HEALTH **I**NNOVATION NE**X**T GENERATION **P**AYMENT & PR**I**CING MODELS **(HI-PRIX):**

Balancing Sustainability of Innovation with Sustainability of Health Care

D1.2: Policy recommendations about successful and flexible implementation of the different schemes to promote access to high-quality affordable innovative health technologies

WP1: Mapping of payment and pricing schemes for health innovation in the EU: implementation, barriers and enablers

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Executive summary

This deliverable provides a consolidated set of policy recommendations to support European health systems in designing, implementing, and sustaining innovative pricing and payment models (IPMs) that balance timely access to high-quality health innovations with healthcare system affordability. It draws on the comprehensive evidence base developed under WP1, including: 1) a systematic mapping of 59 unique pricing and payment scheme types and 173 real-world applications across countries and technology types; 2) in-depth case studies evaluating implementation costs, benefits, and influencing factors for diverse IPMs; 3) extensive stakeholder engagement through surveys and modified nominal group discussions spanning payers, HTA bodies, manufacturers, providers, and patients.

The mapping highlights a diverse and evolving landscape of schemes, ranging from financial-based mechanisms such as price discounts, expenditure caps and instalment payments, to performance-based arrangements such as outcomes-based agreements, each shaped by local governance, evidence needs, attitudes to risk, and infrastructure capacity. While financial schemes dominate current practice, performance-based models are being explored for high-cost technologies with high-uncertainty, such as advanced therapy medicinal products (ATMPs). However, differences in legal frameworks, data infrastructure, HTA processes, and cultural norms across Europe lead to uneven adoption and mixed experiences.

Case studies across four EU countries reveal that although IPMs can generate substantial benefits, including earlier patient access, improved outcomes, risk-sharing for payers, and more predictable revenue for manufacturers. However, they also impose significant human-resource and transaction costs, particularly in design, data collection, monitoring, and reconciliation phases. Performance-based models carry the highest operational burden. Benefits for advanced therapies tend to materialize later in the IPM lifecycle, while costs are front-loaded, highlighting the importance of targeted design, feasibility assessment, and long-term planning.

The stakeholder survey identified persistent system-level barriers that constrain effective IPM deployment: insufficient or fragmented data infrastructure, legal and regulatory obstacles, complex scheme design negotiations, financial management challenges (notably for instalment and amortization models), and significant burden on clinical staff for outcome reporting. Conversely, key enablers include robust data systems, clear legal frameworks, early multi-stakeholder engagement, rational scheme design based on transparent objectives, and pre-existing organizational experience with similar agreements.

Building on these insights, this deliverable proposes actionable policy recommendations structured around four phases of the IPM lifecycle: 1) Initiating and designing schemes, emphasizing value assessment, early dialogue, fit-for-purpose scheme selection, and supportive governance frameworks; 2) Adopting and implementing schemes, prioritizing feasibility checks, investment in interoperable data systems, staff training, and predefined end-of-scheme pathways; 3) Maintaining and sustaining schemes, focusing on consistent data quality, performance monitoring, burden management, and periodic financial and legal review; 4) Closing schemes and determining payment and pricing policy, ensuring transparent exit criteria, accurate reconciliation, simplification when uncertainty is resolved, and non-confidential knowledge sharing. Overall, the findings underscore that while IPMs can support sustainable access to innovation, their success depends on aligning scheme choice with specific policy objectives, ensuring adequate infrastructure and organizational capacity, and fostering collaborative engagement across stakeholders. By providing a structured set of practical recommendations, this deliverable aims to guide EU

policymakers, payers, HTA bodies, and industry stakeholders in strengthening the design and deployment of next-generation payment and pricing models.

1. Deliverable in the context of HI-PRIX

1.1 Background

This **report has been produced as part of the activities foreseen under WP1** "Mapping of payment and pricing schemes for health innovation in the EU: implementation, barriers and enablers", and **specifically under Task 1.3** "Policy recommendations about successful and flexible implementation of the different schemes to promote access to high-quality affordable innovative health technologies".

This report builds on the activities developed as part of prior tasks:

- **Task 1.1** "Mapping of payment and pricing schemes for health innovation";
- **Task 1.2** "Implementation of payment and pricing schemes: costs, benefits, barriers and enablers";

and associated milestones and deliverables:

- **Milestone #1** "Pay for innovation Observatory" – an online catalogue of pricing and payment schemes for health innovation" (Month 12) [1];
- **Milestone #2** "Within-country performance of novel payment/pricing schemes: costs and benefits of implementation" (Month 24) [2];
- **Deliverable 1.1** "Stakeholders judgement on barriers and enablers of novel payment/pricing schemes" (Month 30) [3].

1.2 Rationale for the work package

The development of effective pricing and payment models for health innovation is shaped by a complex interplay of economic incentives, institutional arrangements, and societal expectations. Across Europe and beyond, health systems face increasing pressure to balance the objectives of promoting timely access to innovative technologies, ensuring affordability for payers and patients, and maintaining incentives for continued innovation. At the same time, the diversity of governance structures, financing mechanisms, and market dynamics across countries creates substantial variability in how these objectives are pursued. This variability is further compounded by differences in data infrastructure, evaluation capacity, and the distribution of decision-making authority among national and regional actors. As new health technologies, particularly those that are high-cost or personalized, enter the market, pricing and payment schemes might act as a powerful tool to facilitate sustained access. However, existing pricing and payment frameworks (like price-volume agreements) are often ill-suited to capture the value of these technologies, or to distribute risks and benefits fairly among stakeholders. The result is growing uncertainty about health care sustainability, unequal patient access, and misalignment between innovation outputs and public health goals.

In this context, there is a strong need for systematic understanding of the different types of pricing and payment agreements being used or proposed, as well as the contextual and structural factors that determine whether pricing and payment models succeed or fail in real-world conditions. By combining structured evidence synthesis with stakeholder engagement, this work package has provided a coherent framework to interpret how pricing and payment models operate in practice, what enables or constrains their implementation, and how they can be adapted to different health system environments. Such understanding is essential to inform coherent, evidence-based policy approaches that can reconcile innovation, affordability, and equity across diverse health system environments. In this report, the terms pricing and payment "models," "schemes," "arrangements", or "contracts" are used interchangeably, reflecting the heterogeneity of mechanisms encountered across health systems. This approach avoids unnecessary

terminological rigidity while ensuring consistency with the protocol's framing and the empirical landscape examined.

1.3 Objectives

The objective of this deliverable is to **develop a comprehensive set of policy recommendations supporting the successful and flexible implementation of various pricing and payment schemes designed to enhance access to high-quality, affordable, and innovative health technologies**. Building on a critical synthesis of contextual factors and elements developed earlier in the work package, this work aims to identify practical pathways for real-world application. The resulting policy guidance will assist policymakers, industry actors and any other interested stakeholders in adopting pricing and payment models that foster equitable access to innovation, while strengthening the competitiveness and sustainability of the healthcare sector.

1.4 Structure of the document

This report is structured as follows. **Section 2 (Introduction)** provides a comparative overview of published papers focused on policy recommendations related to pricing and payment schemes, each with different areas of focus. **Section 3 (Methods)** describes the approach followed in this work, including the mapping of existing pricing and payment schemes through a literature review (Section 3.1), case studies of real-life schemes to identify costs, benefits and main influences (Section 3.2), and a survey and nominal group technique with stakeholders to identify barriers and enablers of schemes (Section 3.3). **Section 4 (Results)** summarizes the main findings from these activities, building on the outcomes of our previous tasks, and includes corresponding subsections (4.1-4.3). Finally, **Section 5 (Policy Recommendations)** integrates all the insights and evidence gathered to propose recommendations to inform future policy.

2. Introduction

Innovation payment and pricing schemes are schemes that involve more than merely paying per pill or unit of the technology. They are a useful policy option for decision-makers in situations where there is uncertainty about the clinical or cost-effectiveness of a technology, where paying for the technology raises affordability or budgetary challenges, or where the decision-maker wants to use payment to incentivise more cost-effective use of the technology (eg by paying a different amount for use in patient groups with different levels of potential benefit, or paying only if a particular level of outcome is achieved).

These schemes have potential benefits for all the main stakeholders; payers can reduce their financial risk, manufacturers are able to receive reimbursement for their product in situations where it might otherwise be refused, and patients can gain access to technologies that may otherwise be denied, or only available by private payment. Two particular factors have influenced the perceived need for these schemes. First, accelerated approval policies implemented by the Food and Drug Administration (FDA) and European Medicines Agency (EMA) have led to several new medicines reaching the market with relatively immature clinical data, often with efficacy assessed using surrogate outcomes. Secondly, many modern medicines, in particular Advanced Therapy Medicinal Products (ATMPs) have clinical evidence from single-arm or uncontrolled clinical studies, or large up-front costs with potential benefits far into the future. A variety of innovative payment and pricing schemes exist, some being proposed in the scientific literature, others being applied in actual practice. However, despite the existence of these schemes, there remain considerable doubts about if, and when they should be applied, whether they are useful in securing an improved decision, and whether they are worth the time and effort in designing and conducting them.

In recent years there have been several papers on best practice in designing and conducting schemes, often including policy recommendations. Kolelva-Kolarova et al (2021)[4] conducted a systematic review to identify current financing and reimbursement models for personalized medicine, and to suggest future policy options. One hundred and fifty-three papers were included in the review. Financial-based reimbursement was mainly applied to targeted therapies; performance-based reimbursement was identified mainly for gene therapies (and targeted therapies), and some companion diagnostics. The authors also discuss the facilitators, incentives, barriers and disincentives to the reimbursement of personalised medicine, including the features of the reimbursement models themselves.

Wills and Mitha (2024) [5] conducted semi-structured interviews with 17 individuals, 11 representing 7 different public payers, 6 representing different large technology manufacturers in Canada. The authors identify 6 key success factors that could be used to design suitable and acceptable financial characteristics of outcome-based agreements.

Avsar et al (2024) [6] developed policy recommendations for outcomes-based agreements (OBAs) in Europe, with a focus on ATMPs. A policy sandbox approach was used to engage stakeholders and explore how health technology assessment (HTA) organizations can support reimbursement decisions regarding OBAs for ATMPs. A panel of 38 experts from across the European Union was convened in 2 workshops, representing payers, HTA organizations, patients, registries, and an industry trade body. The recommendations relate to the different stages of developing and conducting an OBA. These are the technology itself (determining whether it is a suitable candidate for an OBA), the OBA design phase, the data collection phase, and the HTA phase following the data collection in the OBA.

