Swedish national reimbursement of new medicines with EMA approval 2018-2020

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Executive summary

Executive summary (1/2)

The present report is a detailed review of national reimbursement status in Sweden for the cohort of new medicines with European Medicines Agency (EMA) approval in 2018-2020. The aim of this report is to present how the Swedish systems for national reimbursement of medicines function from the perspective of pharmaceutical companies, while also creating a basis for dialogue on how to further improve the Swedish systems.

Medicines were categorized according to three main routes to national reimbursement depending on the type of medicine (*communicable disease medicines, prescription medicines and hospital medicines*). The report is mainly based on publicly available data, complemented by date of supply and responses to a survey sent to pharmaceutical companies.

Out of the 126 medicines with EMA-approval in 2018-2020, 83 (66%) were supplied by the company in Sweden. Overall, 70 medicines were nationally reimbursed, which represents 56% of all medicines approved by the EMA in 2018-2020 and 84% of the medicines supplied. On average, nationally reimbursed medicines were nationally reimbursed 287 days after being approved by EMA.

The time from EMA approval to national reimbursement was longer for hospital medicines than for prescription medicines. The lack of a formal way of requesting an assessment as well as the lack of a regulated process and timeframe for the assessment by The Dental and Pharmaceutical Benefits Agency (TLV) or for the New Therapies (NT) council to make a recommendation for hospital medicines are likely to prolong the time to supply and/or national reimbursement of new hospital medicines in Sweden.

Executive summary (2/2)

Based on public information combined with results from a company survey (non-public information), marketing authorisation holders (MAHs) of the 43 non-supplied medicines had been in contact with the national reimbursement systems in 20 cases and had no intention of supplying in 7 cases. It was not possible to obtain information on 16 (37%) non-supplied medicines; this data gap can potentially be explained by the fact that the majority of MAHs of non-supplied medicines have no or limited experience with the Swedish market.

In conclusion, pharmaceutical companies not supplying medicines remains a challenge. This may not be an issue in cases where there are no patients in Sweden and/or effective treatments are available but societal actions may be needed for medicines where a significant patient value could be added. The current system for prescription medicines places the entire responsibility on the company to apply for reimbursement while the opposite is true for the system for hospital medicines.

The complete dataset of publicly available information can be provided upon request to Lif and/or Quantify Research.

Background and objectives

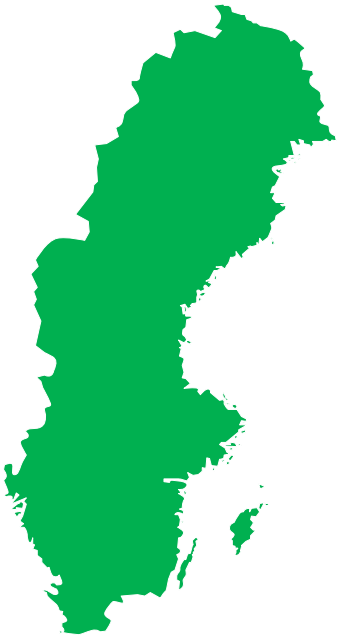
Background

- Each year, the European Federation of Pharmaceutical Industries and Associations (EFPIA) presents its Patients W.A.I.T.* Indicator for new medicines in European countries, assessing indicators of availability of medicines in rolling cohorts:
  - The rate of availability, measured as the number of medicines included in the national reimbursement list (EFPIA's definitions of availability are detailed in the Appendix) in each country compared to the total number of new medicines approved by EMA during the period
  - The average time to market (TTM) for available medicines measured from marketing authorisation (MA) date to the date of national access

- The present report is a detailed review of national reimbursement of new medicines with EMA approval in 2018-2020 in Sweden. This report was conducted by Quantify and commissioned by Lif. Similar analyses have previously been conducted for new medicines approved in 2014-2016, 2015-2017, 2016-2018 and 2017-2019.

- The previous reports led to discussions between the Swedish regions, TLV and Lif on how to evaluate patient access to new medicines in Sweden considering the different routes to reimbursement. During these discussions, the following feedback was received:
  - Not all approved medicines are relevant treatment alternatives in Swedish healthcare
  - The regional perspective and regional possibilities of making medicines accessible to patients (through requisition, individual reimbursement, prescription and import) were missing, making cross-country comparisons difficult
  - 100% of the medicines are accessible in Sweden, but not 100% are, or must be, nationally reimbursed if alternatives exist

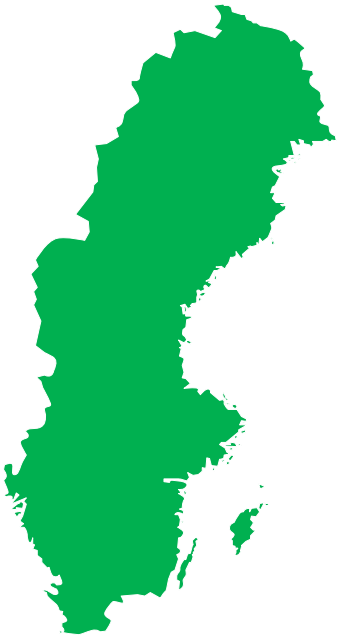
- Based on this feedback and the underlying discussion, this year's report is restructured and rephrased based on revised definitions and methodology (see slide [8]) to more clearly highlight challenges in the processes for national reimbursement decisions and/or recommendations in Sweden from a company perspective.



* W.A.I.T.: Waiting to Access Innovative Therapies

Revisions compared to previous reports

- The main changes made by Lif in this report compared to the previous reports are:
  - This report focuses solely on the Swedish national reimbursement setting
    - No comparisons are made to other countries
    - Even though there are regional routes for reimbursement of medicines, the lack of publicly available data on regional reimbursement hindered a proper assessment of these processes
    - No sales analyses are conducted
  - Medicines are no longer referred to as "available" and "non-available", but rather "nationally reimbursed" and "not nationally reimbursed"
    - National reimbursement of hospital medicines that have not received a recommendation from the NT council is no longer evaluated through sales, rather:
      - Those in national managed introduction with an ongoing assessment are classified as not nationally reimbursed
      - Those not in national managed introduction are classified as nationally reimbursed*
      - This potentially affects the national reimbursement status of 10 hospital medicines approved in 2018-2020
  - Communicable disease medicines and hospital medicines not in national managed introduction are considered nationally reimbursed from the day they were first supplied in Sweden
  - No analysis of replaceability has been conducted based on the feedback described in the previous slide
- This indicates that any comparisons compared to previous reports should be made with care
- With these changes, the report hopefully gives a more correct picture of how the national Swedish reimbursement system functions, based on publicly available information



* These hospital medicines are classified as nationally reimbursed since they can be procured and used by hospitals or regions.

Objectives

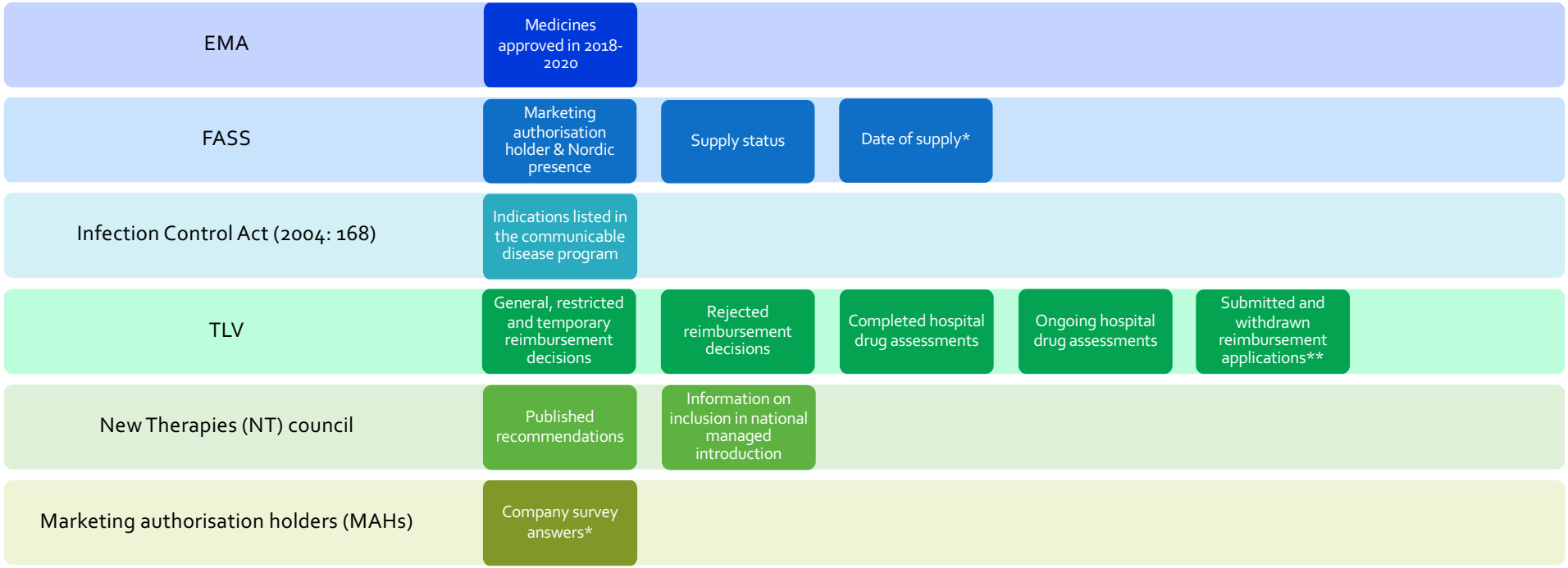
This report aims to:

