# Swedish national reimbursement of new medicines with EMA approval 2020-2022

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# Content

# Brief summary & conclusions

# A majority of all medicines are nationally reimbursed, but some challenges with the Swedish system remains

## This is a detailed review of 141 new medicines approved 2020-2022

- **65 %** (92 out of 141) were **supplied**
  - A majority of all supplied medicines were also nationally reimbursed
- **48 %** (67 out of 141) were **nationally reimbursed**
  - The remaining 74 medicines were not nationally reimbursed.
- The **time** from EMA-approval **to reimbursement** is longer for orphan and oncology medicines compared to medicines overall.
  - Possible explanations include lack of data, need for price negotiation and health economic challenges.

## This report highlight some difficulties with the Swedish system

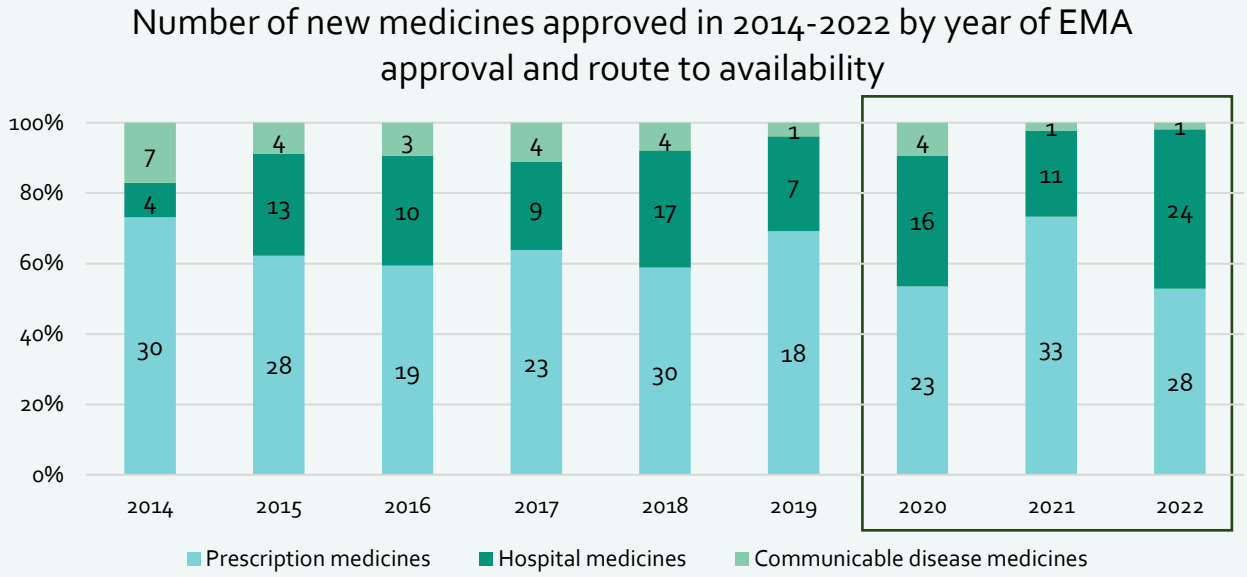
- The **74 non-reimbursed medicines belonged to 56 companies** (MAHs)
  - **32% lacked Nordic presence**.
  - **45%** had **no medicines in** the pharmaceutical **benefits scheme**.
- The Swedish market may in some cases be perceived as complex.
- Other possible explanations (for why some medicines were not reimbursed and/or supplied in Sweden) include: negative decision (actual or perceived), Sweden not being or priority or that an application is under development.

## Additional analyses have been performed showing longer trends

- The full data set includes 372 new medicines with regulatory approval year 2014-2022.
- Data suggests that it takes about 4-5 year until a steady state in the share of nationally reimbursed medicines is reached. This highlights that **reimbursement takes time.**
- A majority of all non-supplied medicines are oncology and/or are used to treat orphan conditions.

# Medicines approved by EMA in 2014-2022

- The focus of the report is on **141 new medicines approved by EMA in 2020-2022**
- Some analyses takes the full data set into account in order to show longer trends
  - In total, this **report includes 372 new medicines with new medicines** approved by EMA in 2014-2022 that were identified in EFPIA's W.A.I.T. report
  - Medicines with withdrawn marketing authorization were excluded



# Background and objectives

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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** 2020-2022 **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.**

# Routes to national reimbursement

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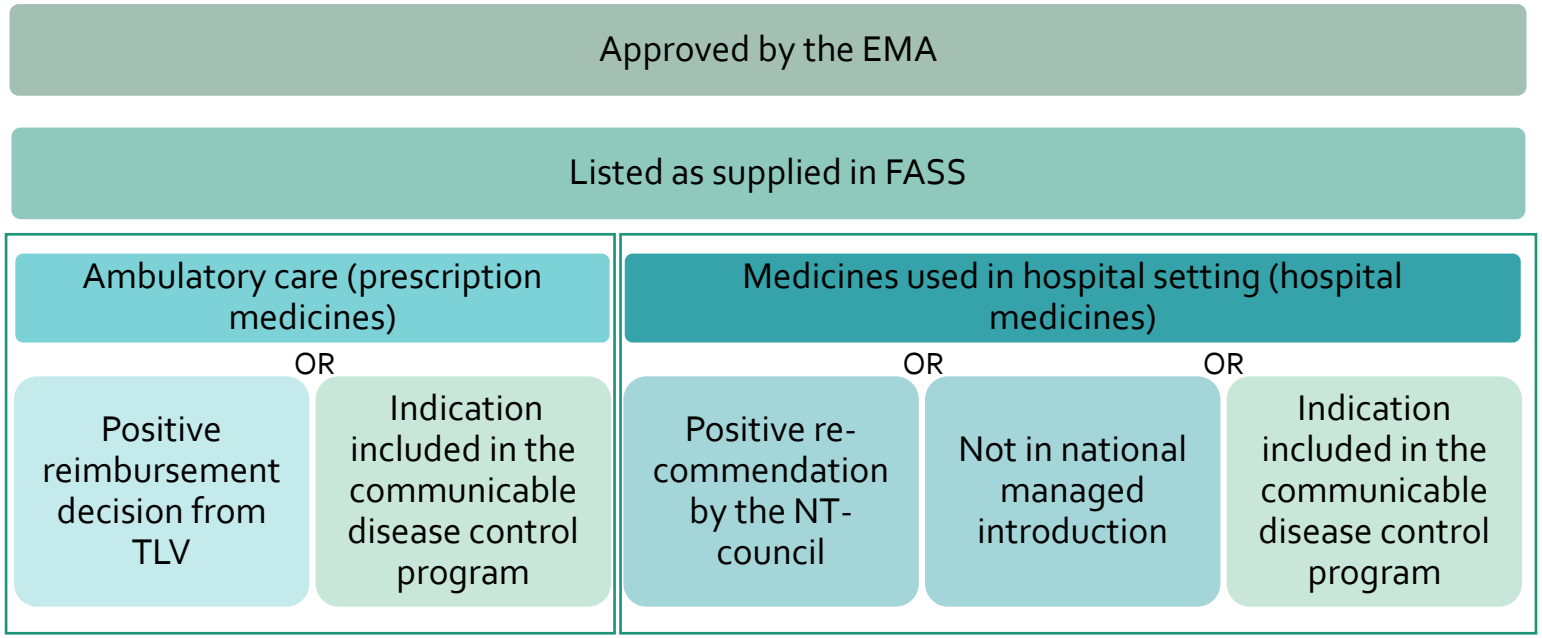
# Study definitions

## 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 21 December 2023,** 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:

- 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**.

