UK PharmaScan

Quality Assurance Criteria

The quality assessor will ensure data entry complies with the following criteria before approving a record. Records that do not comply will be rejected along with details of why. Rejected records will need to be amended and re-submitted for further QA.

There are a number of approve/reject scenarios, please see **Appendix 1** for details. See the *UK PharmaScan* Service Management Guidance document for full QA process.

	Field	Criterion
All sections		
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 refers to only one indication 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 indication field but must show how it differs
6	Proposed indication	Mandatory field. It is not appropriate to complete this field by adding '**TBC**' or '**Not finalised yet**'
7	Abbreviated	Mandatory field.
8	Proposed place in therapy	Mandatory field should not contain phrases such as '*This drug has greater clinical effectiveness than X when used to treat Y*'.
Formulation		
9	Formulation	Mandatory field.

	Field	Criterion
Details		
10	Technology status	Mandatory field.
11	Route	Mandatory field. Value should be Enteral, Inhaled, Parenteral, TBC or Topical. In the rare cases where a single marketing authorisation application covers more than one route, a separate Technology Record should be created for each route.
12	Is there a companion diagnostic test?	Mandatory field.
13	Co-marketing company	Field should be completed if the **'Is the drug being co-marketed?'** field has been marked as '***Yes***'. The company name should be different to originating company name.
Clinical Trial Information		
14	ALL fields in Clinical Trial Information section	External links are accurate and not broken.
Regulatory Information		
15	Current EU stage of development	Mandatory field. See definitions in **Appendix 2**.
16	Orphan drug status	Mandatory field. 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.
17	ATMP classification	All fields can be left blank in the case where the EMA has not considered the question of whether a medicine is an Advanced Therapy Medicinal Product (ATMP). If the first question is answered "YES" then the classification and date fields should be completed. If the first question is answered "NO" then no other information is needed. "NO" should be selected where the EMA finds a medicine is "not an advanced therapy medicinal product" or "CAT cannot conclude on the classification of this product".

	Field	Criterion
18	Estimated regulatory submission date	All records should have either estimated, actual, or a mix of estimated and actual date information. If the record does not have an actual regulatory date included then this field should be completed. The date should be in the future and before the 'estimated licence date' and the 'estimated UK availability date'.
19	Estimated licence date	Mandatory field. All records should have either estimated or a mix of estimated and actual date information. The date should be in the future and the same as or before the 'estimated UK availability date'.
20	Estimated UK availability date	Mandatory field. All records should have either estimated or a mix of estimated and actual date information. The date should be in the future and the same as or later than the 'estimated licence date'.
21	Regulatory dossier submitted	This field should be completed if the company has submitted a marketing authorisation application to the European Medicines Agency or Medicines and Healthcare Products Regulatory Agency. For new chemical / biological entities the regulatory dossier will normally be submitted around one year from estimated UK launch date. For new indications or formulations of existing medicines the regulatory dossier will normally be submitted between six and nine months from estimated UK launch date.
22	Estimated CHMP opinion date	If completed, the date should be in the future and the same or earlier than the '**estimated licence date**' and after the '**estimated regulatory submission date**'. The field should be blank if the product has been **withdrawn**, **suspended** or **discontinued**.
23	Actual CHMP opinion date and CHMP opinion.	If completed, the date should be in the past and the field '**CHMP opinion**' should read '**positive**' or '**negative**' If not completed, the field '**CHMP opinion**' should read '**unknown**'

	Field	Criterion
24	Actual regulatory submission date	All records should have either estimated, actual, or a mix of estimated and actual date information. If the record does not have an estimated regulatory submission date included then this field should be completed. The date should be in the past. It is feasible for the '**regulatory dossier submitted**' field to be completed without a date in the '**actual regulatory submission date**' field (if the company is unable to release the actual date) but ideally an '**actual regulatory submission date**' should be included.
25	Actual licence date	All records should have either estimated or a mix of estimated and actual date information. The date should be in the past.
26	Actual UK availability date	All records should have either estimated or a mix of estimated and actual date information. The date should be in the past. If this field is completed it will trigger archive 90 days from this date.
27	MAA EU withdrawal reason	This field should be completed if there is a date in the '**MAA EU withdrawal date'** field.
28	Reason for suspension	This field should be completed if there is a date in the '**If suspended, date of suspension'** field.
29	Reason for EU discontinuation	This field should be completed if there is a date in the '**If development in EU discontinued, date of discontinuation'** field. If the '**if development in EU discontinued, date of discontinuation**' field is completed, this will trigger archive 90 days from this date.
30	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. If the '**if other reason for archival, date of decision to archive** field is completed, this will trigger archive 90 days from this date.
31	Date response letter issued	This field should be completed if the '***Yes***' option has been selected for '**Response letter issued'** field.
Cost and Budgetary Information		
32	Drug cost range (per patient per year or patient per episode if less than one year)	Mandatory field.
33	Comments	Notes should be added when one of the tick box options has been chosen for **'Is a Patient Access Scheme or alternative discount arrangement planned for this indication? If Yes, please tick all that apply.'** field.

