Trends in National Reimbursement of New Medicines in Sweden

A deep dive in Swedish W.A.I.T data

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Content

Key findings

Nationally supplied medicines

Overall, **311 out of 402** medicines with EMA-approval 2014-2023 were **nationally supplied** (**77 %**) and…

…in this years' cohort (2021-2023), **86 out of 132** medicines were **nationally supplied** (**65 %**)

Please note, companies may supply their medicines in Sweden although a national recommendation/decision has not been performed, was negative and/or is missing.

Nationally reimbursed medicines

Reimbursed medicines overall

64% of all medicines with EMA-approval 2014-2023 were **nationally reimbursed**

Reimbursed medicines this cohort

45% of all medicines in this year's cohort (2021-2023) were **nationally reimbursed**

Time to access

Overall, average **time** from EMA-approval **to reimbursement** was **344 days** and…

…for **this year's cohort**, average **time** from EMA-approval **to reimbursement** was **352 days**.

Tools for reimbursement

This years' cohort (2021-2023)

69% of all reimbursed medicines were **associated with reimbursement restrictions and/or price-agreements**

Overall cohort (2014-2023)

61% of all reimbursed medicines were **associated with reimbursement restrictions and/or price-agreements**

Please note, some medicines may have been subject to reimbursement restrictions and/or price agreements in the past (but not at study cut-off date).

Brief summary & conclusions

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Overview of routes to access

Prescription medicines

Application process
Companies can apply for reimbursement to the governmental agency TLV.

Payer
Reimbursed medicines are financed by the state (through a state grant). A limited amount is paid by patients.

Decision-maker/s
TLV decides if the medicine should be reimbursed.

Sales 2023* –prescription medicines
41.0 bSEK**

Hospital medicines

Application process
No formalized application process. Medicines in the managed introduction: the regions decide which medicines will be evaluated.

Payer
Financed by the regions.

Decision-maker/s
Medicines in national managed introduction: NT-council gives recommendations, region decides. Medicines outside managed introduction – each region decides.

Sales 2023* – hospital medicines
14.1 bSEK**

Over-the-counter medicines (OTC)

Application process
No formalized application process.

Payer
Financed by patients themselves.

Decision-maker/s
No formal actor decides.

Sales 2023* –OTC-medicines
4.8 bSEK**

Exceptions and/or special/other cases

Vaccines in the national vaccination program
Decisions are made by the government (based on assessments by the public health agency, link). No formalized application process.

Communicable diseases
Medicines used to treat communicable disease do not need a TLV decision for reimbursement.

Prescription medicines not reimbursed
Companies can make medicines available even if not reimbursed. Can be paid by patients or in some cases by the regions, for instance through the "exceptional handling"-route ("undantagshantering").

There are additional exceptions to the described routes.
For example, medicines with special license ("licensläkemedel") are automatically approved for reimbursement (by TLV).

*Based on data from tlv.se, **bSEK= billion SEK. Sales value for for prescription medicines only includes reimbursed prescription medicines. Sales value for hospital medicines includes all costs for requisition medicines.

Summary of data findings

More recently approved medicines are reimbursed to a lesser extent

- **Medicines approved 2021-2023 are nationally reimbursed to less extent** compared to medicines approved earlier
  - Consistently with analyses from previous years, it takes ~4 year until share of nationally reimbursed stabilizes
- In particular **orphan drugs and ATMPs** are classified as nationally **reimbursed to less extent**
  - One explanation could be that HTA assessments for these types of medicines are usually more complex

Some analyses are presented focusing on medicines approved 2021-2023

- **65 %** (86 out of 132) were **supplied**
  - Most supplied medicines were also nationally reimbursed
- **45 %** (59 out of 132) were **nationally reimbursed**
- The **time** from EMA-approval **to reimbursement** is longer for orphan and oncology medicines compared to medicines overall.
  - Explanations may include lack of data, need for price negotiations, withdrawn and re-submitted applications and/or health economic challenges.

This report highlights some challenges with the Swedish system

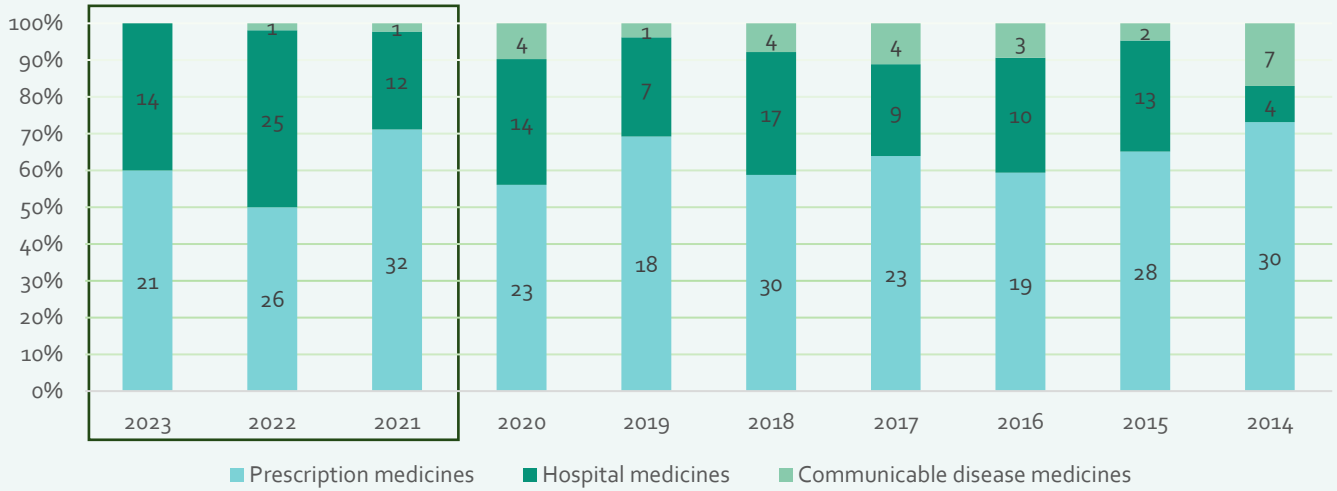
- Most assessed medicines are reimbursed – however, **reimbursement takes time**
  - New orphan, ATMPs and oncology medicines are reimbursed to less extent – HTA for these type of medicines are often complex
- **New medicines** are to a **large degree associated with reimbursement restrictions and separate price-agreements**
  - 69% of all new medicines approved 2021-2023 that are reimbursed are associated with these types of tools

Medicines approved by EMA in 2014-2023

- This report analyses **402 medicines approved by EMA 2014-2023** that were identified in EFPIA's W.A.I.T. report
  - In the present report 35 new medicines have been added (approved 2023)

- Many analyses take the full data set into account in order to show longer trends
  - Some analyses focus on **the most recent years (2021 to 2023)**
  - Medicines with withdrawn marketing authorization were excluded

Number of new medicines approved in 2014-2023 by year of EMA approval and route to availability



Objectives, definitions and background

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Waiting to Access Innovative Therapies (W.A.I.T)

- 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.
- This is a **detailed review of national reimbursement of new medicines with EMA approval in** 2021-2023 **in Sweden**, and **trends** since 2014.
- The aim is to present **the advantages and challenges** of the Swedish system for national reimbursement of medicines **from the perspective of pharmaceutical companies.**

Study definitions

Definition of national reimbursement

National reimbursement was defined as occasions when there are 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 20 December 2024,** was:

Approved by the EMA

Listed as supplied in FASS

Ambulatory care (prescription medicines)		Medicines used in hospital setting (hospital medicines)		
OR		OR		OR
Positive reimbursement decision from TLV	Indication included in the communicable disease control program	Positive re-commendation by the NT-council	Not in national managed introduction	Indication included in the communicable disease control program

If an ATMP medicine has a price agreement with the regions, it is considered nationally reimbursed regardless of supply status. All other non-supplied medicines are considered to lack national reimbursement.