*In the appendix, a more detailed illustration of the paths to national subsidies is provided.

# From EMA approval to supplied in FASS

**EMA-approved medicines 2020-2022**
**141**

| Supplied in FASS | | | Not supplied in FASS | | |
|---|---|---|---|---|---|
| **92 (65 %)** | | | **49 (35 %)** | | |
| Communicable diseases | Prescription medicines | Hospital medicines | Communicable diseases | Prescription medicines | Hospital medicines |
| 5 (5 %) | 55 (60 %) | 32 (35 %) | 1 (2%) | 29 (59 %) | 19 (39 %) |

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

**Medicines supplied in Sweden 2020-2022**
**92**

| Communicable diseases | | Prescription medicines | | Hospital medicines | |
|---|---|---|---|---|---|
| **5 (5 %)** | | **55 (60 %)** | | **32 (35 %)** | |
| Nationally reimbursed | Not nationally reimbursed | Nationally reimbursed | Not nationally reimbursed | Nationally reimbursed | Not nationally reimbursed |
| **5 (100 %)** | **0 (0 %)** | **41 (75 %)** | **14 (25 %)** | **21 (66 %)** | **11 (34 %)** |

A majority of supplied medicines are nationally reimbursed (73 %)

# This year's cohort 2020 - 2022

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# Majority of supplied medicines were also nationally reimbursed

**92** out of **141** (65%) medicines were **supplied**

**67** out of **92** (73%) supplied medicines were **nationally reimbursed**

Average time from EMA approval to supplied in FASS was **33** (*median: 16*) days

Average time from supplied in FASS to national reimbursement was **269** (*median: 214*) days

**Number of medicines and average time from supply to national reimbursement per route:**

| | | | | | |
|---|---|---|---|---|---|
| **Hospital** | n = 21 | **258** (268) days | **Prescription** | n = 41 | **299** (193) days |
| **Communicable diseases** | n = 5 | **0*** 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

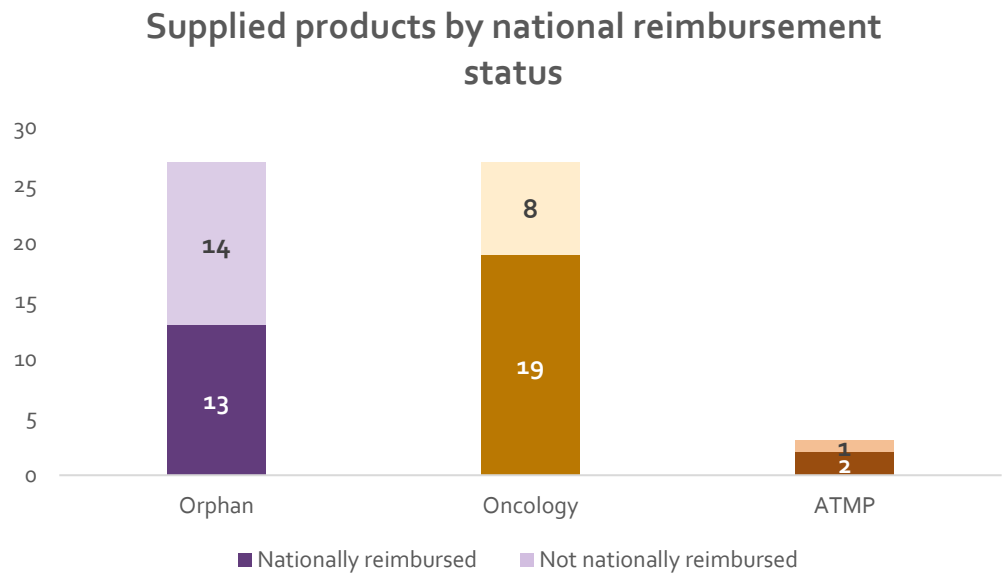
**Note: small samples**

For comparison, overall average:
73% nationally reimbursed of supplied medicines
269 (median: 214) days

A majority (107 of 141; 76%) of all medicines were **either orphan, oncology or ATMP**

**57** out of those **107** (53%) were supplied

**34** out of **57** (60%) supplied medicines were **nationally reimbursed**




**Average time from supply in FASS to national reimbursement for subgroups:**

| Orphan n = 13 | 305 (234) days |
|---|---|

| Oncology n = 19 | 337 (284) days |
|---|---|

| ATMP n = 2 | 609 (609) days |
|---|---|

# Tools for national reimbursement

## Restrictions in the subsidy - 36 (58%) medicines

- **58 %** of the 62 (prescription & hospital) nationally reimbursed medicines had conditions (*reimbursed for a subpopulation or by certain specialists*) for their reimbursement:

**62 % (13 out of 21)**

**56 % (23 out 41)**

## National price agreements – 22 (35%) medicines

- **35 %** of the 62 (prescription & hospital) nationally reimbursed medicines had a price agreement with the regions:

**52 % (11 out of 21)**

**27 % (11 out 41)**

Moreover, 1 product for a communicable disease also had both restrictions and an agreement in place but would have considered nationally reimbursed independent of the reimbursement status and national price agreement.

# Not supplying medicines remains a large concern

**49** out of **141** (35%) medicines were **not supplied**

**20** out of **49** (41%) non-supplied medicines came from MAHs **lacking Nordic presence**

**25** out of **92** (27%) supplied medicines were **not reimbursed**

In total, **74** (49+25) out of **141** (52%) medicines were not reimbursed

**19 medicines** were not supplied
**11 supplied medicines** were not reimbursed

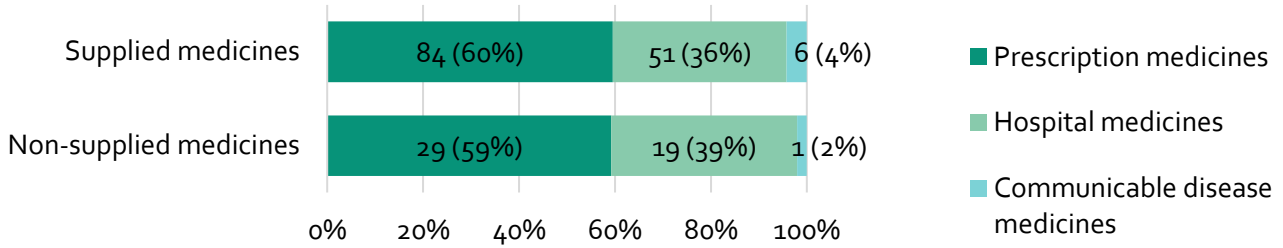
**29 medicines** were not supplied
**14 supplied medicines** were not reimbursed

**1 medicine** was not supplied

**Assessment:**

The large proportion of medicines from MAHs lacking Nordic presence might indicate that the system is perceived as complex, or that other sufficient treatment alternatives are already available.

