



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PMS Iteration 1: analysis of the data efforts & value results and recommendation on the scope

EU ISO IDMP Task Force – 19 February 2016

Presented by Ilaria Del Seppia
Data Standardisation and Analytics, EMA



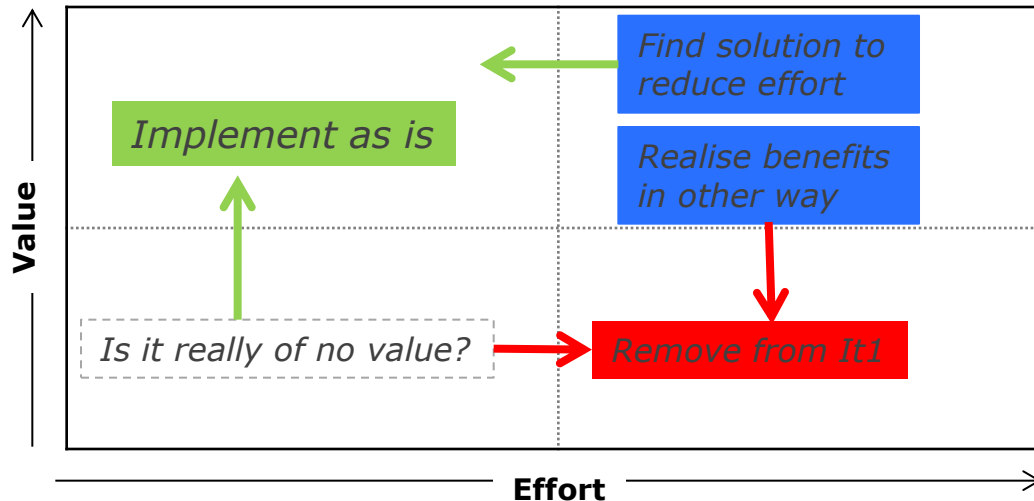
Contents

- Data categorisation methodology
- Aggregated results
- Data element per data element results
- Recommendation for PMS Iteration 1
- Next steps for the EU Regulators (EUNDB)

Data categorisation methodology

- Proposed 92 data elements for PMS iteration 1 where evaluated by: EMA, IT, ES, UK, SE, FR, ET, DE and with inputs from NL
- The evaluation was performed considering the following criteria:
 - The interpretation of the **efforts** is in relation to the costs and efforts of validating and maintaining over time the data element (1 to 5 increasing efforts)
 - The **value** is referring as to whether the data is essential to fulfil our business and regulatory obligations (1 to 5 increasing value)
- The results from all NCAs have been averaged in a single value per data elements
 - Compare EMA Vs NCAs data categorisation per individual data element