- Present how the Swedish systems for national reimbursement of medicines function from the perspective of pharmaceutical companies
- Create a basis for dialogue on how to further improve the Swedish systems

Data collection and definitions

Data collection

- The report is based on the following public and non-public information



- The complete dataset, excluding non-public information, can be provided upon request to Lif and/or Quantify Research

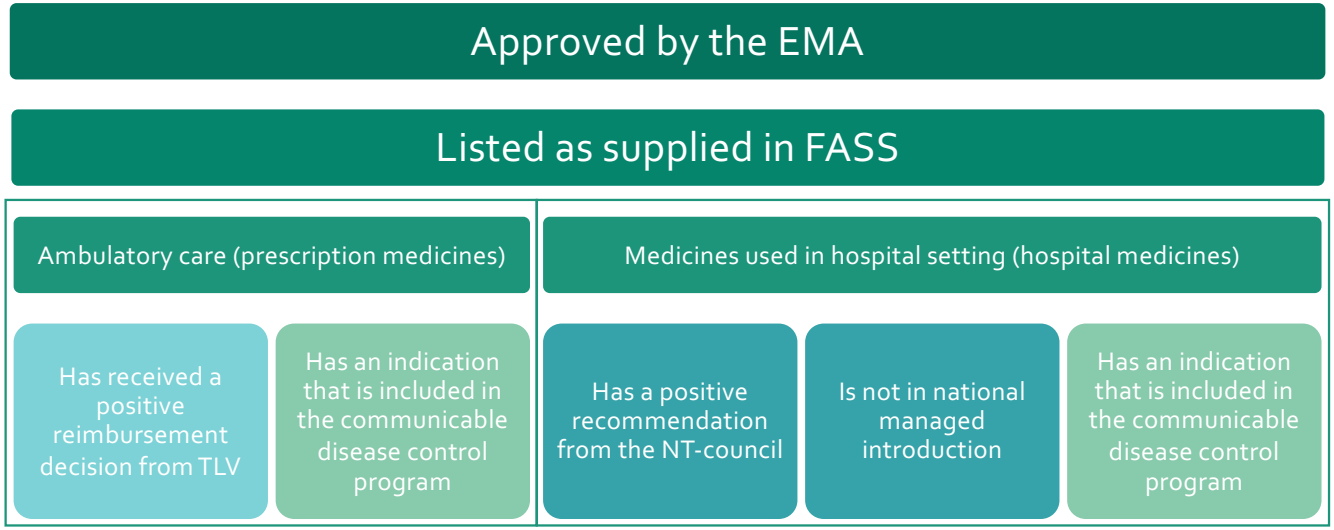
* Non-public information received from source
** Data not openly published on TLV's website but obtained upon request based on the principle of public access to information

Definitions

Definition of national reimbursement

National reimbursement was defined as there existing public documentation stating that the medicine should be partially or fully financed for patients.

For the purpose of this report, a medicine is classified as **nationally reimbursed** if it, on the **cut-off date 21 December 2021**, was:



All other medicines are considered to lack national reimbursement. These may still be available at a regional level or for patient purchase

Routes to national reimbursement

Based on the definition, **three main routes to national reimbursement** are outlined, based on type of medicine:

1. Communicable disease medicines
2. Prescription medicines
3. Hospital medicines

Excluding communicable disease medicines

A medicine is classified as a **communicable disease medicine** if it has at least one indication included in the communicable diseases program.

A medicine is classified as a **hospital medicine** if:

- There is an NT-council recommendation of use at the cut-off date, or
- The medicine is administrated IV (without possibility to self-inject at home), and/or
- The summary of product characteristics (SmPC) states that clinical staff was required for administration.

All other medicines are considered **prescription medicines**.

Routes to national reimbursement

Communicable disease medicines

Automatic reimbursement

Prescription medicines

Company submits application to TLV → TLV assessment → TLV decides on pricing and reimbursement

180 days
(Possible to clock-stop for up to 90 days)

Three-party negotiations and price agreements with the regions can be added

Hospital medicines

NT-council initiates assessment by requesting HE assessment from TLV → TLV requests documentation from company → TLV assessment → TLV publishes HE assessment → NT-council recommendation

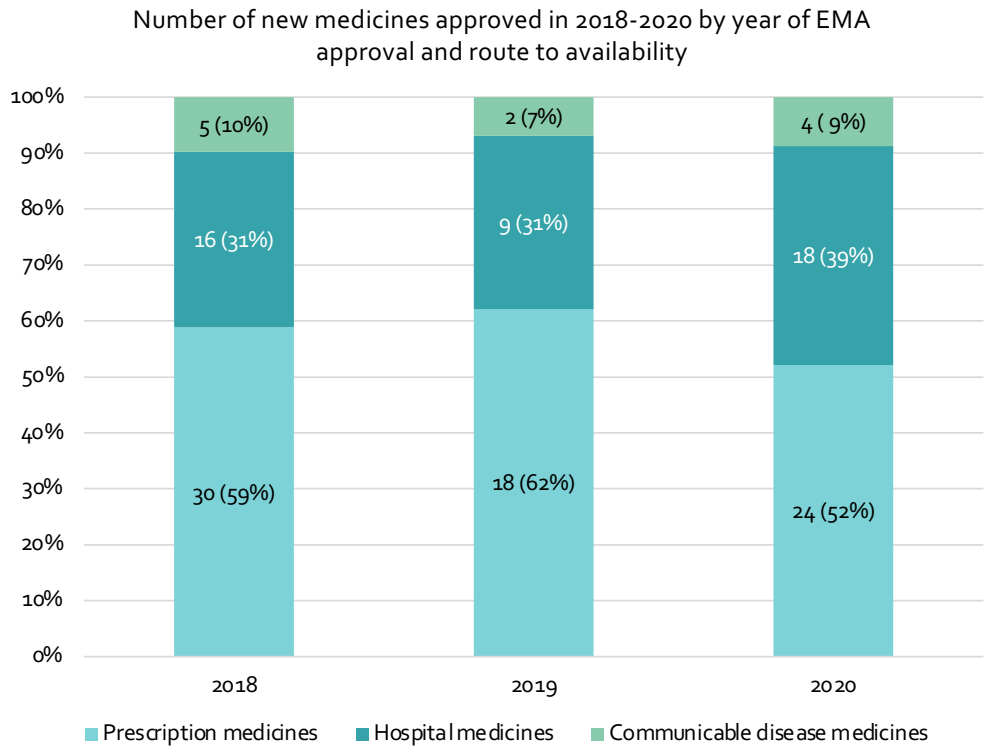
No legal timeframes

NT-council negotiations and price agreements with regions can be added

Medicines approved by EMA in 2014-2020

- In total, this report includes **280 new medicines** with new substances or combinations approved by EMA in 2014-2020 that were identified in EFPIA's W.A.I.T. report*
  - Medicines with withdrawn marketing authorisation were excluded
  - One medicine was excluded due to only being administrated in one Italian hospital

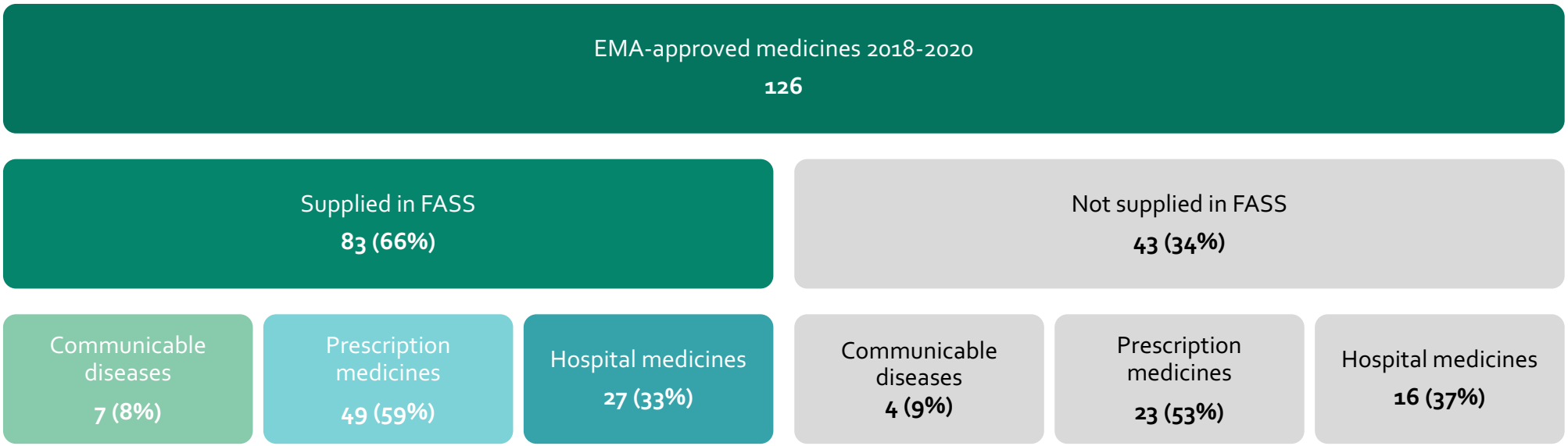
- **The focus of the report is on the 126 new medicines that were approved by EMA in 2018-2020**
  - Some analyses were also made using medicines approved in 2014-2017 in order to show longer trends
    - Data for medicines approved in 2014-2017 were updated, meaning that national reimbursement may have been achieved until the cut-off date (21 December 2021)
  - 51 (40%), 29 (23%) and 46 (37%) medicines were approved in 2018, 2019 and 2020, respectively
  - 32 (25%) were authorized under exceptional circumstances, having a conditional marketing authorisation or as undertaking a post-authorisation safety study (PASS) by the EMA