Non-supplied vs supplied medicines by route



# The 49 non-supplied medicines – will they launch?

## Hospital medicines

- **Of 19 non-supplied medicines**:
  - **3** had negative (& **1** positive) NT recommendation
  - **8** had ongoing evaluation
  - **7** were not in the uptake (would have considered reimbursed if supplied)

## Prescription medicines

- **Of the 29 non-supplied medicines**:
  - **2** had withdrawn TLV applications & **1** had a negative TLV decision
  - **3** had ongoing TLV applications
  - **23** medicines had no public information

## Medicines for communicable diseases

- **1** medicine for a communicable disease were **not supplied**

**Assessment:**

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

**16 out of 19 do not have a negative recommendation**

**26 out of 29 do not have a negative decision**

**If supplied, it would be considered reimbursed**

# …and what about the 25 supplied but not reimbursed medicines?

## Hospital medicines

- **11 supplied were not reimbursed:**
  - **4** had had negative recommendations and the rest (**7**) had evaluations pending (ongoing or planned)

## Prescription medicines

- **14 supplied were not reimbursed:**
  - **4** had negative TLV decisions

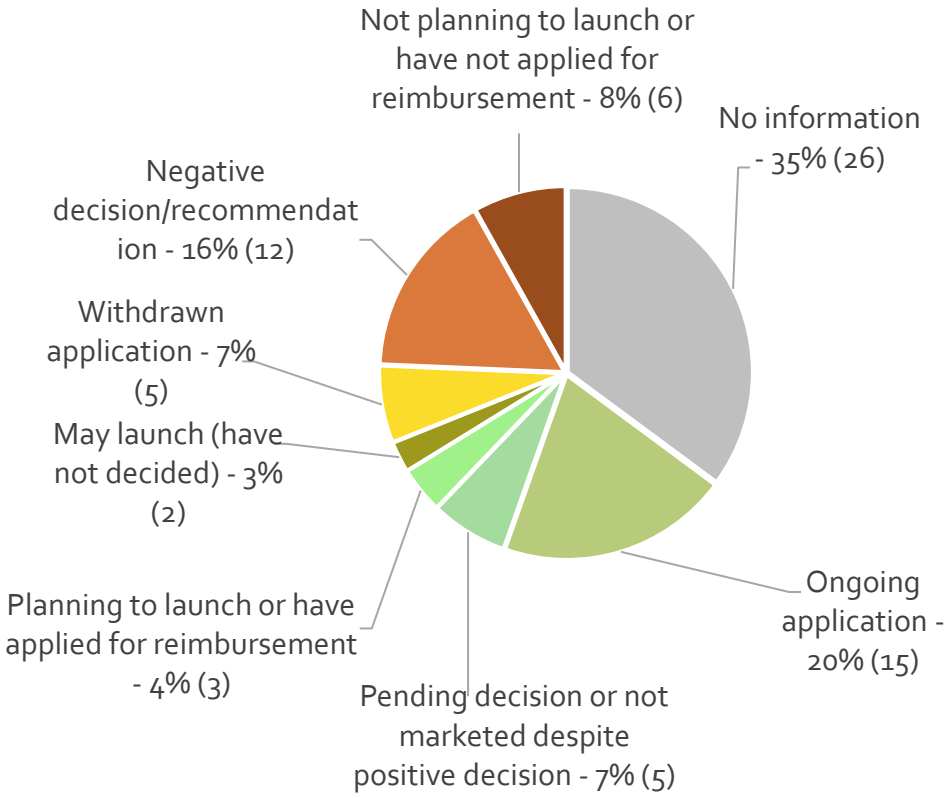
**Assessment:**

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

**7 out of 11 have pending evaluations**

**10 out of 14 do not have negative TLV decisions**

# Prospects for the 74 non-reimbursed medicines becoming reimbursed




**Assessment:**

**34% (25 out of 74)** of these medicines have ongoing application processes, had a pending decision at cut-off date, are planning to launch or may launch

› Many of them **will likely become reimbursed in the future**.

**31% (23 out of 74)** had negative decision/recommendations, withdrawn application or, alternatively, the company does not intent to launch the medicine.

› Many of these medicines **will likely not become reimbursed**.

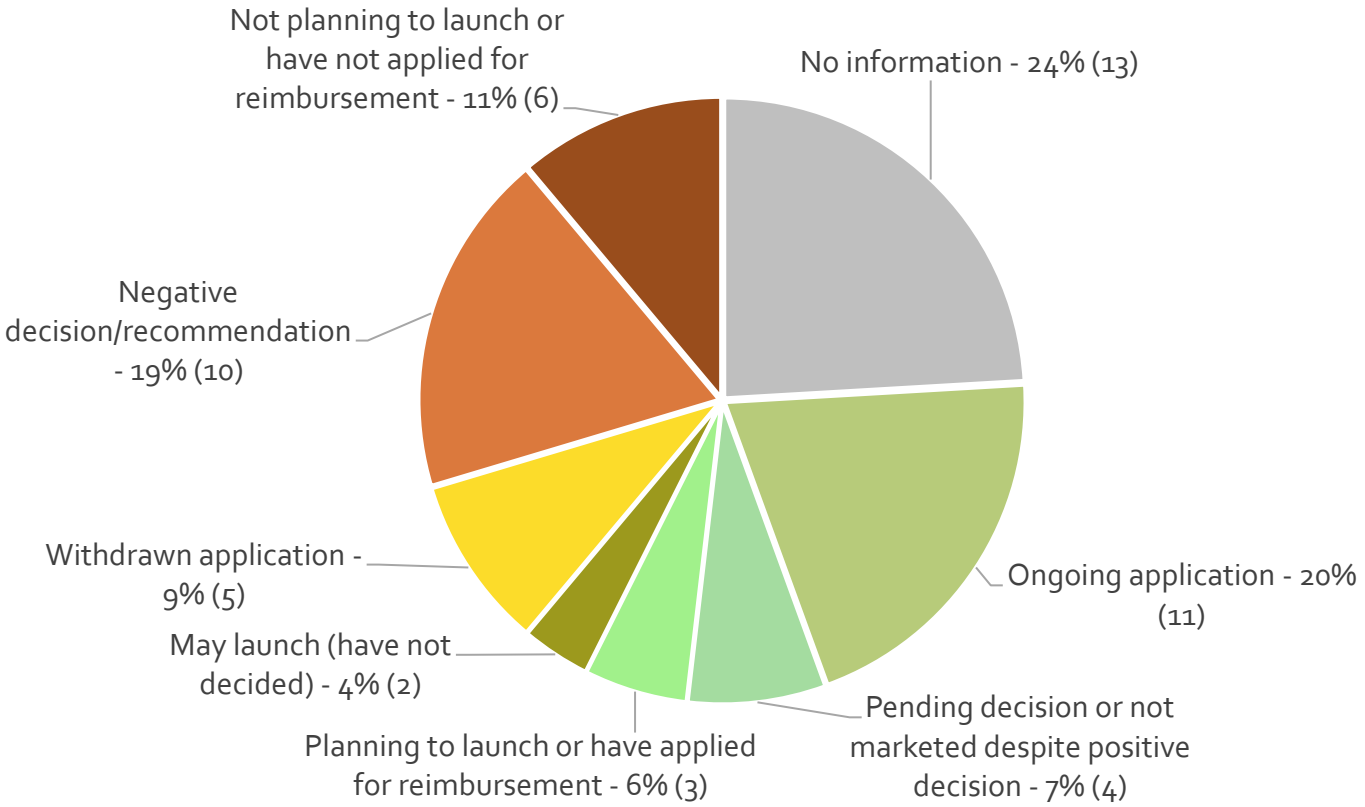
The 74 non-reimbursed medicines belonged to **56 market authorization** holders (MAHs)

- **32%** (18 out of 56) **lacked Nordic presence.**
- **45%** (25 out of 56) had **limited Swedish market experience** (measured as whether they had medicines in the pharmaceutical benefits scheme).

