Pharmaceutical Regulatory Procedures After Brexit

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The **Primary Intelligence** Company

Pharmaceutical Regulatory Procedures After Brexit

Regulatory review procedures have changed after Brexit; this white paper will provide updated timelines in the UK and highlight key transformations to the UK regulatory landscape

Brexit coincided with the pandemic, a pivotal moment in history that presents the UK with unique challenges and significant opportunities to reinvent its regulatory policy strategy. Prior to Brexit, the UK aligned with EU guidelines to grant marketing authorisations to organisations working to commercialise new medicines in the UK. Now, post-Brexit, the Medicines and Healthcare products Regulatory Agency, (MHRA) is the UK's responsible authority and is responsible for redesigning the UK's host of pharmaceutical review procedures and rejuvenating the routes to approval.

*""The pandemic, coupled with the UK's exit from the EU and **a renewed domestic policy agenda, creates both challenges and opportunities for the UK's regulatory policy strategy**, standing as an impetus for the change needed if the UK is to sustain its place as a global life sciences leader."*

ABPI Vision Paper: UK medicines regulatory policy and global influence in a post-pandemic world. November 2021

Section One will outline the key regulatory pathways to approval and their major milestones in the EU. EU timelines will be compared to the new pathways implemented by the UK as the MHRA manage its separation away from European guidelines and procedures. This will serve as a reference for analysts looking to improve forecasting for pharmaceutical marketing authorisation approval dates, and provide a map for how these pathways link together.

The Life Sciences Industry is a critical industry to the UK economy. The research, regulatory and innovation ecosystem in the UK presents an important opportunity for the UK to maintain its position as a global leader in life sciences. Following the separation from the EU, there are both threats and opportunities to the UK maintaining its leadership, and Section Two of this paper will demonstrate examples of UK initiatives for how the UK is building and implementing a regulatory policy strategy to take advantage of the opportunities presented.

While this white paper will outline current knowledge about the regulatory procedures, the landscape is still clouded by uncertainty and constantly evolving. On conducting primary research, Dig Worldwide found that the MHRA remains unsure as to how things will play out after the end of the two-year post-Brexit transition period. While reasonable estimates of likely scenarios can be forecasted, the next five years will show many changes.

Section 1

Procedural Pathways

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
https://www.ema.europa.eu/en
https://www.ema.europa.eu/en/glossary/centralised-procedure
https://www.gov.uk/guidance/european-commission-ec-decision-reliance-procedure
https://www.gov.uk/guidance/unfettered-access-procedure-for-marketing-authorisations-approved-in-northern-ireland
https://www.hma.eu/uploads/media/MRP_flow_chart.pdf
https://www.hma.eu/uploads/media/dcp_flowchart.pdf
https://www.gov.uk/guidance/decentralised-and-mutual-recognition-reliance-procedure-for-marketing-authorisations
https://www.gov.uk/guidance/guidance-on-150-day-assessment-for-national-applications-for-medicines
https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees

Regulatory Procedures Before Brexit

Before Brexit, as an EU member state, the UK had no need to build stand-alone regulatory procedures and policy strategies, and the UK followed procedures laid out by the EU.

Centralised	Decentralised	Mutual Recognition	National

Prior to Brexit, the UK, as an EU Member State (MS), automatically followed or participated in the centralised, decentralised and mutual recognition procedures. For the centralised procedure, an application would be made to the European Medicines Agency (EMA) and the decision would apply in all 28 (now 27) MSs. Most new medicines take this route. In certain cases, approval may be sought in a few target markets, and the applicant would take targeted routes. National: apply in one MS directly to the country's regulatory authority. Decentralized: apply to more than one MS to begin with. Mutual recognition: start with one MS via the national procedure, and expand to other MSs later.

Regulatory Procedures After Brexit

After Brexit, the UK no longer aligns with EU procedures, and the MHRA has developed its own set of procedures for applicants to obtain a GB marketing licence.

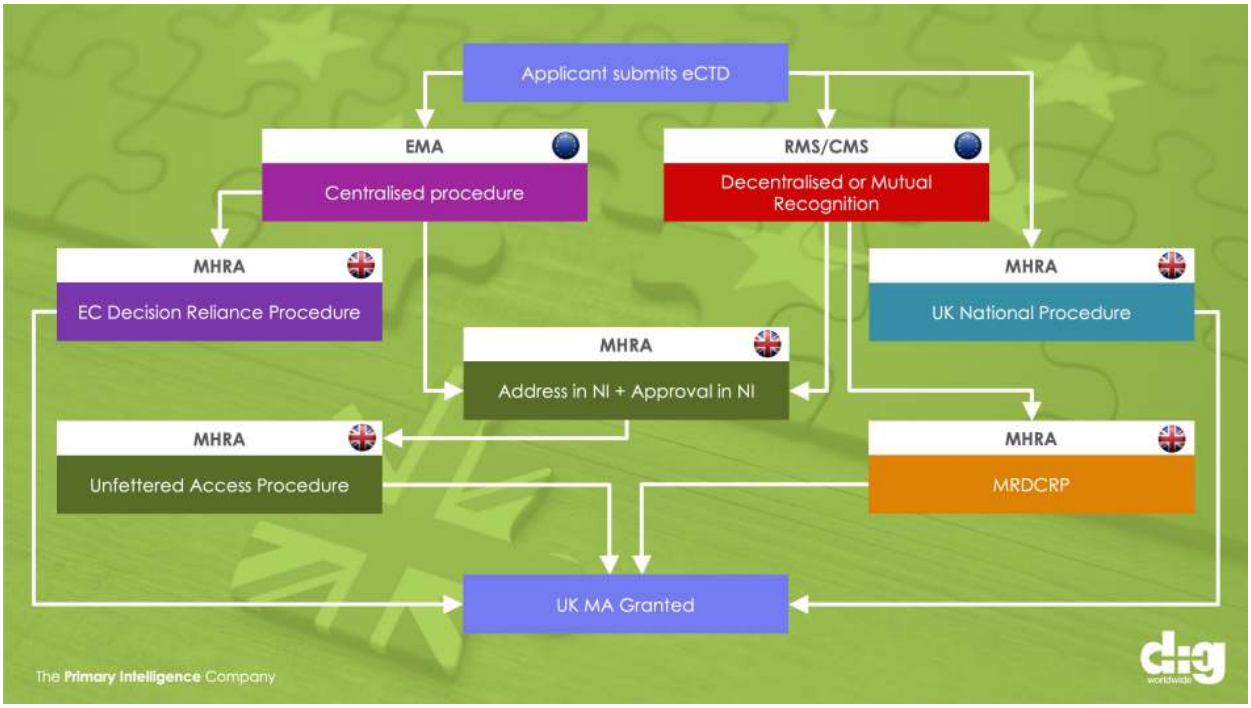
ECDRP	UAP	MRDCRP	National	Rolling Review	ILAP