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:

- 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 – **this can lead to a re-start of the clock**

Hospital medicines

NT-council initiates process by requesting HTA → TLV requests documentation from company → Company submits application to TLV → TLV assessment → TLV publishes HE assessment → NT-council recommendation

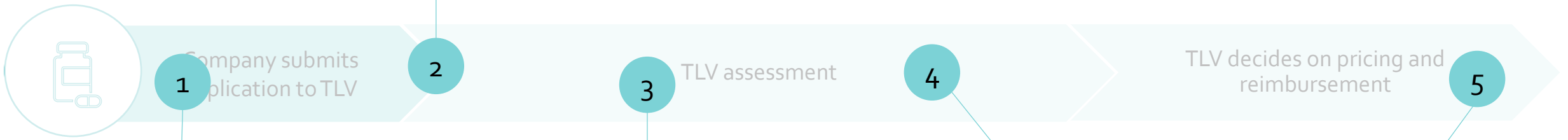
No legal timeframes

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

This is what the application process for prescription medication might look like for companies...

Prescription medicines - what can happen along the way?

1: Possible to impact from company side
2-3: No official way to impact from company side
4-5: Possible to impact from company side



Presentations for the regions:
TLV introduces the medicine to regional representations 'Fullmaktsgruppen' at monthly meeting. If company requests three-party negotiations (with the potential of a net price agreements with the regions) that will be presented

Send in reimbursement application:
Company decides at what point to submit

180 days start ticking at EMA approval.
For products undergoing JCA , it will start ticking from time of submitting JCA report

Three-party negotiations:
If 'Fullmaktsgruppen' accepts, negotiations will be held based on TLV's assessment.
The clock freezes and starts over when TLV receives new information (e.g., a net price or information that no agreement will be signed)
= 180 days can rewind

Assessment process:
No legal time frames. TLV will discuss and present the results of the HTA with the Pharmaceuticals Board which will make the decision (within the limited time period).
The assessment can also include TLV asking questions/requesting more information from the company, or asking clinical expert to provide evidence)

Reimbursement decision:
By the Pharmaceutical Board. If the company disagree, they are invited to argue their case, and can appeal the decision.
If three-party negotiations took place during HTA, the decision will include the outcome

…and this is what the process for hospital medicines in the managed introduction might look like

Hospital medicines - what can happen along the way?
1-3: No official way to impact from company side
5: Possible to impact from company side
7: No official way to impact from company side

Uptake of managed introduction:
Factors regions base the decisions on: Equal use across the country, severity of the condition, (large) resource impact, ethical or political challenges

Request for material:
Timing not known

Send in material:
Company decides at what point to submit

Horizon scanning:
An early assessment report is often published a few months before EMA approval, presenting the clinical evidence and putting it in a Swedish context

Priority of the HTA:
NT-council decides what HTAs TLV should prioritize
1. Unmet need, deemed urgent
2. Important addition (treatment option(s) exist)
3. Treatment option(s) exist, lack of documentation, no known patient in Sweden

Assessment process:
No legal time frames. TLV will present the results of the HTA to the NT-council (instead of the Pharmaceuticals Board). Other than that, similar HTA process as for outpatient medicines (for instance: TLV will ask questions/request more information from the company, ask clinical expert to provide evidence)

Negotiations process:
After HTA publication, the NT-council will publish a recommendation (no official time frame). Prior to that, (price) negotiations can take place but the company will not know and cannot impact if/when negotiations will take place

Routes to national reimbursement

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From EMA approval to supplied in FASS

EMA-approved medicines 2021-2023
132

Supplied in FASS			Not supplied in FASS		
86 (65 %)			**46 (35 %)**		
Communicable diseases	Prescription medicines	Hospital medicines	Communicable diseases	Prescription medicines	Hospital medicines
2 (2 %)	52 (60 %)	32 (37 %)	**0 (0%)**	**27 (59 %)**	**19 (41 %)**

A majority of newly approved medicines were supplied in Sweden (65 %)

FASS is a database developed by Lif in close cooperation with 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 supplied in FASS to national reimbursement

EMA-approved medicines (2021-2023) supplied in Sweden
86

Communicable diseases	Prescription medicines	Hospital medicines
2 (2 %)	52 (60 %)	32 (37 %)
Nationally reimbursed: 2 (100 %)	Nationally reimbursed: 34 (65 %)	Nationally reimbursed: 23 (72 %)
Not nationally reimbursed: 0 (0 %)	Not nationally reimbursed: 18 (35 %)	Not nationally reimbursed: 9 (28 %)

A majority of supplied medicines are nationally reimbursed (69 %)

Trends in national access; 2014-2023

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Comparisons between reports: How many medicines were nationally reimbursed at each cut-off date?

This slide shows the share of reimbursed medicines* in the present and previous four reports. At cut-off (December 20th, 2024), **45%** of all new medicines approved 2021-2023 were nationally reimbursed

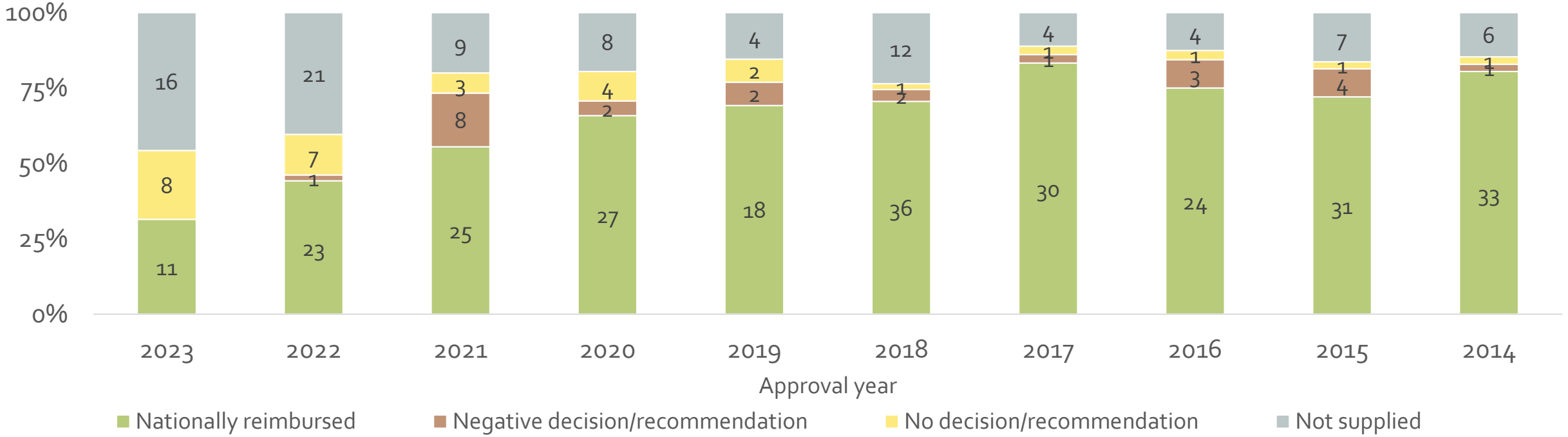
Cut-of date:	December 22, **2020**	December 21, **2021**	December 20, **2022**	December 21, **2023**	December 20, **2024**
	56 % (65 out of 116)	**56 %** (70 out of 126)	**53 %** (62 out of 117)	**48 %** (67 out of 141)	**45 %** (59 out of 132)
Cohort:	**2017-2019**	**2018-2020**	**2019-2021**	**2020-2022**	**2021-2023**

The trend suggests a decreasing proportion of nationally reimbursed medicines

*Based on the sample in each year's report. Note that the definition of reimbursement for hospital medicines has broadened since the report with cut-off date December 22, 2020, was published.

