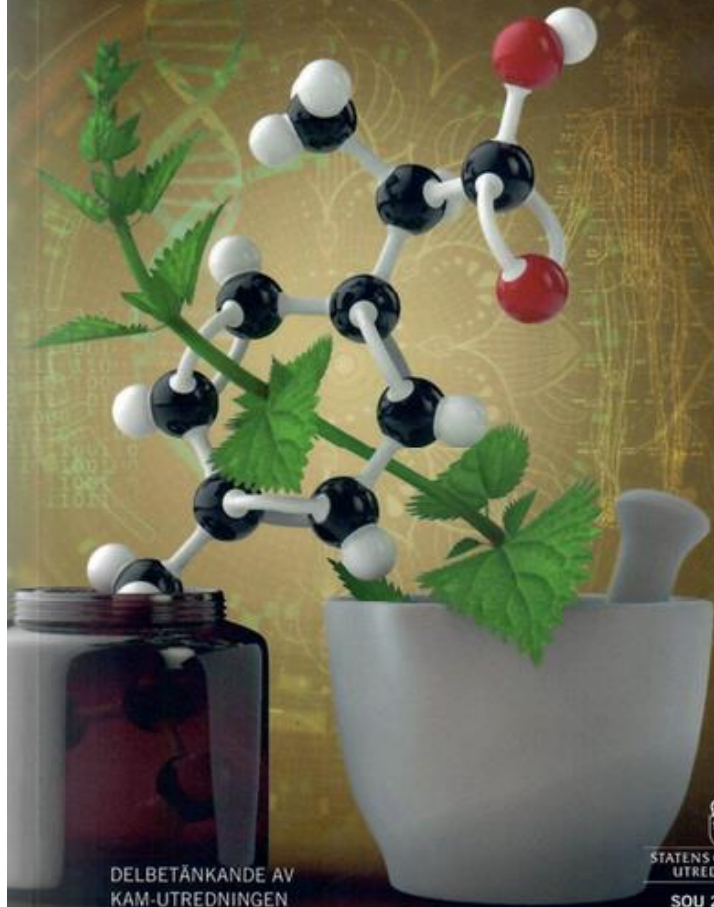


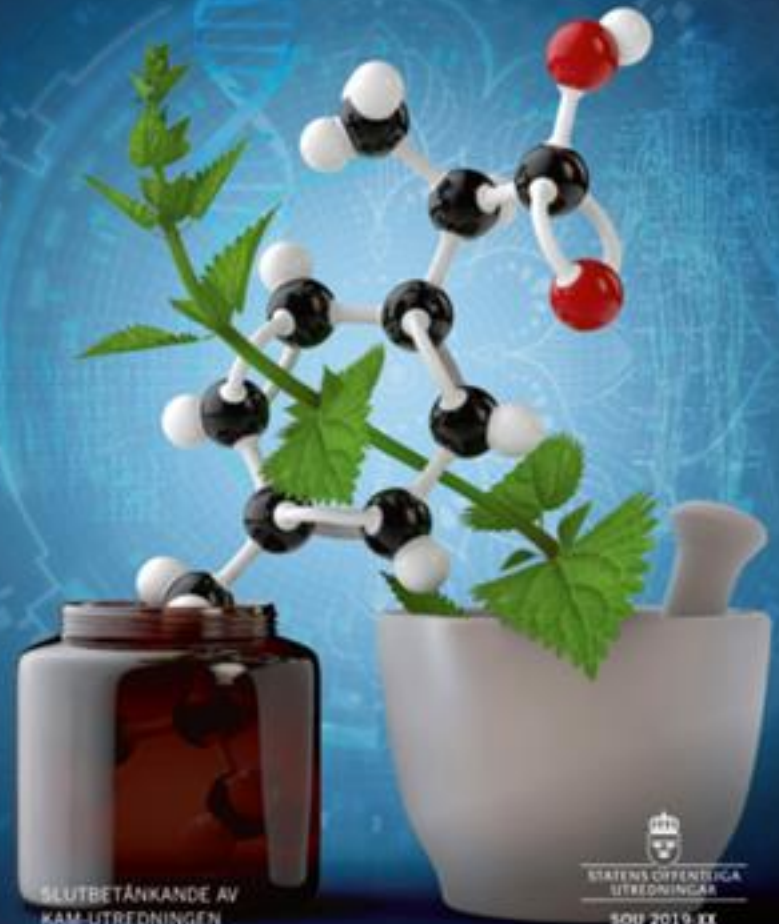
Komplementär och alternativ medicin och vård – säkerhet, kunskap, dialog



