EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management

EMA splitting of the full presentation name of the medicinal product best practice

Procedure and principles to handle product name in the XEVMPD

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

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Summary of changes

This document was re-formatted and the below examples were added following the publication of version 2 of this document on 9 July 2014. Description of editorial changes is not included.

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1. Introduction

This document aims to provide guidance on the splitting of the Full Presentation Name of medicinal products in the context of Article 57 product submission and maintenance, and implements the paragraph *1.2.13. AMP - Presentation Name element structure (AP.13)* of the Detailed guidance on the electronic submission of information on medicinal products for human use by marketing-authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004: Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance.

The implementation is required for Pharmacovigilance purposes and it follows ISO IDMP 11615 *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information* requirements.

2. Medicinal product name definition

- **Article 1(s20) of the Directive 2001/83/EC**

  In accordance with Article 1(s20) of the Directive 2001/83/EC the medicinal product name refers to the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder.

- **Notice to Applicants: Guideline on SmPC Revision 2 (September 2009)**

NAME OF THE MEDICINAL PRODUCT

> **The (invented) name should be followed by both the strength and the pharmaceutical form**. However, when otherwise referring to the medicinal product throughout the SmPC text, the strength and the pharmaceutical form do not have to be mentioned in the name. The International Non-proprietary Name (INN) or the usual common name of the active substance should be used when referring to properties of the active substance(s) rather than those of the product. The use of pronouns (e.g. "it") is encouraged whenever possible.
>
> ***Strength***
> The strength should be the relevant quantity for identification and use of the product and should be consistent with the quantity stated in the quantitative composition and in the posology. Different strengths of the same medicinal product should be stated in the same way, e.g. 250 mg, 500 mg, 750 mg. The use of decimal points should be avoided where these can be easily removed (e.g. 250 microgram, not 0.25 mg). However, where a range of medicinal products of the same pharmaceutical form includes strengths of more than one unit (e.g. 250 microgram, 1 mg and 6 mg), it may be more appropriate in certain cases to state the strengths in the same unit for the purpose of comparability (e.g. 0.25 mg, 1 mg and 6 mg). For safety reasons, micrograms and millions (e.g. for units) should always be spelled out in full rather than be abbreviated.

Pharmaceutical form

> The pharmaceutical form of a medicinal product should be described by a single full Standard Term of the European Pharmacopoeia using the plural form if appropriate (e.g. tablets) (see section 3). If an appropriate standard term does not exist, a new term may be constructed from a combination of standard terms in accordance with the document "Standard Terms, Introduction and Guidance to use". Should this not be possible, the competent authority should be asked to request a new Standard Term from the European Department for the Quality of Medicines (EDQM) of the Council of Europe. No reference should be made to the route of administration or container unless these elements are part of the standard term or where there is a particular safety reason for their inclusion or where there are identical products, which may be distinguished only by reference to the route of administration or to the container. For the expression of the name and strength of (traditional) herbal medicinal products the declaration should be in accordance with existing quality guidelines on herbal medicinal products.

Therefore, in accordance with the SmPC Guideline recommendation, the full name of the medicinal product should be composed of the following elements:

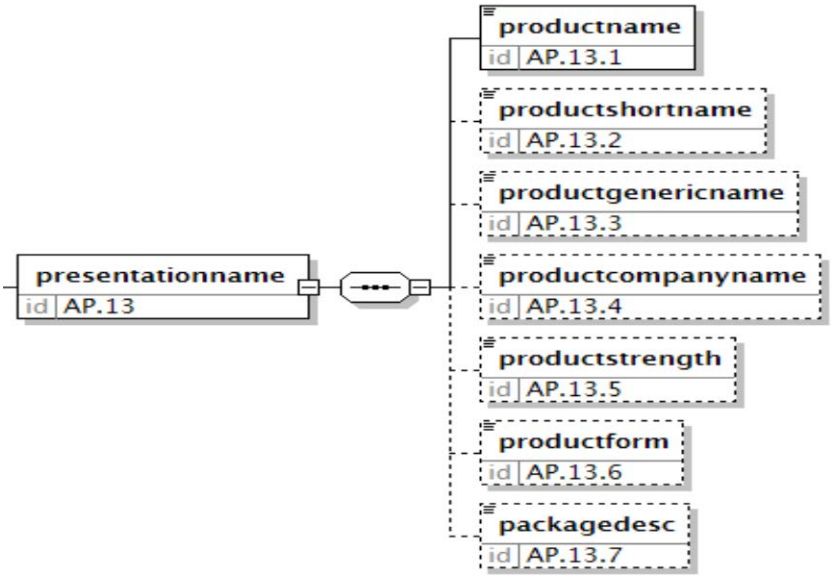
Product name + Strength + Pharmaceutical Form (label)

