Master Data Exchange Quick Reference

European Union

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Required Fields

EU Product Master Data

The following tables list the **required** fields in Product Master Data for compliance regulations.

Product Information Fields

Field	Description	Values
Data Status	Whether the product data is active within TraceLink. **CSV Element Header:** `DataStatus` ⚠ Required for all countries.	• Active – The data can be used in messages and UI functions, and TraceLink pulls the data when necessary. • Inactive – The data cannot be pulled for other functions within TraceLink.
Item Status	The product's commercial status. **CSV Element Header:** `ItemStatus` ⚠ Required for all countries.	• Released – The company approved the product for commercial release. • Alternate items available – The company has alternate items that can take the place of this product. • Phase out – The company phased out this product from production and sale. • Items no longer stocked – The company does not currently stock this product. • Withdrawn – The company removed this product from the market. ⚠ When the product has an **Export From Country** of India, the only **Item Status** options are Released, Items no longer stocked, and Withdrawn.

Item Code Fields

Field	Description	Values
Item Code Type	The unique item code that identifies this product. Products require an item code for every target market. Each item code type can only be used once for each product, except for Internal Material Number. ⚠ At least one Item Code required for all countries. **CSV Element Header:** `ItemCodeType`	For more information, see Identifier and Item Code Types in the *Master Data Exchange Online Help*.
Item Code Value	The value of the **Item Code Type**. The value must be unique within the **Item Code Type**, and special characters (e.g. -, ., /. \) are removed from this value. **CSV Element Header:** `ItemCodeValue`	For more information, see Identifier and Item Code Types in the *Master Data Exchange Online Help*.
Primary Item Code	The radio button indicates the primary item code used by this company. TraceLink uses the primary item code to identify the correct product when the user updates the product master data by importing a CSV file or with an asynchronous message. **CSV Element Header:** `ItemCodePrimary` ⚠ The first Item Code in the CSV must be the **Primary Item Code**.	n/a

Target Markets Fields

Field Name	Description	Values
Country Market Code	Two-letter ISO 3166-1alpha-2:1997 Country Code of the Target Market's country. ⚠ Required for all countries. **CSV Element Header:** `CountryMarket`	n/a
Product Type	Type of product. Traceability regulations differ depending on the product type (e.g. over-the-counter drugs do not fall under DSCSA regulations in the US). For informational purposes only, not compliance reporting.	• Bulk Pharmaceutical – A product that is the main active ingredient in one or more pharmaceutical formulas (e.g. antibiotics). • Derivative Product – A product derived from another chemical compound.

Field Name	Description	Values
	CSV Element Header: `CountryMarketProductType`	• Food Supplement – A medicine available over the counter that is used for health and nutritional benefits. • Medical Device – A device developed and used for a medical purpose. • Nutritional Product – A specific class of over-the-counter product use for health and nutrition benefit. • OTC Drug – A medicine available over the counter. • Prescription Drug – A medicine available by prescription only.
Point of Dispense Verification	Whether or not the product requires verification at or just prior to the dispensation to a patient. **CSV Element Header:** `CountryMarketPointofDispenseVerification`	• Not Required – Verification is not required at or just prior to dispensation to a patient. • Required – Verification is required at or just prior to dispensation to a patient.
PCID	Medicinal Product Package Identifier (PCID) determines the EU Hub's Article 57 Code on Master Data Compliance Reports. ⓘ For more information, see the *EU Compliance Online Help*. **CSV Element Header:** `CountryMarketPCID`	n/a
MAH ID	The company or location identifier of the MAH, which must exist in Company or Partner Master Data. Required if MAH is selected in the **Manufactured By** field. **CSV Element Header:** `CountryMarketMAHId` and `CountryMarketMAHIDType`	For more information, see Identifier and Item Code Types in the *Master Data Exchange Online Help*.
Distribution Partner ID(s)	The trade partner companies or internal locations that the MAH uses to distribute the product in the Target Market (e.g. 3PL). This company must exist in Partner Master Data or as a location in Company Master Data. ⓘ Limit of 10 identifiers in the user interface and 100 identifiers in the CSV import per target market. **CSV Element Header:** `DistributionPartnerID` and	For more information, see Identifier and Item Code Types in the *Master Data Exchange Online Help*.

