APPENDIX A:

OCEANIA

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Australia	Once a drug is approved by the TGA[i,1], the drug is reviewed by the PBS.[ii] The PBS will reimburse a medication that is safe, clinically effective, and cost effective.[2] To determine if this criterion is met, the PBAC,[3] an independent body of experts, is used. The PBAC has two subcommittees: (1) drug utilization subcommittee; and (2) economics subcommittee. The joint value assessment conducted by these subcommittees takes an estimated 17 weeks.[4] Pricing is ultimately decided by the payer, the Department of Health.	No.	Yes.	• PBAC members are appointed by the Australian government and must include 2 consumer representatives.[5] • Patients and caregivers can submit written comments to the PBAC for consideration when a drug is under review. • Some public commenters are invited to participate in consumer hearings and stakeholder meetings.	• It is unclear how patients and members of the public are identified and selected to participate in consumer hearings and stakeholder meetings. • It is unclear how the PBAC takes account for comments from patients and caregivers in its decision-making.	• The PBAC is required to include 2 consumer representatives as members of the PBAC. • Consumer representatives on the PBAC are required to review all comments and summarize key points for the PBAC. • PBAC is also supported by a Consumer Evidence and Engagement Unit within the Department of Health.
New Zealand	Once a drug is approved by MedSafe, the drug is reviewed by Pharmac to determine if it should be covered by the public insurance program.[6] Pharmac employs the PTAC[iii] to conduct an assessment and determine if the medication should be recommended for coverage.[7] The PTAC or Pharmac can also request a specialist advisory committee to conduct a secondary review and issue a recommendation on whether the medication should be covered. After the PTAC's recommendation is provided, Pharmac conducts its own economic assessment and negotiates a price for the medication with the manufacturer. Over the last 5 years, the average application took 21.5 months to be accepted and ranked on the covered medication list.[8]	No.	Yes.	• PTAC must include at least 1 consumer representative.[9] • Each part of the PTAC's analysis must consider the patient, family, whānau and society impact.[10] • Pharmac maintains a Consumer Advisory Committee which advises Pharmac on: (1) strategies, policies, and operational activities around access to and optimal use of medicines; (2) how to best communicate its decisions, policies, and strategies with consumers; and (3) how and when it can best engage consumers in its work. This mandate was extended in 2021 to also advise on medicine funding proposals.	• While the PTAC acknowledges the consumer impact, it is unclear how the PTAC weighs comments from patients and caregivers in its decision-making.	• The PTAC must include at least 1 consumer representative. • The PTAC's assessment considers the impact of medications on patients, caregivers, and indigenous Māori populations. • The Consumer Advisory Committee can provide recommendations to Pharmac on a funding proposal.

[i] Therapeutic Goods Administration [ii] Pharmaceutical Benefits Scheme [iii] Pharmacy and Therapeutics Advisory Committee

ASIA

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Japan	Once a drug is approved by PMDA, it is reviewed by the Central Social Insurance Medical Council (Chuikyo) to determine if the drug should be added to the Drug Price Standard List and covered by the national public insurance. The Chuikyo consists of 20 individuals that represent payers (7), health care providers (7), and academics and those representing the public interest (6).[11] The Chuikyo then has Japan's HTA agency, C2H,[12] conduct an ICER and QALY assessment to determine the price of the drug. The assessment and pricing process is estimated to take 15 months.[13]	Yes, after the C2H assessment is completed, the Chuikyo reviews how the drug is priced compared to the US, UK, France, and Germany.[14] The drug price could increase if it is .75 times less than the average price and may be reduced if it is 1.5 times more than comparative countries.[15]	Yes.	• The Chuikyo allows third-party representatives of the public interest to serve as members.	• There is no process for consumers to provide feedback into the C2H. • There is no requirement for C2H to reconcile patient-based outcomes with pricing decisions.	• The Chuikyo allows third-party representatives of the public interest to be members.
Republic of Korea	Once a drug is approved as safe and effective by the Ministry of Food and Drug Safety, it is reviewed by the HIRA[16] to determine if it should be covered by the NHI.[v] The HIRA refers the drug to the DREC[17] to conduct a cost-effective analysis. A drug must receive a "positive listing" in order to be covered by the NHI. For certain anti-cancer and orphan drugs, the DREC will not use a QALY and instead uses a comparative analysis with France, Germany, Italy Japan, Switzerland, Canada, the UK, and the US.	Yes, for certain orphan drugs and anti-cancer drugs, the DREC conducts a cost-comparison with France, Germany, Italy Japan, Switzerland, Canada, the UK, and the US.[18]	Yes.	• There is not a clear patient engagement process.	• There is not a clear patient engagement process.	• They have recognized that a QALY cannot be adopted in all cases, especially for orphan drugs and anti-cancer drugs.

