Access to and availability of innovative medicines in Norway

Prepared for LMI

IQVIA reference 2945684

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IQVIA – Real World & Analytics Solutions, Nordics

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LMI has asked IQVIA for an update of the analysis of access to innovative medicines in Norway and to add Folketrygd products

The Situation

LMI has asked IQVIA for an update of the analyses of 2021 and 2022 regarding access to innovative medicines in Norway based on most recent data.

Key Research Objectives

LMI has asked IQVIA to update the below research questions that were part of the 2021/22 analysis, as well as an additional analysis of "folketrygd" products:

1. Examine the **availability** of new innovative medicines with a central EU marketing authorisation date between 2017 – 2021 *(previous analysis: 2015-2020)*

2. Examine the **level of usage** of new innovative products launched (i.e. with observed sales) in Norway between 2018 – 2022**,** in comparison to International Reference Price (IRP) countries. *(previous analysis: 2017-2021).*
   This analysis now includes both hospital and "folketrygd" products.

3. Identify the **time** it has taken for products that have HTA proposals during 2018 – 2022, to go through the full evaluation process: from central EU approval to their latest decision. This includes a short analysis of hospital products that are pending documentation (previous analysis: 2013-2021).
   This analysis now includes both hospital and "folketrygd" products.

Results are presented in a PowerPoint report to LMI, in English, in the same format and structure as the reports provided in 2021/22 for these research questions.

Scope definitions on next page

Research question 1 & 2: Availability and Usage

Products included in the analysis and hospital / "folketrygd" classification

- ✓ Research question 1 and 2 are related to **new products**, not separate indications per product
- ✓ Availability is defined by identifiable sales in Norway and IRP countries using IQVIA MIDAS® database, and validated by IQVIA FlexView®
- ✓ International reference price countries (IRP) = Sweden, Finland, Denmark, Germany, UK, Netherlands, Austria, Belgium, and Ireland are used as these are the countries that Norway has chosen as reference countries for pricing.
- ✓ Sales measure used are Standard Units (SU): The lowest dose that is available in a package either being a tablet, capsule, syringe etc. Reason for not using Defined Daily Dose (DDD) is because most hospital products do not have a defined DDD
- ✓ The analysis does not take in consideration prevalence of diseases, restrictions of usage or reimbursement in the countries in scope

Q2: Definition of a **hospital** product, where either:
- ✓ Product is mainly distributed through the hospital channel
- ✓ A metodevarsel has been filed (or metodevurdering is found on *nyemetoder.no*)
- ✓ Listed on Legemiddellisten updated H-resept list per 1 February 2023

Q2: Definition of a **"folketrygd"** product, where either:
- ✓ A metodevurdering submission is classified as "folketrygd" funded by SLV, in their overview of evaluations (Link)
- ✓ Listed with blåresept status on SLVs Legemiddelsøk per May 2023

Research question 3: Evaluation of timelines

Time from EU Central approval to latest decision in Decision Forum

1) Categorization of evaluation status

Indications with a **HTA proposal / metodevarsel** have been evaluated based on public sources and were categorized by status:

- "proposal submitted";
- "under evaluation" and
- "decision given"

2) Evaluation of process timelines

Timelines for **indications** with a **completed evaluation / metodevurdering** - from EMA approval to latest decision in Decision Forum – were evaluated based on three periods during the process:

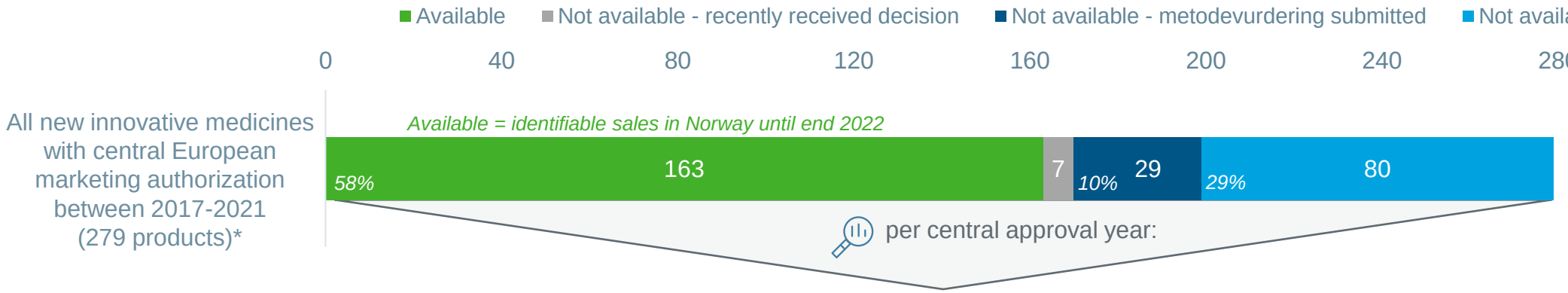
1. Time from EMA approval to documentation submission,
2. Time from first documentation submission to SLV / NoMA* up to completed evaluation,
3. Time from NoMa completed evaluation to latest decision in Decision Forum

**SLV = Statens Legemiddelverk = NoMa = Norwegian Medicines Agency*

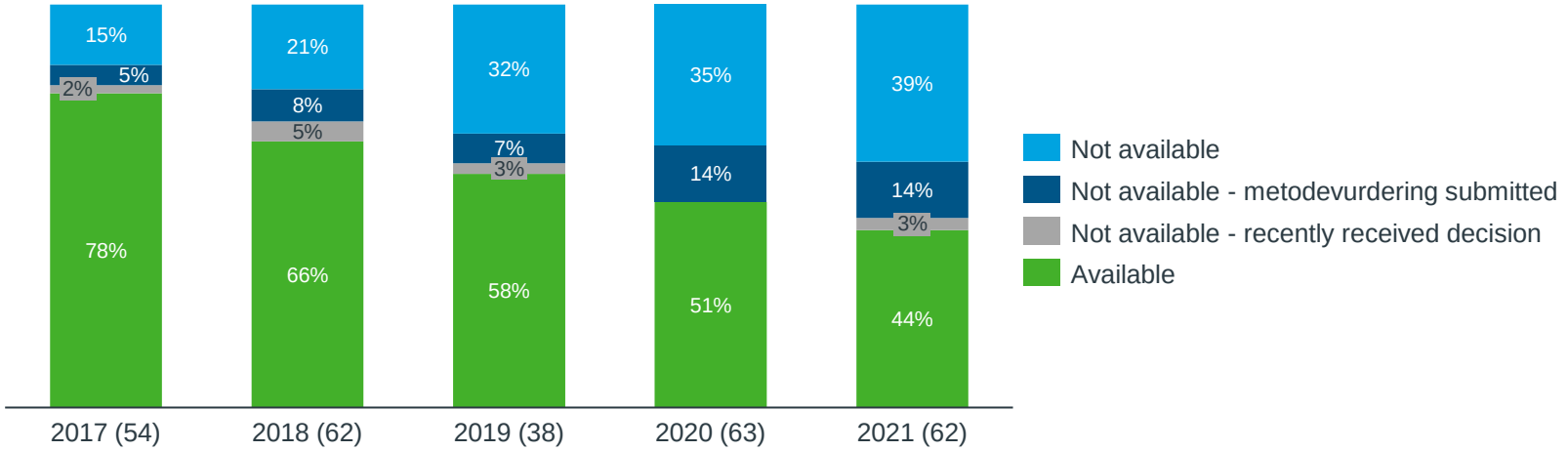
Hospital products

1. **Availability of new innovative medicines**
2. **Usage of new innovative medicines**
3. Time from EU Central approval to latest decision in Decision Forum

~40% (116) of all 279 innovative medicines with central approval during 2017 - 2021 are NOT available in Norway Dec ‘22



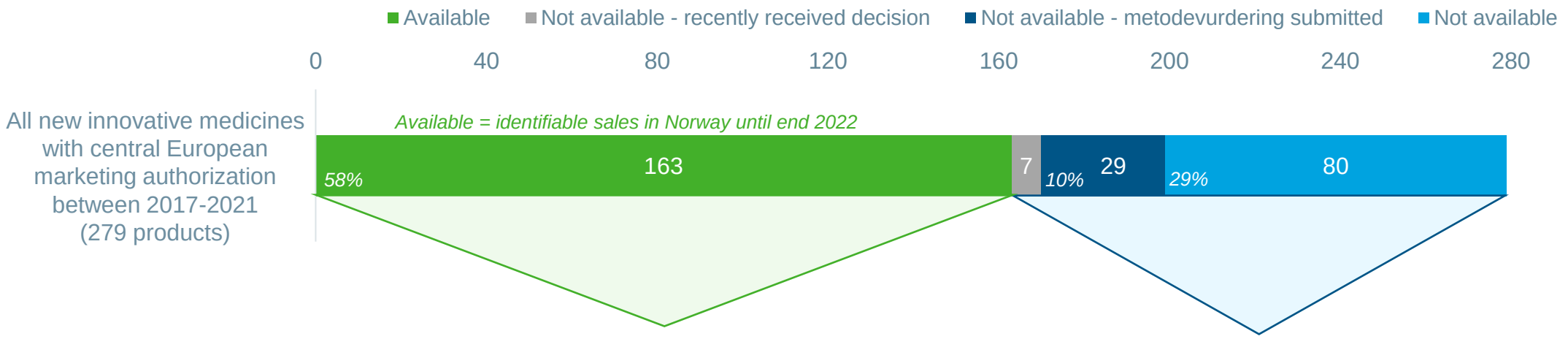
Among more recently (2020-’21) centrally approved innovative medicines, ~49-56% of innovative medicines are NOT available yet in Norway



*Includes both hospital and folketrygd products

Sources: Availability = identifiable sales in IQVIA MIDAS®, IQVIA Flexview®
“Metodevurdering submitted” data collected from nyemetoder.no Date: 26.05.2023

50% of unavailable products are Oncology and Orphan drugs



35%
Orphan drugs

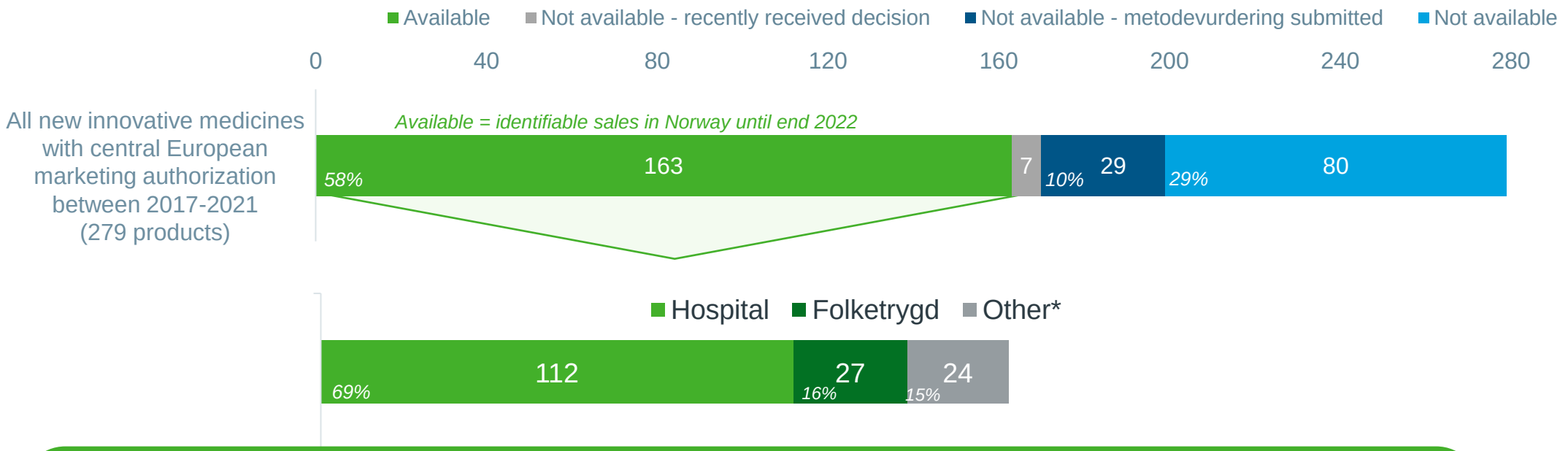
- Orphan drugs make up **35% of the 116 products not available** (no sales) in Norway
- 13% of the 163 medicines available in Norway (2nd group after oncology)
- **22% of all 279 products with EMA** (1st largest group of all EMA)

16%
Oncology

- Oncology drugs make up the 2nd biggest group of innovative medicines and drugs not available yet in Norway
- **14% of all 279 products with EMA** (2nd largest group of all EMA)

Sources: Availability = identifiable sales in IQVIA MIDAS®, IQVIA Flexview®
"Metodevurdering submitted" data collected from nyemetoder.no Date: 26.05.2023

Level of usage is further analyzed and compared to IRP countries – starting with 112 available hospital products



Definition of hospital product in this analysis:
Observed sales in the hospital channel, and/or reimbursed by H-resept, and/or Nye metoder HTA proposal

Definition of "folketrygd" products in this analysis:
Listed with blåresept reimbursement by SLV, or classified with metodevurdering through "folketrygd"

**17 products did not fit in the two categories as they are white prescription, vaccine, or generics. An additional 7 products could not be linked correctly between the Nordic and European sales data and had to be excluded. See appendix.*

Sources: Availability = identifiable sales in IQVIA MIDAS®, IQVIA Flexview®
"Metodevurdering submitted" data collected from nyemetoder.no Date: 26.05.2023

~40% of innovative hospital medicines in Norway have low per capita usage in comparison to IRP countries

All new innovative hospital substances available in Norway between 2017-2021 (112 products)

112

Norway's rank per available hospital product (112), compared to the 9 IRP countries (i.e. rank (1-10))
Rank reflecting average use per capita 3 years after first observed sales in any of the IRP countries

Norway's rank per product – grouped into low – medium – high

Low Usage | Medium Usage | High Usage

45 | 39 | 28

Low usage per capita *40%*

Medium usage per capita *35%*

High usage per capita *25%*

Norway's rank per product (112 products)

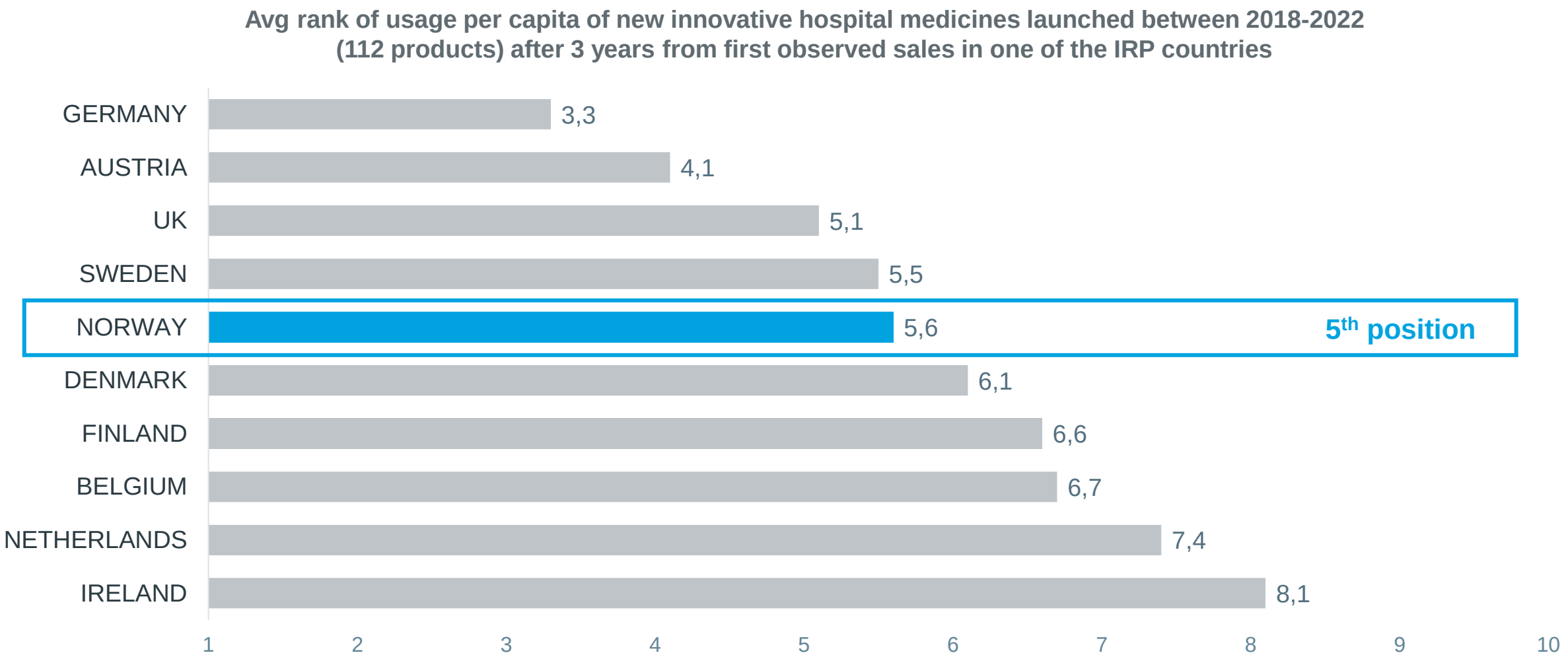
15 | 3 | 20 | 7 | 11 | 15 | 13 | 7 | 10 | 11

Rank: 10 9 8 7 6 5 4 3 2 1

IRP = International Reference Price – Reference countries in Norway = Sweden, Finland, Denmark, Germany, UK, Netherlands, Austria, Belgium, and Ireland

Source: IQVIA MIDAS®, IQVIA Flexview ®

Norway ranks 5th in comparison to the IRP countries measuring usage 3 years after first sales in any of the countries



Note: The analysis does not take in consideration prevalence of diseases, restrictions of usage or reimbursement in the countries in scope

Source: IQVIA MIDAS®, IQVIA Flexview ®

Little correlation was found between usage and indication, administration form, market size or being part of a tender

Norway's usage per product
3 years after first observed sale
in one of the IRP countries
(112 products)

The following areas show **medium to high usage in Norway** compared to somewhat lower in IRP countries:
Oncology (27), Blood Coagulation (10), Respiratory Diseases (6), Other Infection (4), Heart Conditions (2)

There is **little difference in the usage level in Norway** compared to IRP countries:

- Per administration form: Tablet (40), Injection (17), Infusion (18) and Capsule (14)
- Between products with smaller vs larger total sales volumes across IRP countries
- Between products that were part of a tender or not

