### Published Standard Number 1 – Applications (National)

| Application number | Application type | Number of applications | Performance | Target days | Average days |
|---|---|---|---|---|---|
| 1 | Major timetable (National) New MRLs. All other MA applications (excl. MAPI and Copycats) | 43 | 100% | 180.0 | 18 |
| 2 | Standard timetable (National Type II variations. New MA - MAPIs and Copycats. New VHRs) | 42 | 100% | 120.0 | 12 |
| 3 | Shortened timetable (National Renewals (MA and VHR) Type IB variations. New ATC (type B). Out of Scope MRLs) | 269 | 99.6% | 60.0 | 8 |
| 4 | Minor timetable (National) Type IA variations. Administrative Type IB variations. New ATC (Type A/S). ATC variations and renewals. | 471 | 98.3% | 30.0 | 19 |
| 5 | Parallel Assessment with EU Procedures | 713 | 100% | - | 15 |
| 6 | Shared Assessment with International Partners | 0 | - | - | 0 |
| 7 | Batch timetable (National) specific Batch Control | 61 | 98.4% | 20.0 | 4 |
| 8 | Autogenous Vaccines. New & Variations | 7 | 100% | 45.0 | 41 |

### Published Standard Number 1 – Applications (Other)

| Application number | Application Type | Number of applications | Performance |
|---|---|---|---|
| 9 | Mock-up period completed within 20 days (or up to 40 days for parallel applications involving different QRD sources) | 650 | 97.2% |
| 10 | Validation | 1548 | 100% |
| 11 | Issue of authorised documentation | 1992 | 100% |

### Published Standard Number 1 – Applications (European - NI)

| Application number | Application Type | Number of applications | Performance |
|---|---|---|---|
| 12 | New Decentralised (DCP) | 34 | 100% |
| 13 | New Mutual Recognition (MRP) | 2 | 100% |
| 14 | MRP Variations (Type IB & II) and Renewals | 301 | 100% |

### Published Standard Number 2 – Public Assessment Reports

| Application number | Application type | Total number | Performance |
|---|---|---|---|
| 15 | Publishing Summary of Product Characteristics (SPCs) | 93 | 98.9% |
| 16 | Publishing Public Assessment Reports (PuARs) | 28 | 100% |
| 17 | Updating PuARs | 7 | 100% |

### Published Standard Number 3 – Quality of Documentation

| Application number | Application type | Number of applications | Performance |
|---|---|---|---|
| 18 | Unreturned Documents | 3307 | 97.2% |

### Published Standard Number 4 – Product Defects

| Task number | Task | Number of tasks | Performance | Target Days | Average Days |
|---|---|---|---|---|---|
| 19 | Product Defects reports | 41 | 100% | | |
| | High risk <5 days | 2 | - | | |
| | Low risk <10 days | 39 | - | | |

### Published Standard Number 5 – Import, Export and Batch Release Schemes

| Application number | Application Type | No of Apps | Performance | Target Days | Average Days |
|---|---|---|---|---|---|
| 20 | Applications for new pharmaceutical products | 78 | 100% | 15 | - |
| 21 | Applications for new Immunological products | 17 | 100% | 25 | - |
| 22 | Applications for previously imported products | 267 | 99.5% | 15 | - |
| 23 | All other urgent applications | 539 | 99.9% | - | - |
| | Urgent | 0 | | 2 | |
| | Non Urgent | 539 | | 10 | |
| 24 | Instant Import Certificates | 28,300 | - | - | - |
| 25 | Export | 265 | 100% | 10 | 6.0 |
| 26 | Batch Release | 2383 | 100% | 10 | 3.4 |

### Published Standard Number 6 – Pharmacovigilance

| Task number | Task | No. | Performance |
|---|---|---|---|
| 27 | Human, Animal & Environmental AERs | 7595 | 99.9% |
| 28 | PSURs | 1288 | 100% |
| 29 | Inspections | 19 | 100% |

**Published Standard Number 7– Inspections**

| Task number | Task | No. | Performance | Target Days |
|---|---|---|---|---|
| 30 | Inspections within 3 years (GMP) | 20 | 100% | - |
| | Within 5 years (GDP) of last inspection | 23 | Joint with above | - |
| 31 | Inspection Deficiency Reports | 45 | 100% | 30.0 |
| 32 | (GMP) Certificates or (GDP) final reports sent | 45 | 100% | 90.0 |
| 33 | Approval of new Feed business operators and SQP retailer sites | 47 | 100% | 45.0 |
| 34 | Final inspection report to Feed business operators and SQP retailers | 296 | 99.3% | 30.0 |

Our inspection procedures enable us to extend our GMP inspections beyond 3 years and our GDP inspections beyond 5 years where there are exceptional circumstances, provided a documented risk-assessment is carried out. Risk-assessments have been conducted for all sites where it has not been possible for us to inspect them within 3 years due to covid-19 related restrictions.

**Key:**

**100%** Excellent

**>97% - 100%** Excellent, but some targets missed

**92% - 97%** Effective

**< 91%** Ineffective

**Additional information**

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, for example high volume of applications, staff resource, complexity of applications requiring additional input and so on.