

Oncology Pipeline Monitor 2026

Pilot Approach of Using IHSI Data to Inform Hospital Decision-Makers in Austria on Emerging Medicinal Products

Final Report

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Conflict of interest

All authors and the reviewers involved in the production of this report have declared they have no conflicts of interest in relation to the technology assessed according to the Uniform Requirements of Manuscripts Statement of Medical Journal Editors (www.icmje.org).

Disclaimer

The external reviewers did not co-author the scientific report and do not necessarily all agree with its content.
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List of abbreviations

AIHTA	Austrian Institute for Health Technology Assessment
AKT	Protein Kinase B (Proto-oncogene protein c-akt)
ALK	Anaplastic Lymphoma Kinase
ATMP	Advanced Therapy Medicinal Product
BRAF	Proto-oncogene protein B-Raf
CDK	Cyclin-Dependent Kinase
CHMP	Committee for Medicinal Products for Human Use
c-MET	Mesenchymal-Epithelial Transition factor (Proto-oncogene protein c-met)
EC	European Commission
EGFR	Epidermal Growth Factor Receptor
EMA	European Medicines Agency
EU	European Union
FDA	U.S. Food and Drug Administration
FGFR	Fibroblast Growth Factor Receptor
HER2	Human Epidermal growth factor Receptor 2
HSO	Horizon Scanning in Oncology
HTA	Health Technology Assessment
IHSI	International Horizon Scanning Initiative
ISSN	International Standard Serial Number
KIT	KIT Proto-Oncogene (Proto-oncogene protein c-kit)
KRAS	Kirsten Rat Sarcoma viral oncogene homolog
MAA	Marketing Authorisation Application
MedDRA	Medical Dictionary for Regulatory Activities
mTOR	Mechanistic Target of Rapamycin
PARP	Poly(ADP-Ribose) Polymerase
PI3K	Phosphatidylinositol 3-Kinase
PRIME	PRIority Medicines
RAF	Rapidly Accelerated Fibrosarcoma kinase
RAS	Rat Sarcoma viral oncogene homolog
RET	Rearranged during Transfection (Proto-oncogene protein c-ret)
ROS1	ROS Proto-Oncogene 1
RQ	Research Question
SEC	U.S. Securities and Exchange Commission
SOC	System Organ Class
VEGFR	Vascular Endothelial Growth Factor Receptor
WiGEV	Wiener Gesundheitsverbund (Vienna Health Network)

ZUSAMMENFASSUNG

Die Entwicklung neuer Arzneimittel schreitet insbesondere in der Onkologie rasch voran. Die steigende Zahl innovativer und hochspezialisierter Arzneimittel (z.B. zielgerichtete Therapien, Immuntherapien und Zelltherapien) kann erhebliche Auswirkungen auf die künftige klinische Praxis sowie auf die Arzneimittelausgaben im Krankenhaussektor haben. Horizon Scanning kann Entscheidungsträger:innen dabei unterstützen, neue Arzneimittel frühzeitig zu erkennen und sich auf deren potenzielle Auswirkungen vorzubereiten. Es handelt sich dabei um einen systematischen Ansatz zur frühzeitigen Identifikation von Entwicklungen mit mittel- bis langfristiger Relevanz.

Der vorliegende Bericht ist die erste Ausgabe des Onkologie-Pipeline-Monitors, der im Rahmen des Pilotprojekts „Nutzung von IHSI-Daten: Onkologie-Pipeline-Monitor und Drug Alerts für High-Impact-Arzneimittel“ erstellt wurde. Auf Basis von Daten der International Horizon Scanning Initiative (IHSI) werden onkologische Arzneimittel mit einer möglichen EU-Zulassung innerhalb der nächsten zwei Jahre sowie ausgewählte Arzneimittel mit potenziell hohem Impact auf die Versorgung und die Arzneimittelausgaben im österreichischen Krankenhaussektor dargestellt. Darüber hinaus kann der Pipeline-Monitor die Priorisierung von Arzneimitteln im Rahmen des Bewertungsboards für ausgewählte Arzneimittel unterstützen.

Als primäre Datenquelle diente die IHSI-Datenbank. Die onkologische Arzneimittelpipeline wurde anhand zentraler Merkmale der Entwicklung, Zulassung und Indikation beschrieben. Ergänzend wurden gemeinsam mit Vertreter:innen des Krankenhaussektors und klinischen Expert:innen Arzneimittel mit potenziell hohem Impact auf den österreichischen Krankenhaussektor identifiziert und in Kurzprofilen dargestellt.

Zentrale Ergebnisse auf einen Blick

- **Umfangreiche und dynamische Pipeline:** Aus der IHSI-Datenbank haben wir 377 Einträge zu 236 onkologischen Wirkstoffen für 70 verschiedenen Krebsarten extrahiert. Rund ein Drittel der Wirkstoffe wird für mehrere Indikationen entwickelt.
- **Hoher Anteil spezialisierter und innovativer Therapieansätze:** Neben etablierten zielgerichteten Therapien umfasst die Pipeline insbesondere Zell- und Gentherapien, Immuncheckpoint-Inhibitoren, bispezifische Antikörper und T-Zell-Engager sowie Antikörper-Wirkstoff-Konjugate.
- **Ausweitung bestehender Therapien und neue Therapieansätze:** Die Pipeline ist sowohl durch Indikationserweiterungen bereits etablierter Arzneimittel als auch durch neue Wirkstoffe für Erkrankungen mit hohem ungedecktem medizinischem Bedarf geprägt. Mehr als die Hälfte der Indikationen sind Kombinationstherapien.
- **Potenzielle finanzielle Relevanz:** Für rund die Hälfte der Datensätze liegen Kostenschätzungen vor. Bei 90 % dieser Datensätze mit verfügbaren Kostenschätzungen liegen die geschätzten Jahrestherapiekosten über 25.000 € pro Patient:in.
- **20 Arzneimittel mit potenziell hohem Impact identifiziert:** Expert:innen aus dem Krankenhaussektor und der klinischen Versorgung identifizierten 20 Arzneimittel für 25 Indikationen als potenziell besonders relevant für den österreichischen Krankenhaussektor. Für 18 davon wird eine EU-Zulassung im Jahr 2027 erwartet.
- **Schwerpunkt auf neuartigen Therapien und seltenen Erkrankungen:** Die ausgewählten Arzneimittel umfassen insbesondere Zell- und

Gentherapien sowie weitere neuartige Therapieansätze. Knapp die Hälfte weist einen Orphan-Status auf, keine der ausgewählten Indikationen betrifft frühe Krankheitsstadien.

- **Hohe Unsicherheit bei der frühzeitigen Einschätzung:** Die Auswahl und Einschätzung des potenziellen Impacts sind mit Unsicherheiten hinsichtlich des Zulassungszeitpunkts, der tatsächlichen Zulassung sowie der späteren Anwendung und Ausgabenentwicklung verbunden. Die Ergebnisse sind daher als Momentaufnahme und nicht als Prognose zu verstehen.

Der Onkologie-Pipeline-Monitor 2026 bietet eine strukturierte frühzeitige Informationsgrundlage über neue und potenziell versorgungsrelevante Arzneimittelentwicklungen im Krankenhaussektor. Die Ergebnisse verdeutlichen sowohl die Dynamik der onkologischen Arzneimittelentwicklung als auch die potenzielle Bedeutung neuer, häufig hochspezialisierter und kostenintensiver Therapieansätze für die zukünftige Versorgung. Als Folgeprojekt sollte der Monitor durch regelmäßige Aktualisierungen und eine weitere Standardisierung und Validierung der Auswahlmethodik fortgeführt und weiterentwickelt werden.



INTRODUCTION

This report represents the pilot edition of the Summary Reports developed as part of the pilot project 'Use of IHSI Data: Oncology Pipeline Monitor and Drug Alerts for High-Impact Medicines' which explores the use of data from the International Horizon Scanning Initiative (IHSI) to support decision-making in the hospital sector in Austria [1]. The pilot edition focuses on oncology — the therapeutic area that dominates the global clinical trial landscape, accounting for 41% of new trial starts in 2024 [2], and 37% of novel medicines recommended for approval by European Medicines Agency (EMA) in 2025 [3]. It provides a snapshot of the regulatory oncology pipeline and highlights a selection of medicinal products that may have a substantial impact on future clinical practice and pharmaceutical expenditure in the Austrian hospital setting. At the same time, it represents the first Austrian application of IHSI data to systematically monitor emerging medicines from a hospital perspective.

The development and availability of new medicinal products are progressing rapidly, particularly in oncology. The growing number of innovative and highly specialised medicinal products entering the market, including targeted therapies, immunotherapies, and cell therapies, may have substantial implications for future clinical practice and pharmaceutical expenditure in hospitals. For hospital and regional health fund decision-makers, this increasingly dynamic landscape creates challenges for anticipating future developments and preparing for their potential impact. Horizon scanning can support this process by raising awareness of new medicinal products that may come to market in the next few years, thereby enabling decision-makers to assess potential opportunities and challenges and to prepare the healthcare system accordingly. It is a qualitative foresight method aimed at the early discovery of developments not yet on the radar of most experts, decision makers, or the general public, and whose potential is not widely recognised.

Although it is not a predictive tool, it facilitates the systematic exploration of novelties that offer opportunities and challenges in the medium or long-term [4], making it a particularly suitable approach to supporting hospital preparedness for emerging innovation.

Against this background, this pilot project explores how data from the IHSI Database can be used to provide a systematic overview of the regulatory oncology pipeline and to identify medicinal products that may be particularly relevant for hospital and regional health fund planning in Austria. The IHSI Database is a global pharmaceutical intelligence platform that consolidates data from multiple relevant resources into a single, structured and transparent repository of emerging health technologies. It supports policymakers, payers and HTA bodies in anticipating new medicines, preparing health systems for market developments, and informing pricing and reimbursement decisions. IHSI is a member-state-owned, not-for-profit organisation governed exclusively by its participating governmental health agencies, with funding provided through member-state contributions and no pharmaceutical industry funding or involvement.[1]

[1] To learn more about the IHSI, please visit https://ihsi-health.org/about-ihsi/.