[iv] The Pharmaceutical and Medical Device Agency [v] National Health Insurance

NORTH AMERICA

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Canada	Once a drug is deemed safe and effective by Health Canada,[19] Canada's Drug Agency determines if the drug should be reimbursed by the national public health insurance program.[20] Canada's Drug Agency conducts a cost-effectiveness analysis and evaluates feedback from patients and clinicians and provides a reimbursement recommendation. If a positive reimbursement recommendation is received, the pan-Canadian Pharmaceutical Alliance works with manufacturers to determine the price.[21] The Patented Medicine Prices Review Board also reviews patented drugs to determine if the price is fair in comparison to other countries.[22] If a drug price is considered "excessive," Canada can require the price to be reduced to a non-excessive level or the pharmaceutical manufacturer may be required to pay back some of the profits incurred as a result of the "excessive" price.[23] However, a reimbursement recommendation and negotiated price does not guarantee availability as each providence creates its own drug formulary.[24]	Yes, but only by the Patented Medicine Prices Review Board. Comparative countries include Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the UK.[25]	Yes.[26]	• Calls for patient input are advertised once a week through the agency's newsletter.[27] A templated document is used to collect patient feedback that focuses on how the information was gathered; disease experience; perspectives on existing treatments, outcomes, and new treatments; and any companion diagnostic testing that is relevant to the drug under review.[28] • Clinician groups also have their own pathway for comments on a drug under review.[29] It is advertised in the same manner as the patient input, requires conflict of interest disclosure, and allows for feedback on recommendations.[30] • Feedback is summarized in reports and in some cases, noted that feedback was part of the recommendation decision.[31] • The CDEC, an advisory group to the CDA, includes 3 patient representatives.[32]	• Despite patient engagement and price negotiation processes, patients still report being unable to afford their medications.[33]	• Canada's Drug Agency also has several advisory groups including a rare disease advisory group and a patient and community advisory committee.[34] • Clear opportunities for patients and clinicians to engage in reimbursement reviews.[35] • Comprehensive framework explains how patients may engage diverse divisions within Canada's Drug Agency, and recognized the values of patient feedback and perspectives across various stages of drug development.[36]

OTHER

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Israel	Once a drug is approved by the Ministry of Health's Pharmaceutical Division as safe and effective, the Division of Senior Planning, Budgeting and Pricing determines the maximum price of the drug.[37] The maximum price is based on international reference pricing, using the average lowest three costs.[38]	Yes. The maximum price of a drug is determined through a comparative analysis of England, Germany, Holland, France, Belgium, Spain and Hungary, using the average of the lowest three quoted wholesale prices.[39]	No.	• There is no formal or mandated patient engagement process.	• There is no formal or mandated patient engagement process.	• The Public Committee for the Expansion of the Healthcare Services Basket annually determines which new prescription drugs will be added to the reimbursement list in the following year and includes public representatives.[40]

