



R1 Re-engineering the drug preparation - the Swedish model

Dr Eva Sjökvist Saers
APL

Apotek Produktion & Laboratorier AB
Sweden



EAHP 2014 - Eva Sjökvist Saers, Sweden

Disclosure

Eva Sjökvist Saers, CEO of APL
Apotek Produktion & Laboratorier AB



- APL is a state-owned company and a national centre of excellence for compounded pharmaceuticals.
- APL is an “extempore pharmacy”, with license from MPA, that offers compounding services (development and manufacturing of extemporaneous preparations and stock preparations) to community and hospital pharmacies, either directly according to agreements as a part of the hospital pharmacy or as a subcontractor.
- APL offers its services according to equal and non-discriminating conditions, as an assignment from the government.
- The compounding sector is today on a competitive market
- APL is also a CDMO (Contract Development and Manufacturing Organisation) that offers development and manufacturing services to companies within Life Science.



EAHP 2014 - Eva Sjökvist Saers, Sweden

To move from one model to another

Re-regulation of the pharmacy market in Sweden – consequences on the hospital pharmacies with focus on compounding



EAHP 2014 - Eva Sjökvist Saers, Sweden



Earlier model

Re-regulation of the pharmacy market in Sweden – consequences on the hospital pharmacies

- Until 2009/2010 the state-owned company Apoteket had the exclusive right to sell drugs in Sweden – community and hospital pharmacies
- All hospital pharmacies were run by Apoteket, on behalf of each county council according to agreements.
- Preparations of cytotoxics and sterile individual preparations were made at the hospital pharmacies
- Compounding (extemporaneous preparations, stock preparations) was centralised to the four production units of APL (earlier subsidiary to Apoteket)
- One national process owner for the "manufacturing/compounding process" at Apoteket/APL

EAHP 2014 - Eva Sjökvist Saers, Sweden



Earlier model

Development of compounding - earlier model

- The process owner of the manufacturing/compounding process was chairman of a "manufacturing forum"
- Holistic view of activities ongoing at the hospital pharmacies, with a focus on compounding
- Local and national initiatives – joint activities
- Topics e.g.
 - quality assurance/patient safety
 - working environment/ergonomics
 - harmonisation/standardisation/efficiency
 - IS/IT
 - communication/collaborations with health care
 - dose banding
 - automation



EAHP 2014 - Eva Sjökvist Saers, Sweden

APL's extemporaneous pharmaceuticals

- > 10.000 compositions in data base
- ~ 2.000 compositions manufactured frequently
- About 300 stock preparations, of which 140 with a national license from MPA
- Therapeutic areas e.g.:
 - Pediatrics
 - Pain
 - Dermatology
 - Dental care
 - Cardiovascular
 - Stomach/intestine
 - Eyes/ear
 - Gynecology
 - Urology
 - Veterinary



EAHP 2014 - Eva Sjökvist Saers, Sweden

Extemporaneous pharmaceuticals – dosage forms by APL

Aseptic/Sterile

Parenteral preparations

- Vials
- Bottles
- Ampoules
- Bags

Eye/Ear preparations

- Drops
- Ointment
- Gels

Ambulatory systems

Non-sterile

Semi-solids

- Ointments /creams
- Gels
- Lotions
- Suspensions

Liquids

- Oral solutions
- Emulsions
- Suspensions

Solid preparations

- Capsules



EAHP 2014 - Eva Sjökvist Saers, Sweden

APL large scale manufacturing of stock preparations and extemporaneous manufacturing



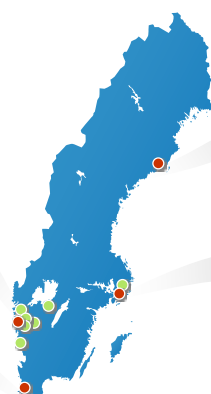
Göteborg

Non-sterile manufacturing
Oral solutions
Supply Chain & Logistics
Extemporaneous pharmaceuticals