- **Notice to Applicants: Annex I of the Summary of Product Characteristics (Version 9, 03/2013)**

  In relation to the trademark, the following guidance is provided:

> **1. NAME OF THE MEDICINAL PRODUCT**
>
> [Guidance on the expression of strength is available in the "QRD Recommendations on the Expression of Strength in the Name of Centrally Authorised Human Medicinal Product (as stated in section 1 of SmPC and in the name section of labelling and PL".]{(Invented) name strength pharmaceutical form} [No ® ™ symbols attached here and throughout the text; "tablets" and "capsules" in the plural.]

- **Presentation Name element structure (AP.13)** of the Detailed guidance on the electronic submission of information on medicinal products for human use by marketing-authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004: Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance:



Detailed description of each element can be found in section *1.2.13. AMP - Presentation Name element structure (AP.13)* of the Detailed guidance on the electronic submission of information on medicinal products for human use by marketing-authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004: Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance.

2.1. Definition of Product name

Considering the definition of product name in the Article 1(20) of the Directive 2001/83/EC and in line with the SmPC Guideline recommendation, the name of the medicinal product should be expressed as Product name + Strength (label) + Pharmaceutical Form (label).

Therefore the Product name is defined as:

- *Invented name; or*
- *Invented name + other designations/trademark; or*
- *INN/Common name + other designations/trademark; or*
- *INN/Common name + company name (label).*

2.2. Definition of 'other designation / trademark'

The definition of 'other designation/trademark' refers to any other designation except the strength/pharmaceutical form (label) part of the product name (e.g. invented name + designations).

Designations include reference to:

- Potency of the product (e.g. EXTRA, FORTE, PLUS, numbers not referring to the strength)
- Combined medication/other ingredients (e.g.: DUO. HT, HTZ)
- Dosage form or Time/Period part (e.g. Express, SR, ER)
- Indication/intended use (e.g. Migraine)
- Target population (e.g. for adult, for children)
- Flavour/formulation part (e.g. Strawberry, sugar free)
- Trademark (e.g. zydis)

Examples of 'other designation/trademark' to be included in the data fields 'Product Short name' (AP.13.2) or 'Product INN/Common Name' (AP.13.3) in the XEVMPD (as applicable) are shown below in bold:

- DrugY **Extra Strength** 400 mg Liquid Capsules
- DrugY **for Children** 50 mg Capsules
- DrugY **for Children Strawberry Singles**
- DrugY **for Children Strawberry**
- DrugY **for Kids and Junior Orange** 40 mg//ml oral suspension
- DrugY **FORTE EXPRESS** 400 mg dengtos tablets
- DrugY **FORTE** 400 mg dengtos tablets
- DrugY 200 **tablet Migraine**, omhulde tablet 200 MG

