



Medicines & Healthcare products
Regulatory Agency

RegulatoryConnect guidance

Understanding application statuses

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Understanding application statuses

The Applications page lets you track your case and removes the need to contact MHRA in order to check the status of submitted applications. You will be able to see information relating to applications submitted by the organisation(s) that you are affiliated with.

The service will show the status of any pending submissions (excluding information updates and Periodic Safety Update Reports (PSURs)), and the latest granted submission for all live authorisations. Historically cancelled licences will not be displayed. You will also not be able to see the actual data that has been submitted for in-flight submissions. The data shown will be refreshed every 24 hours.

Please note that cases will only be displayed when they enter the validation stage on MHRA systems. As such, the data shown on the portal is not synchronous with the submissions portal and there may be a delay with cases being displayed on the portal. In subsequent releases, as submission processes are integrated on the Regulatory Connect portal, cases are expected to be visible from the point of submission.

How colour is used for statuses

Colour cues are used to provide a clear visual for several statuses:

- **GREY** - No action required (e.g. **DATA VALIDATION**)
- **YELLOW** - Applicant must take action (e.g. **AWAITING RFI RESPONSE**)
- **GREEN** - Submissions with a positive outcome (e.g. **GRANTED**)
- **RED** - Submissions with a negative outcome (e.g. **REFUSED**)

Submission statuses

There are a number of submission statuses that are shown within RegulatoryConnect which allow you to track your case and understand where it is in the lifecycle process. Definitions of the different submission statuses are included on RegulatoryConnect and listed below.

Please note that the submission statuses shown will differ across licence types and cases as not all cases will be required to go through the exact same steps.

- **DATA VALIDATION** - We are reviewing and assessing the new data you sent with your application.
- **AWAITING VCR RESPONSE** - We have sent you a Validation Correction Request (VCR) for more information. Your application is paused while we wait for your reply.
- **AWAITING EU INFO** - Your application is under review awaiting verification of imported product details.
- **AWAITING ASSESSMENT** - Your application is in the queue waiting for an assessor/inspector to be assigned.
- **ASSESSMENT** - An assessor is reviewing the application.
- **AWAITING RFI RESPONSE** - We have sent a request for more information. Your application is paused while we wait for your reply.
- **INSPECTION COMPLETED** - Your application inspection is complete.
- **DETERMINATION** - Your application is currently at determination stage.
- **GRANTED** - Your licence has been granted with no conditions.
- **WITHDRAWN** - Your application has been withdrawn after it was submitted. There might be cancellation fees depending on how much work MHRA has done on this application.
- **REFUSED** - Your application has been refused.
- **REJECTED** - Your application has been rejected.
- **INVALID** - The submission is considered as invalid and a new submission is required.

Authorisation statuses

The statuses listed below allow you to understand the authorisation status of your licence:

- **CONDITIONALLY GRANTED** – Your licence is granted under the Conditional Marketing Authorisation scheme.
- **EXCEPTIONALLY GRANTED** - Your licence has been granted under exceptional circumstances.
- **GRANTED** - Your licence is granted without condition.
- **GRANTED WITH CONDITIONS** - Your licence is granted with conditions.
- **LIVE** - Your licence is authorised.
- **LAPSED** - Your licence has not been renewed and therefore are not able to be used to market the product.
- **CANCELLED** - Your licence has been cancelled.
- **DEAD** - Your licence is no longer authorised.
- **PENDING** - Your application is being processed.
- **REFUSED** - Your licence has been refused.
- **REVOKED** - Your licence has been revoked.
- **SUSPENDED** - Your licence has been suspended.

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