Plotting principles

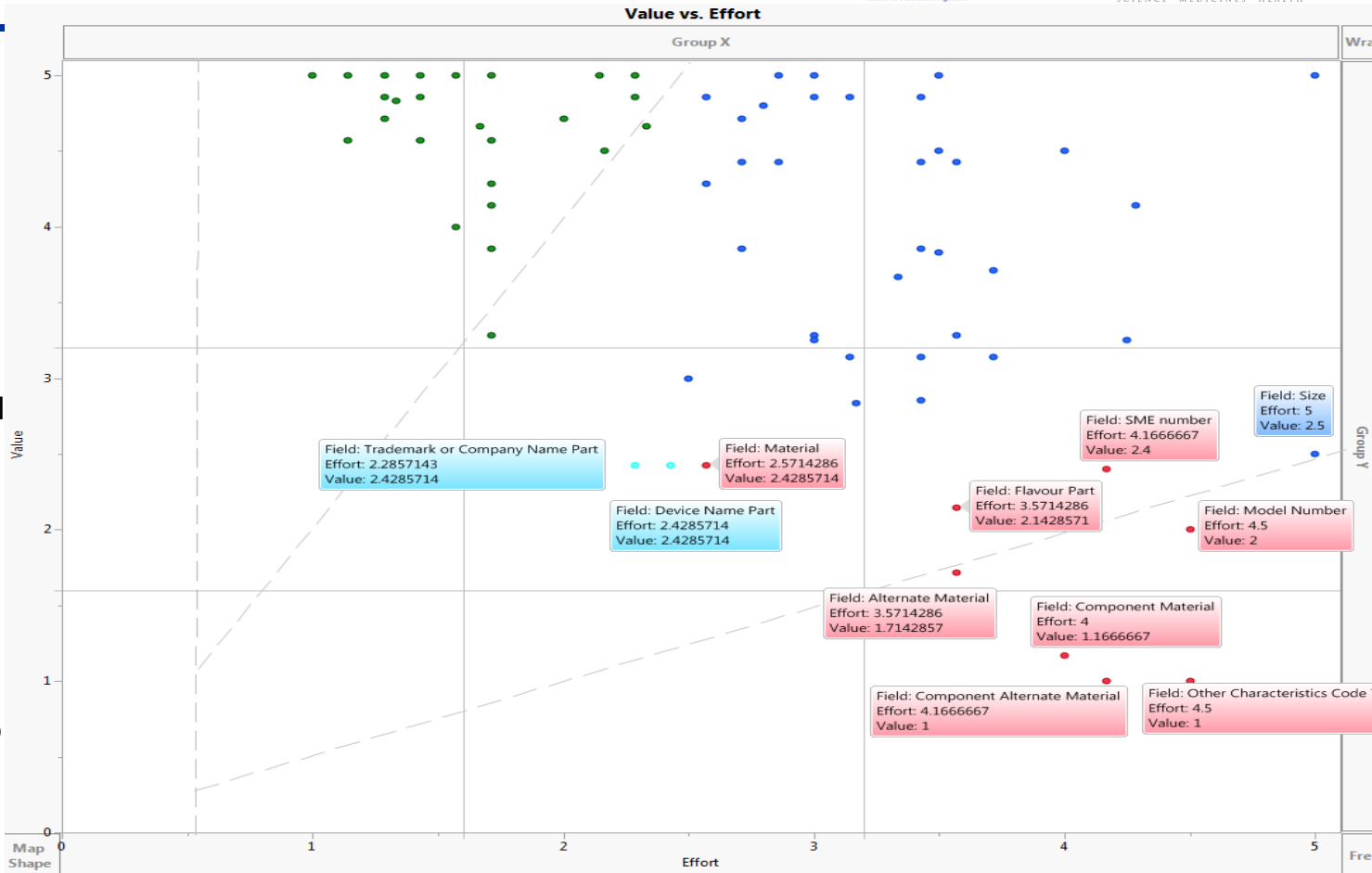


- In green the 'easy to have'
- In blue the 'costly but highly necessary'
- In red the costly and potentially not necessary

