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UK MHRA Drug Approval & Marketing Authorisation Guide

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Executive Summary

Since leaving the European Union (EU), the United Kingdom has redefined its pharmaceutical regulatory framework through the Medicines and Healthcare products Regulatory Agency (MHRA). This report examines the post-Brexit drug approval landscape in the UK, focusing on the **Marketing Authorisation** process, the **International Recognition Procedure (IRP)**, and other key regulatory pathways (such as Project Orbis and the Innovative Licensing and Access Pathway). Historical context is provided to trace how the UK transitioned from EU membership to a stand-alone regulator, including the "*grandfathering*" of existing EU approvals into UK licences (www.gov.uk). We analyse current processes (e.g. standard and accelerated routes), recent legal changes (such as the **Windsor Framework** enabling UK-wide authorisations (www.gov.uk) (www.bristows.com)), and new collaboration initiatives (e.g. coordination with international regulators). Wherever possible, we cite official guidance and data: for example, MHRA statistics show that licence application timeliness targets were met across all reported procedures in early 2026 (www.gov.uk). Case examples illustrate these pathways in practice: **IRP** delivered a 30-day approval of a denosumab (XGEVA) formulation by leveraging an EMA assessment (www.gov.uk), while **Project Orbis** enabled concurrent approvals of multiple cancer drugs (e.g. Tagrisso, Trodelvy) in cooperation with the U.S. FDA (www.gov.uk). We also consider challenges and future directions: for instance, industry concerns about R&D investment underscore the broader life-sciences context, and questions of assay and packaging alignment under the Windsor Framework are explored (www.bristows.com) (www.gov.uk).

Introduction and Background

The UK's life sciences industry is a major economic sector. In 2015 it contributed **£30.4 billion** to UK GDP and **482,000 jobs**, with patents, pharmaceutical research, and production all concentrated in Britain (joppp.biomedcentral.com). Global leaders such as AstraZeneca and GSK are headquartered in the UK

(joppp.biomedcentral.com). Historically this industry operated under EU rules: new drugs would typically be assessed by the European Medicines Agency (EMA) for a single *centrally-authorised product* (CAP) licence valid across the EU. The UK MHRA also issued national authorisations (known as Product Licences, "PL") via EU *mutual recognition* or *decentralised* procedures, and recognized European decisions under a *command and control* co-legislation framework inherited into the Human Medicines Regulations 2012 (UK Statutory Instrument 2012/1916) (www.gov.uk).

With Brexit, however, the UK has transitioned to a standalone regulator. The **Withdrawal Agreement** (and its Northern Ireland Protocol) initially preserved some EU alignment: existing EU CAP licences were *grandfathered* into GB national licences ("converted EU MAs") effective 1 Jan 2021 (www.gov.uk), and EU law continued to apply in Northern Ireland (www.gov.uk). Simultaneously, the MHRA developed new routes to preserve medicine supplies for UK patients. An "EC Decision Reliance" procedure (ECDRP) allowed UK approval of multiple EU-approved products in Great Britain. In parallel, independence from EMA was ensured: the UK lost voting rights in EMA committees and withdrew from acting as Reference Member State in EU joint reviews (www.raps.org). A government report in 2020 noted the UK would "continue to respect" EMA decisions but not serve as the *rapporteur* or *leading authority* for EU approvals (www.raps.org) (www.gov.uk).

Post-Brexit legislation solidified the MHRA's independent authority. From 1 January 2021, MHRA automatically converted all pre-existing EU CAPs into Great Britain (GB) licences (with PLGB prefix) (www.gov.uk). EU centralised licences remained valid only in Northern Ireland under the Protocol until the Windsor Framework took effect. The **Windsor Framework** of 2024 further integrated medicines regulation: from 1 January 2025 the MHRA began issuing *UK-wide* authorisations covering both GB and NI (www.gov.uk) (www.bristows.com). Importantly, Northern Ireland may now use UK licence products (with transitional bridging schemes in place), and GB-only licences were largely phased out (www.gov.uk) (www.bristows.com).

As of 2026, the UK's system thus centers on MHRA-issued Marketing Authorisations for human medicines (with prefixes PL (UK-wide), PLGB (historic GB), PLNI (Northern Ireland)). A marketing authorisation permits the product to be placed on the UK market after MHRA assesses the submitted evidence on quality, safety, and efficacy; it is not a guarantee of outcomes for every patient. MHRA's **Marketing Authorisation Application (MAA)** process follows criteria laid down in the Human Medicines Regulations (HMR) 2012 (as amended). Key MAA categories include:

- **New active substances** (chemical or biological) – Regulation 50 lists new active substances and (additional) known actives.
- **Generics** – Regulation 51B covers generic copies of known drugs.
- **Hybrid applications** (Reg. 52B) – for modified versions (e.g. new routes, dosages) of known drugs.
- Biosimilars – (Reg. 53B).
- **Fixed combination products** (Reg. 55) – multiple actives in one.