This figure 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)
- A company survey (carried out in March – May 2024)
- Janusinfo (information concerning rejection of hospital products going through the NT-council route)

Despite the efforts, and the many different sources used, it was not possible to obtain information for 26 medicines (35 %)

# Prospects for reimbursement of the 54 non-reimbursed medicines with market authorization holders (MAHs) present in the Nordics




- **54 out of 74** non-reimbursed medicines belonged to **MAHs with Nordic company presence.**
- It was possible to gain information on reimbursement status for these medicines to larger extent compared to medicines overall.
- Many of these 54 non-reimbursed medicines will likely become reimbursed in the future:
  - **One out of five** medicines had **ongoing reimbursement process**.
  - About **17 % may launch** (i.e., the company have not decided), are **planning to launch,** have a **pending decision or** have **not marketed** their medicine **despite a positive reimbursement**.

This figure 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)
- A company survey (carried out in March – May 2024)
- Janusinfo (information concerning rejection of hospital products going through the NT-council route)

Despite the efforts, and the many different sources used, it was not possible to obtain information for 13 medicines (24 %)

# Trends in national access; 2014-2022

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

This slide shows the share of reimbursed medicine in the present and previous three reports using a similar cut-off date.

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

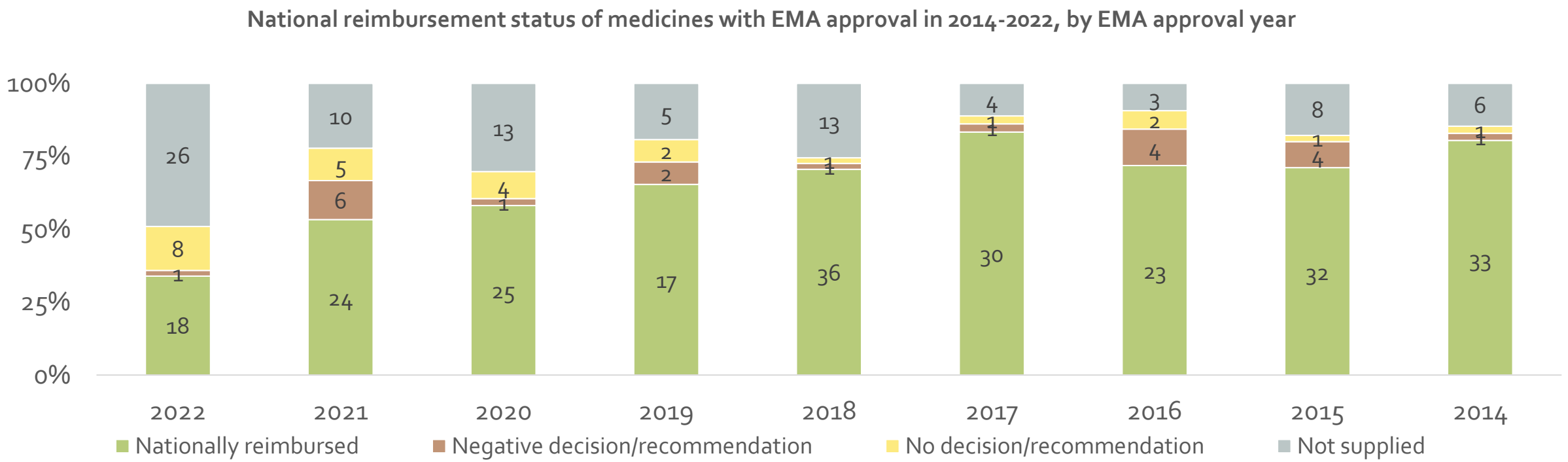
On December 22nd, 2020, 56% of all new medicines approved 2019-2017 were* nationally reimbursed.

On December 21st, 2023, 48% of all new medicines approved 2020-2022 were* nationally reimbursed.

We observe similar results across the reports, even though the trend suggests a decreasing proportion of nationally reimbursed medicines.

*Based on the sample in each year's report.
**Note that this is based on each report definition of national reimbursement. The definition of reimbursement of hospital medicines is broader in this year's report compared to the report with cut-off date December 22, 2020.

# National reimbursement of new medicines over time




About 50 % of all medicines were supplied after ~1 year from market authorization…

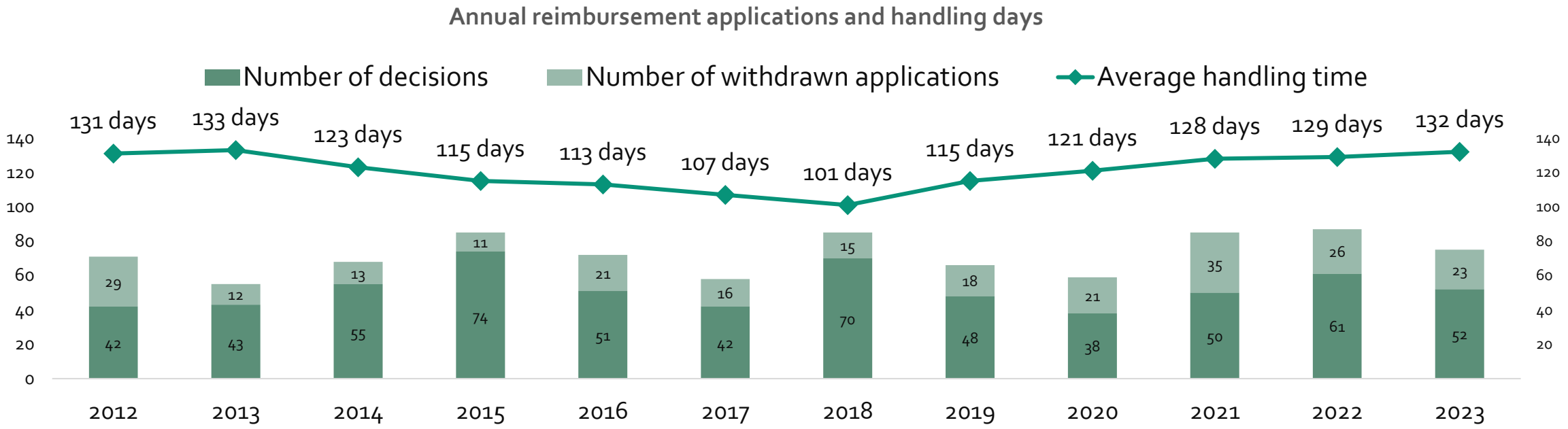
…and this graph suggests that after ~4 years a "steady state" in share of nationally reimbursed products were reached…

…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 2022, based on the situation as of the study's cutoff date (December 21, 2023).