After Brexit, the MHRA is now responsible for all marketing authorisations in the UK and no longer automatically grants a GB licence for approvals obtained by either European centralised, decentralised or mutual recognition routes. All EU approvals valid in the UK prior to Brexit have now been automatically converted to a GB licence by the MHRA. Since Brexit, the MHRA has implemented its own set of procedures for applicants to obtain a GB licence.

Post-Brexit Procedural Map

Navigating pharmaceutical marketing authorisations in the UK and EU

This procedural map navigates the regulatory procedures after Brexit and how the UK procedures align with EU decisions using reliance procedures created by the MHRA. The applicant submits the electronic common technical document (eCTD), a format common to all these procedures in both the UK and EU. A GB licence may be granted by the MHRA after undergoing the relevant reliance procedure in addition to the EU procedure. Alternatively, a GB licence may be granted through bypassing the EU entirely and applying via the UK national route.



There are three main routes to obtain a marketing authorisation in the UK:

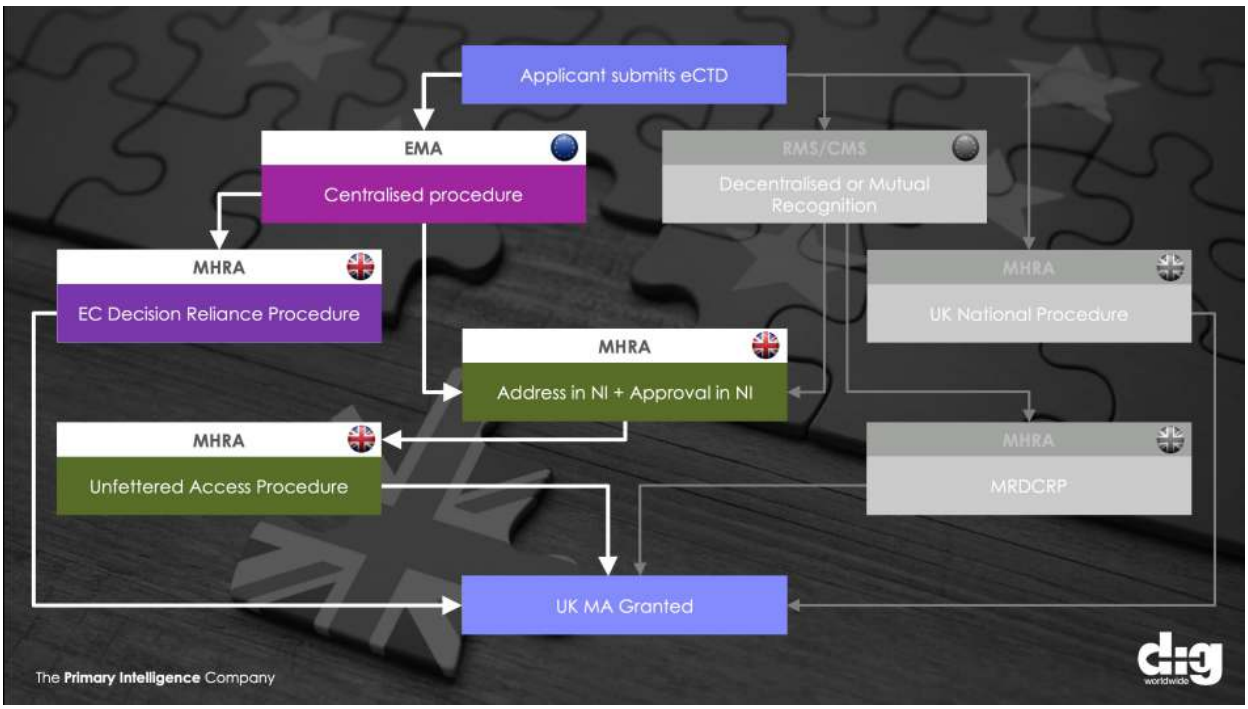
1. *via* the centralised procedure in the EU, and concurrent application to the MHRA's EC decision reliance procedure (ECDRP);
2. *via* the decentralised or mutual recognition procedures, and post-approval application to the MHRA's Mutual Recognition Decentralised Reliance Procedure (MRDCRP);
3. or directly via the UK National Procedure.

In the case of the applicant being located in Northern Ireland, this unlocks the Unfettered Access Procedure, as Northern Ireland remains aligned with some EU regulatory decisions.

Post-Brexit Procedural Map: EU Centralised

Centralised pharmaceutical marketing authorisations in the EU and UK

Prior to Brexit, the EU centralised procedure was the primary route to obtain a GB marketing licence, as the EU centralised procedure is the principal route of access for new medicines to obtain marketing authorisation in the EU. This route provides access to the entire EU market if granted approval following review. Advanced therapies are required by EU law to undergo review via this centralised route.



On leaving the EU, the MHRA created a two-year transition reliance procedure to align with EU decisions regarding centralised medicines approvals: the European Centralised Decision Reliance Procedure, or ECDRP. ECDRP is valid for any marketing authorisation application submitted to the European Medicines Agency between 1st Jan 2021 and 1st Jan 2023.

