EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU IG – EU Implementation Guide

SPOR Taskforce meeting 16th October 2019

Presented by Carlos Aicardo Munoz
PMS Business Lead

Agenda

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N	Item
1.	Context
2.	EU IG comments
3.	EU IG topics addressed by PMS SG
4.	Next Steps – EU IG v2

1. Context

EU Implementation Guide – Timelines

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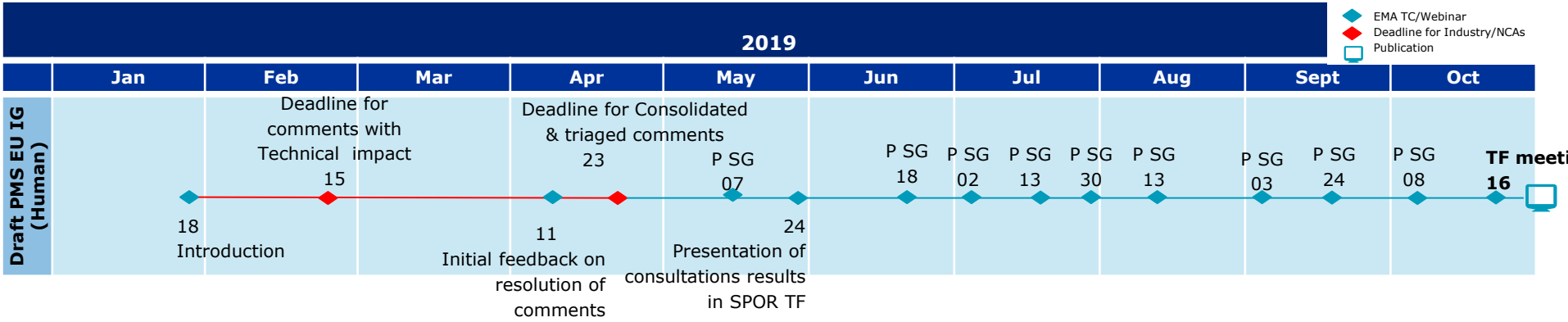
SPOR TF led consultation

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



EU IG Structure

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Chapters 1, 2, 6 and 7 for consultation
Chapters 3-5 and 8 to be created, consulted and released in future versions
(its content may be reviewed)

- 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)

Draft EU IG – v1

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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

For information

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

EU Implementation Guide

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15th of February

599 comments received

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

23th April

1535 comments received
+
435 duplicate comments

NCAs	Industry
Denmark	EuropaBIO
	EFPIA
	IRIISS
	ECI-EEIG
	AESGP
	Medicines for Europe
	Vaccines Europe
	Animal Health Europe
	EUCOPE

EU Implementation Guide – Overview

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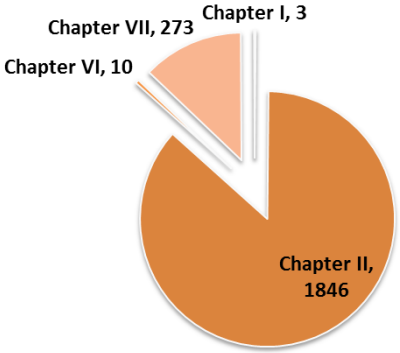
Total comments per Chapter