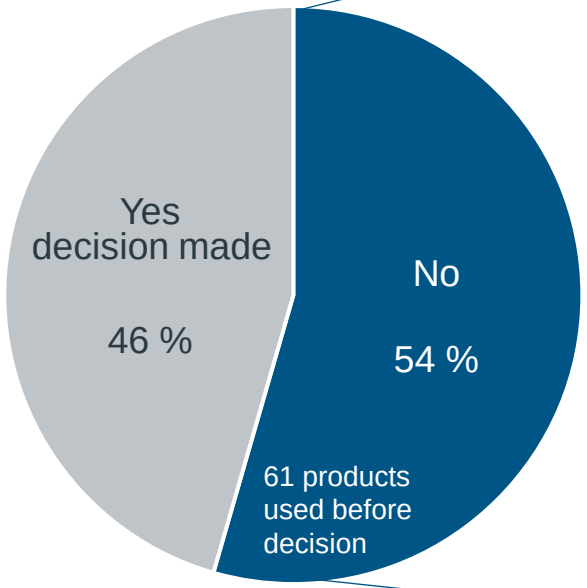
IRP = International Reference Price – Reference countries in Norway = Sweden, Finland, Denmark, Germany, UK, Netherlands, Austria, Belgium, and Ireland

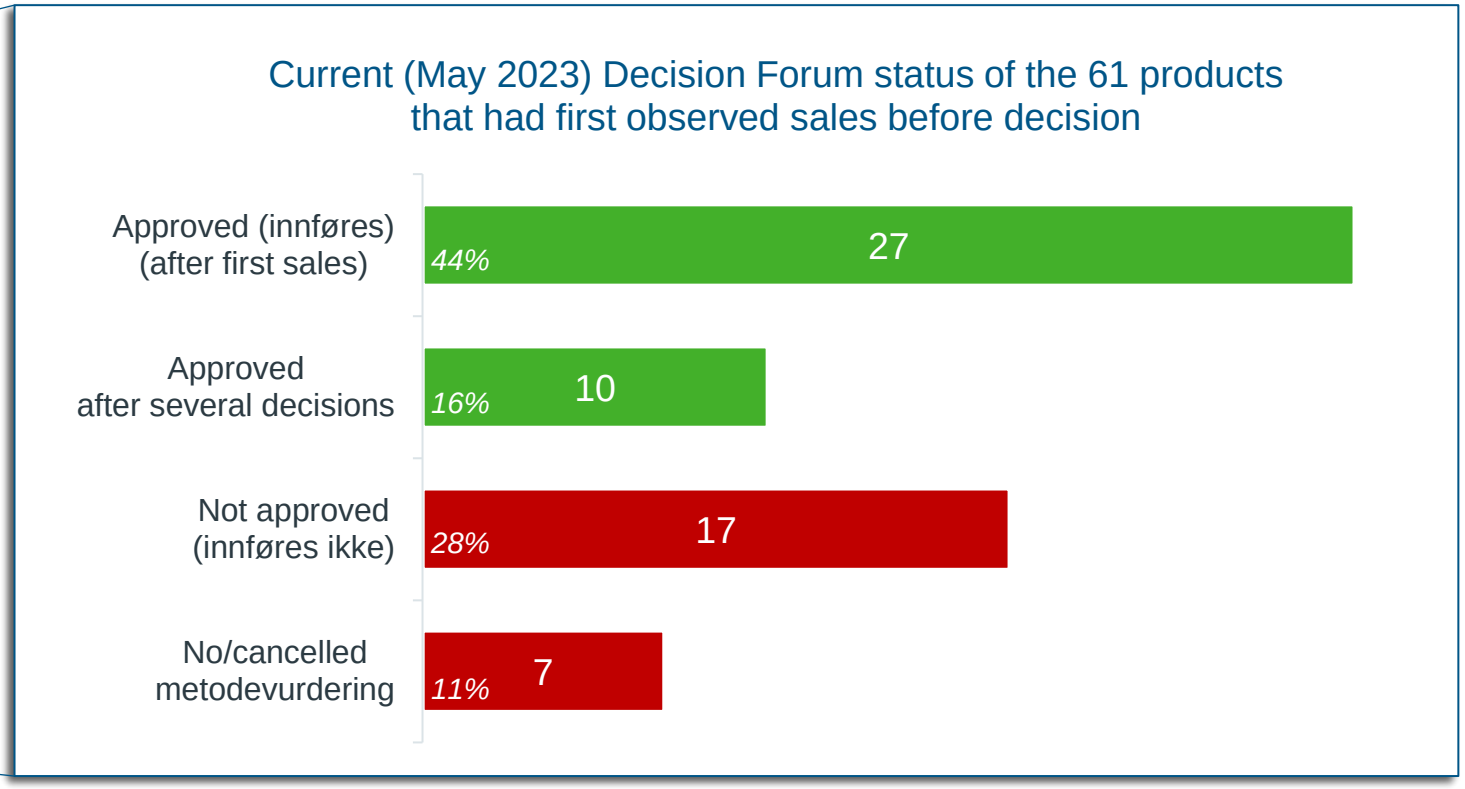
Source: IQVIA MIDAS®, IQVIA Flexview ®

54% of the hospital products hadn't received a reimbursement decision in Decision Forum at the time of first sale in Norway

60% of products used before approval were eventually approved, 40%

Decision-status by Decision Forum at the time of first observed sales in Norway (112 products)





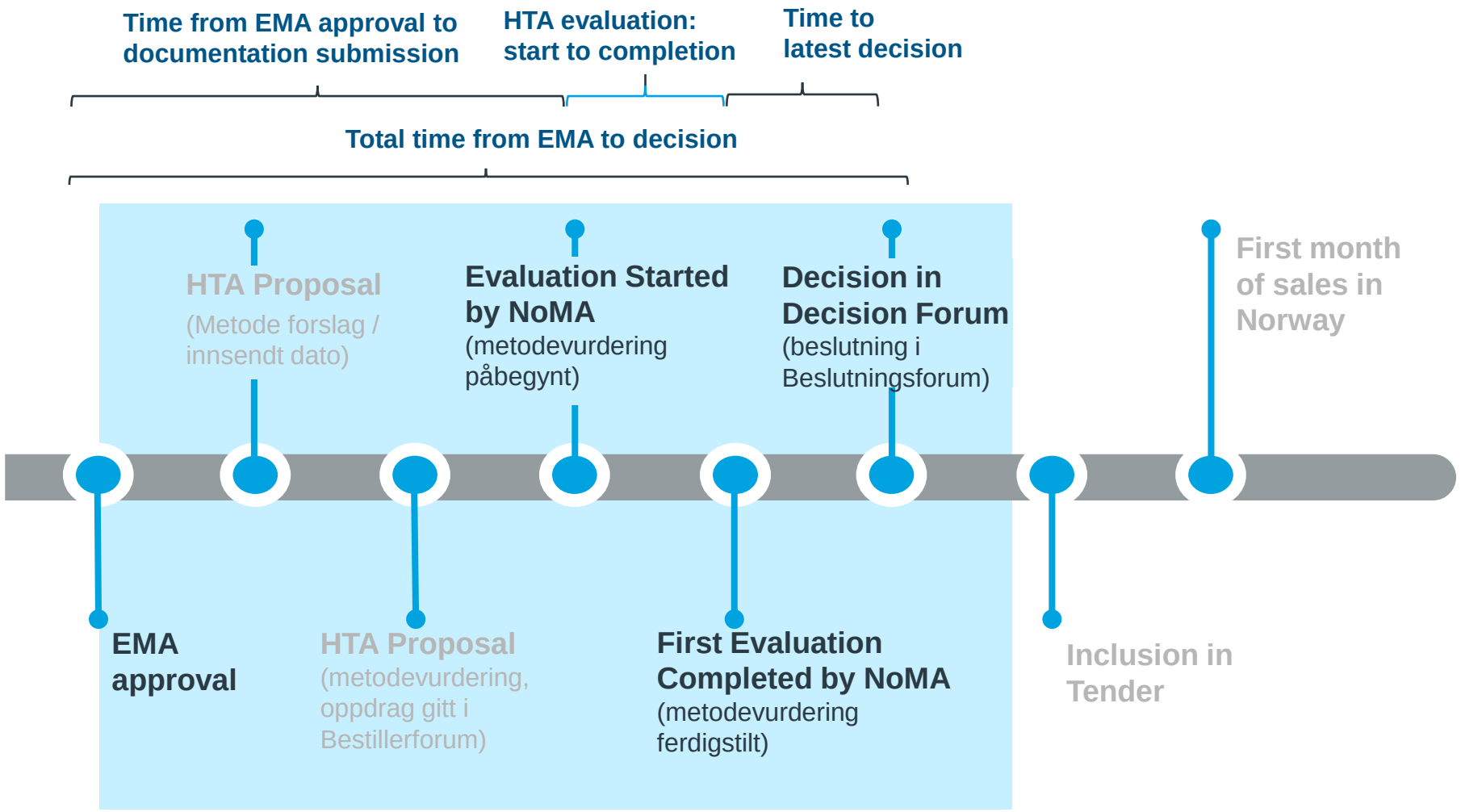
No further analysis of group or individual exceptions have been done.
Decision Forum is the final instance of the HTA evaluation process. See Appendix for detailed overview of the HTA evaluation process in Norway

Source: IQVIA MIDAS®, IQVIA Flexview® . Verdict from DF was collected from nyemetoder.no: Date for data collection: 26.05.2023

Hospital products

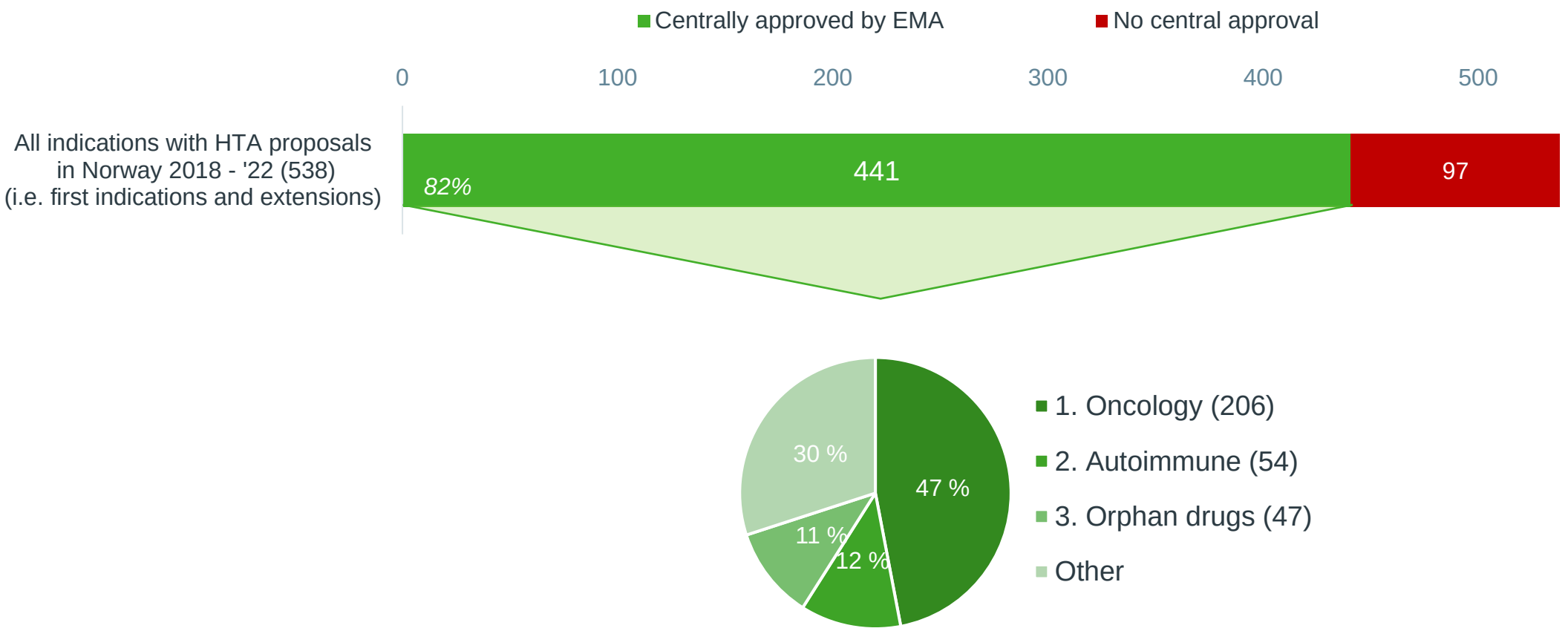
1. Availability of new innovative medicines
2. Usage of new innovative medicines
3. **Time from EU Central approval to latest decision in Decision Forum – per indication**

Research question 3 evaluates indication approvals not product approvals



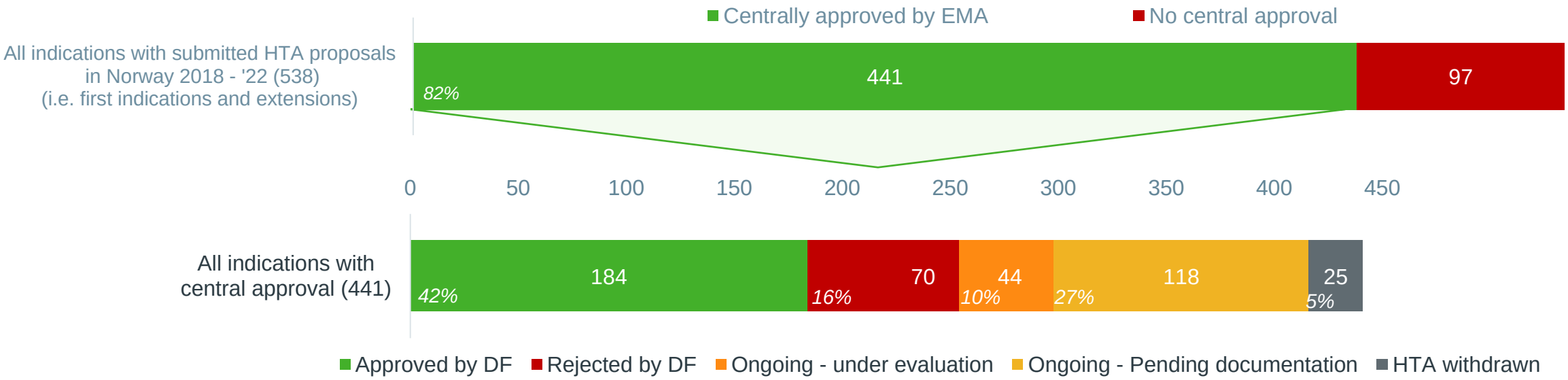
Out of all indications with a HTA proposal in Norway, 82% were centrally approved by EMA

Scope: All indications with HTA proposals in Norway 2018-2022



Source: ema.europa.eu, nyemetoder.no. Data collection: 26.05.2023

Out of all indications with a HTA proposal in Norway and central approval, 42% have been approved by DF

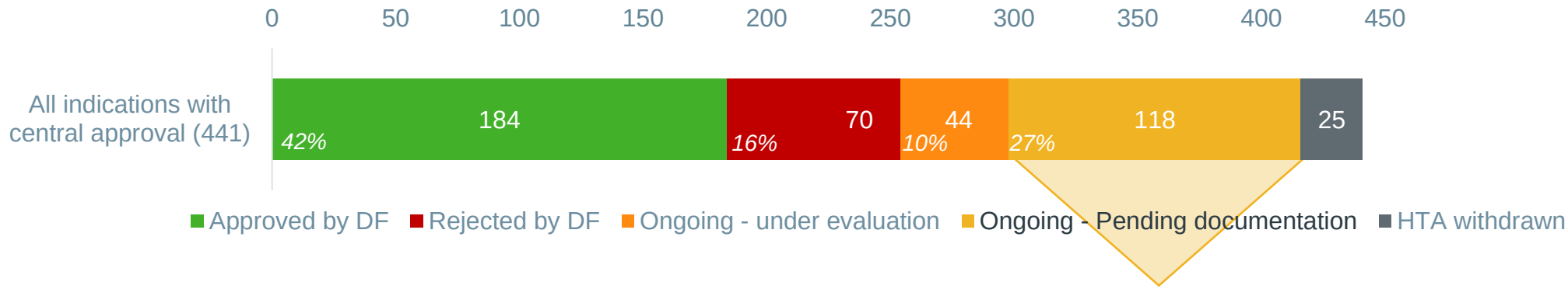


Out of all indications (441) with central approval & HTA proposal in Norway,
~58% have received a decision, while
~37% are under evaluation / pending documentation, and
~5% have withdrawn their HTA proposal

Source: ema.europa.eu, nyemetoder.no. Data collection: 26.05.2023. HTA proposal is defined by the suggestion of HTA evaluation.
More detailed information about the HTA evaluation timeline can be found in the Appendix

Latest data collection date: 26.05.2023

Out of all indications with a HTA proposal in Norway and central approval, 27% are pending documentation



Out of all indications with pending documentation (118):

The majority have an indication in **Oncology** (56; 48%), followed by **Blood disease** (10; 9%)

Within **Oncology**, there is an even split between **indication extensions** (29; 52%) and **new substances** (27; 48%)

~60% of the HTA proposals for which documentation is pending, **are at least 2 years past central approval** date *(see next page)*

26% received central approval less than one year ago

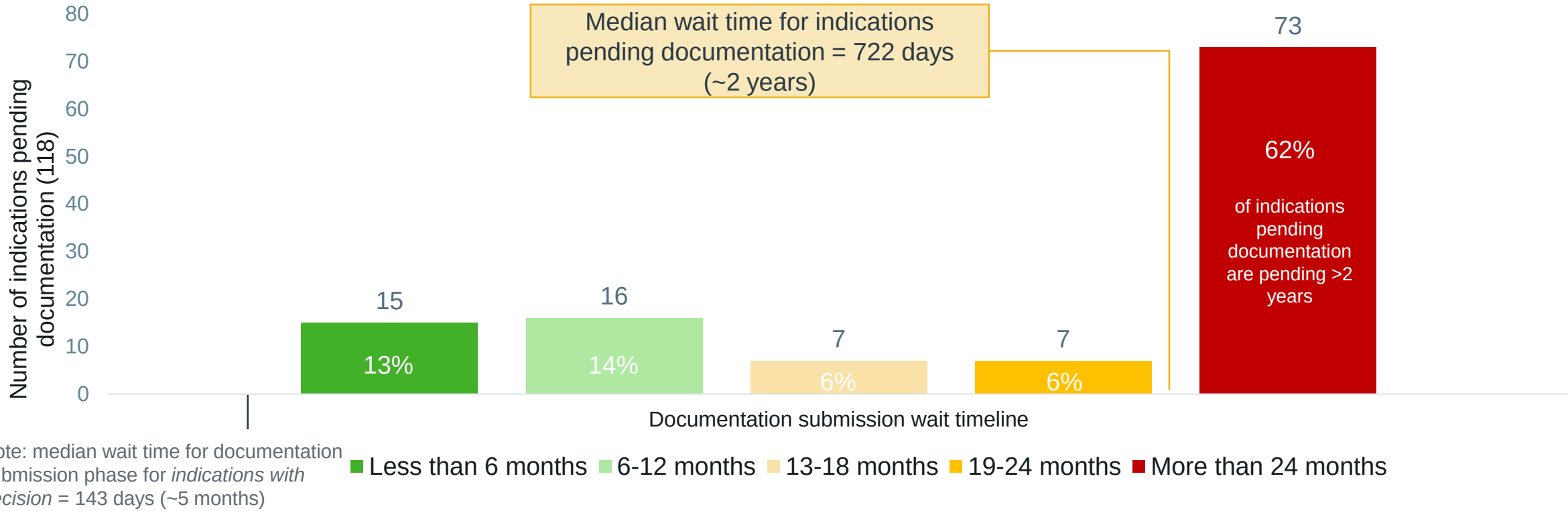
The **companies** with the most approved indications also have a high proportion of cancelled / withdrawn or indications that are still waiting for documentation