	Field	Criterion
34	UK Patient Population	Mandatory field.
35	Please specify	This field needs to be completed if the '***Yes***' option has been selection for '**Is the drug likely to have a significant service impact?'** field.

Appendix 1

	Issue in regulatory section (see list of fields)	Issue in section other than regulatory	Approve/Reject decision
New record OR updated record WITH new information in regulatory section	No	No	Approve
	No	Yes	Approve and email
	Yes	Yes	Reject
	Yes	No	Reject
Updated record WITHOUT new information in regulatory section	No	No	Approve
	No	Yes	Reject
	Yes	Yes	Reject
	Yes	No	Reject

Review the record against the QA criteria, paying particular attention to fields that have been changed (marked with a green spot).

1. If record meets all QA criteria, enter details into QA "Approved" worksheet and click "Approve".

   If information in fields for which there are no QA criteria appears to be inconsistent or unclear, the user should be emailed after the record has been approved.

2. If any of the following fields in the Regulatory Information section do not meet the QA criteria, the record should be rejected (**NB:** An unchanged estimated date may fail QA criteria if it is now in the past). Enter rejection reason into text box and click "Reject".

   - Estimated regulatory submission date
   - Estimated CHMP opinion date
   - Estimated license date
   - Estimated UK availability date
   - EU fast track application anticipated
   - Regulatory dossier submitted
   - Actual regulatory submission date

- Actual CHMP opinion date
- CHMP opinion
- Actual license date
- Actual UK availability date
- Information on EMEA/MHRA decisions
- MAA EU withdrawal date
- MAA EU withdrawal reason
- If suspended, date of suspension
- Reason for suspension
- Other archive date/reason fields
- Are there further plans for trials/refiling?
- If development in EU discontinued, date of discontinuation
- Reason for EU discontinuation

3. If any of the fields above have been updated and the record meets all criteria in relation to those fields, but does not meet other criteria, enter details into “Approved” worksheet and email user explaining the record has been approved despite failing the QA criteria and providing details fields / changes that should be made (standard email below). Click “Approve”.

   If information in fields for which there are no QA criteria appears to be inconsistent or unclear, the user should be emailed after the record has been approved.

4. If there is no new information in the Regulatory fields listed above (although the information does meet QA criteria) but one of the other fields does not meet QA criteria, reject the record.

Appendix 2

EU Stage of Development	Definition
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.
Licensed 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.

For information

- 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 ‘Licensed in member state’ or ‘approved in EU’
- If the record gives an ‘Actual UK availability date’ the stage of development should be ‘Available in the UK’

Appendix 3

Additional information to ask record owners as part of the QA	
Is Paediatric	If the value clearly doesn't match the indication, the record owner will be emailed.
Final indication	Should not be present until available in UK.
Formulation and Route	Check that the two values match.
BNF Chapter	Ask the record owner to add an appropriate BNF chapter. You can suggest a chapter to them.
Disease state	Ask the record owner to choose the most specific option from the drop-down list.
Mode of action	Ask the record owner to include the pharmacological class.
Regulatory procedure	Ask the record owner to provide a regulatory procedure. You may want to include the guidance and point them to p.69 for the options.
Estimated eligible patient population	Ask the record owner to provide a source for any figures they have added to this field. They can state if the figure is from company information.
UK patient population	Ask the record owner to provide a source for any figures they have added to this field. They can state if the figure is from company information.
Additional information to ask for once a drug has an actual licence date / UK availability date	
Final indication	Ask the record owner to add this. It is likely to be the same as the proposed indication unless there has been a change.
Presentation and dosage	Ask the record owner to provide this information.
Estimated eligible patient population	Ask the record owner to provide any information they have available. They should add a source for any details they add.