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| Department for Business, Energy & Industrial Strategy logo |
| BUSINESS IMPACT TARGET:SUMMARY TEMPLATE  |
| Non-qualifying Regulatory Provisions (NQRP) summary reporting template |
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**Regulator:** Medicines and Healthcare products Regulatory Agency (MHRA)

**Business Impact Target Reporting Period Covered:** 17 Dec 2021 – 16 Dec 2022

| **Excluded Category\*** | **Summary of measure(s), including any impact data where available\*\*** |
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| Measures certified as being below *de minimis* (measures with an EANDCB below +/- £5 million) | Legislative amendments to the Human Medicines Regulations 2012 were made in March 2022 to provide a statutory basis for the Early Access to Medicines Scheme (EAMS). The EAMS gives patients with life threatening or seriously debilitating conditions access to medicinal products that are either not authorised or not authorised for that particular clinical use. As this legislation provides a statutory basis for EAMS, which has been in operation since 2014, there are not significant changes in the requirements for businesses who utilise the scheme. An economic impact analysis identified the level of impact to be less than £5 million per annum. As of 1 January 2022, the combined review service, formerly known as the Combined Ways of Working (CWoW) pilot, is now the way that all new Clinical Trials of Investigational Products (CTIMPs) applications are prepared, submitted and reviewed. Combined review offers a single application route for Clinical Trial Authorisation and Research Ethics Committee opinion and a co-ordinated review process leading to a single UK decision for CTIMPs. This is reducing duplication, saving applicants time and effort, and speeding up approval times. A Pilot of Combined Investigational Medicinal Products (IMP)/Device research was introduced on 1 January 2022 to deliver the agency objective for a single decision on research using both a medicine and a device and will provide a more streamlined route for combined IMP/devices clinical trials.  |
| EU Regulations, Decisions and Directives and other international obligations, including the implementation of the EU Withdrawal Bill and EU Withdrawal Agreement | In April 2022, Directive [2022/642/EC](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022L0642) entered into force. This Directive amends Directives 2001/20/EC and 2001/83/EC regarding derogations from certain obligations concerning certain medicinal products for human use. Directive 2022/642/EC stipulates that we publish a list of medicinal products marketed to which these derogations have been granted. In order to comply with our obligations under this Directive, in November 2022, the MHRA published a list on our website: [Marketing authorisations: lists of products using derogations under Directive 2022/642/EC - GOV.UK (www.gov.uk)](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fmarketing-authorisations-lists-of-products-using-derogations-under-directive-2022642ec&data=05%7C01%7Cjudith.m.thompson%40mhra.gov.uk%7Cd091ceb05f964619505108dad83a7a88%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638060042909149270%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=Fs4Ef6DMqvHr%2BQ9Kl0IC5%2BANrF72EUIaJueSfqCxFvs%3D&reserved=0) |
| Measures certified as concerning EU Withdrawal Bill operability measures | The MHRA published the government response to the public consultation on the future regulation of medical devices in the UK. The response outlined the intended regulatory reform including transitional arrangements for CE and UKCA marked devices placed on the Great Britain market. The MHRA announced a 12-month extension to the implementation of the future Medical Devices Regulations, with an aim to bring the new regulations into force by July 2024. [Implementation of the Future Regulations - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period/implementation-of-the-future-regulations)The MHRA has continued to work closely with central government to develop our system of regulation following EU Exit and to secure the supply of medicines for UK patients. In particular, legislative amendments to the Human Medicines Regulations 2012 came into effect in January 2022 to introduce a new route for supply of prescription-only medicines from GB into Northern Ireland. This route is known as the Northern Ireland MHRA Authorised Route (NIMAR) and permits certain medicines authorised by the MHRA in GB to be supplied to Northern Ireland on the basis of the medicine’s authorisation in GB. The MHRA has published updated guidance on the NIMAR: [The Northern Ireland MHRA Authorised Route (NIMAR) - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/the-northern-ireland-mhra-authorised-route-nimar/the-northern-ireland-mhra-authorised-route-nimar)The MHRA has held webinars for stakeholders and worked closely with industry throughout this period on the evolving issues for the supply of medicines, post EU exit.  |
| Activity related to policy development | The MHRA consulted on proposals to improve and strengthen the UK clinical trials legislation, to help make the UK the best place to research and develop safe and innovative medicines. [Consultation on proposals for legislative changes for clinical trials - GOV.UK (www.gov.uk)](https://www.gov.uk/government/consultations/consultation-on-proposals-for-legislative-changes-for-clinical-trials)The MHRA consulted on proposals for changes to the Agency’s statutory fees to ensure the MHRA is resourced to provide the service required for patients, the public and industry, and to achieve full cost recovery in line with HM Treasury principles on Managing Public Money:<https://www.gov.uk/government/consultations/consultation-on-proposals-for-changes-to-the-medicines-and-healthcare-products-regulatory-agencys-statutory-fees> There were a total of 8 public consultations held by the MHRA during the period. These are available at [Policy papers and consultations - GOV.UK (www.gov.uk)](https://www.gov.uk/search/policy-papers-and-consultations?organisations%5B%5D=medicines-and-healthcare-products-regulatory-agency&parent=medicines-and-healthcare-products-regulatory-agency)The MHRA has also engaged with industry on a review into the future position/use of the MHRA’s COVID-19 regulatory flexibilities, which were introduced from March 2020 in response to the COVID-19 pandemic. [MHRA regulatory flexibilities resulting from coronavirus (COVID-19) - GOV.UK (www.gov.uk).](https://www.gov.uk/guidance/mhra-regulatory-flexibilities-resulting-from-coronavirus-covid-19)  |
| Changes to management of regulator | Following the MHRA One Agency transformation, the new organisation structure became fully operational from 1 June 2022. This new operating model is designed around the product lifecycle with a focus on patients and the public. Chief Officers have been appointed to lead on Science, Research and Innovation; Healthcare, Quality and Access; Safety and Surveillance; Partnerships; and Technology.  |

\* For detailed guidance on the exclusion categories, please see <https://www.gov.uk/government/publications/better-regulation-framework>

\*\* Complete the summary box as ‘Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.’ where this is appropriate.