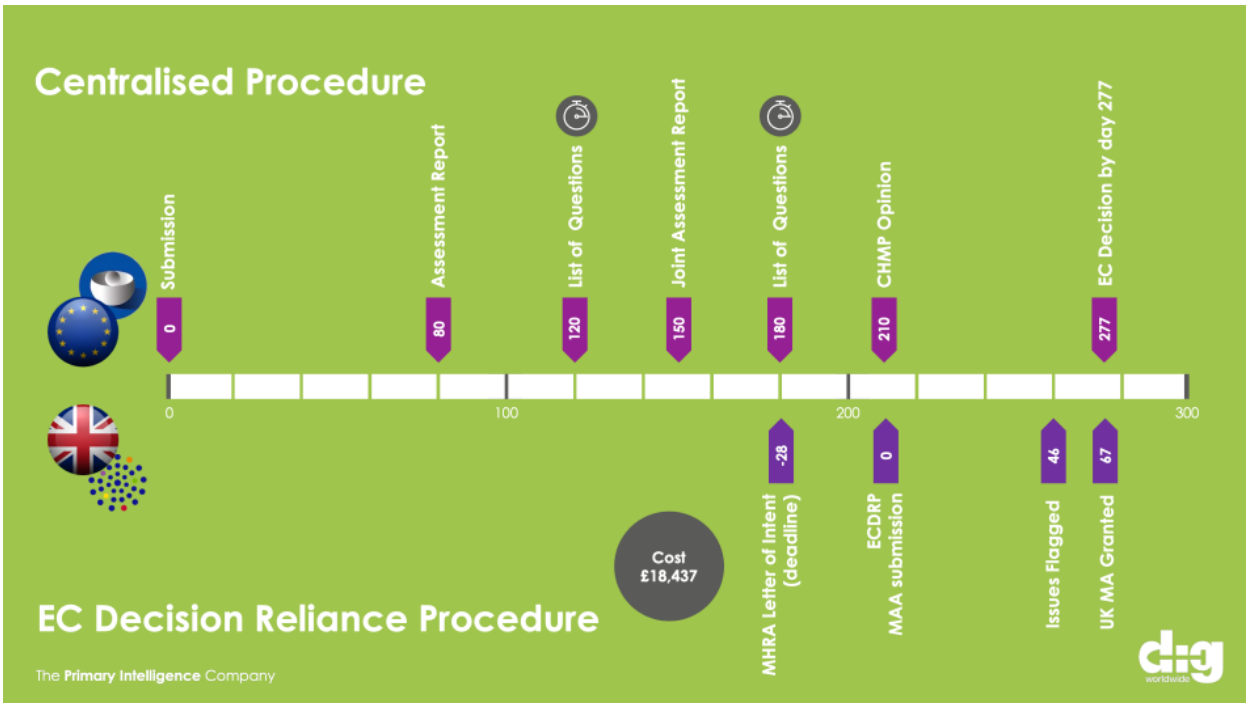
After the 1st Jan 2023, it is yet to be decided by MHRA executives what will happen to this reliance procedure, and the MHRA face uncertainty until either a replacement or continuation of the ECDRP is decided and communicated by MHRA leadership.

A subtlety of the UK's exit from the EU is that Northern Ireland (NI) remains aligned with the EU for new medicines approvals, and if the applicant is headquartered or has a registered address in Northern Ireland, the licence may expand to the full UK market via the Unfettered Access Procedure (UAP).

Centralised vs ECDRP

Centralised procedure for a licence across the EU / UK reliance via ECDRP

Centralised applications are sent to the European Medicines Agency (EMA), the eCTD dossier is reviewed by the Committee for Medicinal Products for Human Use (CHMP). The CHMP draws in experts from Scientific Advisory Groups (SAGs) and working parties to review key aspects, such as safety and quality. Assessment reports are followed by two lists of questions to the applicant, at these points, the clock stops and the timeline is paused as the application generates its responses. The clock restarts after the responses are submitted. By day 210, the CHMP will give its opinion. This opinion forms the basis of whether the EMA approves the medicine, and 67 days later, the EMA (usually) follows the CHMP's decision and publishes a European Public Assessment Report (EPAR). The European Commission then issues the marketing authorisation within 277 days of the application confirmation.