AIHTA has been active in horizon scanning initiatives since 2009, when the programme line on early assessments of new oncological therapies was initiated to support decision-making by regional drug commissions and payers [5]. As part of the previous Horizon Scanning in Oncology (HSO) initiative, 91 early assessments of selected new oncology medicinal products were prepared by the end of 2019, with a focus on products predicted to have significant financial and/or therapeutic implications [6]. Due to the evolving European regulatory environment and Austria's membership in the IHSI network, the focus temporarily shifted in 2020 from active horizon scanning to the preparation of monthly fact sheets on all recently approved oncology indications [6]. Following the establishment of the Austrian Appraisal Board ("Bewertungsboard für ausgewählte Arzneimittel") in 2024, data from the IHSI database has been leveraged to aid decision-makers in identifying high-cost and specialised medicinal products relevant to the hospital setting (and at the intersection of in- and extramural care) with imminent or recent EU marketing authorisation, and in prioritising those that qualify for a full health technology assessment.

Building on this experience, the present pilot project takes a broader forward-looking perspective and explores how IHSI data can be used to systematically monitor medicines in development that may become relevant to hospital care and hospital pharmaceutical expenditure in Austria. The pipeline monitor could potentially also support the prioritisation process of the Austrian Appraisal Board by providing early information on emerging medicinal products that may warrant consideration for further assessment. The pilot is intended to explore how pipeline monitoring could be established as a regular and systematic activity. Rather than predicting future market developments, the monitor is designed to support early identification and structured monitoring of potentially relevant medicines. The experience gained from this pilot may provide the basis for future regular updates and, potentially, an extension of the approach to other therapeutic areas with significant relevance for hospital strategic planning, resource allocation and system preparedness.

AIM AND SCOPE OF THE REPORT

As one of the outputs of the pilot project ‚Use of IHSI Data: Oncology Pipeline Monitor and Drug Alerts for High-Impact Medicines', the Pipeline Monitor Summary Report provides a structured overview of oncology medicinal products in development that may obtain EU marketing authorisation within the next two years, together with a selection of medicinal products associated with a particularly high potential impact if approved [1].

In addition to these aims, the Pipeline Monitor may provide information that could potentially support the prioritisation of medicinal products for further assessment by the Austrian Appraisal Board.

Drawing on data from the IHSI database, the report aims to:

- Provide timely, structured, and actionable information on the emerging oncology pharmaceutical landscape to support strategic and budget planning in the hospital sector in Austria,
- Present a visually accessible, synthesised overview of oncology medicinal products approaching potential market authorisation based on pipeline data from the IHSI database,
- Raise awareness of selected oncology medicinal products with high projected impact through the brief profiles.

In doing so, the report addresses the following research questions (RQ):

- RQ1: Which oncology medicinal products currently in development are expected to obtain EU marketing authorisation and reach the Austrian market within the next two years?
- RQ2: Which of these products are likely to have a significant impact on hospital care and pharmaceutical expenditure in Austria, in particular in the intramural sector and the interface between intramural and extramural care?
- RQ3: How can IHSI data be structured and presented to best support early awareness, strategic decision-making and preparedness in the hospital sector in Austria?

METHODS

The pilot approach was designed from an HTA and health system perspective to identify and characterise emerging oncology medicines that may be relevant for future decision-making in the Austrian healthcare system. The methodology combines systematic identification of the pre-regulatory oncology pipeline using the IHSI Database with an aggregate assessment of the emerging pipeline and an exploratory selection of medicinal products with potentially high clinical, organisational, and economic impact. The approach comprises three steps: (1) initial screening and application of predefined selection criteria, (2) development of a snapshot of the oncology pipeline, and (3) selection and profiling of potentially impactful medicinal products.

STEP 1: Initial screening and selection criteria

The IHSI Database is the primary data source for identifying oncology medicinal products in the European pre-regulatory pipeline. A record in the IHSI Database represents a unique combination of compound, indication, basic pharmaceutical form, and developer (company)[2] . A single new medicinal product from a specific developer may be undergoing multiple clinical studies for separate indications in parallel; these thus appear as standalone records in the IHSI Database.

The IHSI Database offers advanced search and export functions, which are employed to retrieve the list of oncology medicinal products relevant for the Austrian pipeline monitor. The records are restricted by the following criteria:

- Record status: Active; only Originator products (no Generics or Biosimilars)
- MedDRA System Organ Class: Neoplasms Benign, Malignant and Unspecified (incl. Cysts and Polyps)
- IHSI Category: Oncology, Haematology
- Expected opinion of the EMA Committee for Medicinal Products (Estimated): July 2026 to December 2028

Two data extractions from the IHSI Database were used to inform this report. The snapshot of the oncology pipeline (described in detail in Step 2) is based on data extracted on 8 July 2026, which represents the most recent extraction at the time of report preparation. The selection of medicinal products deemed impactful (Step 3), however, was performed on an earlier extraction dated 31 March 2026, as the selection process by hospital and clinical partners required sufficient lead time. The records retrieved using the search criteria described above represent the oncology pipeline as captured by the IHSI Database at the date of extraction.

STEP 2: Snapshot of the pipeline

This section of the report presents anonymised information at aggregate level. The retrieved list of medicinal products was analysed to generate a snapshot of the oncology pipeline as of the date of extraction. The pipeline was broken down by the following characteristics.

Cancer type

Cancer types are coded using the Medical Dictionry for Regulatory Activities (MedDRA) Preferred Terms terminology. MedDRA is a hierarchical classification system used for regulatory submissions, surveillance, and clinical trial registries, and it is embedded in the IHSI Database‘s automated processes. The Preferred Terms describe a condition more broadly than Lowest Level Terms but more specifically than System Organ Class (SOC), enabling distinctions among various cancer types.

Highest stage of development

The highest stage of development corresponds to the most advanced clinical trial in this sequence, from lowest to highest: Phase 1 — 1/2 — 2 — 2/3 — 3. Products under the evaluation of EMA‘s Committee for Medicinal Products (CHMP) at the time of data extraction are presented separately in the accompanying visualisation.

Expected European Commission (EC) Authorisation Date

This refers to the timeframe in which the EU marketing authorisation is expected, typically granted two months after a positive CHMP opinion is issued. It is reported as a combination of month and year. As this information is generally unavailable

[2] Explanations of the methodologies underlying the IHSI Database fields presented in this section were adapted from the IHSI Glossary of Terms [7]



for products in development, IHSI has developed an algorithm to predict key regulatory milestones, particularly the expected submission of the marketing authorisation application (MAA) and the subsequent CHMP opinion. The algorithm integrates multiple types of horizon-scanning signals, including primary completion dates for pivotal clinical trials, company announcements, EMA documentation, and other publicly available third-party sources. Given the numerous scientific, regulatory, and commercial factors that influence the timing of regulatory review and approval, these estimates should be interpreted as indicative rather than definitive.

Drug class

Drug class labels from the IHSI database were consolidated into broader pharmacological categories to enable meaningful comparison across the pipeline. Where a finer-grained breakdown was deemed useful, notably for small-molecule targeted therapies, subcategories by molecular target family were also distinguished. As there is no established drug class hierarchy, drug classes of pipeline products are currently coded in the IHSI database with inconsistent nomenclature. Work is ongoing within the IHSI database to develop a standardised method for reporting drug classes and tracking emerging drug classes. In the meantime, to mitigate this issue, the Claude AI model Opus 4.6 was first tasked with creating a scientifically plausible taxonomy of pharmacological categories based on drugs' mechanism of action and modality, and subsequently with grouping the raw data into these categories. The scientific soundness of the resulting categorisation was reviewed and verified by the authors

EMA Submission type

A MAA can be submitted to EMA as either a New medicine application, a Type II variation, or an Extension of marketing authorisation. A new medicine is a brand name that has not previously been authorised for any indication by EMA. This applies to novel compounds as well as new biosimilars and generics, although this report includes only originators. Where a brand name has previously been authorised in the EU, the marketing authorisation holder may expand the terms of the authorisation by applying for either a Type II variation or an Extension. The distinction between these two pathways is outlined in the Factbox below.

EMA Regulatory Designations

Three EMA designation schemes were considered: Orphan, PRIME (PRIority MEdicines), and Advanced Therapy Medicinal Product (ATMP) classification. These designations share the benefit of ena-bling accelerated development and assessment to me-dicinal products that qualify for the access. For a brief explanation of these schemes, please check the Factbox below. Products classified as „Potential ATMP“ — indicating that ATMP eligibility has been flagged by the IHSI database but not yet formally confirmed — are reported separately from confir-med ATMPs to distinguish between established and anticipated regulatory status.

Indication-related specifications

The anticipated indication wording for which each medicinal product is expected to be authorised in the EU is also estimated by the IHSI. This indicati-on-related information can be broken down across these four dimensions: target age group, stage of disease it is intended to treat, place in treatment (mostly treatment lines), and whether it is expec-ted to be a combination therapy. The following age groups were considered: adults and elderly; adole-scents; and paediatric population (children, and/or infants and toddlers).

Stage of disease is broadly split into advanced- and early-stage cancers. Place in treatment distinguis-hes first-line treatment from second-line and later-line treatments. Products expected to be used in combination with other therapies are distinguished from monotherapies.

Cost

The IHSI Database aims to estimate the per-patient, per-year cost of treatment using cost data from var-ious sources. Cost estimates are reported using five tiers predefined in the IHSI Database:

- Tier 1 (up to €1,000),
- Tier 2 (€1,001 to €25,000),
- Tier 3 (€25,001 to €150,000),
- Tier 4 (€150,001 to €750,000), and
- Tier 5 (above €750,000).

Cost information is not yet available for all pipeline products; the proportion with available estimates is reported alongside the tier distribution.

It should be noted when reading this report that information on the development of medicinal pro-ducts is subject to considerable uncertainty, and predicting when products will reach particular de-velopmental and regulatory milestones is inherent-ly imprecise. International publications describe cli-nical-stage attrition rates of up to 40% (or Phase III to approval) [8, 9], although they can vary substan-tially depending on the technology platform and therapeutic area. Factors that may affect the rea-lisation of projected timelines include clinical trial failures, regulatory delays, shifts in global health policy, and changes in commercial strategy. This should be borne in mind particularly when inter-preting the expected EC authorisation timeline and MAA submission-related projections presented in this report.