National reimbursement of overall cohort in 2024

National reimbursement status of medicines with EMA approval in 2014-2023, by EMA approval year



About 50 % of all medicines were supplied one year after from market authorization…

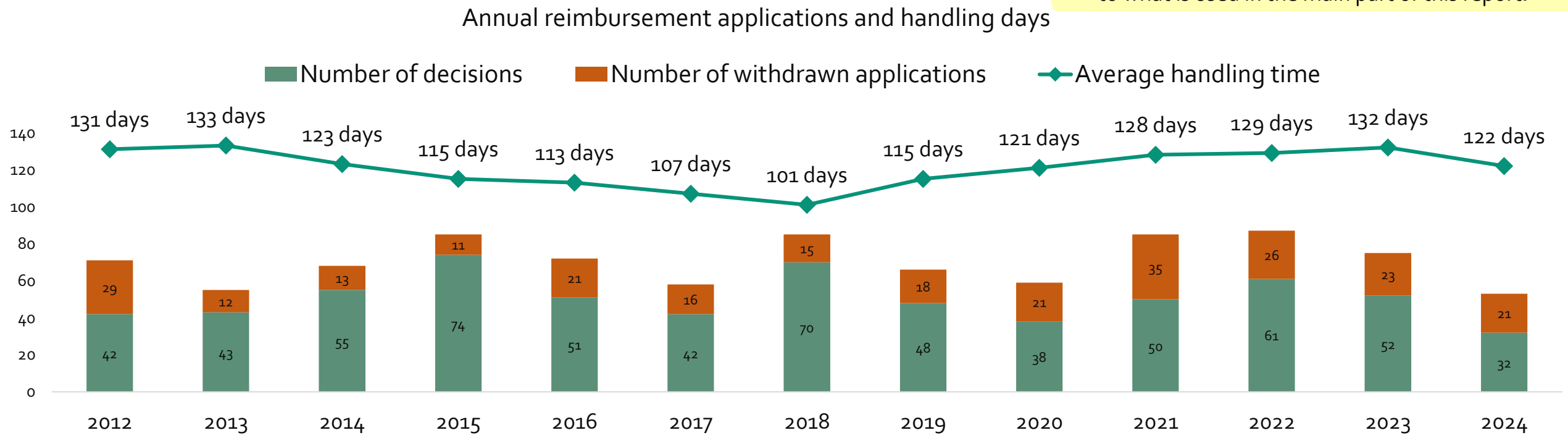
…the figure suggests that after ~4 years a "steady state" in share of nationally reimbursed products were reached…

…however, some medicines are not nationally reimbursed despite a long follow-up period.

This slide shows the reimbursement status for medicines with marketing authorization from 2014 to 2023, based on the situation as of the study's cutoff date (December 20, 2024).

Annual number of reimbursement application and handling days according to TLVs annual reports

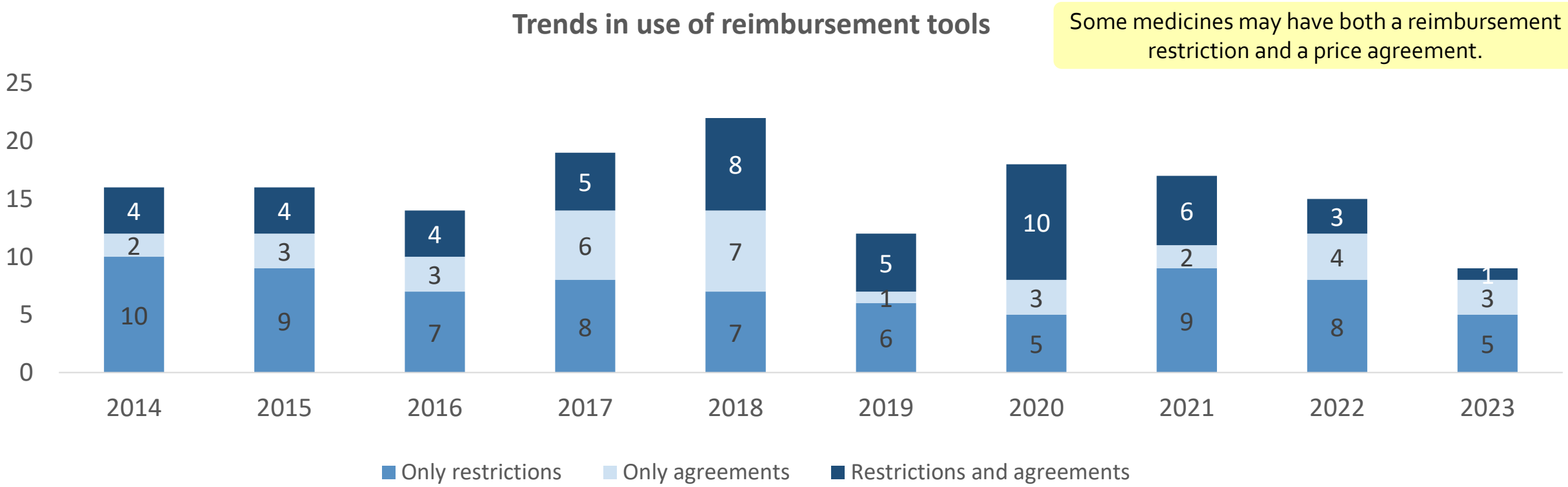
Note! This slide is based on different data compared to what is used in the main part of this report.



The share of withdrawn application fluctuates around 30% annually (of total number of decisions and withdrawn applications). The share of withdrawn decisions peaked in 2021 (41%) and was at its lowest point in 2015 (13%).

*This figure shows overall handling time and number of annual decisions/withdrawn applications at TLV.
**Data from TLV's annual reports. The figure is based on aggregated data from the agency, and the underlying data may differ from that used for other parts of the report. Furthermore, only medicines that go through the TLV process ("prescription route") are included, e.g., the figure does not reflect regional processes.

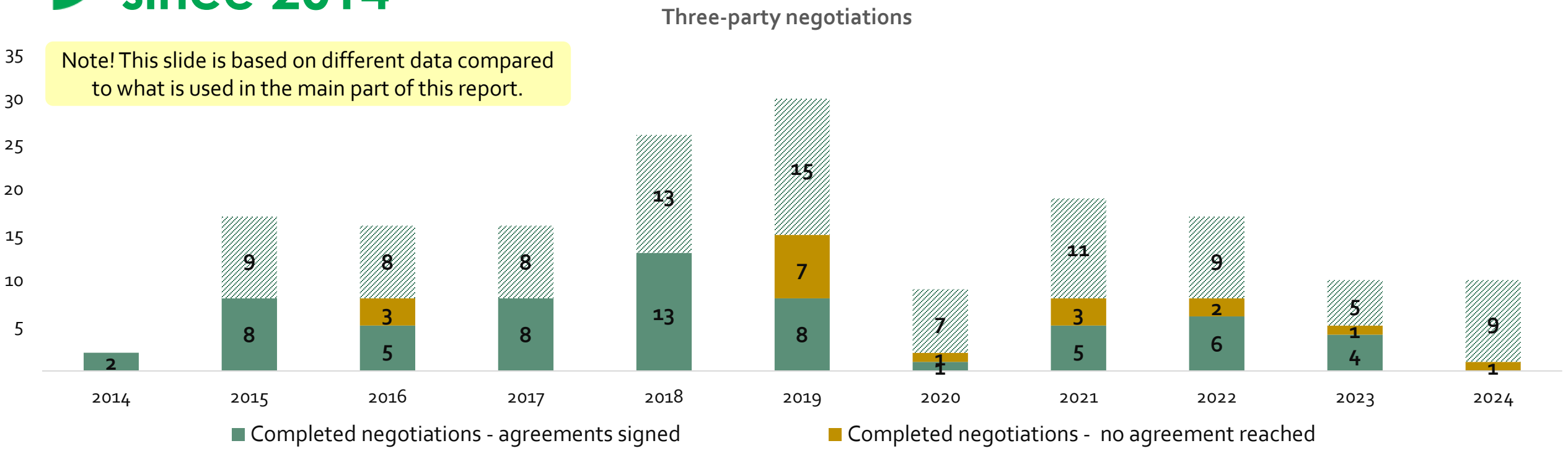
Trends in use of reimbursement tools



Some medicines may have both a reimbursement restriction and a price agreement.

- The lower number of restrictions and/or agreements in medicines approved 2023 can be due to the shorter time period since EMA-approval (e.g., these medicines have likely been evaluated to a lesser extent)
- In the previous years, the share of medicines with a reimbursement restriction was at a stable level while the medicines with agreements was fluctuating