DEL BETÄNKANDE AV
KAM-UTREDNINGEN


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Komplementär och alternativ medicin och vård – ny lagstiftning



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Anneli Milén's ten questions

- why this initiative from the Cabinet?
- why such an assignment (and not directly e.g. to suggest legislation)?
- why an expert to work on it (pros for it)?
- who were represented in the working Group?
- what did you and WG do (work plan) and why?
- main role and suggestions of the first report in March
- how has it been perceived?
- planning the legislation, compromise?
- taking into account political players, others?
- what is the situation now on the proposals?

Terms

- Healthcare
- Complementary and alternative medicine/care
- Integrative care

Anneli Milén's question:
Why this initiative from the Cabinet?

- Coalition government
- Initiatives in the Parliament (from both proponents and critics)
- Ongoing public debate
- Lobbying
- A new inquiry every 6-8 years

Anneli Milén's questions:

Why such an assignment (and not directly e.g. to suggest legislation) and why an expert to work on it (pros for it)?

Conventional Swedish procedures

Anneli Milén's questions:

Who were represented in the Working Group?
What did you and WG do (work plan) and why?

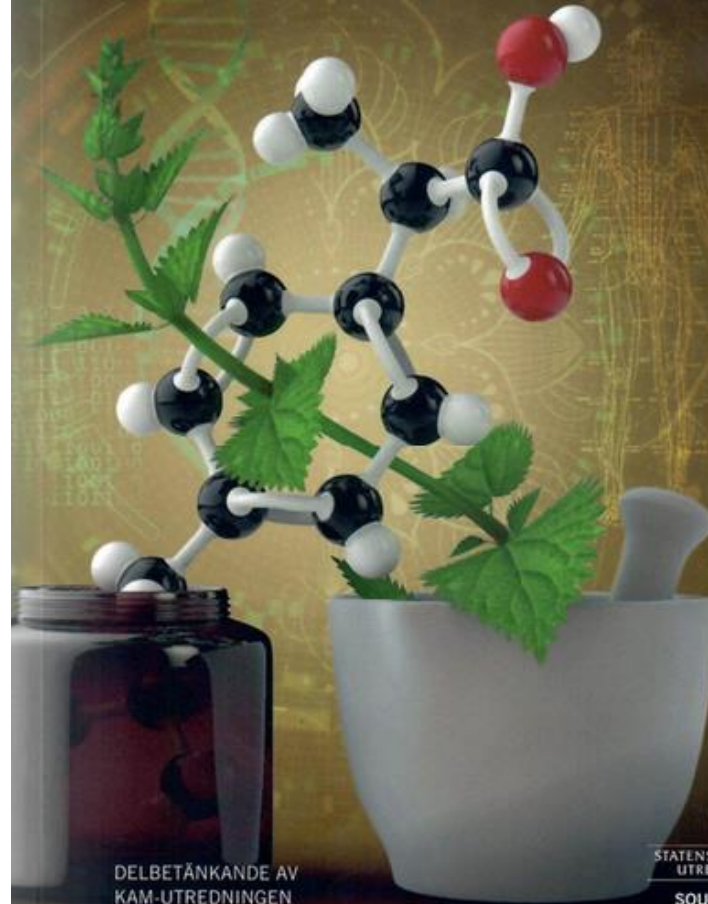
How our inquiry worked

- Secretariat
- Expert committee
- Separate working group on CAM for mental unhealth
- Extensive review of the literature and other written material
- Interviews and focus group dialogues: CAM practitioners, patients, governmental agencies, Ministry of Health, healthcare providers, interest groups, healthcare policy, research, media, etc.
- Study visits
- Attended lectures and conferences on CAM
- External reviewers

Delineations

- Not licenced healthcare professions I (i.e. not chiropractics and naprapathy)
- No evaluation of individual CAM methods
- Not dietary advice or food supplements
- Not methods to generally improve well-being or support personal development
- Not esthetic interventions
- Not religious activities