Aggregated results

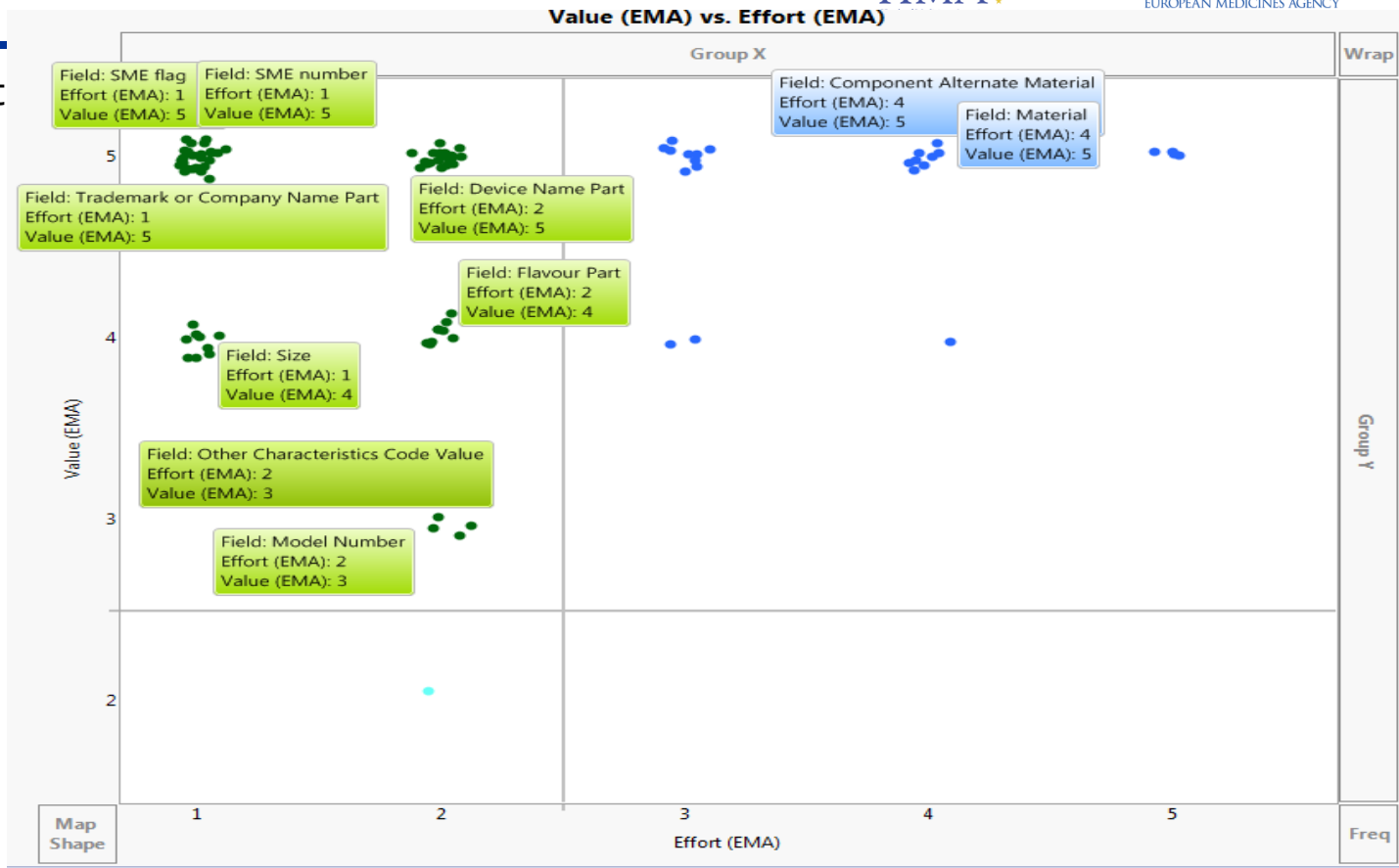
NCA aggregated results

- Dots Colour code:
- In green the 'easy to have'
 - In blue the 'highly costly & highly necessary'
 - In red the costly and potentially not necessary
 - Turquoise low costs and low value
 - in this split the ones under the lower dotted line are the most affected ("true" red).
 - the same colour code of the dots as in the previous slides, to keep track of the differences



EMA Results

- Entire number as not average for EMA
- labels are shown for the data marked as "red" in the NCA evaluation
- Essentially this is a map of "red" from NCA shown in our "green" and "blue"



Data element per data element results

Medicinal Product		Authorisation		Pharmaceutical Products		Package	
MPID	✓	Marketing Authorisation Number	✓	Administrable Dose Form	✓	PCID	✗
Combined Pharmaceutical Dose form	✓	Country	✓	Unit of Presentation	✓	Package Description	✗
IMPID Cross-Reference	✓	Legal Status of Supply	✓	Route of Administration	✓	Package Item (Container) Type	✓
Additional Monitoring Indicator	✓	Authorisation Status	✓	PhPID Sets	✗	Package Item (Container) Quantity	✓
Orphan Designation Status	✓	Authorisation Status Date	✓	Device Type (combined medical device ATMP)	✓	Material	✗
Name (Med Product)	✓	Date of First Authorisation	✗	Device Trade Name (combined medical device ATMP)	✓	Alternate Material	✗
Invented Name Part	✓	SME flag	✓			Component Type	✗
Scientific Name Part	✓	Size	✓	Substance		Component Material	✗
Strength Part	✓	SME number	✓	Ingredient Role	✓	Component Alternate Material	✗
Pharmaceutical Dose Form Part	✓	Status Date	✗	Substance	✗	Manufactured Dose Form	✓
Formulation Part	✓	Procedure Identifier (e.g. MRP number)	✓	Specified Substance	✗	Unit of Presentation	✓
Intended Use Part	✓	Procedure Type (e.g. MRP/DCP)	✓	Confidentiality Indicator	✗	Manufactured Item Quantity	✗
Target Population Part	✓	Country (national authorisation)	✓	Strength Range (Presentation)	✗	Other Characteristics Code System	✓
Container or Pack Part	✓	Marketing Authorization Number (national authorisation)	✓	Strength Range (Concentration)	✗	Other Characteristics Code Value	✓
Device Name Part	✓			Reference Strength Substance	✗	Device Type	✓
Trademark or Company Name Part	✓			Reference Strength Specified Substance	✗	Device Trade Name	✓
Time/Period Part	✓	Authorisation MAH		Reference Strength Range	✓	Device Listing Number	✓
Flavour Part	✓	Identifier	✓			Model Number	✓
MFL Code	✓	Name	✓	Substance			
MF Location	✓	Address	✓	Substance Name	✗	Clinical particulars	
Classification System	✓	Telecom	✓	Substance ID	✗	Indication Text	✓
Classification System Value	✓	Role	✓	Substance Type	✗	Indication as "Disease/Symptom.."	✓
Version Date	✓	Location Address	✓			Co-Morbidity	✗
Version Identifier	✓	Location Role	✓			Intended Effect	✗
Document Type	✓	Identifier	✓				
Document Identifier	✓						
Regulated Document	✓						
Document Effective Date	✓						
Country	✓						
Language	✗						

Full view of the 92 proposed data elements:

- Cell colour -> NCAs assessment (averaged)
- Flag colour -> EMA assessment

Recommendation for PMS Iteration 1

Implementation of PCID

Package	
PCID	X
Package Description	X
Package Item (Container) Type	✓
Package Item (Container) Quantity	✓
Material	X
Alternate Material	X
Component Type	X
Component Material	X
Component Alternate Material	X
Manufactured Dose Form	✓
Unit of Presentation	✓
Manufactured Item Quantity	X
Other Characteristics Code System	✓
Other Characteristics Code Value	✓
Device Type	✓
Device Trade Name	✓
Device Listing Number	✓
Model Number	✓
Material (For Packaging Description)	
Material Name	X
Material ID	X
Substance Type	X



Package	
PCID	X
Package Description	X
Package Item (Container) Type	✓
Package Item (Container) Quantity	✓
Material	X
Component Type	X
Component Material	X
Manufactured Dose Form	✓
Unit of Presentation	✓
Manufactured Item Quantity	X
Device Type	✓
Device Trade Name	✓

Provided by RMS

- Reduce the PCID description by 6 data elements in the package description
- In addition, the proposal is to develop a general term list to describe the material in the package (i.e. not based on the terminology defined by 11238/ 19844): the Material will be managed by RMS → subsequent removal of additional 3 data elements in PMS
- Terminology content to be discussed as part of RMS

