Introduction to "Sykehusinnkjøp" process for gene and cell therapies

The Norwegian Hospital Procurement Trust









«Nye Metoder» and Sykehusinnkjøp HF

- "Nye Metoder" consist of three independent entities:
 - HTA NoMA
 - Negotiations Norwegian Hospital procurement trust
 - Reimbursement decision The regional health authorities
- Sykehusinnkjøp HF
 - Operative responsibility for procurement for the specialist healthcare service
 - Owned by the four regional health authorities
 - Negotiate on behalf of the regional health authorities



Documents (framework for gene and cell therapies)

- The Norwegian Hospital Procurement trust uses standardized documents for the gene and cell therapies agreements
- The document packages consist of :
 - Framework agreement (between HTD and regional health authorities)
 - With attachments
 - Supply agreements (three-party agreement; Between treatment centre, pharmacy and HTD)
 - With attachments
 - Technical apheresis agreement (if relevant)
- The Norwegian version of the agreements should be signed
- The Norwegian Hospital Procurement (SHI) has coordinating role throughout the signing process



Timelines (example)

Ordering (Ordering Forum)

"Early dialog" meeting with SHI and HTD

Health Technology Assessment (NoMA)

SHI contacts HTD for a price offer when a draft report is available

Decision (Decision Forum)

SHI prepares a price note for decision forum based on the submitted price offer

Terms in the framework agreement must be agreed on prior to decision

Positive decision (Decision Forum)

Framework agreement is signed

SHI coordinates contact between HTD and the relevant treatment centres and hospital pharmacies

Supply (and technical apheresis) agreement is signed

Needs to be resolved before decision in Decision Forum

- Price
- Treatment centres
- Content of the framework agreement
- System for ordering (with respect to GDPR and IT security)

<u>Can be resolved within 3 months after the decision in Decision</u> <u>Forum</u>

- · Logistical and financial flow
- Training and training requirements
- Import control, HTDs requirements for hospital/pharmacies handeling of the medicinal product
- Other details in the supply (and technical apheresis) agreement