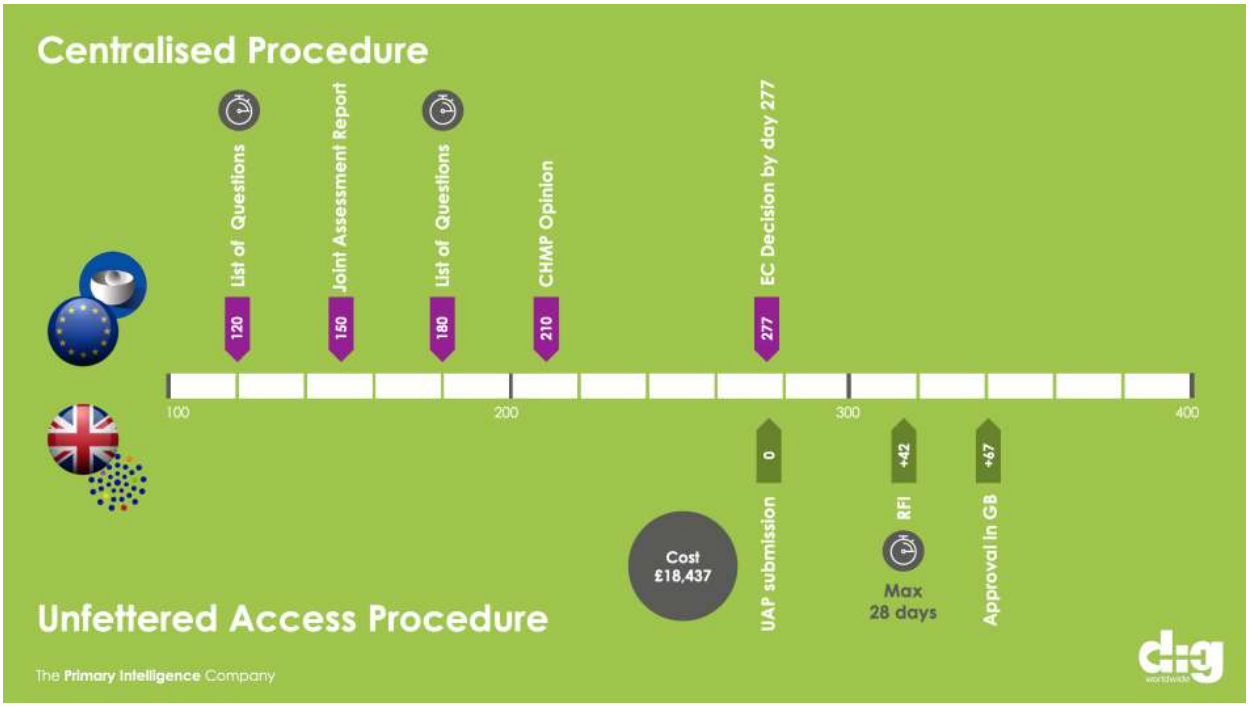


Before Brexit, UK marketing authorisations were automatically granted following EC approval. Applications before 1st Jan 2021 are not required to do anything additional; however after 1st Jan 2021, centralised applications must also apply via the ECDRP to obtain a GB licence. If the application is submitted to the MHRA within 5 days of a CHMP positive opinion, the MHRA will align and grant approval on the same date as the European Commission. A letter of intent is required to notify the MHRA of the incoming application, and can be submitted when a CHMP positive opinion is reasonably expected: up to 28 days before the day-210 application date. The ECDRP acts as an interim procedure underlying the transition period of two years between 1st Jan 2021 and 1st Jan 2023. The MHRA have yet to notify of a replacement and primary intelligence suggests this procedure may be extended.

Centralised vs UAP

Northern Ireland aligns with the EU centralised procedure

Medicines approved by the EU's centralised procedure automatically receive marketing authorisation in Northern Ireland, even after Brexit, because NI remains aligned with the EU's regulatory policies for new medicines review. NI remains aligned, but does not contribute because the regulatory authority responsible for new medicines approval in NI is the UK's MHRA, and there is no longer an MHRA representative within the CHMP. This provides no input into the review process. For the MHRA to provide regulatory oversight for medicines approved in NI looking to expand into the UK, the MHRA have created the Unfettered Access Procedure (UAP) to provide new medicines with 'unfettered access' to the wider UK market.



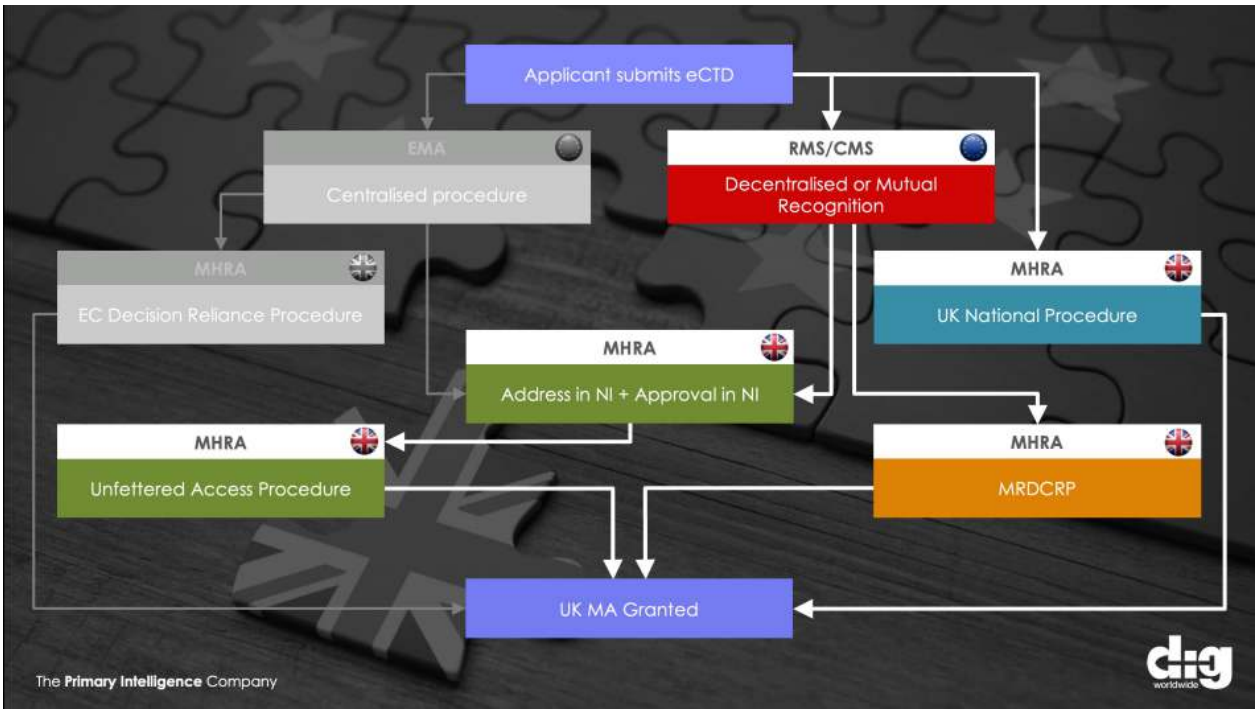
Applicants located in Northern Ireland, i.e. a registered address in NI, have the opportunity to extend the licence to the rest of the UK via the UAP. Applicants can apply via the UAP when the CHMP gives its opinion on day 210; however the application is placed on hold by the MHRA until the EC has issued the final marketing authorisation by day 277. Therefore, the UAP takes 67 days longer than the centralised procedure if an applicant were to obtain a GB marketing licence via this route.

This procedure is active and will continue to operate after the transition period; however the use of the UAP route is only available to applicants with a registered address in Northern Ireland.

Post-Brexit Procedural Map: EU Decentralised

Navigating pharmaceutical marketing authorisations in the UK and EU

The decentralised and mutual recognition procedures enables a reference MS (RMS) to lead the review process, and concerned MSs (CMSs) to peer-review and align with the RMS. These procedures provide routes to a licence for therapies ineligible for the centralised procedures, or for an applicant looking to obtain authorisation in specific target markets. Before Brexit, as a MS, the application could list the UK as a RMS or CMS to obtain a full GB licence via these procedures. After Brexit, as the UK is no longer a MS, applicants have to undertake an additional procedure to obtain a GB licence.