# The increased TLV handling time since 2018 do not seem to be directly linked to number of applications

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

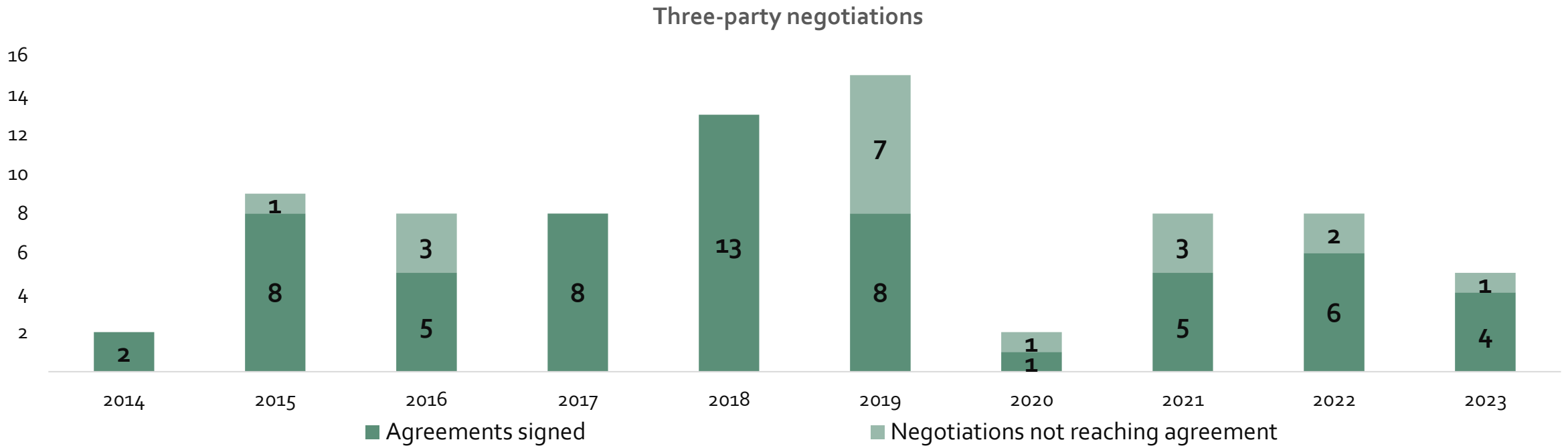



The share of withdrawn application fluctuates around 30% annually (of total number of decisions and withdrawn applications). The share of withdrawn decisions peaked in 2021 (41%) and was at its lowest point in 2015 (13%).

*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.

# The possibility for three-party negotiations has existed since 2014; only a handful such negotiations took place in 2023.

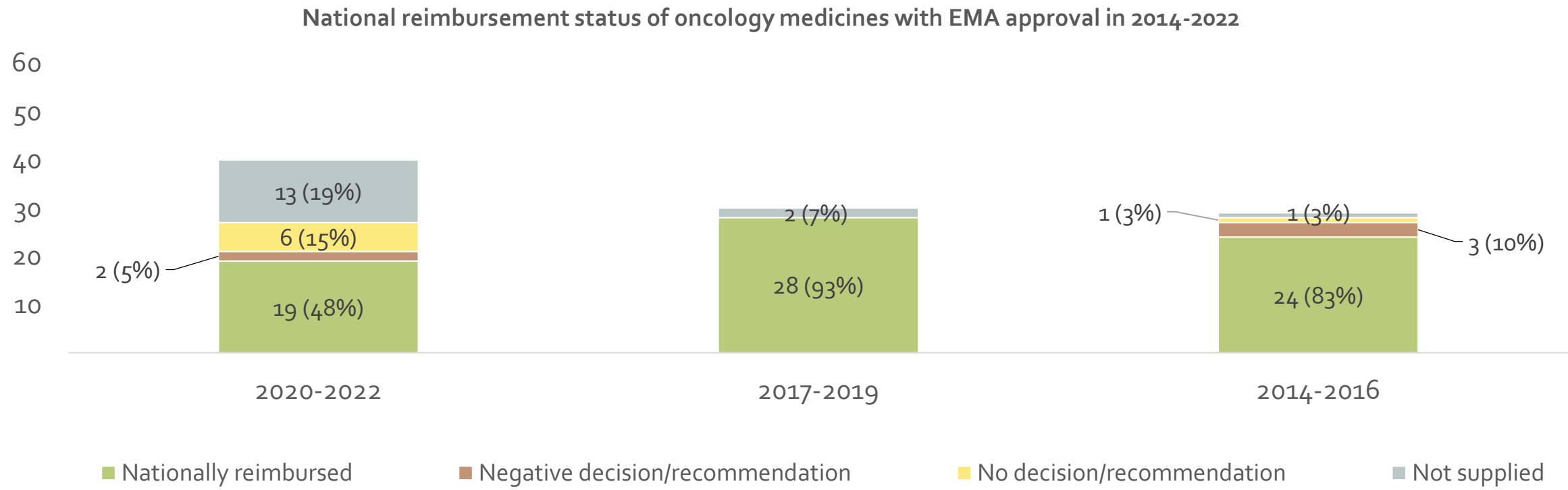
Note! This slide is based on different data compared to what is used in the main part of this report.




Only a handful three-party negotiations took place in 2023. The number of negotiations varies greatly from year to year.

*This figure shows number of three-party negotiations (with signed agreements) 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.

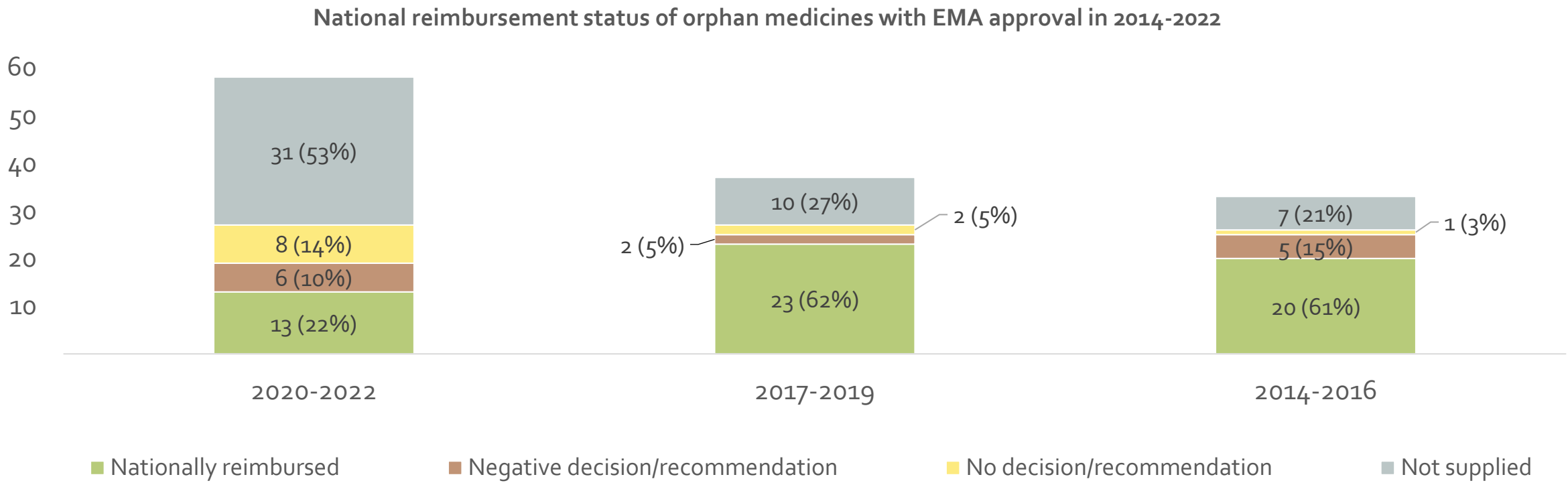
# National reimbursement of oncology medicines over time




**Similarly to conclusions for the overall population, 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 2014 to 2022, based on the situation as of the study's cutoff date (December 21, 2023).