- DrugY **100 tablet Migraine**, omhulde tablet 200 MG
- DrugY 300 mg **SR** Retardkapsel
- DrugY **Rapid Forte** 400 mg lágy kapszula
- DrugY **Ultra Forte** 400 mg Kapsulki elastyczne
- DrugY**caps** 300 mg Soft Capsules
- DrugY **Express Forte** 300 mg capsules, soft
- DrugY 300 **Fastcaps**, 300 mg capsules (molles)
- DrugY **Zavance** 200 mg cápsulas moles
- DrugY**FLASH** 200 mg, comprimé pelliculé
- DrugY**FEM** 100 mg
- DrugY **retard** 100 mg
- Diclofenac Na **retard CF**
- Paracetamol **for Children Six Plus Orange** 200mg/5ml Oral Suspension
- Ibuprofen **for Children 3 Months to 9 Years Strawberry**
- Aspirin **for Children Sachets** 100mg/5ml Oral Suspension
- Loperamide HCL **Orange baby**

3. Practical examples of the Splitting of the Full Presentation Name of a medicinal product

3.1. Product Short Name

EXAMPLE 1

The SmPC of a medicinal product authorised in the UK states the following information:

1. Name of the medicinal product

XYZ® Express 200 mg Liquid Capsules

In line with the guidance provided in Chapter 3.II: XEVPRM User Guidance, the 'Presentation Name' data elements must be specified as follows:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	XYZ® Express 200 mg Liquid Capsules
AP.13.2	productshortname	Product Short Name	XYZ Express
AP.13.3	productgenericname	Product INN/Common Name	
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	200 mg
AP.13.6	productform	Product Form Name	Liquid Capsules

NEW: EXAMPLE 2

The SmPC of a medicinal product authorised in Spain states the following information:

1. NOMBRE DEL MEDICAMENTO

Gemcitabina PharmaZ 200 mg polvo para solución para perfusión EFG

EFG appears to be a standard designation added to generic medicinal products authorised in Spain, standing for Pharmaceutical Generic Equivalent. While the text "EFG" should be captured in the 'Full Presentation Name' data element, it should not be inserted in any of the other data elements:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Gemcitabina PharmaZ 200 mg polvo para solución para perfusión EFG
AP.13.2	productshortname	Product Short Name	

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.3	productgenericname	Product INN/Common Name	Gemcitabina
AP.13.4	productcompanyname	Product Company Name	PharmaZ
AP.13.5	productstrength	Product Strength Name	200 mg
AP.13.6	productform	Product Form Name	polvo para solución para perfusión

NEW: EXAMPLE 3

The SmPC of an allergen medicinal product authorised in Germany states the following information:

1. BEZEICHNUNG DER ARZNEIMITTEL

ALLERGOL® BIRKE/ERLE/HASEL 10 I.R./ml

Lösungen zur sublingualen Anwendung

Wirkstoff: Allergenextrakt aus Pollen von Birke, Erle und Hasel

In this case, "BIRKE/ERLE/HASEL" (birch/alder/hazel) should be handled as an additional designation to the 'Product Short Name' data element, as the full name further defines "Allergenextrakte aus Pollen von Birke, Erle und Hasel" as the exact ingredient.

As for the term "Wirkstoff" (active ingredient), it should not be taken into consideration in the splitting of the full presentation name:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	ALLERGOL® Birke/Erle/Hasel 10 I.R./ml Lösungen zur sublingualen Anwendung Wirkstoff: Allergenextrakte aus Pollen von Birke, Erle und Hasel
AP.13.2	productshortname	Product Short Name	ALLERGOL Birke/Erle/Hasel
AP.13.3	productgenericname	Product INN/Common Name	Allergenextrakte aus Pollen von Birke, Erle und Hasel
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	10 I.R./ml
AP.13.6	productform	Product Form Name	Lösungen zur sublingualen Anwendung

NEW: EXAMPLE 4

The SmPC of an allergen medicinal product authorised in France states the following information:

1. DENOMINATION DU MEDICAMENT

ALLERGOP® Venin De Guêpe Polistes spp. 550 microgrammes, poudre et solvant pour solution injectable

Since the medicinal product name stated in section 1 of the SmPC includes the brand name, the type of allergen contained in the preparation, strength and form names, the presentation name data elements must be specified as follows:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	ALLERGOP® Venin De Guêpe Polistes spp. 550 microgrammes, poudre et solvant pour solution injectable
AP.13.2	productshortname	Product Short Name	ALLERGOP
AP.13.3	productgenericname	Product INN/Common Name	Venin De Guêpe Polistes spp.
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	550 microgrammes
AP.13.6	productform	Product Form Name	poudre et solvant pour solution injectable

NEW: EXAMPLE 5

The SmPC of a medicinal product containing candesartan and hydrochlorothiazide states the following information:

1. Name of the medicinal product

Prodemaz® HCT 25 + 20 mg capsules

2. Qualitative and quantitative composition

Each capsule contains 25 mg of candesartan and 20 mg of hydrochlorothiazide.