Implementation of MA and MAH information

Authorisation	
Marketing Authorisation Number	✓
Country	✓
Legal Status of Supply	✓
Authorisation Status	✓
Authorisation Status Date	✓
Date of First Authorisation	✗
IME tag	✓
IME	✓
IME number	✓
Status Date	✗
Procedure Identifier (e.g. MRP number)	✓
Procedure Type (e.g. MRP/DCP)	✓
Country (national authorisation)	✓
Marketing Authorization Number (national authorisation)	✓
Authorisation MAH	
Identifier	✓
Name	✓
Address	✓
Telcom	✓
Role	✓
Location Address	✓
Location Role	✓
Entity Identifier (e.g. PSMF ID)	✓

Provided by OMS

Recommendation

OMS to provide MAH and QPPV information

Authorisation	
Marketing Authorisation Number	✓
Country	✓
Legal Status of Supply	✓
Authorisation Status	✓
Authorisation Status Date	✓
Date of First Authorisation	✗
Procedure Identifier (e.g. MRP number)	✓
Procedure Type (e.g. MRP/DCP)	✓
Country (national authorisation)	✓
Marketing Authorization Number (national authorisation)	✓

Authorisation MAH	
Identifier	✓
Role	✓
Location Address	✓
Location Role	✓
Entity Identifier (e.g. PhV Syst ID)	✓

- Reduce 7 elements for MAH information
- Info on the location of the PhV System master File is based on the MAH class model

Ingredient	
Ingredient Role	✓
Substance	✗
Specified Substance	✗
Confidentiality Indicator	✗
Strength Range (Presentation)	✗
Strength Range (Concentration)	✗
Reference Strength Substance	✗
Reference Strength Specified Substance	✗
Reference Strength Range	✓

Recommendation

Pharmaceutical Products	
Administrable Dose Form	✓
Unit of Presentation	✓
Route of Administration	✓
PhPID Sets	✗
Device Type (combined medical device ATMP)	✓
Device Trade Name (combined medical device ATMP)	✓

- To maintain the data elements initially proposed
- The proposal from industry to add '*D.2.3.2 Specified Substance Group*' in the ingredient section has been rejected as this information is part of the SMS (Substance dictionary) and do not need to be repeated within the product information

Indication Text and Indication as Disease/Symptoms are manageable for EMA; the latter is already part of Art.57. Co-Morbidity and intended effect are high value and costly for all regulators.

High level Business cases:

- *Free Text*: e-prescription and regulated information in national language
- *Codified values*:
 - for indexing/ searchability purpose in a standardised way
 - Identify product during referral procedure

Recommendation:

- To maintain the 4 values

Clinical particulars	
Indication Text	✓
Indication as "Disease/Symptom.."	✓
Co-Morbidity	✗
Intended Effect	✗

Proposal to implement remaining product information

Medicinal Product	
MPID	✓
Combined Pharmaceutical Dose form	✓
IMPID Cross-Reference	✓
Additional Monitoring Indicator	✓
Orphan Designation Status	✓
Name (Med Product)	✓
Invented Name Part	✓
Scientific Name Part	✓
Strength Part	✓
Pharmaceutical Dose Form Part	✓
Formulation Part	✓
Intended Use Part	✓
Target Population Part	✓
Container or Pack Part	✓
Device Name Part	✓
Trademark or Company Name Part	✓
Time/Period Part	✓
Flavour Part	✓
MFL Code	✓
MFL Location	✓
Classification System	✓
Classification System Value	✓
Version Date	✓
Version Identifier	✓
Document Type	✓
Document Identifier	✓
Regulated Document	✓
Document Effective Date	✓
Country	✓
Language	⌘

We understand the efforts required to provide and maintain the name part token, however the following business cases are compelling:

- Interoperability with ICSRs format
- For EMA, reliable calculation of pharmacovigilance fee
- Power reporting possibilities and data analysis for pharmacovigilance and e-prescription

Redundant with the organisation class
→ information is mapped against Organisation Class



Medicinal Product	
MPID	✓
Combined Pharmaceutical Dose form	✓
IMPID Cross-Reference	✓
Additional Monitoring Indicator	✓
Orphan Designation Status	✓
Name (Med Product)	✓
Invented Name Part	✓
Scientific Name Part	✓
Strength Part	✓
Pharmaceutical Dose Form Part	✓
Formulation Part	✓
Intended Use Part	✓
Target Population Part	✓
Container or Pack Part	✓
Device Name Part	✓
Trademark or Company Name Part	✓
Time/Period Part	✓
Flavour Part	✓
Classification System	✓
Classification System Value	✓
Version Date	✓
Version Identifier	✓
Document Type	✓
Document Identifier	✓
Regulated Document	✓
Document Effective Date	✓
Country	✓
Language	⌘

- Reduce 2 elements from initial proposal as MFL will be mapped by means of the Organisation class

