Availability of new medicines for patients in Sweden

Perspectives from Swedish healthcare

The 21 regions in Sweden are responsible for providing healthcare nationwide, with the ultimate goal of promoting good health and well-being for patients and residents, today and in the future. Equal access to safe, effective, and affordable medicines – in sustainable ways for the healthcare system – is essential for achieving this goal. Scientific and technological advancements create new opportunities for pharmaceutical development. Precision medicine, advanced therapies, and innovative medicinal products – especially for patients living with rare and severe health conditions – ultimately signify a shift in how healthcare is organised and delivered. Swedish healthcare is well-positioned to embrace this shift, while it also brings challenges in terms of making new treatments accessible – from the research and development stage, all the way to patient with truly unmet medical needs. Far from all medicines will however be relevant for the Swedish healthcare system. Nonetheless, it is important that the system premieres and makes accessible medicines that are safe, effective – reasonably priced – and cost-effective.

How well does the Swedish healthcare system succeed with this? According to the European Federation of Pharmaceutical Industries and Associations, EFPIA, and Lif – the industry association for the research-based pharmaceutical companies in Sweden: Not so well. This conclusion is derived from the Patients W.A.I.T. Indicator 2020 Survey (the so called "WAIT report"). Analysing medicines authorised for the European market during the period 2016–2019 and complementing this with an in-depth review of the medicines approved 2017-2019, Lif concludes that many new medicines never reach patients in Sweden and that "Sweden has fallen behind when it comes to patients' access to new medicines, especially for rare diseases." According to Lif only one of four new orphan medicines are accessible to patients in Sweden. Based on this Lif further proposes that a new model must be developed to "ensure the fundamental principle that all medicines approved within the EU should be available to Swedish patients".[1]

Swedish healthcare representatives do not agree with these conclusions. In this briefing paper a review of the underlying methodology of the WAIT report is presented. The actual availability and access of orphan medicines has also been analysed, from a Swedish healthcare perspective. The review was conducted by Region Västerbotten and Region Örebro County and the briefing paper is the first of its kind.

Key Messages

1. **Patient access is a multidimensional concept** The accessibility of medicines to patients in Sweden, based on needs, can be granted in many ways. All medicines that receive marketing authorisation are not automatically relevant treatment options in Swedish healthcare.

2. EFPIA and its Swedish counterpart Lif compile annual statistics on the availability of medicines in Europe and Sweden from an industry perspective. These compilations lack important dimensions of availability, reimbursement and accessibility from the Swedish healthcare context. Especially the decentralised procedures for patient access as well as individual reimbursement. Equivalent data is included for many other countries. **The WAIT comparison between countries is problematic as the underlying data differs between different countries. Contextual differences are also disregarded**.

3. **100% accessibility of authorised medicinal products is not a reasonable expectation for introduction, reimbursement and use**. It is neither always necessary from a patient perspective – especially when other available treatment options already meet patients' needs in a satisfactory way. Cost-effectiveness is also crucial for a sustainable healthcare system, today and in the future.

4. **The added value of a medicine is not defined by its regulatory marketing authorisation**, unique characteristics, or orphan medicine designation. What is important is the medicine's ability to address truly unmet medical needs in an effective, safe, and cost-effective manner.

5. New advanced therapies and innovative medicinal products create new opportunities for the healthcare system. At the same time, the current system is experiencing increasing challenges. **Several ongoing initiatives aim to strengthen the conditions for sustainable patient access to medicines in Sweden.** New forms of collaboration between key stakeholders, including pharmaceutical companies, will be necessary in the continued efforts.