Since "HCT" is not the only active ingredient in this preparation, it should not be separated from the product short name and should instead be considered as an additional designation used by the MAH to identify a particular composition of their product.

As a general rule, the full product name should not be split into both 'Product Short Name' and 'Product INN/Common Name' fields unless the INN name part of the full product name corresponds to the only active ingredient of the preparation (see EXAMPLE 18).

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Prodemaz® HCT 25 + 20 mg capsules
AP.13.2	productshortname	Product Short Name	Prodemaz HCT
AP.13.3	productgenericname	Product INN/Common Name	
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	25 + 20 mg
AP.13.6	productform	Product Form Name	capsules

NEW: EXAMPLE 6

1. Name of the medicinal product

Prodemaz® Candesartan 25 mg capsules

2. Qualitative and quantitative composition

Each capsule contains 25 mg of candesartan.

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Prodemaz® Candesartan 25 mg capsules
AP.13.2	productshortname	Product Short Name	Prodemaz
AP.13.3	productgenericname	Product INN/Common Name	Candesartan
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	25 mg
AP.13.6	productform	Product Form Name	capsules

3.1.1. Product name designation containing number(s)

If the product name designation contains number(s) that are clearly referring to the Strength, such number(s) must not be provided in the data fields 'Product Short name' (AP.13.2) or 'Product INN/Common Name' (AP.13.3) as shown in the below example:

EXAMPLE 7

The SmPC of a medicinal product authorised in Germany states the following information:

1. BEZEICHNUNG DES ARZNEIMITTELS

DrugLV 200 Migraine Filmtabletten

2. QUALITATIVE UND QUANTITATIVE ZUSAMMENSETZUNG

Jede tablette enthält: 200 mg paracetamol

Since the number "200" refers to the strength, the 'Presentation Name' data elements must be specified as follows:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements EVWEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	DrugLV 200 Migraine Filmtabletten
AP.13.2	productshortname	Product Short Name	DrugLV Migraine
AP.13.3	productgenericname	Product INN/Common Name	
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	200
AP.13.6	productform	Product Form Name	Filmtabletten

NEW: EXAMPLE 8

The SmPC of a medicinal product authorised in Italy states the following information:

1. DENOMINAZIONE DEL MEDICINALE

OSSIGENO PHARMAX, 200 bar gas medicinale compresso

The number "200" indicates the maximum pressure at which the gas is compressed and, together with the capacity of the cylinder, defines the content of oxygen in the product. Therefore, the presentation name data elements must be specified as follows:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements EVWEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	OSSIGENO PHARMAX, 200 bar gas medicinale compresso
AP.13.2	productshortname	Product Short Name	
AP.13.3	productgenericname	Product INN/Common Name	OSSIGENO
AP.13.4	productcompanyname	Product Company	PHARMAX

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements EVWEB name	Splitting of the full presentation name of the medicinal product
		Name	
AP.13.5	productstrength	Product Strength Name	200 bar
AP.13.6	productform	Product Form Name	gas medicinale compresso

If the number is not referring to the strength (e.g. it refers to a ratio in case of insulin or to the package content) then it is considered as part of 'other designations' and must be provided in the data fields 'Product Short name' (AP.13.2) or 'Product INN/Common Name' (AP.13.3) as shown in the below examples:

EXAMPLE 9

The SmPC of a medicinal product authorised in Germany states the following information:

1. BEZEICHNUNG DES ARZNEIMITTELS

AriProd 100 Migraine Filmtabletten

2. QUALITATIVE UND QUANTITATIVE ZUSAMMENSETZUNG

Jede tablette enthält: 200 mg paracetamol

Since the number "100" does not refer to the strength, the presentation name data elements must be specified as follows:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements EVWEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	AriProd 100 Migraine Filmtabletten
AP.13.2	productshortname	Product Short Name	AriProd 100 Migraine
AP.13.3	productgenericname	Product INN/Common Name	
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	
AP.13.6	productform	Product Form Name	Filmtabletten

EXAMPLE 10

The SmPC of a medicinal product authorised in the Germany states the following information:

1. BEZEICHNUNG DES ARZNEIMITTELS

Insulin PharmaX Comb 30/70 100 I.E./ml Zylinderampullen mit Injektionssuspension

Since the number "30/70" refers to a ratio, the presentation name data elements must be specified as follows:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements EVWEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Insulin PharmaX Comb 30/70 100 I.E./ml Zylinderampullen mit Injektionssuspension
AP.13.2	productshortname	Product Short Name	
AP.13.3	productgenericname	Product INN/Common Name	Insulin Comb 30/70
AP.13.4	productcompanyname	Product Company Name	PharmaX
AP.13.5	productstrength	Product Strength Name	100 I.E./ml
AP.13.6	productform	Product Form Name	Zylinderampullen mit Injektionssuspension

3.1.2. Product name designation containing target population information

EXAMPLE 11

The SmPC of a medicinal product authorised in the UK states the following information:

1. Name of the medicinal product

XYZ for Children 50 mg Capsules

Since the medicinal product name stated in section 1 of the SmPC does not contain any generic name, and the designation "for Children" is therefore related to the brand name, the 'Presentation Name' data elements must be specified as follows:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements EVWEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	XYZ for Children 50 mg Capsules
AP.13.2	productshortname	Product Short Name	XYZ for Children
AP.13.3	productgenericname	Product INN/Common Name	
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	50 mg
AP.13.6	productform	Product Form Name	Capsules

EXAMPLE 12

The SmPC of a medicinal product authorised in the UK states the following information:

1. Name of the medicinal product

KLM Strawberry for Children

Since the medicinal product name stated in section 1 of the SmPC does not contain any generic name, and the designation "Strawberry for Children" is therefore related to the brand name, the presentation name data elements must be specified as follows:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements EVWEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	KLM Strawberry for Children
AP.13.2	productshortname	Product Short Name	KLM Strawberry for Children
AP.13.3	productgenericname	Product INN/Common Name	
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	
AP.13.6	productform	Product Form Name	

3.2. Product Generic Name

EXAMPLE 13

The SmPC of a medicinal product authorised in the UK states the following information:

1. Name of the medicinal product

ProductABC PharmaZ 200 mg ibuprofen capsules

Since the medicinal product name stated in section 1 of the SmPC contains the brand name, company name, generic name, strength and form name, the presentation name data elements must be specified as follows:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements EVWEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	ProductABC PharmaZ 200 mg ibuprofen capsules
AP.13.2	productshortname	Product Short Name	ProductABC
AP.13.3	productgenericname	Product INN/Common Name	ibuprofen
AP.13.4	productcompanyname	Product Company	PharmaZ

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements EVWEB name	Splitting of the full presentation name of the medicinal product
		Name	
AP.13.5	productstrength	Product Strength Name	200 mg
AP.13.6	productform	Product Form Name	capsules

NEW: EXAMPLE 14

The SmPC of a medicinal product containing methotrexate states the following information:

1. Name of the medicinal product

Methopharmax 50 mg tablets

7. Marketing authorisation holder

PharmaX

Although the full product name suggests a reference to both the active substance and the MAH, the prefix "Metho" cannot be unambiguously associated to the substance methotrexate and therefore should not be submitted in the "Product INN/Common Name" field.