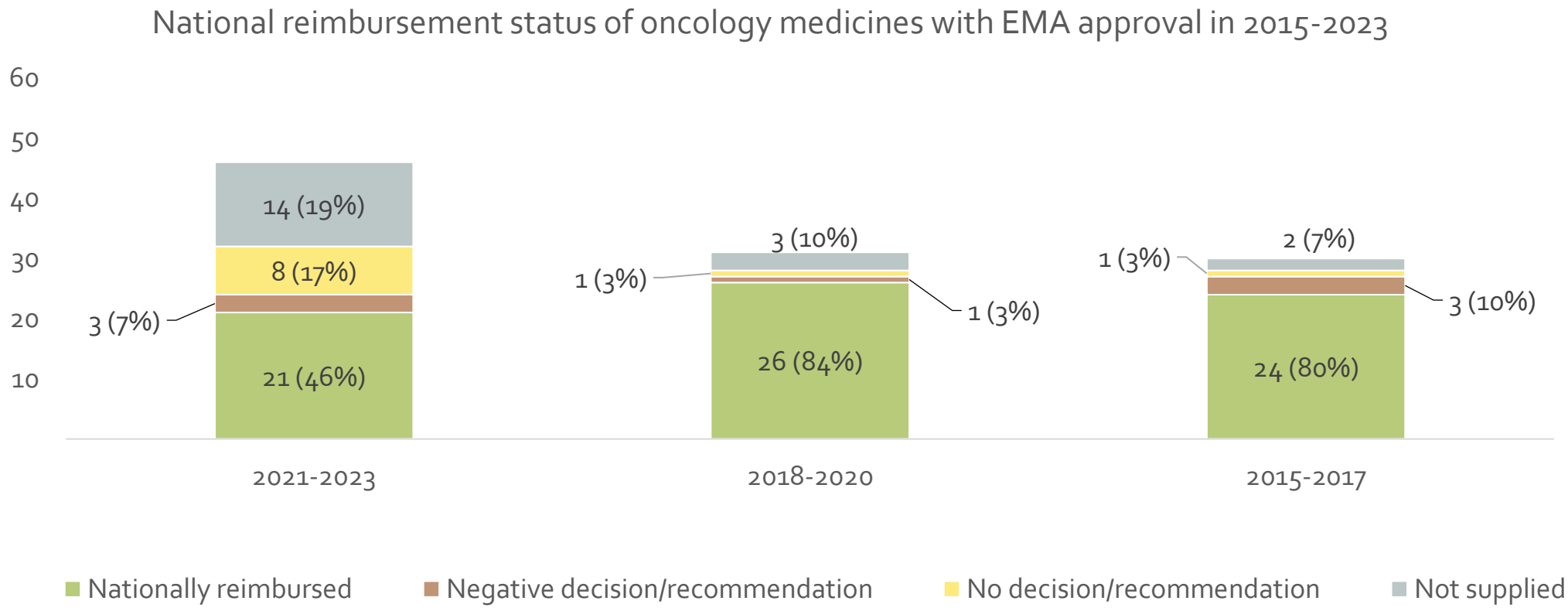
The possibility for three-party negotiations has existed since 2014



- The number of completed and initiated varies greatly, with 54 completed negotiations between 2014-2019 and 24 completed negotiations between 2020 -2024.
- Only one three-party negotiation was completed in 2024, but it did not reach an agreement. The initiated negotiations may be completed in 2025.

- This figure is based on data from TLV's annual reports. The underlying data may therefore differ from that used in other parts of the report. Only medicines that go through the TLV process ("prescription route") are included, e.g., the figure does not reflect the regional process.
- The number of initiated three-party negotiations is not available for negotiations before 2015.
- Furthermore, a medicine could potentially be included twice in a given year in this figure (if the negotiations were initiated and finalized the same year).

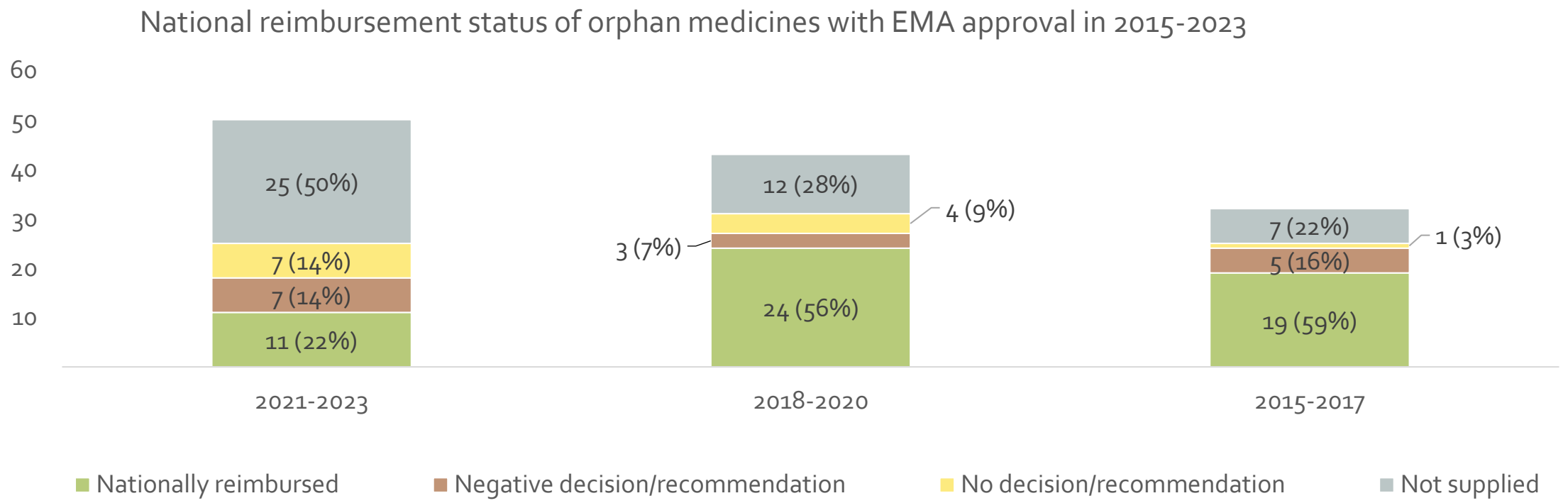
National reimbursement of oncology medicines over time



Similarly to conclusions for all products, oncology medicines approved in the last 3-year period are nationally reimbursed to less extent.

This slide shows the reimbursement status for oncology medicines with marketing authorization from 2015 to 2023, based on the situation as of the study's cutoff date (December 20, 2024).

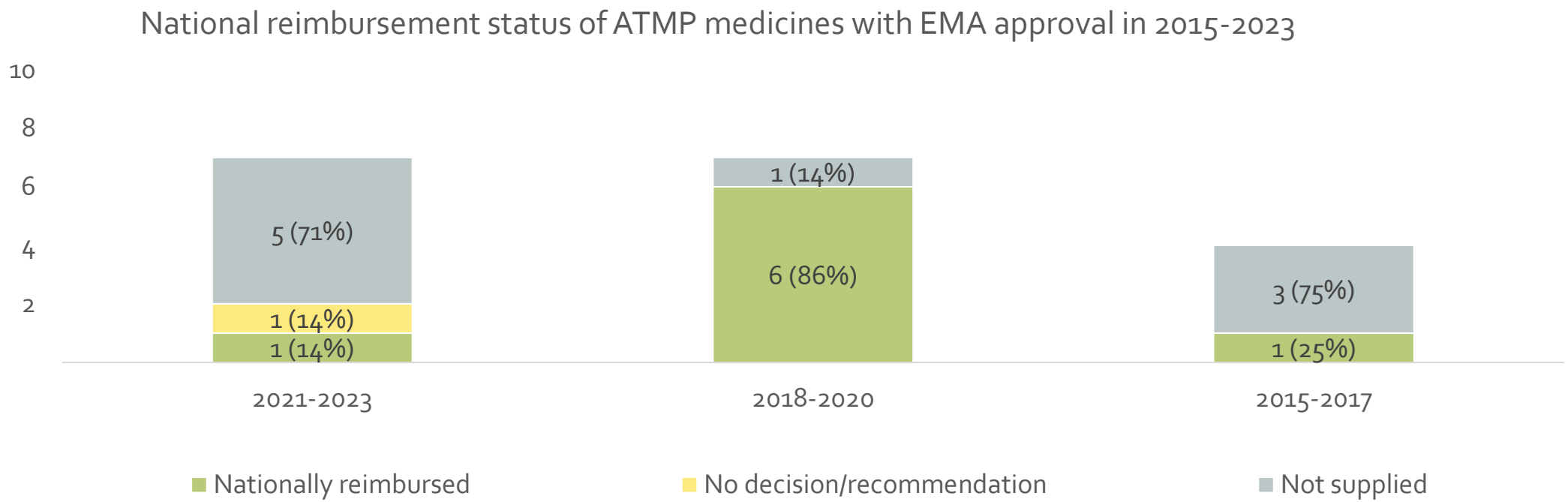
National reimbursement of orphan medicines over time



Similar to what was observed for the all products and oncology medicines, orphan medicines in the older 3-year cohorts are reimbursed to higher extent. Regardless of the three-year period considered, the proportion of reimbursed medicines remains relatively low (compared to how it looks for medicines overall)

This slide shows the reimbursement status for orphan medicines with marketing authorization from 2015 to 2023, based on the situation as of the study's cutoff date (December 20, 2024).

