



Medicines & Healthcare products
Regulatory Agency

MHRA performance

Assessment of New Marketing
Authorisation Applications
and Variations

June 2024



June summary

| Work type | Average time to validation in days | Numbers validated | % validated within statutory time |
|---|--|-------------------|-----------------------------------|
| Validation for new MAAs – all submission routes | 5 | 68 | 84 |
| Validation for variations – all submission routes | 8 | 859 | 98 |
| Work type | Average time to determination in days* | Numbers granted | % granted within statutory time |
| Type IA variations – national | 16 | 596 | 99 |
| Type IB variations – all submission routes | 30 | 727 | 75 |
| Type IB IRP variations | 3 | 266 | 98 |
| Type II variations – all submission routes** | 73 | 205 | 74 |
| Type II IRP variations | 7 | 98 | 100 |
| Initials – NAS MAA national | - | - | - |
| Initials – established medicines MAA*** | 450 | 150 | 3 |
| Initials – established meds IRP route A | 52 | 14 | 100 |
| Initials – established meds IRP route B | 28 | 1 | 100 |
| Initials – NAS IRP route A | - | - | - |
| Initials – NAS IRP route B | - | - | - |
| Work type | Average assessment time in days | Numbers assessed | % assessed within statutory time |
| PIQU | 55 | 162 | 99 |
| Compliance – national MAAs only | 22 | 88 | 83 |

| Work on hand | |
|--|-----|
| Overdue individual Product Licences from backlog of 1167 at 9 Jan 2024 (past the 210 days) as at 1 July 2024**** | 416 |

- * 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
- ****Total overdue individual Product licences (past the 210) days including pending abridged (biologicals removed) national licences (with current clock on or off) is 628 (inclusive of 416 from original backlog at 9 Jan 2024)

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