Bisimilars, purchasing systems and impact of tenders in Norway

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LIS-regulations - § 1

The purpose of the Drug procurement cooperation (LIS) is to prepare the basis and specifications for purchase and delivery agreements of pharmaceuticals in cooperation with the state owned hospitals, and thereby reduce the costs.
Pricing

Price is based on basket countries and exchange rates

Max price:

Average of the 3 lowest

6 months average exchange rates

Recalculated once yearly
Flow of goods

Pharmaceutical company

Wholesaler

Level for tenders

Private pharmacy

Patients

Hospital pharmacy

Hospital

Pharmaceutical company

Wholesaler

Private pharmacy

Patients

Hospital pharmacy

Hospital
Purchase drugs in Norway, who pays?

- **Treatment outside institution**
  - Primary care and specialist health care
    - General reimbursement (Blue prescription) **NI**
    - Individual reimbursement **NI**
    - Non-reimbursed (White prescription) **P**
  - Specialist health care
    - H-prescription **RHA**

- **Treatment in hospital**
  - Regional Health Authority **RHA**

- **Treatment in nursing homes**
  - Township

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**P**: patient  
**NI**: National Insurance (small patient co-payment)  
**RHA**: Regional Health Authority (no patient co-payment)
Where does biosimilars fit in?

- Treatment outside institution
  - Specialist health care
  - General reimbursement (Blue prescription)
    - Filgrastim
    - Somatropin
    - Epoetin
  - Individual reimbursement
    - Filgrastim
    - Somatropin
    - Epoetin

- Treatment in hospital
  - Regional Health Authority
    - Infliximab
    - Hospital tender
    - TNF/BIO tender
  - Filgrastim
  - Epoetin

P: patient
NI: National Insurance
RHA: Regional Health Authority
The National System for the Introduction of New Health Technologies (methods) within the Specialist Health Service

Horizon scanning → New health technologies → Only for specialist health services? Expensive?

- Yes → RHA responsible for possible funding
- No (Yes) → Funding by National Insurance or patient (Home treatment)

Reimbursement application (STA) (NoMA)

- Cost effective → General reimbursement
- Not cost effective → No reimbursement
- Individual reimbursement

No tenders in this system
RHA responsible for possible funding

Suggestions for HTA

«Bestillerforum RHF» (Order Forum)

Orders for HTA

«Beslutterforum RHF» (Decision Forum)

Implementation YES - NO

LIS tender

NoMA (STA drugs)

NoKS (MTA drugs, STA other)

HTA

LIS negotiations

Both hospital use and H-prescription are paid by the hospitals

NoKS: Norwegian Knowledge Centre
MTA: Multiple Technology Assessment
RHF = RHA: Regional Health Authority

The National System for the Introduction of New Health Technologies (methods) within the Specialist Health Service
Filgrastim biosimilar impact

Hospital tender

- Average discount
- Hospital tender

Biosimilar market share volume

Somatropin biosimilar impact

- No tender

- Biosimilar market share volume
- Average discount

Remsima discount compared with Remicade tender price

Remsima (biosimilar infliximab) market share in volume

Remsima market share compared with Remicade tender price.
<table>
<thead>
<tr>
<th>Product</th>
<th>Cost NOK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certolizumab (Cimzia®)</td>
<td>61 035</td>
</tr>
<tr>
<td>Golimumab (Simponi®)</td>
<td>61 414</td>
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<tr>
<td>Abatacept (Orencia®)</td>
<td>104 316</td>
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<tr>
<td>Tocilizumab RoActemra®</td>
<td>107 498</td>
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<tr>
<td>Golimumab (Simponi®)</td>
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<td>Etanercept (Enbrel®)</td>
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<tr>
<td>Etanercept (Enbrel®)</td>
<td>123 126</td>
</tr>
<tr>
<td>Adalimumab (Humira®)</td>
<td>131 602</td>
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</table>

**Product**

<table>
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</thead>
<tbody>
<tr>
<td>Infliksimab (Remsima®)</td>
<td>26 011</td>
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<tr>
<td>Infliksimab (Inflectra®)</td>
<td>41 244</td>
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<tr>
<td>Infliksimab (Remicade®)</td>
<td>83 438</td>
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<tr>
<td>Tocilizumab (RoActemra®)</td>
<td>125 514</td>
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<tr>
<td>Abatacept (Orencia®)</td>
<td>145 228</td>
</tr>
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</table>

TNF/BIO tender 2015

$1 = NOK 7.6$
Cost (NOK) first year treatment UC

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<td>Golimumab (Simponi®)</td>
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<td>68 740</td>
</tr>
<tr>
<td>Infliksimab (Remicade®)</td>
<td>139 063</td>
</tr>
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How to make biosimilars a success

- No stimulation, low implementation
- The authorities should make guidelines for biosimilar use
- Follow up of guidelines should be monitored
- Tenders are an excellent tool to implement biosimilars (if carried out smart)
The future for drugs in Norway

More HTA
More tenders
The main message

Tenders increase biosimilar marketshare
Drug Procurement Cooperation

..more details tomorrow about how we work..