National reimbursement of ATMPs over time



More than 50% of all medicines categorized as ATMP in this year's report are not supplied (or nationally reimbursed).

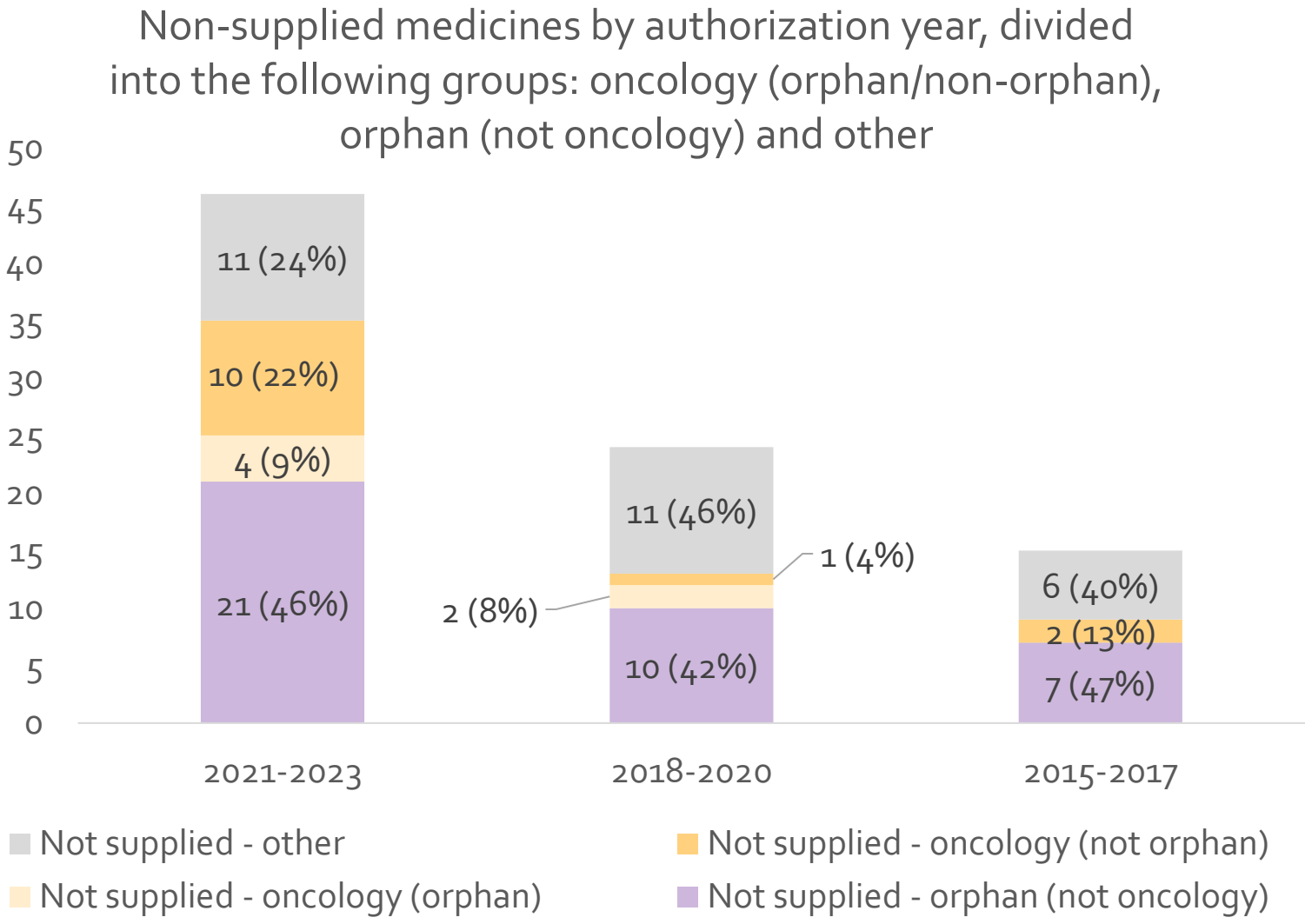
- The number of observations is low which makes interpretations of long-term trends difficult
- It is possible that some ATMPs (those only used in very rare cases) are only supplied when needed.

In this year report the definition of national reimbursement have been updated such that ATMPs are assumed nationally reimbursed if a national agreement with regions exists (regardless of supply status at cut-off date).

ATMP stands for Advanced therapy medicinal products. The sub-classes of ATMPs are: Gene Therapy Medicinal Products, Tissue Engineered Products (TEP), Somatic Cell Therapy Medicinal Products (sCTMP) and combined ATMPs. This slide shows the reimbursement status for medicines with marketing authorization from 2015 to 2023, based on the situation as of the study's cutoff date (December 20, 2024).

A majority of all non-supplied medicines are orphan and/or oncology

>75% of all non-supplied medicines in the latest 3-year period were oncology and/or orphan medicine. In the older 3-year cohorts a larger share of non-supplied medicines were not orphan, nor oncology.



This slide shows the reimbursement status for oncology medicines with marketing authorization from 2015 to 2023, based on the situation as of the study's cutoff date (December 20, 2024).

This year's cohort 2021 - 2023

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Majority of supplied medicines were also nationally reimbursed

86 out of **132** (65%) medicines were **supplied**

59 out of **86** (69%) supplied medicines were **nationally reimbursed**

Average time EMA approval to national reimbursement was **352** (*median: 275*) days

Number of medicines and average time (median) from EMA approval to national reimbursement per route:

Hospital	n = 23	**379** (323) days
Prescription	n = 34	**353** (239) days
Communicable diseases	n = 2	**17*** days

*By definition, all medicines with indications included in the **communicable disease program** that were approved by EMA and supplied in Sweden were **considered nationally reimbursed**.
Note that even if medicines are not (defined) as nationally reimbursed they may still be used on a regional level through other routes of distributions (no such information were collected as a part of this report.)

Lower rates of, and longer time to, national reimbursement for some subgroups

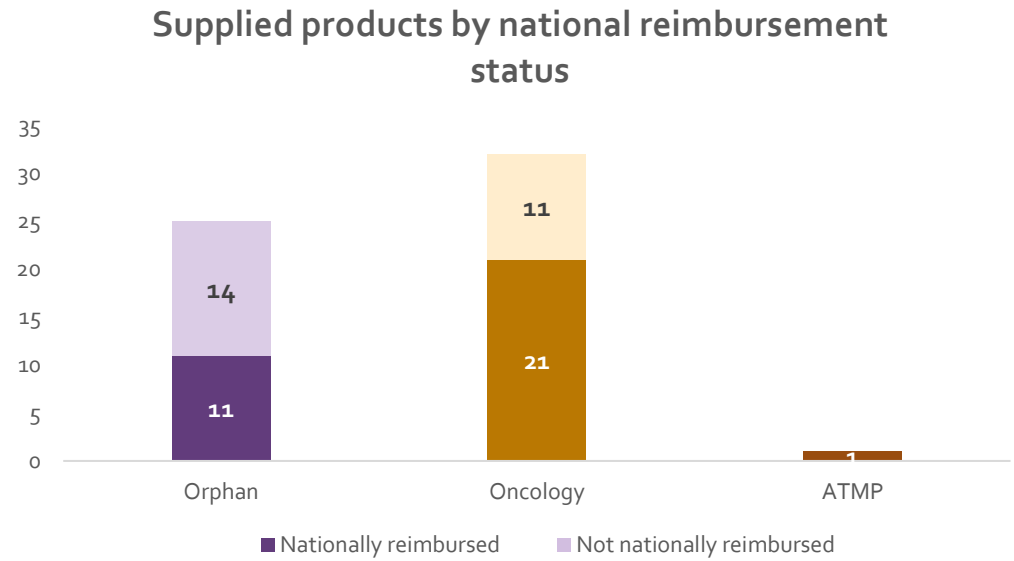
Note: small samples

For comparison, overall average:
69% nationally reimbursed of supplied medicines
352 (median: 275) days

A majority (103 of 132; 78%) of all medicines were **either orphan, oncology or ATMP**

59 out of those **103** (57%) were supplied

33 out of **59** (56%) supplied medicines were **nationally reimbursed**



Average time from EMA approval to national reimbursement for subgroups (median in parenthesis) :