Source: ema.europa.eu, nyemetoder.no. Data collection: 26.05.2023

Latest data collection date: 26.05.2023

~60% of HTA proposals for which documentation is pending, are 2 years past central approval

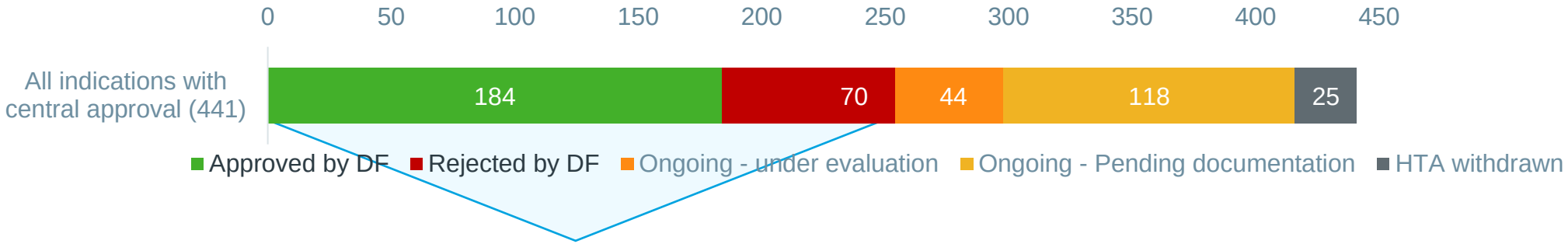
Timelines for "Pending documentation submission"



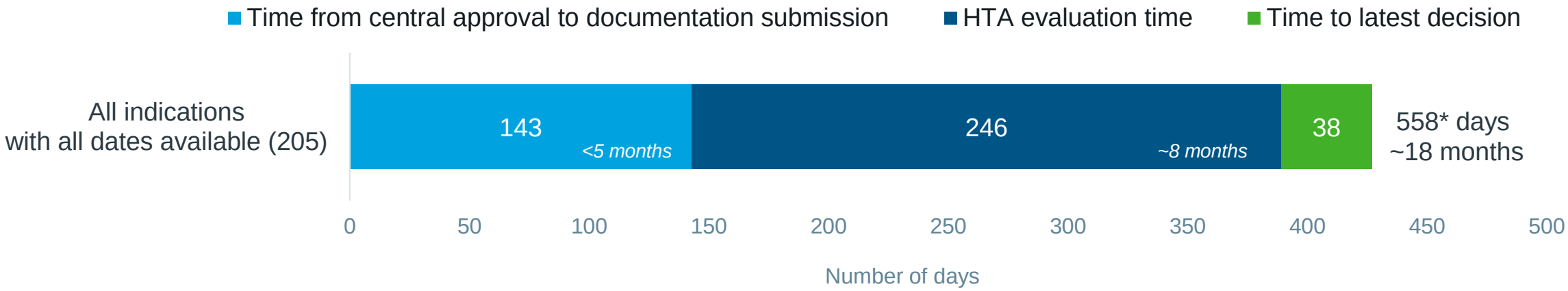
Note: median wait time for documentation submission phase for *indications with decision* = 143 days (~5 months)

Source: ema.europa.eu, nyemetoder.no. Data collection: 26.05.2023. HTA proposal is defined by the suggestion of HTA evaluation.
More detailed information about the HTA evaluation timeline can be found in the Appendix

Out of all indications (205) with a completed HTA evaluation, the median time from central approval to latest decision is 558 days



Median time per HTA phase, 2018-2022

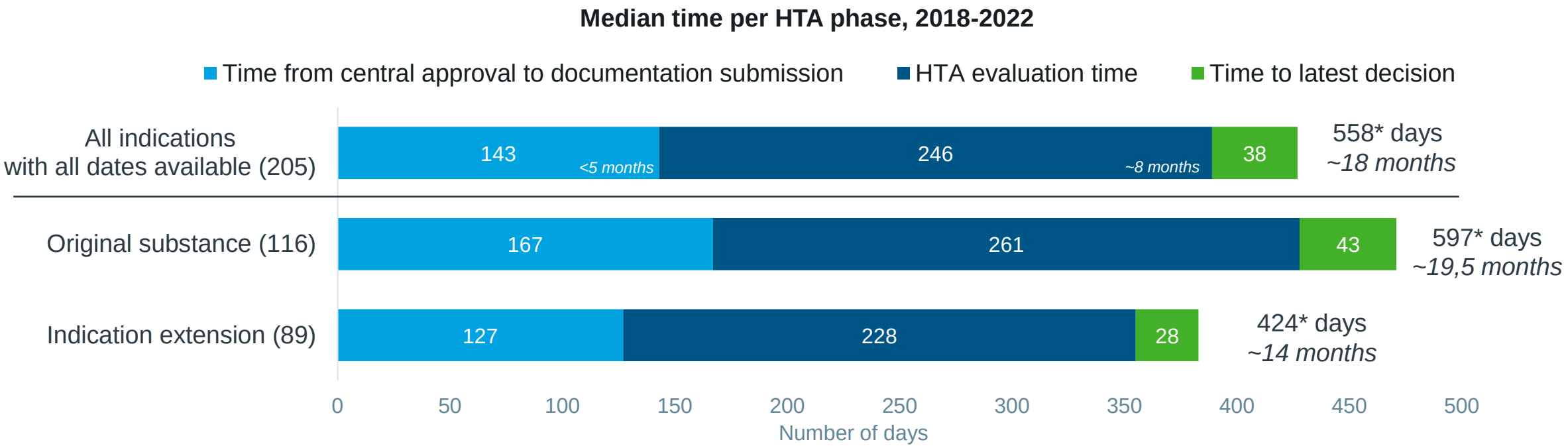


- (n=205): 49 indications are missing one or more dates related to the three phases in scope, which results in 205 indications with all dates available
- *Note: “Total median” is the median of total time from central approval to decision, not the total of the three medians per phase
- The median is less affected by the presence of outliers in the data than the average. Time from central approval to documentation submission and Time to latest decision have the biggest difference between the average and median, which indicates that they contain more outliers than the HTA evaluation time.

Source: ema.europa.eu, nyemetoder.no. Data collection: 26.05.2023

HTA evaluation time is the longest phase – and taking a month longer for new substances than for indication extensions

HTA evaluation is ~2 months longer than the deadline of taking maximum 180 days



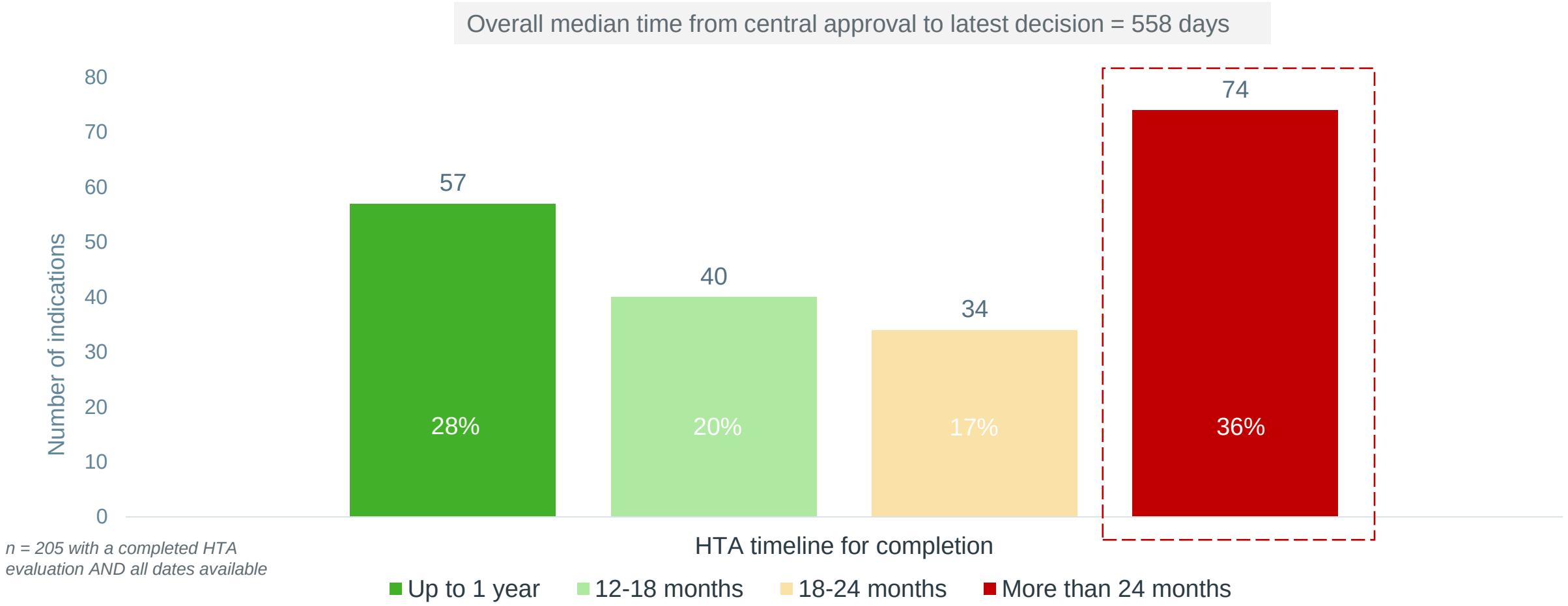
- The median HTA evaluation time & time to submit documentation have **slightly increased in this year's** analysis compared to last.
  - The median timelines for all three phases are slightly longer **for original substances compared to indication extensions**
    - The indications that are **not approved have spent longer time** in HTA evaluation processing, and with largest outliers

Source: Timelines are defined in the detailed methodology slide in the appendix, ema.europa.eu, nyemetoder.no. Data collection: 26.05.2023.

n = 205 with a completed HTA evaluation AND all dates available

Out of the 205 indications with a completed HTA evaluation, 74 indications took more than 2 years until a final decision

Half of the indications eventually not approved took longer than 2 years

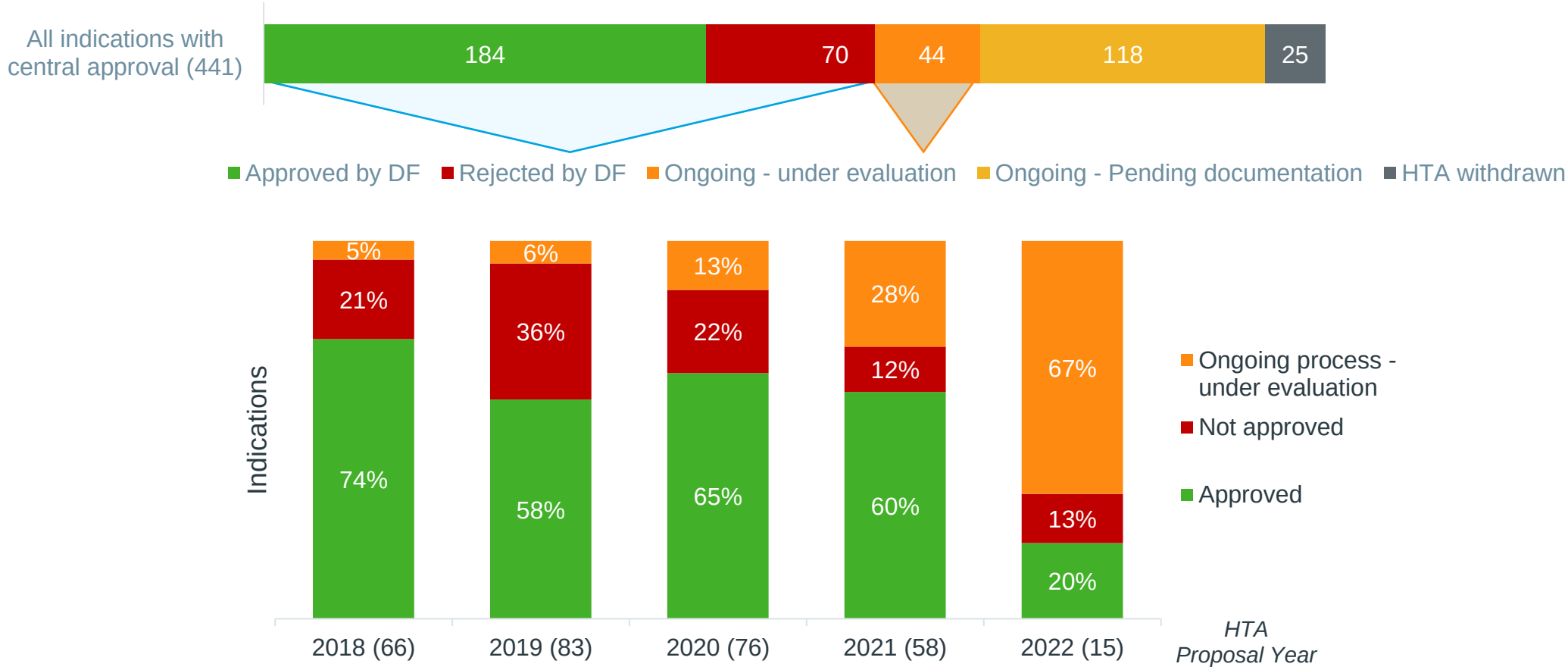


n = 205 with a completed HTA evaluation AND all dates available

Source: ema.europa.eu, nyemetoder.no. Data collection: 26.05.2023

67% of HTA proposals in 2022 are ongoing and lacking a final decision in May 2023

The distribution of status by year of HTA proposal



n = 298: all 254 indications with a decision in DF + 44 ongoing evaluation and/or pending price

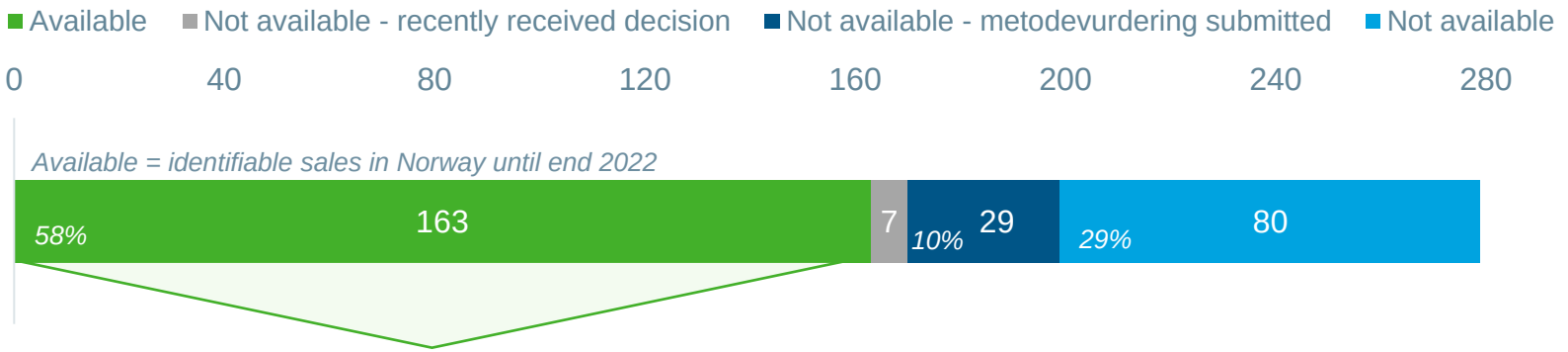
Source: ema.europa.eu, nyemetoder.no. Data collection: 26.05.2023

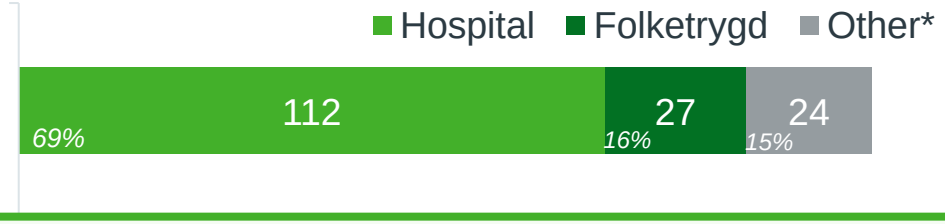
Folketrygd

1. **Availability of new innovative medicines**
2. **Usage of new innovative medicines**
3. Time from EU Central approval to latest decision

Further in-depth analysis focuses on the level of availability of 27 "folketrygd" products

All new innovative medicines with central European marketing authorization between 2017-2021 (279 products)





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Definition of "folketrygd" products in this analysis:
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Sources: Availability = identifiable sales in IQVIA MIDAS®, IQVIA Flexview®
"Metodevurdering submitted" data collected from nyemetoder.no Date: 26.05.2023