Field Name	Description	Values
	`DistributionPartnerType`	

Item Information Fields

Field	Description	Values
Language Code	Language for the item information. ⓘ Must include: • English for EU FMD compliant countries. ⚠ Required for all countries. **CSV Element Header:** `ItemInfoLanguageCode`	n/a
Product Description	Typically includes the product name, dosage, form, and the number of doses. ⚠ Required for all countries. **CSV Element Header:** `ItemInfoProductDescription`	n/a
Product Name	The name of the product. ⚠ Required for all countries. **CSV Element Header:** `ItemInfoDrugName`	n/a
Generic Name	The chemical or non-proprietary name of the product.	n/a

Field	Description	Values
	⚠ Required if: • An EU FMD compliant country is a Target Market and the **Language Code** is English. **CSV Element Header:** `ItemInfoGenericName`	
Manufacturer	The name of the manufacturer or re-packager as it appears on the product label. ⚠ Required for all countries. **CSV Element Header:** `ItemInfoManufacturer`	n/a
Strength	The strength of the product (e.g. 100 mg). ⚠ Required if: • An EU FMD compliant country is a Target Market and the **Language Code** is English. **CSV Element Header:** `ItemInfoStrength`	n/a
EMVS Dosage Form	The form the product is dispensed in according to the EU's standard set of values. ⚠ Required if an EU FMD compliant country is a Target Market and the **Language Code** is English. **CSV Element Header:** `ItemInfoEMVSDosageForm`	n/a
Package Size / Spec	The number of individual doses in the pack. ⚠ Required if:	n/a

Field	Description	Values
	• An EU FMD compliant country is a Target Market and the **Language Code** is English. **CSV Element Header:** `ItemInfoPackageSize`	
EMVS Pack Code	The way the product is packaged to be sold according to the EU's standard set of values. ⚠ Required if an EU FMD compliant country is a Target Market and the **Language Code** is English. **CSV Element Header:** `ItemInfoEMVSPackCode`	n/a

Packaging Information Fields

ⓘ Only serialized functions require **Packaging Information** fields, not lot-level.

Field	Description	Values
Packaging Code Type	The serial numbers for the product are generated according to the packaging code type. If necessary, define a packaging code for each packaging unit of measure that needs to be tracked. ⚠ Required if any other **Packaging Information** fields are entered. **CSV Element Header:** `PackagingCodeType`	• CN-ResCode – This packaging code type is specific to China (must be 5 digits). • GTIN-14 – (Global Trade Item Number) This packaging code type is accepted in any country (must be 14 digits). • NTIN – (National Trade Item Number) This packaging code type is specific to a single country (must be 14 digits).
Packaging Code	The unique value for the **Packaging Code Type**. See **Packaging Code Type** above for the field requirements. If the **Packaging Code Type** is CN-ResCode, fill out **Rescode** instead of **Packaging Code**.	n/a

Field	Description	Values
	⚠ Required if a **Packaging Code Type** is selected. **CSV Element Header:** `PackagingCode`	
Packaging UOM	(Packaging Unit of Measure) Determines the level of the packaging hierarchy for this packaging code. If multiple packaging codes are defined, serial numbers can be generated for each level of the packaging hierarchy. ⚠ Required if a **Packaging Code Type** is selected. **CSV Element Header:** `PackagingUOM`	• Primary – The level of packaging that physically touches the product, i.e. blister packs (not available for CN-ResCodes). • Each – The smallest salable unit of the product. • Inner Pack/Bundle – A grouping of eaches. • Case/Shipper – A grouping of inner packs/bundles or a grouping of eaches if the packaging hierarchy does not include inner packs/bundles. • Pallet – The level of packaging with cases grouped together on a pallet (not available for CN-ResCodes). • None – Available only for CN-Rescodes.
GS1 Company Prefix	Prefix included in the packaging code, assigned by the GS1 organization. ⚠ Required if the **Packaging Code Type** is GTIN-14. **CSV Element Header:** `PackagingGS1CompanyPrefix`	n/a
Data Status	Whether the packaging information data is active or inactive within TraceLink. ⚠ Required if a **Packaging Code Type** is selected. **CSV Element Header:** `PackagingDataStatus`	• Active – The data can be used in messages and UI functions, and TraceLink pulls the data when necessary. • Inactive – The data cannot be pulled for other functions within TraceLink.