EUROPE

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Austria	Once a drug is approved by the AGES[vi] PharmMed and Federal Office for Safety in Health Care, the DVSV[vii] is responsible for determining if it will be included on the positive list for reimbursement.	Yes. When determining the price of a medication, the DVSV will review the price of the drug in all EU Member States. The determined price cannot exceed EU average price.[41]	No.[42]	• There is no formal or mandated patient engagement process.[43]	• Patient organizations are included among the stakeholders listed by the AIHTA, an independent body that provides scientific support to public sector decision-makers. However, AIHTA does not have an official role in the pricing and reimbursement process.[44]	• Patient organizations are included among the stakeholders listed by the AIHTA,[viii] an independent body that provides scientific support to public sector decision-makers. However, AIHTA does not have an official role in the pricing and reimbursement process.[45]
Belgium	Once a drug is approved as safe and effective by the FAMHP,[ix,46] the NIHDI[x] will determine if the drug satisfies the reimbursement criteria. The Minister of Economic Affairs sets the maximum ex-factory price, a key component of the "maximum public price" charged to patients. The maximum public price consists of the ex-factory price, wholesale and pharmacy margins, a pharmacist's dispensing fee for reimbursable products, and a 6% VAT.[47] The CRM[xi] conducts the initial assessment of the product's therapeutic value and recommends if it should be on the positive list.[48]	No.	Yes.[49]	• The Commission for the Reimbursement of Medicines at the NIHDI includes patient representatives in its deliberations.[50] • The CRM[xii] uses structured questionnaires to collect patients' real-world experiences with diseases and treatments.	• There is no mandated patient engagement process for non-orphan prescription drugs.	• For orphan drugs, patients participate through patient organizations, submitting input, commenting on evidence, appeal decisions, and representatives serve as stakeholders on the reimbursement advisory board, provided they do not represent patients who could benefit from the specific medicine.[58]

[vi] Austrian Agency for Health and Food Safety (German: Agentur für Gesundheit und Ernährungssicherheit) [vii] Federation of Austrian Social Insurance Institutions (German: Dachverband der österreichischen Sozialversicherungsträge)
[viii] Austrian Institute for Health Technology Assessment [ix] Federal Agency for Medicines and Health Products [x] National Institute for Health and Disability Insurance [xi] Commission for Reimbursement of Medicines [xii] Commission for Reimbursement of Medicines

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Czech Republic	Once a drug is approved by the State Institute for Drug Control (SIDC), it is responsible for determining reimbursement.[51] To be reimbursed, a product must show "effective therapeutic intervention" must submit both a cost effectiveness analysis (CEA) and a budget impact analysis (BIA). Reimbursement is denied if either is missing or insufficient.[52] Reimbursement is organized into groups of products considered therapeutically interchangeable based on comparable efficacy, safety, and clinical use.[53]	Yes, SIDC sets the reimbursement price using the lowest EU price found for comparable products (only if its market share is 5%+ within the same active ingredient), recalculated from publicly available HTA databases after removing margins and VAT.[54]	Yes.[55]	• For standard prescription drug products, patient input may be considered voluntarily at the HTA body's discretion.[55] • For orphan drug products, patient involvement has been legally required and integrated into the reimbursement process since 2022.[57]	• There is no mandated patient engagement process for non-orphan prescription drugs.	• For orphan drugs, patients participate through patient organizations, submitting input, commenting on evidence, appeal decisions, and representatives serve as stakeholders on the reimbursement advisory board, provided they do not represent patients who could benefit from the specific medicine.[58]
Denmark	Once a drug is approved by the DMA[xiii] as safe and effective, the Danish Reimbursement Board for Evaluation reviews the application to determine if it will be covered by the public health insurance program.[59]	No.	Yes.[60]	• Patient and consumer interests are considered in Denmark's drug reimbursement decisions through a single representative on the Reimbursement Committee.[61] • Patients and patient organizations can also participate in the HTA process, and Denmark integrates their input into HTA reports and final recommendations.[62]	• There is no explicit requirement to reconcile patient-based comments with pricing decisions.	• The patient-involvement strategy formally incorporates scientific evaluation of patient experiences and outcomes to generate patient-based evidence as a core component of HTA.[63] • The Denmark Medicine's Council's 2025-2027 strategy includes strengthening patient involvement by improving support for patient representatives, increasing transparency, collaborating with patient organizations, and making patient values and preferences a clearer part of its medicine-assessment and decision-making processes.[64]