There are two routes for an applicant to obtain a GB marketing licence following approval via the European mutual recognition or decentralised routes: the unfettered access procedure (UAP); and the mutual recognition decentralised reliance procedure (MRDCRP).

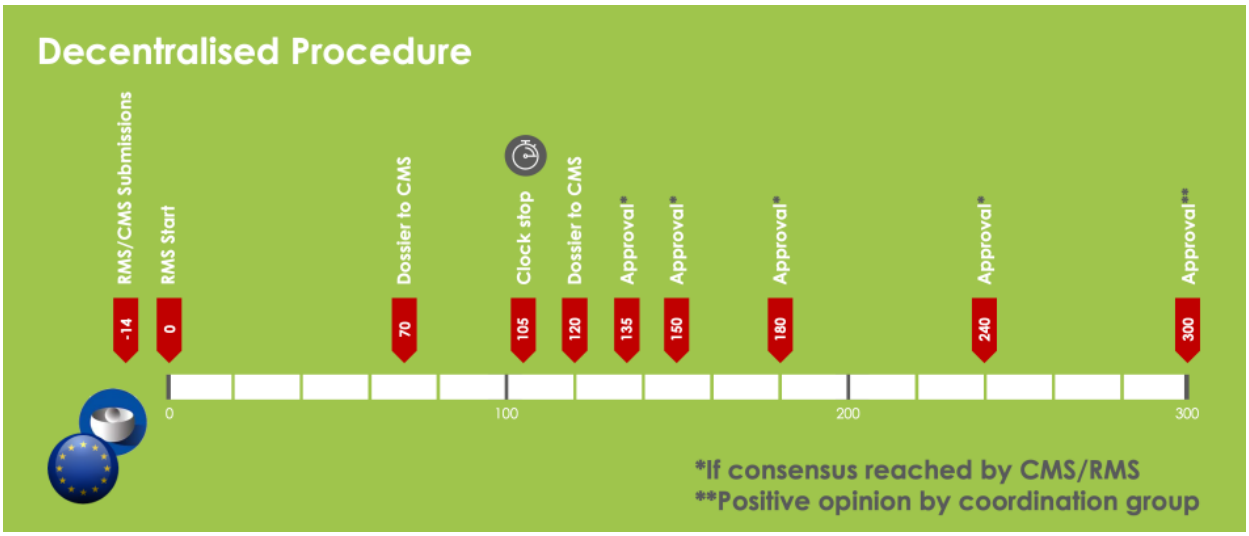
- The UAP is available for any medicines with a NI licence and a registered address in NI. For a medicine to obtain a NI licence via the mutual recognition or decentralised routes, NI must be listed as a concerned member state (CMS). This licence can then be expanded to the whole UK market via the UAP after approval has been granted in NI.
- The MRDCRP is available for any medicine that has been approved in Europe by the mutual recognition or decentralised routes after Brexit. It takes the same length of time as the UAP, 67 days after application is granted in the EU member states, and the applicant is not required to have a registered address in NI and can be located anywhere.

Mutual Recognition and Decentralised

Procedures to obtain authorisation in specific EU target markets

The mutual recognition procedure works to expand on an approval made by the national route in one MS to other MSs. It takes 120 days following the initial 210-day national approval.

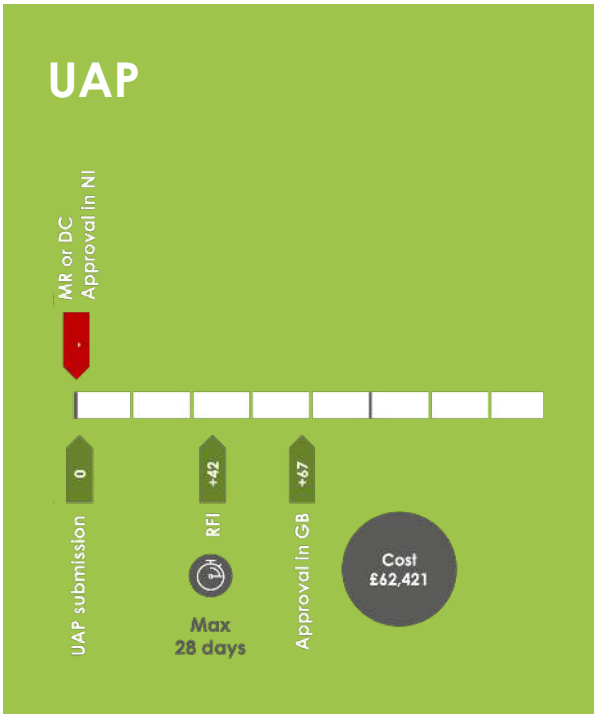
The decentralised procedure allows the applicant to choose two or more member states to apply to. The RMS takes the lead, and there are rounds of discussions between the RMS, CMSs and the applicant until a consensus is reached. There are several potential deadlines following rounds of discussions; the first deadline is on day 135. If a consensus cannot be reached by day 240, a CHMP coordination group steps in to facilitate the discussion and bring a consensus.

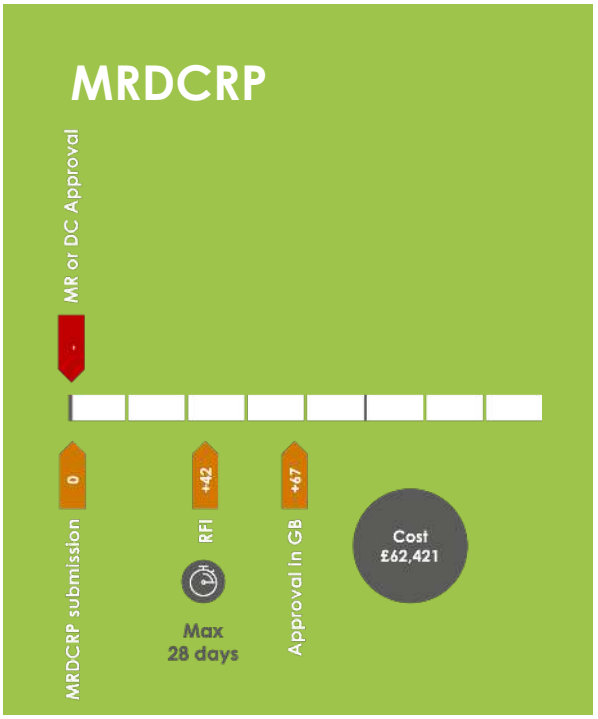


MRDCRP and UAP in Northern Ireland

Procedures to expand non-centralised EU authorisations to the UK market

When approval is granted by more than one MS via the mutual recognition or decentralised routes, a full GB licence can be obtained via either the UAP or MRDCRP. Both these procedures take 67 days, and the application is made on or after the day the approval is granted in the EU member state; therefore a GB licence would be obtained ~67 days later than the EU MSs. The cost of these routes are identical; £62,421. The difference lies in the applicant's status in Northern Ireland (NI).