Callenbach et al (2024) [7] constructed a framework and calculation to compare the consequences of implementing different payment models for high-cost, potentially curative therapies. The framework outlines the steps to determine potentially suitable payment models for these therapies. Consisting of 3 parts, it considers the pressing clinical uncertainties and financial challenges in the reimbursement decision, the relevant outcome measure and whether useable data can be easily collected, and whether it will be possible to provide input parameters for the calculations required. Proof of concept was established by exploring how the framework and calculation tool could be used to provide insights into the optimal payment models for 3 high cost, potentially curable therapies.

McElwee et al (2025) [8] proposed evidence-based steps for the effective selection and implementation of alternative payment models. They conducted a pragmatic literature review and developed a decision guide, showing how payment models could provide solutions to problems organized in 3 broad problem categories: budget impact and uncertainty, value uncertainty and the scope of value assessment and negotiation. Sub-categories of the broader categories were mapped onto alternative payment models and potential solutions determined. Use of the decision guide is illustrated by reference to recent applications of alternative payment models: OBAs for 2 oncology treatments, instalment and OBA models for 2 gene therapies and a subscription model for direct-acting antivirals.

Finally, Farmer and colleagues [9] conducted an evaluation of managed access agreements (MEAs) in England, based on stakeholder experience. They conducted 7 focus groups with key stakeholder groups: HTA representatives, UK government officials, clinical experts, patient group representatives and industry trade body representatives. In all, 57 individuals were involved. They identified 7 aims of MEAs in England, and 5 sets of challenges: delays in the process, evidence generation, stakeholder engagement,

contextual changes (such as developments in methods or emergence of new comparators), and difficulties in contracting for MEAs. The authors also propose 3 key eligibility criteria for technologies entering MEAs: impact on the healthcare system, potential cost-effectiveness, feasibility of the MEA compared with routine reimbursement.

Taken together, these papers contain a wide range of policy advice, although individually they often limit their focus to particular types of health technologies (i.e., ATMPs), particular types of payment or pricing scheme (e.g., OBAs), and/or particular settings. The objectives of Work Package 1 of the EU Horizon Europe research project HI-PRIX were to provide a comprehensive view of the current functioning of innovate payment and pricing schemes by (i) mapping pricing and payment schemes across technology classes, therapeutic areas, setting and healthcare systems/geographies; (ii) documenting and assessing the costs, benefits, barriers and enablers of implementation of innovative payment schemes and (iii) generating recommendations about the successful and flexible application of the different schemes to promote access to high-quality, innovative health technologies at an affordable cost.

The research consisted of three main elements: (i) a systematic review of existing theoretical and applied innovative pricing schemes, with a view to producing a taxonomy that those wishing to implement a scheme could search, in order to identify the best type of scheme for their purpose; (ii) case studies of individual real-life schemes to identify the costs, benefits and the main influencers of these; (iii) a survey and nominal group process with stakeholder groups to identify the barriers and enablers of innovative payment and pricing schemes.

This report draws from these three strands of research to develop policy recommendations for those wishing to develop and conduct innovative payment and pricing schemes in the future.

3. Methods

3.1 Mapping of existing pricing and payment schemes

We initially conducted a comprehensive scoping review of pricing and payment schemes for health technologies. We followed the updated methodological guidance for scoping reviews and adhered to the PRISMA-ScR checklist. The search strategy comprised three scientific bibliographic databases (PubMed/MEDLINE, Web of Science, Scopus) and was designed around two key keyword blocks: one capturing "pricing/payment/reimbursement schemes" and the other capturing "innovativeness" (e.g., performance-based, value-based, risk-sharing). In addition, relevant grey literature (reports, white papers, institutional and stakeholder websites) was explored. Eligibility criteria required studies (or reports) to describe uniquely a type of pricing or payment scheme for health technologies, either proposed theoretically or implemented in practice, and to provide sufficient design detail (objectives, payment timing/modalities, evidence-collection requirements) to allow mapping. Data extraction was performed by two independent reviewers, with a structured extraction matrix covering up to 21 items per scheme type (including scheme name, description, objective, technology type, outcome component, timing of payment, modality of payment, evidence generation requirements). More methodological details can be found in the published study protocol [10], also registered in PROSPERO (registration number: CRD42023444824).

The outcome of this work has been published in the article by Ardito and colleagues titled Design and Features of Pricing and Payment Schemes for Health Technologies: A Scoping Review and a Proposal for a Flexible Need-Driven Classification [11]. The article synthesizes

the extracted data narratively, supplemented by tabular summaries of scheme types and the full list of identified scheme types. The full list of unique types of pricing and payment schemes, as well as examples of applied cases that have been implemented in different countries and healthcare systems, is made publicly available via the online Pay-for-Innovation Observatory (through the HI-PRIX website), that serves as an "living" repository of schemes collected as part of the project. The first version of the observatory was released at the end of the first project year and has then been updated annually, to ensure the repository remains current. Updates have been supported by an AI-based tool for literature reviews, ASReview, and the related methodology has been published in the article by Cavallaro et al titled Machine Learning-Assisted Health Economics and Policy Reviews: A Comparative Assessment [12].

To further enhance the comprehensiveness of our mapping, we also conducted a series of key informant interviews. Specifically, we reached out to 17 key informants, including representatives from national health authorities, HTA bodies, payers, and academic experts involved in pricing and reimbursement decisions across the countries covered by our mapping. Nine interviews were completed (Austria, France, Germany, Italy, Netherlands, Portugal, Spain, Sweden, United Kingdom), while two additional informants provided relevant documentation and clarifications via email correspondence (Lithuania and Baltic countries; Denmark). The interview guide received ethical approval by Bocconi University's Ethical Committee (ID: EA001014). After obtaining oral informed consent from the interviewees, the interviews were recorded and transcribed. A manual thematic analysis of the interviews transcripts was performed, and relevant quotes were organized along seven recurring themes: i) Financial schemes as preferred default; ii) Limited outcome-based payments adoption; iii) Healthcare system characteristics & cultural dynamics; iv) Transparency vs. confidentiality; v) Role of health economics & HTA; vi) European coordination; vii) Data infrastructure needs. The exact codes of the thematic analysis are reported in the Appendix 1. Overall, these interviews allowed us to identify additional schemes that were not captured in the published literature, including cases reported only in national sources or non-English documents, and were also used as a further evidence base to draft the policy recommendations.

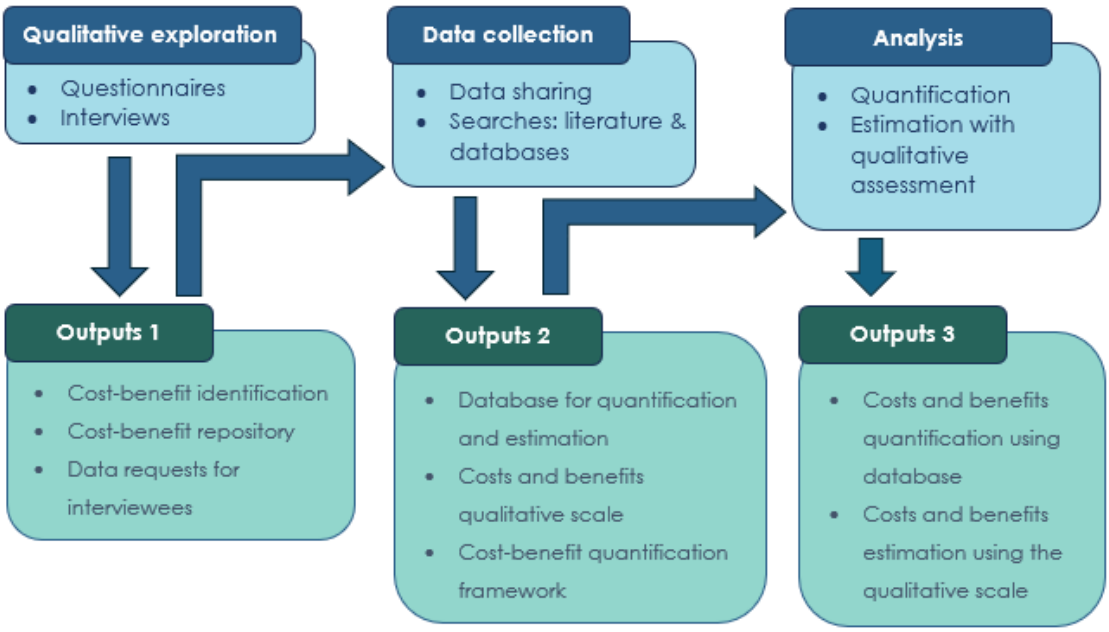
3.2 Case studies of real-life schemes to identify costs, benefits and main influences

To guide the analysis of implementation costs and benefits in real-life case studies, we developed an analytical framework informed by a review of the literature and principles from implementation science [2]. This framework structured the assessment across four distinct phases of IPM implementation capturing the full lifecycle of IPMs: (1) inception and design, (2) adoption and implementation, (3) sustainment and maintenance, and (4) wrap-up and closing. It also identified four key stakeholder groups involved in or affected by IPM implementation: payers and health technology assessment (HTA) bodies, manufacturers, healthcare providers, and patients.

The innovative payment model (IPM) types selected for this study align with the broad typologies of 'financial-based' and 'performance-based' agreements as defined by the OECD for Market Entry Agreements (MEAs) [13]. We selected four case studies based on the availability of public data and stakeholder willingness to participate in interviews. These included: (1) instalment and amortisation payments (IaAP) for CAR-T therapies in Spain and Italy; (2) a financial-based risk-sharing agreement (FBRSA) for antibiotics in Sweden; (3) an outcomes-based agreement (OBA) for gene therapy in Germany; and (4) a portfolio or bundling agreement (PoBA) for oncology therapies in Lithuania. The case studies reflect the diversity of IPM designs and national contexts, and are broadly representative of the innovative schemes referenced in the Pay-for-Innovation Observatory [1].

A mixed-methods approach was applied to analyse the case studies (Figure 1). The first phase involved qualitative exploration through semi-structured interviews with 24 stakeholders across the four stakeholder groups, resulting in a comprehensive cost-benefit repository [2]. In the second phase, a semi-quantitative approach was employed to systematically assess the scale of costs and benefits across all case studies (minor, moderate, significant). In the third phase, interview data were supplemented with secondary sources—including national databases, HTA reports, and peer-reviewed literature— to directly estimate costs and benefits where possible.