Research question 1 & 2: Definitions

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Definition of a **"folketrygd"** product, where either:
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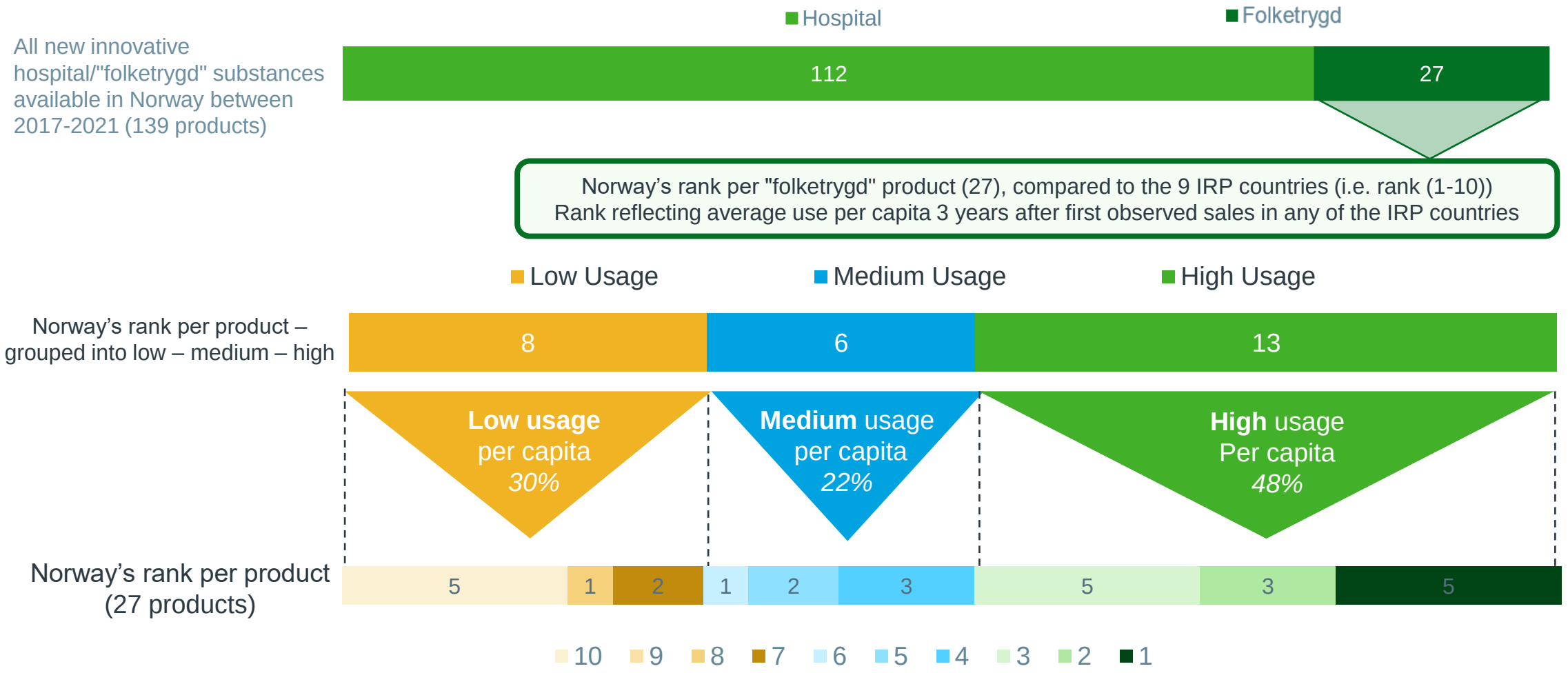
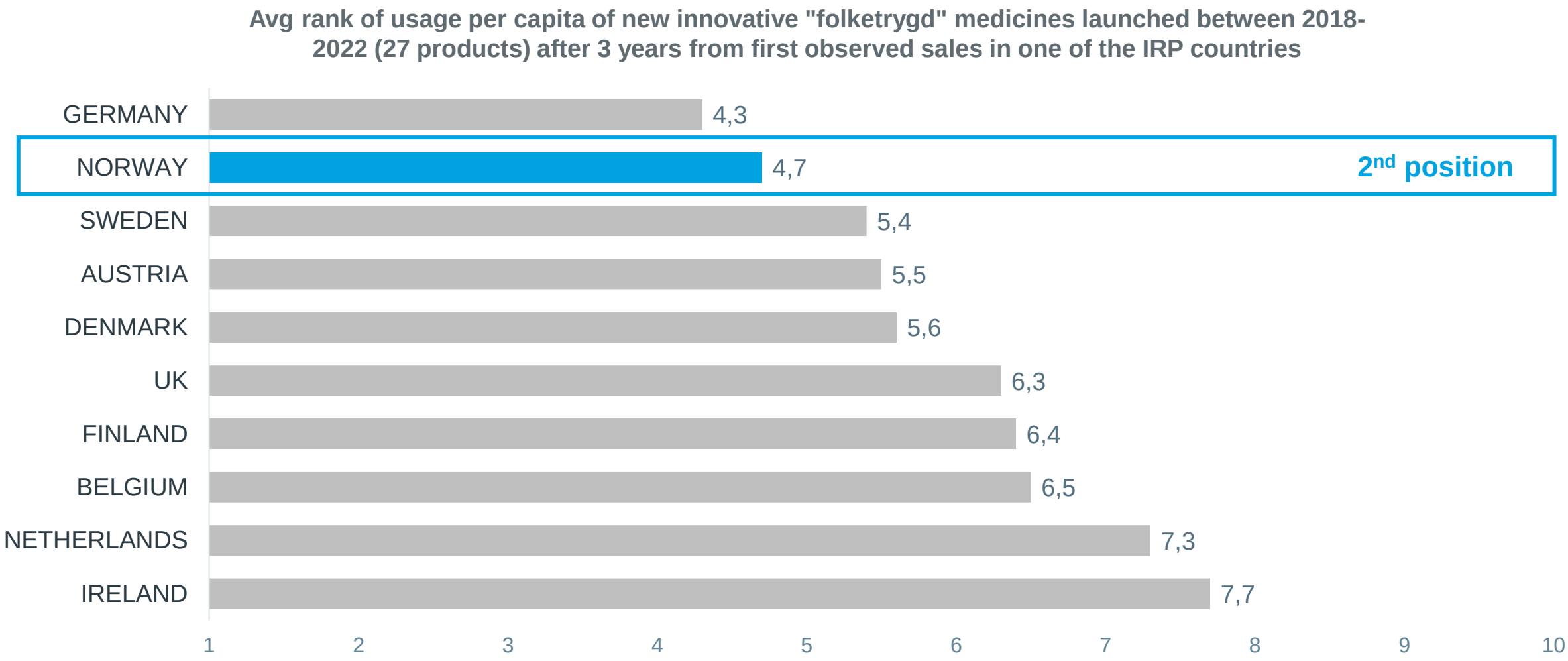
30% of innovative "folketrygd" medicines in Norway have low per capita usage in comparison to IRP countries



IRP = International Reference Price – Reference countries in Norway = Sweden, Finland, Denmark, Germany, UK, Netherlands, Austria, Belgium, and Ireland

Source: IQVIA MIDAS®, IQVIA Flexview ®

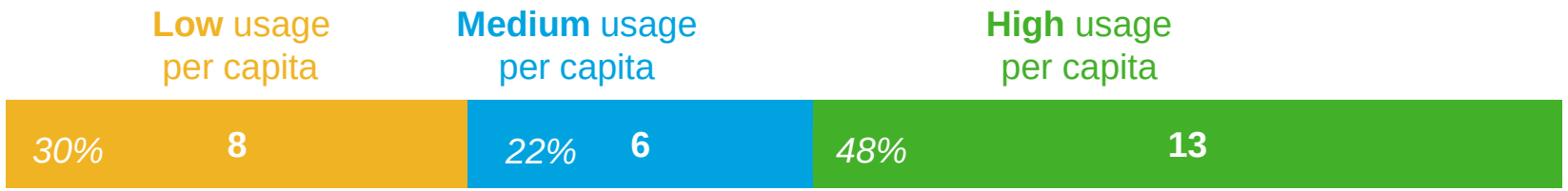
Norway ranks 2nd position after Germany in comparison to the IRP countries after 3 years of usage of innovative medicine



Note: The analysis does not take in consideration prevalence of diseases, restrictions of usage or reimbursement in the countries in scope
Source: IQVIA MIDAS®, IQVIA Flexview ®

Little correlation was found between usage and indication or administration form

Norway's rank per "folketrygd" product 3 years after first observed sales in one of the IRP countries (27 products)



The following areas show **medium to high usage in Norway**:
Diabetes (6), Neurological disorders (6), Respiratory Diseases (5), Women Specific Diseases (2)

There is **little difference in the usage level in Norway** compared to IRP countries:

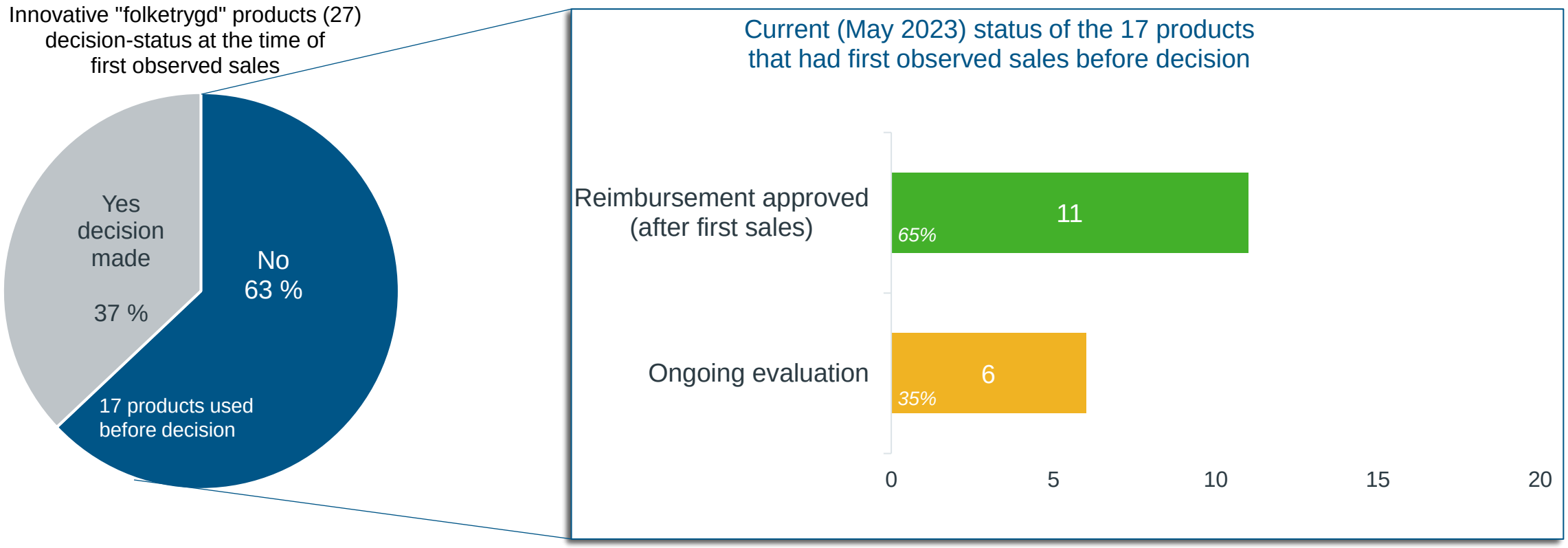
- Per administration form: Tablet (9), Injection (6), Inhalation (6)

IRP = International Reference Price – Reference countries in Norway = Sweden, Finland, Denmark, Germany, UK, Netherlands, Austria, Belgium, and Ireland

Source: IQVIA MIDAS®, IQVIA Flexview®

63% of the "folketrygd" products hadn't received a reimbursement decision at the time of first sales

Comparison of first observed sales in Norway versus "folketrygd" reimbursement decision

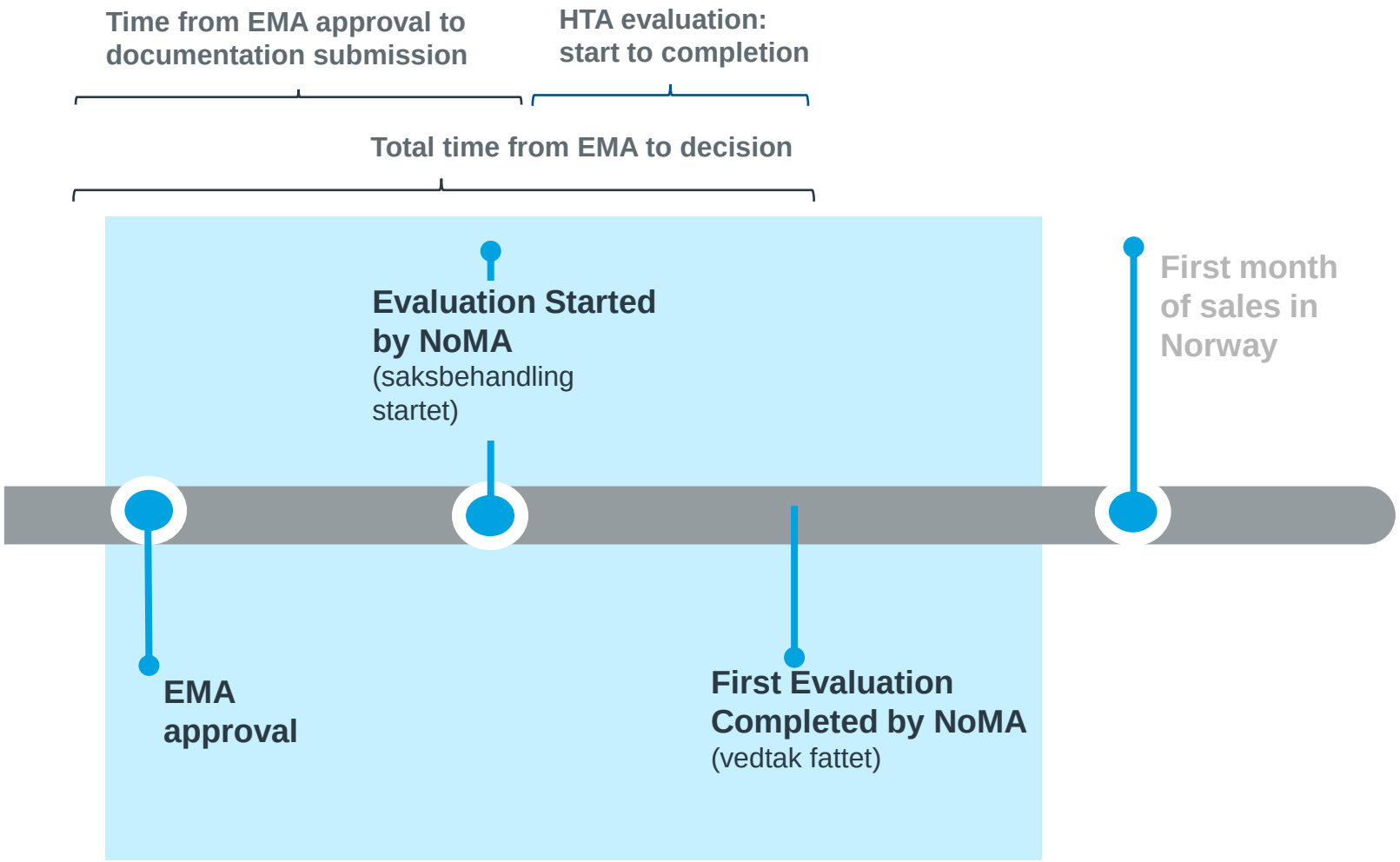


Source: IQVIA MIDAS®, IQVIA Flexview® .

Folketrygd

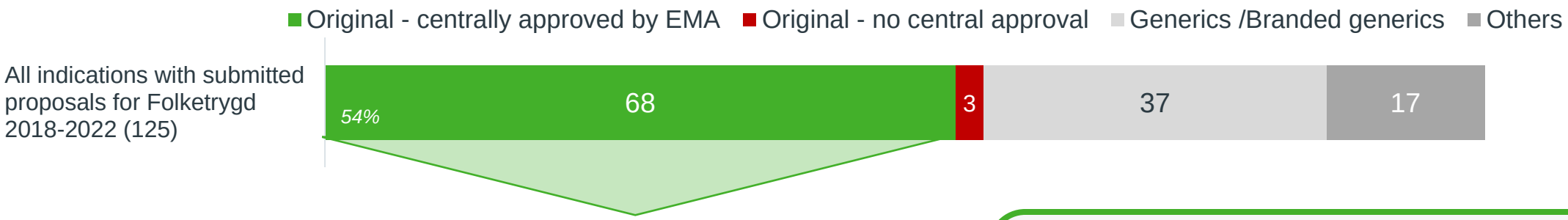
1. Availability of new innovative medicines
2. Usage of new innovative medicines
3. **Time from EU Central approval to latest decision – per indication**

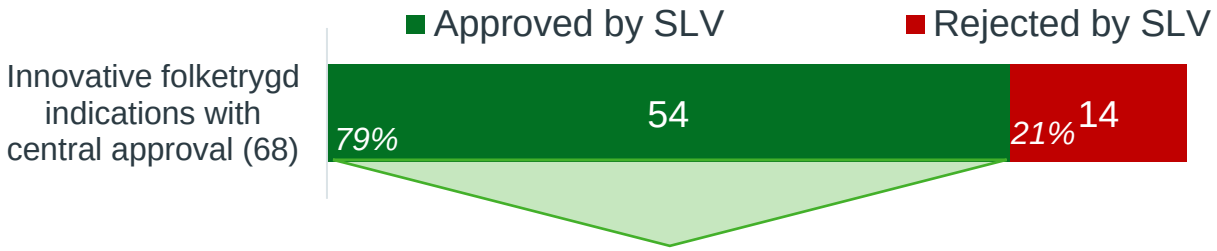
Research question 3 evaluates indication approvals not product approvals



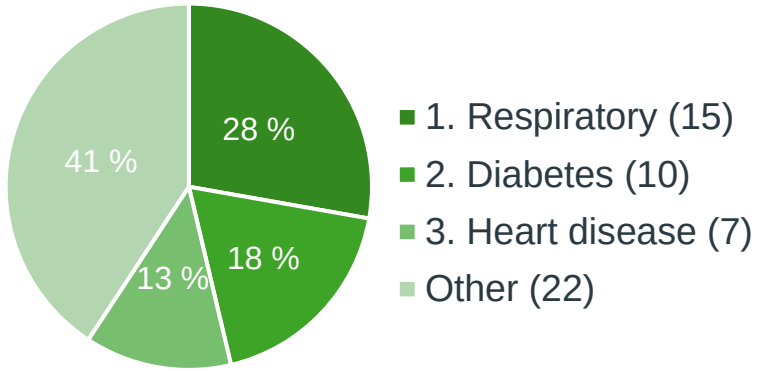
Of the innovative "folketrygd" evaluations with central approval, 79% were approved by SLV to be reimbursed

Scope: all innovative HTA proposals for "folketrygd", 2018-2022





Out of all innovative "folketrygd" evaluations (68) with central approval, 79% have received reimbursement, while 21% have received a negative decision for reimbursement

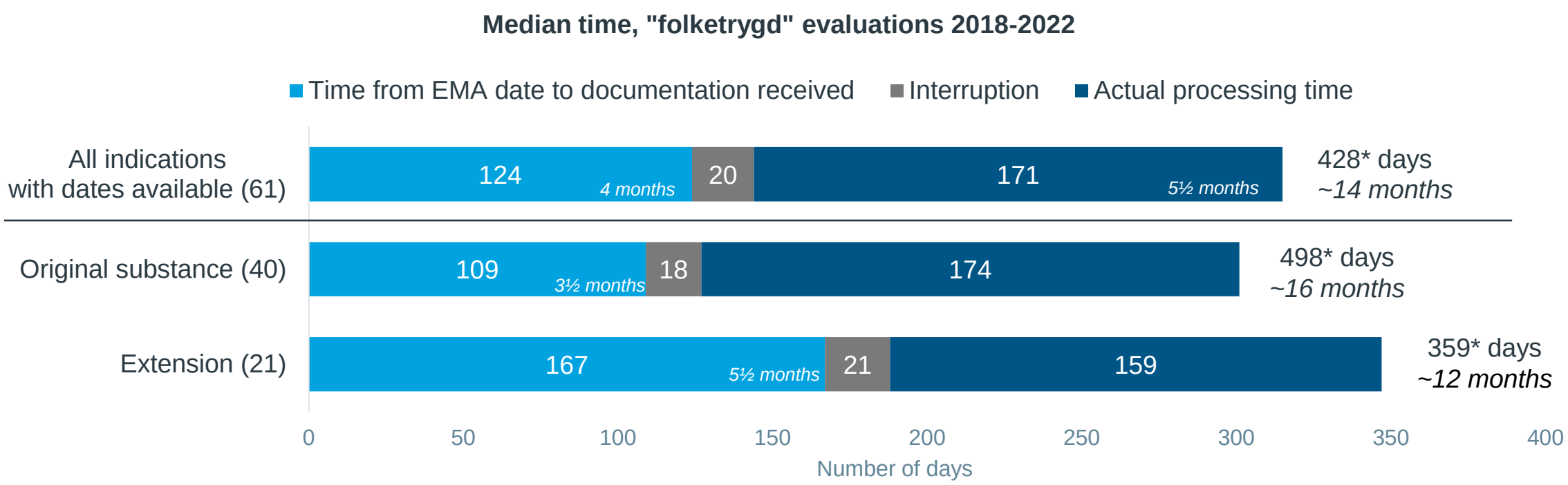


Source: SLV, Metodevurderinger for legemidler – status og rapporter (2023) , IQVIA MIDAS®, IQVIA Flexview®