FACTBOX 1

EMA Submission types:

Commission Regulation (EC) No 1234/2008 (the Variations Regulation) defines a **Type II variation** as a major variation to the previously granted marketing authorisation that may have a significant impact on the quality, safety or efficacy of a medicinal product, but does not fulfil the conditions for extension of a marketing authorisation. Examples include the addition of a new therapeutic indication, major changes to manufacturing processes, or other changes that may significantly affect the product's quality, safety or efficacy.

Certain changes to a marketing authorisation are considered to fundamentally alter the terms of the initial marketing authorisation and therefore cannot be granted following a Type II variation procedure. These changes are to be submitted as **‚Extensions of marketing authorisations'.** Two main categories of changes requiring an extension of marketing authorisation' are following: changes to the active substance and changes to the strength, pharmaceutical form and route of administration [10].

FACTBOX 2

EMA Regulatory Designations:

ATMPs are defined by EMA as medicines for human use that are based on genes, tissues or cells. Main types include: gene therapy medicines, somatic-cell therapy medicines, and tissue-engineered medicines; some ATMPs may also contain medical devices as a part of the medicine. The classification of a medicinal product as ATMP is a voluntary EMA procedure governed by Regulation (EC) No 1394/2007 with the potential to grant health technology developers (HTDs) several regulatory and commercial advantages.

Given the voluntary status of the classification procedure, IHSI identifies the medicinal products which meet the criteria set out in Regulation No 1394/2007 and classifies them as ‚Potential ATMPs'.

Orphan designation is granted to medicinal products that show promise in treatment, prevention, or diagnosis of life threatening or chronically debilitating diseases affecting fewer than 5 in 10,000 people in the EU or offering low returns on R&D investment. The incentives to HTDs include access to scientific advice, reduced fees, and 10-year market exclusivity.

PRiME is an EMA scheme designed to support and optimise the development and assessment of medicines targeting unmet medical needs. The main advantage to HTDs lies in earlier and more intensive regulatory support, such as early dialogue and scientific advice, eligibility for accelerated assessment, among others. It is a highly selective scheme focusing on the most promising medicines with the potential to deliver a major therapeutic advantage: the acceptance rate in 2025 was 29% (16 of 56 applicants were accepted) [3].

For further details on the EMA submission types and regulatory designations, please consult the official website of EMA at link https://www.ema.europa.eu/en/human-regulatory-overview

STEP 3: Selection of medicinal products deemed impactful

The second section of the Results presents a shortlist of selected medicinal products accompanied by brief profiles.

Hospital-based stakeholders and clinical experts identified medicinal products considered potentially highly impactful for the Austrian hospital sector. This includes products expected to be used at the interface of inpatient and outpatient care, as well as those that may lead to shifts in care provision between sectors. For the purposes of this pilot project, high impact was defined broadly as the potential to meaningfully change patient health outcomes and disease management while affecting healthcare costs, resource utilisation, and the organisation and delivery of care in Austria.

The primary inclusion criteria applied by our hospital and clinical experts at the time of the selection were following:

- EMA submission type= New medicine application
- Expected CHMP opinion in year 2027
- Route of administration and pharmaceutical form signalling the intramural administration.

There were no further explicitly defined inclusion or exclusion criteria, but the hospital and clinical experts outlined these rationales that guided their prioritisation:

- High expected economic impact,
- Disruptive mechanism of action,
- Combination therapy potential,
- Ultra-orphan therapies,
- Infrastructure demands,
- Regulatory accelerations, especially from the U.S. Food and Drug Administration (FDA),
- Inclusion of the medicinal product in the IHSI High Impact Report series.

The characteristics of the selected medicinal products were compared with those of the overall oncology pipeline across the dimensions described in the Snapshot of the pipeline section. The results of this comparative analysis are presented in the Results section. It should be noted that the selection methodology used in this first pipeline monitor reflects the pilot phase of the project and should therefore be considered exploratory. In future editions, the selection process is intended to become more explicit, transparent, and reproducible through the application of predefined criteria for identifying high-impact pipeline products. Further details are discussed in the Interpretation of findings.

The last part of the Results section features summary profiles of the selected medicinal products. Each profile includes the following information:

- Active compound and drug class (as it appears in the IHSI database and the respective category),
- Astimated indication,
- Estimated size of the eligible population in Austria,
- Registrational clinical trial and its phase,
- Health technology developer,
- Estimated EC authorisation timeline,
- Maximum duration of related patent protection and
- Selected record attributes (EMA designations, combination therapy, paediatric target population, under CHPM evaluation, Austria among clinical trial sites),
- Expected cost tier.

The estimated size of the eligible population in Austria was derived using the incidence rate provided in the IHSI Database. The crude incidence or prevalence rates of the given condition in Europe



are narrowed down by the IHSI using published epidemiological data on the prevalence of indication-specific characteristics (e.g. biomarker status, disease stage, or prior treatment history) to approximate the population meeting the expected indication wording.

Patent expiry was considered an additional contextual indicator for decision-makers, as it may provide an indication of the potential timing of generic or biosimilar competition and, consequently, of future changes in medicine expenditure. The information should, however, be interpreted as an estimate of the maximum duration of patent protection and does not necessarily correspond to the actual date of loss of market exclusivity or the expected timing of generic or biosimilar entry. As patent information is not provided in the IHSI Database, additional research was conducted to estimate the remaining duration of patent protection for selected medicines included in the oncology pipeline monitor. For this purpose, annual reports on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) were reviewed. Companies whose securities (stocks) are publicly traded in the United States are required under the Securities Exchange Act of 1934 to file a 10-K report each year, giving a comprehensive overview of their business, financial condition and key risks. Under Item 101 of SEC Regulation S-K, companies must describe the duration and effect of patents that are material to their business. Pharmaceutical and biotechnology companies therefore routinely disclose patent information, as the loss of market exclusivity for a product can substantially affect future revenues and is thus of direct relevance to investors. This information is often presented in tabular form, listing for each product or product candidate:

- The type of patent (e.g., composition of matter, method of use, formulation or manufacturing process),
- The jurisdictions covered (typically the United States, Europe and Japan),
- The expected expiry dates.

Some companies also indicate whether these dates include, or may be prolonged by, patent term extensions in the United States or supplementary protection certificates in the EU. Some also report regulatory exclusivities such as data or orphan market exclusivity. Where available, the latest reported patent expiry date relevant to the medicinal product was used to estimate the maximum duration of market exclusivity.

RESULTS

Snapshot of the oncology pipeline

The oncology pipeline comprises a total of 377 records with expected CHMP opinion until December 2028 (see complete list in Appendix). It is composed of 236 active compounds; of these, 155 (65.7%) are associated with a single indication, while 81 (34.3%) are under development for multiple indications. The most extensively represented active compounds in the pipeline are durvalumab and datopotamab deruxtecan, each in development across 13 indications, followed by pembrolizumab with 11 indications. As all three are already authorised in the EU, the associated records represent Type II variation applications for extensions of indication.

Cancer types

The pipeline spans 70 distinct cancer types as classified by MedDRA Preferred Terms. Overall, solid tumor indications account for 278 records (73.7%) and haematological malignancies for 99 records (26.3%). The six most represented conditions are non-small cell lung cancer (51 products; 13.5%), breast cancer (38; 10.1%), plasma cell myeloma (19; 5.0%), bladder transitional cell carcinoma, diffuse large B-cell lymphoma and small cell lung cancer (all three related to 16 products; 4.2%), together accounting for 41.2% of the oncology pipeline. Twenty-two conditions have more than five medicinal products in development, while the remaining 48 conditions (collectively comprising 89 records; 23.6%) each have fewer than five products in the pipeline (see Figure 1).