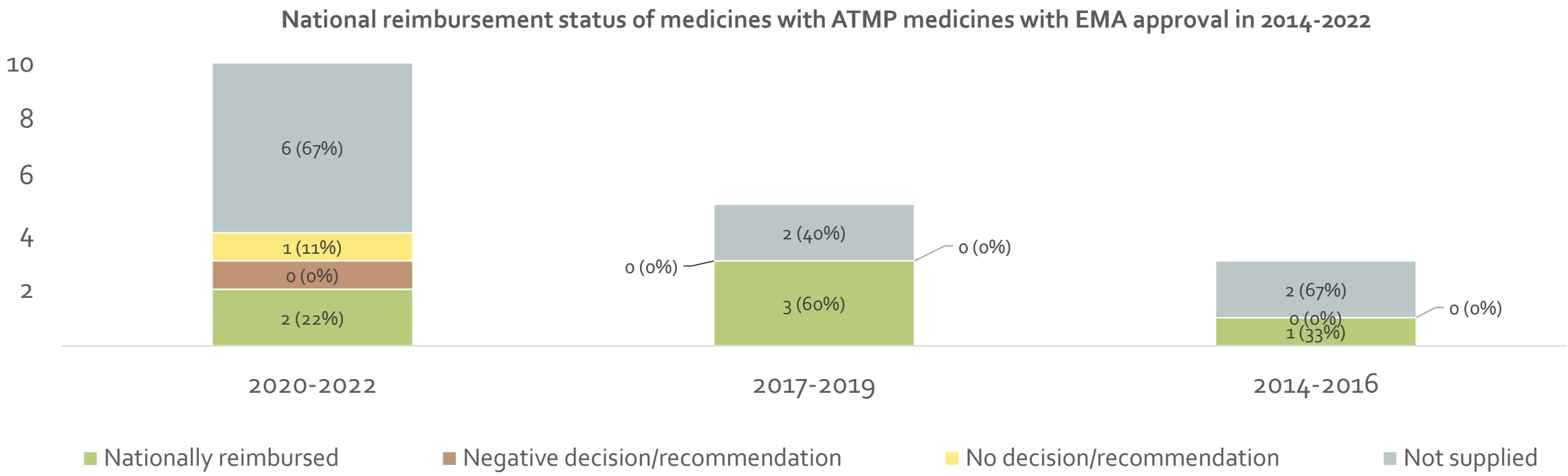
# National reimbursement of orphan medicines over time




**Similar to what was observed for the overall population and oncology medicines, medicines in the older 3-year cohorts are reimbursed to higher extent. However, the proportion of reimbursed medicines is relatively low regardless of the three-year period we consider (compared to how it looks for overall population).**

This slide shows the reimbursement status for orphan medicines with marketing authorization from 2014 to 2022, based on the situation as of the study's cutoff date (December 21, 2023).

# National reimbursement of ATMPs over time

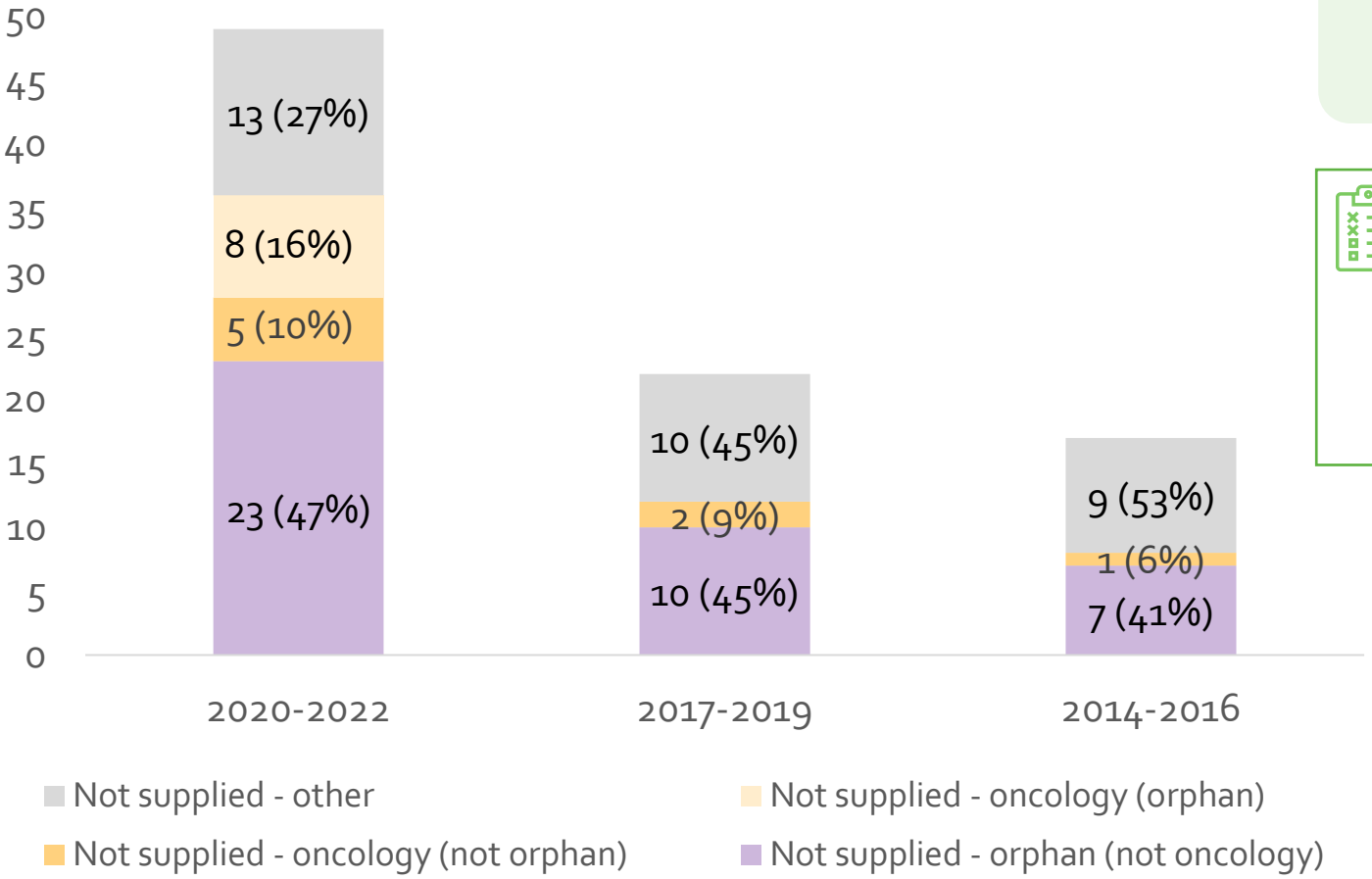



**More than 50% of all medicines categorized as ATMP in this year's report are not supplied (and nationally reimbursed). However, the number of observations is low which makes interpretations of long-term trends difficult.**

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 orphan medicines with marketing authorization from 2014 to 2022, based on the situation as of the study's cutoff date (December 21, 2023).