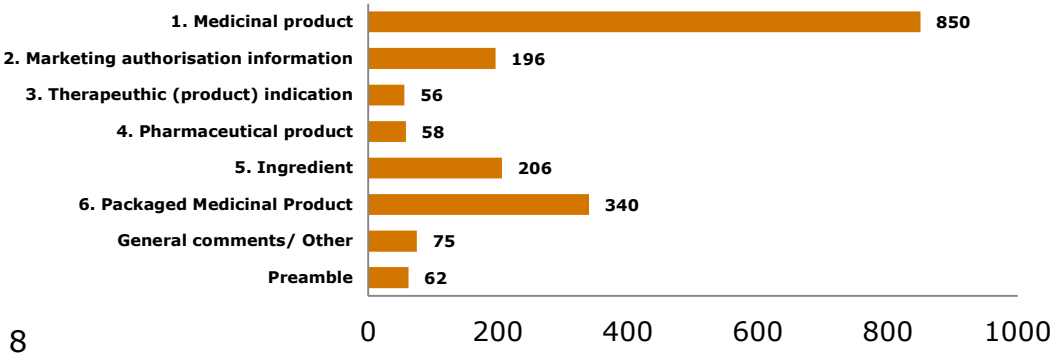


All chapters, 2

Total: 2134

It does not include 435 duplicate comments

Chapter 2 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

EU Implementation Guide – Timelines and Resolution

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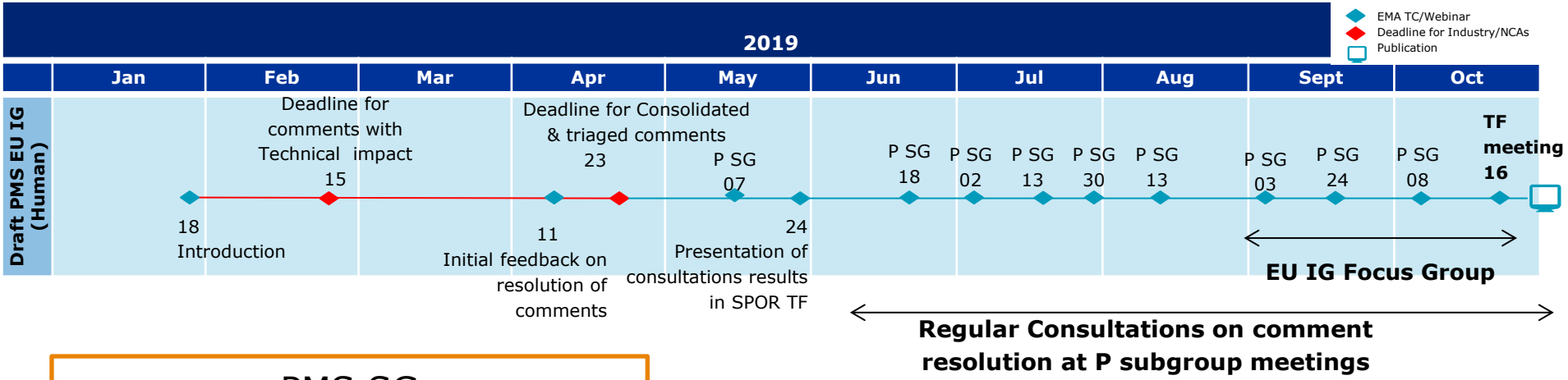
SPOR TF led consultation

Continued collaboration with different stakeholders to resolve controversial topics



PMS SG

EU IG Focus Group (temporary)

EU Implementation Guide – Collaboration

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P Sub Group

EU IG Focus Group (temporary)

Continued collaboration with different stakeholders

- controversial/complex topics
- Examples used
- Extracts of guidance
- Interpretation on ISO

3. EU IG topics addressed by PMS SG

Medicinal product

Combined pharmaceutical form

Legal Status of Supply when defined at package level

Medicinal Product Name - Jurisdiction

Full indication text in plain text / Multilanguage countries

ATC code in other lists other than WHO

Marketing status at package level

Medicinal product

Manufacturer Business Operation at level of Manufacturer and not operation

Product Cross Reference for Transfers / Renewals

Expansion of Biological/Vaccine indicator

Legal Basis for products approved before current regulatory framework

Manufacturer Business Operation type absence reason

Product Cross Reference for Parallel imported products

Marketing authorisation

Difference between Application type and Procedure type in ISO

Procedure type start and end date

Procedure type controlled vocabulary

Marketing authorisation application

Authorisation Status

Application date

Clinical particulars

Additional values related to intended effect

Pharmaceutical product

Link Pharmaceutical product and medical device

Packaged Medicinal Product

Translations for Package Description on multi-language countries

Shelf-Life/Storage conditions link to package item

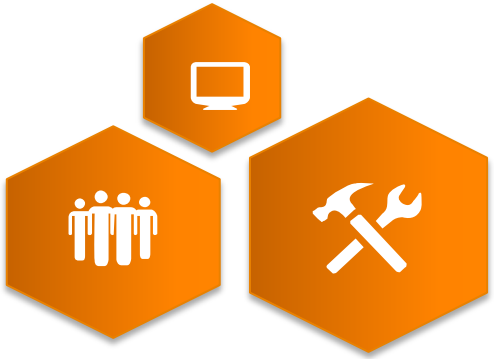
Data needed on devices

Need of manufacturers at package level

EU IG Open Issues

Identify an strategy for product legacy data

How to tackle information of old products that are not covered as current terms in RMS (e.g. previous legal basis)