Malmö

Non-sterile manufacturing
Semi solids



Umeå

Sterile and aseptic manufacturing
Clinical trials materials



Stockholm

Solid preparations
Clinical trials materials
Pharmaceutical/Analytical development
APL Customer Services
Extemporaneous pharmaceuticals

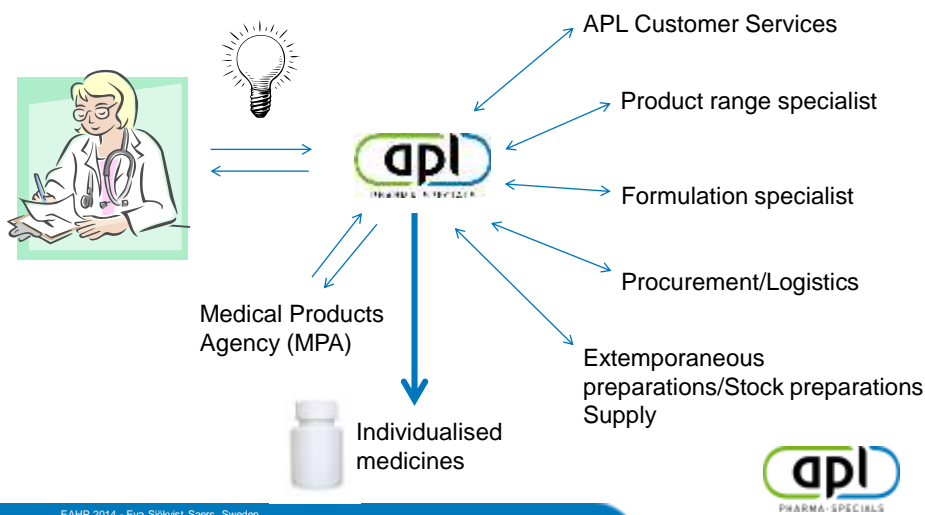
● Preparation at hospitals (tender)

West Sweden: Varberg, Sahlgrenska, Östra, Uddevalla, Skövde, Borås
Stockholm: Solna and Stockholm

EAHP 2014 - Eva Sjökvist Saers, Sweden



Development of individualised medicines for patients with special needs



Current model

Health care at hospitals in Sweden



- At the regional level, responsibility for financing and providing health care is decentralized to the county councils (regions).
- 21 regions are responsible for the organisation and management of health care at the hospitals in each region
- Hospital pharmacy management – procurement process with strict requirements. The requirements are set by the respective regions.
- Only one region manages the hospital pharmacies in-house (Jönköping)

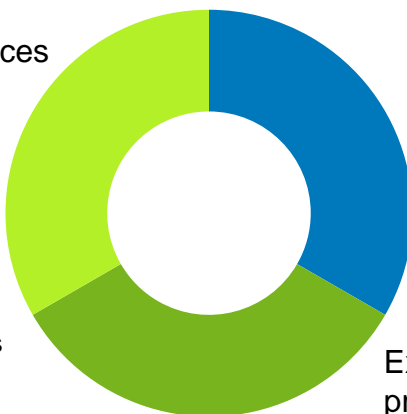


Current model

Contracted services

Pharmaceutical and Clinical services

- medicine support
- inventory mgmt
- medication utilisation review (MUR)
- medicines reconciliation
- support for discharged patients



Procurement and provision of medicines-
Drug supply

Extemporaneous preparations



EAHP 2014 - Eva Sjökvist Saers, Sweden

Current model

Procurement process of hospital pharmacy activities



Balance between
quality and cost

- According to the law on public procurement
- Strict requirements - all mandatory and need to be fulfilled by the provider
- Providers present tender with their suggestions on how to provide the services
- The decision is announced
- The decision can be appealed against by the contractor/s who did not win the procurement
- The length of the contract varies - e.g. 3+2, 4+2, 6+4 years



EAHP 2014 - Eva Sjökvist Saers, Sweden

Requirement specifications (no of mandatory claims)

