

A regional perspective on medicine shortages

Committee of the Regions interregional group on health and wellbeing

2024-04-18



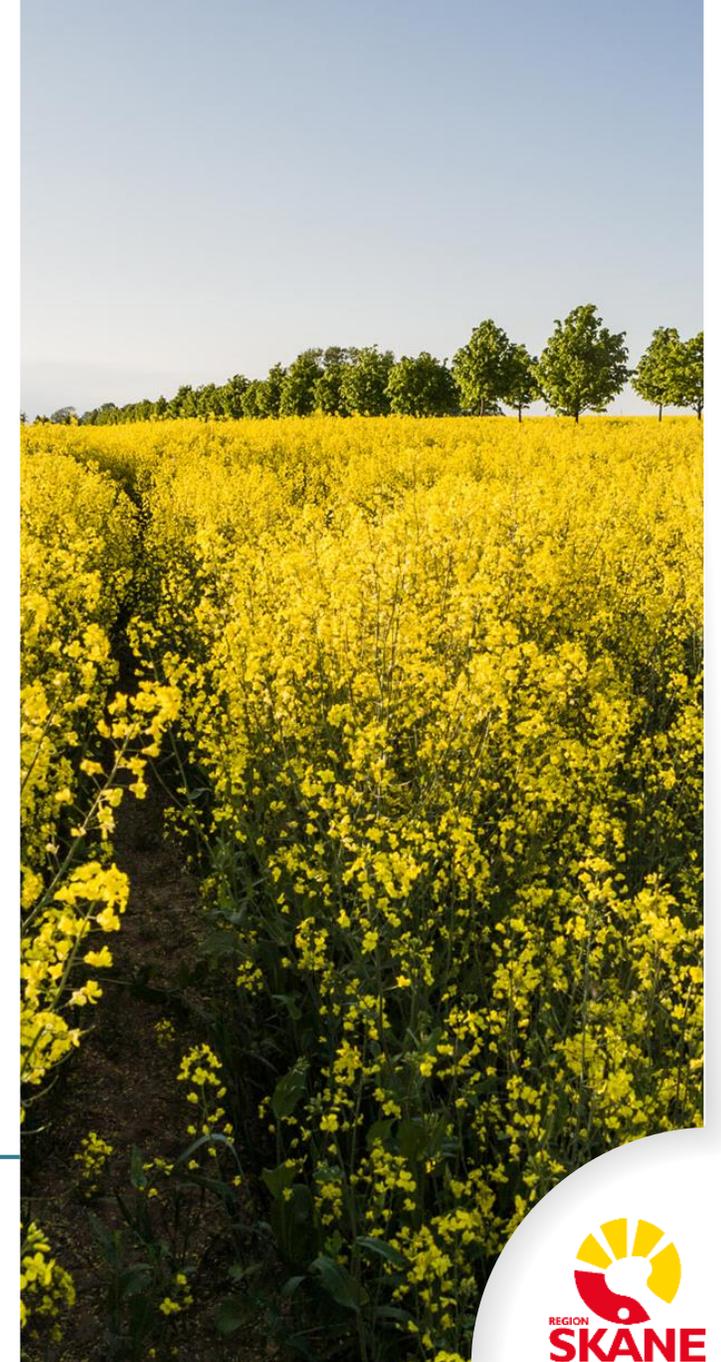
A person with long reddish-brown hair, wearing a bright yellow raincoat, stands with their back to the camera in a field of tall, dry grass. Their arms are outstretched to the sides. In the background, a calm sea meets a grey, overcast sky. The overall mood is serene and expansive.