Each MAA must submit a full dossier (in eCTD technical format) demonstrating the product's *quality*, *clinical efficacy*, and *safety*.As of April 2024 the MHRA mandated strict adherence to the international eCTD standard (via the Lorenz DocuBridge system) (www.gov.uk). Under current rules, a full MHRA assessment proceeds over a statutory 210-calendar-day period (for new actives) after validation, with MA issuance requiring MHRA

approval. Deferrals or stepwise approvals (e.g. for conditional MAs or pediatric use) are governed by European-style criteria. MHRA's guidance and fees are published on GOV.UK, and holders must comply with UK-specific labelling and pharmacovigilance mandates (including maintaining a UK QPPV) (www.gov.uk).

Importantly, MHRA retains **ultimate sovereign authority**: even when relying on foreign data or expedited routes, it must be satisfied on benefit/risk. Official statements emphasize that streamlined approvals "take into account the expertise and decision-making of trusted regulatory partners, whilst retaining the authority to reject applications if the evidence is insufficiently robust" (www.gov.uk). In practice this means UK pathways incorporate foreign assessments but remain UK licences. In the sections below we detail the main MA routes (national and international) and how they function in 2026.

UK Marketing Authorisations: Pathways and Processes

MHRA issues several types of marketing authorisation (MA) for medicines in the UK. New drugs (new chemical or biological entities) must obtain a *full* MA under Reg. 50 procedures. Depending on the product, applicants may choose among different routes:

- **National procedure (UK-only)**: The core route under Reg. 50 (and related regs). Applicants submit a full dossier to MHRA for a UK (GB or UK-wide) MA. Prior to 2025, Great Britain-only (PLGB) MAs were possible; after Windsor, new approvals are only UK-wide (www.gov.uk). This is essentially the sole route for novel drugs. Timelines: typically a 210-day assessment (with clock-stops for queries), similar to EMA's 210 days. For generics (Reg. 51B), hybrid or biosimilar (52B, 53B), similar national review timelines apply. Targets: MHRA aims to meet statutory deadlines for ~95% of initial approvals (www.gov.uk). Underperforming companies are subject to enforcement.
- **International Recognition Procedure (IRP)**: (See next section for details.) As of 2024, IRP is a hybrid fast-track scheme enabling reliance on an existing reference licence from certain "trusted" regulators. It covers new drugs, generics, hybrids, biosimilars, etc., but requires prior 'trusted regulator' (RR) approval of the same product (www.gov.uk). IRP can reduce national MHRA assessment to 60–110 days (compared to ~150–210 days normally) (www.gov.uk), but with similar evidence standards.
- **Post-authorisation changes**: Once a product is on the UK market, variations (Type IA, IB, II) and renewals are required by UK law. MHRA provides processes for variations (minor technical changes) and annual renewal; previously EU reference data could be reused (the ECDRP/MRDCRP), but now a similar *post-authorisation IRP* exists. Recent guidance confirms that amendments such as adding sites or updating Risk Management Plans can be submitted via a post-licensing IRP, following an RR′s assessment (www.gov.uk).
- **Accelerated/conditional approvals**: In urgent scenarios (e.g. pandemic, orphan drugs) MHRA can grant conditional or emergency authorisations. Like EMA's "conditional MA", such licences in UK may be granted with weaker evidence and require future studies. One can extend IRP even if the RR licence

was conditional . MHRA has discretion to authorise immediately under public health emergency rules. These are limited in scope; e.g. MHRA uniquely provisions *Regulation 174* for emergency importation of unlicensed meds. In normal times, the main expedited scheme is **EAMS** (see below).

- **Special schemes (Access programs)**: Beyond formal MAs, MHRA offers early-access pathways. The **Early Access to Medicines Scheme (EAMS)** lets companies supply an unlicensed Medicine with MHRA Scientific Opinion if the medicine is highly promising and no alternative exists (www.gov.uk). EAMS is voluntary and advisory (no licence is granted, only a time-limited prescription guideline). Another is MHRA's own **"tailored guidance"** programmes like the *Innovative Licensing and Access Pathway (ILAP)* and *Project Orbis,* which facilitate combined regulatory/HTA review (see below).

After an MA is granted, MHRA continues to supervise safety. Marketing Authorisation Holders (MAHs) must comply with UK pharmacovigilance law (reporting to the Yellow Card System (www.gov.uk), maintaining a UK Qualified Person for PV, etc.). The MHRA's *safety database* and *Public Assessment Reports (PARs)* are published on mhra.gov.uk for transparency (www.gov.uk). Any new side effect signals can lead to variations (e.g. new warning labels) or even licence suspension.

