



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU IG – EU Implementation guide

SPOR Taskforce meeting 24th May 2019

Presented by Carlos Aicardo Munoz
PMS Business Lead

An agency of the European Union





N	Item
----------	-------------

1.	Context
----	---------

2.	EU IG comments
----	----------------

3.	Resolution Methodology
----	------------------------

4.	Comments resolved
----	-------------------

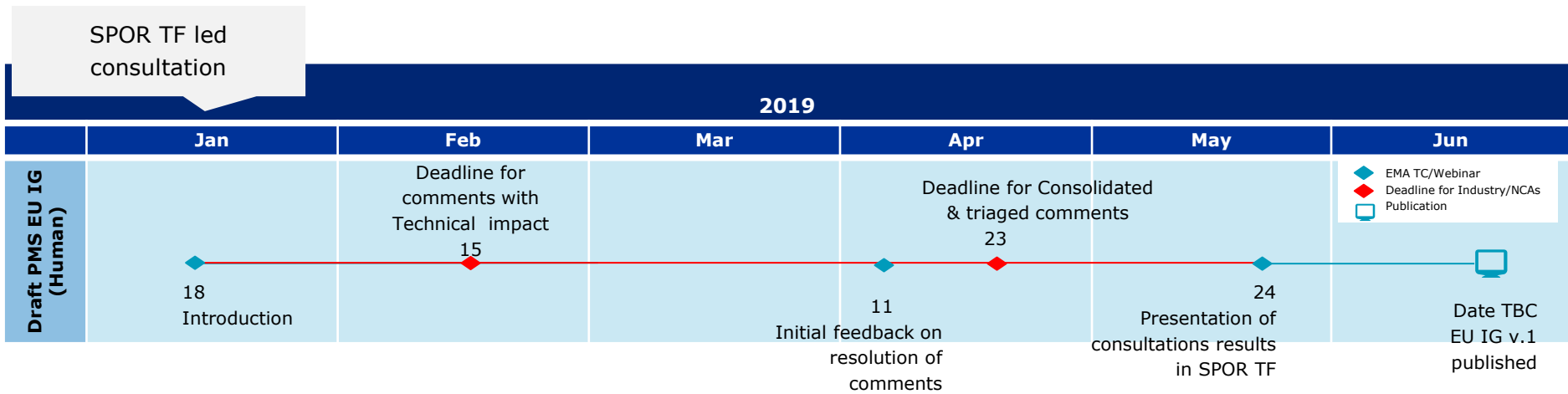
5.	Feedback
----	----------

6.	Next Steps
----	------------



1. Context

On Jan 2019 the consultation on draft v1 Eu IG was launched



Chapters 1, 2, 6 and 7 for consultation

Chapters 3-5 and 8 to be created, consulted and released in future versions

- Introduction
- Chapter 1 – Pre-registration requirements
- Chapter 2 – Initial submission
- Chapter 3 – Maintenance (out of scope of this version)
- Chapter 4 – Data quality assurance (out of scope of this version)
- Chapter 5 – Data access/export (deprioritised/possibly to be removed)
- Chapter 6 – Technical specs on structure and Format
- Chapter 7 – migration guide
- Chapter 8 – examples (out of scope of this version)



Introduction

- **Description:** Introduction and document overview
- **Target audience:** all
- **No pages:** 1/2
- **Note:** introduction refers to the current legal basis of the submission and scope of the medicinal product which should be expanded based on the outcome of discussions and agreement with Regulatory Network

Chapter 1: Pre-registration requirements

- **Description:** Guidance on how to get access to SPOR and what to do prior to submission
- **Target audience:** all
- **No pages:** 1/2
- **Note:** Discussions are still ongoing on User Roles and registration requirements which will be included in the next version of the document.

For information

Chapter 2: Initial Submission

- **Description:** Guidance on which medicinal product information (field and business rules) shall be submitted in the new format
- **Target audience:** Business (operations) and Technical profiles
- **No pages:** 120
- **Note:** this is described as process agnostic since the TOM is not finalised. Business process and requirements will be included in a later version of the IG.