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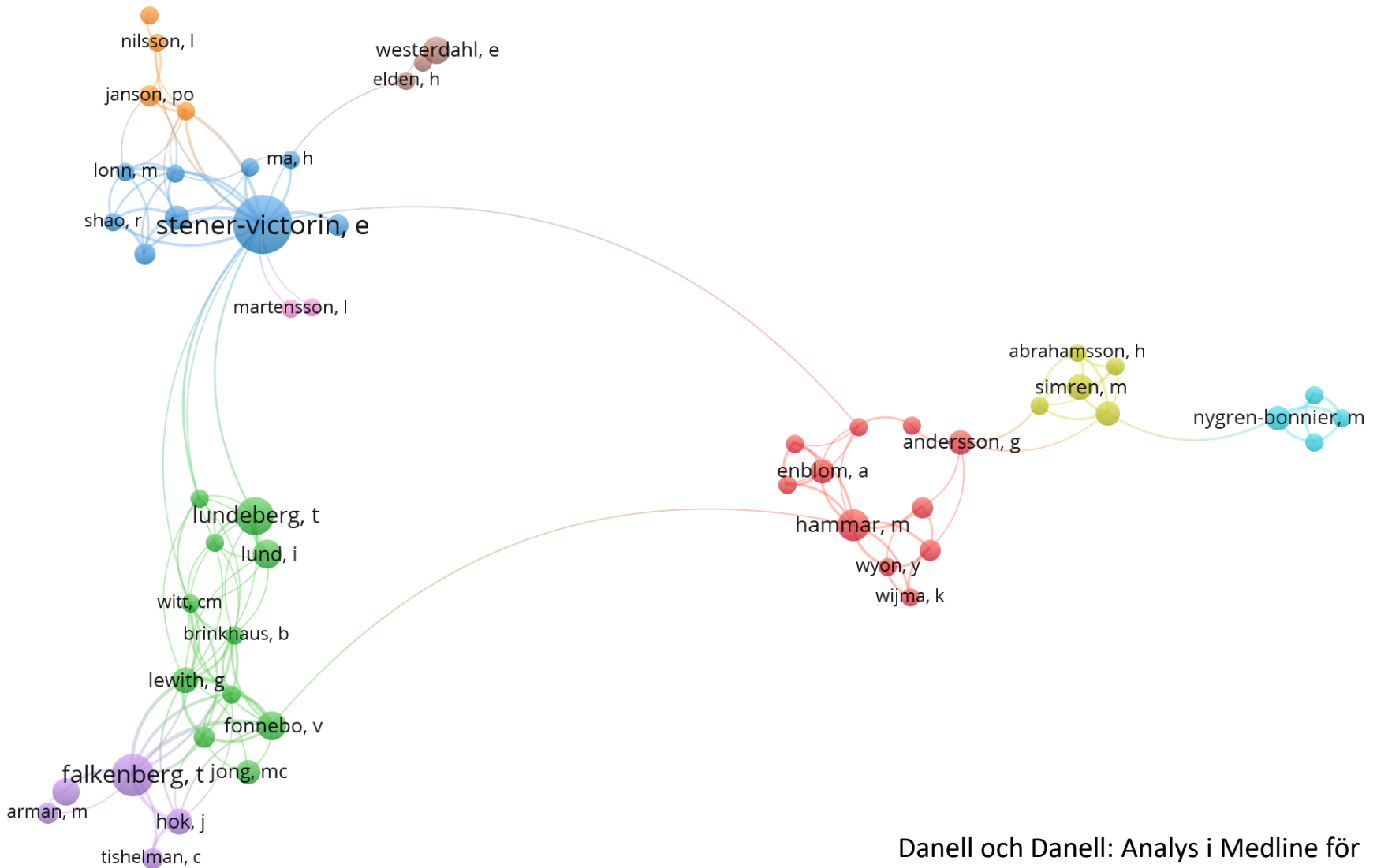
Background information

- Previous inquiries
- Present regulation
- Use of CAM in the population and in patients, including trends and driving forces
- General CAM principles as described by proponents
- Overview of CAM systems and CAM methods
- CAM practitioners and CAM educations in Sweden
- Critics' views on CAM
- CAM proponents' criticism of healthcare
- ... and much more

Our tasks according to the government's directions

- Mapping of research results and ongoing research and mapping of research methods
- Policy for evaluation and regulation of therapies that are not included in healthcare today but perhaps could be included.
- Information system for information about CAM to the public
- "Improve contacts and understanding between established and non-established care"
- "... improve patient safety", "... avoid unserious and dangerous treatment options ..."
- Mental disease a "forbidden area"?