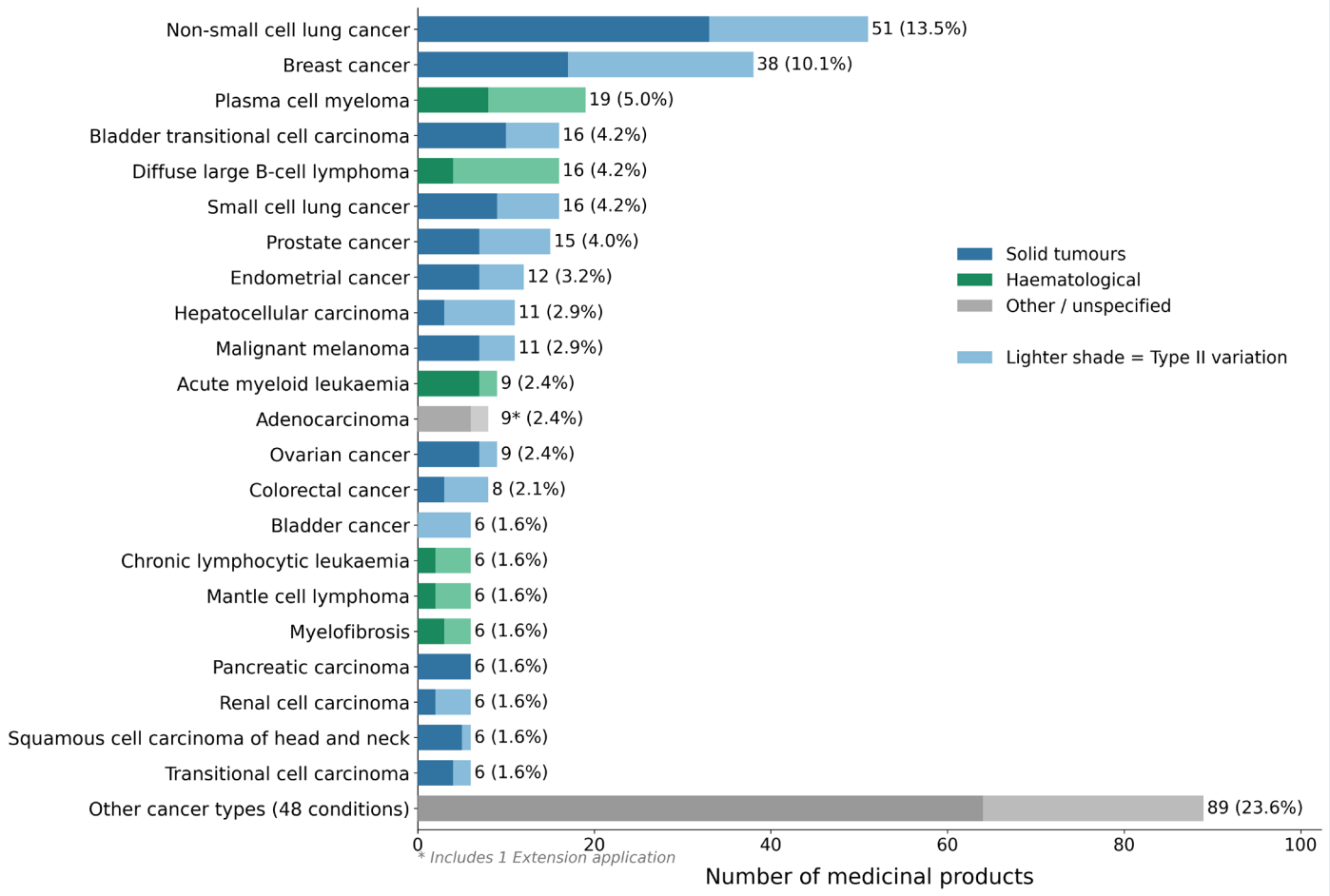
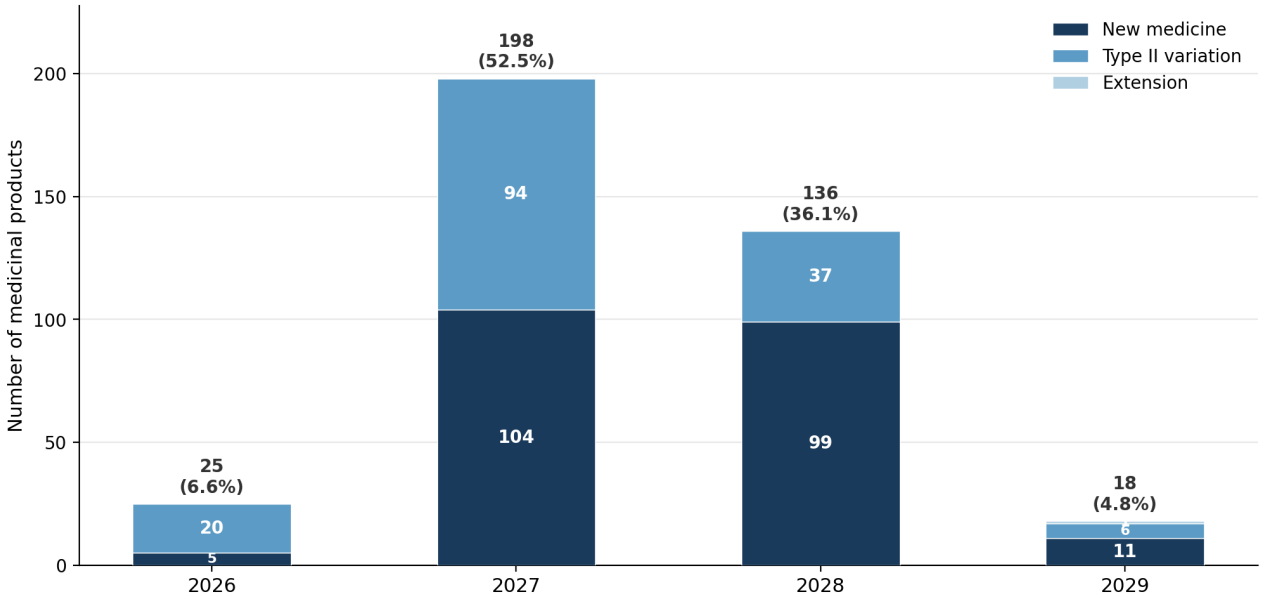


Figure 1: Pipeline composition by cancer types

EMA Submission types

Of the 377 records, 219 (58.1%) correspond to new medicine applications, 157 (41.6%) to Type II variation applications, and one (0.3%) to an extension application (for explanation of the three main EMA submission types, please refer to Factbox 1). The distribution of EMA submission types varies across expected authorisation years. In the remaining months of 2026, 80% (20 of 25) of the expected marketing authorisation approvals are expected to result from Type II variation applications. In 2027, the peak year with 198 anticipated authorisations, the split is expected to be approximately even between new medicine applications (104; 52.5%) and Type II variation applications (94; 47.5%). In 2028, new medicine applications are expected to account for the majority of approvals (99 of 136; 72.8%), with Type II variation applications expected to account for 37 approvals (27.2%) (see Figure 2).

Analysing the EMA submission types distribution across the leading cancer conditions, the non-small cell lung cancer pipeline consists predominantly of new medicine applications (33 of 51; 64.7%), whereas the breast cancer pipeline was predominantly composed of Type II variation applications (21 of 38; 55.5%). At the extremes of this spectrum, pancreatic carcinoma stood out as the only condition with more than 5 pipeline records, all of which were new medicine applications (6 of 6). Bladder cancer, conversely, was the only condition with a comparable pipeline size composed entirely of Type II variation applications (6 of 6), indicating that pipeline activity is driven exclusively by already approved products (all immune checkpoint inhibitors) undergoing further development for new indications, rather than by novel active compounds.



	2026	2027	2028	2029	Total
New medicine	5	104	99	11	219
Type II variation	20	94	37	6	157
Extension	0	0	0	1	1
Total	**25**	**198**	**136**	**18**	**377**

Figure 2: Pipeline composition by EMA submission types

Highest stage of development

The majority of pipeline products has reached Phase 3 clinical trial level of development (239; 63.4%), followed by Phase 2 (52; 13.8%), Phase 1/2 (35; 9.3%), Phase 2/3 (14; 3.7%), and Phase 1 (5; 1.3%). Additional 32 products (8.5%) were under evaluation by the CHMP at the time of data extraction. Among these, the vast majority (28; 87.5%) have completed Phase 3 trials, while two have Phase 2 data, one has Phase 1/2 data, and, notably, one product (cosibelimab for cutaneous squamous cell carcinoma) is associated with a Phase 1 trial only only (see Figure 3).

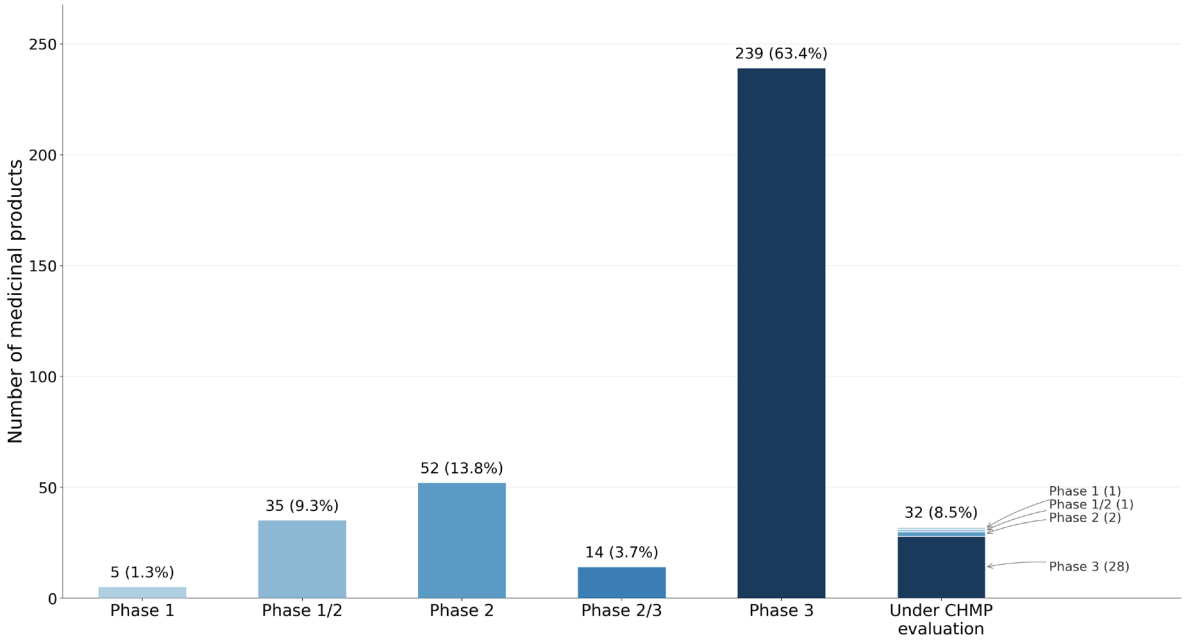


Figure 3: Pipeline composition by highest stage of development

Expected EC authorisation timeline

The chronological distribution of expected EC authorisations reveals a pronounced peak in the anticipated regulatory activity in 2027, when 52.5% of the pipeline products are expected to receive EC approval, followed by 2028 (36.1%). The single month with the highest amount of expected approvals is October 2027 (45 products), followed by August 2027 (34) and April 2028 (29). The period from February to October 2027 accounts for a substantial share of projected authorisations, consistent with the maturation of a large cohort of late-stage products approaching regulatory decisions. A gap is observed in December 2026, with no anticipated authorisations, followed by a rapid escalation into early 2027. Activity is expected to taper from mid-2028 onwards, with monthly counts generally ranging between 7 and 14 products through to February 2029 (see Figure 4).

