

The Norwegian Self-Sufficiency Project Celebrates 20 Year Anniversary

**20 Years
1988-2008**




Norway achieved self-sufficiency with coagulation factors in 1981-1983. In 1985, as a result of the HIV epidemic, the Norwegian Health Authorities decided to replace both non-virus inactivated plasma-derivatives and transfusion plasma by virus inactivated products within the end of 1988, without endangering the established self-sufficiency [1-3]. In April 2008, the Norwegian self-sufficiency project resulting from this decision celebrates its 20-year anniversary, which makes it the longest continuous complete national plasma fraction project with a single fractionator in the world.

Octapharma AG (Switzerland) was the sole partner during these two decades. The current contract, representing the 7th in a row, is valid until the end of June 2009, and a new national tender for the years to come is expected to be issued by mid-2008. Octapharma A.S (Norway) has administered the project from the day of funding (1st of November 1988), in close cooperation with the Red Cross & National Hospital Blood Center and key clinical institutions such as the National/University Hospital and National Institute for Haemophilia in Oslo. The first plasma from Norway was shipped in April 1988, and until the end of March 2008 Octapharma received and fractionated 1,017,000 litres of plasma from 217 plasma shipments into 975 batches of various plasma-derivatives. Today most of the plasma-derivatives are manufactured by Octapharma AB (Sweden), with support from Octapharma Pharmazeutika Produktionsges.m.b.H (Austria) for some special products.

The introduction of new products from the Octapharma portfolio started with albumin and coagulation factors in 1988. The other plasma-derivatives followed the scientific and market developments both at Octapharma and in Norway. Market access was assured for all products based on the national plasma in close collaboration with the Norwegian Medicines Agency, and altogether 17.6 tons of albumin, 220 million IU of coagulation factors (FVIII, FIX, VWF, and prothrombin complex concentrates), 1.1 ton of immunoglobulins [introduced 1994 (IVIG) and 2005 (SCIG)], and 516,000 bags of virus inactivated plasma for infusion (octaplas®; introduced 1993) have been used by the numerous hospitals and other health institutions during the 20 years.

Based on standard dosing of these plasma-derivatives, the amount of finished goods returned by Octapharma is equivalent to more than 1 million treatment episodes (51,000/year and 140/day). Almost 500 patients suffering from chronic coagulation and immune deficiencies have been treated solely with Octapharma products for the last two decades. Drug-related adverse events have been registered in only 1 per 72,000 treatment episodes, which is important in Norway due a decentralized organisation of patient treatment, including extended home therapy of haemophiliacs in a geographically -scattered area.

Since the foundation of Octapharma as a company 25 years ago, research & development of new plasma-derivatives based on own, novel technology and manufactured in state-of-the-art GMP-licensed manufacturing facilities has been the company's main focus. Through important scientific input and conduct of both biochemical studies [4] and human trials Norway has contributed to Octapharma's success, especially for products such as octagam® [5-10], octaplas® [11,12] and uniplas® [13-16]. The early introduction of octaplas® after the first clinical study completion helped Norwegian hospitals to reduce the number and severity of adverse events – and by that costs – in intensive care [17].

All patients admitted to Norwegian hospitals and in need of plasma-derivatives have been treated with virus inactivated products based on plasma of local origin for the past 20 years. This mainstay in national blood therapy was made possible through a well-defined self-sufficiency project, which would not have been possible without the dedicated and professional contribution from the Norwegian blood centers [18], the guidance and support by the national health authorities, and motivation and loyalty shown by key health care personnel and patient organizations [19]. It is our belief that Octapharma, through its active research & development, state-of-the-art product portfolio at any time, high yield and

security in production, and commitment to the principle of self-sufficiency has contributed to not only the medical, but also the economic success of Norway's plasma fractionation project through an optimal utilisation of the local, precious plasma raw material [20].

There is no doubt that the Norwegian Self-Sufficiency Project has been important for Octapharma's development since it has served as a model for other countries that decided to follow the same path. We are proud of having been a part of this project and express our gratitude to all our partners and customers in Norway – with the best wishes for an equally successful future.

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