[xiii] Danish Medicines Agency

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Finland	Once a drug is approved as safe and effective by Fimea,[xiv] the Hila[65] determines the maximum wholesale price.[68]	No.	Yes.[67]	• The Hila allows patient organizations to submit input on the therapeutic value of medicines.[68] However, there is no formal patient engagement process.	• There is no formal or mandated patient engagement process.	• Consumers, patient organizations, and the public can submit input on the therapeutic value of medicines.
France	Once a drug is approved as safe and effective by the ANSM,[xv] the CT[xvi] of the French National Authority for Health evaluates the drugs clinical benefit (SMR)[xvii] and value compared to existing treatments (ASMR).[xvii,69] Based on these assessments, the CT provides recommendations to the Ministers responsible for Health and Social Security, who make the final decision reimbursement.[70] This SMR rating determines the level of reimbursement under the national health insurance system. SMR categories generally include insufficient, mild, moderate, and important, with drugs rated "insufficient" typically not reimbursed. Reimbursement rates for the other categories vary: drugs with a mild SMR are reimbursed at 15%, moderate SMR at 30%, and important SMR at 65%.[71]	No.	Yes.[72]	• The French National Authority for Health has adopted a formal patient engagement framework in which patient representatives are considered experts and are granted the same rights and duties as medical or scientific experts, including the right to remuneration for their time, reimbursement of participation costs, the obligation to declare conflicts of interest prior to participation, and the duty to maintain confidentiality of documents until publication.[73] • The CT includes two representatives of patient associations and health care users.[74] • Individual patients share their experiences of living with the condition and their expectations for new treatments, and may respond to questions from the assessment team to help define the population, reference treatments, and outcome measures. • Patient groups also complete a standardized template covering disease burden, current treatment experiences, and expectations for new technologies, with their contributions published with final recommendations.	• There is no requirement to reconcile patient-based comments with pricing decisions.	• Clear framework for engaging patients and valuing patient perspectives. • Requirement for CT to include patients or consumers. • Processes for both individuals and patient groups to comment on value assessments.

[xiv] Finnish Medicines Agency [xv] National Agency for Medicines and Health Products Safety (French : Agence Nationale de Sécurité du Médicament et des Produits de Santé), https://ansm.sante.fr/page/autorisation-de-mise-sur-le-marche-pour-les-medicaments [xvi] Transparency Committee (French: Commission de la Transparence) [xvii] French: Service Médical Rendu [xviii] French: Amélioration du Service Médical Rendu

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Germany	Once a drug is approved as safe and effective by the G-BA,[xix,75] the pharmaceutical manufacturer sets the price of the drug at market entry. Within six months of launch, the drug undergoes an early benefit evaluation.[76] During the benefit evaluation, IQWiG[xx] conducts a scientific assessment, while the G-BA conducts a benefit assessment to determine if the new drug provides an "added benefit."[77] The G-BA grades added benefit as minor, considerable, or major, depending on outcomes such as reduced mortality, fewer side effects, or improved quality of life. Following the G-BA's decision on added benefit, the manufacturer and the National Association of Statutory Health Insurance Funds[xxi] negotiates a reimbursement price, which takes effect 7 months after launch and applies uniformly to all insurers and patients.[9]	No.	Yes.[78]	• The G-BA includes patient representatives who participate in benefit assessment procedures, but do not have voting rights.[79] • Patient representatives may submit written comments on preliminary reports in the benefit assessment of drugs, participate in discussions, and communicate with the G-BA's Coordination Committee for Patient Involvement.[80] • After evaluating the written and oral comments, the relevant subcommittee prepares a draft resolution that includes which changes to the draft resolution the subcommittee recommends based on the comments received by third parties and the reasons given for not supporting the requested changes.[81]	• Because patient representatives do not have voting rights in the G-BA, their role remains advisory, carrying less weight than providers or health care professionals. • Research indicates that patient preferences were not considered within benefit assessment.[82] • Offers fewer comprehensive patient participation opportunities than other countries.[83]	• Patient representatives are required to be included in G-BA benefit assessments. • There are opportunities for patients to submit written comments. • The G-BA reconciles its decisions with the comments received.
Iceland	Once a drug is approved by IMA[xxii] as safe and effective, the IMA will conduct a cost-effectiveness analysis to determine if it should be covered by the national public insurance program.[84] If a medication is considered "high-cost," the National Hospital Medicines Committee will review it to determine if it should be covered by IMA.[85]	Yes. When determining the price of a medication, the IMA will consider the cost of the drug in Denmark, Finland, Norway, and Sweden.[86]	No.	• There is no mandated patient engagement process.	• There is no mandated patient engagement process.	• The Medicines Committee statutory mandate recognizes it may consult patient organizations as necessary.[87]