Orphan n = 11	**437** (312) days

Oncology n = 21	**495** (444) days

ATMP n = 1	**802** (802) days

Tools for national reimbursement

Restrictions in the subsidy - 32 medicines

- **54 %** of the 59 nationally reimbursed medicines had conditions (*reimbursed for a subpopulation* or by certain specialists*) for their reimbursement:

43 % (10 out of 23)

65 % (22 out 34)

National price agreements – 19 medicines

- **32 %** of the 59 nationally reimbursed medicines had a price agreement with the regions:

57 % (13 out of 23)

18 % (6 out 34)

*Includes but is not limited to patients that previously have tested and failed on alternative treatment options

Not supplying medicines remains a large concern

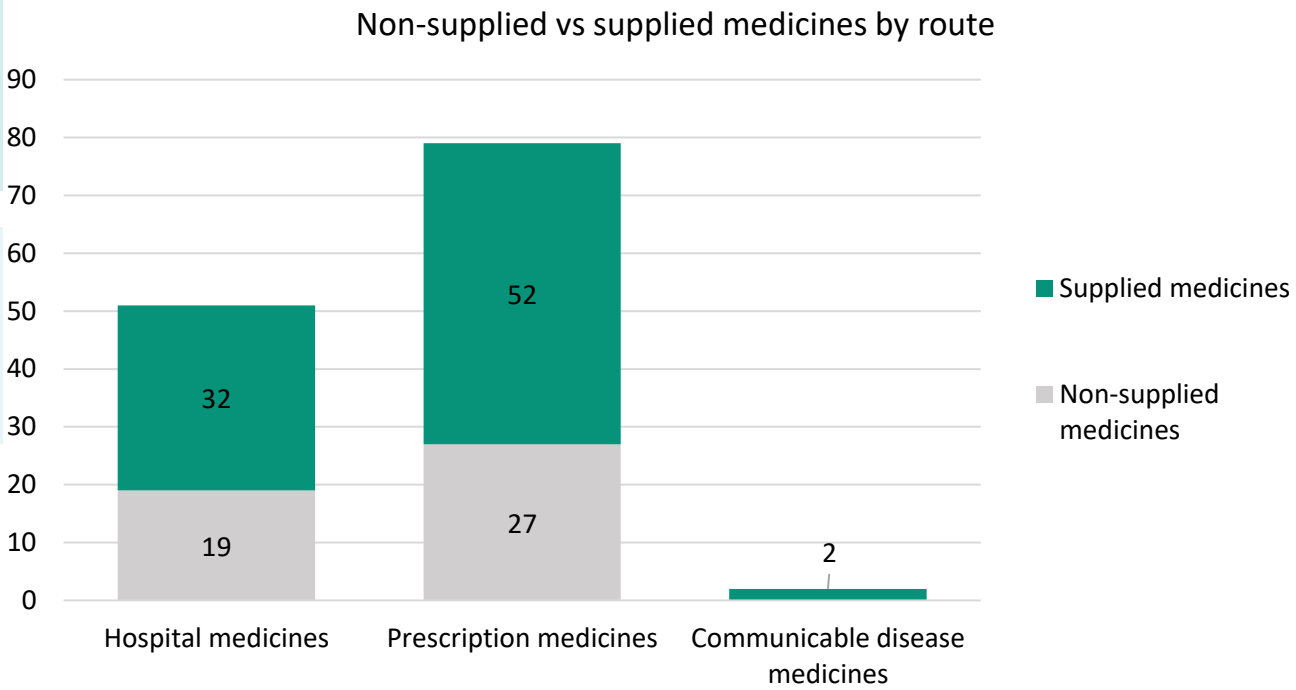
46 out of **132** (35%) medicines were **not supplied**

20 out of **46** (43%) non-supplied medicines came from MAHs **lacking Nordic presence**

19 medicines were not supplied
9 supplied medicines were not reimbursed

27 medicines were not supplied
18 supplied medicines were not reimbursed

All medicines were supplied



The 46 non-supplied medicines – will they launch?

Hospital medicines

- **Of the 19 non-supplied medicines**:
  - **5** had negative NT recommendations
  - **6** had ongoing evaluations
  - **6** were not in the national managed introduction (would have considered reimbursed if supplied)
  - **1** medicine got a negative recommendation after study cut-off and **1** is no longer a part of the national managed introduction (but not marketed at cut-off).

Prescription medicines

- **Of the 27 non-supplied medicines**:
  - **6** had withdrawn TLV applications
  - **3** had ongoing TLV applications & **1** had a positive TLV decision
  - **17** medicines had no public information

Assessment:

A majority of the hospital and prescription medicines may become available in the future

14 out of 19 do not have a negative recommendation

None had a negative decision

…and what about the 27 supplied but not reimbursed medicines?

Hospital medicines

- **9 supplied were not reimbursed:**
  - **4** had negative recommendations
  - **5** had evaluations pending/ongoing

Prescription medicines

- **18 supplied were not reimbursed:**
  - **6** had negative TLV decisions

Assessment:

Many hospital and prescription medicines may become available in the future

- **4 out of 9 have pending evaluations**
- **13 out of 18 do not have negative TLV decisions**

Assessment of whether the 73 non-reimbursed medicines might become reimbursed in the future

18 out of the **73** (25 %) non-reimbursed medicines were reimbursed after cut-off (or not-marketed at cut-off despite a positive decision).

26 out of **73** (36 %) had negative decisions or have had their reimbursement application withdrawn

10 out of these **73** (14%) lack national HTA-assessments and potential reasons for why reimbursement is lacking is mentioned in a report by the regions.

→ *According to the report, these medicines have treatment alternatives, the patient population is very limited (in Sweden), they will not be launched, or it is a hybrid medicine* with treatment alternatives.*

Despite the efforts no information on current reimbursement status was obtained for **19** out of the **73** (26%) non-reimbursed medicines

Status for the 73 non-reimbursed medicines (approved 2023-2024)

Reimbursement status	n (%)
Ongoing (or planned) national process	**11 (15%)**
Reimbursed after cut-off	**6 (8%)**
Reimbursed but not supplied at cut-off	**1 (1%)**
Withdrawn TLV submission	**8 (11%)**
Withdrawn TLV submission - used through regional process	*2 (3%)*
Negative national decision (before or after cut-off)	**13 (18%)**
Negative national decision - used through regional process	**5 (7%)**
No assessment - explanations obtained from the regions	**10 (14%)**
No assessment - treatment alternatives exists	*4 (5%)*
No assessment - limited population	*3 (4%)*
No assessment - will not be launched in Sweden	*2 (3%)*
No assessment - hybrid medicine with treatment alternatives	*1 (1%)*
N/A - other (no information)	**19 (26%)**

*Hybrid medicines are based on the same active substance as a reference medicines but is used for another disease and administered differently.

This slide is based on information from:
- TLV (information concerning rejections and ongoing hospital drug evaluations was gathered from TLVs web page, and additional information was provided by TLV upon request)
- Janusinfo (information concerning rejection of hospital products going through the NT-council route)
- Information from a report by the regions on availability of new medicines (Region Västerbotten and Region Örebro (2024), Kunskapsunderlag, Långsiktigt hållbart tillgängliggörande av särläkemedel i Sverige)

Despite the efforts, and the many different sources used, it was not possible to obtain information for 19 medicines (26 %). Last update of this slide: May 20th, 2025.

Sweden in the European setting – EFPIA portal data

Note! This slide is based on different data compared to what is used in the main part of this report.

In 2022, the pharmaceutical industry created the European Access Hurdles Portal with the aim to improve transparency regarding the root causes of unavailability and delay

The first results were published in 2023, and in May 2025 the third report & a summary slide deck were published
The report includes 94 medicines from EFPIA members receiving EMA approval January 2021 - June 2024

- **76 medicines (80 %) where either reimbursed or filed for pricing & reimbursement in Sweden**
  - 11 products were reported as "*not yet filed*".
    - 7 products were reported as "*not yet filed for pricing & reimbursement but accessible through an alternative scheme*" which could potentially be early access programs, paid out of pocket or available through "exceptional handling" (swedish: undantagshantering)

- **The reasons for non-filing are reported on Nordic level**
  - The most common reason for not filing was "**evidence package unlikely to meet country requirements**" (30%), followed by "**the size of the treatable population**", "**lack of company presence in local market**" (both at 17 %), and "**low value attributed to class competitors**" (at 14 %).