Swedish CAM research networks based on co-authorship



Danell och Danell: Analys i Medline för KAM-utredningen

Our tasks according to the government's directions

- Mapping of research results and ongoing research and mapping of research methods
- **Policy for evaluation and regulation of therapies that are not included in healthcare today but perhaps could be included.**
- Information system for information about CAM to the public
- "Improve contacts and understanding between established and non-established care"
- "... improve patient safety", "... avoid unserious and dangerous treatment options ..."
- Mental disease a "forbidden area"?

CAM methods partly included in healthcare in recent years

A few examples

- Acupuncture (certain indications)
- Mindfulness
- Qigong
- Music therapy
- Hypnotherapy
- Ketogen diet in severe epilepsy

Any common denominator how these methods are being introduced?

No

Policy to introduce CAM methods in healthcare

- The policy should be neutral as to origin of the method - no special track for introduction of methods with CAM background.
- Apply the basic principles of prioritization, decided by the Parliament and applied in the national priority model.
- Include also evidence from studies other than RCT.
- Task by the Ministry to the Swedish Agency for Assessment of Methods in Healthcare and Social Welfare (SBU): Systematic assessment of CAM methods that may be considered to be introduced in healthcare.

Our tasks according to the government's directions

- Mapping of research results and ongoing research and mapping of research methods
- Policy for evaluation and regulation of therapies that are not included in healthcare today but perhaps could be included.
- **Public information system about CAM**
- "Improve contacts and understanding between established and non-established care"
- "... improve patient safety", "... avoid unserious and dangerous treatment options ..."
- Mental disease a "forbidden area"?

Information on CAM to the public, patients and healthcare staff

- Independent Swedish information system on
 - what various CAM methods are
 - what is known about their benefits and risks
 - what a consumer should find out about a CAM practitioner, for instance education and insurance
- Special window in the present healthcare information system (1177 Vårdguiden). National Board of Health and Welfare source owner. Collaboration with Norway and Denmark.
- Information with a consumer rights' focus on the website of the Swedish Consumer Agency
- Governmental agencies in the healthcare area to review their information about CAM.

Our tasks according to the government's directions

- Mapping of research results and ongoing research and mapping of research methods
- Policy for evaluation and regulation of therapies that are not included in healthcare today but perhaps could be included.
- Information system for information about CAM to the public
- **”Improve contacts and understanding between established and non-established care”**
- **”... improve patient safety”, ”... avoid unserious and dangerous treatment options ...”**
- Mental disease a”forbidden area”?

CAM in education of healthcare staff – main proposal

- Aims: Facilitating dialogue between patients and healthcare staff. Improving preconditions for patients to make informed decisions. Improved patient safety.
- Education on CAM in education of physicians, nurses, physiotherapists, psychologists, dieticians and pharmacists, corresponding to 1-2 weeks.