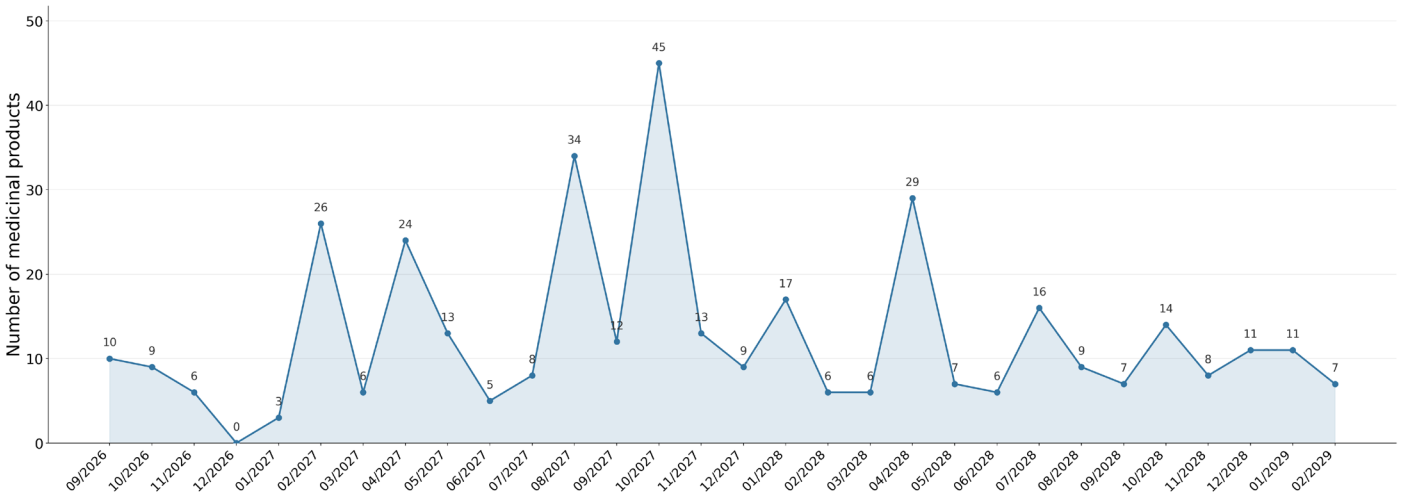


Figure 4: Pipeline composition by expected EC authorisation date

EMA regulatory designations

Three EMA regulatory designation schemes were examined in this analysis: Orphan, PRIME and ATMP classification. Each captures a different aspect of regulatory recognition and can signal medicines of particular relevance to healthcare systems. A detailed description of these designation schemes is provided in Factbox 2. Of the 377 records, 112 (29.7%) carry at least one confirmed EMA regulatory designation, while 265 (70.3%) have none. Orphan designation is the most prevalent, covering 101 records (26.8%), while both the PRIME designation and confirmed ATMP status are reported for 16 records (4.2%). An additional 33 records (8.8%) are classified as potential ATMPs, indicating that ATMP eligibility has been recorded by IHSI but not yet formally confirmed by the Committee for Advanced Therapies. Note that all ATMPs and potential ATMPs belong exclusively to the following drug classes: Cell & Gene Therapies, Cancer Vaccines and Oncolytic Virus Therapies, directly reflecting the definition of ATMPs (see Factbox 2).

Only two records hold all three confirmed designations (brexucabtagene autoleucel for mantle cell lyphoma and afamitresgene autoleucel for synovial sarcoma), with a further six records potentially meeting all three criteria if the potential ATMP status is formally confirmed. Among records with two confirmed designations (n=17), the most common pairing was orphan designation with PRIME designation (9 records). The majority of records with a single designation (n=93) hold Orphan designation as their sole designation (85 records), with six having a confirmed ATMP status (further 25 classified as potential ATMPs) and 2 holding PRIME designation only (see Figure 5).

Designations	Combination	Count	%
3 n=2	Orphan + PRIME + ATMP	**2**	0.5%
	additional Potential ATMPs	*6*	1.6%
2 n=17	Orphan + PRIME	**9**	2.4%
	Orphan + ATMP	**5**	1.3%
	additional Potential ATMPs	*1*	0.3%
	PRIME + ATMP	**3**	0.8%
	additional Potential ATMPs	*1*	0.3%
1 n=93	Orphan	**85**	22.5%
	ATMP	**6**	1.6%
	additional Potential ATMPs	*25*	6.6%
	PRIME	**2**	0.5%
0 n=265	*No EMA designation*	**265**	70.3%
	Total	**377**	100%

Figure 5: Pipeline composition by EMA designations

Drug class grouping

At the unique active compound level (n=236), products are classified into 11 top-level drug class categories. Small-molecule targeted therapies constitute the largest class (102 compounds; 43.2%), followed by cell and gene therapies (26; 11.0%), immune checkpoint inhibitors and bispecific antibody and T-cell engagers (18 each; 7.6%), other monoclonal antibodies (17; 7.2%), and antibody-drug conjugates (16; 6.8%). Cytotoxic chemotherapy accounted for 10 compounds (4.2%), cancer vaccines and radiopharmaceuticals for 6 each (2.5%), and oncolytic virus therapies for 4 (1.7%). Thirteen compounds (5.5%) could not be assigned to a specific category.

Within the small-molecule targeted therapies, the breakdown by target shows that receptor tyrosine kinase inhibitors represent the largest subcategory (29 compounds; 12.3% of the total pipeline), encompassing agents directed at EGFR, HER2, ALK, ROS1, RET, c-MET, KIT, FGFR, and VEGFR targets.

Serine/threonine and pathway kinase inhibitors (13; 5.5%), targeting BRAF/RAF, CDK, PI3K/AKT/mTOR, and checkpoint kinases, constituted the second-largest subcategory. Hormone and endocrine therapies and epigenetic modulators are equally represented (11 each; 4.7%), followed by non-receptor tyrosine kinase inhibitors and other targeted small molecules (9 each; 3.8%). Apoptosis and protein homeostasis agents account for 8 compounds (3.4%), RAS/KRAS pathway inhibitors for 7 (3.0%), and PARP inhibitors for 5 (2.1%) (see Figure 7).

It should be noted that, with a few exceptions (gedatolisib, leuprolide acetate, nanvuranlat, nibrozetone, octreotide, tambiciclib, trilaciclib, and zilovertamab vedotin), all small-molecule targeted therapies with available information on pharmaceutical form are intended for oral administration and therefore fall largely outside the scope of intramural sector.

#	Drug Class (Grouped)	Count	%
1	Small-Molecule Targeted Therapies	**102**	43.2%
2	Cell & Gene Therapies	**26**	11.0%
3	Immune Checkpoint Inhibitors	**18**	7.6%
4	Bispecific Antibody & T-Cell Engagers	**18**	7.6%
5	Other Monoclonal Antibodies	**17**	7.2%
6	Antibody-Drug Conjugates	**16**	6.8%
7	Other	**13**	5.5%
8	Cytotoxic Chemotherapy	**10**	4.2%
9	Cancer Vaccines	**6**	2.5%
10	Radiopharmaceuticals	**6**	2.5%
11	Oncolytic Virus Therapies	**4**	1.7%
	Total	**236**	100%

Figure 6: Pipeline composition by major drug classes

Within the small-molecule targeted therapies, the breakdown by target showed that receptor tyrosine kinase inhibitors represent the largest subcategory (29 compounds; 12.3% of the total pipeline), encompassing agents directed at EGFR, HER2, ALK, ROS1, RET, c-MET, KIT, FGFR, and VEGFR targets. Serine/threonine and pathway kinase inhibitors (13; 5.5%), targeting BRAF/RAF, CDK, PI3K/AKT/mTOR, and checkpoint kinases, constituted the second-largest subcategory. Hormone and endocrine therapies and epigenetic modulators are equally represented (11 each; 4.7%), followed by non-receptor tyrosine kinase inhibitors and other targeted small molecules (9 each; 3.8%). Apoptosis and protein homeostasis agents account for 8 compounds (3.4%), RAS/KRAS pathway inhibitors for 7 (3.0%), and PARP inhibitors for 5 (2.1%) (see Figure 7). It should be noted that, with a few exceptions (gedatolisib, leuprolide acetate, nanvuranlat, nibrozetone, octreotide, tambiciclib, trilaciclib, and zilovertamab vedotin), all small-molecule targeted therapies with available information on pharmaceutical form are intended for oral administration and therefore fall largely outside the scope of intramural sector.

SM	**Small-molecule targeted therapies**	**102**	43.2%
●	**Receptor tyrosine kinase inhibitors** (EGFR, HER2, ALK, ROS1, RET, c-MET, KIT, FGFR, VEGFR)	**29**	12.3%
●	**Serine/threonine & pathway kinase inhibitors** (BRAF/RAF, CDK, PI3K/AKT/mTOR, CHK)	**13**	5.5%
●	**Hormone & endocrine therapies** (SERDs, AR antagonists, GnRH, GR modulators)	**11**	4.7%
●	**Epigenetic modulators** (HDAC, EZH2, BET, menin-MLL, LSD1)	**11**	4.7%
●	**Non-receptor tyrosine kinase inhibitors** (BTK, BCR-ABL, JAK, CSF-1R)	**9**	3.8%
●	**Other targeted small molecules** (IDH, HIF-2α, Notch, SST, etc.)	**9**	3.8%
●	**Apoptosis & protein homeostasis** (BCL-2, cereblon/CELMoD, MDM2/p53, exportin)	**8**	3.4%
●	**RAS/KRAS pathway inhibitors**	**7**	3.0%
●	**PARP inhibitors**	**5**	2.1%

Figure 7: Small-molecule targeted therapies by target groups



The pipeline does not include any first-in-class product, i.e., prototype drugs introducing a completely novel mechanism of action to treat a particular medical condition. However, the first-in-class status is normally assigned only retrospectively, following regulatory approval, particularly by the FDA.

Combining the drug class grouping with the EMA submission types demonstrates that Immune Check-point Inhibitors, Bispecific Antibody & T-Cell Engagers, and ADCs are predominantly represented by already approved medicinal products undergoing further indication development through Type II variation applications. By contrast, Cancer Vaccines (100% new medicine applications), Oncolytic Virus Therapies (100%), Radiopharmaceuticals (80%), as well as Cytotoxic chemotherapies (82%) and Cell & Gene therapies (69%), are mostly novel compounds expected to be submitted as new medicine applications. A cross-tabulation by expected authorisation timeline is consistent with this pattern: immune checkpoint inhibitors, despite accounting for the largest share of the early pipeline (17% of combined 2026 and 2027 authorisations), decline markedly in the later period (7% of combined 2028 and 2029 authorisations), which may suggest that the scope for further indication expansion is becoming more limited for this established therapeutic modality. ADCs, also driven largely by Type II variations, show a different trajectory (7% to 12%), which may indicate that this platform is at an earlier stage of its indication-expansion cycle. Smaller modalities such as cancer vaccines and radiopharmaceuticals also show a proportionally greater presence in the later pipeline, although the small absolute numbers warrant cautious interpretation. These shifts should, however, be interpreted cautiously given the uncertainty associated with later-pipeline estimates.

