| **FHIR Resource and Data Elements** | **Description** |
| --- | --- |
| **Bundle** | |
| id | System generated UUID used uniquely identify this resource |
| Version | Incremental version number for this ePI document (e.g., 1, 2, 3, 4, 5) |
| Date of last update | Date of last revision for this version of the authorized ePI document. |
| Identifier | Business assigned identifier to uniquely identify this version of the ePI |
| Type | Defines the type of Bundle. For ePI, the type must always be “Document”. |
| Time Stamp | Original date of approval for this ePI. This date remains the same across all versions of the ePI. |

| **FHIR Resource and Data Elements** | **Description** |
| --- | --- |
| **Composition** | |
| id | System generated UUID used uniquely identify this resource |
| Language | The language of this ePI’s narrative text. ISO two letter language code. |
| Text | Narrative description of this ePI |
| Version | Incremental version number for this Composition (e.g., 1, 2, 3, 4, 5) |
| **contained** | Images are included as contained binary resources. One contained element per image. |
| **Binary** | Binary resource for encoded images. |
| Id value | Unique identifier for this image. |
| Content Type value | File type for the binary content (e.g., SVG, PNG, JPEG). |
| Data | Actual base64 encoded content for the image. |
| **Extension** | This extension is an implementation work around to avoid unnecessary validator errors, and expected to be drop in future profile releases, and is used to ensure that images used in ePI sections are properly referenced in the FHIR resource. |
| **Value Reference** |  |
| Reference value | The use of the imageReference extension avoids warning and error messages in common FHIR validators. |
| identifier | Unique business identifier for this version of the Composition. |
| status | Status of this resource (e.g., Active, retired). |
| **Type** | The type of ePI document template (e.g., healthcare professional, patient information, instruction for use, pack label) |
| **coding** |  |
| system | Reference to the terminology system where document type codes and display values are stored. |
| code | Health authority assigned code for this document type. |
| display | Human readable text for this document type. |
| Subject | Cross-reference to the Medicinal Product Definition(s) associated with this ePI. |
| Date | Date of last revision for this version of the authorized EPI document. |
| Author | Cross-reference to the Organization resource representing the Market Authorization Holder |
| Title | Simple title for this ePI document. |
| **Section** |  |
| Title | Section heading defined by the market authorization holder. |
| **coding** | Section heading defined by the health authority. Cannot be changed by the market authorization holder |
| system | Reference to the terminology system where section heading codes and display values are stored. |
| code | Health authority assigned code for this section heading. |
| display | Human readable text for this section. |
| **text** | Narrative text for this section (e.g., paragraphs, bulleted lists, tables). |
| Status value | The status of the narrative (i.e., always “generated”). |
| div xmlns | Defines a division or a section of the XHTML narrative. |
| paragraph | Paragraph text |
| Bulleted list | Ordered or unordered bulleted list |
| Table | Tables |

| **FHIR Resource and Data Elements** | **Description** |
| --- | --- |
| **Organization** | |
| id | System generated UUID used uniquely identify this resource |
| identifier | Business assigned unique identifier(s) for this organization. E.g., health authority assigned identifier |
| Active | Whether this Organization Resource is still in active use. |
| Type | Type of organization. E.g., marketing authorization holder, manufacturer. |
| Name | Legal name of the organization |
| alias | Alternative name(s) for this organization. E.g., if Legal name is in Thai language, the alias could be the English name. |
| description | Narrative description of this organization |
| **contact** | Phone, email, website details for this organization related to the ePI |
| telecom: phone | Organization’s phone number(s) for |
| telecom: email | Organization’s email address for |
| telecom: url | Organization’s websites related to |
| **Address** | Organizations address |
| type | Defines whether this is a mailing address (i.e., postal); or a physical address that can be visited (i.e., physical); or both. |
| text | Full address |
| line | Street name and number |
| City | City in which the organization is physically located |
| state | State, province, or prefecture in which the organization is physically located |
| postal code | Postal code for the area |
| Country | ISO two letter country code for the country in which the organization is located. |