Our tasks according to the government's directions

- Mapping of research results and ongoing research and mapping of research methods
- Policy for evaluation and regulation of therapies that are not included in healthcare today but perhaps could be included.
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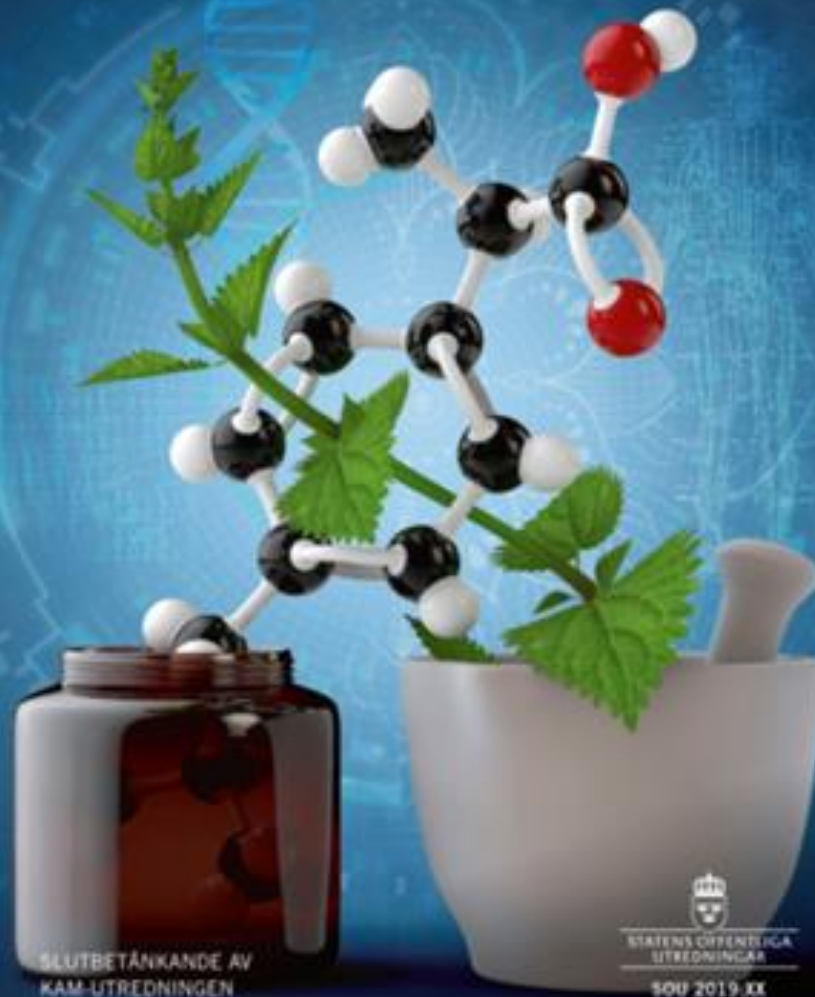
Additional directive from the government

Review the legislation on CAM

Anneli Milén's questions

Planning the legislation, compromise?

Komplementär och alternativ medicin och vård – ny lagstiftning



New separate law

Today:

Regulation on CAM dispersed in the Patient Safety Act, primarily targeted to healthcare providers and staff.

Our proposal:

Regulations collected in a new separate law.

Overriding considerations

- Balance between safety concerns vs. overregulation (the CAM consumer's possibilities to make his/her own decisions).
- Modernization of the legislation

Safety issues

Three particularly vulnerable groups

- Those with severe disease
- Children
- Fetuses

Three particular risk domains

- Herbal drugs (and similar)
- Psychotherapies
- Advice to terminate healthcare treatment

”Forbidden diseases”

Today:

- Forbidden for others than healthcare staff to treat patients with cancer, epilepsy and diabetes

Our proposal:

- General prohibition to treat severe diseases* (both somatic and mental)
- Treatments aimed at symptom relief permitted also in patients with serious disease.

* defined in the law proposal

Children and pregnant women

Today:

- Forbidden to treat children under the age of 8.
- Forbidden to treat diseases in conjunction with pregnancy and delivery

Our proposal:

- Regardless of severity, it should be prohibited to investigate and treat
 - diseases as such in children under the age 15
 - diseases as such in conjunction with pregnancy and delivery
- Treatment aimed at symptom relief* is permitted for children (regardless of age) and pregnant women.

* defined in the law proposal

Övriga bestämmelser

Område	Idag	Förslag
Anmälningsskyldiga smittsamma sjukdomar	Förbjudet	Förbjudet
Narkos	Förbjudet	Förbjudet
Kirurgiska ingrepp	---	Förbjudet
Injektioner	---	Förbjudet
Radiologisk behandling	Förbjudet	Utmönstras (annan reglering räcker)
Utprovning av kontaktlinser	Förbjudet	Utmönstras (onödigt detaljerat)
Behandling under hypnos	Förbjudet	Utmönstras, föråldrat
Personligt möte	”Brevkvacksalveri” förbjudet	Utmönstras, föråldrat

Anneli Milén's questions

How has it been perceived?

What has been debated the most?

- Delineations: Severe disease, treatment aimed at symptom relief
- 15-year age limit for children
- Symptom relieving therapies in serious disease + children and pregnant women
- The inquiry at large:
 - Too CAM hostile: Only cosmetic changes, the grand expectations have not been met
 - Too CAM friendly: encourages the use of unscientific methods and geschäft

Anneli Milén's questions

Taking into account political players, others?

What is the situation now on the proposals?

- The Ministry of Health and Social Welfare has had a broad referral process, deadline Oct 31
- The responses are now compiled
- Decision by government on its positions: Proposals to the Parliament? Tasks to the governmental agencies?
- Our proposal: New law as of Jan 1, 2021