Figure 1 Methodological approach for the costs and benefits quantification



Source: HI-PRIX WP1, milestone deliverable M2[2]

3.3 Survey and nominal group process with stakeholder groups to identify barriers and enablers of schemes

We focused our analysis on five commonly used IPMs: Indication-Based Pricing (IBP), OBAs, IaAPs, FBRSAs, and PoBAs [2]. To understand stakeholders' perceptions of the most critical barriers and enablers to implementing these IPMs, we employed a two-stage qualitative approach.[3] In the first stage, we surveyed 31 experts, representing various stakeholder types involved in the IPM implementation lifecycle, from nine European countries, the US and the UK. Participants identified the most important barriers and enablers for each IPM overall, as well as for each phase of implementation. These results informed the development of shortlists for each IPM, which were used in the next stage of research. Deliverable D 1.1 [3] provides greater details on the specifics of the survey and the results we collected.

The second stage consisted of two virtual modified nominal group (NG) discussions—each of which focused on a selection of IPMs—with a subset of survey respondents. We also provide greater details on the components of the traditional NG that we modified for this research in deliverable D 1.1 [3]. Ahead of each NG, participants received pre-reads including the shortlists of barriers and enablers for discussion. They were also invited to propose additional items or request clarifications. During the NGs, participants ranked short-listed items on a 0-100 scale, discussed the results, and re-ranked items based on group

discussion and feedback. The sessions concluded with a roundtable on policy recommendations to address the barriers considered most challenging and to leverage the enablers deemed most important.

We analysed results using participants' raw and normalised scores to account for individual variation in scoring and complemented these with qualitative insights from the NG discussions and the survey. In addition, we mapped barriers and enablers to their relevant implementation phases to anticipate where challenges and supports may be concentrated, and explored differences in scoring patterns across stakeholder types by combining results from the NG and the survey.

4. Results

4.1 Mapping of existing pricing and payment schemes

The synthesis reported hereafter refers to the pricing and payment schemes available in the Pay-for-innovation Observatory as of 30/11/2025. These figures reflect subsequent updates based on three literature searches (in year 1, and at the end of year 2 and year 3 of the project), as well as a consolidation of the first release of the Observatory published in Ardito et al. [10,11]. In addition to the literature searches, the targeted interviews allowed to complement our evidence base and identify additional pricing and payment schemes that were not captured through the literature. Such interviews allowed us to identify new or locally implemented schemes, that were not available in the published literature or that were reported only in national languages.

Altogether, a total of 59 unique types of pricing and payment schemes for health technologies have been mapped, whether proposed in principle or implemented in practice. Of these, 58% (34/59) had been implemented in real-world contexts, while 42% (25/59) were theoretical or conceptual only. These are illustrated in Table 1.

Table 1. Unique types of pricing and payment schemes

Scheme name	Description
Adjusted Cost-Effectiveness Threshold Framework for Orphan Drugs	A pricing approach for orphan drugs that adjusts the standard cost-effectiveness threshold to ensure manufacturers receive a return aligned with industry-wide expectations given higher R&D and revenue risks.
Advance Market Commitment (AMC)	A mechanism in which purchasers commit in advance to buying a set quantity of a drug at an agreed price to stimulate development and ensure supply for products meeting predefined specifications.
Benchmark-based sales-delinked payment model for antibiotics	A payment model for antibiotics in which manufacturers are compensated based on meeting predefined value or milestone benchmarks rather than sales volume.
Benefit-Based Advance Market Commitment (BBAMC)	A value-based AMC model for vaccines where manufacturers receive tiered payments based on how well their product meets specified effectiveness standards and preferred payer characteristics.
Blended Discount Model	A pricing model that combines periodic rebates with a final rebate linked to the treatment's clinical outcomes, suitable for therapies requiring long-term evaluation.
Bundled pricing/payment	A model that consolidates multiple pharmaceutical or care-related services into a single payment that may also include additional manufacturer-provided patient support.
Combination-based pricing	A pricing model that assigns value and negotiates prices for drug combinations to reflect their added therapeutic benefit compared with the individual components.
Conditional treatment continuation (Risk Sharing)	A scheme in which continued reimbursement is granted only for patients who meet predefined clinical response criteria, with non-responders often treated at reduced or no cost.

Cost Sharing	A model where the manufacturer provides a discount on the initial treatment cycles so that all eligible patients can access therapy at a reduced cost.
Cost-plus pricing	A pricing method that sets the therapy price by adding a profit margin to the cost of producing and distributing the treatment, including R&D and other inputs.
Coverage with evidence development (CED)	A reimbursement approach that provides temporary coverage for new technologies contingent on collecting additional evidence to reduce uncertainty.
Diagnosis Confirmation Model (DCM)	A dual-price model for antibiotics where an initial lower "empiric use" price applies until diagnosis is confirmed, after which a full price is charged for continued treatment.
Discounts or rebates (confidential)	An agreement in which manufacturers provide confidential price reductions, either upfront or as rebates paid back after use.
DRG add-on payments	Supplemental payments added to standard hospital tariffs to cover high-cost drugs or medical devices that would otherwise exceed Diagnosis-Related Group (DRG) reimbursement levels.
Drug pricing index	A pricing approach for cancer drugs that uses cost-effectiveness, clinical benefit, GDP per capita, and income inequality metrics to estimate a value-based price.
Expenditure Capping	A scheme in which the manufacturer supplies a medicine at no additional cost once agreed volume or spending thresholds are exceeded.
External (International) Reference Pricing (ERP)	A pricing method that uses the price of a medicine in selected reference countries to guide or set the price in the domestic market.
Free initial treatment/Free doses	A model where manufacturers provide a predetermined number of initial treatment units at no cost, after which regular pricing applies.
Generic or biosimilar price linked to originator product	A pricing rule that mandates specific percentage reductions from the originator price for generics and biosimilars.
Generic pricing linked to number of generic manufacturers	A model in which generic prices reflect market competition, decreasing as more manufacturers enter.
Generics: blind tenders & sole supply contracts	A tendering system where payers solicit anonymous bids for exclusive supply of generic drugs, typically renewed at regular intervals.
Indication-based pricing	A pricing approach that assigns different prices for the same drug depending on its value and effectiveness in specific indications.
Indication-based pricing with outcomes guarantee	A variant of indication-based pricing in which manufacturers commit to outcome guarantees to address uncertainty in clinical and economic performance across indications.
Insurance-type model for antibiotics	A model in which healthcare systems jointly pay a fixed annual fee plus a per-use price to ensure antibiotic availability while delinking manufacturer revenue from sales volume.
Internal reference pricing (IRP)	A reimbursement approach where payers group interchangeable medicines and set a common reference price for all products within that group.
Managed Access Protocols (MAPs)	Structured reimbursement arrangements for high-cost medicines that define eligibility, monitoring, and conditional coverage based on clinical outcomes and HTA criteria.
Marginal Value-Based Reimbursement (MVBR)	A pricing model that adjusts reimbursement in combination therapies so each medicine is rewarded according to its marginal contribution to overall treatment value.
Memorial Sloan Kettering Cancer Center Drug Abacus Framework	A value-based pricing tool for oncology drugs that calculates an economically justified price based on weighted scores across multiple clinical and contextual domains.
Multi-Indication Pricing (MIP) Model	A pricing model that sets a single launch price based on value and volume across all approved indications and recalculates it as new indications and evidence emerge.
Multi-Tier Pharmaceutical Pricing Framework: Integrating Regional Cost-Plus and National Value-Based Approaches	A multi-tiered funding model that combines regional cost-plus reimbursement with national value-based pricing to distribute financial responsibility for innovative medicines.
Nation-wide budget thresholds for individual innovative agents	A budget-cap model that allows broad patient access to innovative medicines as long as total national spending for each product stays within a predefined limit.
Netflix plus model	A subscription-style pricing model that pays manufacturers a fixed fee for unlimited access to certain medicines while enabling negotiated discounts and encouraging competitive tendering.
Netflix/Subscription model	A model that provides manufacturers a fixed annual payment decoupled from sales volume, offering unlimited access to a medicine while mitigating market failures.
Optional Delinked Reward System (ODRS)	A voluntary scheme in which manufacturers choose between traditional pricing or selling a drug at a cost-based price in exchange for a long-term reward tied to its assessed health benefits.

Pattern/process of care agreements (PPC)	A reimbursement model where payment is triggered when a patient follows a specified treatment pathway or protocol.
Payer License Agreement (PLA) (subscription-based pricing model)	A subscription-like payment model in which the payer covers the entire eligible population for a fixed price linked to expected system-wide savings, with costs spread over multiple years.
Payment at Results, Annuity-Style, or Installment Payment Model	A performance-based scheme where payment is split into tranches that are released only when predefined clinical milestones are met.
Payment by results, outcome guarantees	A model where reimbursement depends on achieving patient-level or population-level outcomes, with refunds or price adjustments for non-responders.
Performance-based reimbursement for Digital Health Applications (DiGA)	A reimbursement model that ties payment to real-world digital health outcomes and clinical improvements, with shared responsibility between manufacturers and statutory insurers.
Price linked to patients' willingness to pay	A pricing approach that aligns drug prices with societal willingness-to-pay estimates based on cumulative health benefits and long-term population value.
Price-volume agreement	A pricing model in which the drug's price decreases as usage increases, often incorporating discounts, formulary tiers, and utilization controls tied to sales volume.
Price-Volume Agreement under Asymmetric Information	A model that designs incentive-compatible contracts allowing optimal price reductions based on uncertain or imperfect information about expected market size and demand.
Price-Volume Agreement with Exponential Decay	A scheme in which the price declines exponentially as more patients are treated, typically halving each time the treated population doubles.
Pricing anchored to RCT performance (RCT performance-based pricing)	A performance-linked pricing model that adjusts drug prices according to achievement of predefined clinical milestones demonstrated in randomized clinical trials.
Rate of return pricing	A pricing model that guarantees manufacturers a predetermined rate of return after covering development and marketing costs, with mechanisms to limit excess profits.
Reimbursement Scheme for Digital Health Applications (DiGA) under Germany's Digital Healthcare Act (DVG)	A reimbursement model allowing digital health applications to set free prices initially, followed by negotiated pricing based on demonstrated positive healthcare effects.
Specialised Funds	Targeted public financing mechanisms that provide early access and conditional coverage for high-impact medicines while generating evidence to guide long-term reimbursement decisions.
Success fee	An ex-post payment model in which manufacturers are reimbursed only for patients who benefit from the therapy after a pre-agreed evaluation period.
Technology leasing reimbursement strategy (TLRS)	A model that spreads payments over the expected lifespan of a technology based on periodic assessments of its cost-effectiveness and observed real-world performance.
Tendering/Negotiations	A competitive procurement process in which payers invite manufacturers to bid for supply contracts, typically to secure lower prices and ensure adequate supply.
Three-Part Pricing (TPP)	A tiered pricing model that adjusts drug prices across three phases, namely evaluation, reward, and access, according to evidence generation, demonstrated effectiveness, and adoption goals.
Tiered-pricing framework (TPF)	A model where generic drug prices decline automatically as additional manufacturers enter the market, reducing allowable reimbursement thresholds over time.
Transitional Coverage for Digital MDs	A temporary reimbursement pathway that enables early access to CE-marked digital medical devices while additional evidence is generated to support long-term coverage decisions.
Transitional Coverage for MDs	A temporary reimbursement pathway that enables early access to CE-marked medical devices for serious conditions while permanent listing and additional evidence generation are underway.
Two-Part Pricing (2PP)	A pricing model that combines an upfront entry fee with a per-use charge, allowing differentiation among payers based on expected volume.
Value informed, affordable pricing ("VIA pricing")	A model that sets willingness-to-pay thresholds based on disease severity and budget impact to align drug prices with societal value and affordability.
Value-based pricing (VBP)	A pricing approach that sets reimbursement levels according to a therapy's assessed clinical and economic value, often using cost-effectiveness thresholds.
Value-Based Pricing with Net Present Value (NPV) Adjustment	A model that prices new technologies based on the discounted lifetime value they deliver, using financial NPV concepts applied to health and cost outcomes.
Value-Based Reimbursement for Generics	A reimbursement model that rewards generic manufacturers based on supply chain resilience and reliability to reduce shortages and protect patient care