| **FHIR Resource and Data Elements** | **Description** |
| --- | --- |
| **Medicinal Product Definition** | |
| id | System generated UUID used uniquely identify this resource |
| identifier | Business assigned unique identifier(s) for this organization. E.g., product license number or market authorization number for the product. |
| subject | Cross-reference to the Medicinal Product Definition(s) associated with this ePI. |
| type | Type of authorization |
| description | Narrative description of what the authorization is for. |
| region | Jurisdiction in which the authorization was granted (i.e., ISO two letter country code) |
| status | Status of this resource (e.g., Active, retired). |
| statusDate | The date the status was assigned |
| holder | Cross-reference to the Organization Resource related to the Market Authorization Holder. |
| **Route** |  |
| **coding** |  |
| system | Reference to the terminology system where codes and display values are stored. |
| code | Code for the route of administration |
| display | Display text for the route of administration |
| Version | Incremental version number for this ePI document (e.g., 1, 2, 3, 4, 5) |
| Status | Status of this resource (e.g., Active, retired). |
| Status date | The date the status was assigned |
| **Legal Status of Supply** | Product category or product type |
| **coding** |  |
| system | Reference to the terminology system where product category/type codes and display values are stored. |
| code | Code for the product type/category |
| display | Display text for the product type/category |
| Name |  |
| Product name | Full name of the medicinal product |
| **Part** | A fragment of the product name |
| Part | Editable text for the proprietary name |
| Type |  |
| **coding** |  |
| system | Reference to the terminology system where codes and display values are stored. |
| code | Code for the proprietary name |
| display | Display text for the proprietary name |
| **Part** | A fragment of the product name |
| Part | Editable text for the non-proprietary name |
| Type | Type of product name part |
| coding |  |
| system | Reference to the terminology system where codes and display values are stored. |
| code | Code for the Non-proprietary name part |
| display | Display text for the Non-proprietary name part |
| **Part** | Editable text for the strength part |
| Type | Type of product name part |
| coding |  |
| system | Reference to the terminology system where codes and display values are stored. |
| code | Code for the strength part |
| display | Display text for the strength part |
| **Part** | Editable text for the pharmaceutical dose form |
| Type | Type of product name part |
| coding |  |
| system | Reference to the terminology system where codes and display values are stored. |
| code | Code for the pharmaceutical dose form |
| display | Display text for the pharmaceutical dose form part |
| Usage | Country and language |
| **Country** | Country code for where this name applies |
| coding |  |
| system | Reference to the terminology system where country codes and display values are stored. |
| code | Code for the ISO two-letter country |
| display | Display name for the country |
| **language** | Language code for this name |
| **coding** |  |
| system | Reference to the terminology system where language codes and display values are stored. |
| code | ISO two-letter language code |
| display | Display name for the language |

| **FHIR Resource and Data Elements** | **Description** |
| --- | --- |
| **Manufactured Item Definition** | |
| id | System generated UUID used uniquely identify this resource |
| identifier | Business assigned unique identifier(s) for this Manufactured Item. |
| status | Status of this resource (e.g., Active, retired). |
| **Manufactured dose form** | Dose form of the product in its primary packaging |
| **coding** |  |
| system | Reference to the terminology system where pharmaceutical dose form codes and display values are stored. |
| code | Code for the pharmaceutical dose form |
| display | Display text for the pharmaceutical dose form |
| **Unit of presentation** | Unit of presentation for the product |
| **coding** |  |
| system | Reference to the terminology system where unit of presentation codes and display values are stored. |
| code | Code for the unit of presentation |
| display | Display text for the unit of presentation |
| manufacturer | Cross-reference to the Organization resource for the manufacturer or market authorization holder. |
| **properties** | Physical attributes of the medicinal product |
| colour | Colour of the medicinal product |
| flavour | Flavour of the medicinal product |
| score | Describes whether the medicinal product is scored |
| shape | Describes the shape of the medicinal product |
| surface form | Describes whether the medicinal product’s surface is convex or concave |
| size | Describes the dimensions of the medicinal product |
| image | Cross-reference to the Binary resource for the encoded version of the image |
| imprint | Describes whether the medicinal product has an imprint |
| text | Narrative description of the medicinal product |

| **FHIR Resource and Data Elements** | **Description** |
| --- | --- |
| **Ingredient** | |
| id | System generated UUID used uniquely identify this resource |
| identifier | Business assigned unique identifier(s) for this ingredient. |
| status | Status of this resource (e.g., Active, retired). |
| for | Cross-reference to the Manufactured Item this ingredient is associated with. |
| role | Whether the ingredient is active or inactive |
| allergenic indicator | Flags if the ingredient is a known allergen |
| **substance** | The substance that comprises this ingredient |
| system | Reference to the terminology system substance codes and display values are stored. |
| code | Code for this substance. |
| display | Human readable text for this substance. |
| **strength (Presentation - quantity)** | The presentation quantity of the substance expressed per unit of presentation |
| presentationQuantity |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| **strength (Presentation - ratio)** | The presentation quantity of the substance expressed as a ratio |
| numerator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| denominator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| **strength (Presentation - RatioRange)** | The presentation quantity of the substance expressed as a range |
| lowNumerator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| highNumerator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| denominator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| **strength (Concentration - quantity)** | The concentrationquantity of the substance expressed per unit of presentation |
| presentationQuantity |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| **strength (Concentration - ratio)** | The concentrationquantity of the substance expressed as a ratio |
| numerator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| denominator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| **strength (Concentration - RatioRange)** | The concentrationquantity of the substance expressed as a range |
| lowNumerator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| highNumerator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| denominator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| basis |  |
| referenceStrength | Describes moiety as the quantity of substance. |
| substance | Cross-reference to the substance identifier |
| strength | Quantity of substance |
| **strengthQuanitity** | The quantity of the substance expressed per unit of measure. |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| **strengthRatio** | The quantity of the substance expressed as a ratio. |
| numerator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| denominator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| **strengthRatioRange** | The quantity of the substance expressed as a range. |
| lowNumerator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| highNumerator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |
| denominator |  |
| value | Numeric quantity |
| unit | Unit of measure |
| system | Reference to the terminology system where unit of measure codes and display values are stored. |
| code | Code for this unit |

| **FHIR Resource and Data Elements** | **Description** |
| --- | --- |
| **Substance Definition** | |
| id | System generated UUID used uniquely identify this resource |
| identifier | Business assigned unique identifier(s) for this substance. |
| version | Incremental version number for this ePI document (e.g., 1, 2, 3, 4, 5) |
| status | Status of this resource (e.g., Active, retired). |
| name | Human readable name for this substance. |