



Health Technology Assessment and Haemophilia in Sweden

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Background

Sweden is currently doing the first cost-benefit analysis of pharmaceutical products for Hemophilia A.



TLV – Tandvårds- och läkemedelsförmånsverket

- Decides on new subsidizations
- Negotiates prices
- Reviews existing subsidizations



The review process

Start up

- The pharmaceutical companies are asked to provide data studies, etc. related to the drugs being reviewed

Mapping Phase (6 -12 months)

- Processing the files from the Industry
- Collecting and study of scientific and health-economic literature for the group of medicines
- External assistance from medical expertise



The review process 2

Decision-making Phase (1-2½ years)

- May ask the pharmaceutical companies for additional data
- Positive to new and un-published data
- Patient organizations can provide TLV with their opinions

Decision

- For each of the reviewed drug on whether it still be subsidized or not. Sometimes with request to decrease the price.
- Recommendation on therapy method



TLV 2

TLV started the review in November 2009, initially for FVIII, FIX and vWD products.

In February 2010 the pharmaceutical industry submitted information on their products.

There has been many delays in the process; reorganizations at TLV, pharmacy reforms and review now limited to Factor VIII.



Pharmaceuticals now included in the review are

Advate

Helixate NexGen

Immunate

Kogenate Bayer

Octanate

Recombinate

ReFacto AF

Haemate

Wilate



Mapping phase - Literary review by SBU

“SBU has the mandate of the Swedish Government to comprehensively assess healthcare technology from medical, economic, ethical, and social standpoints.”



Mapping Phase → SBU report

Published in May 2011, Review included A, B and vWD. Swedish experts prominent in the group were

Erik Berntorp (Chair)

Jan Astermark

Fariba Baghaei

Margareta Holmström

Rolf Ljung

Jan Palmblad

Pia Petrini

Lennart Stigendal



Conclusions of SBU report

Treatment is effective & Prophylaxis is effective, but not enough evidence to draw scientific conclusions on dosage, Inhibitor treatment, start of prophylaxis etc.

-> “It is essential to create a national treatment register that includes defined quality indicators.”

English version available from

<http://www.sbu.se/en/Published/Yellow/Treatment-of-Hemophilia-A-and-B-and-von-Willebrand-disease/>



Back to the Review process

NDA's signed with TLV's expert group. Included are Erik Berntorp, Pia Petrini, Lennart Stigendal, Margareta Holmström, Fariba Baghaei och Jan Astermark – similar to the SBU group.

FBIS participation: expect to access the same material and offered to sign NDA's.

First meeting between FBIS and TLV scheduled for mid-November.



Speculating on the decision

Quite optimistic. It seems unlikely that, based on insufficient data, TLV would recommend a change in dosage.

A possible outcome is that costs will be reduced through renegotiated prices.

Accepting a high cost per QALY could set an important precedence and puts TLV in a difficult position



The role of the patient organization

Follow the process and be informed. Understand the game, the participants, where they come from and their stakes.

Participate as soon as possible. Best time to influence the decision is before it is made. Show competence and you will be accepted as a credible stakeholder.

Show an independent agenda from the industry

Ensure everyone sings from the same hymn sheet where possible: Doctors, experts, patients and industry.



Förbundet Blödarsjuka i Sverige
Swedish Hemophilia Society

Thank you for your attention!