Latest data collection date: 26.05.2023

Out of all indications (61) with a completed evaluation, the median time from central approval to latest decision is 428 days

Documentation submission takes longer for extended indications compared to the initial request



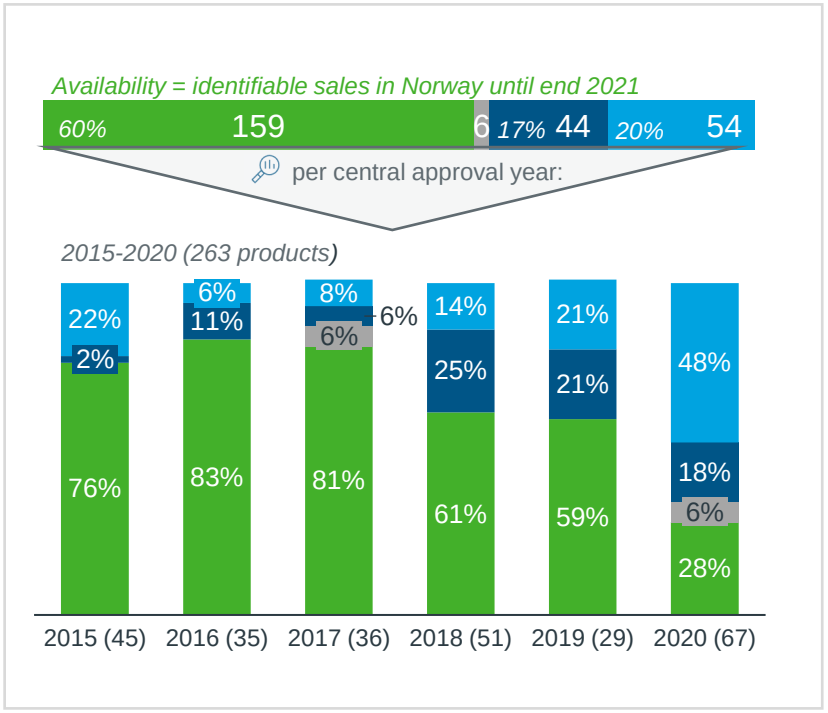
- (n=61): 7 indications are missing one or more dates related to the phases in scope, which results in 61 indications with all dates available
- *Note: “Total median” is the median of total time from EMA date to final decision, not the total of the medians per phase
- Interruption is defined as the clock-stop when SLV puts the evaluation on hold after requesting additional documentation. Actual processing time is not including the time spent during clock-stop. Total time does include clock-stop as it starts with EMA to final decision.

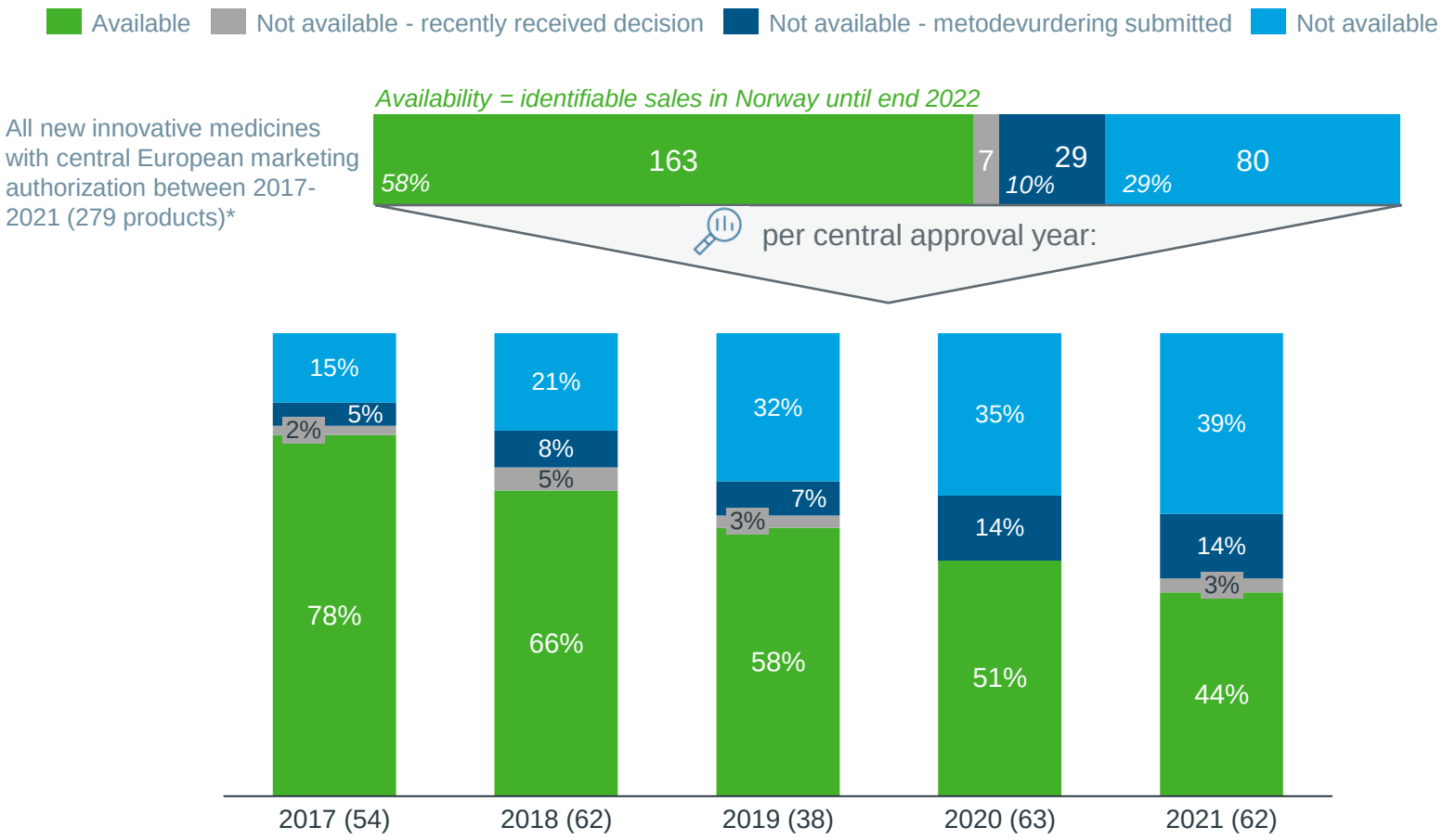
Source: SLV, Metodevurderinger for legemidler – status og rapporter (2023)

Appendix: Comparison of hospital products and indications 2022 vs 2023 analysis

The share of available products in Norway in 2022 is 58%, similar to the 60% of last year's analysis of 2021

The 2-3 latest years usually show a lower share of available medicines



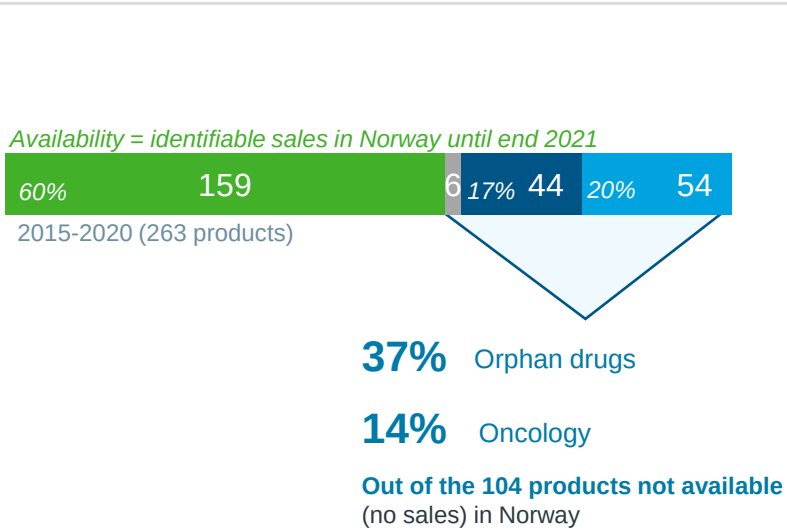


*Includes both hospital and folketrygd products

Note: Time periods for the two analyses are slightly different. 2022 analysis covers 6 years, while 2023 analysis covers 5 years.

Largest share of unavailable products continue to be Orphan and Oncology drugs

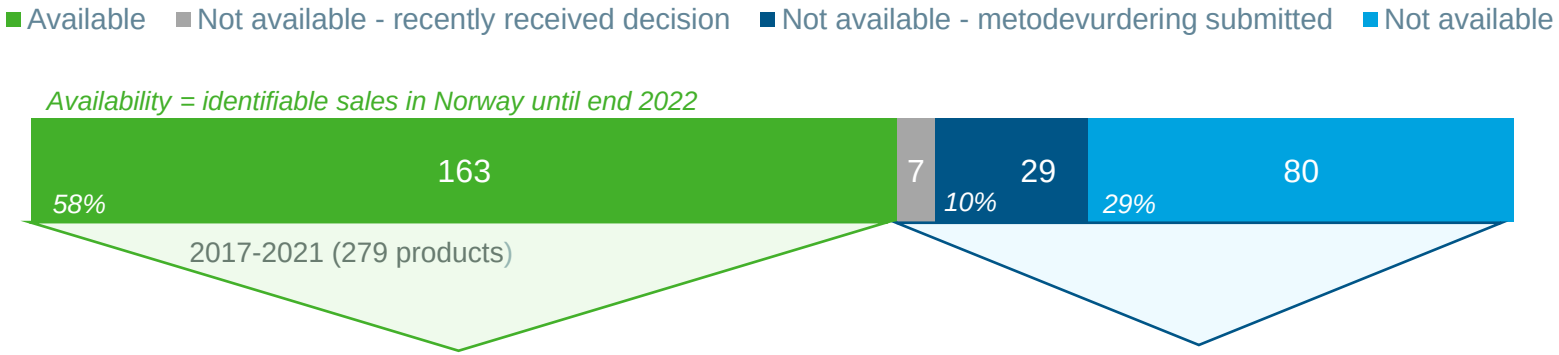
These are also largest among the total of centrally approved medicines



37% Orphan drugs

14% Oncology

Out of the 104 products not available (no sales) in Norway



35% Orphan drugs

- Orphan drugs make up **35% of the 116 products not available** (no sales) in Norway
- 13% of the 163 medicines available in Norway (2nd group after oncology)
- **22% of all 279 products with EMA** (1st largest group of all EMA)

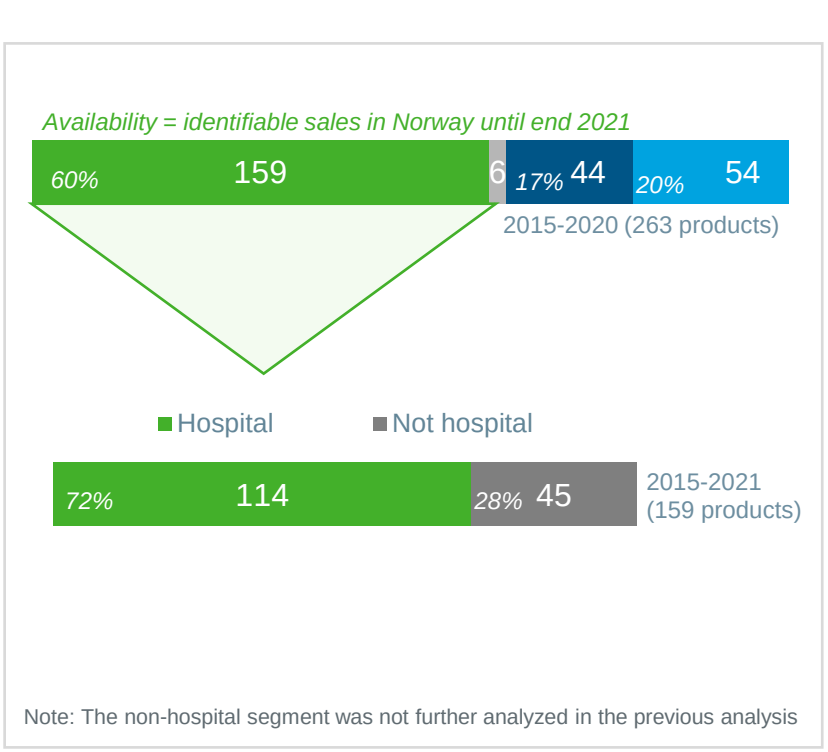
16% Oncology

- Oncology drugs make up the 2nd biggest group of innovative medicines and drugs not available yet in Norway
- **14% of all 279 products with EMA** (2nd largest group of all EMA)

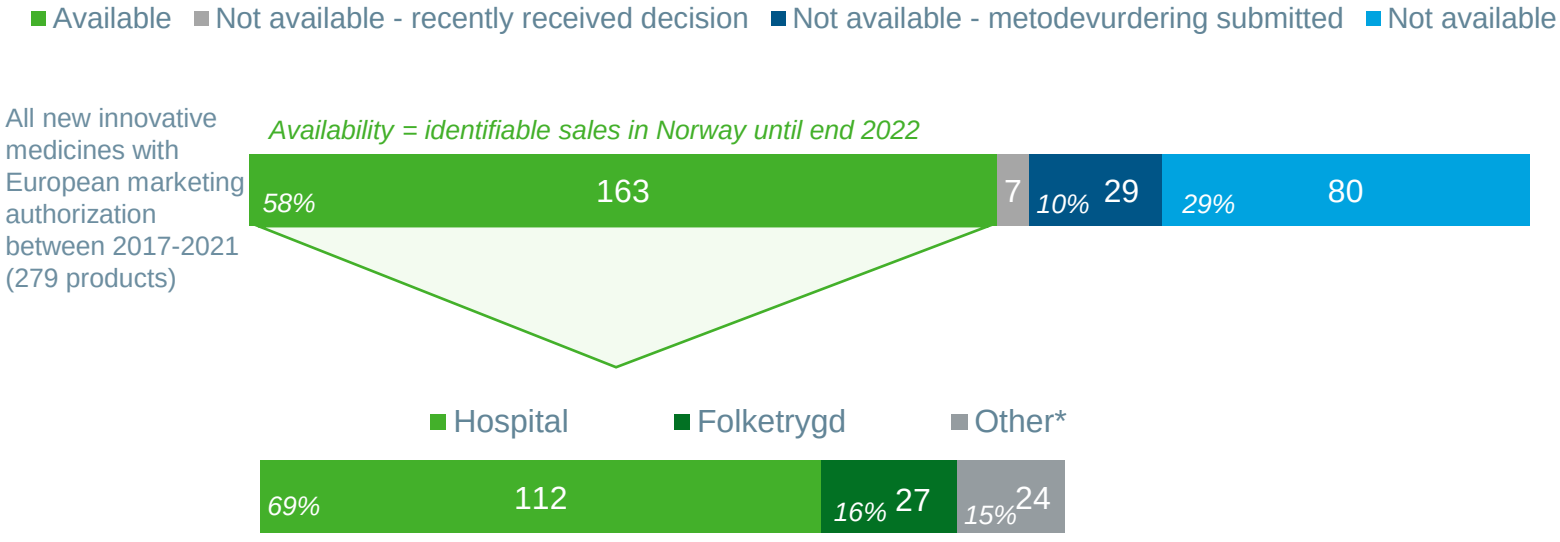
Note: Time periods for the two analyses are slightly different. 2022 analysis covers 6 years, while 2023 analysis covers 5 years.

Hospital products cover the highest share of available EMA approved substances

This year's analysis also goes in-depth on the usage of innovative "folketrygd" products



Note: The non-hospital segment was not further analyzed in the previous analysis

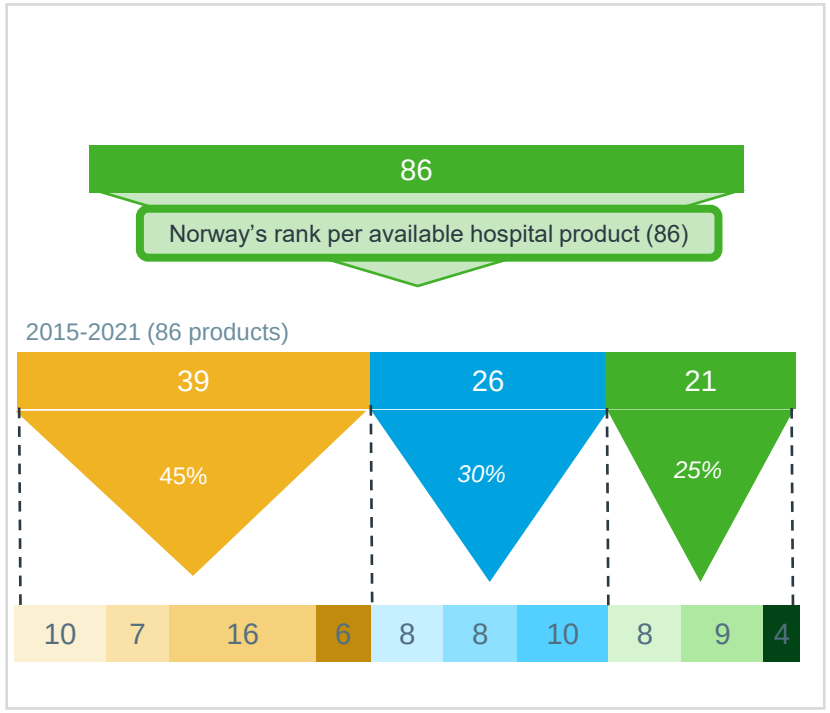


**17 products did not fit in the two categories as they are white prescription, vaccine, or generics. An additional 7 products could not be linked correctly between the Nordic and European sales data and had to be excluded. See appendix.*

Note: Time periods for the two analyses are slightly different. 2022 analysis covers 6 years, while 2023 analysis covers 5 years.