[xix] Federal Joint Committee (German: Gemeinsamer Bundesausschuss), https://ansm.sante.fr/page/marketing-authorisation-for-medicines [xx] German Institute for Quality and Efficiency in Health Care (German: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) [xxi] GKV-Spitzenverband [xxii] Icelandic Medicines Agency

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Ireland	Once a drug is approved by the HPRA,[xxiii] the HSE[xxiv] determines which drugs will be reimbursed by the public health insurance program.[88] The HSE contracts with the NCPE[xxv] to conduct a QALY assessment.[89] The NCPE conducts a QALY assessment and provides a recommendation on whether the drug should be reimbursed. Patient organizations can provide comments on the day-to-day experience of living with a health condition and the value of a potential treatment.[90]	Yes. During the "rapid assessment," the NCPE[xxvi] reviews cost-effectiveness in other countries.[91]	Yes.	• Patient organizations can submit comments to NCPE regarding the value and lived experience with treatments.	• The guidelines are unclear on the value of patient engagement and submissions.[92] • There is a need for greater inclusion of patient voices throughout the HTA process.[93] • Recent recommendations call for methodological changes, including the incorporation of subgroups based on social determinants of health, patient-reported outcomes, and real-world experiences. • Reports can be difficult for patient groups and patients to understand.[94]	• Patient organizations have an opportunity to submit comments.
Italy	Once a drug is approved as safe and effective by the IMA,[xxvii] the NPA[xxviii] will determine if the drug should be reimbursed and covered by the NHS.[xxix,95]	During the review, the CSE[xxx] will consider the reimbursement decisions of other countries.[96] [xxx] Scientific and Economic Committee for Medicines.	Yes.	• There is no mandated patient engagement process.	• There is no mandated patient engagement process.	• Patient organizations and scientific associations are recognized as relevant stakeholders but there is no requirement to engage with them or weigh or reconcile their feedback.
Luxembourg	The CNS[xxxi] covers all medications included on the "positive list."	Yes. The government does not negotiate directly with pharmaceutical companies. Instead, it imports 80% of its medications from Belgium, Germany, and France. The price of the drug is based on its cost in the originator country.[97]	No.	• Patients can submit public comments, but there is no codified patient engagement process.	• There is no patient engagement process.	• There is no patient engagement process.

[xxiii] Health Products Regulatory Agency [xxiv] Health Service Executive [xxv] National Centre for Pharmacoeconomics [xxvi] National Centre for Pharmacoeconomics [xxvii] Italian Medicines Agency [xxviii] National Pharmaceutical Agency [xxix] National Health System [xxvii] Italian Medicines Agency [xxviii] National Pharmaceutical Agency [xxix] National Health System [xxxi] Caisse Nationale de Sante

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Netherlands	Once a drug is deemed safe and effective by the Medicines Evaluation Board,[98] the Ministry of Health, Welfare, and Support determine if the drug should be reimbursed by the public insurance programs.[99] To support the reimbursement assessment, the Ministry of Health conducts a comparative analysis of prices in Belgium, France, Norway, and the UK.[100] The National Health Care Institute is also contracted to conduct a QALY assessment and provide a reimbursement recommendation to the Minister of Health, who ultimately decides if a drug should be covered.[101]	Yes. The Ministry of Health compares prices to Belgium, France, Norway, and the UK. Germany was previously included but in 2021, it was replaced by Norway, which had lower prescription drug costs.[102]	Yes.	• Patients can submit comments, but there is no codified patient engagement process.[103]	• It is unclear how patient groups and advocates are valued and engaged.[104]	• Patient organizations are consulted by the National Health Care Institute when conducting a QALY.[105]
Norway	Once a drug is approved as safe and effective by NoMA,[xxxii] it conducts an assessment to set a maximum pharmacy price for the approved drug.[106] NoMA conducts an HTA assessment using a QALY and reviews international reference prices to set the maximum pharmacy price.[107]	Yes. When establishing the maximum price, NoMA reviews prices in Sweden, Finland, Denmark, Germany, Great Britain, the Netherlands, Austria, Belgium, and Ireland.[108] NoMA uses the three lowest prices available. If a drug is not available in at least three countries, it uses the average price available.[109]	Yes.	• Patients can submit comments and engage with the HTA assessment.[110]	• There is no requirement to reconcile patient-based comments with pricing decisions.	• Patients can submit comments during the HTA assessment.