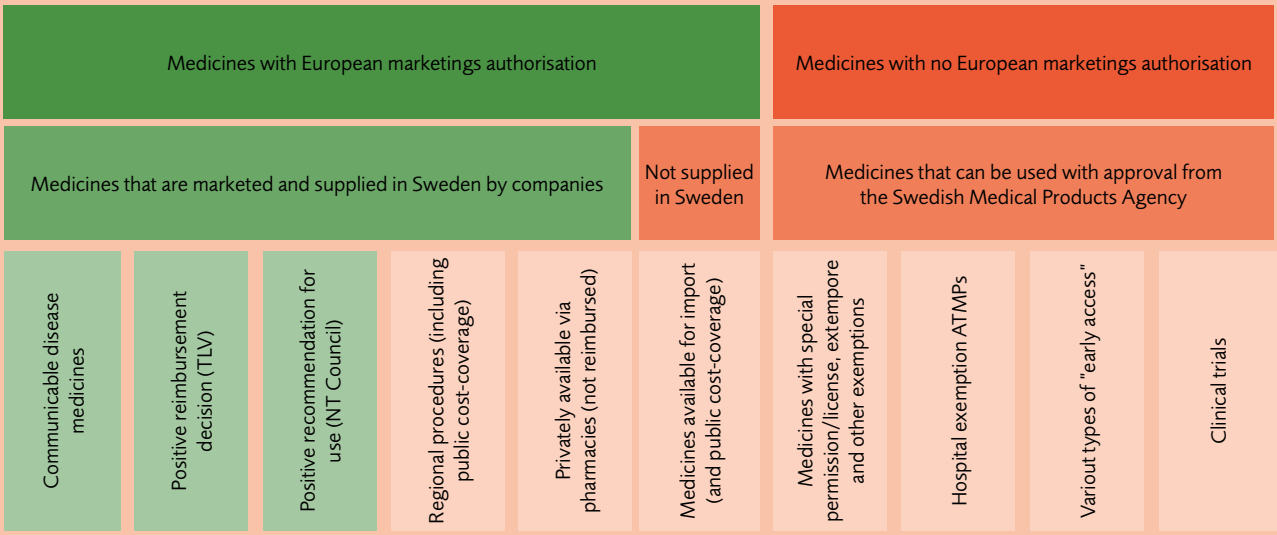
1 See e.g. IQVIA (2021), EFPIA Patients W.A.I.T. Indicator 2020 Survey; EFPIA (2021), The root causes of unavailability and delay to innovative medicines: Reducing the time before patients have access to innovative medicines; Quantify (2021), Access to new medicines with EMA approval 2017–2019 in Sweden (and the equivalent Swedish version); Life-time, Fyra av tio läkemdel når aldrig Sverige (published 2021-04-22) and Dags att vision blir verklighet (published 2021-06-10).