~40% of hospital medicines in Norway have low per capita usage in comparison to IRP countries, compared to 45% previous analysis

Same share of High usage products as in last year's analysis



All new innovative hospital substances available in Norway between 2017-2021 (112 products)

112

Norway's rank per available hospital product (112), compared to the 9 IRP countries (i.e. rank (1-10))
Rank reflecting average use per capita 3 years after first observed sales in any of the IRP countries

Norway's rank per product – grouped into *low – medium – high*

Low Usage | Medium Usage | High Usage

45 | 39 | 28

Low usage per capita *40%*

Medium usage per capita *35%*

High usage Per capita *25%*

Norway's rank per product (112 products)

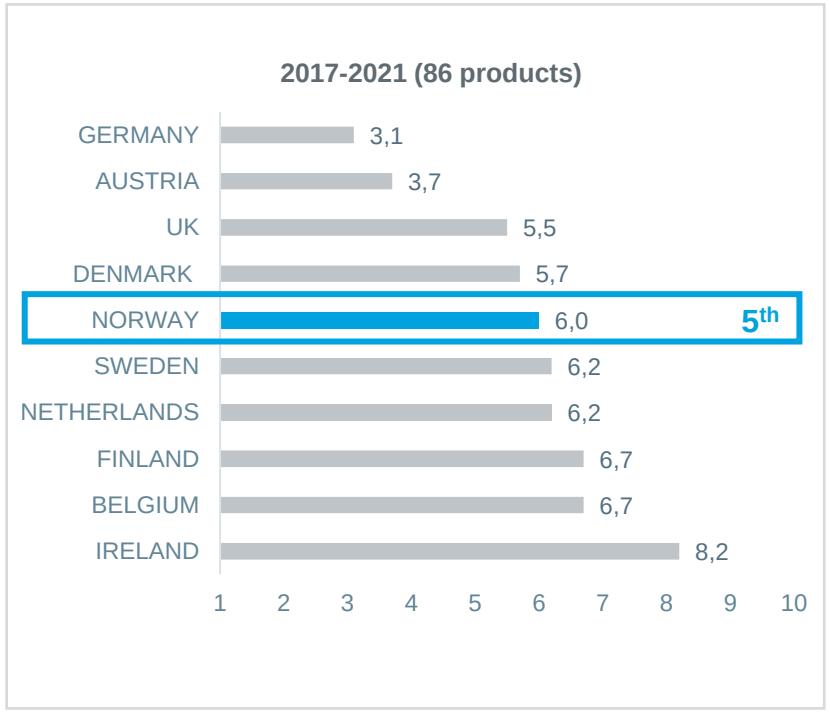
15 | 3 | 20 | 6 | 11 | 15 | 13 | 7 | 10 | 11

10 9 8 7 6 5 4 3 2 1

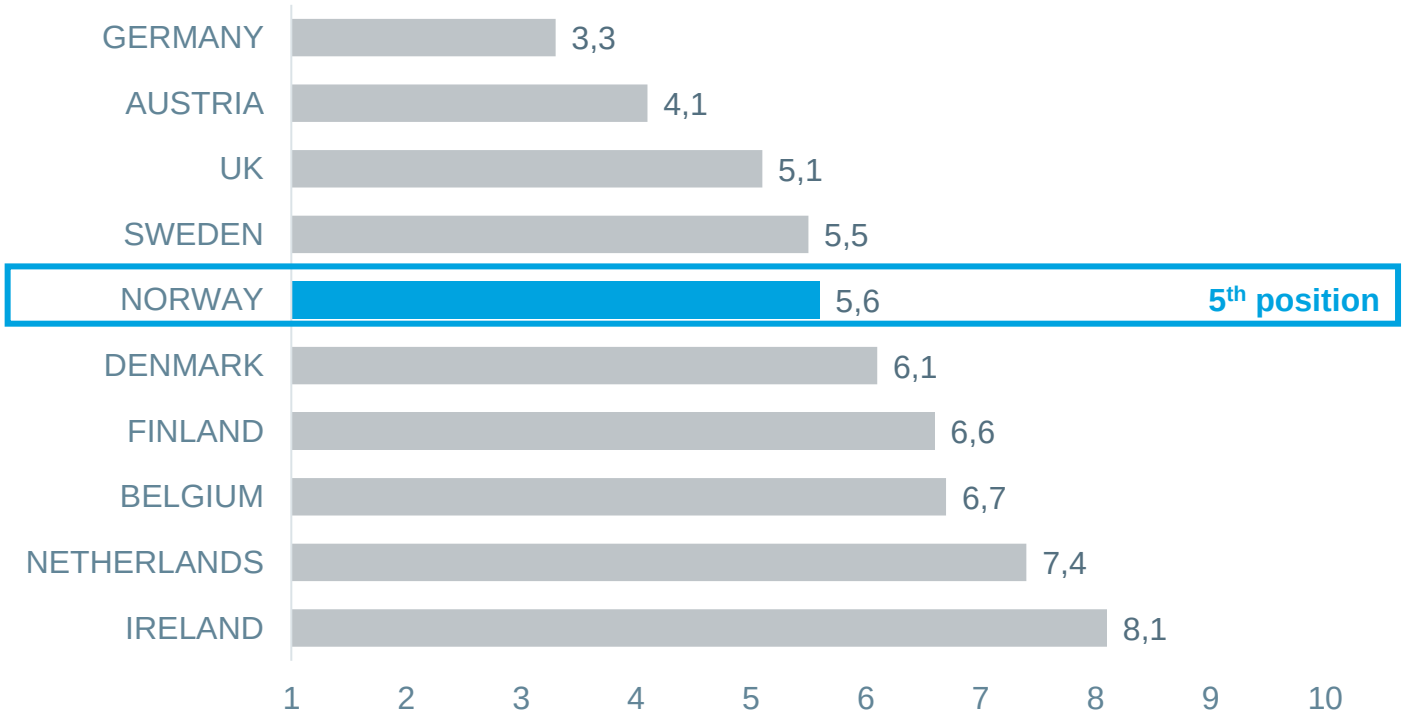
Note: Time periods for the two analyses are slightly different. 2022 analysis covers 6 years, while 2023 analysis covers 5 years.

Norway maintains the 5th position like last year

3 years after central approval the usage in Norway is comparable to the Nordic countries



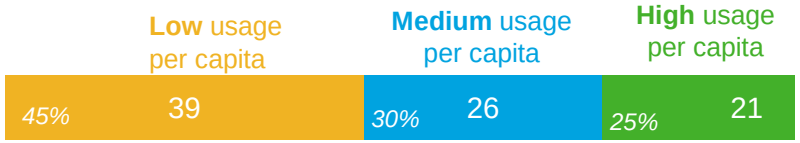
Avg rank of usage per capita of new innovative hospital medicines launched between 2018-2022 (112 products) after 3 years from first observed sales in one of the IRP countries



Note: Time periods for the two analyses are slightly different. 2022 analysis covers 6 years, while 2023 analysis covers 5 years.

There continues being little correlation between usage and indication, administration form, market size and tenders

2017-2021 (86 products)

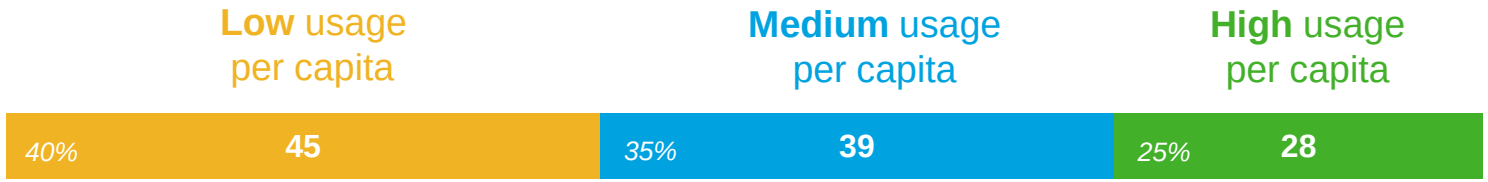


The following areas show **medium to high usage in Norway** compared to IRP countries: Orphan (12), Blood Coagulation (7), Respiratory Diseases (3), Women Specific Diseases (1)

There is **little difference in the usage level in Norway** compared to IRP countries:

- Per administration form: Tablet (46), Injection (22), Infusion (15) and Mikstur (3)
- Between products with smaller vs larger total sales volumes
- Between products that were part of a tender or not

Norway's usage per product 3 years after first observed sale in one of the IRP countries (112 products)



The following areas show **medium to high usage in Norway** compared to somewhat lower in IRP countries: Oncology (27), Blood Coagulation (10), Respiratory Diseases (6), Other Infection (4), Heart Conditions (2)

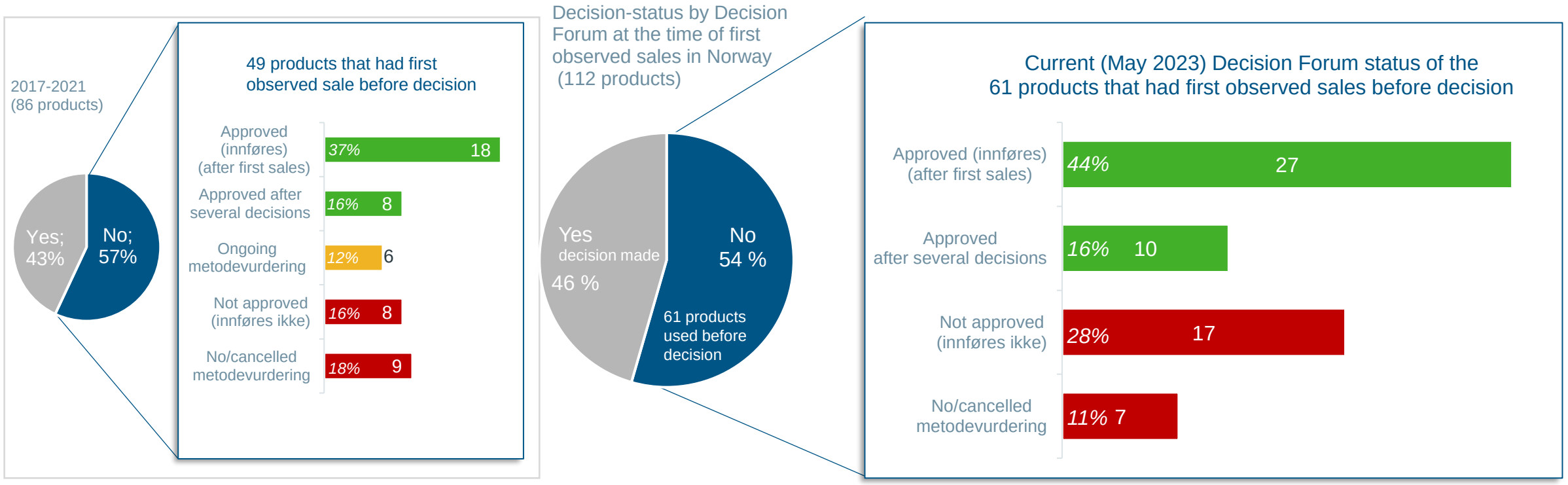
There is **little difference in the usage level in Norway** compared to IRP countries:

- Per administration form: Tablet (40), Injection (17), Infusion (18) and Capsule (14)
- Between products with smaller vs larger total sales volumes across IRP countries
- Between products that were part of a tender or not

Note: Time periods for the two analyses are slightly different. 2022 analysis covers 6 years, while 2023 analysis covers 5 years.

Similar to the last analysis, more than 50% of the products show first sales before a reimbursement decision

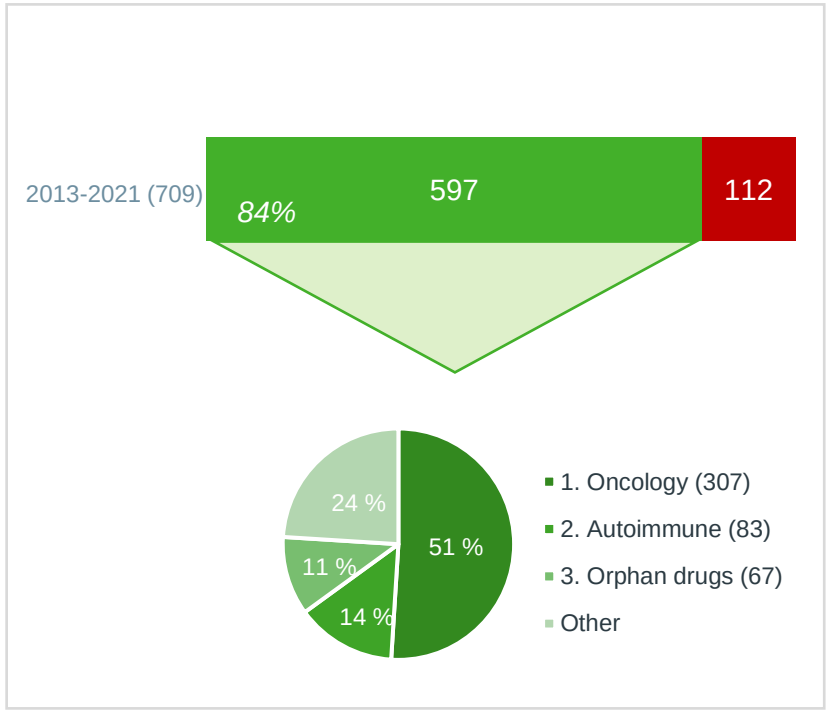
A slight decrease in percentage, but higher number of products in this year's analysis



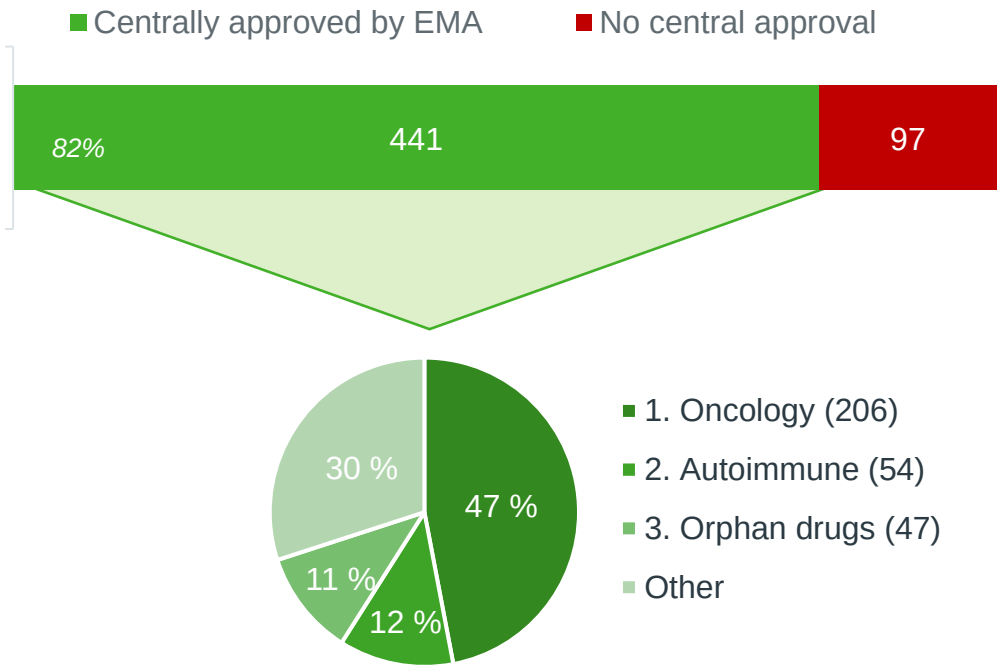
Note: Time periods for the two analyses are slightly different. 2022 analysis covers 6 years, while 2023 analysis covers 5 years.

Moving to the analysis of indications, the share of central approvals among HTA proposals is similar to the 2022 analysis

Top three therapeutic areas continues to be oncology, autoimmune and orphan drugs

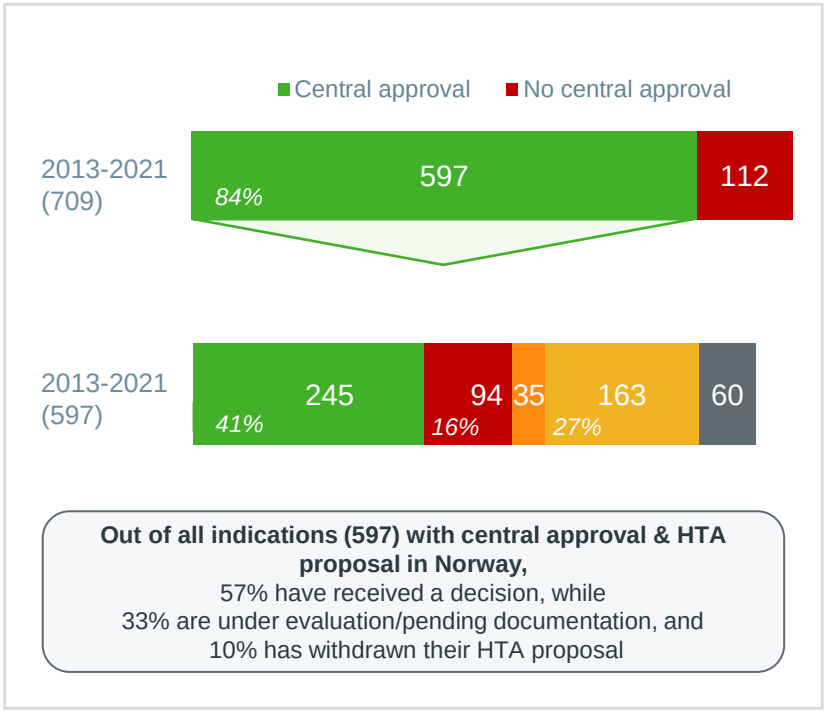


All indications with HTA proposals in Norway 2018-'22 (538) (i.e. first indications and extensions)

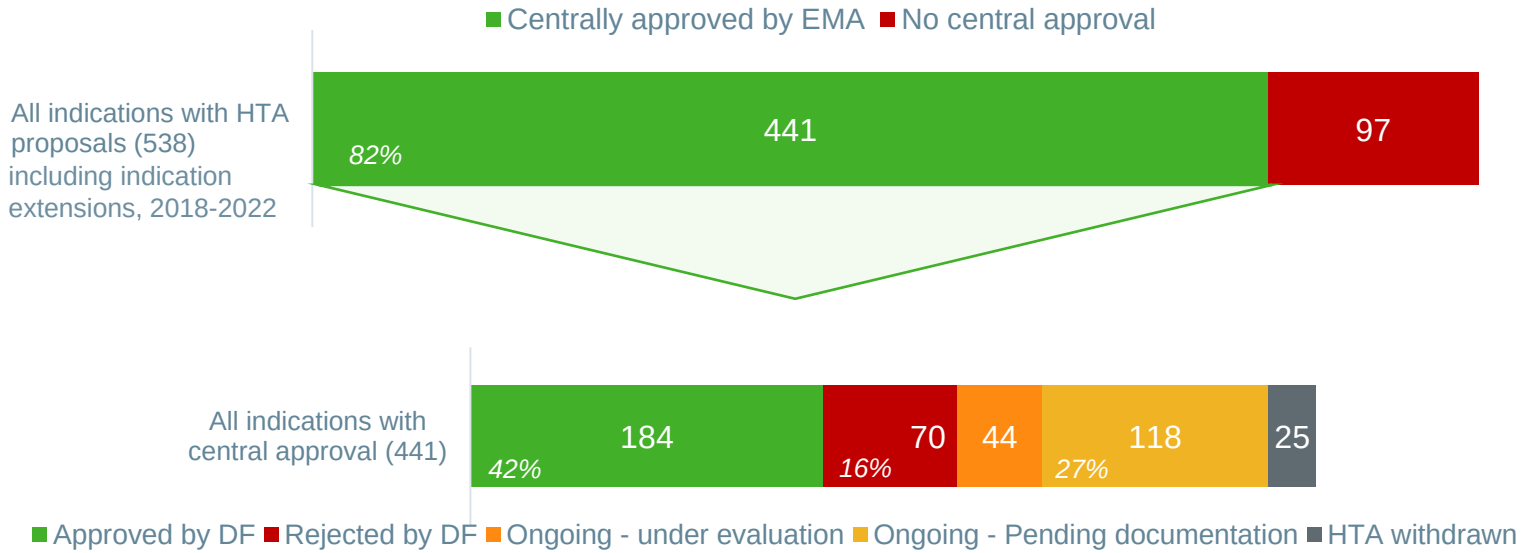


Note: Time periods for the two analyses are different: 2022 analysis covers 9 years, while 2023 analysis covers 5 years.