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

Not supplied medicines by authorization year, divided into the following groups: oncology (orphan/non-orphan), orphan (not oncology) and other




**>70% of all non-supplied 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.

**Assessment:**
The introduction of medicines used to treat oncology and/or orphan conditions appears to be slower than medicines overall (this seems to be particularly true for orphan medicines).

This slide shows the reimbursement status for oncology medicines with marketing authorization from 2014 to 2022, based on the situation as of the study's cutoff date (December 21, 2023).

# Discussion

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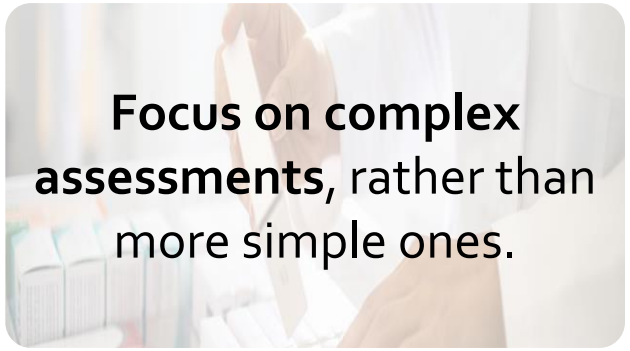
# How do we create good conditions for access to new medicines in Sweden?

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

- About 60% of all nationally reimbursed, hospital and prescription, medicines in the latest three-year cohort had restrictions in the subsidy and 35% had national price reimbursements.

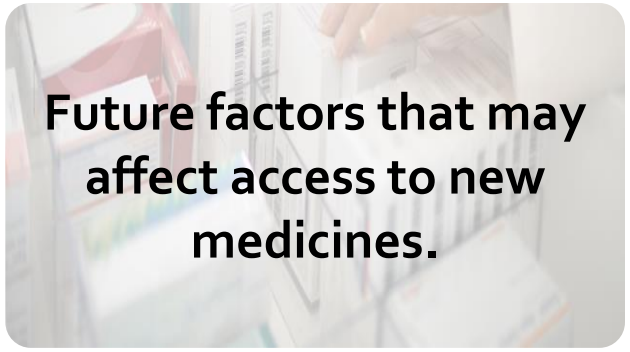
› There is a continued need for such tools to ensure continued access to new medicines.



**Focus on complex assessments**, rather than more simple ones.

- Data suggests that national reimbursement of orphan and oncology medicines is slower than medicines overall. Moreover, a majority of all non-supplied medicines belongs to these two subgroups.

› If TLV develops simplified processes for easier assessments, this may free time for more complex evaluations (such as oncology and/or orphan medicines).



**Future factors that may affect access to new medicines.**

- On the European level, changes in pharma legislation and HTA regulation may impact access to new medicines, for instance if prolonging of regulatory protection is linked to launch in all countries.

› Increased incentives to submit material, which may have an impact on access to new medicines.
› In addition, TLV has several ongoing governmental assignments (such as strengthen the access to medicines for rare diseases), which may also have an impact access to new medicines.

# Appendix

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# Data collection

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

| | | | | | |
|---|---|---|---|---|---|
| EMA | Medicines approved in 2014-2022 | List of ATMPs | Conditional marketing authorisation | Information on single-arm trials | |
| FASS | Marketing authorisation holder & presence in the Nordics | Supply status | Date of supply* | | |
| Communicable Diseases Act (2004: 168) | Indications listed in the communicable disease program | | | | |
| TLV | General, restricted and temporary reimbursement decisions | Rejected reimbursement decisions | Completed hospital drug assessments | Ongoing hospital drug assessments | Submitted and withdrawn reimbursement applications* |
| New Therapies (NT) council | Published recommendations | Information on inclusion in national managed introduction* | | | |
| Marketing authorisation holders (MAHs) | Company survey answers** | Company websites*** | | | |

- The complete 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.
* Data not openly published on TLV's website but obtained upon request based on the principle of public access to information.
** Non-public information received from source.
*** Used to obtain information on share (and number) of companies with non-supplied medicines that are locally present in the Nordics.

# 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 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

# 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 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 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 |

# Medicines with EMA approval 2020-2022 included in the report (1/3)

| Medicines included in the report: 67 supplied and nationally reimbursed medicines | | | |
|---|---|---|---|
| Adtralza | Idefirix | Padcev | Tecartus |
| Amvuttra | Inrebic | Phesgo | Tepmetko |
| Atectura Breezhaler / Bemrist Breezhaler | Jemperli | Piqray | Tezspire |
| Beovu | Jyseleca | Polivy | Trixeo Aerosphere |
| Bimzelx | Kaftrio | Ponvory | Trodelvy |
| Brukinsa | Kapruvia | Recarbrio | Tukysa |
| Byfavo | Kerendia | Rekambys | Vabysmo |
| Calquence | Kesimpta | Retsevmo | Vazkepa |
| Cibinqo | Leqvio | Roclanda | Verquvo |
| Enerzair Breezhaler / Zimbus Breezhaler | Lumykras | Rozlytrek | Vocabria |
| Enhertu | Lupkynis | Rukobia | Voraxaze |
| Evrenzo | Mayzent | Rybelsus | Vumerity |
| Evrysdi | Ngenla | Ryeqo | Vydura |
| Fetcroja | Nubeqa | Saphnelo | Vyepti |
| Gavreto | Ontozry | Scemblix | Zeposia |
| Givlaari | Orgovyx | Spevigo | Zolgensma |
| Hepcludex | Orladeyo | Sunlenca | |

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

# Medicines with EMA approval 2020-2022 included in the report (2/3)

| Medicines included in the report: 25 supplied non-nationally reimbursed medicines | |
|---|---|
| Arikayce liposomal | Opdualag |
| Aspaveli | Pemazyre |
| Bylvay | Reblozyl |
| Drovelis/Lydisilka | Rybrevant |
| Ebvallo | Sarclisa |
| Enspryng | Sibnayal |
| Filsuvez | Tabrecta |
| Fintepla | Tavlesse |
| Koselugo | Tecvayli |
| Livtencity | Voxzogo |
| Lunsumio | Wegovy |
| Minjuvi | Xofluza |
| Nexviadyme | |