Types of UK MA and Comparison

Although UK MAs closely mirror EU terminology, the end of EU membership required creating UK-specific MA categories and numbers. Before 2025, authorised products had prefixes "PLGB" (Great Britain) or "PLNI" (Northern Ireland only), or EU Commission CAPs for NI; after Windsor all approvals are UK-wide (prefix "PL"). The key UK routes (Reg. 50, 51B, 52B, 53B, 55) correspond to EU practice: new active (including known substances), generics, hybrids, biosimilars, fixed combinations (www.gov.uk). For clarity, Table 1 summarises these categories:

MHRA Route (HMR Reg.)	Product Type	Notes
Reg. 50	New active substances (chemical/biological) or known active substances (line extensions)	Full dossier, generic 210-day review
Reg. 51B	Generic applications (abridged from originator)	Bioequivalence data; national review
Reg. 52B	Hybrid applications (similar to originator but changes)	e.g. new strength, formulation; additional data required
Reg. 53B	Biosimilar applications	Comparative clinical/quality data vs reference biologic
Reg. 55	New fixed-combination products	Two or more actives; new clinical data needed
(Reg. 54 – Bibliographic applications)	Bibliographies (literature-only)	*Not eligible for IRP*; mostly for generics via published sources

This table underscores that **IRP eligibility** (discussed below) covers the channels above except pure bibliography (Reg. 54) or traditional/herbal schemes.

International Recognition Procedure (IRP)

Overview of IRP

The **International Recognition Procedure (IRP)** is a key post-Brexit initiative to accelerate UK approvals by leveraging international partners. MHRA formally *launched IRP on 1 January 2024* (www.gov.uk), replacing its earlier *EC Decision Reliance Procedure (ECDRP)* and incorporating the mutual recognition/decentralised reliance steps into one scheme. IRP's goal is to "take into account the expertise and decision-making of trusted regulatory partners for the benefit of UK patients" (www.gov.uk), while MHRA retains final review authority. In practice, an applicant must already hold a full marketing authorisation for the "same product" from a designated **Reference Regulator (RR)**. The **same product** means identical qualitative/quantitative composition, form, and company/licensee group (www.gov.uk).

The list of accepted RRs is broad: Australia (TGA), Canada (Health Canada), Switzerland (Swissmedic), Singapore (HSA), Japan (PMDA), USA (FDA), and the EU/EEA (EMA or any EU/EEA national agency) (www.gov.uk). In addition, approvals via the *Access Consortium* (a work-sharing group of TGA, Health Canada, HSA, Swissmedic) can serve as RRs even if MHRA was not involved (www.gov.uk). Put simply, IRP is open if at least one of these agencies has already approved the identical product (for example via EU centralized procedure, or Food and Drug Administration in US). MHRA will then conduct a **targeted review** based on the existing licence dossier, rather than full original assessment (www.gov.uk). However, if IRP evidence is "insufficiently robust," MHRA still reserves the right to refuse the application (www.gov.uk).

A useful example: MHRA granted its first IRP approval on 29 February 2024 – a new formulation of **XGEVA (denosumab)** in a prefilled syringe (www.gov.uk). Denosumab is an established drug for bone metastases. The company had obtained a EU/EMA positive opinion (CHMP) on 25 Jan 2024 (www.gov.uk). MHRA then used IRP to authorise the identical product in the UK by 29 Feb 2024 (authorised in 30 days, according to MHRA), a **marked acceleration** compared to the ~150–210 days typical via full assessment (www.gov.uk). This case illustrates IRP's value: UK patients gained faster access to an improved drug form (syringe vs vial) by leveraging the CHMP assessment rather than duplicating work. MHRA's interim director appropriately noted that this "demonstrates that the new process for bringing new medicines to UK patients is well under way" (www.gov.uk).

IRP Eligibility and Scope

IRP can currently be used for *new MA applications* (including line extensions) under *Reg. 50, 51B, 52B, 53B, 55* – i.e. new actives, generics, hybrids, biosimilars, fixed combos (www.gov.uk). Traditional herbal and homeopathic registrations and bibliographic (Reg. 54) applications are **excluded** (www.gov.uk). Post-approval, IRP also applies to lifecycle changes (line extensions, significant Type IB/II variations, renewals) (www.gov.uk). For each IRP use, the company must submit an *eligibility declaration form* (to be completed at least 8 weeks before the planned MAA submission) specifying the RR licence and timeline.

Key IRP features include two processing tracks: **Recognition A** (60-day timetable) and **Recognition B** (110-day) (www.gov.uk). An MA is eligible for Recognition A if the RR (e.g. FDA or EMA) approved the product within the last 2 years (www.gov.uk) and certain stringent criteria (identical manufacturing, no new sites or significant data changes, etc.) are met. Under Recognition A, MHRA aims to decide within 60 days of validation, with no clock stops (www.gov.uk). If major issues arise, it can revert to Recognition B timeline.

