Medicines & Healthcare products Regulatory Agency

# MHRA performance

## Assessment of New Marketing Authorisation Applications and Variations

**October 2024**

# September summary

| Work type | Average time to validation in days | Numbers validated | % validated within statutory time |
|---|---|---|---|
| Validation for new MAAs – all submission routes | 3 | 55 | 83 |
| Validation for variations – all submission routes | 5 | 679 | 99 |
| **Work type** | **Average time to determination in days*** | **Numbers granted** | **% granted within statutory time** |
| Type IA variations – national | 13 | 618 | 96 |
| Type IB variations – all submission routes | 13 | 584 | 97 |
| Type IB IRP variations | 2 | 160 | 99 |
| Type II variations – all submission routes** | 139 | 180 | 57 |
| Type II IRP variations | 39 | 47 | 87 |
| Initials – NAS MAA national | 208 | 3 | 33 |
| Initials – established medicines MAA*** | 578 | 78 | 1 |
| Initials – established meds IRP route A | 55 | 12 | 75 |
| Initials – established meds IRP route B | 104 | 2 | 100 |
| Initials – NAS IRP route A | - | - | - |
| Initials – NAS IRP route B | 110 | 1 | 100 |
| **Work type** | **Average assessment time in days** | **Numbers assessed** | **% assessed within statutory time** |
| PIQU | 42 | 83 | 100 |
| Compliance – national MAAs only | 25 | 76 | 82 |
| **Work on hand as of 1 October 2024 ****** | | | |
| Total overdue individual Product Licences | | | 353 |

- * Regulatory clock on days from validation to determination
- ** Type II variations – This is a crude estimation of 90 days as there are different work types and different procedure types grouped together
- *** Includes national and reliance route conversions
- **** Overdue individual Product licences (past the 210) days shows all pending abridged (biologicals removed) national licences (with current clock on or off) with regulatory clock on days over 210

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