* The complete dataset of publicly available information can be provided upon request to Lif and/or Quantify Research

Supply of new medicines in Sweden

From EMA approval to supplied in FASS

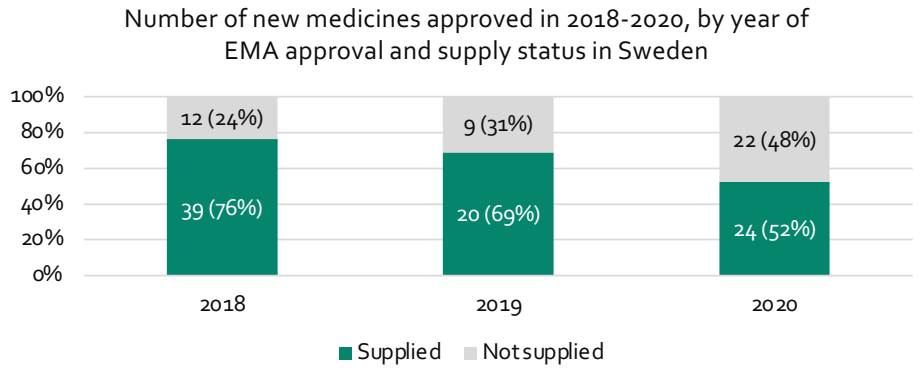


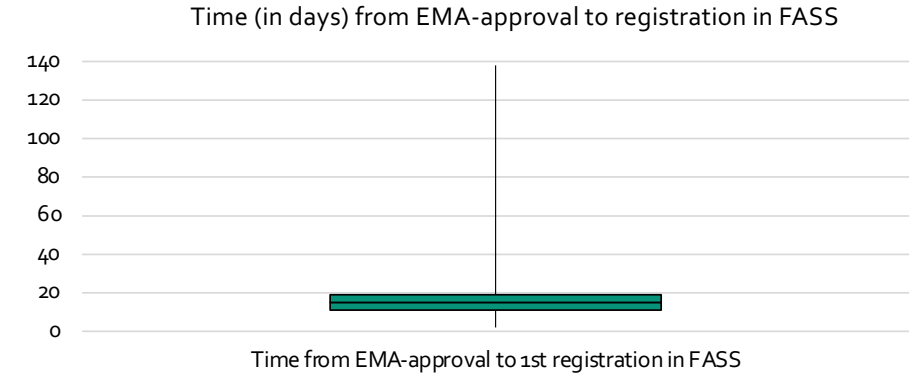
FASS is a database developed by Lif in close cooperation with the pharmaceutical companies that provides extensive, quality assured and up-to-date information about all medicines supplied in Sweden.

The basic information comes from Nationellt Produktregister för Läkemedel (NPL – the national product registry for medications), which is automatically downloaded to the FASS database. SmPCs, package leaflets and all other information are provided and uploaded by the pharmaceutical companies.

From EMA approval to supplied in FASS

- At the cut-off date, 83 (66%) of the 126 medicines with EMA-approval in 2018-2020 were supplied by the company in Sweden according to FASS
  - 43 medicines were not supplied in Sweden
    - Medicines may still have ongoing reimbursement processes
    - An attempt was made to identify whether TLV decisions or NT recommendations existed (see slide [18])
  - As expected, the proportion of medicines supplied increases with time from EMA approval; a bigger proportion of medicines approved in 2018 was supplied than those approved in 2019 or 2020
- Medicines supplied in Sweden on average (median) took 18 (15) days from EMA approval to be registered as supplied **for the first time** in FASS



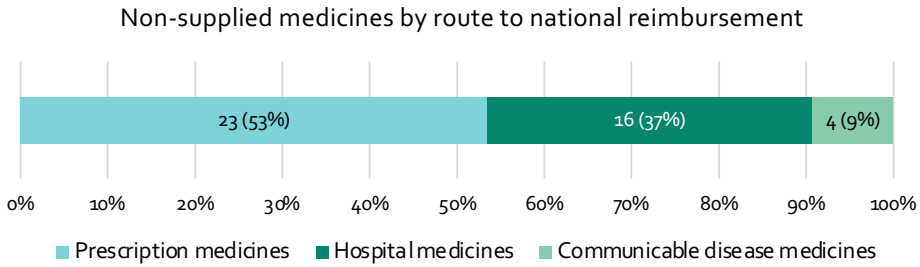


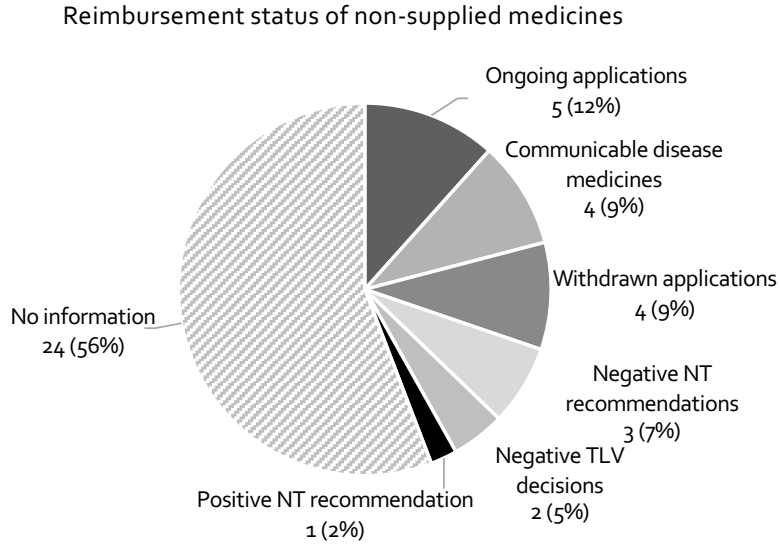
Non-supplied medicines – medicine characteristics

- At the cut-off date, 43 (34%) of the 126 medicines were not supplied by the company in Sweden according to FASS
  - 16 (37%) were subject to additional monitoring by EMA (i.e., authorised under exceptional circumstances, having a conditional marketing authorisation or PASS)
  - A bare majority (53%) were prescription medicines

- Based on publicly available information,
  - 5 medicines had negative TLV decisions or NT recommendations
  - 5 medicines had ongoing assessments
  - 5 medicines would be classified as nationally reimbursed if supplied due to being communicable disease medicines or having a positive NT recommendation
  - 4 medicines had withdrawn TLV applications
  - Public information was missing for 24 (56%) medicines
    - A company survey was conducted in order to gain further insights into why some medicines were not supplied

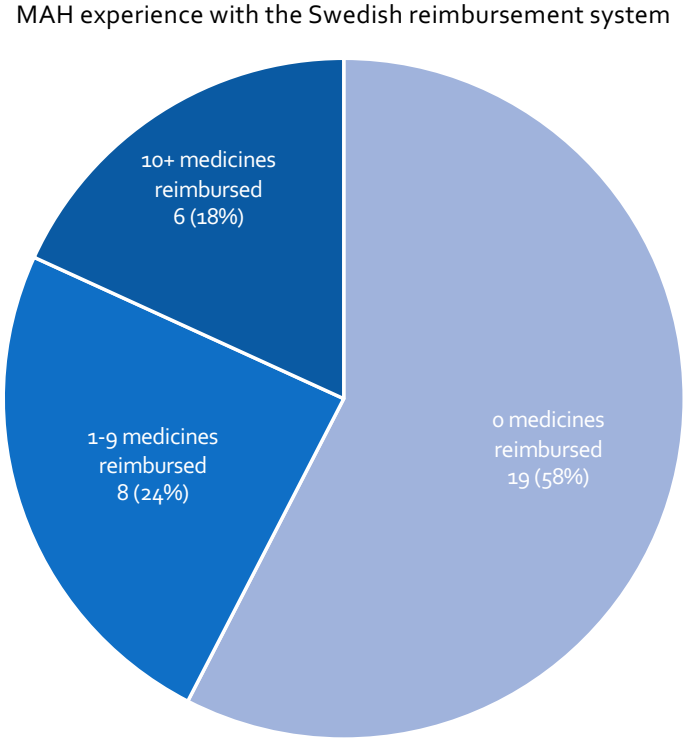
MAHs are not required to supply their medicines before applying for national reimbursement in Sweden.