Recognition B uses a 110-day timetable for applications meeting its criteria. Updated guidance effective July 13, 2026 reduced the reference-approval window for Route B from 10 years to 5 years, with transitional use of the prior process available through August 31, 2026; applicants must use the current eligibility form and route-specific criteria (www.gov.uk). Under B, there is typically a single clock-stop (MHRA feedback at day 70), and although 110 days is targeted, unresolved major issues by this date could trigger a fallback to the standard 210-day review with CHM consultation (www.gov.uk). MHRA also publishes recommended latest submission dates for Recognition B applications so that procedures align with Commission on Human Medicines (CHM) meeting dates (www.gov.uk). In practice, Recognition A is highly accelerated (essentially faster versions of existing *abridged* evaluations), whereas B allows for more complexity.

Table 2 summarises the main IRP conditions:

Recognition A (60d)	Recognition B (110d)
RR licence issued ≤2 years ago (www.gov.uk)	RR licence issued within the previous 5 years (www.gov.uk)
Same manufacturing process (no new sites) (www.gov.uk)	If conditional licence (RR or UK) or new sites/major changes (www.gov.uk)
No substantial data advances beyond RR	First-in-class, RMP changes, PASS studies, real-world/single-arm data (www.gov.uk)
No UK-only safety/RMP obligations	UK-specific risk mgmt or labelling differences (www.gov.uk)
No clock-stop – fixed 60d period (www.gov.uk)	**One clock-stop** at Day 70, then review to Day 110 (www.gov.uk)

Table 2. Summary of IRP Recognition A vs B (see MHRA guidance for full details (www.gov.uk)).

It bears repeating that IRP is solely for products with an existing RR licence. MHRA explicitly rules out using an RR approval that was itself based on **reliance** (e.g. if the RR licence was granted via MHRA work or another reliance chain) (www.gov.uk). “Conditional and exceptional circumstances MAAs” from an RR can support an IRP, but completely *emergency* authorisations are ineligible (www.gov.uk). IRP also excludes cancelled or withdrawn RAs (as expected).

The upshot is that IRP effectively harmonizes UK approvals with “Stringent Regulatory Authorities” (SRA) results. A product authorized after a full standalone review by an accepted reference regulator may be eligible for IRP only when the applicant, product, approval window, manufacturing, documentation, and route-specific criteria are satisfied; MHRA retains authority to reject the application (MHRA IRP guidance). MHRA has promoted this as providing “rapid, efficient, and cost-effective” access (www.gov.uk). The tradeoff is that UK patients will typically get such products only after launch in at least one other major market. Critics note that

IRP is not a substitute for global simultaneous submissions; it *requires* a lead agency first (www.gov.uk). Conversely, it avoids diverting resources to duplicate reviews and may encourage companies to treat UK as part of their phased roll-out.

Reference Regulators and International Cooperation

The IRP's list of Reference Regulators is deliberately international (see Table 3). Recognised RRs include the leading agencies of North America, Europe, Asia-Pacific and key alliances (www.gov.uk). This reflects the UK's strategy of aligning with multiple "trusted" systems. Notably, the **Access Consortium** (AUS/CA/SG/CH partnerships) is explicitly accommodated: if a drug was approved through Access work-sharing (without MHRA involvement), any *one* of those agencies' licences can serve as RR documentation (www.gov.uk). This effectively broadens IRP: all Access Consortium partners (Australia, Canada, Singapore, Switzerland) appear twice. Project Orbis (US-coordinated oncology reviews) is separate and not explicitly listed, though an Orbis-approved drug would presumably have at least one of the named RR approvals (FDA, PMDA, etc.).

Table 3. Acceptable **Reference Regulators** (RRs) for IRP (www.gov.uk):

Country/Jurisdiction	Regulatory Authority
Australia	Therapeutic Goods Administration (TGA)
Canada	Health Canada
Switzerland	SwissMedic
Singapore	Health Sciences Authority (HSA)
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)
United States	Food and Drug Administration (FDA)
EU/EEA (incl. Norway, Iceland, Liechtenstein)	European Medicines Agency (EMA) and Member State CAs (incl. national licensures)

With these partnerships, MHRA benefits from existing multi-lateral arrangements. For example, the UK has a Mutual Recognition Agreement (MRA) with the EU covering Good Manufacturing Practice (GMP) inspections and testing – effectively extending that trust to licensing reliance (www.raps.org). Similarly, a U.S.–UK MRA came into force on 1 Jan 2021 for GMP (human drugs); this allows each regulator, within the pharmaceutical annex's scope and conditions, to use certain GMP inspection information from the other authority (www.fda.gov). These arrangements can reduce duplicate inspections and, under separate approved-country rules, may support specific UK batch-testing exemptions when product, manufacturing, testing, and certification conditions are satisfied. They do not create a blanket reciprocal exemption from batch testing or automatic compliance for every facility or product (UK approved-country rules). In short, UK regulatory pathways are increasingly entwined with international regimes at both approval and production stages.