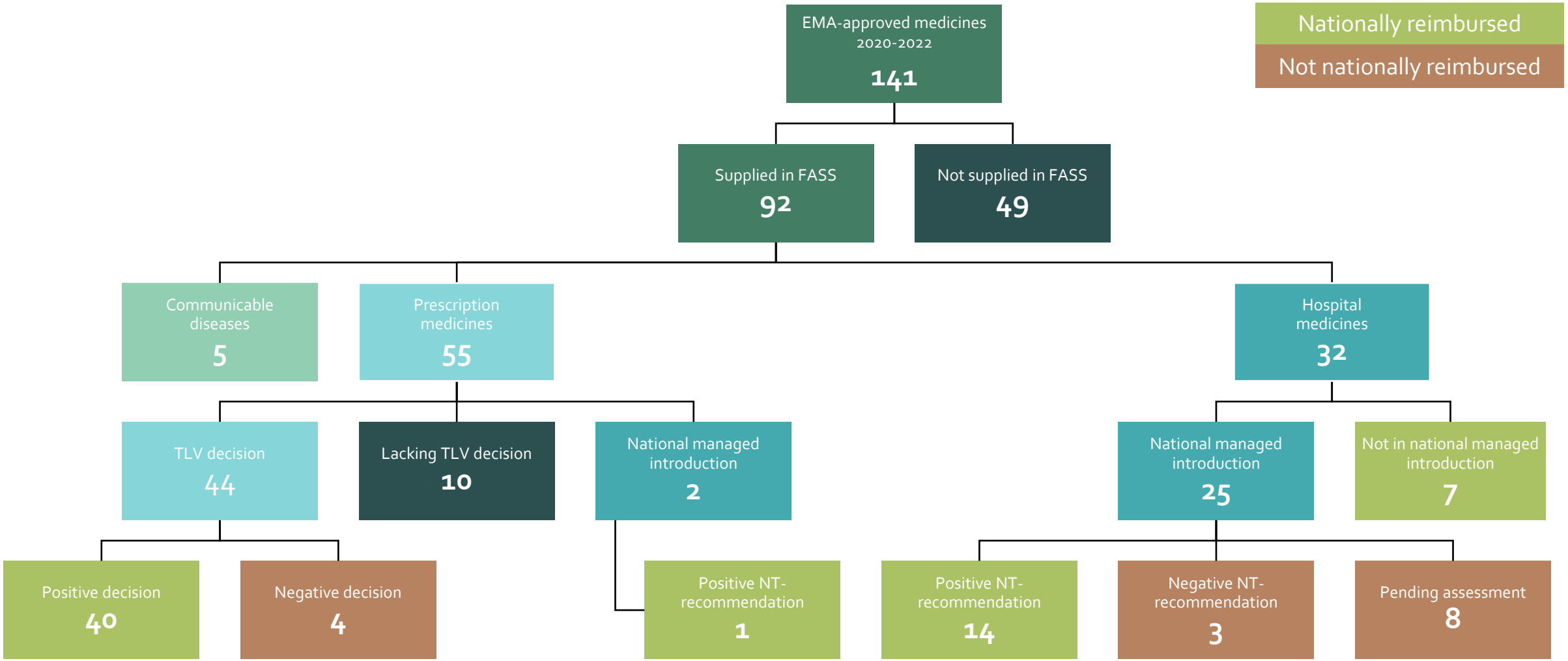
As of the cut-off date (21 December 2023)

# Medicines with EMA approval 2020-2022 included in the report (3/3)

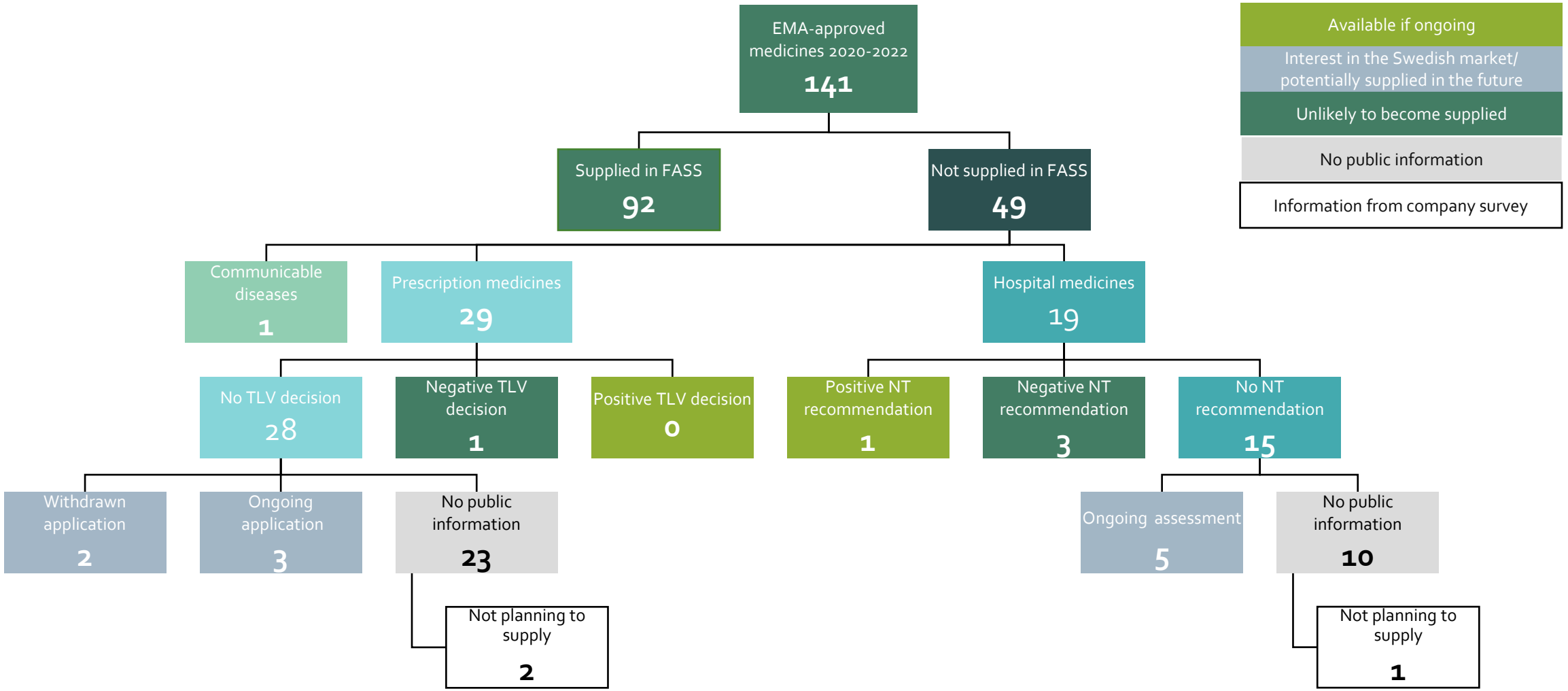
| Medicines included in the report: 49 non-supplied medicines | | |
|---|---|---|
| Abecma | Klisyri | Roctavian |
| Artesunate Amivas | Libmeldy | Skytrofa (previously Lonapegsomatropin Ascendis Pharma) |
| Ayvakyt | Livmarli | Sogroya |
| Blenrep | Mounjaro | Sunosi |
| Breyanzi | Mycapssa | Tavneos |
| Carvykti | Nexpovio | Tecovirimat SIGA |
| Copiktra | Nilemdo | Trepulmix |
| Daurismo | Nulibry | Uplizna |
| Dovprela (previously Pretomanid FGK) | Nustendi | Upstaza |
| Eladynos | Obiltoxaximab SFL | Vyvgart |
| Elzonris | Oxbryta | Xenleta |
| Enjaymo | Oxlumo | Xenpozyme |
| Evkeeza | Pluvicto | Yselty |
| Imcivree | Pyrukynd | Zokinvy |
| Isturisa | Qinlock | Zynlonta |
| Kimmtrak | Quviviq | |
| Kinpeygo | Rayvow | |

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

# Overview: Medicines supplied in Sweden



# 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.