The product name should rather be considered as an invented name given by the MAH, and the 'Presentation Name' data elements must be specified as follows:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Methopharmax 50 mg tablets
AP.13.2	productshortname	Product Short Name	Methopharmax
AP.13.3	productgenericname	Product INN/Common Name	
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	50 mg
AP.13.6	productform	Product Form Name	tablets

NEW: EXAMPLE 15

1. Name of the medicinal product

MTX PharmaX 50 mg tablets

7. Marketing authorisation holder

PharmaX

In this case, "MTX" is an approved and widely known abbreviation for methotrexate and should therefore be submitted in the "Product INN/Common Name" field:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	MTX PharmaX 50 mg tablets
AP.13.2	productshortname	Product Short Name	
AP.13.3	productgenericname	Product INN/Common Name	MTX
AP.13.4	productcompanyname	Product Company Name	PharmaX
AP.13.5	productstrength	Product Strength Name	50 mg
AP.13.6	productform	Product Form Name	tablets

3.3. Product Company Name

EXAMPLE 16

The SmPC of a medicinal product authorised in Italy states the following information:

1. DENOMINAZIONE DEL MEDICINALE

Ibuprofene Extra Forte 400 mg Capsule liquide

7. TITOLARE DELL'AUTORIZZAZIONE ALL'IMMISSIONE IN COMMERCIO

PharmaXYZ S.r.l.

Since the medicinal product name stated in section 1 of the SmPC does not contain any MAH name, the name of the MAH as indicated in section 7 of the SmPC must be entered in the "Product Company Name" (without the description of the MAH's legal status):

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements EVWEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Ibuprofene Extra Forte 400 mg Capsule liquide
AP.13.2	productshortname	Product Short Name	
AP.13.3	productgenericname	Product INN/Common Name	Ibuprofene Extra Forte
AP.13.4	productcompanyname	Product Company Name	PharmaXYZ
AP.13.5	productstrength	Product Strength	400 mg

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements EVWEB name	Splitting of the full presentation name of the medicinal product
		Name	
AP.13.6	productform	Product Form Name	Capsule liquide

EXAMPLE 17

The SmPC of a medicinal product authorised in Italy states the following information:

1. DENOMINAZIONE DEL MEDICINALE

Paracetamolo XPharm compresse effervescenti

7. TITOLARE DELL'AUTORIZZAZIONE ALL'IMMISSIONE IN COMMERCIO

PharmaABC S.p.A.

The Company name stated in section 1 of the SmPC and the MAH name stated in section 7 of the SmPC are not identical.

Since the medicinal product name stated in section 1 of the SmPC does not contain any brand name and the company name is present, the company name as stated in section 1 of the SmPC must be entered in the "Product Company Name" data element.

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Paracetamolo XPharm compresse effervescenti
AP.13.2	productshortname	Product Short Name	
AP.13.3	productgenericname	Product INN/Common Name	Paracetamolo
AP.13.4	productcompanyname	Product Company Name	XPharm
AP.13.5	productstrength	Product Strength Name	
AP.13.6	productform	Product Form Name	compresse effervescenti

EXAMPLE 18

The SmPC of a medicinal product authorised in Spain states the following information:

1. NOMBRE DEL MEDICAMENTO

Ácido Acetilsalicilico 150 mg Comprimidos Gastrorresistentes

7. TITULAR DE LA AUTORIZACIÓN DE COMERCIALIZACIÓN

PharmaDFG S.r.l.

Since the medicinal product name stated in section 1 of the SmPC does not contain any company name, the name of the MAH as indicated in section 7 of the SmPC must be entered in the "Product Company Name" data element (without the description of the MAH's legal status):

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Acido Acetilsalicilico 150 mg Comprimidos Gastrorresistentes
AP.13.2	productshortname	Product Short Name	
AP.13.3	productgenericname	Product INN/Common Name	Ácido Acetilsalicilico
AP.13.4	productcompanyname	Product Company Name	PharmaDFG
AP.13.5	productstrength	Product Strength Name	150 mg
AP.13.6	productform	Product Form Name	Comprimidos Gastrorresistentes

3.4. Product Strength Name

EXAMPLE 19

The SmPC of a medicinal product authorised in the UK states the following information:

