

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

| <b>Application number</b> | <b>Application type</b>   | <b>Number of applications</b> | <b>Performance</b> | <b>Target days</b> |
|---------------------------|---|-------------------------------|--------------------|--------------------|
| 1                         | Complex timetable<br>(National new MA applications)<br>Complex new MA applications, e.g.<br>novel therapies, new actives          | 44                            | 100%               | 210.0              |
| 2                         | Major timetable<br>(National) New MRLs. All other MA<br>applications (excl. MAPI and<br>Copycats)                                 | 11                            | 100%               | 180.0              |
| 3                         | Standard timetable<br>(National Type II variations. New<br>MA - MAPIs and Copycats. New<br>VHRs)                                  | 131                           | 100%               | 120.0              |
| 4                         | Shortened timetable<br>(Type IB variations. New ATC<br>(type B). Out of Scope MRLs)   | 196                           | 85.2%              | 60.0               |
| 5                         | Minor timetable<br>(National) Type IA variations.<br>Administrative Type IB variations.<br>New ATC (Type A/S). ATC<br>variations. | 1033                          | 87.3%              | 30.0               |
| 6                         | Parallel Assessment with EU<br>Procedures   | 633                           | 99.5%              | -                  |
| 7                         | Shared Assessment with<br>International Partners  | 1                             | 100%               | -                  |
| 8                         | Batch timetable<br>(National) specific Batch Control  | 73                            | 100%               | 20.0               |
| 9                         | Autogenous Vaccines. New &<br>Variations  | 8                             | 87.5%              | 45.0               |

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

| <b>Application number</b> | <b>Application Type</b>   | <b>Number of applications</b> | <b>Performance</b> |
|---------------------------|---|-------------------------------|--------------------|
| 10                        | Mock-up period completed within<br>20 days (or up to 40 days for<br>parallel applications involving<br>different QRD sources) | 673                           | 96.9%              |
| 11                        | Validation  | 1340                          | 40.9%              |
| 12                        | Issue of authorised documentation   | 2660                          | 20.4%              |

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

| <b>Application number</b> | <b>Application Type</b>       | <b>Number of applications</b> | <b>Performance</b> |
|---------------------------|-------------------------------|-------------------------------|--------------------|
| 13                        | New Decentralised (DCP)       | 19                            | 100%               |
| 14                        | New Mutual Recognition (MRP)  | 9                             | 100%               |
| 15                        | MRP Variations (Type IB & II) | 401                           | 99.3%              |

**Published Standard Number 2 – Public Assessment Reports**

| Application number | Application type                                     | Total number | Performance |
|--------------------|--|--------------|-------------|
| 16                 | Publishing Summary of Product Characteristics (SPCs) | 127          | 100%        |
| 17                 | Publishing Public Assessment Reports (PuARs)         | 69           | 100%        |
| 18                 | Updating PuARs                                       | 8            | 100%        |

**Published Standard Number 3 – Quality of Documentation**

| Application number | Application type     | Number of applications | Performance |
|--------------------|----------------------|------------------------|-------------|
| 19                 | Unreturned Documents | 4172                   | 97%         |

**Published Standard Number 4 – Product Defects**

| Task number | Task                    | Number of tasks | Performance |
|-------------|-------------------------|-----------------|-------------|
| 20          | Product Defects reports | 54              | 100%        |
|             | High risk <5 days       | 4               | -           |
|             | Low risk <10 days       | 50              | -           |

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

| Application number | Application Type                              | No of Apps | Performance | Target Days |
|--------------------|---|------------|-------------|-------------|
| 21                 | Applications for new products                 | 167        | 98.7%       | 15/25       |
| 22                 | Applications for previously imported products | 270        | 99.6%       | 15          |
| 23                 | All other urgent applications                 | 319        | 99.6%       | -           |
|                    | Urgent  | 0          |             | 2           |
|                    | Non Urgent                                    | 319        |             | 10          |
| 24                 | Instant Import Certificates                   | 30,536     | -           | -           |
| 25                 | Export  | 170        | 100%        | 10          |
| 26                 | Batch Release                                 | 1831       | 99.5%       | 10          |

**Published Standard Number 6 – Pharmacovigilance**

| Task number | Task                               | No.  | Performance |
|-------------|------------------------------------|------|-------------|
| 27          | Human, Animal & Environmental AERs | 3159 | 77%         |
| 28          | PSURs                              | 1328 | 100%        |
| 29          | Inspections                        | 15   | 93%         |

**Published Standard Number 7– Inspections**

| <b>Task number</b> | <b>Task</b>  | <b>No.</b> | <b>Performance</b> | <b>Target Days</b> |
|--------------------|--|------------|--------------------|--------------------|
| 30                 | Inspections within 3 years (GMP)                                     | 24         | 100%               | -                  |
|                    | Within 5 years (GDP) of last inspection                              | 36         | Joint with above   | -                  |
| 31                 | Inspection Deficiency Reports  | 46         | 100%               | 30.0               |
| 32                 | (GMP) Certificates or (GDP) final reports sent                       | 41         | 100%               | 90.0               |
| 33                 | Approval of new Feed business operators and SQP retailer sites       | 36         | 100%               | 45.0               |
| 34                 | Final inspection report to Feed business operators and SQP retailers | 246        | 100%               | 30.0               |

**Published Standard Number 8 – Enforcement**

| <b>Task number</b> | <b>Task</b>            | <b>No.</b> | <b>Performance</b> |
|--------------------|------------------------|------------|--------------------|
| 35                 | Quarterly VMR Breaches | 2          | 100%               |
| 36                 | Intelligence Activity  | 29         | 100%               |

**Published Standard Number 9 – Residues**

| <b>Task number</b> | <b>Task</b>                   | <b>No.</b> | <b>Performance</b> |
|--------------------|-------------------------------|------------|--------------------|
| 37                 | Quarterly Non-Compliance Data | 2          | 100%               |
| 38                 | Sample Testing                | 24,559     | 91.5%              |

**Additional information**

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