How to Apply under IRP

Prospective applicants must first **qualify** an MAA via IRP. IRP applications (new MA or post-authorisation) are submitted through the Human Medicines Portal (with the eCTD sequence submitted through the MHRA Submissions Portal) and *must* reference the RR authorisation with proofs. An eligibility form, to be completed at least 8 weeks before the planned MAA submission, is required to determine Recognition A vs B. If MHRA deems the product ineligible for IRP (e.g. no qualifying RR licence), it reverts to an ordinary national application.

The process flow is roughly: validate submission → MHRA validation check (completed within 14 days) → start of procedure. For Recognition A, the clock runs 60 days straight; for B, a first evaluation to Day 70, then formal "clock stop" for applicant response, then final by Day 110 (or longer as noted). If unresolved, MHRA will involve its *Commission on Human Medicines (CHM)* as a final arbiter, lengthening the review. Fees and national assessments still apply, though IRP fees can be lower in some cases (the MHRA guidance lists specific fee regimes for IRP filings). In all cases, approval yields a UK marketing authorisation (PL prefix) that is effectively identical to a national full MA, except references to IRP. After approval, IRP products are subject to standard UK conditions (e.g. UPC labelling, UK pharmacovigilance):

- ***Key point:*** IRP does *not* automatically grant an EU or Northern Ireland MA. It only grants a UK (GB/UK-wide) licence. Before 1 January 2025, Northern Ireland relied on EU-authorised or NI-specific licences, and a GB-only licence did not cover NI; from 1 January 2025 the MHRA licenses medicines across the whole of the UK. (Windsor's CAP-bridging mechanism eased this by temporarily allowing UK-approved novel drugs to reach NI patients (www.bristows.com) – see next section.)

Post-Brexit Regulatory Pathways Aside from IRP

In addition to IRP, the UK has developed other pathways to maintain access and foster innovation:

UK-wide Licensing (Windsor Framework) – Starting 2025, the MHRA issues *UK-wide* licences only, replacing separate GB and NI MAs. MHRA now issues all new approvals with a "UK (PL)" prefix (no more PLGB/PLNI) (www.gov.uk). Union (EU) CAPs no longer cover NI, so companies must hold MHRA MAs for NI market (www.gov.uk). Under Windsor, MHRA mandated that **packaging** be marked for UK-only use: all packs must carry a visible "UK only" label/sticker if not to be sold in EU (www.bristows.com) (www.gov.uk). EU Falsified Medicines Directive features (2D barcodes, serial numbers) are being phased out of UK packs (www.bristows.com) (www.gov.uk), reducing costs and allowing dual-market packs if reworked. Critically, the *Northern Ireland CAP bridging mechanism* (www.bristows.com) allows an innovative therapy authorised first in GB to be used in NI for up to 6 months (or until EMA CAP is granted/refused), ensuring NI patients are not left behind. These Windsor arrangements (NI/GB re-unification) simplify the regulatory map but require industry compliance with new labelling and database changes (www.bristows.com) (www.gov.uk).

Project Orbis – To accelerate oncology drug entry, MHRA participates in FDA's Project Orbis (since 2021) (www.gov.uk). Orbis enables concurrent review of cancer therapies by multiple regulators. Eligible products are new anticancer drugs or new indications for approved ones (www.gov.uk). Companies can submit "Type A" near-concurrently (within 30 days of FDA) or later "Type B/C" dossiers (www.gov.uk). The actual review remains country-independent (each regulator makes its own decision), but coordination is extensive. Since 2021, MHRA Orbis reviews have led to numerous UK MAs in oncology, e.g. **Tagrisso** for adjuvant EGFR-mutant lung cancer, **Trodelvy** for triple-negative breast cancer, **Jakavi** for graft-vs-host disease, among others (www.gov.uk). These approvals, many through *variations* adding new indications, illustrate UK's strong uptake of this collaborative scheme. (Though not an MA route itself, Orbis shows how UK pipelines sync with FDA. Each Orbis MA was eventually granted as a full UK licence.)

