

Pre-Paid HPRA Quality Defect Report Card

HPRA TEL: 01-676 4971 FAX: 01-676 4061

Please complete (in BLOCK LETTERS) with as much information as possible.

EXACT NAME OF PRODUCT

PHARMACEUTICAL FORM

STRENGTH

TYPE OF CONTAINER

BATCH NUMBER

EXPIRY DATE

NAME OF PA / VPA / EU or other MA HOLDER

PA / VPA / EU or other MA NUMBER (Important)

Please state where you obtained the product from. (Please give name and address in box below)

FROM WHOLESALER (Wholesaler Name)

FROM MANUFACTURER (Manufacturer Name)

Please describe in detail the Defect, giving as much information as possible:

WERE ALL UNITS IN THE PACK AFFECTED (If applicable)? YES NO

DEFECT NOTICED BY: PHARMACIST PATIENT OTHER (please specify)

ARE SAMPLES AVAILABLE FOR SENDING TO HPRA? YES NO

If YES, please retain samples for 14 days. If we require a sample for inspection, we will contact you within 14 days.

If a wholesaler, marketing authorisation holder or manufacturer was notified of the defect, please state the name and company of the person you notified:

YOUR NAME & ADDRESS:

Tel:

Do you agree to HPRA providing your name / your pharmacy name to the Investigating Company for their own follow-up with you?

YES NO

DATE _____

Postage
will be
paid by
Licensee

No Postage
Stamp
necessary if
posted in
Republic
of Ireland

BUSINESS REPLY SERVICE
Licence No. DN 1094

Compliance Department
Market Compliance Section
Health Products Regulatory Authority
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