

PRODUCT SAFETY USAGE AND SUPPLY SUBCOMMITTEE
Annual Report to the Association of Hemophilia Clinic Directors of Canada
April 2004

Chair: Dr. K. Sue Robinson

Members: Drs. Pat McCusker, Man-Chui Poon, Georges Rivard and Jerry Teitel, Alan
Tinmouth

Over the last year, the Product Safety Usage and Supply Subcommittee has been involved in the following activities.

- 1) CBS requested our Committee to review the information on Advate and prepare a formal Submission Review. We reviewed the manufacturing, pharmacokinetics, efficacy and safety data which included six Advate studies and we submitted conclusions and recommendations. This was done by Drs. Rivard, Teitel and Robinson on behalf of our Safety Committee and was submitted to CBS July 2003.
- 2) In June 2003, Drs. Poon, Rivard and Robinson attended a meeting of the National Technical Working Group on Blood and Blood Product Utilization mainly to discuss the use of Niasase. They were invited mainly to be consultants on the use of Niasase in inhibitor patients. A subcommittee, called the Niasase Medical Task Force, was developed including hematologists, hematopathologists, surgeons, anaesthetists, critical care specialists, including our three Committee members. A policy framework including a position statement about the use of Niasase in Canada and an algorithm for its use was developed and was endorsed by the NTWG in November. There is a follow-up teleconference April 26, 2004.
- 3) Dr. Robinson, as a representative of the Blood Safety Subcommittee, became a member of the Patient Notification System (PNS) Advisory Committee. There is an ongoing effort to promote the PNS in the Canadian Hemophilia Population, particularly through CBC and CHS. The Blood Safety Subcommittee has been asked if there is a better or additional way other than providing information including distribution of pamphlets to promote the PNS through the clinics.

Respectfully submitted,

K. Sue Robinson, MD, FRCPC

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