

Parallel Import - Tell and Do (TaD) Variations

Code	Variation Description	Change Description	Tell and Do	Examples/Notes	Documents to be submitted
57	UK MA number	Change in Marketing Authorisation number of the UK reference product	Yes	Continue processing, if confident it is a Change of Ownership and the UK-cross referenced product is the same.	TaD Cover sheet Application form only
	UK MAH name and/or address	Change in the name and/or address of the Marketing Authorisation Holder of the UK reference product			
51	EU MAH name and address change for CAP	Change in the name and address of the Marketing Authorisation Holder of the imported product.	Yes	ONLY for centrally authorised products licenced by the EMA.	TaD Cover sheet Application form only
51	EU MAH name and address change for non-CAP	Change in the name and address of the Marketing Authorisation Holder of the imported product.	Yes	ONLY in the instances where the entity remains the same. For example but not limited to Sanofi S.p.A to SANOFI s.r.l.	TaD Cover sheet Application form Sample scan

52	Manufacturer name change for CAP	Change in the name of the Manufacturer of the imported product	Yes	ONLY for centrally authorised products licenced by the EMA.	TaD Cover sheet Application form Labels Patient Information Leaflet (PIL)
52	Manufacturer name change non-CAP	Change in the name of the Manufacturer of the imported product	Yes	ONLY in the instances where the entity remains the same.-For example, but not limited to: GlaxoSmithKline S.p.A. to GlaxoSmithKline Manufacturing S.p.A.	TaD Cover sheet Application form Labels Patient Information Leaflet (PIL) Sample scan
58	Manufacturer site change for CAP	Change in the address of the Manufacturer of the imported product	Yes	ONLY for centrally authorised products licenced by the EMA.	TaD Cover sheet Application form Labels Patient Information Leaflet (PIL)
58	Manufacturer site change non-CAP	Change in the address of the Manufacturer of the imported product	Yes	ONLY in the instances where the entity remains the same	TaD Cover sheet Application form Patient Information Leaflet (PIL) Labels Sample scan