Non-supplied medicines – MAH characteristics

- 43 non-supplied medicines were marketed by 33 unique MAHs
- A majority (16; 58%) of MAHs had no prior medicines included in the Swedish reimbursement system based on information from TLV's price and decision database
- 41% of MAHs did not have local presence in any of the Nordic countries



Discussion

- 66% of all new medicines approved by the EMA 2018-2020 were supplied in Sweden

- For national reimbursement of new medicines in Sweden, MAHs not supplying medicines on the Swedish market is a challenge
  - However, 14 medicines had indicators suggesting they may become supplied
    - 5 were being evaluated as hospital medicines
    - 4 had submitted/withdrawn applications to TLV
    - 4 were communicable disease medicines
    - 1 had received a positive NT-recommendation
  - 5 medicines had received negative decisions/recommendations, which potentially discourages MAHs from supplying the medicines in Sweden.
  - In cases where treatment alternatives exist, there is no patient population or if the MAH can offer the medicine to patients by a different way than national reimbursement, the lack of supply of medicines may not necessarily create problems for patients

- There is a lack of publicly available information on the reimbursement status for most of the non-supplied medicines
  - This indicates that MAHs may not have applied for national reimbursement
  - A company survey was conducted in order to understand the company perspective on why medicines were not supplied

- The lack of presence in the Nordics or prior experience of the Swedish reimbursement system suggests that many MAHs marketing non-supplied medicines lack experience from the Swedish market
  - This may indicate a lack of interest in, or a perceived complexity of, the Swedish reimbursement systems

- Despite not being supplied, some medicines may be used on a regional level by other routes of distribution. No such information was collected as part of this report

Nationally reimbursed medicines

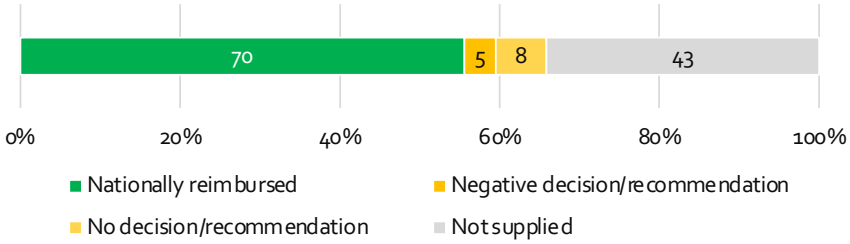
Nationally reimbursed medicines in Sweden (1/2)

National reimbursement

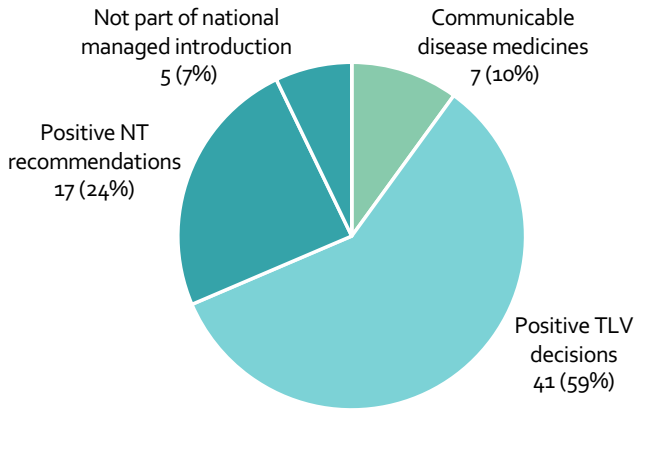
- Overall, 70 medicines were nationally reimbursed in Sweden, this was
  - 56% of all medicines approved by the EMA in 2018-2020
  - 84% of the medicines registered as supplied
- Among the 70 medicines,
  - A majority (41; 59%) had positive decisions from TLV
  - 17 (24%) had positive NT recommendations
  - 7 (10%) were indicated in communicable diseases
  - 5 (7%) medicines were hospital drugs which were not in national managed introduction
- Restrictions in the national reimbursements in comparison to the approved indications were present in 33 (47%) TLV decisions and NT recommendations
- The national reimbursement depended on national price agreements in 24 (34%) TLV decisions and NT recommendations
- 13 medicines were not classified as nationally reimbursed because they had a negative TLV decision or NT recommendation, lacked a TLV decision (prescription medicines) or were in national managed introduction but did not yet have a published recommendation (hospital medicines)
  - Further information about these 13 medicines is presented in the section Other reimbursement routes

5 non-supplied medicines would have been classified as nationally reimbursed if supplied.

National reimbursement of all medicines approved by EMA in 2018-2020



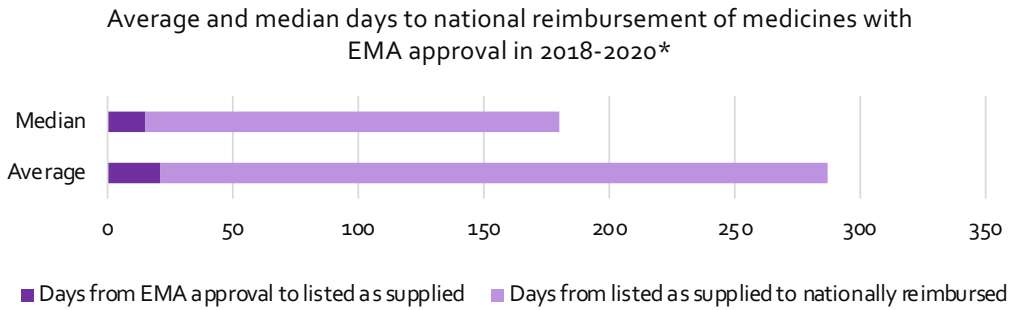
Reason for national reimbursement among 70 reimbursed medicines approved by EMA in 2018-2020



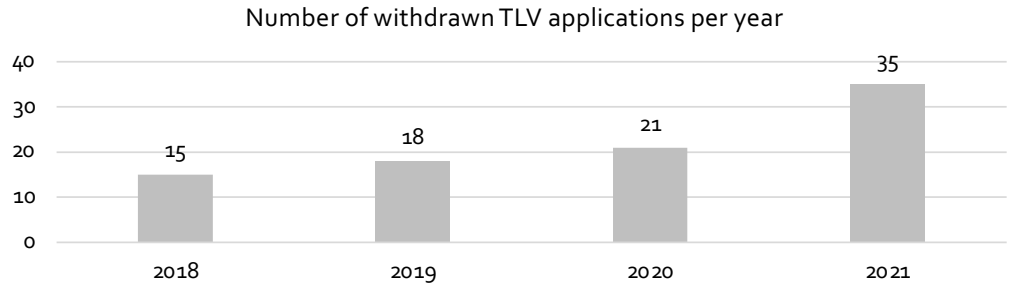
Nationally reimbursed medicines in Sweden (2/2)

Time to national reimbursement

- Overall, nationally reimbursed medicines were on average (median) nationally reimbursed 287 (180) days after EMA approval
  - Medicines were supplied 21 (15) days after EMA approval
  - Medicines were nationally reimbursed 266 (165) days after being supplied
- MAHs marketing nationally reimbursed medicines were generally quick to supply these medicines in Sweden.
  - The longest time from EMA approval to date supplied was 138 days
- Based on information from TLV, the number of withdrawn applications in 2018-2021 increased from 15 in 2018 to 35 in 2021
  - Given that some of these medicines are included in the current report, these withdrawals will affect the time to national reimbursement



* Note: this includes communicable disease medicines and hospital medicines not in national managed introduction (i.e., medicines classified as nationally reimbursed when registered as supplied in FASS)



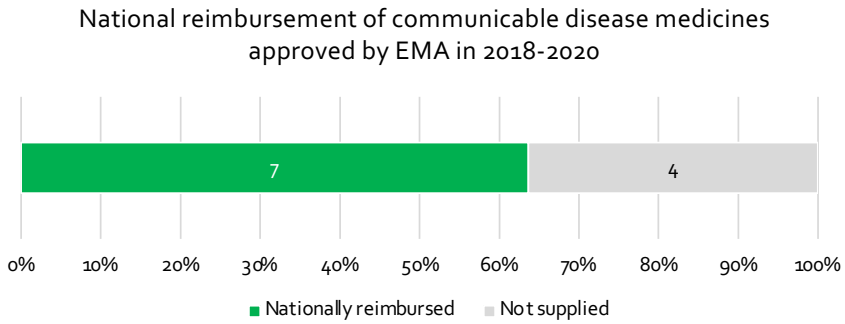
National reimbursement of communicable disease medicines

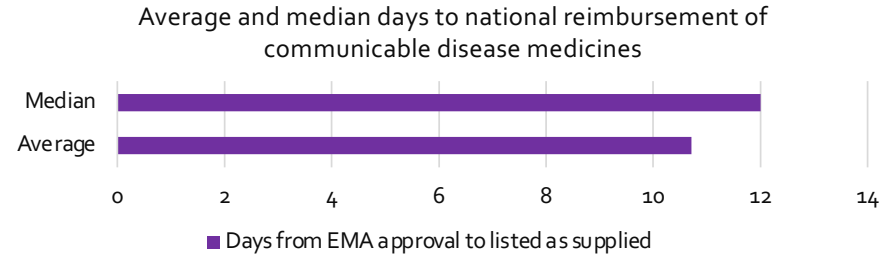
National reimbursement

- By definition, all medicines with indications included in the communicable disease program that were approved by the EMA and supplied in Sweden were considered nationally reimbursed
  - 7 out of 11 medicines (64%) were supplied in Sweden, and thereby classified as nationally reimbursed

Time to national reimbursement

- Average (median) time to national reimbursement of communicable disease medicines was 11 (12) days
- By definition, these medicines were classified as nationally reimbursed on the first day that they were registered as supplied in FASS
  - Any delays in time to national reimbursement can only be explained by delays in supplying the medicine



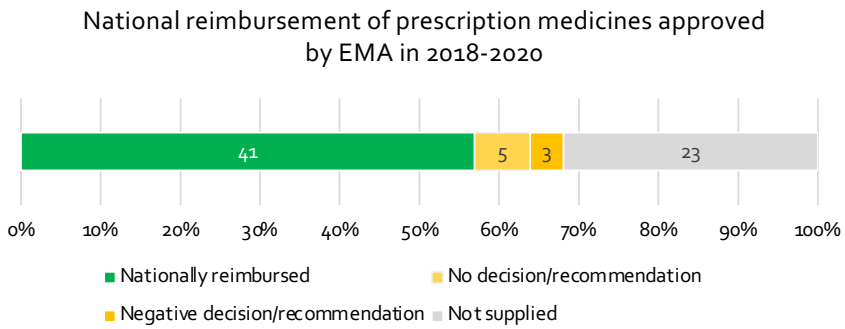


Communicable disease medicines were considered automatically nationally reimbursed from the first date of registration as supplied in FASS.