1. Name of the medicinal product

VaccineABC 3 microgram/strain suspension for injection

Influenza vaccine (split virion, inactivated)

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	VaccineABC 3 microgram/strain suspension for injection Influenza vaccine (split virion, inactivated)
AP.13.2	productshortname	Product Short Name	VaccineABC
AP.13.3	productgenericname	Product INN/Common Name	Influenza vaccine (split virion, inactivated)
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	3 microgram/strain
AP.13.6	productform	Product Form Name	suspension for injection

EXAMPLE 20

The SmPC of a medicinal product authorised in the UK states the following information:

1. Name of the medicinal product

Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) KSG Biologics, suspension and emulsion for emulsion for injection

Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)

If the same INN/Common name is stated multiple times in the name stated in section 1 of the SmPC, it must only be entered once during the process of the splitting of the full presentation of the name:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) KSG Biologics, suspension and emulsion for emulsion for injection Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)
AP.13.2	productshortname	Product Short Name	
AP.13.3	productgenericname	Product INN/Common Name	Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)
AP.13.4	productcompanyname	Product Company Name	KSG Biologics
AP.13.5	productstrength	Product Strength Name	
AP.13.6	productform	Product Form Name	suspension and emulsion for emulsion for injection

EXAMPLE 21

The SmPC of a medicinal product authorised in the UK states the following information:

1. Name of the medicinal product

VaccineDEF 2013/2014 influenza virus vaccine suspension

Since the strength is not included in the medicinal product name stated in section 1 of the SmPC and a vaccine season (i.e. 2013/2014) is included, the field "Product Strength Name" (AP.13.5) must specify the vaccine season:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	VaccineDEF 2013/2014 influenza virus vaccine suspension

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.2	productshortname	Product Short Name	VaccineDEF
AP.13.3	productgenericname	Product INN/Common Name	influenza virus vaccine
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	2013/2014
AP.13.6	productform	Product Form Name	suspension

EXAMPLE 22

The SmPC of a medicinal product authorised in France states the following information:

1. DENOMINATION DU MEDICAMENT

Vaccin inactivé de la bronchite infectieuse aviaire 2013/2014 5mcg/ml Suspension injectable

7. TITULAIRE DE L'AUTORISATION DE MISE SUR LE MARCHE

Pharma Y

Since the strength as well as the vaccine season (e.g. 2013/2014) are included in the medicinal product name stated in section 1 of the SmPC, the field "Product Strength Name" (AP.13.5) must specify the strength only (without including the vaccine season).

Since no company name is included in section 1 of the SmPC, the name of the MAH as stated in section 7 of the SmPC must be entered in the "Product Company Name" data element (AP.13.4):

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Vaccin inactivé de la bronchite infectieuse aviaire 2013/2014 5mcg/ml Suspension injectable
AP.13.2	productshortname	Product Short Name	
AP.13.3	productgenericname	Product INN/Common Name	Vaccin inactivé de la bronchite infectieuse aviaire
AP.13.4	productcompanyname	Product Company Name	Pharma Y
AP.13.5	productstrength	Product Strength Name	5mcg/ml
AP.13.6	productform	Product Form Name	Suspension injectable

EXAMPLE 23

The SmPC of a medicinal product authorised in France states the following information:

1. DENOMINATION DU MEDICAMENT

Vaccin inactivé de la bronchite infectieuse aviaire Suspension injectable

7. TITULAIRE DE L'AUTORISATION DE MISE SUR LE MARCHE

Pharma Y

Since no strength and no vaccine season are included in the medicinal product name stated in section 1 of the SmPC, the field "Product Strength Name" (AP.13.5) must be left blank.

