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Introduction

A symposium on hemophilia B and its treatment with factor IX concentrates in a pan-European forum is long overdue. For many years, such issues have been overshadowed by discussions relating to the management of hemophilia A with factor VIII concentrates. Many such discussions in Europe have become politicized by the recent European Community directive EC89/381, which advocates self-sufficiency in blood and blood products. In a number of instances, pragmatic issues relating to patient management have become subservient to matters of national self-interest. The situation with factor IX concentrates is less distorted by political involvement: cryosupernatant, the source material for factor IX, is produced through the blood transfusion services of member states and is surplus to demand. Some ten factor IX preparations, either nationally licensed or unlicensed, are currently manufactured within the public sector and some five licensed preparations are available from commercial sources. With the increasing harmonization of regulatory affairs and licensing issues throughout Europe, a unique situation will soon emerge where all factor IX concentrates can compete on a level playing field. In such circumstances, where issues of safety, efficacy, adverse events, and cost-effectiveness will be the final arbiters of quality, the goalposts cannot be shifted in favor of national self-advantage.

The proceedings of this symposium address the diverse safety issues relating to current factor IX preparations. The specific subject of the thrombogenicity of factor IX materials will be assessed in terms of both the in vitro and in vivo characteristics of available products. Practical issues relating to clinical experience with monoclonal antibody-purified factor IX will then be examined. Because the diverse properties and characteristics of a number of factor IX concentrates are compared, where appropriate, specific comments will be made as to the continued viability of such therapeutic agents in clinical practice. Additionally, the feasibility of standardized treatment protocols for patient management will be explored. At the symposium on which these proceedings are based, interaction was encouraged. These articles provide insofar as possible a written record of the exchange of ideas, concepts, and experience within a free forum.

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