For consultation

Chapter 6: API Technical Specifications

- **Description:** Technical specifications for the API, contains description of principles, security, resources, calls, end-points.
- **Target audience:** IT/ technical profiles
- **No pages:** 80

Separate consultation work stream

Chapter 7: PMS Migration Guide

- **Description:** migration rules between xEVMPD and PMS including backwards compatibility rules.
- **Target audience:** Art.57 stakeholders/ Business / IT/ technical profiles
- **No pages:** 45
- **Note:** n/a

For information



2. EU IG comments

15th of February

599 comments
received

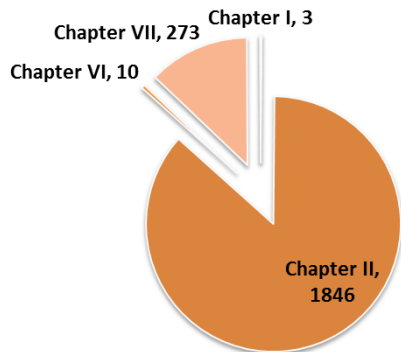
23th April

1535 comments received
+
435 duplicate comments

NCA	Industry
Norway, Sweden, Estonia, Spain, Austria, Germany Bfarm, France Human ANSM and France Vet ANMV	EuropaBIO
	EFPIA-IRISS
	ECI-EEIG
	AESGP
	Medicines for Europe
	Vaccines Europe

NCA	Industry
Denmark	EuropaBIO
	EFPIA
	IRISS
	ECI-EEIG
	AESGP
	Medicines for Europe
	Vaccines Europe
	Animal Health Europe
	EUCOPE

Total comments per Chapter



All chapters, 2

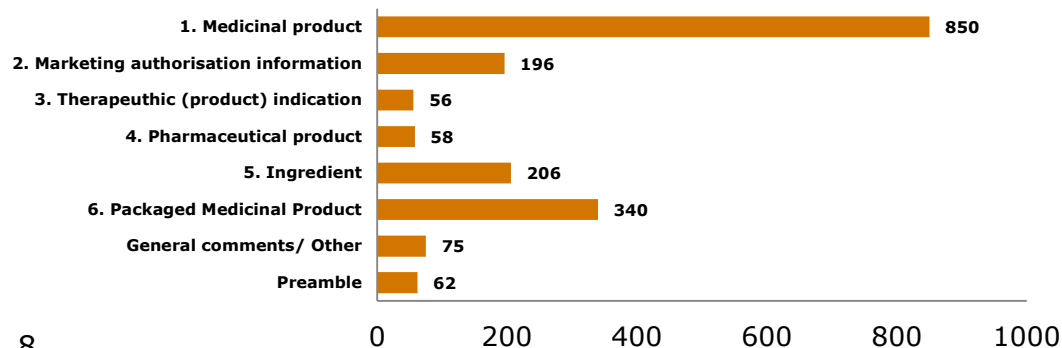
Total: 2134

**It does not include
435 duplicate comments**

Chapter 2 Medicinal Product domain comments

1.1. Medicinal product identifier (MPID)	40
1.2. Domain	9
1.3. Type	19
1.4. Combined pharmaceutical dose form	35
1.5. Legal status of supply	9
1.6. Additional monitoring indicator	9
1.7. Orphan Designation Status	14
1.8. Paediatric use indicator	13
1.9. Full Indication text	27
1.10. EURD ID	15
1.11. Product Classification	70
1.12. Marketin Status	92
1.13. Medicinal Product Name	176
1.14. Master File	19
1.15. Contact (QPPV)	25
1.16. Pharmacovigilance enquiry information	16
1.17. Attached document	103
1.18. Product cross-reference	49
1.19. Manufacturing Business Operation	110