1. From the CMDh requirements for tracking products addressed by the Falsified Medicines:
 - Handled via the addition of two values as a flag in the classification system no additional data elements are required (i.e. today in Article 57 Medicinal Product Type)
2. Request to add elements necessary to track **shortages of products** and to review the **Marketing Status** to include the market status flag
 - Implementation of Marketing information would require 3 fields :
 - Country
 - Marketing Status
 - Marketing Date
 - Implementation of shortage would require 2 fields :
 - Risk of shortage supply
 - Comment

Next steps from EUNDB

- Confirm the terminology to RMS subgroup
 - By end of February
- Define the Business Cases for each data elements in details
- Define the target operating model implementation and the validation strategy

Thank you for your attention

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

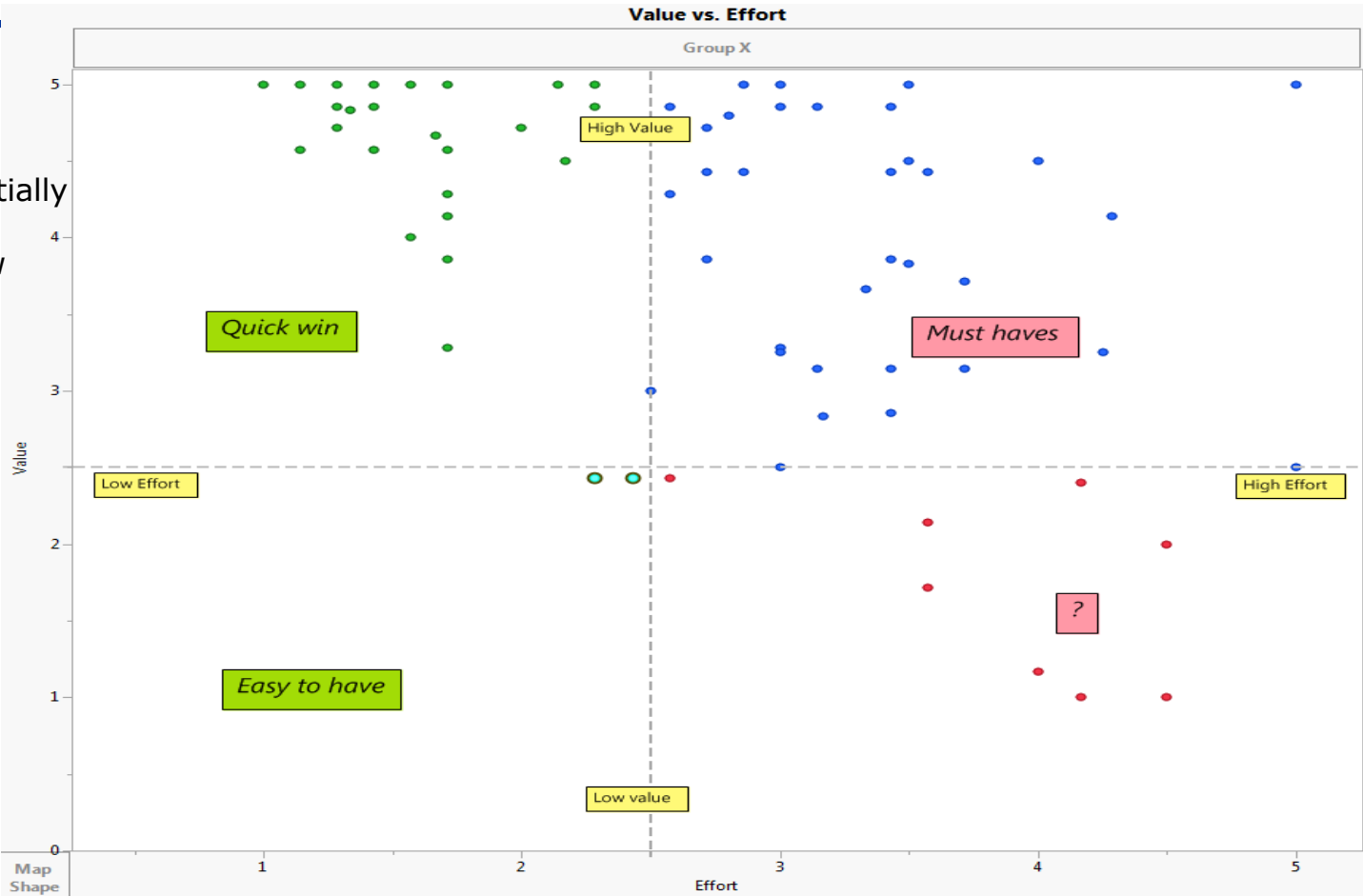
Send a question via our website www.ema.europa.eu/contact

Follow us on  **@EMA_News**

Background slides

NCA averaged results

- Dots Colour code:
- In green the 'easy to have'
 - In blue the 'highly costly & highly necessary'
 - In red the costly and potentially not necessary
 - Turquoise low costs and low value