Unfettered Access Procedure

- Applicants must possess a NI licence from the EU mutual recognition or decentralised procedure; thus the applicant must have listed NI as a CMS during the application.
- NI can be listed as a CMS but cannot act as an RMS because the MHRA is a UK organisation and also the competent authority for NI.
- Applicants are required to have a registered address in NI to be eligible for the UAP.

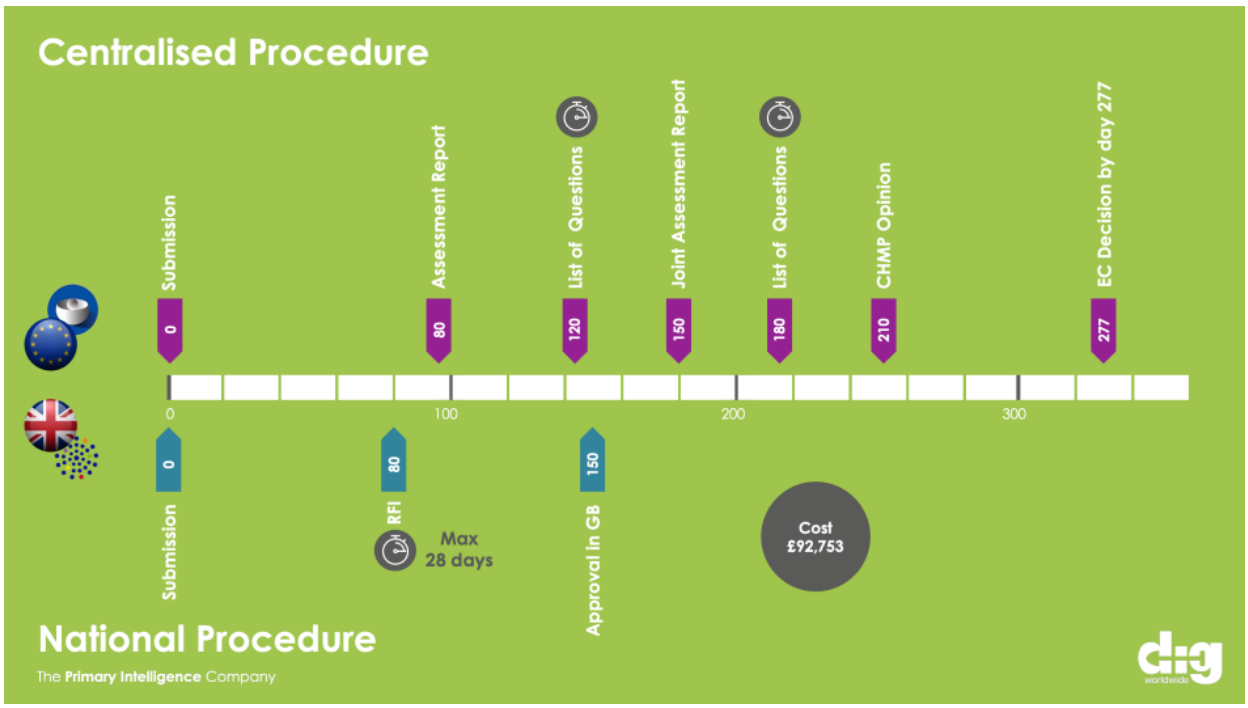
MRDCRP

- MRDCRP is only available for approvals made via the mutual recognition or decentralised procedures; if a licence is obtained only via a MS national procedure, it must first expand to another territory via the mutual recognition route to be eligible to submit an application via the MRDCRP.
- If an applicant has been granted a NI licence, it must withdraw NI as a CMS before applying via the MRDCRP.
- Applicants are not required to be registered in NI to be eligible for MRDCRP.

National Procedure

150-day national procedure provides a decision faster than centralised route

At the time of publication (June 2022), an extension to the transition procedure (the ECDRP) is yet to be confirmed. The UAP and the MRDCRP results in a delayed approval in the UK compared with European member states, and there also remain some areas of contention with the Northern Ireland Protocol in continually evolving political negotiations. Bypassing this uncertain and shifting landscape, the MHRA has created an element of certainty for applicants in the form of a condensed UK National Procedure. This procedure to obtain a GB licence makes the time-to-approval for new medicines significantly shorter than the EU centralised procedure, with a final decision within 150 days and time-limited clock stop to 28 days.



The clock starts when the application is confirmed by the MHRA on day 0. The dossier is in the form of the eCTD, the same format as required by the EMA for centralised review. By day 80, there is a request for further information (RFI), and the timeline pauses for maximum of 28 days as the applicant submits its responses. On receipt of the responses, the clock restarts and a decision is reached by day 150. This pathway leads to a MHRA decision 127 days before the centralised procedures, and 60 days before EU MS national procedures. The procedure is in operation and will continue after the 1st Jan 2023, the end of the transition period. Should the MHRA leadership team decide not to extend or replace the transitional ECDRP, this national procedure is likely to be the main route to a GB licence from Jan 2023.

