

## Published Standard Number 1 – Applications (National)

| Application number | Application type  | Number of applications | Performance | Target days |
|--------------------|---|------------------------|-------------|-------------|
| 1                  | Complex timetable<br>(National new MA applications)<br>Complex new MA applications, e.g. novel therapies, new actives | 4                      | 100%        | 210.0       |
| 2                  | Major timetable<br>(National) New MA applications (excl. MAPI and Copycats)   | 2                      | 100%        | 180.0       |
| 3                  | Standard timetable<br>(National Type II VRA. New MA - Copycats. New VHRs)   | 21                     | 100%        | 120.0       |
| 4                  | Shortened timetable<br>(Type IB VRA. New ATC (type B). Out of Scope MRLs)   | 32                     | 100%        | 60.0        |
| 5                  | Minor timetable<br>(National) Type IA VNRA. Administrative Type IB VRA. New ATC (Type A/S). ATC variations.           | 158                    | 99.4%       | 30.0        |
| 6                  | Parallel Assessment with EU Procedures  | 96                     | 97.9%       | -           |
| 7                  | Batch timetable<br>(National) specific Batch Control  | 15                     | 100%        | 20.0        |
| 8                  | Autogenous Vaccines. New & Variations   | 2                      | 100%        | 45.0        |

## 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) | 126                    | 100%        |
| 10                 | Validation   | 188                    | 94.7%       |
| 11                 | Issue of authorised documentation  | 451                    | 100%        |

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

| Application number | Application Type              | Number of applications | Performance |
|--------------------|-------------------------------|------------------------|-------------|
| 12                 | New Decentralised (DCP)       | 1                      | 100%        |
| 13                 | New Mutual Recognition (MRP)  | 0                      | -           |
| 14                 | MRP Variations (Type IB & II) | 43                     | 100%        |

## Published Standard Number 2 – Public Assessment Reports

| Application number | Application type                                     | Total number | Performance |
|--------------------|--|--------------|-------------|
| 15                 | Publishing Summary of Product Characteristics (SPCs) | 14           | 100%        |
| 16                 | Publishing Public Assessment Reports (PuARs)         | 8            | 100%        |
| 17                 | Updating PuARs                                       | 0            | -           |

## Published Standard Number 3 – Quality of Documentation

| Application number | Application type     | Number of applications | Performance |
|--------------------|----------------------|------------------------|-------------|
| 18                 | Unreturned Documents | 742                    | 96.8%       |

## Published Standard Number 4 – Product Defects

| Task number | Task                    | Number of tasks | Performance |
|-------------|-------------------------|-----------------|-------------|
| 19          | Product Defects reports | 8               | 100%        |
|             | High risk <5 days       | 2               | -           |
|             | Low risk <10 days       | 6               | -           |

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

| Application number | Application Type                              | No of Apps | Performance | Target Days |
|--------------------|---|------------|-------------|-------------|
| 20                 | Applications for new products                 | 22         | 100%        | 15/25       |
| 21                 | Applications for previously imported products | 14         | 100%        | 15          |
| 22                 | All other urgent applications                 | 36         | 100%        | -           |
|                    | Urgent  | 0          | -           | 2           |
|                    | Non Urgent                                    | 36         | -           | 10          |
| 23                 | Instant Import Certificates                   | 4131       | -           | -           |
| 24                 | Export  | 26         | 100%        | 10          |
| 25                 | Batch Release                                 | 226        | 100%        | 10          |

## Published Standard Number 6 – Pharmacovigilance

| Task number | Task  | No. | Performance |
|-------------|---|-----|-------------|
| 26          | Human, Animal & Environmental AERs                        | 72  | 100%        |
| 27          | Validate & extract all UK data from PSURs                 | 198 | 100%        |
| 28          | PSUR Data fully validated, database closed by 25/12/2025  | 0   | -           |
| 29          | Send final inspection report to MAH                       | 2   | 100%        |
| 30          | Number of Benefit-Risk reports validated                  | 88  | 100%        |
| 31          | Number of Benefit-Risk reports undergoing full assessment | 0   | -           |
| 32          | Number of standard signal notifications                   | 16  | -           |
| 33          | Number of urgent signal notifications                     | 0   | -           |

## Published Standard Number 7– Inspections

| Task number | Task   | No. | Performance      | Target Days |
|-------------|--|-----|------------------|-------------|
| 34          | Inspections within 3 years (GMP)                                     | 1   | 100%             | -           |
|             | Within 5 years (GDP) of last inspection                              | 3   | Joint with above | -           |
| 35          | Inspection Deficiency Reports  | 6   | 100%             | 30.0        |
| 36          | (GMP) Certificates or (GDP) final reports sent                       | 5   | 100%             | 90.0        |
| 37          | Approval of new Feed business operators and SQP retailer sites       | 6   | 100%             | 45.0        |
| 38          | Final inspection report to Feed business operators and SQP retailers | 31  | 100%             | 30.0        |

## Published Standard Number 8 – Enforcement

| Task number | Task                   | No. | Performance |
|-------------|------------------------|-----|-------------|
| 39          | Quarterly VMR Breaches | 0   | -           |

## Published Standard Number 9 – Residues

| Task number | Task                          | No.  | Performance |
|-------------|-------------------------------|------|-------------|
| 40          | Quarterly Non-Compliance Data | 0    | -           |
| 41          | Sample Testing                | 3029 | 95.5%       |

### Additional information

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