorisation by the EMA under the Mutual Recognition procedure and has not yet been launched on the market in the UK.

**Approved in EU:** The product has been granted a marketing authorisation by the EMA, either under the Centralised or the Mutual Recognition procedure, but has not yet been launched on the market in the UK.

**Available in UK:** The product has received a marketing authorisation valid in the UK from either the EMA or the MHRA, has been launched on the market in the UK and may be prescribed within the product licence for the relevant indication and patient population.

**NB:** Technologies following an **EU decentralised Regulatory procedure** may vary from this logic.