Indication-related specifications

- **Age group:** The overwhelming majority of pipeline medicinal products are intended for the adult population only (345; 91.5%). Thirty-two products (8.5%) include adolescents within the target age group of their estimated indication, while 18 include children, and 11 also include infants and toddlers. Two medicinal products are developed exclusively for paediatric populations (infants, toddlers, children, and adolescents) (see Figure 8). The conditions most frequently represented in the paediatric-inclusive pipeline (n=32) are acute myeloid leukaemia (5 products), malignant melanoma (3), and synovial sarcoma (3).
- **Combination therapies:** 195 of the pipeline products (51.7%) are combination therapies, while 182 (48.3%) are monotherapies. Chemotherapy is the dominant backbone partner (present in 59 combination regimens), followed by immune checkpoint inhibitors mentioned in 47 various combination regimens (of which 23 contain pembrolizumab).
- **Place in treatment and stage of disease:** Broadly, 124 indications (32.9%) are intended for first-line treatment, the vast majority targeting advanced or metastatic disease (at least 82). Only 43 indications in the overall pipeline (11.4%) were clearly identifiable as targeting early-stage or resectable cancers (15 in first-line early-stage settings and 28 in adjuvant or neoadjuvant settings), which underscores the predominant focus of oncology pipeline development on advanced, relapsed, or refractory disease.

	Only adults and elderly	Also for adolescents	Also for children and adolescents	Total
Adult and elderly	345	14	16	**375**
Paediatric only	-	-	2	**2**
Total	**345**	**14**	**18**	**377**

Figure 8: Pipeline composition by target population based on age

Cost

More than half of the pipeline records (192, 50.9%) had cost estimates available in the IHSI Database. Most pipeline records with available cost estimates qualify for Tier 3 (Estimated European Cost of €25,001 to €150,000)- 124 (32.8% of the overall pipeline); followed by Tier 4 (Estimated European cost of €150,001 to €750,000) with 49 products (13.0% of the pipeline). No product has an estimated per-year per-patient cost exceeding €750,000 (see Figure 9).

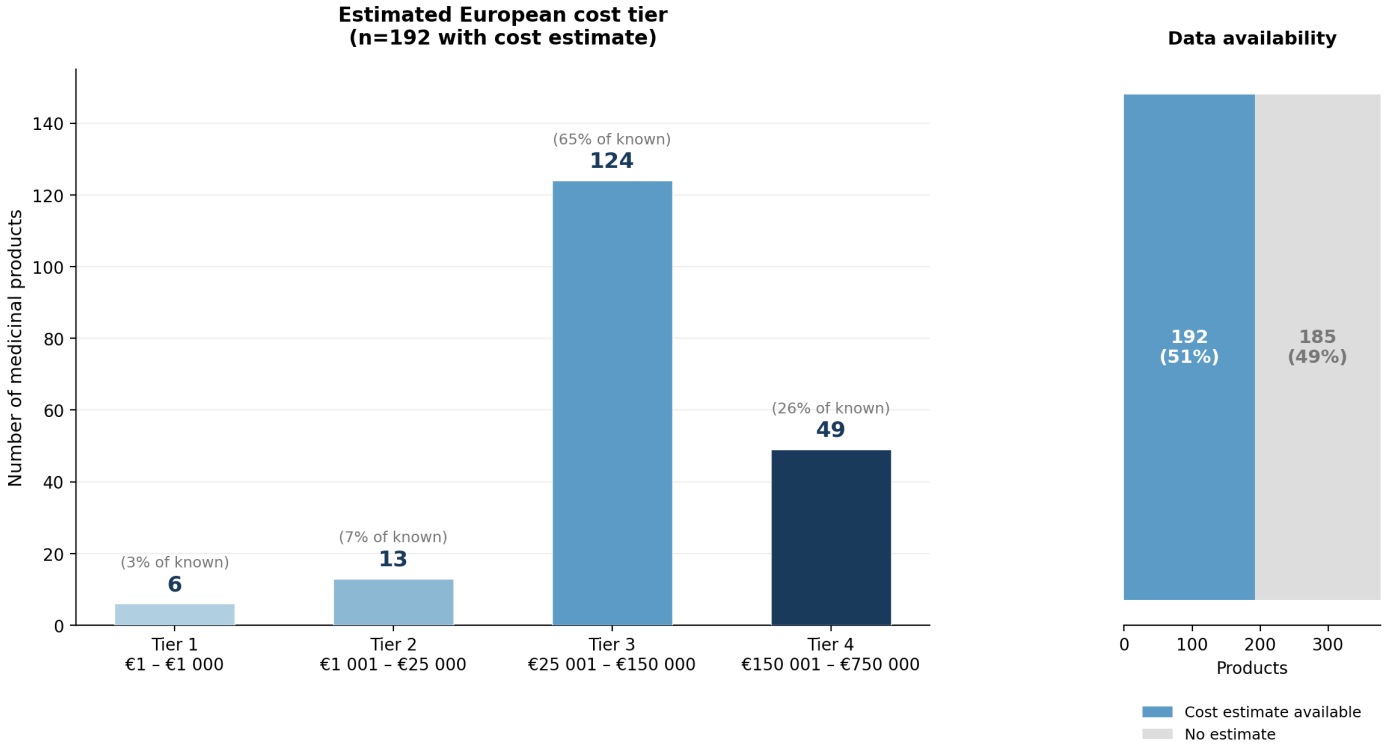


Figure 9: Cost distribution of the pipeline

Selected medicinal products deemed highly impactful

Characterisation of the selected medicinal product

The hospital and clinical experts involved in the selection prioritised 20 medicinal products developed for 25 indications. This is how they compare to the overall oncology pipeline across the chosen dimensions:

- **Cancer types:** The selection spans 20 distinct cancer types and includes rare cancer types that have only a minor representation in the overall pipeline, such as blastic plasmacytoid dendritic cell neoplasia, synovial sarcoma, osteosarcoma, pleural mesothelioma, and Waldenström's macroglobulinaemia. At the same time, multiple products were selected for the two most represented pipeline conditions- non-small cell lung cancer (3) and breast cancer (2), as well as small cell lung cancer (2); therefore, we present the medicinal products for the lung cancer in a separate table.
- **Submission types:** The selection contains only one Type II variation (tarlatamab, which was classified as a new medicine at the time of the prioritisation). New medicine applications account for 58% of records pipeline-wide.
- **Highest stage of development:** The selection is dominated by products in Phase 2 of development, which represent 52% of the selection, compared with only 14% of the overall pipeline. Two products are currently under CHMP evaluation (compared to 9% of the overall pipeline): one based on Phase 2 registrational trial data and one based on Phase 3 data.
- **Expected EC authorisation timeline:** With the exception of two products expected to be authorised in the first quarter of 2028, all selected products are expected to receive EU marketing authorisation in 2027, which is the peak year for regulatory activity in the overall pipeline (53% of products).
- **EMA designations:** Nearly half of the selected products carry at least one EMA designation, the orphan designation (27% in the overall pipeline). Three of these products have been granted an additional PRIME designation (compared with only nine products with both Orphan and PRIME designations in the overall pipeline), and one also holds confirmed ATMP status (compared with only five products with both Orphan designation and confirmed ATMP status pipeline-wide). Among the selected products without any confirmed EMA designation, six carry at least a potential ATMP status (24% of the selection, compared with 7% of the overall pipeline).
- **Drug class grouping:** The selection is disproportionately represented by cell & gene therapies (11% of the overall pipeline vs 30% of the selection), while small-molecule targeted therapies are represented by only one selected product. The selection also prioritised medicinal products from innovative drug classes with only a minor pipeline representation: oncolytic virus therapies (two selected products out of four in the overall pipeline), radiopharmaceuticals and cancer vaccines (one selected product out of six in each class).
- **Paediatric population:** Of the 32 pipeline products with an indication covering adolescents, four were selected (representing 16% of the selected products and 9% of the overall pipeline). However, none of the selected products has an indication for children below 10 years of age
- **Combination therapies:** Eleven of the 25 selected indications (44.0%) are combination therapies, with chemotherapy as the most common backbone (included in 5 regimens).
- **Place in treatment:** Six of the selected indications (24.0%) are intended for the first-line setting, a lower proportion than in the overall pipeline (32.9%). None of the selected products targets an early-stage or resectable disease setting, indicating a clear orientation toward advanced, persistent, or recurrent disease, predominantly in second-line or later treatment settings.
- **Cost:** No cost estimates were available for 13 of the selected products (52%). Seven selected products belong to cost Tier 4 (13.0% of the overall pipeline vs 28.0% of the selection), and four to Tier 3 (32% of the overall pipeline, 17% of the selection).

In addition to the analysed characteristics, the selection stands out for the increased **FDA regulatory engagement.** 72% of the selection has already been approved or is under review by the FDA, compared to just 23% of the overall pipeline. The FDA Designations also differentiate the selection from the overall pipeline, with a significant representation of products with Breakthrough Therapy (56% selection vs 16% pipeline) and Priority Review designations (44% selection vs 13% pipeline).