National reimbursement of prescription medicines

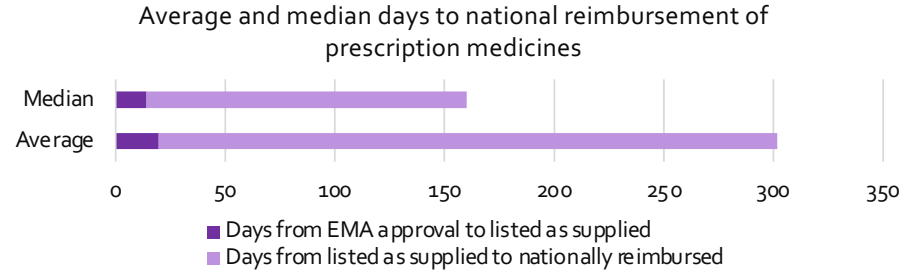
National reimbursement

- 41 prescription medicines approved by the EMA in 2018-2020 had positive TLV decisions
  - This was 57% of all approved prescription medicines and 84% of the prescription medicines registered as supplied
- 15 (37%) of 41 medicines had national price agreements
- 8 supplied medicines were classified as not nationally reimbursed
  - 5 lacked TLV decisions
    - Reimbursement submissions had been withdrawn in 4 cases, based on information supplied by TLV; no public information was available in the remaining case
  - 3 had received negative TLV decisions
    - The costs of these medicines were not considered reasonable compared to the effect



Time to national reimbursement

- Prescription medicines were on average (median) supplied 20 (14) days and nationally reimbursed 302 (160) days after EMA approval
- The average handling time in 2021 was 128 days, including price negotiations, according to TLV's annual report
  - TLV has 180 days (with a possibility to ask for an additional 90 days to submit new material) to handle the application from the date an application is submitted and considered complete
- Factors potentially causing delays in national reimbursement are:
  - MAHs waiting to apply for reimbursement
  - MAHs withdrawing reimbursement applications and applying multiple times

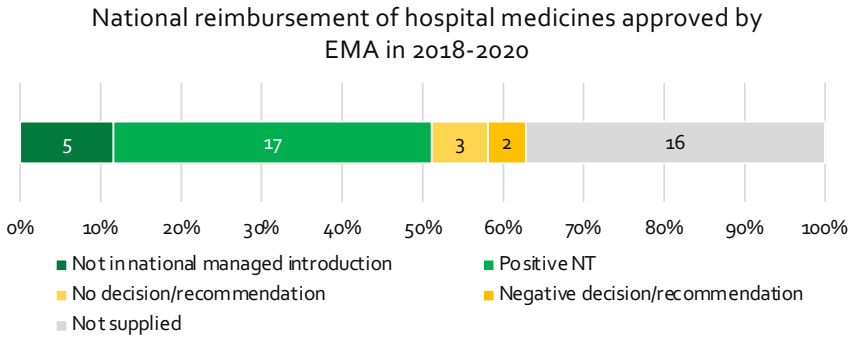


Prescription medicines were considered nationally reimbursed from the date of the TLV decision.

National reimbursement of hospital medicines

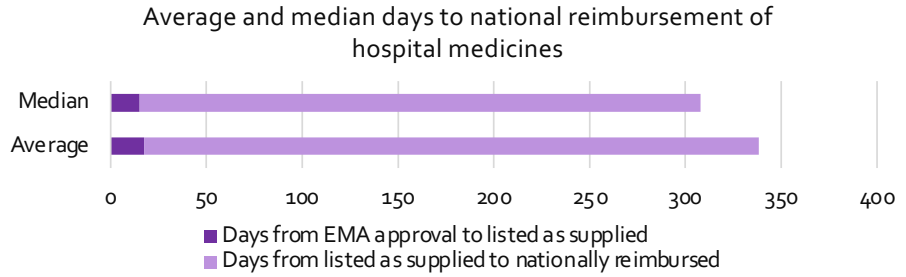
National reimbursement

- 22 hospital medicines approved by the EMA in 2018-2020 were nationally reimbursed in Sweden
  - This was 51% of all approved hospital medicines and 81% of the hospital medicines registered as supplied
  - 17 had positive NT recommendations
  - 5 were not in national managed introduction
- 9 (41%) of 22 medicines had national price agreements
- 5 supplied medicines were classified as not nationally reimbursed
  - 3 because they were in national managed introduction and had ongoing assessments, indicating that these medicines may become nationally reimbursed in the future
  - 2 because they had negative recommendations from the NT-council



Time to national reimbursement

- Hospital medicines were on average (median) supplied 15 (17) days after EMA approval and nationally reimbursed 321 (293) days after they were supplied
- Factors potentially causing delays in national reimbursement are:
  - Delays in inclusion of medicines in national managed introduction. This factor is out of companies' control as inclusion in national managed introduction cannot be applied for
  - MAH delays in sending material for assessment to TLV
  - Long-spun health-economic assessments by TLV
  - Long-spun price negotiations



Hospital medicines were considered nationally reimbursed from the date of NT recommendation. Medicines not in national managed introduction were considered nationally reimbursed from the date of registration as supplied in FASS.

Discussion

- The majority of supplied medicines were classified as nationally reimbursed in Sweden
  - Restrictions to the national reimbursements and national price agreements were present in many cases, indicating that the incremental cost-effectiveness ratio was only considered reasonable for some subgroups or that the MAHs and decision-makers had reached different conclusions in their evaluations of the medicines' values
    - This may reflect different price expectations between companies and decisionmakers. If the willingness-to-pay is perceived as lower in Sweden than in other countries, Sweden may no longer be perceived as an early launch country

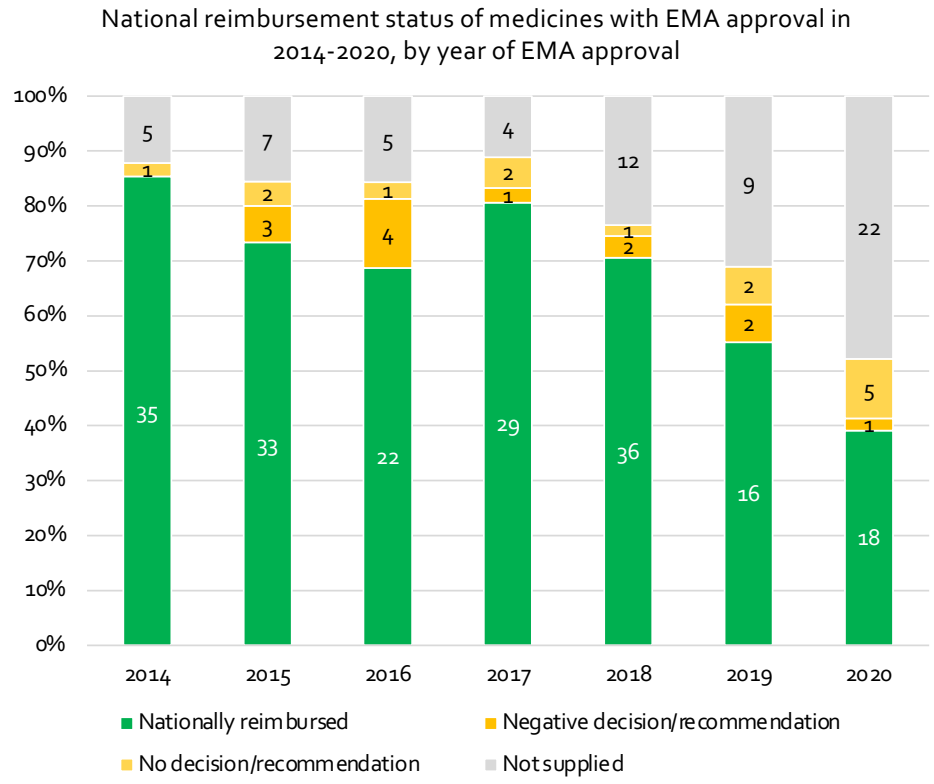
- The number of withdrawn applications to TLV increased from 15 in 2018 to 35 in 2021
  - This is affected by the number and types of medicines that were approved each year (see slide National reimbursement over time). 40%, 23% and 37% of the included medicines were approved in 2018, 2019 and 2020, respectively
  - Some supplied, non-reimbursed medicines had withdrawn reimbursement applications, this may indicate that
    - MAHs were planning to re-submit, for example due to awaiting additional data, or
    - There were disagreements between the MAH and the decisionmakers on the value of the medicine, or
    - The MAH will try other routes to reimbursement than the national process

