URGENT TYPE III VOLUNTARY RECALL

NEORAL* (Cyclosporine oral solution) 100mg/mL

NOVARTIS

January 8th, 2013

Subject: **VOLUNTARY RECALL of NEORAL* (cyclosporine oral solution) 100 mg/mL LOT H5131**

Dear Distributor/Wholesaler/Pharmacist

NOVARTIS Pharmaceuticals Canada Inc., in consultation with Health Canada, has decided to initiate a voluntary Type III recall at the wholesaler/distributor and pharmacist levels due to a potential defect in the neck of the glass bottle of NEORAL* (cyclosporine oral solution) 100 mg/mL, DIN 02150697, 50mL bottles, lot H5131 (expiry date: 31 January 2015).

The defect, which occurred during the filling of lot H5131 of NEORAL* (cyclosporine oral solution) 100 mg/mL, resulted in damage to some bottle necks due to an incorrect set up of the crimping machine. As a consequence, bottle integrity cannot be guaranteed and there may be leakage in some bottles or the bottle necks could break upon opening. The defect is readily observable upon opening the bottle and any such product should be discarded and not used. The defect is limited to this lot only.

Advice to Distributors/Wholesalers/Pharmacists:

- Not to dispense **NEORAL* (cyclosporine oral solution) 100 mg/mL lot H5131**;
- To return **NEORAL* (cyclosporine oral solution) 100 mg/mL lot H5131 only** to CLS Med-Turn International for destruction; see attached communication on the return process.
- Distributors/Wholesalers are to send a Recall Notice to their customers who were shipped **NEORAL* (cyclosporine oral solution) 100 mg/mL** lot H5131 only.

Novartis Pharmaceuticals Canada Inc. reiterates its commitment to the delivery of quality pharmaceutical products.

Managing marketed health product-related adverse reactions is dependent upon health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious or unexpected adverse reactions in patients receiving **NEORAL* (cyclosporine oral solution) 100 mg/mL lot H5131** should be reported to Novartis Pharmaceuticals Canada Inc., or Health Canada at the following addresses:

Novartis Pharmaceuticals Canada Inc.
385 Bouchard Blvd.
Dorval, (QC) H9S 1A9
e-mail address: drug.safety@novartis.com

Any suspected adverse reaction can also be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
OTTAWA, Ontario, K1A 0K9
Tel: (613) 957-0337 or Fax: (613) 957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866 234-2345 Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

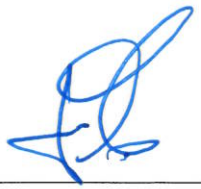
The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties,* http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

For other inquiries related to this communication, please contact Health Canada at:

Marketed Health Products Directorate
mhpd_dpsc@hc-sc.gc.ca
Tel: (613) 954-6522 Fax: (613) 952-7738

Should you have any questions or require additional information regarding the use of **NEORAL* (cyclosporine oral solution) 100 mg/mL**, please contact Novartis Pharmaceuticals Canada Inc., Medical Information at 1-800-363-8883 (medinfo.canada@novartis.com).

Sincerely,



Jean Godin, MD
VP, Clinical & Regulatory Affairs & Chief Scientific Officer

* **NEORAL** is a registered trademark