As for the schemes implemented in real-world contexts, 173 applied cases were identified, corresponding to 22 out of the 34 unique types of pricing and payment schemes. The most common categories of applied schemes documented in the literature were coverage with evidence development (CED), with 53 applied cases, followed by payment by results (outcome guarantees), with 49 applied cases, and reimbursement schemes under the DiGA framework, with 17 applied schemes. These schemes were implemented in different countries globally, with the majority coming from the US (73 schemes), Italy (23 schemes), Germany (18 schemes), and the UK (16 schemes). In terms of technology types, more than half the schemes (90, 52%) were applied to drugs, 23 (13%) to medical devices, 19 (11%) to digital medical devices, 16 (9%) to in vitro diagnostics, 13 (8%) to ATMPs, 10 (6%) to medical imaging, and only one each to vaccines (1%) and medical procedures (1%).

This mapping reflects that the landscape of pricing and payment schemes for health technologies is characterized by significant diversity, reflecting the multiple objectives, settings, and policy priorities found across health systems. Over the years, numerous attempts have been made to categorize these schemes into coherent typologies or taxonomies. While these efforts have provided useful conceptual clarity, they often fall short of capturing the fluidity and complexity of real-world applications. In practice, pricing and payment arrangements are shaped by context-specific factors, such as the nature of the technology, the stage of evidence development, the level of uncertainty, stakeholder preferences, and the broader regulatory and reimbursement environment. As a result, rigid classifications tend to oversimplify or obscure the dynamic and adaptive nature of these schemes, limiting their usefulness as practical tools for decision-making.

To address this challenge, we adopted a different approach that emphasizes flexibility and user-driven exploration. Rather than developing yet another fixed taxonomy, we sought to create a framework that makes existing schemes more accessible and comparable across several design features and elements. Our approach builds on a multidimensional mapping of the main types of pricing and payment arrangements, considering their underlying purposes, structural characteristics, outcome components, and the types of uncertainty they are designed to address. These dimensions are not intended as rigid categories, but as analytical lenses that can be combined and weighted differently depending on the needs of the user.

Through this structure, users, whether policymakers, payers, or researchers, can navigate the existing landscape in a flexible manner, selecting and combining schemes according to their specific policy objectives or implementation contexts. For instance, a decision-maker interested in managing uncertainty related to clinical effectiveness may focus on schemes emphasizing evidence generation, while another concerned with budget impact or affordability may prioritize financial-based arrangements. This flexible, needs-driven approach enables a more realistic and operational use of the existing knowledge base. It supports not only better understanding of the diversity of pricing and payment mechanisms but also encourages learning and innovation by showing how existing models can be adapted or recombined rather than replaced. By moving away from rigid taxonomies toward a multidimensional framework, we aim to provide a practical tool that aligns with the heterogeneity of health technologies, the variability of evidence across product lifecycles, and the evolving challenges of health systems.

4.2 Case studies of real-life schemes to identify costs, benefits and main influences

We developed a comprehensive cost-benefit evaluation framework for IPM implementation, which supported the development of a comprehensive complementary

cost-benefit inventory capturing both all generalisable and context-specific impacts.[2] The framework and inventory were validated through four case studies representing distinct IPM types.

The analysis identified a broad range of costs and benefits associated with the implementation of IPMs across the case studies. A complete inventory is presented in Table 2. The costs included human resource costs and transaction costs (e.g. clinical monitoring, legal and IT support, infrastructure, and financial administration) for payers, manufacturers, and providers. The benefits encompassed gains for patients, such as improved efficacy, safety, and quality of life. Manufacturers mainly benefited from earlier revenue and return on investment, while payers and providers gained from cost savings, risk-sharing, and earlier access to therapies.

Additionally, IPMs have the capability to contribute to broader system-level gains such as knowledge spillovers, scientific advancement, infrastructure improvements, and a more innovation-friendly environment.

Table 2 Cost-benefit inventory across IPMs for different stakeholders

	Cost/benefit category	Payers	Manufacturers	Providers	Patients
Costs	HR costs	• Negotiation • Set-up of scheme • Maintenance • Payment processing (e.g., re. IPM risk-sharing nature) • Wrap-up • Opportunity costs	• Negotiation • Set-up of scheme • Maintenance • Payment processing (e.g., re. IPM risk-sharing nature) • Wrap-up • Opportunity costs	• Set-up of scheme • Maintenance • Payment processing (e.g., re. IPM risk-sharing nature) • Wrap-up • Upskilling • Opportunity costs	
	Transaction costs (excluding HR)	• Clinical monitoring • Infrastructure for IPM implementation • Legal costs • IT costs • Finance costs	• Clinical monitoring • Infrastructure for IPM implementation • Supply chain, logistics, and storage • Legal costs • IT costs • Finance costs	• Clinical monitoring • Infrastructure for IPM implementation • Supply chain, logistics, and storage • IT costs	
	Medicine cost Health-related cost Other costs	• Price*			• Out of pocket costs • Unexpected adverse events • Hospitalisations • Travel and transport • Insufficient information on treatment and training
Benefits	Health-related benefits	• Efficacy/Safety • QoL		• Efficacy/Safety • QoL	• Efficacy/Safety • QoL
	Revenue		• Earlier Revenue and return on investment		

Cost/benefit category	Payers	Manufacturers	Providers	Patients
Cost savings	• Risk-sharing with reduced costs to asset • Cost-offset		• Cost-offset	
Early access	• Early access	• Earlier access to market or market launch	• Early access	• Early access
Spillovers and other positive externalities	• Knowledge spillover to other schemes • Infrastructure spillovers • Innovativeness and preparedness to absorb	• Knowledge spillover to other schemes or countries • Knowledge spillover to better product value understanding • Risk sharing and generation of RWE	• Scientific spillover • Infrastructure spillover • Upskilling HR • Innovation environnent e.g. Clinical trials • Provider accreditation	
Other benefits	• Political win	• Predictability of revenue		• Quicker and more optimal adoption

* This cost was not mentioned in the interviews but was inferred from the evidence, which suggested that earlier access led to earlier revenue for the manufacturer and, consequently, an earlier price cost for payers.

The analysis of IPMs identified their implementation as targeted solutions to pricing and access barriers that conventional discounts could not address. Each scheme responded to a specific need, such as managing high upfront costs and clinical uncertainty (CAR-T and gene therapies), addressing market failure (antibiotics in Sweden), or enabling access by improving affordability (oncology in Lithuania).

Interviews and semi-quantitative analysis revealed that across all case studies, IPM implementation introduced greater complexity and higher costs compared to conventional agreements, particularly for payers, manufacturers, and providers, who faced substantial human resource and transaction costs across all implementation phases. These costs were especially pronounced in OBAs due to the need to define and measure outcomes, establish monitoring infrastructure, and conduct ongoing evaluations. Additional context-specific costs included medicine-related expenses, minor patient costs (e.g., transport), and potential revenue losses under the Swedish supply guarantee framework.

IPM implementation also generated significant benefits, including earlier access to therapies, improved patient outcomes, the potential for cost savings through risk-sharing, and enhanced revenue opportunities for manufacturers. Broader system-level gains were also noted, such as knowledge spillovers, infrastructure development, and the generation of real-world evidence.

The analysis highlighted the temporal and dynamic nature of IPM implementation costs and benefits. While substantial costs arose across all implementation phases, benefits such as improved outcomes, cost savings, and reduced uncertainty emerged during adoption and maintenance. Stakeholders may manage this trade-off by reducing implementation costs or using IPMs as transitional tools toward more efficient schemes once the issue prompting their implementation has been resolved. Table 3 summarises all costs and benefits, as well as their average measures across all IPMs. Further details by scheme and overall are provided in Deliverable M2 [2].

