

Published Standard – No.1 – Applications (National)

| | App Type | No. of Apps | Performance | Target Days | Average Days |
|---|--|--------------------|--------------------|--------------------|---------------------|
| 1 | Complex timetable (National new MA applications) Complex new MA applications, e.g. novel therapies, new actives | 0 | - | 210.0 | - |
| 2 | Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats) | 9 | 100% | 180.0 | 18.0 |
| 3 | Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs) | 35 | 100% | 120.0 | 7 |
| 4 | Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs) | 195 | 99.5% | 60.0 | 10 |
| 5 | Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals. | 199 | 99.5% | 30.0 | 7 |
| 6 | Batch timetable (National) specific Batch Control. | 28 | 100% | 20.0 | 1 |
| 7 | Autogenous Vaccines. New & Variations | 5 | 100% | 45.0 | 36 |

Published Standard – No.1 – Applications (Other)

| | App Type | No. of Apps | Performance |
|----|-----------------------------------|--------------------|--------------------|
| 8 | Mock ups | 518 | 97.9% |
| 9 | Validation | 886 | 100% |
| 10 | Issue of authorised documentation | 1382 | 99.9% |

Published Standard – No.1 – Applications (European)

| | App Type | No. of Apps | Performance |
|----|--|--------------------|--------------------|
| 11 | New Centralised (CAP) | 17 | 100% |
| 12 | New Decentralised (DCP) | 50 | 100% |
| 13 | New Mutual Recognition (MRP) and New DCP | 49 | 100% |
| 14 | MRP Variations (Type IB & II) and Renewals | 319 | 100% |

Published Standard – No. 2 – Public Assessment Reports

| | App Type | Total No | Performance |
|----|--|-----------------|--------------------|
| 15 | Publishing Summary of Product Characteristics (SPCs) | 0 | - |
| 16 | Publishing Public Assessment Reports (PuARs) | 0 | - |
| 17 | Updating PuARs | 10 | 100% |

Published Standard – No. 3 – Quality of Documentation

| | App Type | No of Apps | Performance |
|----|----------------------|-------------------|--------------------|
| 18 | Unreturned Documents | 2779 | 98.0% |

Published Standard – No. 4 – Import, Export and Batch Release Schemes

| | App Type | No of Apps | Performance | Target Days | Average Days |
|----|--------------------------------|-------------------|--------------------|--------------------|---------------------|
| 19 | Applications for new products | 181 | 99.4% | 15 | 2.0 |
| 20 | All other applications | 544 | 99.4% | | |
| | • Urgent | 0 | | 2 | - |
| | • Non-Urgent | 544 | | 10 | 1.0 |
| | Instant Certificates (Apr-Jan) | 21271 | - | - | - |
| 21 | Export | 485 | 100% | 10 | 5.1 |
| 22 | Batch Release | 2770 | 100% | 10 | 3.3 |

Published Standard – No. 5 – Pharmacovigilance

| | Task | No. | Performance |
|----|------------------------------------|-------------|--------------------|
| 23 | Human, Animal & Environmental AERs | 9292 | 99.58% |
| 24 | PSURs | 1334 | 100% |
| 25 | Inspections | 20 | 100% |

Published Standard – No. 6 – Inspections

| | Task | No. | Performance | Target Days | Average Days |
|----|---|------------|--------------------|--------------------|---------------------|
| 26 | Inspections within 3 years (GMP) or 5 years (GDP) of last inspection. | 73 | 98.6% | - | - |
| | • GMP | 37 | | - | - |
| | • GDP | 36 | | | |
| 27 | Final Inspection Reports | 73 | 98.6% | 90.0 | 20.0 |
| 28 | Product defect reports | 47 | 100% | - | - |
| | • High risk <5 days | 3 | | | |
| | • Low risk <10 days | 44 | | | |

Key:**Dark Green** - Excellent 100%**Light Green** - Excellent, but some targets missed**Amber** - Effective**Red** - Ineffective**Additional information about ‘ambers’ and ‘reds’**

The VMD continuously monitors all targets and puts in place countermeasures, where possible, to ensure targets are met.

However, sometimes a performance standard may fall into the effective or ineffective category and there are a number of reasons why this may happen, e.g. high volume of applications, staff resource, complexity of applications requiring additional input, etc