

Published Standard – No.1 – Applications (Centralised)

| | App Type | No. of Apps | Performance |
|---|--|--------------------|--------------------|
| 1 | Centralised: New MAs / Extensions | 20 | 100% |
| 2 | Centralised – UK as Rapp: Variations / Renewals | 13 | 100% |

Published Standard – No.1 – Applications (DCP)

| | App Type | No. of Apps | Performance |
|---|--|--------------------|--------------------|
| 3 | DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 70) | 27 | 100% |
| 4 | DCP – UK as RMS: New MAs & Variation-Extensions (Phase 1 – Day 120) | 22 | 100% |
| 5 | DCP – UK as RMS: New MAs & Variation-Extensions (Phase 2) | 30 | 100% |
| 6 | DCP – UK as CMS: New MAs & Variation-Extensions (Phase 1) | 48 | 100% |
| 7 | DCP – UK as CMS: New MAs & Variation-Extensions (Phase 2) | 40 | 100% |

Published Standard – No.1 – Applications (MRP)

| | App Type | No. of Apps | Performance |
|----|---|--------------------|--------------------|
| 8 | MRP – UK as RMS: New MAs (Phase 1) | 28 | 100% |
| 9 | MRP – UK as RMS: New MAs (Phase 2) | 9 | 100% |
| 10 | MRP – UK as CMS: New MAs (Phase 2) | 17 | 100% |
| 11 | MRP – UK as RMS: Type IA Variations | 85 | 100% |
| 12 | MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 1) | 158 | 100% |
| 13 | MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 1) | 218 | 98.6% |

| | App Type | No. of Apps | Performance |
|----|---|--------------------|--------------------|
| 14 | MRP – UK as RMS: Type IB & II Variations, and Renewals (Phase 2) | 92 | 100% |
| 15 | MRP – UK as CMS: Type IB & II Variations, and Renewals (Phase 2) | 127 | 99.2% |

Published Standard – No. 1 – Applications (National)

| | App Type | No of Apps | Performance | Target Days | Average Days |
|----|--|-------------------|--------------------|--------------------|---------------------|
| 16 | New MAs & Variation-Extensions: <i>Initial Assessment</i> | 19 | 100% | | |
| | • 75 Day Clock | 0 | | 75 | - |
| | • 90 Day Clock | 9 | | 90 | 75.8 |
| 17 | New MAs & Variation-Extensions <i>Sign-Off</i> | 15 | 86.7% | | |
| | • 130 Day Clock | 2 | | 130 | 37.5 |
| | • 180 Day Clock | 13 | | 180 | 151 |
| 18 | New Homeopathic | 1 | 100% | - | - |
| 19 | Type IA Variations | 106 | 100% | 30 | 21.9 |
| 20 | Type IB / II Variations: <i>Initial Assessment</i> | 150 | 99.3% | | |
| | • Type IB | 90 | | 30 | 17.4 |
| | • Type II | 31 | | 60 | 47.3 |
| | • Renewal | 21 | | 60 | 57.5 |
| 21 | Type IB / II Variations: <i>Sign-Off</i> | 179 | 99.4% | | |
| | • Type IB | 128 | | 30 | 4.9 |
| | • Type II | 34 | | 60 | 29.6 |
| | • Renewals | 17 | | 60 | 38.5 |
| 22 | Admin Variations | 34 | 100% | | |
| | • < 10 Changes | 34 | | 30 | 24.6 |
| | • > 10 Changes | 0 | | 60 | - |
| 23 | ATCs | 14 | 100% | | |
| | • Type A/S | 7 | | 30 | 22.1 |
| | • Type B | 5 | | 50 | 29.8 |
| | • Variations / Renewals | 2 | | 30 | 0 |
| 24 | Batch Release | 2682 | 100% | 10 | 1.2 |

| | App Type | No of Apps | Performance | Target Days | Average Days |
|----|------------------------|------------|-------------|-------------|--------------|
| 25 | Specific Batch Control | 12 | 100% | 20 | 1.2 |
| 26 | AVA | 3 | - | 45 | 33.5 |

Published Standard – No. 1 – Applications (Other)

| | App Type | No of Apps | Performance |
|----|--------------------------------------|------------|-------------|
| 27 | Mock-Ups | 430 | 98.8% |
| 28 | Validation | 805 | 100% |
| 29 | Issue of authorisation documentation | 1061 | 99.8% |

Published Standard – No. 2 – Quality of Documentation

| | App Type | Total No | Performance |
|----|-----------------------------|----------|-------------|
| 30 | Authorisation Documentation | 2093 | 97.9% |

Published Standard – No. 3 – Import and Export Certificates

| | App Type | No of Apps | Performance | Target Days | Average Days |
|-----|-------------------------------|------------|-------------|-------------|--------------|
| 31 | Applications for new products | 174 | 100% | 15 | 3.0 |
| 32 | All other applications | 1887 | 99.8% | | |
| | • Urgent | 164 | | 2 | 0 |
| | • Non-Urgent | 1723 | | 10 | 2 |
| 600 | Export | 600 | 100% | 10 | 6.1 |

Published Standard – No. 4 – Public Assessment Reports

| | App Type | No of Apps | Performance | Target Days | Average Days |
|----|-----------------------------|------------|-------------|-------------|--------------|
| 34 | Publish link to SPC, or EMA | 132 | 100% | 30 | 12.0 |
| 35 | Publish PAR within 120 days | 74 | 100% | 120 | 94.0 |
| 36 | Update PAA within 60 days | 307 | 99.3% | 60 | 9.0 |

Published Standard – No. 5 – Pharmacovigilance

| | Task | No. | Performance |
|----|--|-------------|--------------------|
| 37 | Human, Animal & Environmental AERs | 5955 | 100% |
| 38 | Human, Animal & Environmental AERs – Follow Up | 2758 | 99.7% |
| 39 | PSURs | 1477 | 99.5% |
| 40 | Inspections | 9 | 100% |

Published Standard – No. 6 – Inspections

| | Task | No. | Performance | Target Days | Average Days |
|----|---|------------|--------------------|--------------------|---------------------|
| 41 | GMP Inspections within 3 years of last inspection | 29 | 100% | - | - |
| 42 | GDP inspections within 5 years of last inspection | 36 | 100% | - | - |
| 43 | Send deficiency or post inspections letter | 62 | 100% | | |
| | • GMP | 28 | | 30 | 21 |
| | • GDP | 34 | | | |
| 44 | Issue GMP Certificates and final inspection reports | 32 | 100% | | |
| | | | | 90 | 73 |
| 45 | Send final inspection report to wholesaler site | 50 | 100% | | |

Key:**Dark Green** -**Excellent 100%****Light Green** -**Excellent, but some targets missed****Amber** -**Effective****Red** -**Ineffective**