Table 3 Heatmap of costs and benefit scoring across all analysed case studies

	Inception & design				Adoption & implementation				Sustainment & maintenance				Wrap-up & closing			
	PH	M	Pr	Pa	PH	M	Pr	Pa	PH	M	Pr	Pa	PH	M	Pr	Pa
Human Resource cost	2.2	2.4	1.2	0.0	2.2	2.4	1.2	0.0	2.2	1.6	1.4	0.0	1.2	0.8	0.2	0.0
Transaction cost	0.4	1.4	0.0	0.0	0.4	1.4	0.4	0.0	0.4	1.6	0.6	0.0	0.0	0.0	0.0	0.0
Health-related costs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0	0.0	0.0	0.0	3.0	0.0	0.0	0.0	3.0
Medicine-related cost	3.0	0.0	0.6	0.0	3.0	0.0	0.6	0.0	3.0	0.0	0.6	0.0	3.0	0.0	0.6	0.0
Other costs	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.0	0.6	0.0	0.4	0.0	0.6
Health related benefits	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0	2.6	3.0	0.0	0.0	2.4	2.4
Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.6	0.0	0.0	0.0	0.4	0.0	0.0
Cost savings	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.2	0.0	1.8	0.4	2.0	0.0	1.4	0.0
Early access	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	1.8	1.4	1.2	1.8	1.8	1.2	1.2
Spillovers/ pos. externalities	1.0	0.8	0.0	0.0	1.0	0.8	0.0	0.0	1.2	0.8	1.2	0.0	0.6	0.8	1.0	0.0
Other benefits	0.6	1.2	0.0	0.0	0.6	0.6	0.0	0.0	0.0	0.4	0.0	0.0	1.2	2.2	0.0	0.0

Abbreviations: PH: Payer/HTA, M: Manufacturer, Pr: Provider, Pa: Patients.
Colour shades correspond to scale of score. Average scoring reported across all case studies. Scoring for case studies: 3- Significant, 2- Moderate, 1- Minor, 0- not reported

4.3 Survey and nominal group process with stakeholder groups to identify barriers and enablers of schemes

In Table 4, we present the main results of our analysis below, with Table 2 and Table 3 highlighting the top-scoring barriers and enablers, respectively, for each IPM.

Table 4. Most challenging barriers for each IPM, with mean scores presented in parentheses.

OBAs	IBP	IaAPs	FBRSAs	PoBAs
Lack of infrastructure for data collection and monitoring (**82.14**)	Infrastructure and data limitations (**85**)	Legal and regulatory hurdles (**81.43**)	Negotiating an acceptable FRSA design (**71.25**)	Negotiating an acceptable PoBA (**83.75**)
Negotiating an acceptable OBA design (**71.43**)	Legal and regulatory barriers (**80**)	Complex financial management (**76.43**)	Infrastructure and data limitations (**70**)	Infrastructure and data limitations (**67.5**)

Burden on clinical staff (**66.43**)	Designing an optimal model (**63.57**)	Negotiating an acceptable model (**74.29**)	Financial sustainability and planning (**55.63**)	Challenges with stakeholder relations and buy-in (**64.38**)

Source: deliverable D1.1.[3]

Several cross-cutting themes emerged across IPM barriers. Data infrastructure limitations were identified as a top barrier in four of the five IPMs. Similarly, negotiating an acceptable design and legal/regulatory hurdles appeared across IPMs. These barriers can therefore be understood as affecting IPM implementation more broadly (Table 5).

Table 5. Most important enablers for each IPM, with mean scores presented in parentheses.

OBAs	IBP	IaAPs	FBRSAs	PoBAs
Sufficient infrastructure and funding (**92.86**)	Established data infrastructure and monitoring systems (**85.71**)	Agreed conditions of termination of the agreement in the technology fails during the amortization period (**85.71**)	Sufficient infrastructure (**89.38**)	Early dialogue between stakeholders (**71.25**)
Clear legal and regulatory guidelines (**83.57**)	Change in legal framework to allow IBP (**85.71**)	Existing infrastructure (**79.29**)	Simplicity/ease of implementation (**76.25**)	Budget predictability and affordability (**70**)
Data accuracy and optimisation to achieve OBA's goals (**79.29**)	Rational design and application of IBP (**68.57**)	Pre-existing experience or frameworks to guide implementation (**77.86**)	Capacity to reduce financial uncertainty (**75**)	Enhanced financial planning and collaboration (**63.13**)

Source: deliverable D1.1.[3]

The most important enablers mirrored the barriers affecting multiple IPMs. Existing data infrastructure and supportive legal/regulatory environments were viewed as especially important for several IPMs. Similarly, enablers addressing the barrier of designing an acceptable model, such as rational IPM design and pre-existing knowledge or frameworks, appeared across IPMs. The alignment between top barriers and enablers indicates that these themes are seen as central in successful IPM implementation. Ultimately, these recurring themes highlight priorities for high-impact policy interventions that can be applied flexibly across IPM types.

Barriers and enablers that participants scored highly only for specific IPMs can reveal important themes for stakeholders looking to operationalise these IPMs. For instance, burden on clinical staff and data accuracy and optimisation were considered to be a top barrier and enabler, respectively, for OBAs. Taken together, these findings reflect an inherent trade-off that exists in implementing OBAs: imposing additional work on staff and collecting meaningful patient outcome data to enable adoption and patient access to innovation.

For IaAPs, by contrast, stakeholders considered complex financial management as a top barrier and agreed conditions of termination as a highly important enabler. These results

underscore the unique accounting difficulties associated with IaAPs and the need for strategies to mitigate risk due to their complex payment timelines. This contrasts with FRBSAs, for which participants identified ease of implementation and capacity to reduce financial uncertainty as key enablers, suggesting that this payment model may be considered more straightforward to implement compared to other IPMs. Conversely, points related to stakeholder relations—highlighted as both a barrier and enabler—for PoBAs suggest that they might require earlier dialogue and collaboration, as countries have limited experiences implementing such models. Deliverable D1.1 [3] details the results of each IPM, as well as what may have motivated these results and how discussions during the NG changed how participants scored each item.

In some instances, certain stakeholders' priorities differed from those of the wider group. For OBAs, academics uniquely highlighted early stakeholder engagement and buy-in as critically important. On the other hand, payers alone identified having willing and well-trained staff, as well as pre-existing frameworks, experience and leadership, as two of the most important enablers. These differences could ultimately reflect diverging priorities between those who study IPMs from a holistic perspective—typically in early implementation phases—and those who are practically engaged with IPMs throughout the entire implementation lifecycle. For IaAPs, payers were the only group to rank financial sustainability as a critical barrier. Survey responses suggested that this might reflect concerns among payers that IaAPs are used to 'obscure' unduly high medicine prices, thereby raising long-term affordability concerns.

Recurring barriers and enablers also provide insight into the implementation phases where bottlenecks are most likely to occur. We found that the barriers considered most difficult arise across multiple implementation phases, suggesting that successful adoption requires diverse expertise and resources throughout the implementation lifecycle. Conversely, the most important enablers tend to affect early stages of implementation, highlighting that actors must make upfront investments to capitalise on those viewed as most critical. Deliverable D1.1 [3] provides further detail on the implementation phases most impacted by barriers or enablers for each IPM.

5. Actionable policy recommendations

5.1 Our proposed set of policy recommendations

The following policy recommendations are structured according to the four phases of the implementation framework illustrated above. The framework was designed to reflect the full lifecycle of pricing and reimbursement schemes, recognising that different challenges, opportunities, and decision points are faced at each stage. As such, recommendations are structured around: i) initiating and designing schemes; ii) adopting and implementing schemes; iii) maintaining and sustaining schemes; and, iv) closing and determining payment and pricing policy. When relevant, stakeholder-specific challenges have also been reflected in the recommendations, in line with the proposed framework.

Organising the recommendations by phase provides an approach that allows policy guidance to be aligned directly with the practical sequence of tasks that payers, healthcare providers, manufacturers and patients undertake when agreeing, introducing, operating, and concluding such schemes.

Initiating and designing schemes

- **Evaluate value before action**. Before considering a scheme, assess the incremental costs and effectiveness of the technology through a health technology assessment. This should serve to identify the key value or uncertainty drivers, thus allowing for appropriate and targeted selection of IPM where relevant.
- **Learn from existing models**. Consider viable alternatives by searching the P4I Observatory and existing databases, and, if possible, consult with those who have already implemented a particular type of scheme.
- **Match scheme type to objectives**. Payment models should be utilised to ensure that the treatment options that are of value to patients and health systems are appropriately incentivised and supported to reach patients in a timely manner. Therefore, the type of innovative scheme must be selected to achieve the main policy objective(s) by addressing the issues that prevent these to be met (e.g. reducing uncertainty about the costs or effectiveness of the technology; reducing the annual financial burden of adopting the technology; or ensuring the efficient adoption of the technology). Always assess whether an IPM model is needed to address the prevailing issue/objective, or whether a price negotiation or confidential discount would achieve this in a more streamlined and efficient way.
- **Strengthen early multi-stakeholder engagement**. Convene early dialogue between payers, HTA, providers, patients, and manufacturers to align on the access problem, target indications, feasible endpoints, and acceptable risk allocation, particularly for PoBAs and OBAs, where stakeholder buy-in is pivotal. These discussions should anticipate the costs, benefits and potential barriers. It may be helpful to curate templates (e.g. model selection decision trees, standard operating procedures, clause libraries, case repositories) to speed design and reduce transaction costs.
- **Build enabling legal and governance frameworks.** Adapt national/regional legal frameworks to explicitly permit IPMs (especially important for IBP and IaAPs, which may otherwise be challenging to implement in some health systems). Consider and evaluate targeted legislative amendments, guidance on value added tax (VAT)/rebate handling, allowance for confidential rebates, and recognition of multiyear commitments. Clear contracting guidelines would strengthen efficient early dialogue, especially for performance-based schemes (e.g. provision of templates, definition of data privacy norms, audit expectations, etc.)
- **Design schemes to be fit-for-purpose and workable**. Design choices will vary by scheme but could include consideration of: appropriate, workable and clear endpoints; how to minimise reporting burden; pre-defining dispute resolution and termination conditions; establishing monitoring rules; agreeing optimal time horizons (e.g. what uncertainties may be addressed within a reasonable timescale for a scheme). Utilise existing infrastructure and registries where available; this can reduce design complexity and future transaction costs.
- **Leverage cross-country collaboration**. Consider activating cross-country participation in specific phases of the scheme (e.g. data collection) to achieve some policy objectives and to encourage knowledge exchange networks for countries/regions with less IPM experience (e.g. Benelux, Nordic countries networks).

Adopting and implementing schemes

- **Re-engage stakeholders early to confirm feasibility and align on risk mitigation**. Before proceeding with the chosen type of scheme, determine whether there are any budgetary, legal or practical constraints and ensure appropriate arrangements are in place to allow implementation of the planned scheme. Discuss the scheme

with the relevant stakeholder groups to understand their concerns and to find ways of mitigating them.