Colour code: cell colour for NCAs analysis, flag colour represent EMA

Medicinal Product		Authorisation		Pharmaceutical Products		Package	
MPID		Marketing Authorisation Number		Administrable Dose Form		PCID	
Combined Pharmaceutical Dose form		Country		Unit of Presentation		Package Description	
IMPID Cross-Reference		Legal Status of Supply		Route of Administration		Package Item (Container) Type	
Additional Monitoring Indicator		Authorisation Status		PhPID Sets		Package Item (Container) Quantity	
Orphan Designation Status		Authorisation Status Date		Device Type (combined medical device ATMP)		Material	✘
Name (Med Product)		Date of First Authorisation		Device Trade Name (combined medical device ATMP)		Alternate Material	✘
Invented Name Part		SME flag				Component Type	✘
Scientific Name Part		Size		Substance		Component Material	✘
Strength Part		SME number	✓	Ingredient Role		Component Alternate Material	✘
Pharmaceutical Dose Form Part		Status Date		Substance		Manufactured Dose Form	
Formulation Part		Procedure Identifier (e.g. MRP number)		Specified Substance		Unit of Presentation	
Intended Use Part		Procedure Type (e.g. MRP/DCP)		Confidentiality Indicator		Manufactured Item Quantity	
Target Population Part		Country (national authorisation)		Strength Range (Presentation)		Other Characteristics Code System	✓
Container or Pack Part		Marketing Authorization Number (national authorisation)		Strength Range (Concentration)		Other Characteristics Code Value	✓
Device Name Part				Reference Strength Substance		Device Type	
Trademark or Company Name Part				Reference Strength Specified Substance		Device Trade Name	
Time/Period Part		Authorisation MAH		Reference Strength Range		Device Listing Number	✓
Flavour Part	✓	Identifier				Model Number	✓
MFL Code		Name		Substance			
MF Location		Address		Substance Name		Clinical particulars	
Classification System		Telecom		Substance ID		Indication Text	✓
Classification System Value		Role		Substance Type		Indication as "Disease/ Symptom.."	✓
Version Date		Location Address				Co-Morbidity	
Version Identifier		Location Role				Intended Effect	
Document Type		Identifier					
Document Identifier							
Regulated Document							
Document Effective Date							
Country							
Language							

Total of 11 red fields for NCAs:

- 5 high value but highly costly for EMA too
- 6 are less costly for EMA

Medicinal Product		Authorisation		Pharmaceutical Products		Package	
MPID	✓	Marketing Authorisation Number	✓	Administrable Dose Form	✓	PCID	
Combined Pharmaceutical Dose form	✓	Country	✓	Unit of Presentation	✓	Package Description	
IMPID Cross-Reference		Legal Status of Supply	✓	Route of Administration	✓	Package Item (Container) Type	✓
Additional Monitoring Indicator	✓	Authorisation Status	✓	PhPID Sets		Package Item (Container) Quantity	✓
Orphan Designation Status		Authorisation Status Date	✓	Device Type (combined medical device ATMP)		Material	
Name (Med Product)	✓	Date of First Authorisation		Device Trade Name (combined medical device ATMP)		Alternate Material	
Invented Name Part	✓	SME flag				Component Type	
Scientific Name Part	✓	Size				Component Material	
Strength Part	✓	SME number				Component Alternate Material	
Pharmaceutical Dose Form Part	✓	Status Date				Manufactured Dose Form	✓
Formulation Part		Procedure Identifier (e.g. MRP number)	✓	Substance		Unit of Presentation	✓
Intended Use Part		Procedure Type (e.g. MRP/DCP)	✓	Specified Substance		Manufactured Item Quantity	
Target Population Part		Country (national authorisation)	✓	Confidentiality Indicator		Other Characteristics Code System	
Container or Pack Part	✓	Marketing Authorization Number (national authorisation)	✓	Strength Range (Presentation)		Other Characteristics Code Value	
Device Name Part	✓			Strength Range (Concentration)		Device Type	
Trademark or Company Name Part	✓			Reference Strength Substance		Device Trade Name	
Time/Period Part				Reference Strength Specified Substance		Device Listing Number	
Flavour Part				Reference Strength Range		Model Number	
MFL Code							
MF Location							
Classification System	✓						
Classification System Value	✓						
Version Date	✓						
Version Identifier							
Document Type	✓						
Document Identifier	✓						
Regulated Document	✓						
Document Effective Date	✓						
Country	✓						
Language							

39 fields are green for both NCAs and EMA.

