Summary of Envelope Requirements

The following table provides a high-level summary of the requirements of the Envelope elements.

Table 1 Summary of Envelope Element Requirements

Envelope Element	Source	Constraints	Special characters allowed?
Application Type	Coded list	N.A.	No
SG eCTD ID	HSA eCTD Portal	e########sg####	No
Application Number	PRISM, HSA-issued DMF number	eΦΦΦΦΦΦΦΨ or "e015:" followed by one or more digits	None apart from ":"
INN	Sponsor	Lower-case letters only No empty values	Yes
Product Type	Coded list	N.A.	No
DMF Number	HSA-issued	"015:" followed by one or more digits	None apart from ":"
PMF Number	HSA-issued	"005:" followed by one or more digits	None apart from ":"
Proprietary Name	Sponsor	free text (alpha numeric) No empty values	Typical: dash, en-dash, comma, forward slash, backslash
SIN Number	PRISM	SIN#####Ψ 'SIN' and Ψ: Upper-case letters only	No
Submission Type	Coded list	N.A.	No
Submission Number	PRISM number, PV, DMF, Other	ΦΦΦΦΦΦΦΨ or "PV" or "DMF" or "Other"	

Sequence Type	Coded list	N.A.	No
Sequence Description	Sponsor	free text, alpha-numeric	Typical: dash, en-dash, comma, colon, forward slash, backslash
Sequence Date	Sponsor	YYYY-MM-DD	No
Sequence Number	Sponsor	####	No
Related Sequence Number	Sponsor	####	No
Contact Type	Coded list		No
Contact Name	Sponsor	upper or lower case	Typical: period dash
Contact Email	Sponsor	name@company.cat	Typical: @ period dash underscore
Contact Phone	Sponsor	+CC AC Number CC may be 1,2,3 digits AC may have () Number can have dashes or periods	Typical: + dash period open/close parentheses

Footnote: #: digit only; Φ: digit or alphabet; Ψ: alphabet only

Table 2 Submission Number Requirement by Submission Type

Sub Type	Description	Sub. Number Type	Occurrence
sub-type-1	NDA	PRISM	Multiple
sub-type-2	NDA-V	PRISM	Multiple
sub-type-3	GDA	PRISM	Multiple
sub-type-4	GDA-V/CECA	PRISM	Multiple
sub-type-5	MAV1	PRISM	Multiple
sub-type-6	MAV1-V	PRISM	Multiple
sub-type-7	MAV2	PRISM	Multiple
sub-type-8	MIV1-PI	PRISM	Multiple
sub-type-9	MIV1-PI-V	PRISM	Multiple
sub-type-10	MIV1-CMC	PRISM	Multiple
sub-type-11	MIV1-CMC-V	PRISM	Multiple
sub-type-12	MIV2-N	PRISM	Multiple
sub-type-13	MIV2-DnT	PRISM	Multiple
sub-type-14	PV-EDU/RMP Materials-N	"PV"	One
sub-type-15	PV-PBRER/RMP Reports	"PV"	One
sub-type-16	Reg Cond (non-PV)	"Other"	One
sub-type-17	DMF	"DMF"	One
sub-type-18	Baseline	"Other" – Not a DMF "DMF" – DMF	One
sub-type-20	Transfer of Application	PRISM – Not a DMF "DMF" – DMF	Multiple One
sub-type-21	Other Regulatory Activity	"Other"	One

- *Multiple* means at least one is required, multiple are allowed and it cannot be duplicated.

- *One* means exactly one

- Submission Number of "DMF" applies for any Product Type "DMF".

- Submission Type of *Baseline* (sub-type-18) will have a Submission Number of "Other", <u>unless</u> the Product Type is DMF.

- Submission Type of *Transfer of Application* (sub-type-20) will have a PRISM-type Submission Number, <u>unless</u> the Product Type is DMF.