- The mean and median time from EMA approval to national reimbursement was longer for hospital medicines than for prescription medicines, despite 5 being defined as nationally reimbursed at the date of supply
  - For hospital medicines, there is no formal way of applying for reimbursement, potentially delaying companies in supplying medicines
  - Additionally, there is no formal maximum duration for the TLV assessment of hospital medicines or for the NT-council to make a recommendation
    - There is currently a known lack of resources at TLV, potentially delaying assessments of hospital medicines

National reimbursement over time

National reimbursement over time

- To evaluate whether medicines can be assumed to become supplied and/or nationally reimbursed over time, we analysed data for all medicines approved by the EMA in 2014-2020, excluding medicines with withdrawn marketing authorisations
  - The definitions presented in slide [12] were used and the data were updated at the cut-off date (21 December 2021)
- The proportion of medicines supplied was higher among medicines approved in 2014-2017 than in 2018-2020
  - Among 154 medicines approved in 2014-2017:
    - 21 (14%) of medicines were not supplied (varying between 10-14% per year)
    - 14 (9%) of medicines were supplied but not nationally reimbursed (varying between 2-16% per year)
- The proportion of medicines supplied did not reach 100% for any of the annual cohorts



Discussion

- Medicines with a longer follow-up time are naturally more likely to be supplied and nationally reimbursed in Sweden

- The results suggest that it takes approximately 3-4 years from EMA approval for medicines to become nationally reimbursed
  - Some medicines are not nationally reimbursed or supplied despite a long follow-up time
  - This is likely affected by e.g., the types of medicines approved in each year

- Approximately one in ten medicines approved in 2014-2017 were not supplied at the cut-off date in December 2021. Potential reasons for this are that:
  - Some medicines may not have a patient population in Sweden
  - Some MAHs may have stopped supplying their medicines as new, more effective treatments have become available
  - Some MAHs may have stopped supplying their medicines because they did not receive a positive decision/recommendation

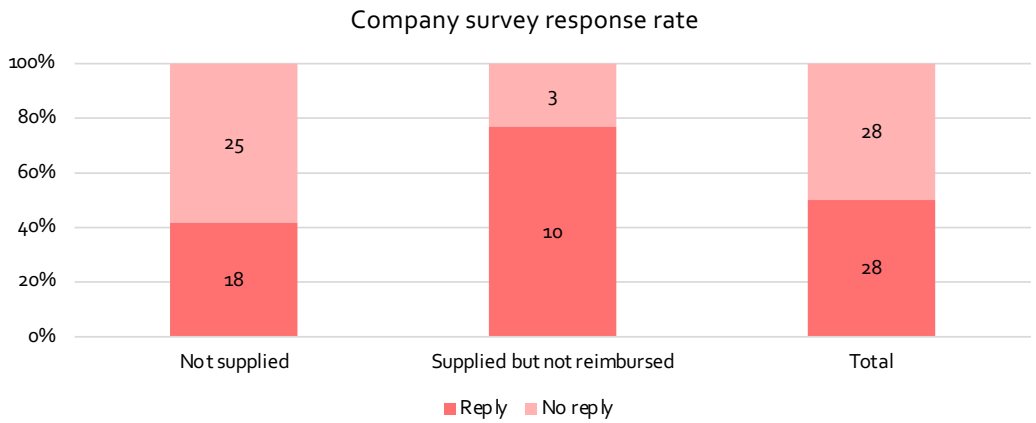
- For medicines where a significant patient value could be added, society may consider a more active role in mapping national reimbursement with patients needs

Company survey

Background and participation

- To understand why some medicines approved 2018-2020 were not supplied or supplied but not nationally reimbursed, from the MAH's perspective, an e-mail survey was sent to all 45 unique MAHs of the:
  - 43 medicines that were not supplied
  - 13 medicines that were supplied but not nationally reimbursed

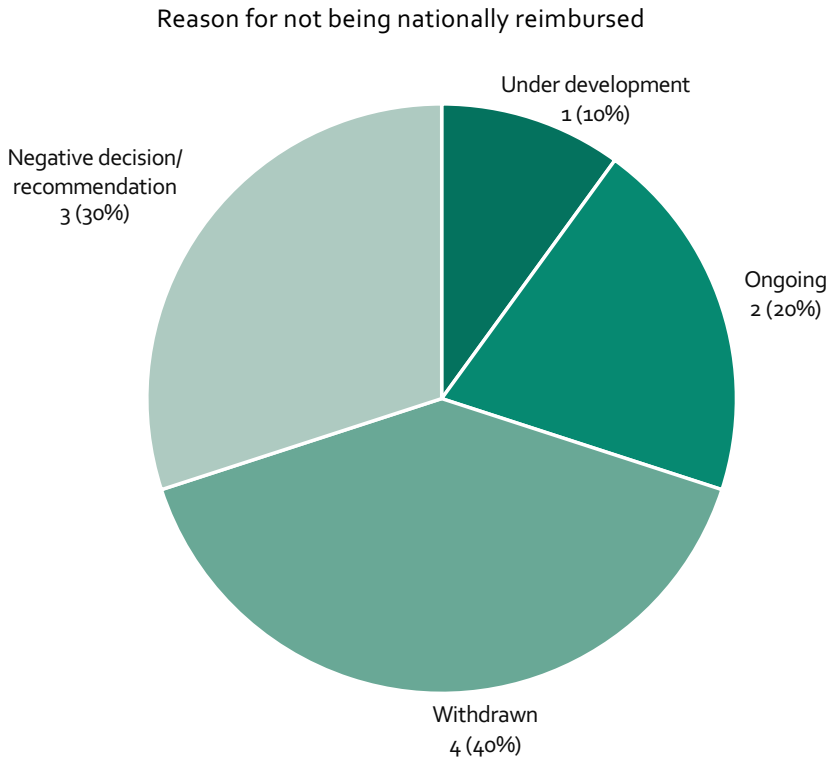
- Replies were received for 28 (50%) of all medicines from 21 (47%) MAHs
  - Answers were received for 18 (42%) medicines that were not supplied
  - Answers were received for 10 (77%) medicines that were supplied but not reimbursed
  - Among responders, 81% were locally present in the Nordics and 62% had at least one other medicine in the Swedish reimbursement scheme
  - Among non-responders, 36% were locally present in the Nordics and 28% had at least one other medicine in the Swedish reimbursement scheme



Why were 13 supplied medicines not nationally reimbursed?

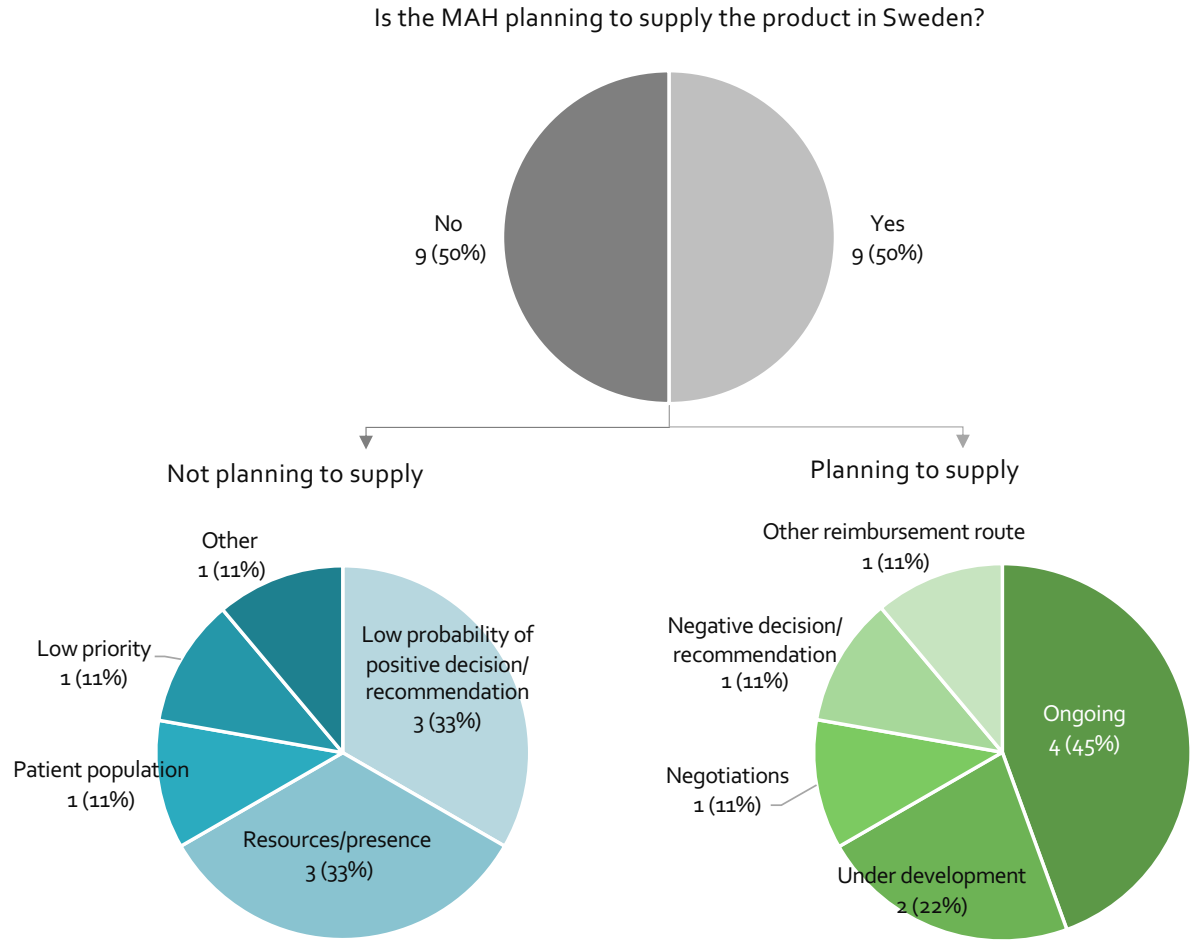
- Answers were received from 10 individual MAHs marketing 10 medicines

- The MAHs had applied or planned to apply for national reimbursement for all 10 medicines
  - 4 had a withdrawn submission
  - 3 had received a negative decision/recommendation
  - 3 applications were under development or ongoing



Why were 43 medicines not supplied?