Tender in Stockholm county council for extemporaneous manufacturing

- Tender invitation (general claims 34)
- Assignment (4)
- Organisation (23)
- Quality management (11)
- Supply of goods (22)
- Ordering process (29)
- Distribution (23)
- Supply reliability (3)
- Opening hours and availability (7)
- Monitoring (4)
- Principles for pricing (8)
- Clinical trial materials (5)
- Environmental issues (2)
- Performance (14)
- *Approx. 190 mandatory claims*



EAHP 2014 - Eva Sjökvist Saers, Sweden

Contractors to date

Service	Apoteket**	APL*	Apotek Hjärtat**	ApoEx	Unimedic*	Region Jönköping (in-house)
A. Drug supply	X	-	X	X	-	X
B. Pharmaceutical services	X	-	X	X	-	X
C. Extemporaneous preparations						
- Cytotoxics	X	X	X	-	-	X
- Sterile preparations	X	X	X	-	-	X
- Individual compounded preparations (sterile / non sterile)	-	X	-	-	-	-
- Stock preparations	-	X approx 300	-	-	X approx 15	-

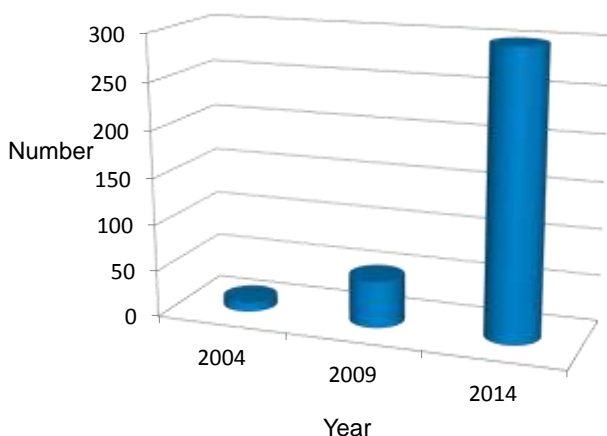
* extempore pharmacy ** pharmacy chain with community and hospital pharm.



EAHP 2014 - Eva Sjökvist Saers, Sweden

Increased focus on optimal drug utilisation and patient safety in the county councils

Pharmacists employed by the county councils



- Increased competence
- Experience from hospital pharmacy management
- More initiated procurers of services
- Some services performed in-house
- Innovation in partnership



EAHP 2014 - Eva Sjökvist Saers, Sweden

Forum for national development of activities at hospital pharmacies incl. extemporaneous preparations

- Swedish Society of Pharmaceutical sciences
- Swedish Society of Hospital Pharmacy



Section for members from e.g. hospital pharmacies, county councils, authorities

- Swedish Association of Local Authorities and Regions



Working group for pharmacists employed by the county councils



EAHP 2014 - Eva Sjökvist Saers, Sweden

Some consequences of the current model

- Competition and diversity drive innovation
- Competition lowers the price
- A variety of services and solutions available from different providers
- Some issues become more significant (IT, logistics etc)
- Fragmentation with less overview
- Regional aspects rather than national
- Cost cutting can lead to less time for continuous training/education of staff
- Competition leads to less openness between players



EAHP 2014 - Eva Sjökvist Saers, Sweden

Thanks to

Lars-Åke Söderlund

Swedish Society of Pharmaceutical sciences (board) /Apoteket

Sari Frigård

Swedish Society of Hospital Pharmacy (chairman) / Apoteket

Magnus Munge

Swedish Society of Hospital Pharmacy (board) /
County council of Kronoberg

Eva Einarsson

Apotek Hjärtat Business unit Health care



EAHP 2014 - Eva Sjökvist Saers, Sweden

eva.sjokvistsaers@apl.se

Thank you!



Together we contribute to drugs
that improve and save lives!
We are proud of that!

EAHP 2014 - Eva Sjokvist Saers, Sweden

