EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# SMS update Q3 2019

ISO IDMP Task Force

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# SMS Highlights (I)

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- SMS Phase 1 went live on 26th July 2019.

- No new bugs were found in Production and all functionalities are working as expected.

- Review of outstanding bugs identified during the UATs has been completed and will be addressed in maintenance releases in 2020.

- The only change for Industry was blocking of registration of development substances in xEVMPD (IMP).

- Substances for clinical trials have to be requested (pre-registered) via EMA Service Desk before use in regulatory submissions.

- EMA will register these substances to ensure the use of the same substance ID across the whole lifecycle of the medicinal product.

# Procedures in SMS scope

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**Current scope**

- Clinical trials (XEVMPD and EudraCT)
- Orphan Designation (IRIS)
- Marketing Authorisation, Variations and Renewals (eAF)
- GxP Certificates (EudraGMDP)
- Safety reporting/Article 57 (XEVMPD)

**Next phase (Q1 2020)**

- PRIME
- Innovative Task Force
- ATMP classification/certification
- Eligibility for centralised procedure
- Accelerated review
- Article 58

# SMS Highlights (II)

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- Migration of Veterinary substance data from SIAMED to SMS is expected to be completed in the coming months.

- Holistic review of SMS Phase 2 Use Cases (SPOR Portal + merging & nullification functionalities) completed. Development was planned to start in Q1 2020 and Go-Live in Q3 2020 – *subject to project budget & prioritisation*

- Discussions regarding substance confidentiality and impact on eAF/CESP are ongoing - 2 main topics:

  1. Publication of vet substance names before product approval.
  Proposed solution: register vet substances with company code until marketing authorisation granted.

  2. Company codes in eAF can't be identified by NCAs.
  Proposed solution: Adding SMS ID and link to SPOR Portal in the eAF dropdown list to allow NCAs to access the full substance data.

# SMS Statistics Year to Date

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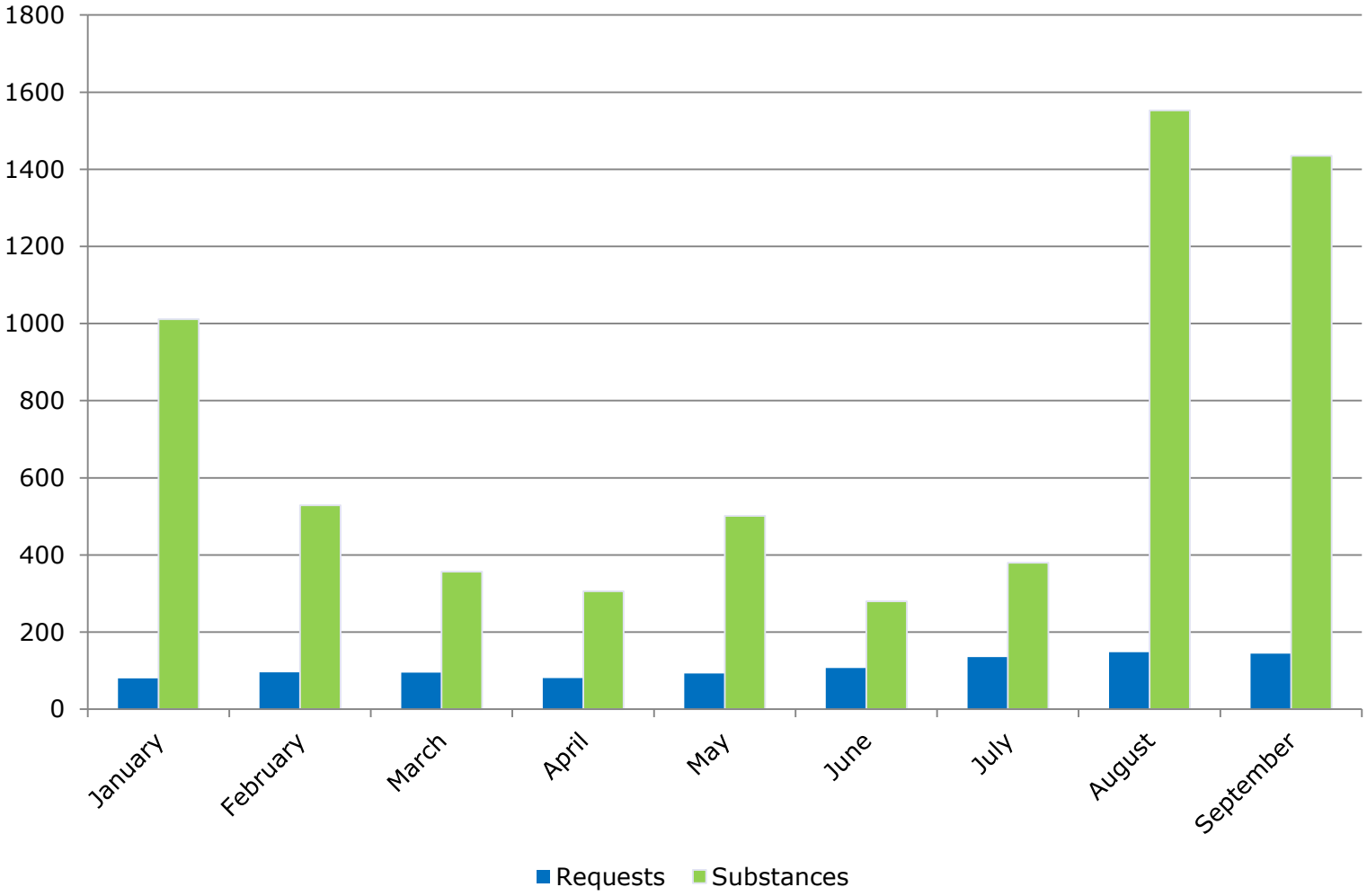

# SMS Statistics September 2019

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| Request Type | Requests | % |
|---|---|---|
| Clinical Trials | 51 | 37% |
| Safety reporting/Article 57 (XEVMPD) | 33 | 24% |
| Orphan Designation | 24 | 17% |
| MA, Variations, Renewals (eAF) | 18 | 13% |
| GxP certificates (EudraGMDP) | 12 | 9% |
| PRIME, ATMP, etc. (Pre-Authorisation) | 4 | 3% |
| **Total** | **139** | **100%** |

| Request Type | Substances | % |
|---|---|---|
| MA, Variations, Renewals (eAF) | 1613 | 83.4% |
| Safety reporting/Article 57 (XEVMPD) | 226 | 11.7% |
| Clinical Trials | 53 | 2.7% |
| Orphan Designation | 26 | 1.3% |
| GxP certificates (EudraGMDP) | 12 | 0.6% |
| PRIME, ATMP, etc. (Pre-Authorisation) | 5 | 0.3% |
| **Total** | **1935** | **100%** |

# Thank you for your attention

## Further information

Please send any queries to:
**Jaume.gonzalez@ema.europa.eu**

Please create substance requests in EMA Service Desk Portal:
**https://servicedesk.ema.europa.eu**

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