

Send the form to: Läkemedelsverket  
Box 26  
S-751 03 Uppsala  
Sweden  
[RIC@mpa.se](mailto:RIC@mpa.se)

## Notification of change in labelling and/or package leaflet - national change

Information about the medicinal product:	
Name of the medicinal product	Strength and pharmaceutical form
Asp No. and Marketing Authorisation No. Asp No: MA No:	ATC-code
Approved pack size(s)	

Marketing Authorisation Holder:	Local representative:
Name	Name
Address	Address

Manufacturer responsible for batch release:
Name
Address

Background and scope of the change

<input type="checkbox"/> Proposed mock-up of the labelling is enclosed. <input type="checkbox"/> Currently approved mock-up of the labelling is enclosed. <input type="checkbox"/> Package leaflet with marked change(s) is enclosed. <input type="checkbox"/> The proposed change(s) will not affect the SmPC. <input type="checkbox"/> We certify that no other change(s) has been made. <input type="checkbox"/> Change(s) will be implemented from, date
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Contact person:		
Name	Company	
Address	Phone	Fax
	e-mail	

Signature		
Signature	Clarification of signature	Date