Region Skåne

Together, we make life more possible

Responsibilities

- Healthcare
- Public transport
- Sustainable regional development
- Culture



An average day in Region Skåne

43

children are born

76 000

laboratory analyses are made

25 500

health care visits

900 000

m² of care facilities cleaned

465 000

trips made by bus/train

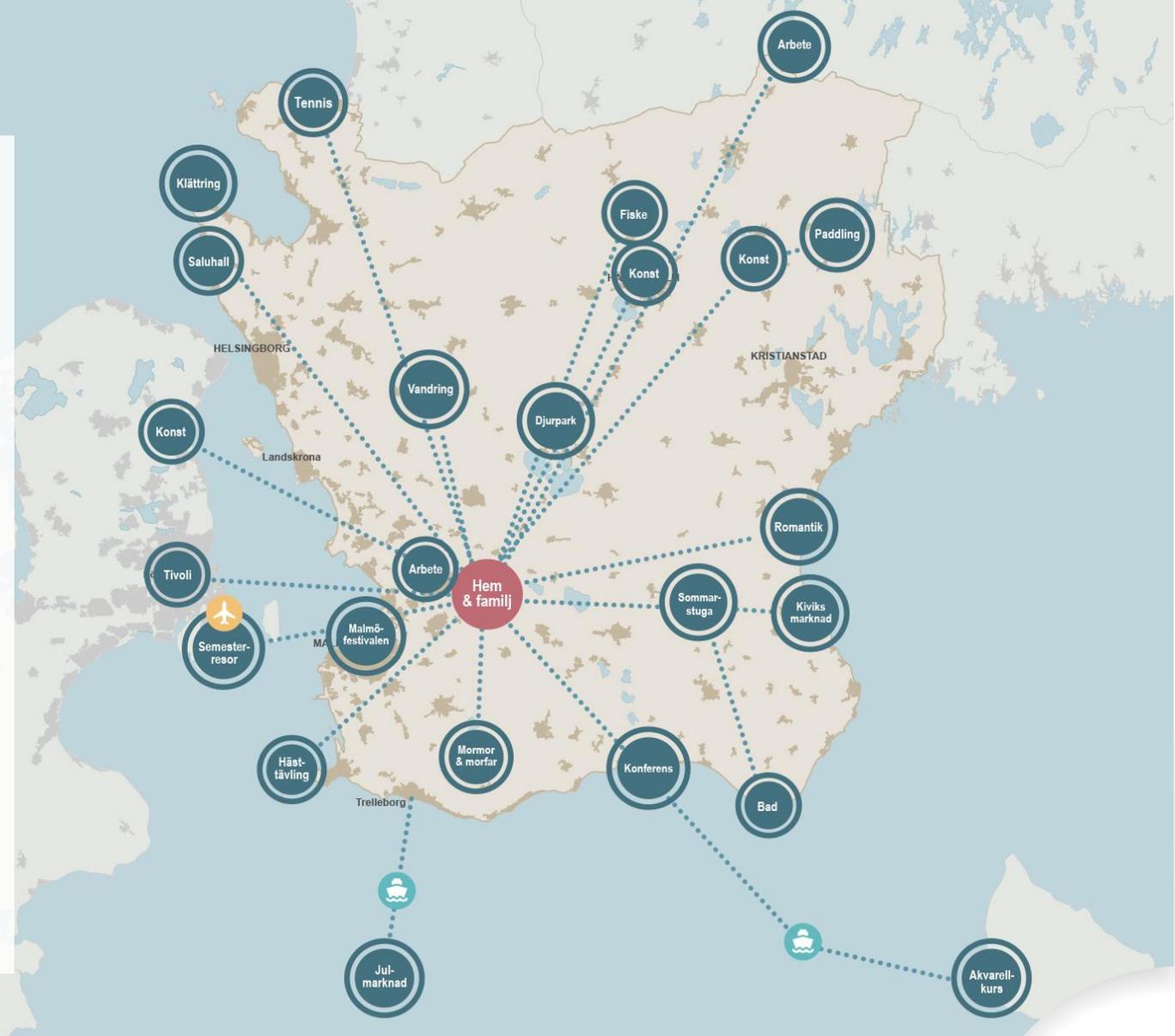
*... and every day the
population of Skåne
grows by*

36 people



Skåne

- 33 Municipalities
- Population - 1,4 million
- Many cities and short distances
- Four universities
- Part of Greater Copenhagen with a population of 4 million



Swedish association of local and regional authorities

290 municipalities.

21 regions ~ 132 000 to ~ 2 415 000 inhabitants.

A member organisation

An employer's organisation

An interest organisation

Together, municipalities and regions account for about **20 per cent** of GDP and **70 per cent** of public consumption.

The sector employs **25 per cent** of the working population, equivalent to just over one million people.