Since no company name is included in section 1 of the SmPC, the name of the MAH as stated in section 7 of the SmPC must be entered in the "Product Company Name" data element (AP.13.4):

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Vaccin inactivé de la bronchite infectieuse aviaire Suspension injectable
AP.13.2	productshortname	Product Short Name	
AP.13.3	productgenericname	Product INN/Common Name	Vaccin inactivé de la bronchite infectieuse aviaire
AP.13.4	productcompanyname	Product Company Name	Pharma Y
AP.13.5	productstrength	Product Strength Name	
AP.13.6	productform	Product Form Name	Suspension injectable

EXAMPLE 24

The SmPC of a medicinal product authorised in France states the following information:

1. DENOMINATION DU MEDICAMENT

Vaccin inactivé de la bronchite infectieuse aviaire Suspension injectable

(2013/2014)

7. TITULAIRE DE L'AUTORISATION DE MISE SUR LE MARCHE

Pharma K

Since the vaccine season (i.e. 2013/2014) is not part of the Full Presentation Name (AP.13.1) even if the season is stated in brackets in section 1 of the SmPC, it is not to be specified in the "Product Strength Name" field (AP.13.5).

Since no company name is included section 1 of the SmPC, the name of the MAH as stated in section 7 of the SmPC must be entered in the "Product Company Name" data element (AP.13.4):

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Vaccin inactivé de la bronchite infectieuse aviaire Suspension injectable
AP.13.2	productshortname	Product Short Name	
AP.13.3	productgenericname	Product INN/Common Name	Vaccin inactivé de la bronchite infectieuse aviaire
AP.13.4	productcompanyname	Product Company Name	Pharma K
AP.13.5	productstrength	Product Strength Name	
AP.13.6	productform	Product Form Name	Suspension injectable

3.5. Product Form Name

NEW: EXAMPLE 25

The SmPC of a medicinal product authorised in UK states the following information:

1. Name of the medicinal product

Peritoneal Dialysis Solution PHARMAX

3. Pharmaceutical form

Peritoneal Dialysis Solution

Since the term "Peritoneal Dialysis Solution" is already used to populate the "Product INN/Common Name" field and no duplication of information should take place when splitting the full presentation name; "Product Form Name" (AP.13.6) should be left blank:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	Peritoneal Dialysis Solution PHARMAX
AP.13.2	productshortname	Product Short Name	
AP.13.3	productgenericname	Product INN/Common Name	Peritoneal Dialysis Solution
AP.13.4	productcompanyname	Product Company Name	PHARMAX
AP.13.5	productstrength	Product Strength Name	
AP.13.6	productform	Product Form Name	

NEW: EXAMPLE 26

The SmPC of a medicinal product authorised in Germany states the following information:

1. BEZEICHNUNG DER ARZNEIMITTEL

PRODEMAZ® LÖSUNG 1% LÖSUNG ZUR ANWENDUNG AUF DER HAUT

Two references to the pharmaceutical form of the product are present in the full presentation name; since the first ("LÖSUNG") precedes the strength of the product, it can be assumed the MAH uses this designation to characterize a specific formulation of their product, which should therefore be captured together with the product short name, as follows:

Art 57 data elements ref. code	Art 57 data elements ref. name	Art 57 data elements ref. EV WEB name	Splitting of the full presentation name of the medicinal product
AP.13.1	productname	Full Presentation Name	PRODEMAZ® LÖSUNG 1% LÖSUNG ZUR ANWENDUNG AUF DER HAUT
AP.13.2	productshortname	Product Short Name	PRODEMAZ LÖSUNG
AP.13.3	productgenericname	Product INN/Common Name	
AP.13.4	productcompanyname	Product Company Name	
AP.13.5	productstrength	Product Strength Name	1%
AP.13.6	productform	Product Form Name	LÖSUNG ZUR ANWENDUNG AUF DER HAUT

4. Annex I: Reference documents for definition and principles

1. Detailed guidance on the electronic submission of information on medicinal products for human use by marketing-authorisation holders to the European Medicines Agency in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004: Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance.
2. Article 1(20) of the Directive 2001/83/EC
3. Notice to Applicants: a Guideline on SmPC Revision 2 (September 2009)
4. Notice to Applicants: Annex I of the Summary of Product Characteristics (Version 9, 03/2013)
5. ISO 2012:11615 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information