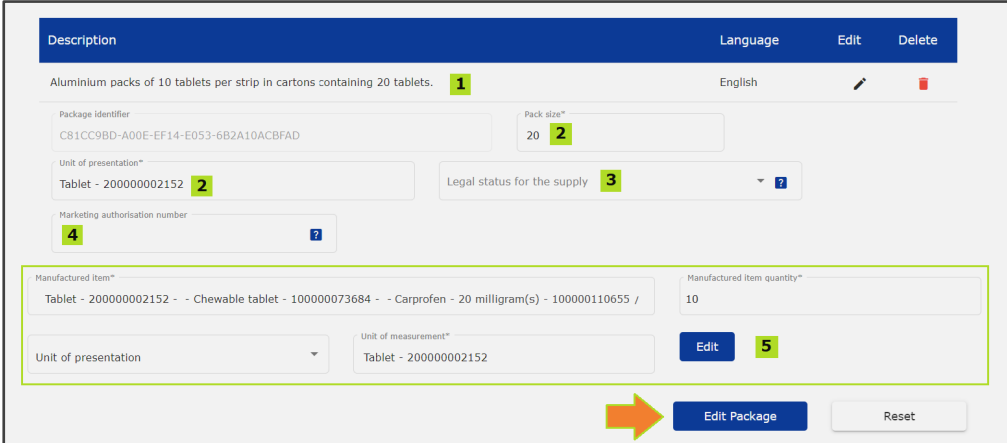


- ▶ This document is intended to **provide guidance to Competent Authorities (CAs) on how to update package information for their products to prevent potential negative impacts on other users**, such as Marketing Authorisation Holders (MAHs) or other systems that rely on this information for their purposes, **in case the update is performed incorrectly**.
- ▶ **The maintenance of correct package information by CAs is paramount for MAHs** as provisioning for both Volume of sales and Availability status is done at package level. To this end, the first step that MAHs shall do is to map the identifiers of the packages in their systems to the identifiers in UPD. Therefore, **it is essential that the package identifiers remain stable over time**.
- ▶ Since UPD went live, **the mapping of packages based on the identifiers has been a challenge for MAHs** who have seen on numerous occasions how identifiers have changed as a result of incorrect package updates made by the CAs.

## When a package should be updated?

CAs shall use the **'Edit Package'** option if any of the below attributes need to be updated **1)** having approved a Variation requiring or not requiring assessment or **2)** having to correct incorrect data:

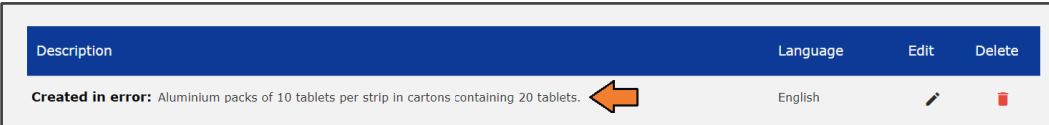
1. Package information
2. Pack size
3. Legal status for the supply – when provided at package level
4. Marketing authorisation number - when provided at package level
5. Manufactured item information



The screenshot shows the 'Edit Package' interface in the UPD system. The interface is divided into several sections. At the top, there is a 'Description' field with the text 'Aluminium packs of 10 tablets per strip in cartons containing 20 tablets.' and a 'Language' dropdown set to 'English'. Below this are fields for 'Package identifier' (C81CC9BD-A00E-EF14-E053-6B2A10ACBFAD), 'Pack size\*' (20), 'Unit of presentation\*' (Tablet - 200000002152), and 'Marketing authorisation number' (4). There is also a 'Legal status for the supply' dropdown. The 'Manufactured item' section is highlighted with a green box and contains a table with columns for 'Manufactured item' and 'Manufactured item quantity'. The 'Unit of presentation' and 'Unit of measurement' are also visible. A blue arrow points to the 'Edit Package' button at the bottom right.

## When a package should be deleted?

CAs shall use the **'Delete Package'** option if **1)** a package needs to be deleted as a result of a Variation requiring or not requiring assessment or **2)** it has been created in error. **In this latter case, we kindly ask you, prior to deleting the package, edit its description and include at the beginning 'Created in error:'** as illustrated in the following example:



The screenshot shows the 'Delete Package' interface. The 'Delete' button is highlighted in red. The description field contains the text 'Created in error: Aluminium packs of 10 tablets per strip in cartons containing 20 tablets.' and a blue arrow points to this text.

**Kindly refrain from deleting and recreating packages when having to performed and Edit Package action. Doing so will alter the identifiers essential for MAHs in their mapping process. When you have doubts, please liaise first with the MAH.**

**If you encounter any issue while performing updates, please contact EMA for support.**