There is little change in the share of indications approved, rejected and pending documentation



Out of all indications (597) with central approval & HTA proposal in Norway,
57% have received a decision, while
33% are under evaluation/pending documentation, and
10% has withdrawn their HTA proposal

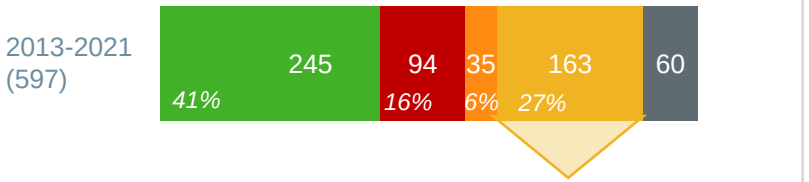


Out of all indications (441) with central approval & HTA proposal in Norway,
58% have received a decision, while
37% are under evaluation/pending documentation, and
5% has withdrawn their HTA proposal

Note: Time periods for the two analyses are different: 2022 analysis covers 9 years, while 2023 analysis covers 5 years.

Among indications pending documentation, the majority are still in oncology, now followed by blood diseases

Continued even split between oncology indication extensions and new substances



Out of all indications with pending documentation (163)

The majority have an indication in **Oncology** (82; 50%), followed by **Orphan drugs** (17; 10%)

Half of the HTA proposals for which documentation is pending, **are at least 2 years past central approval** date

The companies with most approved products also have a high share of cancelled / withdrawn products

Out of all indications with pending documentation (118):

The majority have an indication in **Oncology** (56; 47.5%), followed by **Blood disease** (10; 8.5%)

Within **Oncology**, it is split even between **indication extensions**(29; 52%) and new substances (27; 48%)

~60% of the HTA proposals for which documentation is pending, **are at least 2 years past central approval** date *(see next page)*

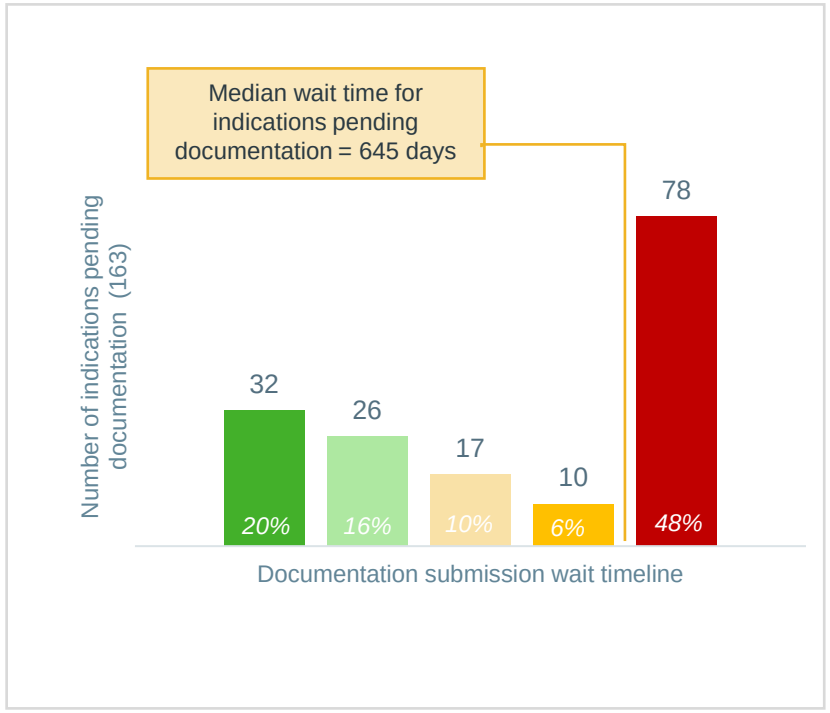
26% received central approval less than one year ago

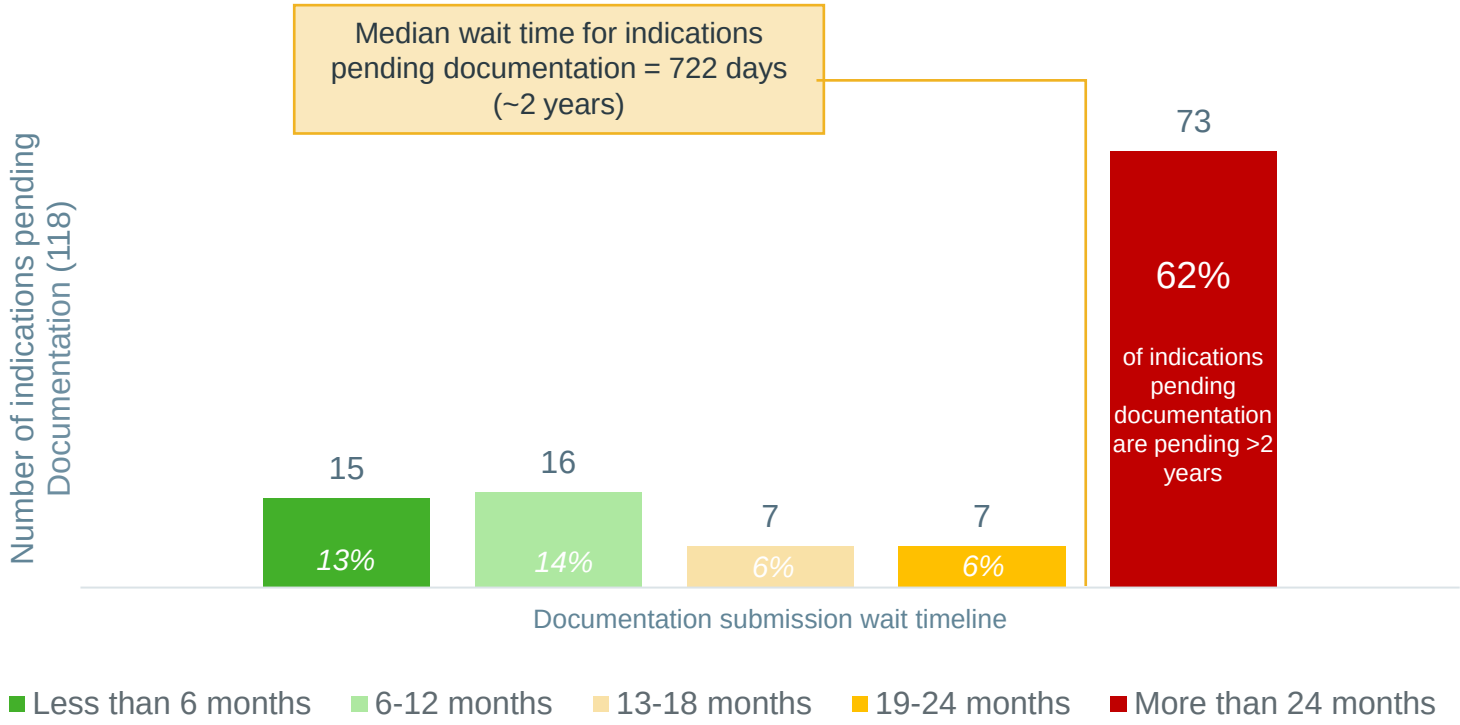
The companies with the most approved indications also have a high proportion of cancelled / withdrawn or indications that are still waiting for documentation

Note: Time periods for the two analyses are different: 2022 analysis covers 9 years, while 2023 analysis covers 5 years.

~60% of HTA proposals for which documentation is pending, are 2 years past central approval, more than in the previous analysis

~2-3 months increase in the median wait time for HTA proposals for which documentation is pending

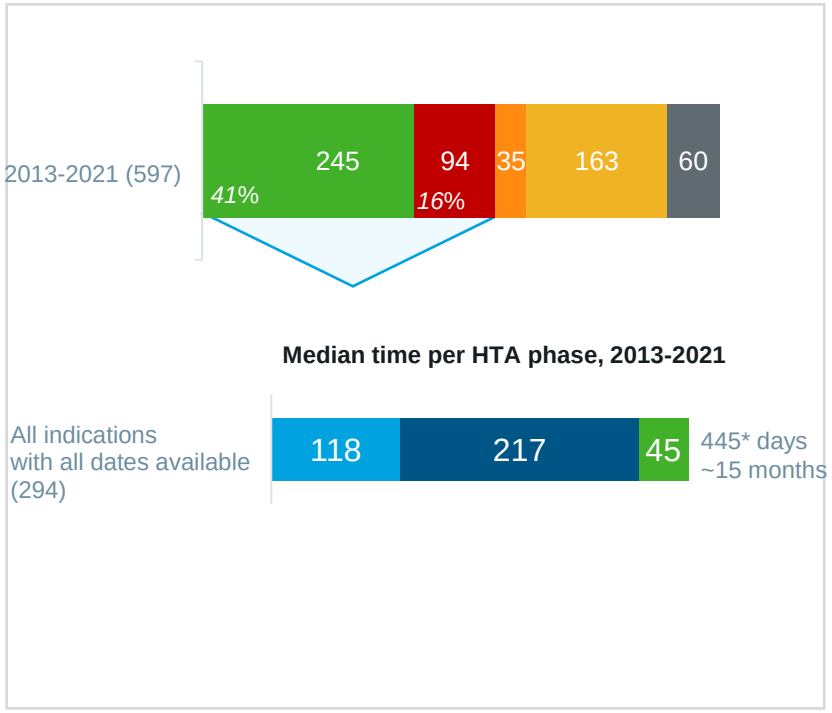


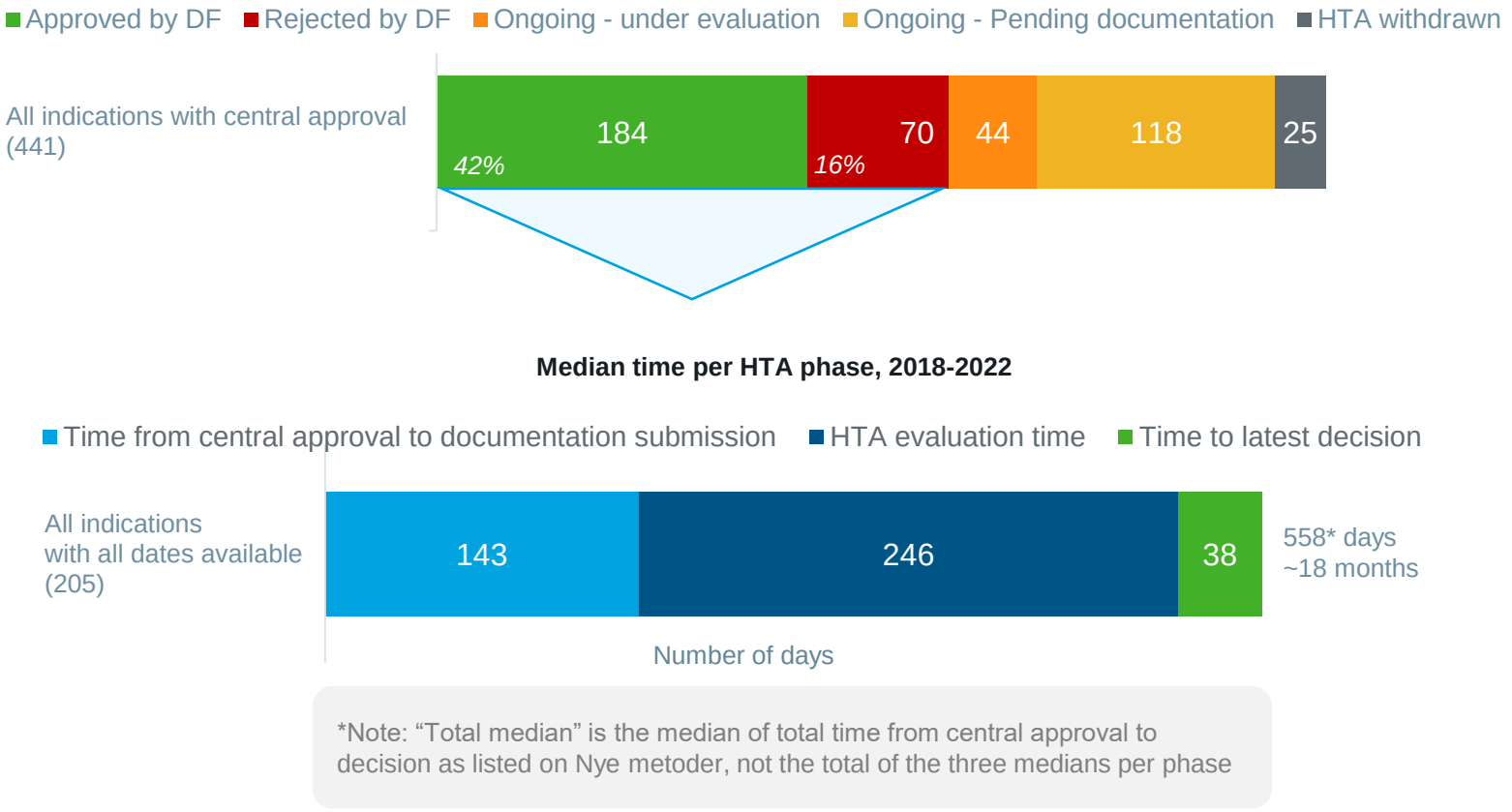


Note: Time periods for the two analyses are different: 2022 analysis covers 9 years, while 2023 analysis covers 5 years.

The median time from central approval to latest decision has increased by ~3 months compared to last year's analysis

Since the analysis has a shorter time frame, fewer products are included than last year



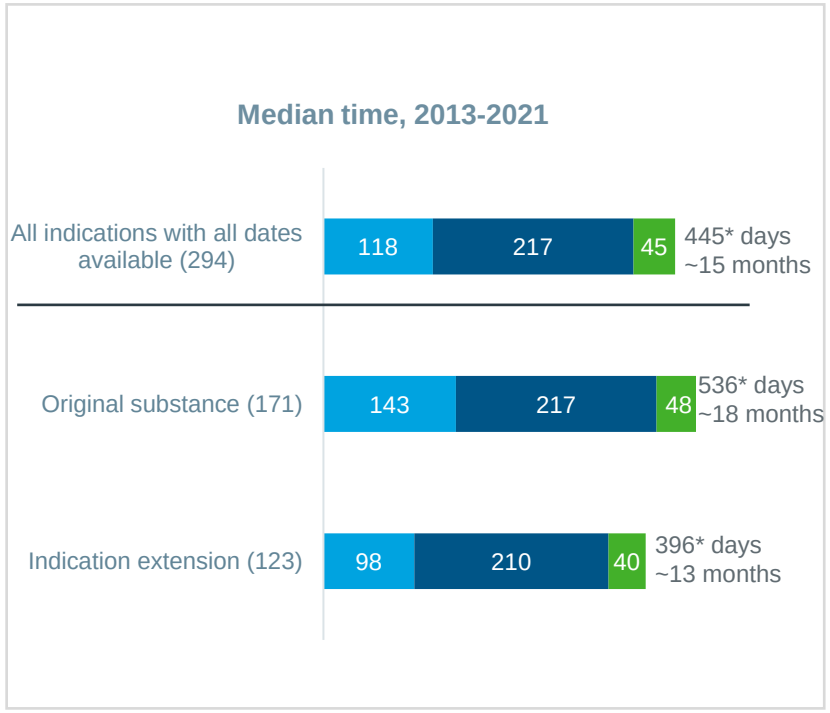


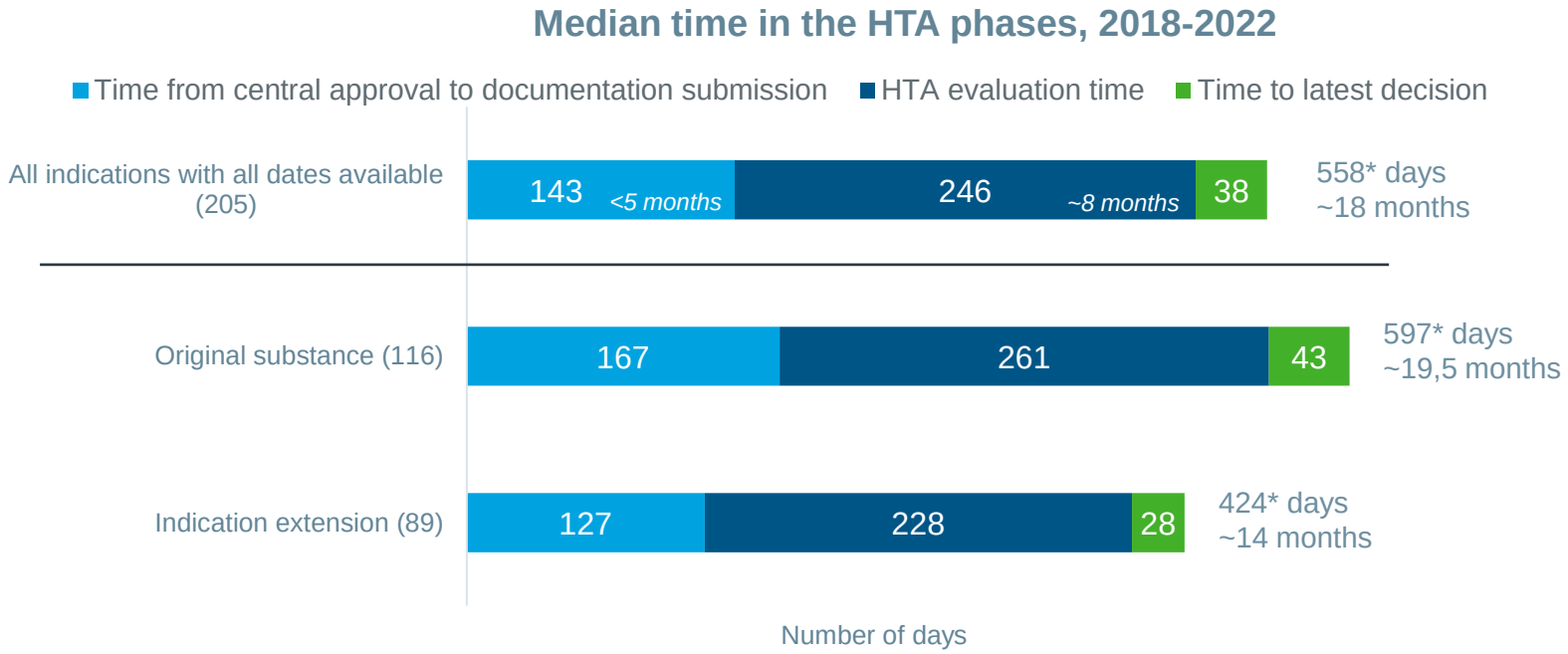
*Note: "Total median" is the median of total time from central approval to decision as listed on Nye metoder, not the total of the three medians per phase

Note: Time periods for the two analyses are different: 2022 analysis covers 9 years, while 2023 analysis covers 5 years.