Discussion

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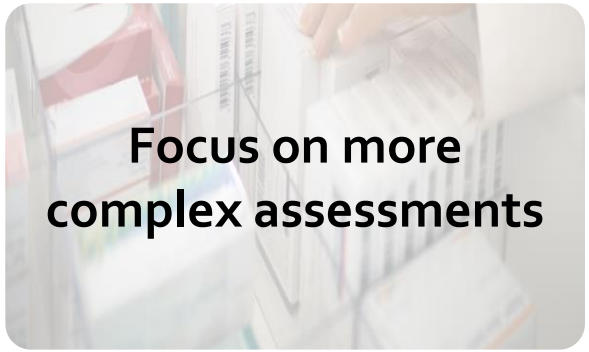
How do we create good conditions for access to new medicines in Sweden?

Continued **need for "tools"** such as reimbursement restrictions and price agreements

- **Reimbursement restrictions and net price agreements** are important tools for national reimbursement
  - **A majority of all new medicines** are associated with those tools (69% of the medicines approved 2021-2023 and 61% for full dataset).
  - A continuous work to improve ability to facilitate, and sign, price agreements is part of the most recent agreement on pharmaceutical expenditures (link).

Clear pathway to market access

- The route to reimbursement varies for medicines (e.g., if it is administered in a hospital setting or not)
  - Although the share of reimbursement filing is high relative to many other countries (link)…
  - …many non-supplied medicines belong to companies lacking Nordic presence (link) and insufficient evidence package has been identified as a key reason why companies choose not to file for reimbursement (in the Nordics) (link) — suggesting that the system may be perceived as complex
  - **There is a continued need to clarify and streamline the path to market access.**



Focus on more complex assessments

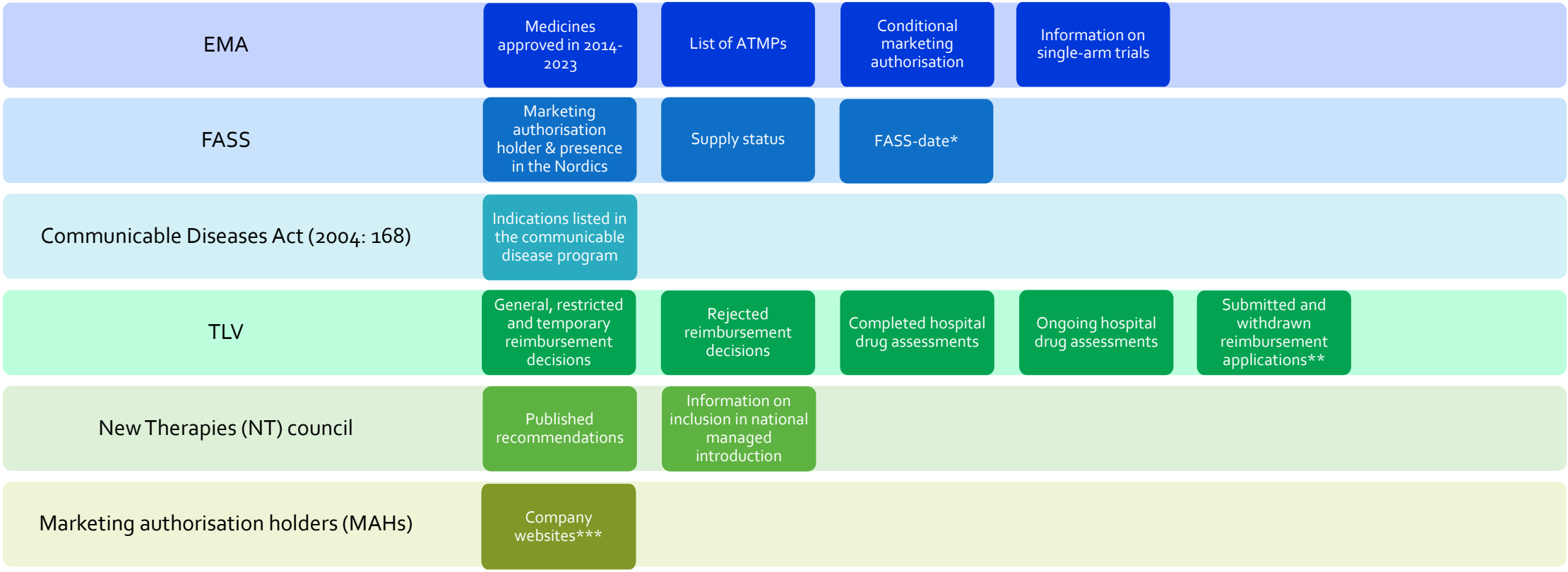
- TLV is expected to place greater emphasis on **budget impact** in the future, driven by the introduction of new tools designed to improve access to treatments for ultra-rare diseases (link)).
  - Adds a layer of complexity to the assessments.
  - **Streamlining reimbursement procedures** for cases with limited budget impact and lower uncertainty may **allow greater focus and capacity for evaluating more complex submissions.**

Appendix

QUANTIFY

Data collection

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



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

Several of these sources may have been used to extrapolate information; a medicine with ongoing hospital drug assessment may for instance also be subject to inclusion in the national managed introduction.
* Date from FASS was extracted and used as a proxy for reimbursement date in certain situations, i.e., for communicable diseases and supplied hospital medicines outside the managed introduction.
** Data not openly published on TLV's website but obtained upon request based on the principle of public access to information.
*** Used to obtain information on share (and number) of companies with non-supplied medicines that are locally present in the Nordics.

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***: measuring 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 necessarily a 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 while decision is pending (where system permits)	
Availability through a special program (e.g. managed entry agreements)	
Limited reimbursement on a national named patient basis (individual patient)	Available (marked NBP^)
Available only within the private market at the patient's expense	Only privately available
Not reimbursed, or not reimbursed while awaiting decision	Not available

Medicines with EMA approval 2021-2023 included in the report (1/3)

Medicines included in the report: 59 supplied and nationally reimbursed medicines			
Adtralza	Imjudo	Opfolda	Sunlenca
Amvuttra	Inrebic	Orgovyx	Tecvayli
Aquipta	Jaypirca	Orladeyo	Tepmetko
Artesunate Amivas	Jemperli	Padcev	Tezspire
Bimzelx	Kapruvia	Pemazyre	Trodelvy
Breyanzi	Kerendia	Pombiliti	Tukysa
Brukinsa	Kesimpta	Ponvory	Vabysmo
Byfavo	Kimmtrak	Retsevmo	Vazkepa
Cibinqo	Lumykras	Roclanda	Veoza
Elfabrio	Lunsumio	Rukobia	Verquvo
Elrexfio	Lupkynis	Ryeqo	Voraxaze
Enhertu	Nexviadyme	Saphnelo	Vumerity
Evrenzo	Ngenla	Scemblix	Vydura
Evrysdi	Omvoh	Sotyktu	Vyepti
Finlee	Ontozry	Spevigo	

As of the cut-off date (21 December 2023)

Medicines with EMA approval 2021-2023 included in the report (2/3)

Medicines included in the report: 27 supplied non-nationally reimbursed medicines	
Aspaveli	Minjuvi
Bylvay	Mounjaro
Camzyos	Opdualag
Columvi	Quviviq
Drovelis/Lydisilka	Rybrevant
Ebvallo	Sibnayal
Enspryng	Tabrecta
Filsuvez	Talvey
Imcivree	Tepkinly
Inaqovi	Tibsovo
Koselugo	Voxzogo
Litfulo	Wegovy
Livtencity	Xofluza
Lyfnua	