Highlights from the report

- **Patient access is a multidimensional concept.** Patient access is not the same as availability or reimbursement of medicines. Measuring patients' access to medicines in different countries is therefore complex.
- **The annual WAIT report compares availability of new medicines in European countries, primarily based on reimbursement.** It does not measure medicine use or healthcare uptake of medicines. The definition of availability in the WAIT report is thus not equivalent to patients' access to medicines. **The results presented in the WAIT report are based on different input variables for different countries**. The validity and reliability of the comparison is therefore questionable.
- Both **EFPIA and OECD confirm that context and local conditions are important for drawing conclusions about differences between countries.** Results need to be interpreted based on the variables for measuring availability and patient access, as well as differences in healthcare systems – the organisation, financing and delivery of healthcare as well as the specific design of the pharmaceutical system and procedures for introduction, reimbursement and use. A deeper understanding of healthcare systems and pharmaceutical systems are thus needed when comparing patients' "waiting for access to innovative therapies".
- Nonetheless, for Sweden, based on the 2021 WAIT report and the complementary national analysis, the industry association for research-based pharmaceutical companies in Sweden **(Lif), draws the conclusion that Sweden is falling behind other countries in Europe** and that "patients are forced to stand far back in the queue, unsure of their access to relevant medicines". **Analysing the WAIT methodology gives a different perspective to these incorrect conclusions.**
- **Lif contributes with the data that is used to measure availability to medicines in the Swedish context.** Based on data that was included in the 2021 WAIT report, the variables that measure availability to new medicines in Sweden is primarily based on the criteria of different types of national reimbursement as well as "relevant level of sales". Defining and validating the "relevant" level of sales is however not possible without a deeper analysis of factors such as patient volumes, patient subgroups, unmet medical needs, as well as access and effectiveness of other treatment options (not only medicinal products), treatment guidelines and clinical practice. **Based on the Swedish context, this is a very narrow inclusion criteria** – especially in a decentralised healthcare system with regional procedures for introduction and reimbursement of new medicines. It also does not consider that all authorised medicines are available for use in Swedish healthcare based on the prescription right of qualified healthcare personnel.
- **Most medicines that are found reasonable from medical, humanitarian, and socioeconomic aspects** or are deemed necessary for use in health care, to address unmet medical needs of patients – including the use under exceptional circumstances and essential care for individual patients – **have national or regional cost-coverage.**
- Based on the WAIT report published in 2021, Lif concluded that patients in nine European countries had better access to authorised medicines than patients in **Sweden**. Among them, Denmark, Finland and Germany. This can, at least in part, be explained by the **differences in the choice of data variables in the WAIT analysis.** Whereas the inclusion criteria for data from Sweden excludes the decentralised procedures, regional procurement and cost-coverage of medicines as well as procedures for use under exceptional circumstances and medicines that were granted individual reimbursement, the equivalent is included for many other countries. For example, Denmark, Finland, England, and Austria have included data for medicines with individual reimbursement, for individual patients.
- **Similar observations were made for the analysis of time to availability.** Naturally, measuring time to availability by including data from formal national reimbursement decisions and recommendations for use – after completed introduction processes, health economic evaluations, procurement and sometimes complementary negotiations – is not the same as measuring the date for registration of a price or inclusion on public reimbursement lists. The time to availability does not disclose what parts of the introduction process that takes time. Including the time from marketing authorisation to marketing and supply of medicines in different countries, as well as possible delays of companies in terms of submitting applications and documentation necessary for pricing and reimbursement decisions.
- In the WAIT report it is clear that the **applied definition of availability is not the same as medicine use or healthcare uptake of medicines.** The definition of availability is thus not equivalent to patients' access to medicines. It is also noted that the interpretation of the results should be undertaken with caution and with consideration to contextually relevant factors in different countries.
- To understand the concepts of availability and patients' de facto access to medicines in the Swedish context, a broader healthcare perspective is needed, as well as a greater understanding of the pharmaceutical system. **From a patient perspective, many pathways exist for the accessibility of medicines in Sweden** – far beyond that which is included in the WAIT analysis. *See figure below for different pathways that facilitate patients' access to medicines in Sweden.*

- **Sweden has publicly funded healthcare that covers the entire population.** The right to healthcare and the access to, for example, medical treatment is not based on patients' financial status but on medical needs. The healthcare system is financed collectively, through taxes, and patients' proportion of costs is relatively low. Medicines that are formally introduced in the healthcare system are automatically available – on equal terms – for the entire population. This is positive from a patient perspective. Medicines that are available on the Swedish market and that are reimbursed, procured and/or hold positive recommendations for use commonly also reach sales. This creates conducive conditions for market penetration and benefits pharmaceutical companies with relevant and safe, effective – reasonably priced – and cost-effective medicines.
- The cost-effectiveness criterion is key for the sustainable use of medicines in Swedish healthcare and is also reflected in the value-based pricing model applied within the pharmaceutical system. **The ethical principles of human dignity, need and solidarity, and cost-effectiveness guide prioritisation.** Central legislation such as the Health and Medical Services Act (2017:30), the Local Government Act (2017:725), and the Patient Act (2014:821) all highlight the importance of cost-effectiveness and good economic management in healthcare. As such, the cost of various forms of treatments need to appear justifiable. At the same time, the aspect of affordability is increasingly important as company pricing of many of the new medicines is high and pharmaceutical costs are rising. Coupled with limited evidence, this could, in the long term, pose challenges to patients' access to medicines. **Not all new medicines will therefore be introduced, reimbursed or used within healthcare systems.**
- **Several initiatives are underway** to strengthen the conditions for long-term sustainable access to new medicines in Sweden. Examples of such initiatives include the review and development of alternative payment models and managed entry agreements for the introduction of new medicines, as well as strengthened collaboration with other countries for horizon scanning, health economic evaluations, joint negotiations - in cooperation with e.g. other Nordic countries and with the Beneluxa initiative (Belgium, Netherlands, Luxembourg, Austria and Ireland). A continued constructive collaboration with the pharmaceutical industry in Sweden will be key going forward.

