# Standard Text for Use in the Combination Product / Override Table

## Objective

To be able to describe in a standard way to facilitate filtering and querying, why an entry is present in the Combination Product / Override Table to provide support for the ongoing maintenance of this table for CCDD Generation.

## Entry type

This column in the Combination Product / Override Table has a standard text that gives the reason for the product being present in the Table – as opposed to having its NTP and MP generated directly from DPD data in the “normal” way. The standard text that should be used in this column is shown in the table below.

If a row has more than one reason for being present, the standard text should be separated by an ampersand symbol (e.g. DF - CS & Str – Unit).

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| **Standard Text** | **Full Text** | **Description and Scope** |
| MAI Comp | Multiple Active Ingredient Component Combination Product | More than one of the components in the combination product contains at least one active ingredient substance; for three or more components, one may contain only inactive/placebo (e.g. in a tri-phasic COC with 7 days placebo) |
| Inact Comp | Inactive Ingredient Component Combination Product | Only one of the components in the combination product contains at least one active ingredient substance; the other(s) contain inactive substances such as lactose (acting as placebo) |
| Kit | Kit with diluent | Only one of the components in the combination product contains at least one active ingredient substance; the other(s) is diluent for the (main) component |
| Comp Kit | Complex Kit | A combination product with complex components (not simple diluent, but inert substances) e.g. gas to generate a foam product |
| Salt + Strength | Override: Salt and Strength Issue | Enalapril & combinations; telmisartan & combinations; DPD description of PAI/BoSS and strength varies; override used to create single set of NTPs |
| Ingredient | Override: Ingredient Substance Issue | One of the active ingredient substances is described differently in DPD than all the rest - usually a salt mismatch between BoSS and precise active ingredient substance |
| Dose form | Override: Dose form Issue | The dose form in the DPD does not fit CCDD Guidelines and is not transformable; excludes specifically oral liquid/oral solution or syrup and cutaneous liquid/cutaneous solution (see below) |
| DF - OS | Override: Dose form Issue specifically oral solution | The dose form in the DPD is oral liquid but the NTP dose form should be oral solution |
| DF - CS | Override: Dose form Issue specifically cutaneous solution | The dose form in the DPD is cutaneous liquid but the NTP dose form should be cutaneous solution |
| DF - POS | Override: Dose form Issue specifically powder for oral solution | The dose form in the DPD is powder but the NTP dose form should be powder for oral solution |
| DF - Syr | Override: Dose form Issue specifically syrup | The dose form in the DPD is oral liquid but the NTP dose form should be syrup to match other NTPs (rather than cutaneous solution which is a parent concept) |
| Str - Unit | Override: Strength units issue | The strength units of measure used in the DPD do not match CCDD Guidelines and/or do not match other products to give a single NTP (e.g. 0.0nn mg rather than nn mcg or nn mg/mL rather than nn%) |
| Str - Desc | Override: Strength description issue | The strength description used in the DPD do not match CCDD Guidelines and/or does not match other products to give a single NTP (e.g. patch rate not stated, per 5mL etc.) |
| Str - Round | Override: Strength rounding issue | The strength description used in the DPD for one or more products that should form an NTP group is a mismatch by a small and clinically insignificant amount, usually linked to decimal rounding (e.g. 17.5 rather than 17.6) |

## Change Plan

This column in the Combination Product / Override Table has a standard text that describes any pending/outstanding action for the DPD that would address the issue such that the product would correctly generate its NTP and MP directly from DPD data in the “normal” way.

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| **Standard Text** | **Full Text** | **Description and Scope** |
| Unlikely | DPD Data change is unlikely | The necessary change to DPD data is unlikely to happen  There may be various reasons for this: e.g. the product is old and rarely used and the effort to affect a change too great; the data is not incorrect, just does not match to other products (e.g. a mg/mL strength rather than a % strength) |
| DPD review | DPD reviewing change request | A change to DPD data has been requested but a decision is yet to be made. The request may have been sent to the DIN Issuance unit or review bureau |
| DPD change pending | A change in DPD data is pending | A change to DPD data is expected but requires additional steps (e.g. regulatory processes) before the data in DPD can be changed. |
| Registry | Change pending in registry | The necessary change required to generate according to CCDD guidance will not happen in DPD and therefore will require a change of data field (s) in the registry |