Section 2

The UK Landscape

https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2020
https://www.gov.uk/government/publications/life-sciences-vision
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/857348/Life_sciences_industrial_strategy_update.pdf
https://www.legislation.gov.uk/ukpga/2021/3/enacted#:~:text=An%20Act%20to%20make%20provision,the%20protection%20of%20health%20and
https://www.gov.uk/government/consultations/the-appointment-and-operation-of-the-patient-safety-commissioner
https://www.recoverytrial.net/
https://www.gov.uk/government/publications/taskforce-on-innovation-growth-and-regulatory-reform-independent-report
https://www.nhsx.nhs.uk/
https://ourfuturehealth.org.uk/
https://www.gov.uk/guidance/rolling-review-for-marketing-authorisation-applications
https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine
https://www.gov.uk/guidance/innovative-licensing-and-access-pathway
https://www.nice.org.uk/guidance/TA781
https://www.gov.uk/guidance/guidance-on-project-orbis
https://www.gov.uk/guidance/access-consortium

Attracting Medicine Development in the UK

The Life Sciences Industry is a strategic priority for a post-Brexit UK

The life sciences industry is a key opportunity for UK global economic competitiveness after Brexit. The UK Official Statistics found the life sciences industry contributed £89bn to the UK economy in 2020. The development of innovative treatments is a key component of this industry and Brexit presents both challenges and opportunities to navigate when it comes to new medicine development in the UK. A 2021 Vision Paper has laid out how the UK will approach this endeavour. The UK is on a mission to "make the UK the best place in the world to discover, develop, test, trial, launch and adopt new treatments and technologies". Widespread changes are already under way in UK regulatory policies, and the Life Sciences landscape is likely to be transformed over the next decade.

*"...make the UK the best place in the world to **discover, develop, test, trial, launch and adopt** new treatments and technologies..."*

HM Government: Life Sciences Vision.
July 2021

2021 Life Sciences Vision

Departure from EU legislation has provided the UK with the opportunity to rewrite the rulebook. The Life Sciences Vision lays out the UK's intended direction for the life sciences industry.

The three key priorities in the Life Sciences Vision:

1. Supporting research and development in life sciences
2. Leveraging the NHS to rapidly accelerate trials and adopt novel treatments
3. Creating a supportive ecosystem for life science commercialisation

The vision lays out the UK's strategy to support innovation and reduce regulatory burden while maintaining patient safety.

Wide Changes to UK Regulatory Landscape

Medicines and Medical Devices Act 2021

On 11th Feb 2021, the Medicines and Medical Devices Act received royal assent and is now written in law. It bestows widespread power for the Secretary of State for Health to amend the existing regulatory framework for medicines and medical devices.

- Provide the UK with legislative means to depart from EU rules and regulations
- Allow straightforward amendment of existing laws through statutory instruments
- Dr. Henrietta Hughes OBE has been appointed as the first commissioner for patient safety to advocate for patient groups
- Implement a common law approach based on judgement of proportionality rather than code-based legislation – with changes to regulations based on assessing the predicted impact of a regulatory decision

Medicines and Medical Devices Act 2021

COVID-19 RECOVERY Trial and TIGRR

The Taskforce on Innovation, Growth and Regulatory Reform (TIGRR) outlines a series of directives for how the UK will make wide-spread changes to the regulatory landscape post-Brexit. Key sections: (11) lays out directives for changes to clinical trials and (12) on digital health technology.

Taskforce on Innovation, Growth and Regulatory Reform (TIGRR)

- The TIGRR recommendations seek to bring healthcare delivery, R&D and regulatory review much closer together to increase efficiencies and remove hurdles
- Section 11 looks to dramatically change the clinical trials regulatory landscape
- The COVID-19 RECOVERY trial is a key driver of these changes - the trial recruited over 47,000 patients and debunked ineffective treatments and identified effective treatments
- This trial design will be implemented across key major indications including Alzheimer's, cancer and mental health

NHS Digitisation to Facilitate Clinical Research

The UK will develop and implement a centralised heath data spine, NHSx, with standardised formats for data collection for both healthcare delivery and research purposes. This continual assessment of real-world evidence will be facilitated through digitisation for innovative clinical trial models.

- The NHS will leverage digitisation and data analysis for both front-line healthcare delivery and research purposes, including real-world evidence generation and clinical trial innovation
- Digitised clinical trials will assess real world data for digital and biomarker endpoints towards personalised/precision medicine
- Our Future Health is an NHS initiative and data analysis platform made of digital patient portals with 5m volunteers with the goal to find treatments and biomarkers for cancer, Alzheimer's, heart disease, arthritis, diabetes and stroke
- Researchers apply with proposals to analyse the OFH data pool

NHSx + Our Future Health

Earlier Regulatory Input

The UK is reinventing its regulatory policy strategy to reflect the Life Sciences Vision, and we can expect to see significant changes over the next few years. Since Brexit, the UK has created two procedures that enable earlier input from the MHRA and other stakeholders to bring medicines to market sooner. These procedures are Rolling Review and the Innovative Licensing and Access Pathway (ILAP).

Rolling Review

Rolling review is when components of the final dossier for application obtain regulatory feedback before the final submission. This procedure is intended to streamline development by offering periodic regulatory interaction and advice to reduce the risk of failure. The dossier is in the form of the eCTD, which is comprised of 5 modules: prescribing information; eCTD summaries; quality data; non-clinical study reports; and clinical study reports. This format is common to US, Canada, EU, China and Japan. For applications via the rolling review, modules are submitted as they are ready, and feedback is given in 60 day cycles. 90 days before the final submission of all the modules together, a pre-submission meeting is organised with MHRA, and 60 days before there is a meeting for a compliance check (CC) and paediatric investigation plan (PIP). After submission of the whole eCTD dossier, a decision is made within 100 days, with a clock stop and request for further information on day 60.

First country to approve Pfizer/BioNTech's Cominarty COVID-19 Vaccine

- The first COVID-19 vaccine approval was in the UK due to the expedited rolling review process
- Pfizer/BioNTech submitted the modules for Cominarty and data was reviewed as the packages became available, receiving MHRA feedback on each of the modules
- The UK granted approval in October 2020, the first authorisation in the world for a vaccine against COVID-19, granted under the 'emergency use' designation
- The MHRA approved Cominarty two months before the FDA and EMA, which approved Cominarty for emergency and conditional use respectively in December 2020

Earlier Regulatory Input

Innovative Licensing and Access Pathway (ILAP)

ILAP is a new pathway aimed at reducing the time to market for innovative medicines by allowing applicants to access enhanced regulatory and stakeholder input through collaborations along the course of development. ILAP comprises of two parts - the Innovation Passport designation and a Target Development Profile.