Chapter 2 comments



Development of the EU IG throughout the P&SM phases



EUROPEAN MEDICINES AGENCY

Iteration 1

We are here



Phase 1

Phase 2

Phase 3

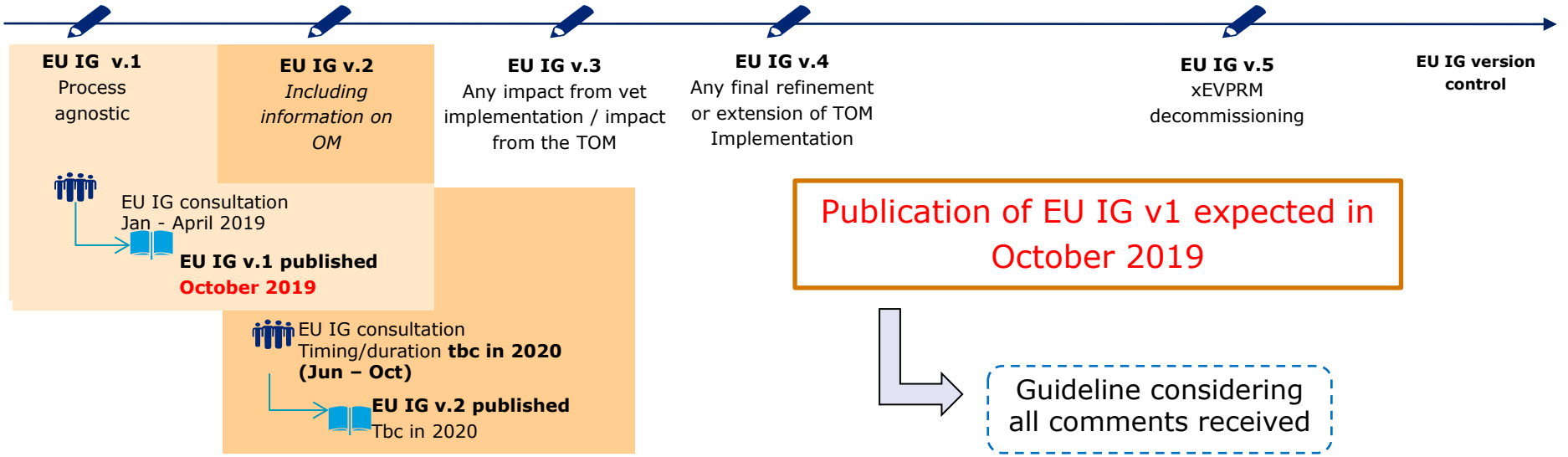
Phase 4

Phase 5

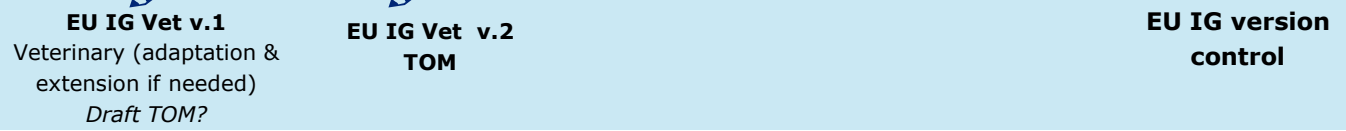
Phase 6

Phase 7

Human only

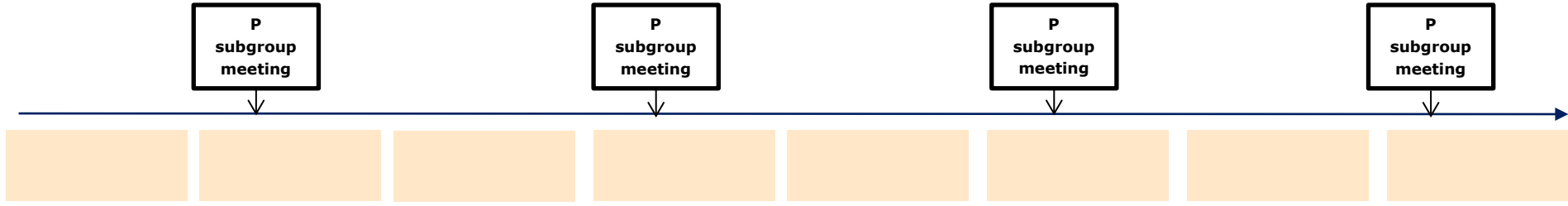


Veterinary - To be confirmed





3. Methodology



Involvement on P subgroup members in comments resolution

1 week

- controversial/complex topics
- Examples used
- Extracts of guidance

Use of P subgroup meetings

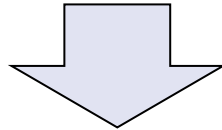
- Discussion every two weeks
- Target for topics for discussion to be brought 1 week in advance of the meeting



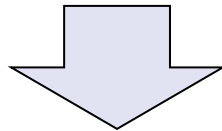
4. EU IG comments resolved



Number of comments received on when during the process and by which stakeholder a particular data field needs to be filled in



V1 of EU IG is process agnostic – it describe the data elements and business rules in accordance with the LDM for PMS – IDMP compatible



Implications of TOM on the EU IG to be considered in future versions/consultation of the EU IG

ISO / FHIR Resources differences in cardinality; e.g. Guidance states resource "must be specified/mandatory" whereas FHIR message marked as optional

FHIR resources cover the full IDMP

IDMP has been simplified when possible

FHIR resources are granular (roughly corresponding IDMP subject areas)

FHIR resources are a superset of the PMS Logical Data Model

A number of FHIR profiles shall be provided with the Implementation Guide

These profiles will classify classes and attributes as mandatory, conditional, optional or never

