Metodevurdering (HTA)

Samarbeid nå og i framtiden

Statens legemiddelverk

Metodevurderinger

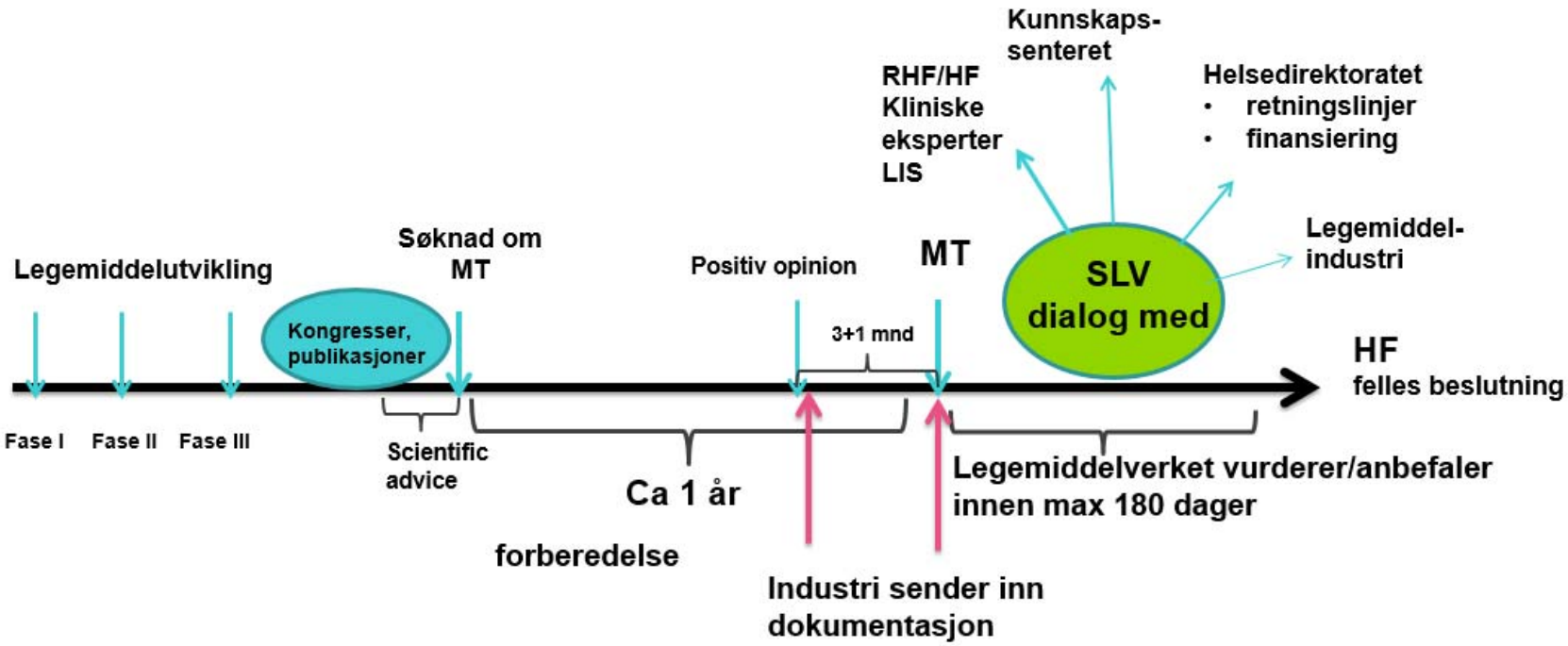
- Health Technology Assessement = Metodevurderinger
  - Mini-metodevurderinger
    - Sykehus
  - Hurtig metodevurderinger (Singel technology assessment)
    - Statens Legemiddelverk
    - Folkehelseinstituttet
  - Fullstendige metodevurderinger
    - Folkehelseinstituttet

Blåresept versus sykehus

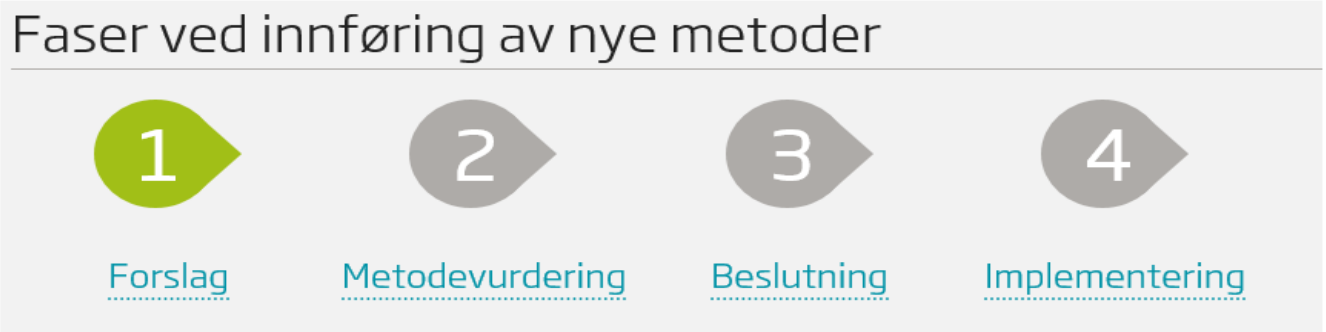
- Søknad om forhåndsgodkjent refusjons (blåresept)
  - ➡ frivillig