Profiles of the selected MPs

Key attributes (illustrated with pictograms in the final report)

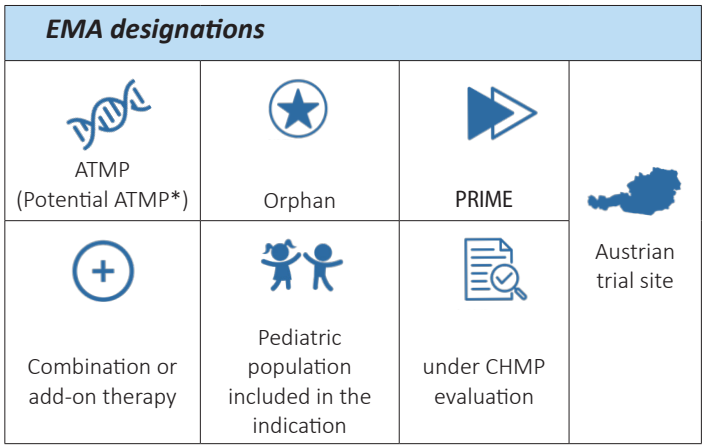
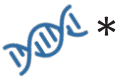


Table 1: Medicinal products selected for lung cancer indications

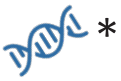
Compound name and drug class (categorised)	Indication and estimated eligible population in Austria	Estimated Cost Tier	Attributes	Registrational trial and phase	Developer	Timeline
Ifinatamab deruxtecan B7-H3–directed antibody-drug conjugate *(Antibody-Drug Conjugates)*	Condition: Small cell lung cancer Place in treatment: second line or later Stage of disease: extensive stage Estimated eligible population in Austria: 158-222 patients	Not available		NCT05280470 Phase 2	Daiichi Sankyo	Est. EC approval: 09/2027 Max. patent protection: 2034
Sintilimab Anti-PD-1 monoclonal antibody *(Immune Checkpoint Inhibitors)*	Condition: Non-small cell lung cancer Place in treatment: first line Stage of disease: advanced or metastatic Disease specific: non-squamous Combination agents: pemetrexed and platinum Estimated eligible population in Austria: 1998-2066 patients	Tier 3 (€25 001 to €150 000)		NCT03607539-not confirmed as registrational Phase 3	Eli Lilly	Est. EC approval: 02/2027
Tarlatamab DLL3-Targeted Bispecific T-Cell Engager *(Bispecific Antibody & T-Cell Engagers)*	Condition: Small cell lung cancer Place in treatment: third line or later Stage of disease: relapsed/ refractory Estimated eligible population in Austria: 68-138 patients	Tier 3 (€25 001 to €150 000)		NCT05060016 Phase 2	Amgen	Est. EC approval: 10/2027 Max. patent protection: 2036

Compound name and drug class (categorised)	Indication and estimated eligible population in Austria	Estimated Cost Tier	Attributes	Registrational trial and phase	Developer	Timeline
Telisotuzumab vedotin Antibody drug conjugate (Antibody-Drug Conjugates)	Condition: Non-small cell lung cancer Place in treatment: second line or later Stage of disease: locally advanced or metastatic Disease specific: c-Met over-expressing, EGFR wild-type non-squamous Estimated eligible population in Austria: 212 patients	Tier 3 (€25 001 to €150 000)		NCT03539536, NCT04928846 Phase 3	AbbVie	Est. EC approval: 10/2027 Max. patent protection: Undefined: between 2026 and 2040
Zenocutuzumab HER2 and HER3 bispecific antibody (Bispecific Antibody & T-Cell Engagers)	Condition: Non-small cell lung cancer Place in treatment: second line Stage of disease: locally advanced unresectable or metastatic Disease specific: NRG1 fusion-positive Estimated eligible population in Austria: 4 patients	Tier 4 (€150 001 to €750 000)		NCT02912949 Phase 2	Genmab	Est. EC approval: 09/2027 Max. patent protection: Earliest 2035, latest 2043

Table 2: Medicinal products selected for other indications

Compound name and drug class (categorised)	Indication and estimated eligible population in Austria	Estimated Cost Tier	Attributes	Registrational trial and phase	Developer	Timeline
Anitocabtagene autoleucel BCMA-directed CAR-T cell therapy *(Cell & Gene Therapies)*	Condition: Plasma cell myeloma Place in treatment: fourth line or later Stage of disease: relapsed or refractory Estimated eligible population in Austria: 111 patients	Tier 4 (€150 001 to €750 000)		NCT05396885 Phase 2	Gilead Sciences	Est. EC approval: 01/2028 Max. patent protection: 2038
Camrelizumab Anti-PD-1 monoclonal antibody *(Immune Checkpoint Inhibitors)*	Condition: Hepatocellular carcinoma Place in treatment: first line Stage of disease: advanced Estimated eligible population in Austria: 120-148 patients	Tier 2 (€1001 to €25 000)		NCT03764293 Phase 3	HLB Therapeutics	Est. EC approval: 10/2027
Cretostimogene grenadenorepvec Oncolytic immunotherapy (*Oncolytic Virus Therapies)*	Condition: Bladder transitional cell carcinoma Place in treatment: second line Stage of disease: persistent or recurrent Estimated eligible population in Austria: 36-41 patients	Tier 4 (€150 001 to €750 000)		NCT04452591 Phase 3	CG Oncology	Est. EC approval: 09/2027 Max. patent protection: patents expiration between 2036 and 2038

Compound name and drug class (categorised)	Indication and estimated eligible population in Austria	Estimated Cost Tier	Attributes	Registrational trial and phase	Developer	Timeline
Gedatolisib pan-PI3K/mTOR inhibitor (*Small-Molecule Targeted Therapies)*	Condition: Breast cancer Place in treatment: second line or later Stage of disease: locally advanced or metastatic Combination agent: fulvestrant Estimated eligible population in Austria: 313-922 patients	Not available		NCT05501886 Phase 3	Celcuity	Est. EC approval: 10/2027 Max. patent protection: December 2029
Gedatolisib pan-PI3K/mTOR inhibitor (Small-Molecule Targeted Therapies)	Condition: Breast cancer Place in treatment: second line or later Stage of disease: locally advanced or metastatic Combination agent: fulvestrant and palbociclib Estimated eligible population in Austria: 313-922 patients	Not available		NCT05501886 Phase 3	Celcuity	Est. EC approval: 03/2028 Max. patent protection: December 2029
Igv-001 Cell therapy *(Cell & Gene Therapies)*	Condition: Glioblastoma Place in treatment: first line Stage of disease: newly diagnosed Combination agents: radiotherapy and temozolomide Estimated eligible population in Austria: 101 patients	Not available		NCT04485949 Phase 2	Imvax	Est. EC approval: 10/2027
Iopofosine i 131 Ionising radiation emitters *(Radiopharmaceuticals)*	Condition: Lymphoplasmacytoid lymphoma/immunocytoma Place in treatment: third line or later Estimated eligible population in Austria: 17 patients	Not available		NCT02952508 Phase 2	Cellectar Biosciences	Est. EC approval: 09/2027 Max. patent protection: likely until 2034/ 2035 (without extension)
Iopofosine i 131 Ionising radiation emitters *(Radiopharmaceuticals)*	Condition: Waldenstrom's macroglobulinaemia Place in treatment: third line or later Stage of disease: relapsed or refractory Estimated eligible population in Austria: 17 patients	Not available		NCT02952508 Phase 2	Cellectar Biosciences	Est. EC approval: 09/2027 Max. patent protection: likely until 2034/ 2035 (without extension)
Letetresgene autoleucel T-cell receptor (TCR) therapy (*Cell & Gene Therapies)*	Condition: Synovial sarcoma Place in treatment: second line or later Stage of disease: advanced (metastatic or unresectable) Estimated eligible population in Austria: 2 patients	Tier 4 (€150 001 to €750 000)		NCT03967223 Phase 2	US WorldMeds	Est. EC approval: 09/2027

Compound name and drug class (categorised)	Indication and estimated eligible population in Austria	Estimated Cost Tier	Attributes	Registrational trial and phase	Developer	Timeline
Lifileucel Tumor infiltrating lymphocytes (TILs) *(Cell & Gene Therapies)*	Condition: Cervix carcinoma Place in treatment: second line or later Stage of disease: recurrent, metastatic, or persistent Estimated eligible population in Austria: 1 patient	Tier 4 (€150 001 to €750 000)		NCT03108495 Phase 2	Iovance Biotherapeutics	Est. EC approval: 01/2028 Max. patent protection: 2042
Orca-t Allogenic cellular therapy *(Cell & Gene Therapies)*	Condition: Haematological malignancy Stage of disease: advanced Combination agents: tacrolimus Estimated eligible population in Austria: 1.198 patients	Not available		NCT05316701 Phase 3	Orca Bio	Est. EC approval: 09/2027
Ost31-164 Immunotherapeutic vaccine *(Cancer Vaccines)*	Condition: Osteosarcoma Place in treatment: maintenance Stage of disease: resected, pulmonary recurrent Estimated eligible population in Austria: 8-12 patients	Not available		NCT04974008 Phase 2	OS Therapies	Est. EC approval: 11/2027 Max. patent protection: between 2029 and 2038
Pegargiminase *Hydrolase enzyme (Other)*	Condition: Pleural mesothelioma Place in treatment: first line Stage of disease: unresectable malignant Combination agents: pemetrexed, cisplatin, and carboplatin Estimated eligible population in Austria: 166-175 patients	Not available		NCT02709512 Phase 2/3	Polaris	Est. EC approval: 09/2027
Penpulimab Anti PD-1 monoclonal antibody *(Immune Checkpoint Inhibitors)*	Condition: Nasopharyngeal cancer Place in treatment: first line Stage of disease: primary metastatic Combination agents: cisplatin and gemcitabine Estimated eligible population in Austria: 3-7 patients	Tier 3 (€25 001 to €150 000)		NCT04974398 Phase 3	Akeso	Est. EC approval: 09/2027
Pivekimab sunirine CD123-targeting antibody–drug conjugate *(Antibody-Drug Conjugates)*	Condition: Blastic plasmacytoid dendritic cell neoplasia Place in treatment: first line Disease specific: CD123-positive Estimated eligible population in Austria: 2 patients	Not available		NCT03386513 Phase 1/2	AbbVie	Est. EC approval: 10/2027

Compound name and drug class (categorised)	Indication and estimated eligible population in Austria	Estimated Cost Tier	Attributes	Registrational trial and phase	Developer	Timeline
Vusolimogene oderparepvec Genetically modified oncolytic viral therapy *(Oncolytic Virus Therapies)*	Condition: Malignant melanoma Place in treatment: second line Stage of disease: advanced Combination agents: nivolumab Estimated eligible population in Austria: 240-323 patients	Not available		NCT03767348 Phase 3	Replimune	Est. EC approval: 10/2027 Max. patent protection: 12 years from granted biologic exclusivity period
Vusolimogene oderparepvec Genetically modified oncolytic viral therapy *(Oncolytic Virus Therapies)*	Condition: Neoplasm, Solid tumour Place in treatment: second line Disease specific: MSI-H or dMMR Combination agents: nivolumab Estimated eligible population in Austria: NA	Not available		NCT03767348 Phase 2	Replimune	Est. EC approval: 10/2027 Max. patent protection: 12 years from granted biologic exclusivity period
Zamtocabtagene autoleucel Bispecific targeted CD20/CD19 chimeric antigen receptor (CAR) T-cell therapy *(Cell & Gene Therapies)*	Condition: Diffuse large B-cell lymphoma Place in treatment: second line Stage of disease: relapsed/refractory Estimated eligible population in Austria: 43-111patients	Tier 4 (€150 001 to €750 000)		NCT04844866 Phase 2	Miltenyi Biomedicine	Est. EC approval: 04/2027
Zenocutuzumab HER2 and HER3 bispecific antibody *(Bispecific Antibody & T-Cell Engagers)*	Condition: Pancreatic carcinoma Place in treatment: second line Stage of disease: locally advanced unresectable or metastatic Disease specific: NRG1 fusion-positive Estimated eligible population in Austria: 1 patient	Tier 4 (€150 001 to €750 000)		NCT02912949 Phase 2	Genmab	Est. EC approval: 09/2027 Max. patent protection: February 2035