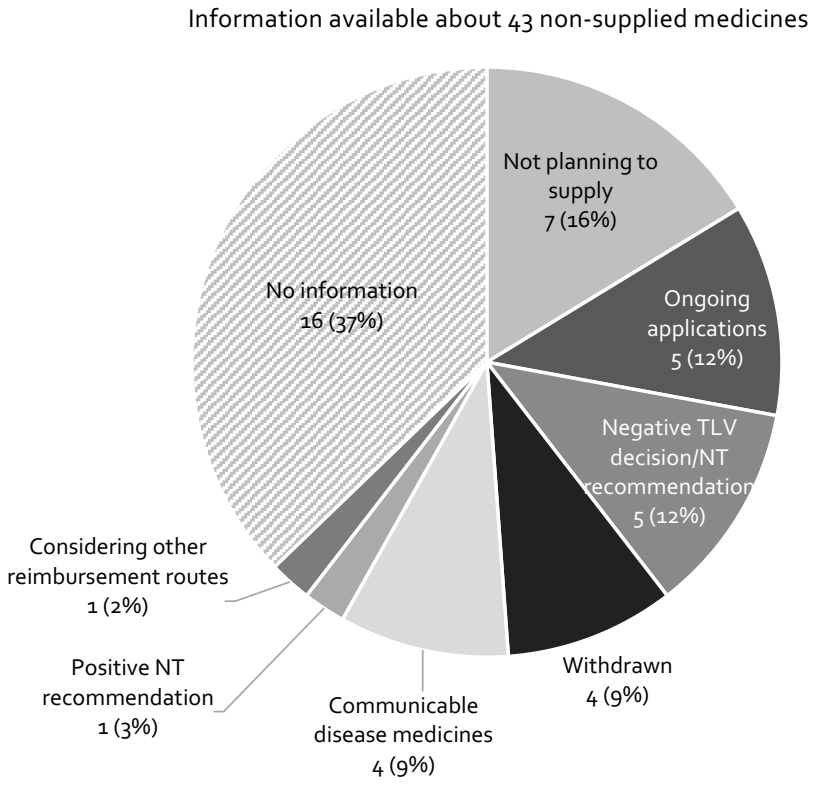
- Answers were received from 14 individual MAHs marketing 18 medicines
- Among MAHs planning to supply, companies were in different stages of the process
  - MAHs were still developing the submission in 2 (22%) cases
  - Most medicines (4; 45%) had ongoing reimbursement processes; additionally, 1 (11%) was negotiating with decision-makers
- Among MAHs not planning to supply, the main reasons were:
  - Lacking the necessary resources or presence (3; 33%)
  - Having a low probability of receiving a positive TLV decision or NT recommendation (3; 33%)



Are the 43 non-supplied medicines going to be supplied?

- The company survey contributed with information on 8 of the 27 non-supplied medicines for which there was no publicly available information (see slide [18])
  - In one case, the MAH was considering other routes to reimbursement rather than the national process
  - 7 medicines were not planned to be supplied in Sweden (further details on slide [34])
    - 4 of these were prescription medicines and 3 were hospital medicines

- Despite the survey, it was still not possible to obtain information on 16 medicines



Discussion

- The response rate of the company survey were supplied in 50% of the cases
  - Responders were more likely to be present in the Nordics and have at least one other medicine in the Swedish reimbursement scheme than non-responders, especially for non-supplied medicines
- Most MAHs of supplied, non-reimbursed medicines had either received a negative decision/recommendation or withdrawn the application
  - Withdrawals may be an indication of e.g., MAHs waiting for additional data to resubmit
  - Supplying the medicine despite a withdrawal or a negative decision/recommendation may indicate that the company is examining other reimbursement routes
    - Both of these answers also indicate a value disagreement between MAHs and decisionmakers
- MAHs of non-supplied medicines,
  - Were planning to supply their medicines in 50% of the cases; this may have been done since the study cut-off date
  - Were not planning to supply their medicines in 50% of the cases, mainly due to a lack of resources/presence or because the probability of national reimbursement was too low

Conclusions

Conclusions

- This review of national reimbursement systems in Sweden shows that 7 of 10 medicines approved in 2018-2020 are supplied in Sweden
  - A majority (6 of 10) are nationally reimbursed – among these, many had restrictions compared to the approved indication and/or national price agreements, indicating differences in valuations of medicines between MAHs and TLV/the NT-council
    - This may affect Sweden's position as an early launch country
- Attracting MAHs to supply medicines remains a challenge
  - Many MAHs marketing non-supplied medicines lack presence and/or experience with the Swedish national reimbursement systems
    - This may be an indication that there is a lack of interest or that the systems are perceived as complex. MAHs may, for example, not know that there are alternative routes to reimbursement in Sweden
  - Medicines approved in 2014-2017 were to a greater extent supplied and nationally reimbursed than those in 2018-2020 but the rate never reached 100%
    - In cases where there is no patient population or when effective treatment alternatives exist, this is not necessarily an issue but strategies should be developed to follow up these medicines and ensure that patient value is not lost
- The national system for reimbursement of prescription medicines solely relies on companies to apply for reimbursement. A consequence of this may be that medicines marketed by small companies, companies lacking resources or with a limited interest in the Swedish market may not be useable
- The lack of timeframes and a clear process to request an assessment for hospital medicines are complicating factors that potentially deter MAHs and prolong the time to supply or national reimbursement of new hospital medicines in Sweden
- There is need for joint efforts from pharmaceutical companies and public stakeholders such as TLV and the Swedish regions to ensure that national processes are effective in order to attract MAHs to supply their medicines in Sweden

The complete dataset of publicly available information can be provided upon request to Lif and/or Quantify Research.

Appendix

EFPIA's definitions

- **Rate of availability**: measured by the number of medicines available to patients in European countries. For most countries this is the point at which the product gains access to the reimbursement list (this does not necessarily indicate uptake / usage)
- **Time to availability**: measured by the average time between marketing authorisation and availability, using days from the date of marketing authorisation to the day of completion of post-marketing authorisation administrative processes (whether it is attributable to companies or competent authorities)
- Since the present report explores the different routes to accessibility depending on the type of medicine, there is not a direct correspondence between EFPIA's categories of availability and the definitions used in this report.

Availability definition

Description	Status
Full reimbursement through a national reimbursement system	Available
Full automatic reimbursement by a hospital budget (e.g. Nordic system)	
Limited reimbursement to specific subpopulations of approved indication	Available (marked LA*)
Limited reimbursement on a named patient basis (individual patient basis)	
Limited reimbursement while decision is pending (where system permits)	
Availability through a special program (e.g. managed entry agreements)	
Available only within the private market at the patients expense	Only privately available
Not reimbursed, or not reimbursed while awaiting decision	Not available

Colour codes

- EMA approved medicines
- Supplied in Sweden (FASS)
- Not supplied in Sweden (FASS)
- Communicable disease medicines
- Prescription medicines
- Hospital medicines
- Time from EMA approval to listed as supplied in FASS
- Time from listed as supplied in FASS to national reimbursement
- Nationally reimbursed
- Not nationally reimbursed
- Not supplied

Medicines included in the report (1/3)

Medicines included in the report: 43 non-supplied medicines		
Adakveo	Libmeldy	Staquis
Alofisel	Luxturna	Sunosi
Amglidia	Mepsevii	Tecartus
Arikayce liposomal	Mulpleo (previously Lusutrombopag Shionogi)	Trepulmix
Ayvakyt	Myalepta	Trogarzo
Daurismo	Nilemdo	Verkazia
Dovprela (previously Pretomanid FGK)	Nustendi	Xenleta
Fintepla	Obiltoxaximab SFL	Xerava
Giapreza	Oxlumo	Zeposia
Givlaari	Palynziq	Zolgensma
Hepcludex	Quofenix	Zynquista
Ilumetri	Rhokiinsa	Zynrelef
Kaftrio	Rizmoic	Zynteglo
Kigabeq	Rubraca	
Lamzede	Rxulti	

Medicines included in the report (2/3)