Consider the impact of TOM in the guidance

Identifiers: PMS stable identifier, PCIDs, MPIDs and PhPID

4. Next Steps – EU IG v2

Development of the EU IG throughout the P&SM phases

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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 v.2
Including information on Operating Model

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

EU IG consultation
Jan - April 2019

EU IG v.1 published
Oct– Nov 2019

EU IG consultation
Timing/duration **tbc in 2020**

EU IG v.2 published
Tbc in 2020

Publication of EU IG v1 expected in October - November 2019

Guideline considering all comments received

Open topics to be considered in future EU IG releases

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

Next steps - Road to EU IG v2

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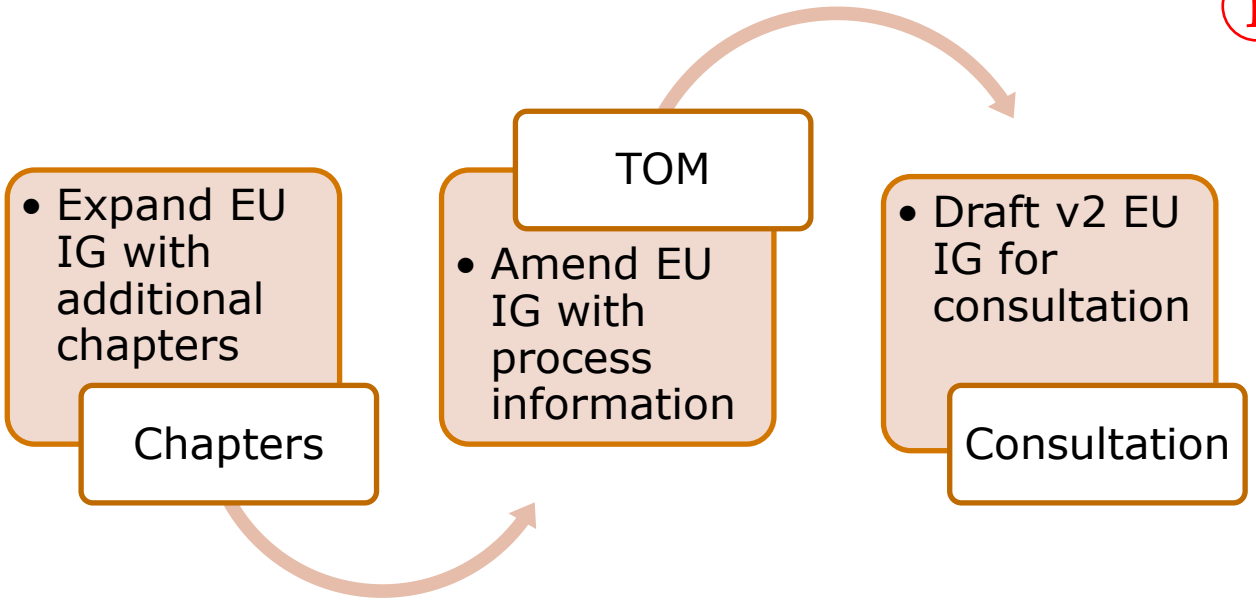

Decision on TOM needed

Whenever there is a decision: 3 months to adjust the guideline

If no decision, IDMP OM

submission of product data after regulatory procedure

Consultation EU IG v2

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2134 comments + 435 duplicated comments

1st EU IG consultation has proven to be useful **but** a burdensome exercise

- **High stakeholder involvement and interest on PMS/SPOR**
- Similar comments addressing the same issue not filtered during the triage
- Limited resources at EMA as a result of the BCP

Need for a more efficient EU IG consultation

Methodology to be agreed at SG level

Development of the EU IG throughout the P&SM phases

EUROPEAN MEDICINES AGENCY

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EU IG version control

Contributions

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The EU IG comment resolution team






PMS SG

EU IG Focus Group

Any questions?

Further information

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