Notice to Hospitals

November 3, 2014

Dear Medical Staff,

Please distribute this notice to relevant departments in your institution.

Subject: Shortage of Hoffmann-La Roche Ltd. Health Canada approved TNKase® (tenecteplase) 50 mg vials (DIN: 02244826) and temporary replacement with TNKase 50 mg vials (Lot # 655800) from a currently unapproved manufacturing site with Canadian label.

As previously communicated, there is a shortage of TNKase 50 mg vials due to capacity constraints within the manufacturing supply chain. This shortage began on October 1, 2014 and will continue until approximately mid-December.

In order to manage the capacity constraints within the supply chain, an additional manufacturing site was submitted to Health Canada and is currently under review. The TNKase 50 mg vials produced at this site are currently unauthorized.

As of today, hospitals may request special access to the TNKase 50 mg vials from the unapproved manufacturing site through SAP. The programme will consider requests on an institutional basis for limited supplies to bridge this anticipated gap when alternative approved therapies or procedures are deemed inappropriate. Requests may be initiated by individual practitioners/institutions in anticipation of one or more patients, **based on normal historical product consumption for 6 weeks**. Requests should specify all indications for which the drug will be used on an emergency basis and outline the circumstances under which alternatives are considered inappropriate. Requests should be faxed to SAP in the usual manner.

Every effort is made by SAP to process requests within 24 hours of receipt. If the request is complete and the clinical rationale is deemed acceptable (i.e. aligned with Canadian Product Monograph), a Letter of Authorization will be issued to the manufacturer and copied to the requesting practitioner. The product authorized under the SAP will be the TNKase 50 mg vials with Lot Number 655800 and expiry date February 2016.

- *Due to shortage of Health Canada approved TNKase 50 mg vials, hospitals may request special access to TNKase 50 mg vials (Lot # 655800) via Health Canada's Special Access Programme (SAP) manufactured at a new unapproved site currently under review by Health Canada from* ***November 3 to approximately mid-December 2014****.*

Hoffmann-La Roche Limited/Limitée *7070 Mississauga Road Mississauga, Ontario L5N 5M8* *Tel. / Tél. : 905-542-5555 Fax / Téléc. : 905-542-7130* *www.rochecanada.com*

- *Hospitals may request access on an institutional basis by submitting **SAP Form B** request. For more information about this process, please consult the following web site or call the SAP main line:*

  http://www.healthcanada.gc.ca/sap
  (613) 941-2108 (telephone)
  (613) 941–3194 (fax)

- *TNKase 50 mg vials made available through SAP will be Canadian-labelled product and as such, the lot # printed on the packaging can be used to differentiate which material is currently from the unapproved drug product manufacturing site.*
  - *This applies to Canadian-labelled, unapproved stock with Lot Number 655800, expiry date February 2016.*
  - *The diluent provided with the TNKase for the purpose of the SAP will be identical to the diluent approved for the Canadian market.*

- *Practitioners are responsible for reporting on the use of the drug, including itemized lists of patients who will receive the drug and any adverse events encountered with its use. For further information on reporting requirements, consult section 6.1 of the Guidance Document for Industry and Practitioners – Special Access Programme for Drugs (available at the Web site address mentioned above).*

If a request is authorized through SAP, a Letter of Authorization will be faxed to Hoffmann-La Roche Ltd. and copied to the practitioner/institution. Hoffmann-La Roche Ltd. will subsequently reach out to the contact name on the Letter of Authorization to discuss ordering and shipping procedure.

If you have any questions regarding the SAP process, please contact the SAP main line as listed above. Questions regarding TNKase can be directed to*:* Drug Information Department at Hoffmann-La Roche Ltd. at 1-888-762-4388, Monday to Friday, between 8:30 a.m. and 4:30 p.m. (Eastern Standard Time).

Sincerely,

Lorenzo Biondi
VP Medical and Regulatory Affairs
Hoffmann-La Roche Limited

Hoffmann-La Roche Limited/Limitée *7070 Mississauga Road Mississauga, Ontario L5N 5M8* *Tel. / Tél. : 905-542-5555 Fax / Téléc. : 905-542-7130* *www.rochecanada.com*