- Innlevering av dokumentasjon til Nye metoder
  - ➡ frivillig, men ingen bruk uten HTA vurdering

Vurdering av nye sykehuslegemidler



Metodevarsling - sykehus



- Legemiddelverket lager metodevarsler
  - Nye virkestoff
  - Indikasjonsutvidelser
- Publiseres midlertidig i MedNytt
- Kontakter firma
  - Innlevering av dokumentasjon ihht Legemiddelverkets retningslinjer
- Alle kan bestille metodevurderinger

Samarbeid med industri (nå)

- Hjelp med metodevarsel
  - Ved ikke sentral prosedyre (CP)
- Formøter med industrien
  - I forhold til innsending av dokumentasjon til metodevurdering

Samarbeid med industri (framtiden)

- Nasjonal(NoMA) (www.legemiddelverket.no)
- Parallel scientific advice (regulatorisk og health-technology-assessment myndigheter).

  (Parallel scientific advice from regulators and health-technology-assessment bodies)
- EUNnetHTA (EUnetHTA joint action 3 (2016-2020))
- MEDEV (orphan drugs) (MEDEV: MoCA Pilot Project)
- ADAPT SMART (ADAPT SMART EU)

Nasjonal veiledning og rådgivning

- Legemiddelverket tilbyr formøter til firmaer som ønsker veiledning i forbindelse med innsending av helseøkonomiske analyser. Uansett fase legemiddelet befinner seg i.
- Kontakt oss via

  Ask-us@legemiddelverket.no

  post@legemiddelverket.no

Parallell HTA

- The European Medicines Agency (EMA) offers scientific advice and protocol assistance in parallel with health-technology-assessment (HTA) bodies. This procedure aims to allow medicine developers to gain feedback from regulators and HTA bodies at the same time, at any point in the developmental lifecycle of medicines. This helps them to establish the evidence that both parties will need to determine a medicine's benefit-risk balance and value as efficiently as possible.
- Lik tilnærming til SA
- HTA perspektiv
- Sentraliserte prosedyrer
- Både sykehus og blåresept preparater
- Nye virkestoff eller indikasjonsutvidelser

Parallell HTA (II)

- P.t. er det legemiddelfirma som velger den HTA som skal delta. Melder til EMA
- Omtrent samme tidslinje som SA med noe avvik
- Felles SA/parallell HTA møte hos EMA
- Ikke nødvendigvis samme HTA / regulatoriske myndigheter som deltar
- Legemiddelverket har allerede deltatt i 6 parallelle HTA (flere terapiområder)

EUnetHTA Joint Action 3 (2016 - 2020)

- Work package 5 aim: To bridge the gaps between patients, caregivers, technology developers, current registry holders, authorities in the health care sector, HTA producers and HTA users.
- Its main objective is to help generate the right evidence all along the technology life cycle and develop tools that support the collection and use of high quality data that is relevant to the range of organizations and stakeholders.
- This Work Package consists of two strands:
  Strand A: Early dialogues (initial evidence generation), and
  Strand B: Post-Launch Evidence Generation and Registries.
- Legemiddelverket deltar aktiv i Joint Action 3, work package 3, 4 og 5

Accelerated Development of Appropriate Patient Therapies (ADAPT SMART)

- ADAPT SMART: This project, led by the European Medicines Agency, seeks to establish collaborative solutions to foster the development of Medicines Adaptive Pathways to Patients (MAPPs) in Europe, encouraging more efficient ways of developing and regulating medicines. Bringing together patients, regulators, industry, Health Technology Assessment (HTA) bodies, payers, and academics, it has the key objective to provide patients with more appropriate access to innovative medicines.
- Fra industrien: IMI
  - IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA.

- (Legemiddelverket er ikke (p.t.) HTA body representant)

MEDEV (MoCA prosjekt)

- MoCA (Mechanism of Coordinated Access to Orphan Drugs)provides a mechanism for European countries to collaborate on coordinated access to Orphan Medicinal Products (OMPs)
- The objectives of pilot projects shall be to establish and facilitate “early dialogue” between companies and competent authorities for pricing and reimbursement, to ultimately helping to speed up access for patients in EU Member States to the product in question.
- Participation in MoCA is open to several stakeholder groups, as per the following list:
  - National competent authorities for pricing and reimbursement
  - Patients: Currently represented on a horizontal basis by EURORDIS.
  - Candidate marketing authorisation applicant/holders willing to be involved in a pilot focused on a particular product of theirs.
  - Pharmaceutical industry at large
  - Experts from the EMA, EUnetHTA or other scientific committees/HTA agencies as well as individual medical experts or selected representatives from the pharmaceutical industry may also be invited and involved in specific pilots as appropriate and relevant, and upon the general agreement of all other regular participants.

Følg oss

@legemiddelinfo

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Statens legemiddelverk