Medicines included in the report: 70 supplied and nationally reimbursed medicines				
Adynovi	Dovato	Kymriah	Polivy	Talzenna
Aimovig	Emgality	Libtayo	Poteligeo	Tegsedi
Ajovy	Enerzair Breezhaler / Zimbus Breezhaler	Lorviqua	Prevymis	Trecondi
Alunbrig	Erleada	Mayzent	Recarbrio	Trixeo Aerosphere
Atectura Breezhaler / Bemrist Breezhaler	Evenity	Mektovi	Rekambys	Ultomiris
Beovu	Fasenra	Mylotarg	Rinvoq	Vaborem
Bevespi Aerosphere	Fetcroja	Nerlynx	Rozlytrek	Verzenios
Biktarvy	Hemlibra	Nubeqa	Rybelsus	Veyvondi
Braftovi	Idefirix	Ocrevus	Segluromet	Vitrakvi
Cablivi	Imfinzi	Onpattro	Skyrizi	Vizimpro
Calquence	Jivi	Ozempic	Spravato	Vocabria
Crysvita	Jorveza	Phesgo	Steglatro	Vyxeos liposomal (previously known as Vyxeos)
Delstrigo	Juluca	Pifeltro	Steglujan	Xospata
Doptelet	Jyseleca	Piqray	Takhzyro	Yescarta

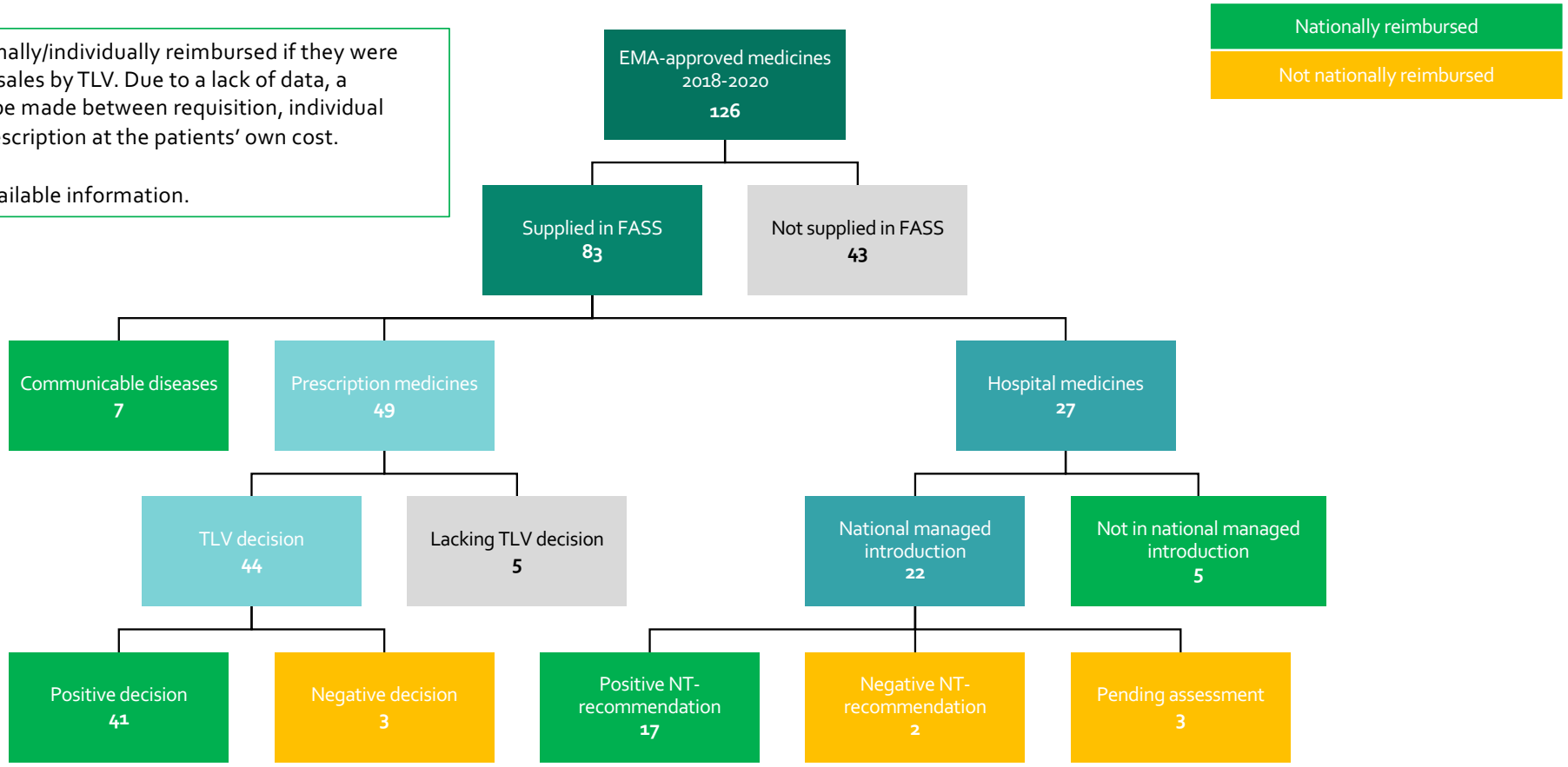
Medicines included in the report (3/3)

Medicines included in the report: 13 supplied non-nationally reimbursed medicines
Baqsimi
Besremi
Blenrep
Epidyolex
Intrarosa
Isturisa
Leqvio
Namuscla
Reblozyl
Sarclisa
Symkevi
Tavlesse
Waylivra

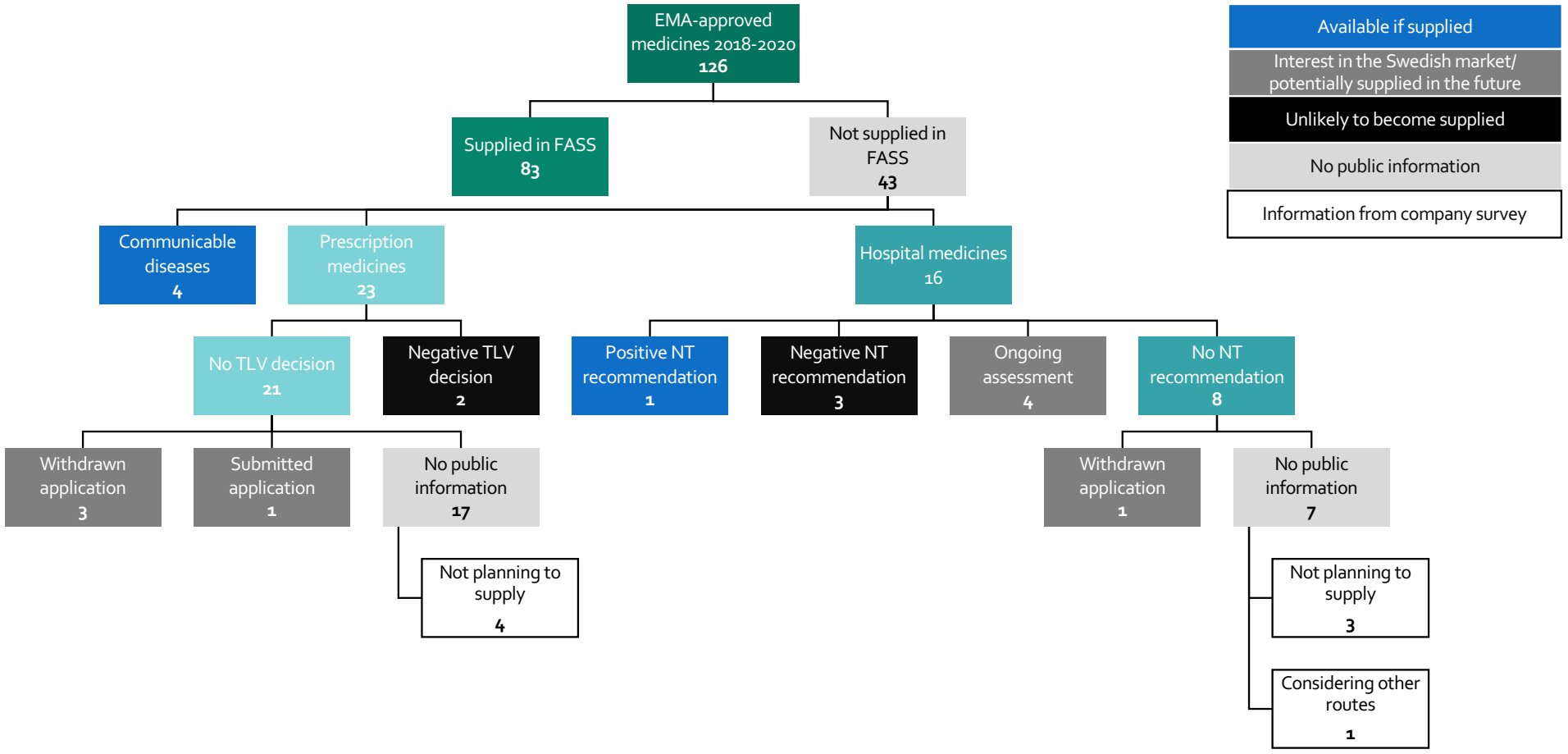
Overview: Medicines supplied in Sweden

Medicines were regionally/individually reimbursed if they were reported to have had sales by TLV. Due to a lack of data, a distinction could not be made between requisition, individual reimbursement or prescription at the patients' own cost.

Note: only publicly available information.



Overview: Medicines not supplied in Sweden



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The complete dataset of publicly available information can be provided upon request to Lif and/or Quantify Research.