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APPLICATION FOR WAIVER
Section 29(3) of the Medicines Act (395/87)

- **Waiver applications shall be submitted on this form (one marketing authorisation/registration per form)**
- **The grounds for the waiver shall be given on the appendix.**

Under section 29(1)(3) of the Medicines Act, a marketing authorisation or registration lapses, i.e. ceases to be valid, if an authorised or registered product has not been placed on the market within three (3) years of the granting of the registration or authorisation or if an authorised or registered product has been absent from the market for a period of three (3) consecutive years.

Under section 29(3) of the Medicines Act, for reasons relating to the health of humans or animals or for other particular reasons, the Finnish Medicines Agency may upon application from the marketing authorisation or registration holder decide that the marketing authorisation or registration shall not lapse pursuant to section 29(1)(3). Application to continue the validity of a marketing authorisation or registration shall be submitted to the Finnish Medicines Agency no later than three (3) months prior to the expiry of the three-year time limit (Medicines Act 395/87, section 29).

Product type

☐ Human medicinal product ☐ Veterinary medicinal product ☐ Registered product

PRODUCT DATA

Marketing authorisation number / Registration number	Procedure number (mutual recognition/decentralised procedure)
Date of issue of marketing authorisation/registration	
Name of medicinal product	
Strength	
Pharmaceutical form	
Name of marketing authorisation/registration holder	

CONTACT INFORMATION FOR APPLICANT

Name of company	
Surname	Given name
Address	
Telephone	Fax
Email address	

OTHER ITEMS OF NOTE

SIGNATURE

Date	Signature

PLEASE RETURN THE SIGNED FORM AND APPENDIX TO:

Finnish Medicines Agency
PO Box 55
FI-00034 FIMEA, FINLAND

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APPENDIX
Grounds for continuing validity of Marketing authorisation/Registration

MA no. / Reg.no

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