- **Invest in data and operational infrastructure.** Commission or upgrade national/regional data systems as needed to track relevant outcomes, usage and/or financial data. Prioritise automated, routine clinical data flows and interoperable billing/outcomes registries. Consider whether schemes that require data that are not routinely available would be feasible and what extra investment in data gathering or systems would be required. Accredit treatment centres and establish clear governance arrangements for the scheme, including responsibilities for monitoring progress, data collection and analysis, and independent oversight/audit.
- **Ensure sustainable data quality and methodological consistency.** Automate outcome capture where possible. For schemes involving additional data collection from non-routine sources, consider making additional funds available to support and maintain the data collection phase. Develop agreed-upon standards for outcome definitions, statistical thresholds, missing-data handling, and minimum sample sizes to avoid inconclusive assessments evaluations. To mitigate data errors, standardize forms and reduce duplicate entry.
- **Plan for post-scheme decisions**. Discuss the arrangements that will be put in place at the end of the scheme (e.g. whether existing users of the technology can continue regardless of the results, which party will pay for their continuation, whether further price negotiations will occur, and under what circumstances). Some schemes may require alternative invoicing mechanisms and cross-year processes (e.g. IaAPs) requiring managing processes for their closing to be anticipated and pre-defined at adoption.
- **Resource and upskill the people that are critical for operating the IPM**. Provide training for clinicians, pharmacists and administrative teams as necessary, particularly for OBAs, where the burden on clinical staff is considered a critical obstacle. Assign dedicated coordinators for data capture and reconciliation. Some schemes may require dedicated communications to clinical communities and patient groups on scheme scope, endpoints, and operational implications.

Maintaining and sustaining schemes

- **Monitor performance over time**. Monitor results over time and at pre-specified intervals. Establish and use feedback loops that provide interim results and demonstrate to treatment site staff the value of the data they provide (e.g. especially in OBAs). It is also important to monitor and measure clinical and administrative staff burden and adjust protocols where necessary to keep schemes viable.
- **Maintain stakeholder relations and transparency.** Address transparency limitations proactively. Where confidentiality is required, establish clear protocols for sharing non-sensitive information to enable actors to leverage experience and sustain trust.
- **Maintain active legal and financial governance**. This will differ by scheme. For IaAPs, manage complex financial schedules proactively (e.g. late payments, inflation/discount rates, cross-year cash flows) and review sustainability regularly from the payer perspective. For FBRSAs/PoBAs, it may be necessary to monitor market evolution (e.g. new therapies and comparator changes) and reopen terms to preserve value and avoid perverse HTA impacts.

Closing schemes and determining payment and pricing policy

- **Define clear exit and continuation rules**. Operate final assessment and pre-agreed termination conditions. For IaAPs, in particular, it may be necessary to consider

protocol for when a technology fails during the amortisation period. Avoid patient inequities by specifying transparent criteria for treatment continuation or discontinuation once the scheme ends.

- **Reconcile payments and update policy baselines.** Ensure accurate payment reconciliation and document price adjustments. Establish and apply a process to revise the conditions outlined when the scheme was adopted and implemented and determine the payment and pricing policy for the technology going forward. Simplify if uncertainty is resolved: consider switching to a simpler type of scheme or simple discount after the initial uncertainty has been resolved, or the objective of the scheme has been achieved.
- **Share non-confidential learnings**. Capture and publicly document operational insights into how schemes worked and their outcomes. Ensure the scheme details—excluding confidential personal and financial information—are publicly available to contribute to existing databases and support stakeholders in other jurisdictions considering innovative schemes. Share this information through national and cross-country knowledge networks.

6. Conclusions

This work consolidates evidence from the mapping of innovative pricing and payment schemes for health technologies, real-world case studies, and structured stakeholder engagement to provide actionable recommendations for health systems seeking to balance access, affordability, and innovation. The evidence collected highlights that while innovative payment models can address key uncertainties and enable earlier access to high-value technologies, their effectiveness depends on context-specific design choices, robust data and governance infrastructure, and sustained multi-stakeholder collaboration. Persistent cross-country challenges, including data limitations, legal and organizational barriers, and the operational burden of complex schemes, highlight the need for coordinated investment and shared learning across health systems. By offering a scheme lifecycle-based framework and pragmatic guidance, this report aims to support policymakers and other stakeholders (payers, manufacturers), in designing more feasible, transparent, and sustainable agreements, ultimately contributing to equitable access to innovation and long-term health system resilience.

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Appendix

Appendix 1 – Thematic analysis of the interview transcripts

Austria

Theme	Exact quotes
Financial schemes as preferred default	• *We have the discounts and rebates.* • *We have negotiations, price volume agreements.* • *Yeah, discounts or rebates and the price volume.* • *So, the price volume agreements are very common for in the health insurance system, like for extramural prices for common drugs like in which there are high volumes.*
Limited outcome-based payments adoption	• *Real instances where those schemes [outcome-based] were used and in that case we had difficulties in finding real world applications for Austria.* • *Then we have conditional treatment risk sharing.* • *Then just one question because we saw that sometimes the performance based the schemes are the ones a little bit problematic in the collection of data.* • *We are assessing everything that has a positive CHMP opinion, like we start to assess things before they are approved because Austria has the position of always being the first in Europe to pay for something.* • *Germany, Austria, Switzerland in terms of cross country outcome-based agreement can be a solution.*
Healthcare systems characteristics (+cultural dynamics) affecting pricing and access	• *We have a dual system, that is that all drugs that are being prescribed in the extramural setting like with physicians and private practice, there is a drug list on everything that is allowed to be prescribed from.* • *It's very intransparent, the whole system, and this is meant to be intransparent because no country, no region with the public hospital would ever say we don't reimburse cancer drug XYZ.* • *Those who do it, the insurers or the hospital owners, they don't publish.* • *The payers for the hospitals want to have all patients being treated in the extramural setting and the insurers who pay for the extramural settings are very happy if all patients go to the hospitals.* • *So there is no culture, no clinical, no political culture to say no to anything.* • *The bread that exactly the budget is the national, but it's being fed by the regions like in a certain percentage from each regions depending on the size.* • *Because they don't need them and they have a lot of money in the system to monitor the drugs.* • *But the political strategy for the media and for the patients is we say yes, and what happens thereafter, we don't know actually, since we are doing the assessments, we are quite surprised that still the National Commission is saying yes to everything because there are drugs in it with so little effects or so little value that I would say no, but they don't dare to still, so the culture has not changed.* • *So the negotiators of the nine regions come together and they form a team.*
Transparency vs. confidentiality	• *No, there is nothing public on this issue on pricing and reimbursement, nothing at all.* • *And since none of the of these are public, I do not know, but it's not only me, but anybody in Austria knows what kind of cancer drugs are being on the drug list in Tyrol and what kind of cancer drugs are being reimbursed.* • *In Vienna, we just don't know and the regions don't want to make that public.* • *This is the dilemma in Austria and because in the times back of the SMR therapies like with Zolgensma, the parents started to travel with their children from region to region to find a physician, to pay or a public hospital holding that pays for this.* • *Whether this has been ever successful or not, I cannot tell you because again, this is confidential and that's it.* • *Yes, first, it's very intransparent, the whole system, and that this is meant to be intransparent because no country, no region with the public hospital would ever*

	say we don't reimburse cancer drug XYZ. *• Those who do it, the insurers or the hospital owners, they don't publish.* *• Nobody knows because this is then the confidential part, the pricing and the frequency of use of those things, but it is the demand to us for the assessors from this national committee was to be as concrete as possible with the recommendations concerning diagnosis of a certain disease concerning line of therapy for a certain disease, features of the of the patients, etcetera, in order not to broaden the indication too widely.* *• But it's it's not publicly debated.*
Role of health economics and HTA	*• Yeah, well, I have to say that there is not even an institution, academic institution for health economics in Austria.* *• So this logic hinders the use of health economics, whether something eventually is being more cost-effective if people are being treated in the extramural instead of hospitals.* *• So maybe also with the new HTA regulation and joint clinical assessment, this could be of help in a way that's in theory that 27 member states should be aligned also on the Pico.*
European coordination	*• Germany, Austria, Switzerland in terms of cross country outcome-based agreement can be a solution.*
Data infrastructure needs	*• In connection with the SMR registry in Switzerland, this is the Smart Care registry, so the data of the children have to be documented.* *• Then just one question because we saw that sometimes the performance based the schemes are the ones a little bit problematic in the collection of data.* *• Second, for rare diseases, Austria is very small, like if we stay with Zolgensma, there are eight SMR children born per year, so you can't even if you collect the data for 10 years, there is no possibility of making any analysis. So there are no data collections only for Austria for rare diseases, for this obvious reason that we are too small to collect data to make conclusions.* *• But we very much hope for the Darwin or any other European health data space initiatives for European registries that one knows earlier whether all those highly innovative and costly drugs actually fulfill the expectations.* *• Started to be very, very complicated to collect those data and make sense of those data.* *• We do not need to have Scandinavian-like or Benelux-like registries.* *• So those registries must be must really have a long term follow up to understand whether it's only improving or actually healing a therapist.* *• Difficult to get the allowance to look into this registry because the registry is being paid for by Novartis.* *• Otherwise the registries are closed because most of the time they're being paid for by industry and we just don't know how often the drugs are being given and whether they are being given exactly in the indication that we have recommended or whether because of lobbyism or pressure they are being given in the broader indication group, we don't know, but it's not me, it's nobody knows.* *• No, we actually had to work again commissioned by the politicians or by the payers to make a report on registers in Austria and we found around 90 registries.* *• Some of them were being exactly the same indication group in Tyrol and in Vienna, but they did never spoke to each other, that they have the same kind of registry, etcetera.* *• It's a huge chaotic data space and yes, there is a there is a certain strategy to have national registries for indications.*