The Innovation Passport is a designation that unlocks both the Target Development Profile, and a separate FDA initiative for oncology medicines, Project Orbis (pg.18).

Three criteria to obtain an innovation passport:

1. Life threatening condition with significant patient need
2. Innovative medicine, new chemical or biological entity or an advanced therapy
3. Has the potential to offer benefits to patients

Following the Innovation Passport designation, the applicant then procures a target development profile, where a product-specific team of experts are assigned to the development of the 'living document' that evolves with the therapy's development, and includes guidance for collaborating with UK stakeholders to coordinate evidence generation and evaluation.

Lumykras: first ILAP candidate to receive positive NICE recommendation

- Lumykras is a game-changing drug for patients with non-small cell lung cancer, and was recommended through Project Orbis, an FDA work-sharing initiative for oncology medicines
- Lumykras was granted conditional authorisation in the UK on 10th Sept 2021, ~ four months before the EU granted the same on 6th Jan 2022
- Conditional marketing authorisation was granted based on the CodeBreak200 trial - 10 months before the primary completion date
- Lumykras is the first new technology submitted through ILAP to receive a positive recommendation by the National Institute of Clinical Excellence (NICE) and the Scottish Medicines Consortium (SMC), which it achieved in March 2022

LUMYKRAS

Global Work Sharing

Brexit presents the UK with the opportunity to join global work sharing projects

Brexit presents a risk for the UK in the loss of the significant shared work between member states when it comes to regulatory review for new medicines. However, within this risk also lies an opportunity for work-sharing collaborations and partnerships further afield. There currently exist two such initiatives: the FDA-led Project Orbis and the Access Consortium.

A significant difference between these groups and EU work-sharing is that at the end of the process, each country in Project Orbis or the Access Consortium are sovereign over its final decision, whereas EU member states require coordination groups to come to a consensus between reference and concerned member states.

Project Orbis

Project Orbis is an international regulatory alliance coordinated by the FDA, with a framework for concurrent review in the UK, US, Australia, Canada, Switzerland, Singapore and Brazil. It is focused on the review of oncology drugs. Therapies can be recommended for inclusion in Project Orbis by the MHRA to the FDA if they have an Innovation Passport (pg.17).

There are three types of frameworks for Project Orbis work sharing:
Type A: If the application to all the countries are within three months, work is shared between the FDA and other territories.
Type B: If the application is over three months apart to the different countries, the FDA does the majority of the work and there is some work sharing.
Type C: If the application has already been approved by the FDA, the FDA will share the completed review documents.

Global Work Sharing

The Access Consortium

The Access Consortium began in 2007 as a work-sharing consortium between Australia, Canada, Singapore and Switzerland (ACSS). After Brexit, the UK joined as a member from the 1st January 2021 and the group's name changed from ACSS to Access.

For an application to be considered for the Access Consortium, an applicant must submit identical documents to each of the competent authorities in the member countries. The UK on joining have stipulated that the application must be in the form of the eCTD. On receipt of this dossier, one country's authority takes the lead for reviewing an application, the reference authority, and concerned authorities then peer review. The review process takes a maximum of 180 days (without clock-stops); after this review, each country's authority makes its own decision whether to approve the therapy.

The Access Consortium's working groups facilitate lines of communication to exchange information on regulatory issues and challenges faced by the participating regulatory authorities, including issues on clinical trials, marketing authorisations and pharmacovigilance among other topics. There are several working groups, such as the working group for new active substances, and groups also for generics, biosimilars and complementary health products. There is also an IT Architecture Working Group and a working group for Collaboration on International Council for Harmonisation (ICH).

An Opportunity to Streamline Regulatory Work

Although the MHRA retains some access regulatory work done in Europe by grace of the reliance procedures, the UK has lost its seat at the table. There will also be significant additional MHRA capacity required to undertake its newfound responsibilities. Consortiums for work sharing outside the EU, such as Project Orbis and the Access Consortium, are important opportunities for the UK to both streamline review work with other regulatory authorities, and also work together to find common solutions to common challenges.

Pharmaceutical Regulatory Procedures After Brexit

Concluding Remarks

The UK's approach to regulatory procedures after Brexit is yet to be laid out in full, and the MHRA is yet to communicate its plan following the end of the transition period. It is yet to be determined whether the ECDRP will be extended, replaced by another comparable procedure or removed entirely, as the UK's MHRA pushes applications through its 150-day national procedure. This shortened national procedure is an incentive for applicants to commercialise in the UK.

The reliance procedures allow for the MHRA to retain some access to European regulatory review work as the dossiers submitted include the responses from European regulatory authorities. This enables the MHRA to align with work that has already been done; however the reliance procedures from the mutual recognition or decentralised routes, the UAP and MRDCRP, can only be started after the final decision, leading to delayed access to the UK market. While the UK faces a challenge by losing access to the European regulatory review process, there is also, however, the corresponding opportunity to forge work-sharing partnerships outside the EU.

The UK is seeking to further differentiate itself, recognising the importance of the Life Sciences Industry as an area of critical economic importance in a post-Brexit UK. The government is rewriting the rule-book towards wide-scale regulatory reform which will have significant impact across development stages from R&D to the clinical trial landscape, right on through to the regulatory review of new products and eventual healthcare delivery - with all of these components benefitting from tighter communication and collaboration via a centralised data-spine.

The data-spine and focus on real world data will help to bring regulatory review earlier into the development pathway, and innovative review procedures already working towards this mission have been implemented. This has provided the UK with an edge for bringing certain medicines to market sooner. The revised legislation in the Medicines and Medical Devices Act 2021 has enabled widespread changes outlined in the TIGRR directives, and the landscape is likely to change greatly over the next decade.

As the UK government reinvents the regulatory landscape following its exit from the European Union, significant changes are unfolding in the UK across medicine development from inception to launch.

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