Medicines & Healthcare products
Regulatory Agency

RegulatoryConnect guidance

Navigating the RegulatoryConnect portal

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Contents

RegulatoryConnect Portal – the service

The RegulatoryConnect portal will provide greater transparency and visibility for regulatory assessments for industry. The functionality will let industry users log in using existing MHRA submission credentials and access RegulatoryConnect, where they will be able to:

- Use the Applications page to track the status of an application and see which stage it is at.
- Use the Current Granted View page to view live authorisation details, including status, key data and documents held against existing licences.

These services are available to those making applications to the MHRA on behalf of their organisation as an administrator or user.

Future functionality and features will be added to RegulatoryConnect later in the year, including the ability to submit applications and variations to the MHRA through the service.

Please note that if you receive any server errors, it is recommended that you try to log out of the service and log back in as a first attempt of remediation.

Using the Applications page

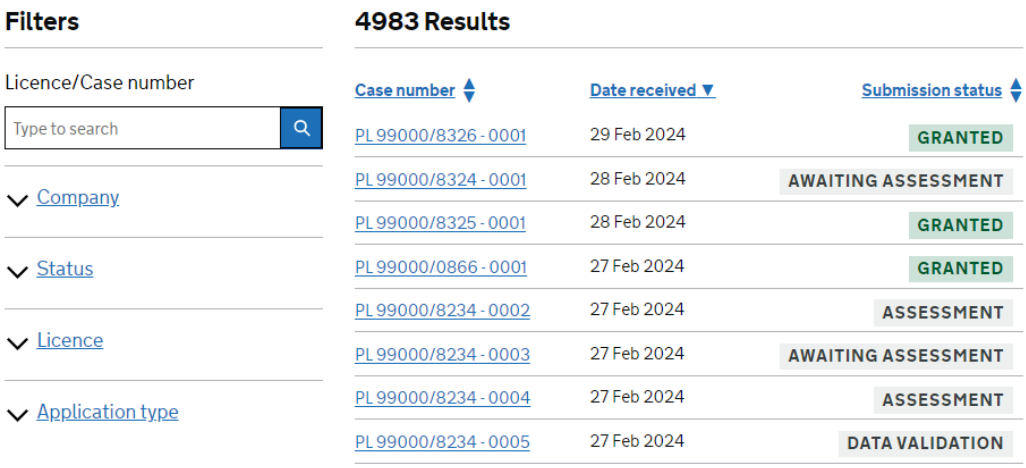
The Applications page provides you with the capability to track your case and removes the need to contact MHRA to check the status of submitted applications. You will be able to see information relating to applications submitted by the organisation(s) that you are affiliated with.

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.

The applications page has several sort and filter options available to help you to find the information that you're looking for.

- At the top of the results section, you can use the arrows to sort information – for example, you can sort by most recently received
- On the left-hand side of the page, you can use the Licence/Case number search box to directly search for a licence or case number that you are looking for (minimum 3 characters). Please note that there needs to be a space between PL and the rest of the case number
- The left-hand side of the page also has multiple filters where you can narrow down listed applications to a specific view



Above: screenshot of the Applications page, including the filters available to users.

Applications

Remove all filters

From company × 3 PHARMALABS PLC (RAMAS LAUNCH ONLY)

For status × Awaiting Assessment

Filters

Licence/Case number

Type to search

Company

Status

1 Selected

- [ ] Assessment
- [x] Awaiting Assessment
- [ ] Awaiting EU info (PLPI)
- [ ] Awaiting RFI Response
- [ ] Awaiting VCR Response
- [ ] Data validation
- [ ] Determination

304 Results

Case number	Date received ▼	Submission status
PL 99000/8330 - 0001	6 Mar 2024	AWAITING ASSESSMENT
PL 99000/8327 - 0001	5 Mar 2024	AWAITING ASSESSMENT
PL 99000/8329 - 0001	5 Mar 2024	AWAITING ASSESSMENT
PL 99000/8309 - 0002	4 Mar 2024	AWAITING ASSESSMENT
PL 99000/8324 - 0001	28 Feb 2024	AWAITING ASSESSMENT
PL 99000/8234 - 0003	27 Feb 2024	AWAITING ASSESSMENT
PL 99000/8315 - 0001	15 Feb 2024	AWAITING ASSESSMENT
PL 99000/0742 - 0015	14 Feb 2024	AWAITING ASSESSMENT
PL 99000/0742 - 0017	14 Feb 2024	AWAITING ASSESSMENT
PL 99000/0742 - 0019	14 Feb 2024	AWAITING ASSESSMENT
PL 99000/8304 - 0003	8 Feb 2024	AWAITING ASSESSMENT
PLGB 99000/8148 - 0008	7 Feb 2024	AWAITING ASSESSMENT