Medicinal Product		Authorisation		Pharmaceutical Products		Package	
MPID		Marketing Authorisation Number		Administrable Dose Form		PCID	
Combined Pharmaceutical Dose form		Country		Unit of Presentation		Package Description	
IMPID Cross-Reference	✓	Legal Status of Supply		Route of Administration		Package Item (Container) Type	
Additional Monitoring Indicator		Authorisation Status		PhPID Sets		Package Item (Container) Quantity	
Orphan Designation Status	✓	Authorisation Status Date		Device Type (combined medical device ATMP)	✓	Material	
Name (Med Product)		Date of First Authorisation		Device Trade Name (combined medical device ATMP)	✓	Alternate Material	
Invented Name Part		SME flag	✓			Component Type	
Scientific Name Part		Size	✓	Substance		Component Material	
Strength Part		SME number		Ingredient Role		Component Alternate Material	
Pharmaceutical Dose Form Part		Status Date		Substance		Manufactured Dose Form	
Formulation Part	✓	Procedure Identifier (e.g. MRP number)		Specified Substance		Unit of Presentation	
Intended Use Part	✓	Procedure Type (e.g. MRP/DCP)		Confidentiality Indicator		Manufactured Item Quantity	
Target Population Part	✓	Country (national authorisation)		Strength Range (Presentation)		Other Characteristics Code System	
Container or Pack Part		Marketing Authorization Number (national authorisation)		Strength Range (Concentration)		Other Characteristics Code Value	
Device Name Part				Reference Strength Substance		Device Type	✓
Trademark or Company Name Part				Reference Strength Specified Substance		Device Trade Name	✓
Time/Period Part	✓	Authorisation MAH		Reference Strength Range	✓	Device Listing Number	
Flavour Part		Identifier	✓			Model Number	
MFL Code	✓	Name		Substance			
MF Location	✓	Address		Substance Name		Clinical particulars	
Classification System		Telecom	✓	Substance ID		Indication Text	✓
Classification System Value		Role	✓	Substance Type		Indication as "Disease/ Symptom..."	✓
Version Date		Location Address	✓			Co-Morbidity	
Version Identifier	✓	Location Role	✓			Intended Effect	
Document Type		Identifier					
Document Identifier							
Regulated Document							
Document Effective Date							
Country							
Language							

23 data elements are blue for NCA and green for EMA:

- Potentially EMA can provide those to NCAs to reduce costs?

Medicinal Product	Authorisation	Pharmaceutical Products	Package
MPID	Marketing Authorisation Number	Administrable Dose Form	PCID ✕
Combined Pharmaceutical Dose form	Country	Unit of Presentation	Package Description ✕
IMPID Cross-Reference	Legal Status of Supply	Route of Administration	Package Item (Container) Type
Additional Monitoring Indicator	Authorisation Status	PhPID Sets	Package Item (Container) Quantity
Orphan Designation Status	Authorisation Status Date	Device Type (combined medical device ATMP)	Material
Name (Med Product)	Date of First Authorisation ✕	Device Trade Name (combined medical device ATMP)	Alternate Material
Invented Name Part	SME flag		Component Type
Scientific Name Part	Size	Substance	Component Material
Strength Part	SME number	Ingredient Role	Component Alternate Material
Pharmaceutical Dose Form Part	Status Date	Substance ✕	Manufactured Dose Form
Formulation Part	Procedure Identifier (e.g. MRP number)	Specified Substance	Unit of Presentation
Intended Use Part	Procedure Type (e.g. MRP/DCP)	Confidentiality Indicator	Manufactured Item Quantity
Target Population Part	Country (national authorisation)	Strength Range (Presentation)	Other Characteristics Code System
Container or Pack Part	Marketing Authorization Number (national authorisation)	Strength Range (Concentration) ✕	Other Characteristics Code Value
Device Name Part		Reference Strength Substance	Device Type
Trademark or Company Name Part		Reference Strength Specified Substance	Device Trade Name
Time/Period Part	Authorisation MAH	Reference Strength Range	Device Listing Number
Flavour Part	Identifier		Model Number
MFL Code	Name	Substance	
MF Location	Address	Substance Name	Clinical particulars
Classification System	Telecom	Substance ID	Indication Text
Classification System Value	Role	Substance Type	Indication as "Disease/ Symptom.."
Version Date	Location Address		Co-Morbidity
Version Identifier	Location Role		Intended Effect
Document Type	Identifier		
Document Identifier			
Regulated Document			
Document Effective Date			
Country			
Language			

5 fields are green for NCA but costly for EMA:

- NCAs to support EMA

Medicinal Product	Authorisation	Pharmaceutical Products	Package
MPID	Marketing Authorisation Number	Administrable Dose Form	PCID
Combined Pharmaceutical Dose form	Country	Unit of Presentation	Package Description
IMPID Cross-Reference	Legal Status of Supply	Route of Administration	Package Item (Container) Type
Additional Monitoring Indicator	Authorisation Status	PhPID Sets	Package Item (Container) Quantity
Orphan Designation Status	Authorisation Status Date	Device Type (combined medical device ATMP)	Material
Name (Med Product)	Date of First Authorisation	Device Trade Name (combined medical device ATMP)	Alternate Material
Invented Name Part	SME flag		Component Type
Scientific Name Part	Size	Substance	Component Material
Strength Part	SME number	Ingredient Role	Component Alternate Material
Pharmaceutical Dose Form Part	Status Date	Substance	Manufactured Dose Form
Formulation Part	Procedure Identifier (e.g. MRP number)	Specified Substance	Unit of Presentation
Intended Use Part	Procedure Type (e.g. MRP/DCP)	Confidentiality Indicator	Manufactured Item Quantity
Target Population Part	Country (national authorisation)	Strength Range (Presentation)	Other Characteristics Code System
Container or Pack Part	Marketing Authorization Number (national authorisation)	Strength Range (Concentration)	Other Characteristics Code Value
Device Name Part		Reference Strength Substance	Device Type
Trademark or Company Name Part		Reference Strength Specified Substance	Device Trade Name
Time/Period Part	Authorisation MAH	Reference Strength Range	Device Listing Number
Flavour Part	Identifier		Model Number
MF Code	Name	Substance	
MF Location	Address	Substance Name	Clinical particulars
Classification System	Telecom	Substance ID	Indication Text
Classification System Value	Role	Substance Type	Indication as "Disease/ Symptom.."
Version Date	Location Address		Co-Morbidity
Version Identifier	Location Role		Intended Effect
Document Type	Identifier		
Document Identifier			
Regulated Document			
Document Effective Date			
Country			
Language			