INTERPRETATION OF FINDINGS

Oncology pipeline snapshot

Innovation versus indication expansion

The oncology pipeline snapshot reveals a landscape shaped by two concurrent dynamics: the continued expansion of established therapeutic platforms into new indications, and the emergence of novel modalities targeting areas of high unmet need. On the one hand, the significant proportion of Type II variations (42%) indicates that a substantial portion of R&D activity is driven by indication broadening and extensions of established therapeutic platforms, especially for existing immune checkpoint inhibitors and targeted therapies. The near-even split between monotherapy and combination therapy reinforces this pattern. With many pipeline entries representing extensions or modifications of established combination regimens, innovation is characterised by incremental therapeutic advances and add-on costs for healthcare systems, as the new therapies are layered onto existing standards of care. By contrast, conditions with a high proportion of new medicine applications tend to be those associated with persistent unmet need, such as pancreatic carcinoma [11]as well as rare cancers such as synovial sarcoma. The concentration of novel medicines in these settings may reflect, at least in part, the role of regulatory incentives such as those derived from Orphan and PRiME designations in supporting development in areas of high unmet need.

The continued emphasis on precision oncology

The increasing granularity of indications, with the vast majority of products targeting precisely delineated populations defined by disease stage, prior treatment exposures, genomic alterations, and biomarker expression, underscores the continued fragmentation of cancer into molecularly distinct diseases. The pipeline suggests that by 2028, oncology is likely to become even more biomarker-driven, rendering treatment decisions increasingly dependent on sophisticated molecular and companion diag-nostics that enable more precise fpatient selection. While this precision promises clinical benefits through improved patient selection, an increased likelihood of treatment response and potentially fewer off-target toxicities, it also poses challenges for health systems in terms of diagnostic infrastructure requirements, as access to molecular testing may become a critical determinant of equitable access to innovative cancer care [12]. In addition, the narrowing of indications and, consequently, the decrease in the number of eligible patients for each therapy may create incentives for premium pricing of niche therapies.

The advanced-disease and adults-only bias

The pipeline is heavily oriented toward advanced and metastatic disease, with only 11% of indications clearly targeting early-stage and resectable cancers. This trend may reflect both scientific and regulatory considerations, as clinical development in advanced and heavily pre-treated populations may allow treatment effects to be evaluated in smaller and potentially shorter studies, making advanced disease an important regulatory entry point for many new therapies. The pipeline also provides comparatively limited coverage of paediatric oncology: only 8.5% of indications include adolescents and just 4.8% include children. However, it is important to recognise that therapies successfully developed in advanced disease or initially for adult populations can eventually be translated into use in earlier, curative-intent pathways and, where biologically appropriate, in paediatric populations. From a policymaker‘s perspective, this issue is particularly relevant, because the greatest population-level gains in cancer outcomes often arise from interventions delivered earlier in the disease course, as well as by therapies that improve outcomes for children. Therefore, it might be beneficial to consider whether existing development and regulatory incentives strike an appropriate balance between extending survival in advanced disease and improving cure rates.



Cost and access implications

Among the 192 products with available cost estimates, 90% exceeded the per-patient cost threshold of €25 000, with 49 products estimated to exceed €150 000. It should be noted that these costs represent only the acquisition costs of the medicinal products. The overall cost of treatment with these innovative therapies also includes genomic testing, administration in specialised treatment centres, monitoring requirements, and management of treatment-related toxicities. Coupled with the combination-regimen profiles of nearly half of the pipeline products, these findings suggest that health systems may face increasing budgetary pressure as these products reach the market.

Selected high-impact medicinal products

Selection characteristics

The product selection prioritised by the hospital and clinical experts is characterised by a high proportion of novel biologics and products developed by smaller or mid-cap companies, primarily targeting advanced or relapsed/refractory rare cancers. Most have already obtained FDA approval or are undergoing FDA review, often on the basis of promising early-phase (mostly Phase 2) evidence, with several having benefited from accelerated regulatory pathways. In the EU, these products also exhibit a notably higher concentration of orphan and other regulatory designations than the overall oncology pipeline, reflecting both the rarity of the targeted conditions and the urgency of therapeutic need. Collectively, they represent a cohort of potentially high-impact therapies expected to enter the EU market around 2027.

Two-fold uncertainty

Identifying medicinal products with the potential to have a high impact before marketing authorisation is inherently uncertain, with the uncertainty being two-fold: First, regulatory outcomes remain uncertain, as products in clinical development may fail to demonstrate a favourable benefit–risk balance, encounter delays, or be withdrawn before completing the regulatory process. For comparison, while the IHSI Database expects 104 new oncology medicinal products to be approved in 2027 (see Figure 2 Pipeline composition by EMA submission types), EMA recommended the approval of only 38 medicines containing a new active substance in 2025, 14 of which were oncology medicines [3]. This contrast illustrates the substantial uncertainty and high attrition rate associated with the regulatory development. Second, even for products that ultimately receive marketing authorisation, their impact on healthcare systems is difficult to predict in advance. Clinical uptake, treatment guidelines, competing therapies, pricing, and the actual size of the eligible patient population all influence the extent to which a medicine will affect clinical practice and healthcare expenditure. Consequently, any pre-authorisation assessment of potential impact should be regarded as a prospective estimate rather than a definitive prediction.

Evidence maturity

The high proportion of products at relatively early stages of clinical development also indicates that evidence available at the time of marketing authorisation may remain immature, creating additional uncertainty for subsequent HTA and economic evaluation.

Prospective approaches

Nevertheless, these uncertainties do not preclude a structured approach to identifying products that are more likely to have a substantial impact. A weighted scoring system based on characteristics associated with regulatory success and potential health-system impact could provide a transparent and reproducible selection method. Although no single characteristic is sufficiently predictive on its own, several regulatory and development features have been associated with an increased likelihood of approval or with medicines that subsequently have a substantial impact on clinical practice. Characteristics such as individual regulatory designations, although not guaranteeing marketing authorisation, provide useful signals of development maturity and regulatory confidence. For example, the FDA Breakthrough Therapy designation is reserved for medicines supported by preliminary clinical evidence suggesting substantial improvement over available therapy and has been associated with more efficient development and a higher likelihood of delivering high therapeutic value. [13, 14]. Similarly, EMA PRIME is a highly selective scheme intended for promising medicines that are expected to deliver a major therapeutic advantage to populations with unmet medical needs, and it provides enhanced scientific and regulatory support throughout development [14] [3]. imilarly, factors such as the absence of effective therapeutic alternatives and signals of potentially high treatment costs may provide additional evidence when assessing a product‘s potential clinical and economic impacton the Austrian healthcare system. Combining such characteristics within a weighted scoring system may therefore offer a more robust basis for prospective identification of medicinal products associated with both a higher likelihood of regulatory approval and a substantial clinical, organisational, or economic impact. Nevertheless, to ensure that such a framework reflects the priorities of Austrian hospital and clinical stakeholders, any proposed scoring system will require formal validation by project partners prior to its implementation.

Further considerations and limitations

It should be noted that the accuracy of the information presented in this report is inherently dependent on the quality and reliability of the information available in the IHSI Database. Moreover, the size of the pipeline is a result of the restrictions imposed in the search criteria - in particular, the expected tim-ing of the CHMP opinion between July 2026 and December 2028- and this, in turn, depends on the precision of the IHSI algorithm in estimating anticipated regulatory events and the emergence of new horizon scanning signals. The estimated number of medicinal products is therefore subject to change, as the anticipated timelines, especially the estimated MAA submission, are subject to considerable uncer-tainty, and medicinal products may be added or removed from the pipeline as they meet the search cri-teria.

For instance, the oncology pipeline extracted on 31 March 2026 for the purposes of product selection by our partners consisted of 405 records- the search yielded nearly 30 additional hits compared to the 8 July 2026 extraction. This difference illustrates the dynamic nature of the pipeline rather than necessarily indicating an error in the underlying data. Some products that were under CHMP evaluation in March have received the CHMP opinion in the meantime, or the MAA was withdrawn by the developers themselves. However, most of the missing records no longer qualified for the December 2028 authorisation threshold, as the expected date of the CHMP opinion in the IHSI Database had been postponed by a couple of months. The remaining records were archived by the IHSI, with the most frequent reason be-ing termination of technology development by the developer following unsatisfactory trial results.

In addition, the patent expiry information was obtained through an additional targeted search and should therefore be interpreted separately from the IHSI-derived pipeline information. Patent expiry does not necessarily correspond to the actual timing of generic or biosimilar market entry.



CONCLUSION AND OUTLOOK

In conclusion, the dynamic nature of the oncology pipeline highlights the need for regular updates to maintain an up-to-date horizon scanning monitor and to support the planning needs of Austrian healthcare stakeholders. The results should be interpreted as a snapshot of the emerging oncology pipeline at the time of data extraction rather than as a prognostic forecast of future marketing authorisations. Changes in expected regulatory timelines, development status, and the emergence or discontinuation of medicinal products contribute to both data-related and inherent uncertainty. Consequently, the monitor is intended to support the early identification and prioritisation of potentially relevant medicinal products, rather than to predict future regulatory outcomes or provide definitive estimates of future expenditure.

As a pilot, this project demonstrates the potential value of a structured oncology pipeline monitor as an early source of information for Austrian healthcare decision-makers, supporting horizon scanning, HTA, and healthcare planning. A follow-up project could further standardise and validate the selection and prioritisation methodology, establish regular update cycles, and refine criteria for assessing potential clinical, organisational, and economic impact. At the same time, further development and increased granularity of the IHSI Database could improve the completeness, timeliness, and usability of the underlying data. Together, these developments could strengthen the use of horizon scanning to anticipate emerging technologies, identify areas requiring early HTA attention, and support informed resource allocation decisions.

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