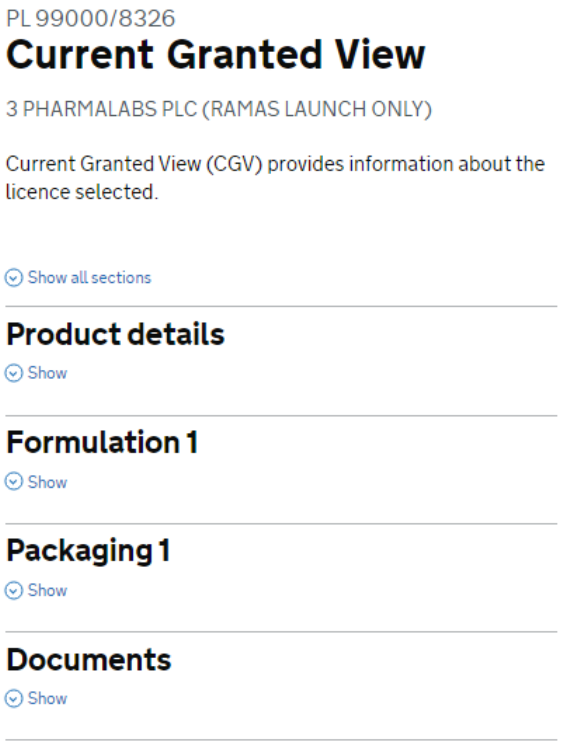
Above: screenshot showing filters applied to the Applications page. You can see the filters added at the top of the screenshot. These can be removed by clicking the cross shown next to each filter.

Using the Current Granted View page

The Current Granted View (CGV) page surfaces key data for live authorisations. It is accessible from the Applications page and provides information related to a specific licence selected. For product licences, the dataset shown is based on the same data shown through RAMA XL as well as key documents. The following data is currently visible:

- Product details
- Formulation
- Packaging
- Documents - Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL) & labels.

For process licences (PcL), the service displays a subset of certification data for in-scope licence types.



Above: screenshot of the Current Granted View page, displaying section headings which reflect the information available within this view.

Using the contact form

The RegulatoryConnect contact form provides support for queries relating to the RegulatoryConnect portal and services. General MHRA queries and questions related to other systems and services (for example, MHRA Submissions) should continue to be raised through existing support channels.

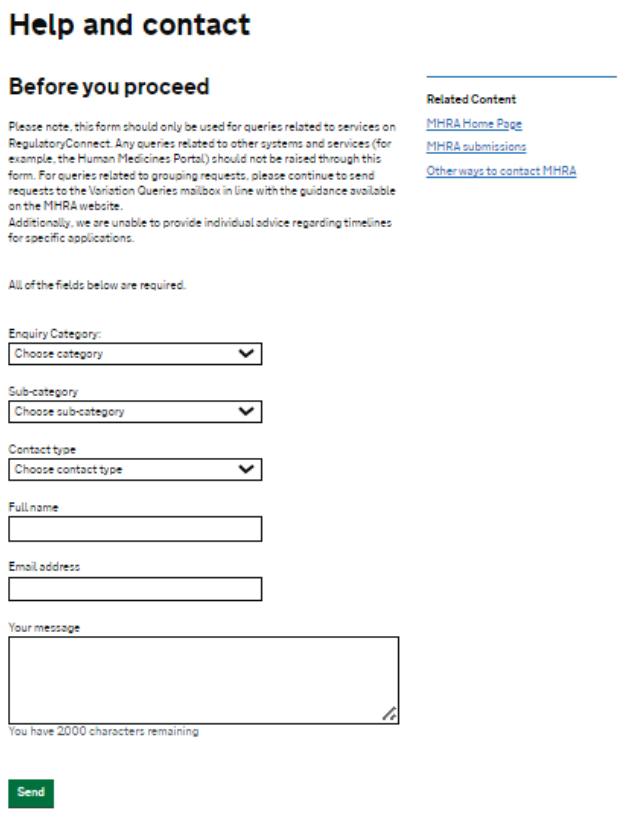
The contact form can be used for:

- Account issues
- Regulatory advice

The contact form should *not* be used for:

- Assessment timeframes
- Variation groupings

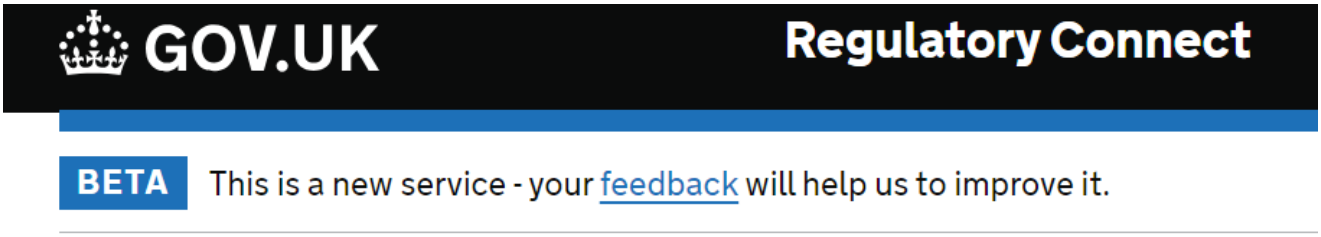
Please note that this contact form should not be used to make grouping requests. Please continue to send requests to the Variation Queries mailbox in line with the guidance available on the MHRA website. The team that monitors responses to the contact form will be unable to provide individual advice regarding timelines for specific applications.



Above: screenshot of the contact form available on RegulatoryConnect.

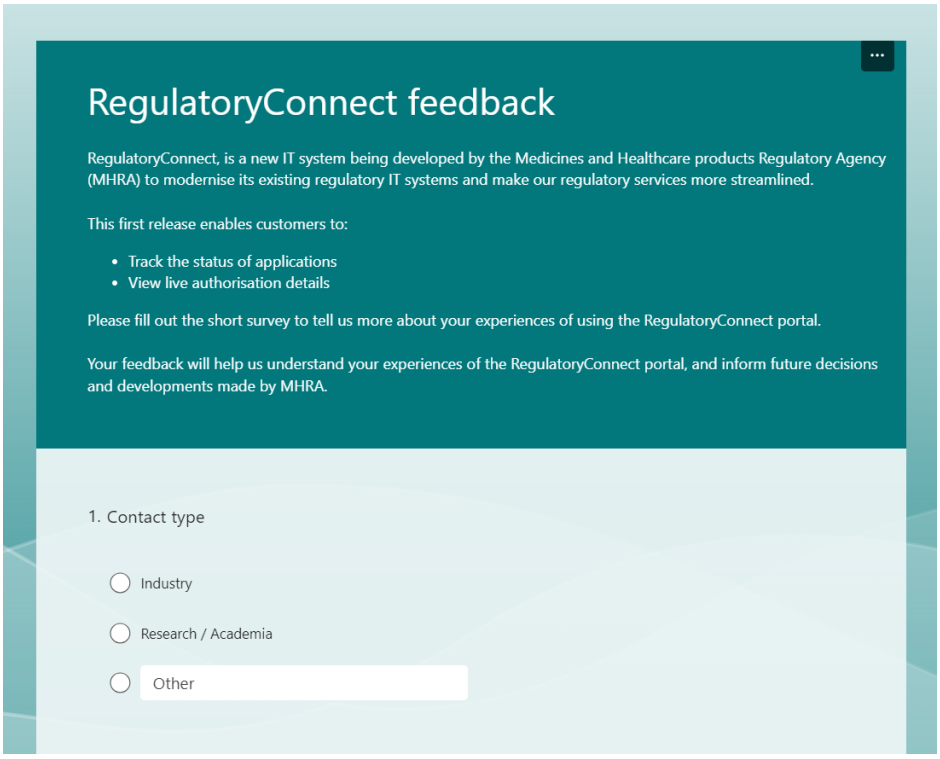
Providing feedback on RegulatoryConnect

Your feedback will help us understand your experiences of the RegulatoryConnect portal.



Above: screenshot of a link to the feedback form for RegulatoryConnect.

The feedback link can be accessed as shown above. This will direct you to a short survey that will help inform future functionality and service improvements.



Above: screenshot of the RegulatoryConnect feedback form.