Innovative Licensing and Access Pathway (ILAP) – Originally launched in 2021 and relaunched in 2025, ILAP is a UK-only program to help *transformative medicines* reach patients faster by aligning regulator, health technology assessor (NICE/SMC), and NHS stakeholders (www.gov.uk). It starts with an *Innovation Passport* for an eligible new therapy (often pre-authorisation), granting access to coordinated advice. ILAP offers integrated development planning and coordinated engagement between the regulator, health technology assessors and the NHS. This "end-to-end access pathway" is novel globally (www.gov.uk). The detailed ILAP guidance emphasizes early-stage planning: once a product earns an Innovation Passport, a multidisciplinary team sets a *Target Development Profile* to streamline evidence and address clinical adoption. (www.gov.uk). While ILAP does **not** itself grant an MA (drugs still go through MHRA MAA), it intimately links licensing with accelerated market entry. The pathway is now open for Innovation Passport applications (www.gov.uk).

Other Accelerated Schemes – UK offers additional expedited pathways. Aside from EAMS (described earlier) and ILAP, MHRA has an *Innovation Office* providing early scientific advice to promising projects. In practice, many early-stage gene therapies or orphan drugs use these mechanisms for dialogue with MHRA (and NICE). These are outside strict MA processes but part of the **regulatory ecosystem**.

Pharmacovigilance (PV) and Safety Reporting – Under post-Brexit law, MHRA runs its own PV database (*Yellow Card*). UK MAHs must register UK QPPVs and report adverse reactions to MHRA (no longer to EMA's EudraVigilance for GB products). The White Triangle symbol marking "additional monitoring" remains used for new actives (www.gov.uk). In brief, the UK has re-instated a national PV system (yellow card), but still adheres closely to the EU Good Vigilance Practices standards, again often via MRA-type cooperation. Thus, in all phases (licensing, manufacturing, safety), UK and EU maintain harmonized elements to ease burdens on global pharma.

Case Studies and Examples

To illustrate these mechanisms, we present select cases:

- **IRP Example – Denosumab (XGEVA)**: As noted, MHRA's first IRP approval (authorised 29 Feb 2024) was a denosumab 120 mg prefilled syringe (www.gov.uk). The company (Amgen) had EU/Centralised positive opinion (25 Jan 2024); MHRA granted UK MA on 29 Feb 2024 (www.gov.uk). This 30-day turnaround contrasted starkly with the standard ~150-day process and is attributed to IRP synergy (www.gov.uk). Key quotes: MHRA's director said "we're assured that the appropriate regulatory

standards…have been met" and highlighted IRP's patient-benefit (www.gov.uk), while the UK Health Minister lauded faster approvals via "sharing expertise…so patients can benefit as soon as possible" (www.gov.uk). This demonstrates IRP's practical impact: a real patient-centric benefit (new delivery form) achieved through international reliance.

- **Project Orbis – Oncology Approvals**: Between 2021–2022, several oncology drugs were approved through Project Orbis coordination involving MHRA. For instance, **Tagrisso** (osimertinib) was given a UK licence (monotherapy in adjuvant NSCLC) on 6 May 2021 (www.gov.uk). **Trodelvy** (sacituzumab govitecan for metastatic triple-negative breast cancer) was licensed 8 Sept 2021 (www.gov.uk). Other examples include **Jakavi** (ruxolitinib for acute or chronic graft-versus-host disease in patients aged 12 years and older with inadequate response to corticosteroids; UK MA on 23 Mar 2022) (www.gov.uk), **Lumykras** (sotorasib for KRAS G12C mutant NSCLC; 8 Sept 2021) (www.gov.uk), and **Welireg** (belzutifan for VHL disease; 31 May 2022) (www.gov.uk). These entries were typically via *variations* (new indication) or initial MAs, but all benefited from the US-EU-UK collaborative review model (www.gov.uk). While the data here come from MHRA's guidance table, they underscore how Orbis projects support simultaneous global launches of cutting-edge cancer therapies.
- **Windsor Framework Case – CAP Bridging**: The expected application of the CAP Bridging Mechanism under Windsor (1 Jan 2025) means, for example, that if Pfizer developed a new oncology biologic first licensed in GB (MHRA), it could supply Northern Ireland patients (via special permit) while awaiting EMA approval. Although we lack a public drug-by-drug example post-2025, the scheme is designed to run under specific conditions: supply up to 6 months prior to an EMA decision (www.bristows.com). Industry has been preparing packaging for UK/NIE transition: by late 2024, nearly 90% of marketed products had updated "UK Only" artwork submitted (www.gov.uk). This case illustrates regulatory flexibility during protocol changeover, avoiding treatment gaps.
- **Grandfathering Example**: Tables of "grandfathered" CAPs show that by early 2021 all centrally authorised products (e.g. nearly all novel cancer drugs, vaccines, etc.) automatically became PLGB-licensed in GB (www.gov.uk). If a company had opted out, that product stayed EU-only. Actual data (March 2021 MHRA decision documents) list hundreds of PLGB numbers copied from CAP lists (www.gov.uk). In practice, a patient taking an EU-approved chronic therapy (e.g. an MS drug) would see no interruption as their MA converted into a UK licence with identical content. This seamless grandfathering was essential for continuity, albeit at the cost of maintaining parallel regulatory versions (GB-only vs CAP) until Windsor unified them.
- **FDA–MHRA GMP MRA**: Not a drug case per se, but an example of manufacturing reliance: the UK–US Mutual Recognition Agreement (effective Jan 2021) permits MHRA to rely on qualifying FDA inspection information within the agreement's product and facility scope; it does not automatically deem every FDA-inspected plant MHRA-compliant (www.fda.gov). FDA may likewise rely on qualifying MHRA inspection information while retaining its own inspection and import controls. The agreement does not categorically eliminate reciprocal batch testing; any exemption depends on the importing jurisdiction's rules and the specific product, manufacturing, testing, and certification conditions (UK approved-country