Germany

Theme	**Exact quotes**
Financial schemes as preferred default	*• So it's easier just to negotiate a rebate either individually or together with other health insurance funds, so on the national level, or just to ask, as it's currently being done, to the Ministry of Health.* *• But it means price reductions and though they have one price negotiation in*

	the beginning after AMNOG and any new measure, any new instrument would mean in practice further reduction.
Limited outcome-based payments adoption	*• So theoretically, at least based on our social codebook, it is possible to negotiate contracts like that [outcome-based], but it's just not been done for various reasons, the main reason being the fact that it's difficult.* *• Negotiating a contract, for example, based on certain outcomes that are reached in individual patients means monitoring patients and normally health insurance funds do not have any access, so they do not have any data of patients and what they get, what kind of treatment they get and what outcomes are achieved so they know when people die.* *• It means a kind of a study that has to be performed, but before that, one has to agree on an appropriate endpoint or outcome.* *• Not a lot of companies are happy about the suggestion of one of our health insurance fund, Technical Kangenkasse (?), which wants to follow up the performance of drugs in practice and then to adjust the price.* *• We have lots of registries, but the access is extremely difficult because the implementation is difficult because these registries were not meant to collect all these data, for example on confounders, we need to interpret the final results, so lots of further aspects have to be documented by the participating positions.* *• Will have a not very helpful result, let's call us that way, so it's really difficult and that's why just recently we also discussed that this regulation should be stopped again.* *• That's very clear and our AMNOG approach is a value-based approach and it's quite clear, but it's not a pay for performance so it's a different thing and but all drugs are all new drugs are priced based on their value..*
Healthcare systems characteristics (+cultural dynamics) affecting pricing and access	*• So they don't know much more, and in many cases of course it's important to monitor certain patient relevant endpoints and only doctors have access to that.* *• And the company just thought, well, if I can get access in Germany, I'll go along with the study because the alternative was bad, so but nobody believes it will do any good thing.* *• They might refer to it if they don't have the staff to perform HTA themselves, but in my opinion, the original idea, to have earlier access in countries, in Eastern countries, it does not help to support this idea because that's an individual decision of the companies.*
Transparency vs. confidentiality	No explicit quote identified in the transcript
Role of health economics and HTA	*• Currently they are involved with I think about 60-70 people from Germany in the EU HTA they are involved in four of seven assessments because it's difficult to find assessors and co-assessor currently from other countries.* *• They have a further step on the assessment of drugs and we don't see that.*
European coordination	No explicit quote identified in the transcript
Data infrastructure needs	*• To have a general rebate on all drugs to save a little bit of money, negotiating a contract, for example, based on certain outcomes that are reached in individual patients means monitoring patients and normally health insurance funds do not have any access, so they do not have any data of patients and what they get, what kind of treatment they get and what outcomes are achieved so they know when people die.* *• Another point is that many companies approached health insurance funds in Germany and so in the meantime, after some time when they had some real world data available from other sources, that it's not really helpful to have such a contract because they might have to pay back a lot of money because their trucks didn't perform so well in practice as they did in the clinical trials, and this is a crucial point in Germany.* *• Of course there are individual cases where in the course of the AMNOG procedure in a re-evaluation or if a comparator changed after some time or if*

some new data were available, prices were increased, but it's maybe a handful of drugs where they supplied and in all other cases any new or further instrument any further.
• There is companies that, well, great, finally also in Germany we had the chance to provide further non randomized data and to show our added value.
• Second point, it takes a very, very long time in practice to collect this data, so it's not possible to collect this data in one year.
• For a lot of work and further on, companies might not be able to show an added benefit with these data.

Italy

Theme	Exact quotes (English translated)
Financial schemes as preferred default	*• Financial-based Managed Entry Agreements (MEAs) — discounts, price–volume caps, and cost-sharing — are the most common tools to manage uncertainty and budget impact.* *• Financial-based MEAs are simpler, so we use them.*
Limited outcome-based payments adoption	*• Outcome data are used to trigger renegotiations rather than pre-defined payback rules.* *• Performance-based MEAs (Payment by Results or risk-sharing) are used selectively, especially for high-cost drugs with measurable survival outcomes.* *• We apply a Payment by Results agreement when we can define a robust, unambiguous definition of therapeutic failure.*
Healthcare systems characteristics (+cultural dynamics) affecting pricing and access	• The national agency AIFA leads centralized HTA and negotiation, but regional payers influence implementation and budgets. • MEAs are described as a "cushioning mechanism" to absorb uncertainty due to limited evidence or short follow-up in clinical trials. • We are no longer in an experimental phase — we have experience and internal know-how on how to apply MEAs effectively.
Transparency vs. confidentiality	• The type of MEA (financial or outcome-based) is published in official AIFA determinations, but specific discount rates, refund percentages, and thresholds remain confidential. • Usually, the scheme is mentioned as 'Payment by Results' or 'Cost-sharing' as per contractual conditions, but the detailed parameters are not disclosed.
Role of health economics and HTA	• The goal is to verify that the medicine is used appropriately and to gather real-world outcomes compared to trial data. • HTA is used pragmatically to support negotiations and post-market evaluations rather than to determine access strictly by cost-effectiveness thresholds.
European coordination	• Outcome-based collaboration across countries would be theoretically useful for very rare diseases, but practically difficult because of different eligibility criteria and systems
Data infrastructure needs	• The AIFA registry platform is a major data source for real-world evidence, enabling MEA monitoring and renegotiation after 2-3 years. • The registry system allows us to verify, at the level of individual patients, whether treatments meet the expected outcomes. • Heavy administrative workload and need for specialized staff remain challenges.

Portugal

Theme	Exact quotes
Financial schemes as preferred default	*• So most of our [schemes] are based on a financial agreement and some, if in addition outcomes results that are that may condition the financing, but the base is always a financial agreement.* *• But the price that is negotiated is public or it can, and in most cases it's the case, the price discount is confidential that is mentioned in our agreement with the with the company.*

	• *98% are based on the price discount.* • *In addition, we also have in several agreements a ceiling, a cap expenditure.* • *In in addition to the price discount, but sometimes in some medicine that mostly in the outpatient setting our some sometimes it's useful to have this ceiling because the use can be wider than the indication that was reimbursed and so it's also an indirect way of limiting the use of the medicine to the indications that were approved.* • *So we also have a lot of management entry agreements with a cap expenditure.* • *So besides price discount and cap expenditure, we also have price volume agreements that are this type of financial payment scheme is most used to medicines that have or are going to have multiple indications like the immuno-oncology.* • *We also have the contracts that have a financial component and also an outcome-based part.*
Limited outcome-based payments adoption	• *We also have the contracts that have a financial component and also an outcome-based part and.* • *Basically we try to have all those one shot drugs that the administration is once and then the results are expected to be lifetime or at least 10 years or five years we for those medicines we try to have to add to the financial agreement an outcomes based component so that we are paying or in a phased way with phased payments.* • *So we have these outcome based agreements for some oncology and some rare disease.* • *So only for those medicines we are using the outcome based agreement.* • *Price, volume and financing and and added by clinical outcomes and we have most of our new drugs under this kind of management entry agreements.* • *I think one point that you mentioned about the data that is, I think these management entry agreements are useful, but sometimes they can increase the burden of our teams because we send, we monitor, we collect data, we monitor and the companies try not to pay as much as we are asking and so they frequently they say no that is not correct…* • *Some diseases are more difficult to measure for.* • *The administrative burden is high and the companies tend to pressure for these more, say, glamorous agreements and we try to push for more financial and more with more direct results.*
Healthcare systems characteristics (+cultural dynamics) affecting pricing and access	• *We use the dispensing data and we have a system that collects that data for decades, so it's quite robust for hospital sector.*
Transparency vs. confidentiality	• *There are no rules written or publicly available for the for our partners.* • *The agreements are confidential, but sometimes when we do, when we present our pricing and reimbursement schemes, we mentioned the types of financial agreements that we have.* • *We don't make that information public.* • *But the price that is negotiated is public or it can, and in most cases it's the case, the price discount is confidential that is mentioned in our agreement with the with the company.* • *We share that information with the hospitals, but of course there is a lack of transparency here and it makes harder for hospitals to make cost comparisons with different treatments.* • *Even if you share the information, sometimes they don't use it because it's the information is assessed by the top persons in the hospital and sometimes the doctors don't have access to that information, so, For us it's good because we*

	have I think better prices that we wouldn't have without this price, the confidential prices counts.
Role of health economics and HTA	No quote.
European coordination	*• But nonetheless, it's quite a burden to have these additional European assessments on top of our national assessments.*
Data infrastructure needs	*• Just to complete because we have, we have a very strong collection of data from the hospitals also in the medicines that are dispensed in the outpatient we have a National Center that calculates all the medicines that were prescripted and companies must set the data that we have because it's like a third party collecting all the data and we work with all that data.* *• It requires also the work from the health professionals to fill those registry.* *• We use the dispensing data and we have a system that collects that data for decades, so it's quite robust for hospital sector.* *• We also use the data that we also collect since 2007 from the hospital sector.* *• Most of the contracts are revised in a period of two years and based on the results of the monitoring we may change the conditions, the price is usually the trend is to decrease.*

Netherlands

Theme	**Exact quotes**
Financial schemes as preferred default	*• You said it's for payers, with theoretical frameworks and practical examples, but the final financial deals never become public.* *• We know most payers prefer simple price discounts, but sometimes that's not appropriate… if there's high uncertainty, even a big discount may not make a drug worthwhile for patients.* *• They can be reimbursed if data collection and further studies are done, plus a special financial agreement, which isn't explicitly cost-effectiveness-based.* *• We don't know, the discounts are confidential.* *• And price reductions wouldn't change the conclusion if the uncertainty about effectiveness is too high; they'd still fail reimbursement.* *• Same in the UK: there's a scheme, but we never know the discount size.* *• ZIN does the assessment of effectiveness; usually that's fine, but uncertainty about cost-effectiveness leads to large requested discounts.* *• We advise the Ministry on the needed discount size, but the final price is never revealed.* *• There were many debates on whether this counted as conditional reimbursement or a financial agreement.*
Limited outcome-based payments adoption	*• For example, in the Netherlands we had a pay-for-performance agreement for omalizumab in 2016.* *• Without formal legal powers, they built their own control programs: risk-sharing, pay-for-performance, data collection.*
Healthcare systems characteristics (+cultural dynamics) affecting pricing and access	*• We know most payers prefer simple price discounts, but sometimes that's not appropriate—if there's high uncertainty, even a big discount may not make a drug worthwhile for patients.* *• Some publications describe it; one is the Drug Access Protocol, supported by Dutch oncologists.* *• We published a 2019 article on "personalized reimbursement." It started in oncology: companies paid for the first 16 weeks of treatment; if the patient was still responding afterward, the insurer took over reimbursement.* *• It wasn't a government program but an insurer initiative, supported by ZIN as an innovation experiment though it didn't fit neatly into legal frameworks.* *• Currently we're working on a national reform to combine the two pathways—the government's and the insurers'—into one unified system.*