In brief: the Swedish health care system

Tax-financed and decentralised.

The regions finance most of the health care and provide most of the services.

Covers all residents – relatively few have an additional private health care insurance (dental care for adults aged 24 and over is mainly financed by the patient).

Every region must provide its residents with health care of good quality and promote good health in the entire population.

Sweden has

- ~ 1 150 healthcare centres
- ~ 60 county/district hospitals with emergency ward (day and night)
- 7 university hospitals

The share of private providers varies significantly between different regions.



A pharmaceutical legislation that ensures the long-term sustainability of national health care systems

- "Affordability, Access and Availability" – a balance between these priorities is fundamental for the long-term sustainability of healthcare systems and patient access to equal, effective and safe care.
- Support to innovation and industrial competitiveness is important. So is healthy competition, diversified access to medicines and robust pharmaceutical preparedness.
- Access to generic medicines within a reasonable time is necessary to be able to introduce new medicines in a sustainable way. This is also important for preparedness and to reduce vulnerabilities in case of shortages.



What is important for balance?

- Medicines are authorised based on robust, relevant and reliable evidence.
- Use anti-competitive measures with caution and target more accurately actual treatment gaps. Incentives for antimicrobials are needed but must be predictable.
- Minimise the risk of shortages for all medicines, new as well as older and established ones.
- Safeguard national exceptions and decision-making within national health systems.
- Consider environmental sustainability of medicines from a holistic perspective.



Are the Commission's proposals on shortages sufficient?



Focus efforts to prevent and address shortages. A functioning pharmaceutical supply chain is a fundamental prerequisite for robust health systems and is therefore important from a preparedness perspective.



More cautious use of protection mechanisms such as data protection and market exclusivity promotes diversified access to medicines. This reduces vulnerabilities to shortages and strengthens the security of supply.



Clarify the link between liability and consequences and the possibility of sanctions for companies that fail to provide information or establish plans to prevent and manage shortages.



Balance sanctioning measures with incentives and conditions for companies to maintain a wide range of products on the market. Not jeopardise the availability of important but perhaps less profitable older medicines.

Collaboration in Sweden to prevent and handle shortages

- The Swedish Medical Products Agency is the coordinating authority in Sweden. Companies must report risks of shortage to the authority. Current drug shortages are compiled in a list and shared publicly.
- Representatives from healthcare, pharmacies and the Agency discuss medicines at risk of critical shortages every week to identify risks early and handle upcoming shortages.
- A forum with all actors in the supply chain discusses risks of disruptions, trends, current work etc on a more comprehensive level.
- The regions also cooperate between them to handle critical shortages and make the product last longer or redistribute between them.
- Cooperation functions well at national level and creates conditions for also being a good partner in EU cooperation.
- Not all shortages reported to the Agency pose a problem – there are often alternatives.

Conclusions

- A focus on preventing and addressing shortages is welcome
- We need to pay attention to both new and older products
- The generics and biosimilars industry is important to ensure broad product range and thus reduce vulnerabilities
- Use anti-competitive measures with caution to promote diversified access



Thank you!



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- Replik i Dagens Samhälle om [läkemedel och marknadstillträde](#).
- Podd om regionernas och TLVs syn på förslaget till ny läkemedelslagstiftning: [Nytt poddavsnitt om nya EU-lagstiftningen om läkemedel - Janusinfo.se](#)
- Tandvårds- och läkemedelsförmånsverket (TLV) rapport om vouchers: [Recent report shows low cost-effectiveness of AMR-vouchers](#)
- Varför den europeiska läkemedelslagstiftningen behöver utgå från hälso- och sjukvårdens behov: [Debattartikel](#)
- Varför forskning och utveckling behöver ske i samverkan och för rätt patientgrupper: [Sällsynta sjukdomar kräver samverkan](#)
- Exempel på retrospektiva studier som visar evidens vid godkännande av läkemedel är undermålig och inte tillräcklig när det gäller att visa effekt på överlevnad och livskvalitet: [Reimbursed Cancer Drugs](#) och [Availability of evidence of cancer drugs](#)
- Exempel på läkemedel som efter introduktion och lång tid av användning tappar sina godkännanden p g a brist på visad effekt: [Translarna](#) och [Adakveo](#)