LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Please send the form to: RIC@lakemedelsverket.se

Notification regarding optional anti-tampering device on packages for human medicinal products

Notification regarding anti-tampering device is only required for human medicinal products or product categories subjected to prescription mentioned in Annex I of Commission Delegated Regulation (EU) 2016/161 and for human medicinal products or product categories not subjected to prescription not mentioned in Annex II of the same regulation.

Notification is made by Marketing authorisation holder/Registration holder/Local representative/Parallel importer	
Company name	
Address	Postal code and city
Contact person	
Phone	E-mail

Notification regarding – tick the appropriate box below

☐ The anti-tampering device has already been implemented.

☐ The anti-tampering device is to be implemented from (month and year)
Please state the date of the first planned release of packages bearing anti-tampering device.

☐ The anti-tampering device is to be removed from (month and year)
Please state the date of the first planned release of packages not bearing anti-tampering device.

Medicinal product *If the application concerns several medicinal products, a list of the below requested information can be attached.*	
Name of the medicinal product	
Pharmaceutical form and strength	Asp no: Marketing Authorisation no: Source country (parallel imported medicinal product):

Packaging information – tick the appropriate box below

☐ The notification applies to all packages.

☐ The notification only applies to some packages.
Please state which ones:
Type of packaging and pack size

Other information