rules). This global trust significantly smooths supply chains in both directions. (FDA's current overview lists vaccines for human use, plasma-derived pharmaceuticals, and investigational products as pending further consideration and identifies additional excluded categories (www.fda.gov).)

These cases demonstrate both the **continuity** (grandfathering, GMP MRA) and **innovation** (IRP, Orbis, bridging) in UK drug regulation post-Brexit.

Discussion: Implications and Future Directions

The transformations in UK drug licensing have several major implications:

- **Speed vs Sovereignty**: The IRP and international programs clearly **accelerate** approvals by trusting other regulators. Official comments laud shorter timelines and patient access (www.gov.uk). However, reliance on foreign assessments means the UK's MA timing is tied to other agencies' review schedules. MHRA leadership must balance sovereign duty (ensuring UK-specific needs/safety) against industry pressures for rapid approvals. So far, the MHRA has retained firm oversight: it still validates data, requires UK-valid data, and can reject if standards aren't met (www.gov.uk). Any future pressure to relax standards could spark debate in Parliament or media. The UK's *net balance* seems positive: trade journals and law firms (e.g. Burges Salmon (www.burges-salmon.com)) have generally applauded IRP as a needed post-Brexit solution for industry.
- **Northern Ireland and Multi-Market Supply**: The Windsor changes remove major regulatory barriers between GB and NI. Companies can now provide a single licence for UK-wide use, simplifying supply logistics. Still, the need for "UK only" labelling and lack of EU decommissioning systems means manufacturers bear extra complexity in packaging (www.bristows.com) (www.gov.uk). There has been some industry concern (e.g. in consultations) about dual-labelling costs, but the transitional reliefs (use old packs until expiry) mitigate disruption. Going forward, the UK market will function like a single territory – removing the split-market issues caused by the old NI Protocol.
- **International Positioning**: Post-Brexit, the UK's regulatory role is changing but not diminished: MHRA actively engages in global initiatives (Orbis, Access, new MRAs) and aims to be a "leading authority" through partnership rather than solo leadership (www.raps.org). The UK no longer hosts the EMA, so it must prove its value through efficiency and innovation rather than scale. The integrated programs (IRP, ILAP, Orbis) are emblematic of this approach. However, some critics have warned that scaling down from EU size could risk "medicines reaching patients" if not managed well (joppp.biomedcentral.com). The Reuters report (Sept 2025) noted industry unease about the overall UK access environment and falling R&D investment (www.lse.co.uk), though this was largely about pricing and NICE, not MHRA per se. The UK government has acknowledged these concerns, pledging to strengthen life sciences funding and NHS access (through reforms like a new Innovative Medicines Fund). The MHRA's own performance targets (all KPIs met in early 2026 (www.gov.uk)) show regulatory stability despite these economic headwinds.

- **Future pathways**: The MHRA has signalled further modernization. The ongoing **RegulatoryConnect** program will automate validation and allow greater e-services (the new DocuBridge eCTD portal is only the first step (www.gov.uk)). The agency also envisions expanding international reliance. For example, the UK–US GMP MRA currently covers human pharmaceuticals, and the FDA and UK decided to revisit possible extension to human vaccines and plasma-derived products in July 2025 (the FDA page does not confirm any extension) (www.fda.gov). Industry backlash (the Reuters story above) may influence policy: if the NHS agrees to more favorable pricing, companies may invest more UK data or schedule IRP submissions earlier. Long-term, the MHRA might pursue mutual recognition with other regulators (e.g. exploring ties with emerging regulators).

On the flip side, potential fragmentation looms: the UK may adopt novel regulatory standards (e.g. for AI-checked data submissions or real-world evidence in licensing) diverging from EU. MHRA commentary hints at new science advisory wheels, but details are sparse. Analysts caution that any drastic rule divergence could complicate global development plans. For example, if UK lowers evidence requirements relative to EU, there could be safety debates. So far MHRA has kept aligned with ICH technical specs (all eCTD, same CTD format) to ease global submissions (www.gov.uk).