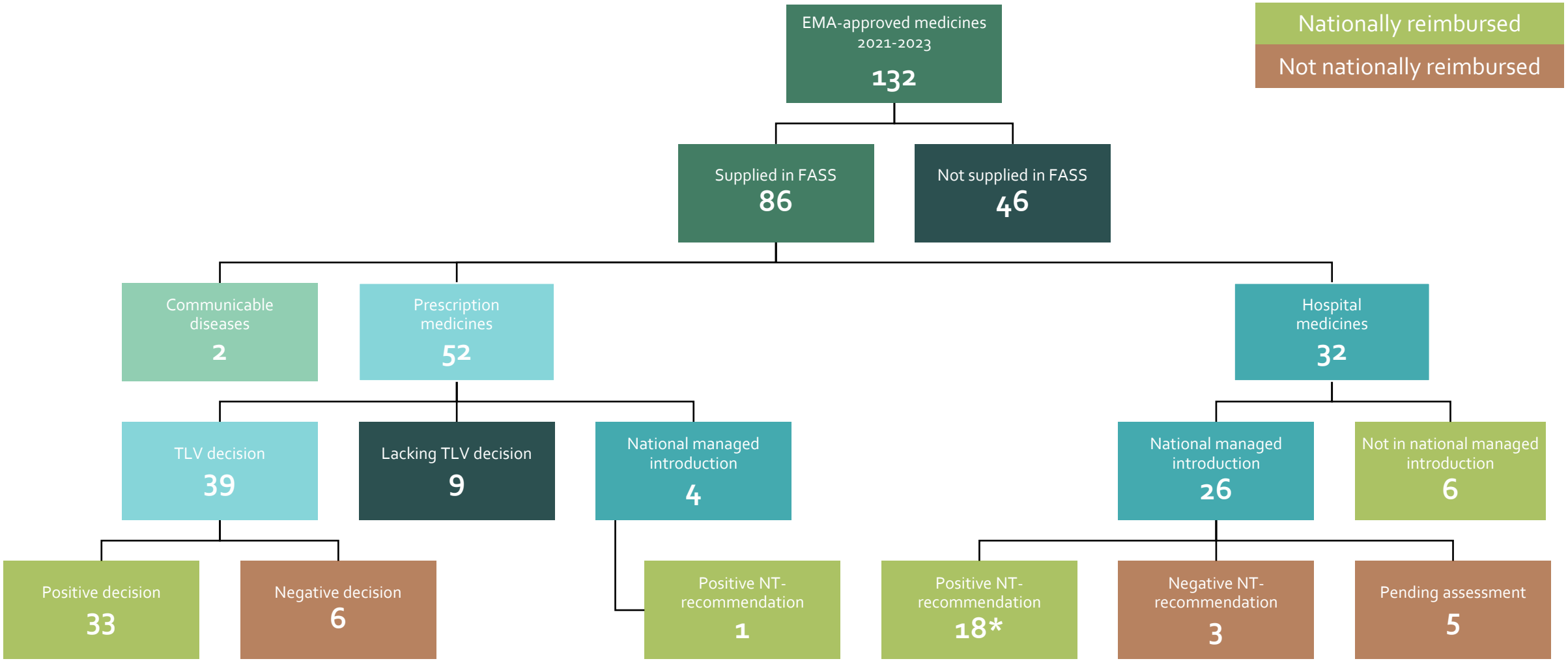
As of the cut-off date (21 December 2023)

Medicines with EMA approval 2021-2023 included in the report (3/3)

Medicines included in the report: 46 non-supplied medicines		
Abecma	Livmarli	Tavneos
Agamree	Loargys	Tecovirimat SIGA
Akeega	Lytgobi	Tevimbra
Briumvi	Mycapssa	Uplizna
Carvykti	Nexpovio	Upstaza
Copiktra	Nulibry	Vafseo
Ebglyss	Orserdu	Vanflyta
Eladynos	Pluvicto	Vyvgart
Elzonris	Pyrukynd	Xenpozyme
Enjaymo	Qinlock	Yorvipath
Evkeeza	Rayvow	Yselty
Gavreto	Rezzayo	Zilbrysq
Hemgenix	Roctavian	Zokinvy
Hyftor	Skytrofa (previously Lonapegsomatropin Ascendis Pharma)	Ztalmy
Kinpeygo	Sogroya	Zynlonta
Klisyri		

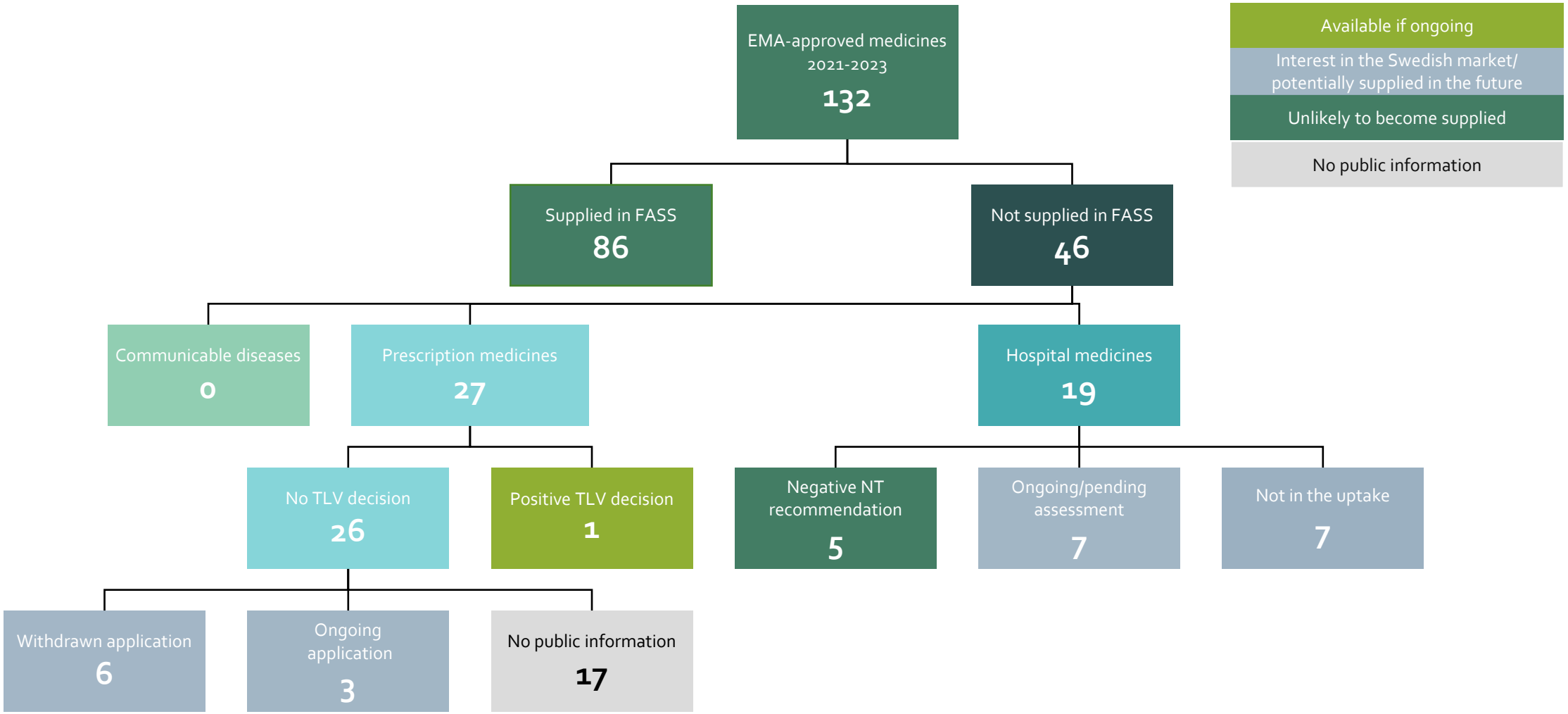
As of the cut-off date (21 December 2023)

Overview: Medicines supplied in Sweden



* Includes 2 medicines with national agreements, but no issued recommendation and 2 hospital medicines approved through the TLV process.

Overview: Medicines not supplied in Sweden



FASS-date: The definition of ”date of supply” will be *revised* in future report

- Date of supply is assumed to be the date when a medicine is registered as ”supplied” on fass.se, referred to as ”FASS-date”. This date was obtained using publication date at fass.se (as a proxy for ”true” date of supply).
  - In future reports we are planning on using first ”marketing date” as a measure for date of supply rather than the FASS-publication date (i.e., initial marketing date in Sweden based on data from FASS).

- This report only assesses time from EMA-approval to reimbursement. Nonetheless, the ”date of supply” is used in some cases as a proxy for reimbursement date (6 medicines in this years’ cohort, medicines with EMA-approval 2021-2023) , this includes:
  - Supplied medicines used to treat communicable diseases
  - Supplied hospital medicines that are not a part of the national managed introduction.

Our assessment shows that the previously used FASS-date is in most cases an earlier date than the ”first marketing date” that is intended to be used in upcoming reports.

- ➢ This report states that average time from EMA approval to national reimbursement was 352 days (for this years’ cohort, 2021-2023).
- ➢ The average time from EMA approval to reimbursement would have been 391 days (for this years’ cohort, 2021-2023) instead if we are using the revised FASS-date definition, when applicable, i.e. ”first marketing date”.

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