14 fields are costly and highly valuable for both EMA and NCAs

Additional information: industry's major concerns
[for considerations]

Table ID (match to excel)	Attribute (Date Field)	Concern
7-18	Name parts	<p>Not a major concern for company 1 as very few fields relevant. Medium concern for company 2 as relevant and not extracted in that format in a structured way (manual extraction required). Additional clarification required re Company name. Ballot comments highlight a potential confusion between Trademark[®] or TM and what is meant here – the company name (as per XEVMPD definition). Ballot comment requests a name change for the field to avoid confusion</p>
26	Document effective date	<p>date of the revision of the text within SmPC (Section 10) but currently not mandatory in XEVMPD. Requires opening each SmPC - huge work. Additionally experience shows that the effective date is not always included in the version available for submission and that there are different understandings of what is required for this date.</p>
33-34	Authorisation status and status date	<p>Not (big) concern for Company 1 as in RIMS, although will require some specific migration rules. Flagged as potentially bigger concern for others though ie finding info re 50 year old info etc. What is feedback from other companies?</p>

Concerns from industry (2)

Table ID (match to excel)	Attribute (Date Field)	Concern
47	Marketing Status	Low concern for company 1 as in RIMS. What about other companies? Note from Andrew that could be difficult. Also need confirmation re granularity – ISO implies Authorisation level but would need to be PCID level in reality
52	Indication Text	<p>acknowledged high work effort to open each SmPC to extract text for most companies. There can be different interpretations as to how the text should be organized which is a balance between ease and specificity. To provide the most specific information will be the most effort but may be of most value:</p> <ul style="list-style-type: none"> - Lacking clarity on the content: the full text or the section that covers the MedDRA LLT only to be included? (very long, cross-reference to other SmPC sections, might include age information), multiple fields. - Formatting issue to be expected with text extraction (headers, bulleted items, underlined sub-sections, numbers with exposure eg. 106) - Need to have a mechanism to allow data update during the text review or submit only when text is approved.
54-56	Co-Morbidity Intended Effect	<p>not in XEVMPD. Need to retrieve from SmPC when applicable; high work effort to open SmPC to extract this information.</p> <ul style="list-style-type: none"> - Needs to be done by product experts due to complexity. - rumours that coding to the lowest-level MedDRA terms plus the disease status, co-morbidity, population, etc. could increase the indication list ten-fold or more. This is of serious concern - Need to know structure of dictionary and medical terminology for the coding - Maintenance process needs clarification (e.g. MedDRA updates, review of existing codes, replacement of codes?) - Process clarification needed if codes do not exist in all languages, can the English version be the reference?

Concerns from industry (3)



Table ID (match to excel)	Attribute (Date Field)	Concern
116	Specified substance	<ul style="list-style-type: none"> - Clarity required if this is for excipients or only active substances? - Significant effort to retrieve all specified substance information - would need to assess with CMC, not located in DB so far - Each SS Group should be considered ndependently. 1, 2 and 3, whether it is applicable to active, adjuvant and excipient and whether it is inclusion n the SmPC or the dossier that should be the determinant. Ie. So if PhEur is not stated in the SmPC then it is out of scope, or is it the Module 3 that determines if it should be stated? - Group 2: Manufacturers for excipients is an issue: high number, only information of suppliers' available, numerous sources, ...) - Company 2 believe Specified substance group 3: Grade would make sense for excipients.
180-188	Package Container details	<ul style="list-style-type: none"> -Primary packaging details readily available but secondary packaging less so. Clarification required as per requirements for iteration 1. -kits containing multiple components, especially if they contain products to be transformed or taken separately, require a more complete package hierarchy.” - Structure of the products and what would be assigned to what needs clarification. - Lack of officially worked examples. - Model does not clearly describe devices (administration, integrated). See examples in below text pages. - Do not believe that all this information is required to define a PCID. PCID can be determined by solely a different package description. This should be done at this stage. Further details could be considered for Iteration 4
237-242	Substance details	<p>Data not currently captured in structured format – high work effort assessed to retrieve this information. Concern as to how this information will be made available (even if part of Ginas) and what input will be required from industry/how this will be coordinated.</p> <p>Not clear but are these fields referring to the materials in devices? Two main issues</p> <ol style="list-style-type: none"> 1. It has been defined that packaging materials are outside the scope of 11238/19844 so cannot be using IDs for this as they won't exist. 2. Is materials referring only to contact materials. This would simplify matters <p>However, this should be deferred to Iteration 4</p>