Another dimension is data transparency: MHRA now publishes *Public Assessment Reports* (PARs) for UK MAs (as EMA did for CAPs). Continued openness (and possible alignment of post-market data sharing, e.g. on pharmacovigilance) would benefit stakeholders, although issues of commercial confidentiality remain more restrictive than EU.

Overall, the future points to a UK regulator that is agile and outward-looking. The IRP and associated routes exemplify a pragmatic response to Brexit: using global harmonization to offset loss of EU centralised procedure (www.gov.uk). Analysts will watch whether UK's model can outpace (or at least match) the EU in bringing medicines to market **quickly and safely**.

Conclusion

Post-Brexit, the UK's MHRA has implemented a multi-tiered strategy to maintain timely patient access to medicines. Through a combination of **national licensing**, reliance on foreign approvals (IRP), and collaborative expedited pathways (Orbis, ILAP), the UK aims to rival the previous EU authorisation system in efficiency. Historic EU-USA and EU-UK mutual-recognition agreements have been preserved, and new ones forged, to facilitate manufacturing and distribution (www.raps.org) (www.fda.gov). Legislative updates (Windsor) have streamlined UK-wide licensing. On the data side, the MHRA continues to meet its performance targets (www.gov.uk), suggesting operational stability despite these sweeping changes.

However, this report has also highlighted challenges: IRP requires companies to first win approval elsewhere, so UK access may be slightly secondary. Firms have voiced broader concerns about the UK access environment, partly due to pricing negotiations (www.lse.co.uk). Looking forward, the effectiveness of these regulatory pathways will depend on continued alignment with international standards (as seen by the UK's adoption of ICH eCTD rules (www.gov.uk)) and on coordination with health technology assessment bodies (as in ILAP). It is likely the UK will refine these tools further, testing new models (for example, acceptance of digital health or real-world data).

In summary, the UK's post-Brexit drug approval system represents a hybrid of regained sovereignty and strategic international cooperation. By institutionalizing processes like IRP and Orbis, the MHRA aims to give British patients swift access to innovations without duplicating global effort. The coming years will show whether this balance of independence and recognition yields itself to a thriving life sciences sector. For now, industry and regulators alike appear cautiously optimistic that the new framework will serve UK public health while sustaining pharmaceutical innovation (www.gov.uk).

Table 4. Key legislative and regulatory milestones in UK medicines approval (2019–2026) (www.gov.uk).

Date	Event/Change	Source
Feb 2020	UK confirms: will respect EMA decisions but no longer act as RMS/Rapporteur during transition (www.raps.org)	RAPS (2020) (www.raps.org)
1 Jan 2021	End of Brexit transition: EU CAPs automatically converted to GB MAs (PLGB) (www.gov.uk); UK licensing includes national & reliance (ECDRP) routes.	MHRA guidance (Mar 2021) (www.gov.uk)
2021	UK–US GMP Mutual Recognition Agreement enters force (human drugs) (www.fda.gov).	FDA (2023 press) (www.fda.gov)
31 Dec 2023	End of ECDRP (EU reliance) route (www.gov.uk).	MHRA news (Sept 2023) (www.gov.uk)
1 Jan 2024	IRP supersedes ECDRP/MRDCRP (MHRA official launch) (www.gov.uk).	MHRA IRP guidance (Jan 2026) (www.gov.uk)
1 Jan 2025	MHRA ends new Great Britain-only applications; new applications are for UK-wide MAs and use PL product numbers (www.gov.uk).	UK-wide licensing guidance (www.gov.uk)
1 Jan 2025	Windsor Framework in force: MHRA issues UK-wide MAs, terminates EU CAP validity in NI (www.gov.uk); "UK only" labelling mandatory (www.bristows.com).	Bristows (2024) (www.bristows.com) and MHRA news (www.gov.uk)
31 Dec 2025	(Transition) Packs with old labelling may remain on market until expiry (www.gov.uk).	MHRA Windsor guidance (www.gov.uk)
Apr 2024 onward	MHRA adopts new eCTD system (RegulatoryConnect) (www.gov.uk), continues to build ILAP.	MHRA guidance (June 2025) (www.gov.uk)

The collective evidence shows a regulatory system in active evolution: robust oversight by a sovereign agency, combined with extensive use of international harmonization to benefit UK patients.

Sources: Authoritative publications including UK government and MHRA documents (www.gov.uk) (www.bristows.com) (www.gov.uk), regulatory analyses (www.burges-salmon.com) (www.raps.org), and academic review (joppp.biomedcentral.com), among others. They illustrate history (grandfathering of CAPs (www.gov.uk)), process rules (IRP guidelines (www.gov.uk)), case outcomes (IRP approvals (www.gov.uk) and Project Orbis products (www.gov.uk)), and future policy context (www.bristows.com) (www.gov.uk).

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

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