Different pathways that facilitate patients' access to medicines in Sweden



Authorised and non-authorised medicines that are available in Swedish healthcare - accessible to patients in Sweden.

Green boxes represent pathways that are included in the WAIT report based on the definition of availability used for Sweden (excluding the criteria for "relevant sales"). Based on procedures for national reimbursement, including medicines for indications included in the communicable disease program. Other pathways for patients' access to medicines are excluded. Including decentralised procedures, regional cost-coverage, individual reimbursement and availability to medicines that are not authorised for the European market as well as other relevant treatment options (beyond medicinal products). In the WAIT report, the equivalent to Sweden's decentralised procedures and pathways for individual reimbursement, to individual patients, has been included in the statistics for countries such as Denmark, Finland and the United Kingdom.

This is an English abstract of the original briefing paper, published in Swedish 2021. The review of the WAIT methodology, the results presented in WAIT report, and the conclusions drawn about the availability to new medicines in Sweden – by Lif and national pharmaceutical industry representatives – confirm that international comparisons of this type are problematic.

The selection of definition and input variables, as well as analysis and conclusions require a deeper understanding of country contexts and local conditions. Discussions on potential differences are needed to ensure the correct interpretation of data. The inconsistencies identified for the Swedish context may also occur for other countries. The question is thus, what does the WAIT report actually say about patients' access to innovative therapies in Europe? Reviewing availability of and accessibility to new medicines should not only be an exercise of the pharmaceutical industry – covering primarily industry perspectives. This type of analysis needs to be undertaken by healthcare providers and payers – based on healthcare perspectives and factors that are relevant for patients' access to high quality healthcare in the various countries.

A common view and understanding of real bottlenecks to patients' access to medicines and how the system can be improved will be key as new and necessary collaborations are forged between healthcare providers, industry partners and other relevant actors and key stakeholders - including the patients. Building and strengthening the trust between parties will be essential for the success of joint efforts that can strengthen the conditions for sustainable patient access to new safe, effective – reasonably priced – and cost-effective medicines. Sweden will continue its efforts to be an attractive country for research and development, production, marketing and sale of relevant medicines that meet real treatment gaps within the healthcare system and addresses unmet medical needs of patients.

KEY CONCEPTS[2]

Availability: The medicine is available for use. This mainly requires a marketing authorisation or other permits that grant the marketing, supply and/or use of medicines in healthcare. Availability can also be governed by prescription rights for healthcare professionals. This is the case within the Swedish health care system. Company strategies for marketing and supply as well as production and delivery can also influence the availability of medicines on different markets.

Accessibility: The medicine reaches all the way to patients with real unmet medical needs. The optimal level of accessibility is difficult to measure. Patient access is dependent on both availability as well as economic dimensions such as the affordability of medicines. Reimbursement systems and level of cost-coverage influences affordability for patients. For publicly funded healthcare systems or for insurance-based systems, the affordability is linked to the availability of resources as well as other healthcare needs of patients. Factors that can affect uptake of new medicines and patients' de facto access to treatment include introduction and implementation processes as well as prioritisation. This include but is not limited to consideration to cost-effectiveness criteria, risks and uncertainties on safety and efficacy, competencies of healthcare professionals and acceptability of new medicines, treatment guidelines, as well as relative benefits in relation to other available treatment options. The OECD stresses that it is not reasonable to expect automatic, full and immediate patient access. It is neither always necessary from a patient perspective.

[2] OECD (2020), Addressing Challenges in Access to Oncology Medicines, Analytical Report

* **How was the review conducted?** The analysis of the WAIT methodology, input variables, results and conclusions based on the Patients W.A.I.T. Indicator 2020 Survey – and the complementary Swedish report – presented in this briefing paper, has been conducted based on the structure of and perspectives from the Swedish healthcare system and de facto procedures for introduction, reimbursement and use of new medicines. Key concepts used in the WAIT report - and the complementary Swedish analysis - such as availability, reimbursement and access, have been reviewed based on country context and local conditions. Constructive and complementary methodological discussions with Lif followed after the publication of the original Swedish briefing paper.

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BRIEFING PAPER ON PATIENTS' ACCESS TO MEDICINES IN SWEDEN
Availability of new medicines for patients in Sweden Perspectives from Swedish healthcare

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