The median HTA evaluation time has increased by ~1 month, slightly more for original substances

Median time to latest decision has slightly decreased

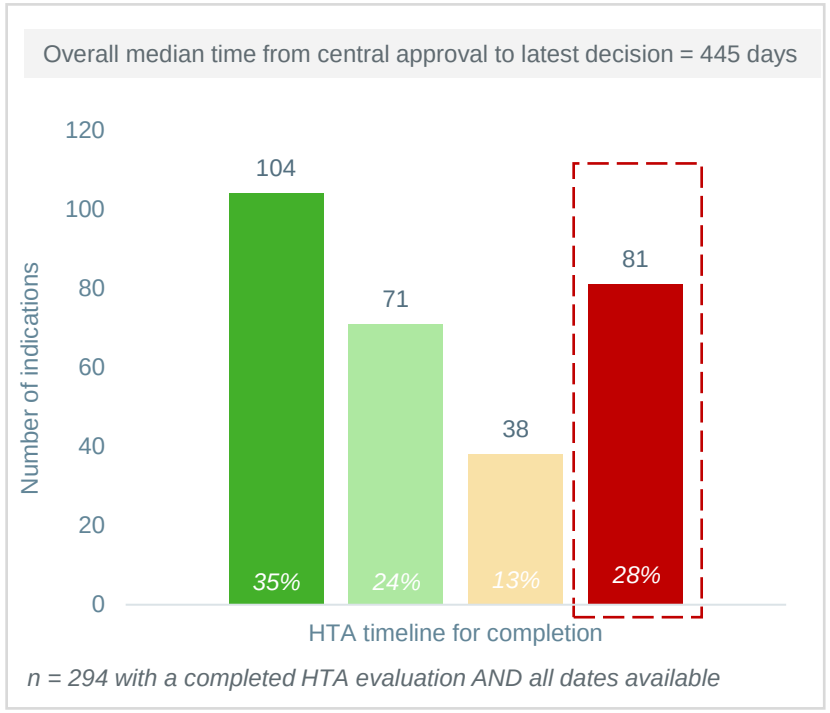


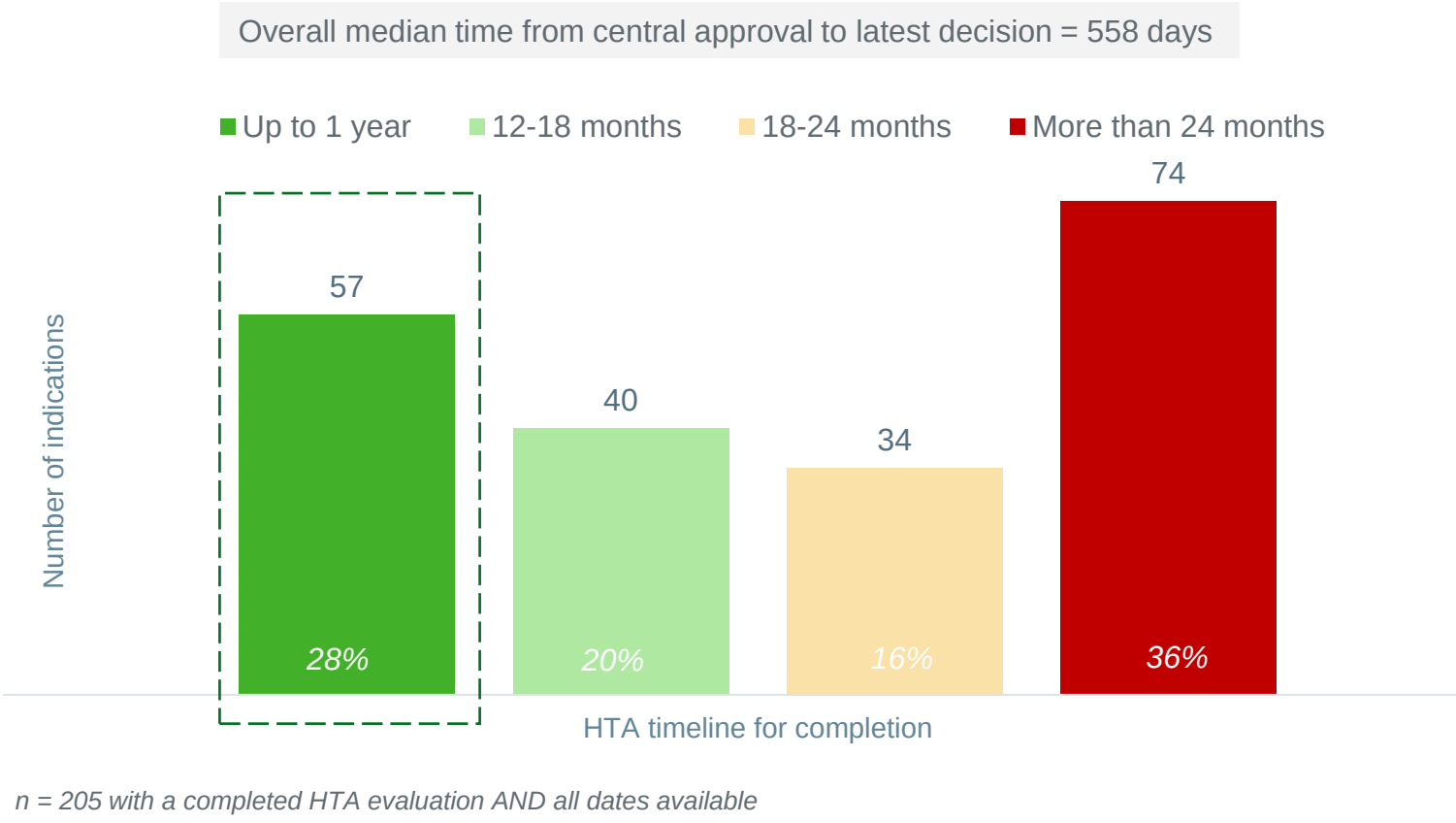


Note: Time periods for the two analyses are different: 2022 analysis covers 9 years, while 2023 analysis covers 5 years.

The share of products with HTA timeline over 24 months has increased compared to the previous analysis

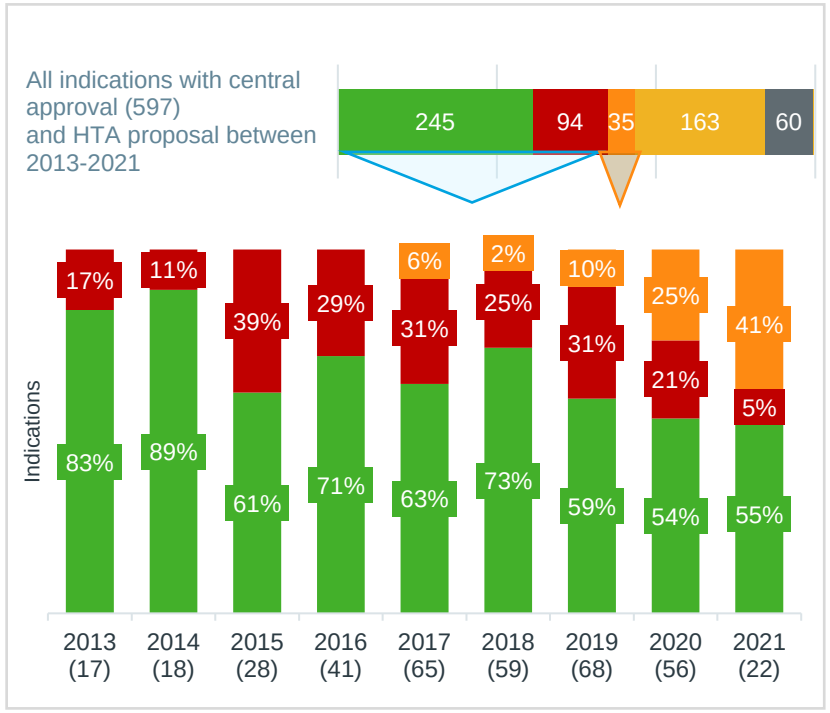
The share of products with HTA timeline less than a year has decreased

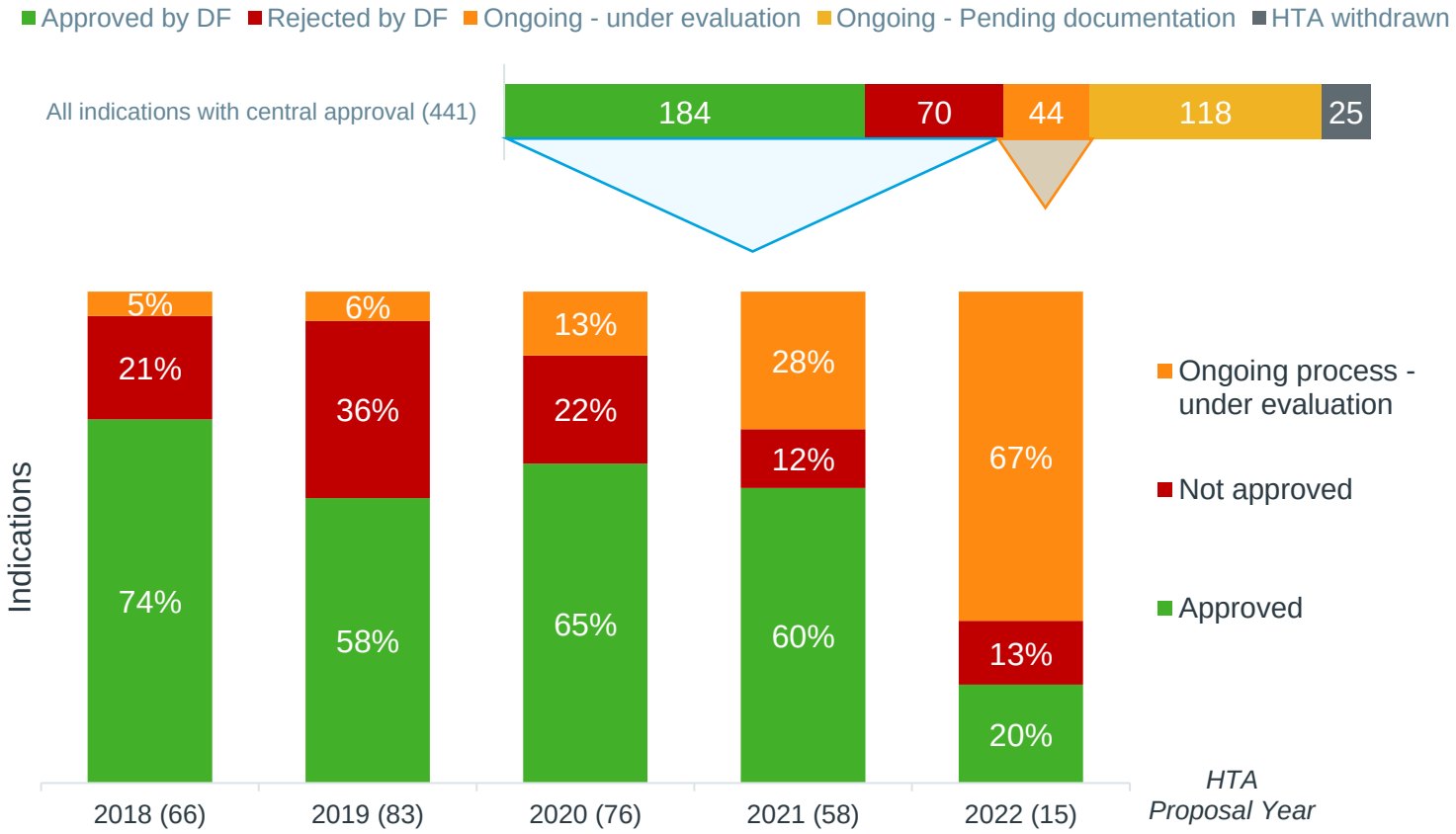




Note: Time periods for the two analyses are different: 2022 analysis covers 9 years, while 2023 analysis covers 5 years.

Compared to the last analysis, there is a higher share of proposals still under evaluation during their first year





Note: Time periods for the two analyses are different: 2022 analysis covers 9 years, while 2023 analysis covers 5 years.

Appendix:
Details on methodology

Research question 3: Methodology overview

Time from EU Central approval to latest decision in Decision Forum

1) Categorization of evaluation status

538 indications with a **HTA proposal / metodevarsel** have been evaluated based on public sources and were categorized by status:

- "proposal submitted";
- "under evaluation" and
- "decision given"

2) Evaluation of process timelines

Timelines for **205 indications** with a **completed evaluation / metodevurdering** - from EMA approval to latest decision in Decision Forum – were evaluated based on three periods during the process:

1. Time from EMA approval to documentation submission,
2. Time from first documentation submission to SLV / NoMA* up to completed evaluation,
3. Time from NoMa completed evaluation to latest decision in Decision Forum

**SLV = Statens Legemiddelverk = NoMa = Norwegian Medicines Agency*

Methodology: Categorization of evaluation status

Time from EU Central approval to latest decision in Decision Forum

Latest data collection date: 26.05.2023

Data sources:

Nye Metoder & Statens Legemiddelverk (SLV)

- A complete list of all metodevarsel / HTA proposals registered in Nye Metoder's system between 2018-2020 was received directly from Nye Metoder as an excel workbook April 2021, and 2021-22 were added from Statens legemiddelverk excel file online "Saksbehandlingsstatus for metodevurderinger" were added - combined to a total of **538** substances and extensions of indications

- Each proposal has been looked up on nyemetoder.no, and examined to collect the status of the application and the dates relating to the different evaluation steps

Identified status categories of indications and definitions in Norwegian:

Nye Metoder splits the evaluation in three steps, IQVIA has analysed further status based on the application details:

- **Forslag** – *Venter på dokumentasjon / Metodevurdering trukket eller avbestilt / LIS utarbeider prisnotat / Oppdrag gitt i Bestillerforum*
- **Metodevurdering** – *oppdrag gitt / påbegynt / ferdigstilt*
- **Beslutning i Beslutningsforum** – *innføres / innføres ikke / ny beslutning etter flere runder*

Methodology: Evaluation of process timelines

Time from EU Central approval to latest decision in Decision Forum

Latest data collection date: 26.05.2023

Sources of data:

European Medicine Agency
- EMA approval dates and status collected from ema.europa.eu, and used as a starting point in the calculation of time between the EMA approval and submission of required documentation for the metodevurdering/HTA application

Nye Metoder
- The dates relevant to the different evaluation steps were collected to calculate the time spent on each part of the process

Identified process timelines of indications:

1. Time from EMA approval to documentation submission:
   - Submission is complete when documentation has been delivered. This is then the date that NoMA evaluation starts
   - Note that documentation submission may occur before EMA approval – it is still EMA approval date that is the starting point in this evaluation
2. Evaluation time from first documentation submission to NoMA completed evaluation
   - The analysis has not further investigated the time that evaluations were put “on hold” (clock-stop) due to requests for additional information to be provided by pharma companies
3. Time from NoMA completed evaluation to latest decision in Decision Forum
4. *Note that mathematically, the total median time is usually different than the total of the medians per phase*

Methodology: Clarification of scope and possible limitations

Time from EU Central approval to latest decision in Decision Forum

Scope:

- The process times were categorized into three process steps from Nye Metoder. The analysis has not further investigated the time that evaluations were put “on hold” (clock-stop) due to requests for additional information to be provided by pharma companies. It does not include a further analysis of situations where Decision Forum took multiple decisions: the latest decision is counted only
- The project does not include an evaluation of situations where companies choose to NOT submit an HTA proposal or choose NOT to submit documentation.

Notes on timeframes used:

- Dates of EMA approval, Norwegian HTA proposal, evaluation and latest decision are based on publicly available information, available per the latest collection date, most often May 26, 2023. Updated decisions or other information have not been taken into account. The dates are taken from the general overview of indications and timelines, not from the more detailed version in HTA log per indication where additional evaluation times are listed
- Published dates have been assumed correct
- EMA dates for substances with multiple indication extensions can be complicated to identify correctly. In some cases the “Positive opinion” had to be used or online press releases for oncology indication extensions

Methodology: Categorization of evaluation status Q1 & Q2

Latest data collection date: 26.05.2023

Data sources:

Statens Legemiddelverk (SLV)

- A complete list of all metodevarsel / HTA proposals categorized as "folketrygd" by SLV between 2018-2020 was exported from their website, https://legemiddelverket.no/offentlig-finansiering/metodevurderinger - combined to a total of **125 "folketrygd"** substances and extensions of indications

- Each proposal has been examined to collect the status of the application and the dates relating to the different evaluation steps

Identified status categories of indications and definitions in Norwegian:

IQVIA has categorized evaluation status based on the application details:

- **Metodevurdering** – *vurdering av innsendt dokumentasjon / refusjonsvedtak*
- **Beslutning** – *forhåndsgodkjent refusjon innvilges (approved by SLV) / innvilges ikke (not approved by SLV)*

Methodology: Evaluation of process timelines Q3

Time from EU Central approval to latest decision

Latest data collection date: 26.05.2023

Sources of data:

European Medicine Agency
- EMA approval dates and status collected from ema.europa.eu, and used as a starting point in the calculation of time between the EMA approval and submission of required documentation for the metodevurdering/HTA application

SLV
- The dates relevant to the different evaluation steps were collected to calculate the time spent on each part of the process

Identified process timelines of indications:

1. Time from EMA approval to documentation submission:
   - Note that documentation submission may occur before EMA approval – it is still EMA approval date that is the starting point in this evaluation
2. Time the evaluation is interrupted and put on-hold while waiting for additional documentation.
3. Actual processing time: Evaluation time from documentation submission to reimbursement decision, deducting the days the evaluation is put on hold

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