IDMP

- Big LDM
- With smaller views

PMS

- A subset of FHIR/IDMP
- FHIR profiles applied

FHIR technology may be used as a message for other systems/use cases beyond IDMP/PMS where the attribute in discussion is not required to be mandatory

FHIR

- Take IDMP, keep it modular
- Reuse FHIR classes
- Simplify structures

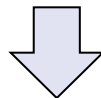
comments questioning conformance as mandatory field

'Combined pharmaceutical dose form' is a single term to describe two or more manufactured dose forms intended to be combined to create a single administrable dose form

If pharmaceutical dose form is also the administrable dose form (e.g. tablet)



*no need for combining manufactured item to prepare the administrable dose form and **this field is to be left blank.***



Conformance changed from **mandatory to conditional**





Number of comments requesting clarity on the business rule in case of products with different status of supply (e.g. OTC and subject to prescription) - sections 1.5 (MP level) and 6.3 (Packaged MP level)

- The legal status of supply is defined both at product and package level
- There are cases where for the same product will have different pack sizes with a different legal status of supply.
- For these cases the legal status of supply will have to be captured at package level.
- The legal status of supply at package level will need to be entered only if the legal statuses of supply differ between package sizes.

Comments received to update current RMS list

- It is identified that RMS list needs to be adapted to cover a hierarchy and more granular terms available at National level while maintaining a controlled vocabulary valid across the EU

comments questioning reason behind this field not being included in class clinical particulars (currently in PMS LDM in medicinal product class)

- The full indication text should be reported as defined in 4.1 SmPC  clarification in EU IG
- Indication text not be used within the clinical particulars because that field is repeatable for each individual indication  moved to a different class (differences between ISO and PMS LDM)
- Within this class, therapeutic indication can support languages/translation (for countries with multiple languages, e.g. Belgium)

Comments on the format supported in this field (e.g. indications with bold, italics, tables)

- The field will allow only for plain text. It will not be possible to include diagrams and tables



5. Feedback from Stakeholders on consultation exercise

During P subgroup meeting on 11th April the following feedback was requested

- What were the main issues affecting the guideline?
- Were the timelines proposed adequate?
- Was the information/instructions from EMA clear on this exercise?
- Given the number of duplicated comments do you see any other way to improve/create a more focused review for v2?



Main issues

Additional examples needed (e.g. select one product and use as example throughout the guidance)

Additional improvements to the feedback spreadsheet suggested

Timelines

Overall timeline provided for this exercise considered suitable (January – April)

1st deadline (15th Feb) on technical comments considered short but can be understood due to parallel consultation on API

Instructions

Overall instructions and objective of the exercise were very clear

Additional information on the extent of feedback for technical comments affecting API in first deadline would have been useful (e.g. what type of comments could impact API)

Duplicated comments

Triage at the level of stakeholders useful to reduce duplicated comments



6. Next Steps

EU IG Guidance to be expanded to include:

- **User roles** and additional relevant registration requirements
- **Examples** and additional **conventions/business guidance** based on the experience from the NCA Data Pilot (Issues provided by industry has been taken into account and should be covered)
- **FHIR Profiles** and Business rules within the FHIR message/API specification are to be included in the context of the regulatory processes (e.g. initial MA as well as variations, transfer of Marketing Authorisation, etc)
- To be further covered in Chapters 3-5 and 8

Development of the EU IG throughout the P&SM phases

Iteration 1

We are here

Phase 1

Phase 2

Phase 3

Phase 4

Phase 5

Phase 6

Phase 7

Human only

EU IG v.1

Process agnostic



EU IG consultation
Jan - April 2019

EU IG v.1 published
October 2019



EU IG consultation
Timing/duration **tbc in 2020**
(Jun - Oct)

EU IG v.2 published
Tbc in 2020

EU IG v.3

Any impact from vet implementation / impact from the TOM

EU IG v.4

Any final refinement or extension of TOM Implementation

EU IG v.5

xEVPRM decommissioning

EU IG version control

Publication of EU IG v1 expected in October 2019

Preparation of EU IG v2

Inclusion of information on OM

Draft remaining chapters

Veterinary - To be confirmed

EU IG Vet v.1

Veterinary (adaptation & extension if needed)
Draft TOM?

EU IG Vet v.2
TOM

EU IG version control



Any questions?

Further information

Carlos Aicardo Munoz carlos.aicardo@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Follow us on  **@EMA_News**