	• ZIN participates (I'm in the coordination group of HTAR); the insurers are not direct participants because they lack capacity, but we cooperate closely.
Transparency vs. confidentiality	*• The agreement is public (in Dutch).* *• The regulation asks companies to be transparent about the price—but that's a major hurdle; no one wants to.* *• In practice it became only partly transparent.* *• The program isn't very attractive—many companies skip it because it's a lot of work for a small market and includes tough price-transparency demands.* *• We don't know—the discounts are confidential.* *• We don't know where talks broke down; that's all confidential.* *• We're all trapped in confidential pricing, and it's getting worse.* *• HTA bodies compare with other treatments that also have confidential or non–cost-effective prices—it's a vicious circle.*
Role of health economics and HTA	*• We also had the older JS0/JS4 schemes, with re-evaluation of cost-effectiveness after four years, but we stopped because it proved impossible to perform reliable new evaluations.* *• They can be reimbursed if data collection and further studies are done, plus a special financial agreement, which isn't explicitly cost-effectiveness-based.* *• The "lock" was created because we had an open system: hospital drugs could enter reimbursement without assessment.* *• The lock now selects the big-budget drugs for assessment and, if needed, negotiation.* *• ZIN does the assessment of effectiveness; usually that's fine, but uncertainty about cost-effectiveness leads to large requested discounts.* *• Over time more hospital drugs entered without assessment.* *• They formed a national negotiation team and a clinical assessment team.* *• The goal is to decide who should do what and which tools and assessments are needed.* *• I'm secretary of the Scientific Advisory Board in the Netherlands, and some members also work on NICE dossiers—so they often know files earlier, as NICE assessments tend to happen sooner in time.*
European coordination	No explicit quote identified in the transcript.
Data infrastructure needs	*• They can be reimbursed if data collection and further studies are done, plus a special financial agreement, which isn't explicitly cost-effectiveness-based.* *• Without formal legal powers, they built their own control programs—risk-sharing, pay-for-performance, data collection.*

Spain

Theme	Exact quotes
Financial schemes as preferred default	No explicit quote identified in the transcript.
Limited outcome-based payments adoption	*• In some cases, related with some outcome based risk sharing agreement.* *• To a new pay for solutions and to an outcome based payment.* *• So all this movement from pay-for-device to an outcome-based, move companies to a new business models to selling products or devices.* *• Then to move to provide services and some sometimes it's very difficult for companies to move to these new business models.* *• The healthcare provider that wants to promote a new project is discussing with Aquas about the most suitable outcomes, also with the payer, and then we establish a common group between the three institutions in order first of all to try to evaluate the rightness of the information systems in order to get the outcomes.*

	• *We establish a period of time for getting these outcomes and then we evaluate the quality of this information and then we decide this go on a go with the procuring.* • *Before to establish the final outcomes for granting the contracts or for monitoring the results of the contracts […]* • *Common groups, common working groups with companies in order to share and to follow on this information and maybe to remove some outcomes, to add new ones, whatever the situation...* • *And we are also involving patients in getting these outcomes.*
Healthcare systems characteristics (+cultural dynamics) affecting pricing and access	• *All the initiatives are lead by the payer.* • *So, is the because our system it's a Beveridge healthcare system.* • *So Ministry of Health is defining the strategy, public payer is implanting this strategy.* • *And since 2012, yeah, 2011-2012 Aquas is a health technology assessment, a public agency owned by Ministry of Health. Aquas is acting as procure in some of these innovative actions and then is scaling and deploying at system level.* • *Payer could be a provider mainly with drugs and then healthcare providers are being procured mainly with medical devices and AI.* • *So if it's an a strategic unsolved unmet need, then payer is leading; in some cases the promoter is the payer, then Aquas is leading as main procurement institution.* • *So we had all the information of Catalan healthcare systems and before granting the contracts.* • *It won't be easy [to generalize to other regions] because Catalonia has a different healthcare systems than the rest of the Spain.*
Transparency vs. confidentiality	• *Of course, there are different kind of healthcare systems with different, with different governance, with different roles of payers, private, public ones, public insurance.* • *So every year Aquas publish all the performance of the activity of healthcare providers.* • *Because we are, we are giving high transparency.* • *All our activities are published, are public activities, so there is no problem for sharing all this information and maybe some information related with new new approaches or new projects that we are working on at this moment.*
Role of health economics and HTA	• *And since 2012, yeah, 2011-2012 Aquas is a health technology assessment, a public agency owned by Ministry of Health.*
European coordination	• *Some of these initiatives are cross-border projects, so taking advantage of different healthcare systems.*
Data infrastructure needs	• *So we are asking companies to submit the algorithms to a validation with our data.* • *In some situations, primary care is providing, mainly monitoring systems to hospitals, for example with pacemaker primary care is monitoring.*

Sweden

Theme	Exact quotes
Financial schemes as preferred default	• *What the only thing we know about is, you know, straight rebates, linear rebates, volume-based.* • *Some examples where we have combined price-volume, so, so we pay a certain quite high amount for the first patients and then we pay less and less until some kind of ceiling and I guess when you've reached the ceiling.*

	• *I think it is fair to say that the main obstacle for anything else than price volume is time and resources.* • *So financial based management agreements are much easier because that's where you in writing conclude and agree if you have a sales volume...* • *I will get the 15% rebate or a 70% rebate, provided that I don't tell anyone…*
Limited outcome-based payments adoption	• *The last 10 years or since 10 years, we have moved more into managed entry agreements.* • *An outcome-based agreement with a follow up of clinical effectiveness in the actual clinical care situation is normally preferred by everyone.* • *And I already, before the pandemic, said when I listen to the payers, not only in Sweden, but to the payers, my conclusion is that managed entry agreements… they are dead because payers have the opinion that, either way, the outcome results fall out, they will still sit be sitting there with the paycheck.* • *To join forces on procurement, because in Italy you think that your system with the registries for the new therapies is serving your purposes very well and it's very difficult for the rest of us to see… to get some insights.*
Healthcare systems characteristics (+cultural dynamics) affecting pricing and access	• *But we have no budget to cover the costs that is it's paid by the regions and every year there is a general grant.* • *Lump sum negotiated between the government and the regions.* • *The regions are in the driver's seat.* • *They need to both the regions and the the company need the buyer and the seller needs to be interested and then we can facilitate the process because we have not a lot of knowledge and we do the health economic.* • *As far as now the regions are quite self dependent or self deciding, but everyone realises that if the regions could come together, they would be one a better purchaser, a stronger purchasing power.* • *We send a more open-ended report to the NT (?) Council that is an organization within the regional system and they also don't make decisions, but they make recommendations.*
Transparency vs. confidentiality	• *Efficient, though also less transparent.* • *If not, payment models because that was in the background, I don't think we made that public.* • *Transparent as possible with our methods, but honestly, when it comes to the agreements, they are quite often under secrecy.*
Role of health economics and HTA	• *They need to both the regions and the the company need the buyer and the seller needs to be interested and then we can facilitate the process because we have not a lot of knowledge and we do the health economic.* • *The treatments, the comparators, uh, the actual treatment, the intervention in scope and health economics.* • *Can you put that into your health economic model in terms of price and patient numbers, etcetera.* • *You know, the health economics isn't really part of the HTA work.*
European coordination	• *Cross-national, cross-border collaborations if we talk about countries with a fairly similar GDP per capita and purchasing power.*
Data infrastructure needs	• *First real world data, second oncology and third precision medicines and payment models.* • *Almost no guidance or especially no agreement if we set up a follow, a follow up in the registry, a new registry or an established one, and decide that we shall gather all patient data we can.* • *Deciding that the data we collected were unconclusive.* • *We cannot use the data for decision making because XYZ or any letter in the in the alphabet really because we have not agreed.* • *We could talk about data quality, register quality, etcetera, but we have nothing that correlates to AP (?) value.* • *We cannot pay more or less based on these data.*

United Kingdom

Theme	Exact quotes (Mike's notes)
Financial schemes as preferred default	*• NICE's payment and pricing activities fall into 3 categories: simple patient access schemes, which are essentially simple discounts/rebates on the list price; managed access schemes, which are organised under two programmes, the Cancer Drugs Fund and the Innovative Medicines Fund; commercial access schemes, which control the use of the technology consistent with NICE's guidance.* *• NICE has a general preference for simple patient access schemes where possible, as the other types of arrangement often place extra burden on the NHS, in monitoring the arrangements.* *• If there is mention of a 'Patient Access Scheme' with no further qualification, this means that a discount exists.* *• Therefore, NICE generally prefers a simple discount rather than arrangements like these, as they are easier to monitor.* *• We discussed the fact that this payment method would be particularly useful for gene therapies, but in the UK most gene therapies that have been approved in the UK have just had a simple discount.* *• If similar cases arose today, they would either have a simple discount, or would be handled by one of the market access schemes.* *• Technologies appraised under NICEs 'Highly Specialised Technologies' programme (eg orphan drugs) have largely been approved with simple discount.* *• However, the preference is still for simple price reductions.*
Limited outcome-based payments adoption	*• NICE has a general preference for simple patient access schemes where possible, as the other types of arrangement often place extra burden on the NHS, in monitoring the arrangements.* *• Commercial access schemes are specific to each technology, and have often proved difficult to manage.* *• This was for several reasons, but the main reason was that the UK Treasury (Ministry of Finance) would not let the NHS pay for medicines by that method.* *• If there is considerable uncertainty about the outcome(s) for patients, but the technology is likely to be cost-effective by NICE's criteria at the price agreed if the outcome is as predicted by the economic model, further time can be allowed for data collection, for a maximum of 5 years, in order to reduce the uncertainty around the outcome(s).* *• This is mainly because of the burden in collecting data and/or monitoring has on the NHS.*
Healthcare systems characteristics (+cultural dynamics) affecting pricing and access	No explicit quote identified in the transcript.
Transparency vs. confidentiality	*• Occasionally, NICE or NHS England has agreed to more complex arrangements, although the details are not generally made public.*
Role of health economics and HTA	*• At this point, the assessment and pricing decision is made in the light of the prevailing situation.* *• Currently, most individual cases last 2-3 years, but the tumour-agnostic drugs will be on the Cancer Drugs Fund for 5 years, since the assessment covers many tumour types and the numbers of patients treated of some types may small.*
European coordination	No explicit quote identified in the transcript.

Data infrastructure needs	• *NICE has a general preference for simple patient access schemes where possible, as the other types of arrangement often place extra burden on the NHS, in monitoring the arrangements.* • *If there is considerable uncertainty about the outcome(s) for patients, but the technology is likely to be cost-effective by NICE's criteria at the price agreed if the outcome is as predicted by the economic model, further time can be allowed for data collection, for a maximum of 5 years, in order to reduce the uncertainty around the outcome(s).* • *The data collected could be from an ongoing clinical trial or real world data, either by using routinely collected data (eg SACT data for cancer drugs) or by establishing a registry.* • *At the end of the prescribed data collection period, the technology is re-appraised by NICE to assess whether it can enter normal commissioning (payment).* • *This would take account of the results of data collection and any other relevant factors, such as the emergence of new therapies.* • *This is mainly because of the burden in collecting data and/or monitoring has on the NHS.*