January 25, 2013

The Secretary of the 19th Expert Committee on Selection and Use of Essential Medicines
Medicine Access and Rational Use
Department of Essential Medicines and Health Products
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27, Switzerland
Email: elmsecretariat@who.int

Dear Sir or Madam,

Canada’s Support for Whole Blood and Red Blood Cells to be Listed as WHO Essential Medicines

Health Canada is aware of international efforts to list whole blood and platelets as essential medicines within WHO. An international dialogue has been held on this subject with much support. For example, in addition to the application by the American Association of Blood Banks, an international professional group, it is also endorsed by members of the WHO Blood Regulators Network (letter of support from WHO BRN submitted to WHO on December 11, 2012 by members from Health Canada; U.S. FDA; SwissMedic, Switzerland; the Ministry of Health, Japan; Paul Ehrlich Institute, Germany; Therapeutic Goods Administration, Australia and the MSNA, France). We are writing to provide support from Health Canada through the Biologies and Genetic Therapies Directorate.

Health Canada believes that whole blood and red blood cells (RBC) are medicines which satisfy the priority healthcare needs of the Canadian population for treatment of anemia, hemorrhage and other blood disorders. Therefore, listing by WHO of whole blood and RBC as essential medicines reflects our reality that these are essential medicines. We believe that availability of blood and its components are necessary medicines for all countries and a listing by WHO will serve to promote global availability of these essential biological therapeutics.

Within Canada, blood and blood components are regulated under the authority of federal legislation embodied within Canada’s Food and Drugs Act and Regulations. Regulatory oversight for blood and its components is provided according to the well-established framework for more traditional pharmaceuticals and biologic medicines. There is a mandatory review of blood for safety, quality and efficacy. An authorization is required from Health Canada’s Biologics and Genetic Therapies Directorate
before whole blood, RBCs and other blood components are allowed to be marketed and distributed as medicinals for treatment of patients.

Canada has one of the safest blood systems globally and is self-sufficient in production of labile blood components. Our blood operators, Héma Quebec and the Canadian Blood Services hold federal blood establishment licenses which ensure compliance with good manufacturing practices. Operational systems are in place for ensuring blood safety including donor screening, safe measures for blood collection and component production, laboratory testing and haemovigilance. All of the above are governed by national standards and regulatory review and oversight. Collectively, these measures reflect those which govern other medicines in Canada which are currently listed as WHO essential medicines.

In summary, Health Canada supports and recommends that whole blood and RBCs be listed as essential medicines by WHO.

Sincerely,

Dr. Robert Cushman
Director General, Biologics and Genetic Therapies Directorate
Health Canada

Dr. Peter R. Ganz
Director,
Centre for Blood and Tissues Evaluation
Biologics and Genetic Therapies Directorate

c.c. Mr. Kees de Joncheere, Director, Department of Essential Medicines and Health Products, WHO
(dejoncheerec@who.int)