[xxxii] Norwegian Medical Products Agency (Formerly Norwegian Medicines Agency)

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Spain[111]	Once a drug is approved as safe and effective by the AEMPS,[xxxiii] the Ministry of Health is responsible for determining if the drug should be covered by the SNS.[xxxiv,112] Spain recently revised its drug pricing process in 2024. Under the new framework, a Governance Council will oversee the pricing process.[113] The Governance Council will oversee two HTAs, one for medicines and one for health technologies.[114] The HTA for pharmaceuticals will conduct a cost-effectiveness analysis and provide a report to the HTPA.[xxxv] The HTA assessment is not permitted to state if the drug should be covered by the SNS. The HTPA reviews the HTA report and consults with its members to determine if a drug should be covered by the SNS.	No.	Yes.	• The HTPA is required to include one patient organization representative and one consumer organizations representative.[115]	• Ongoing reforms to the system have created uncertainty around the HTPA's transparency, particularly regarding how consumer feedback is reconciled with decision making process.	• The HTPA is required to include consumer and patient representatives.[116] • The HTA does not have the ability to provide a recommendation, allowing the HTPA to better discuss the merits of a drug without a pre-existing recommendation in mind. • The HTPA is required to provide a recommendation on whether a medicine should be covered and justify its recommendation in a public report.[117]
Sweden	Once a drug is deemed safe and effective by the MPA,[xxxvi] the Dental and Pharmaceutical Benefits Agency (TLV)[xxxvii] determines if the drug should be reimbursed.[118] The TLV works with the Pharmaceutical Benefits Board to conduct a QALY and determine if the drug should be reimbursed.[119]	No.[120]	Yes.	• There is no clear patient engagement process.	• There is no clear patient engagement process.	• There is no clear patient engagement process.

[xxxiii] Spanish Agency of Medicines and Medical Devises (Spanish: Agencia Española de Medicamentos y Productos Sanitarios) [xxxiv] Sistema Nacional de Salud is the public health insurance program [xxxv] Health Technology Positioning Group
[xxxvi] Medical Products Agency [xxxvii] Swedish: Tandvårds- och läkemedelsförmånsverket

COUNTRY	ASSESSMENT PROCESS	DOES THE PROCESS USE INTERNATIONAL REFERENCE PRICING?	DOES THE PROCESS USE A QALY?	PATIENT ENGAGEMENT PROCESS	CONCERNS WITH CONSUMER ENGAGEMENT PROCESS	POSITIVE APPROACHES
Switzerland	Once a drug is deemed safe and effective by the Swiss Agency for Therapeutic Products (Swissmedic),[121] the FOPH,[xxxviii,122] determines if the drug should be reimbursed on the Specialties List. To determine if a drug should be reimbursed, FOPH conducts an internal assessment on cost-effectiveness and an external assessment of international reference prices.[123]	Yes. The external reference is based on prices set in Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Sweden, and the UK.[124]	No.[125]	• There is no clear patient engagement process.	• There is no clear patient engagement process.	• Swissmedic developed a patient and consumer organization working group to identify how patients and consumers can be more involved in the agency's work.[126]
United Kingdom	Once a drug is approved by the Medicines and Health Care Products Regulatory Agency,[127] NICE[xxxiv] conducts a clinical effectiveness and cost-effectiveness review. NICE uses independent experts and committees in conducting their analysis and ultimately provides a recommendation to the NHS on which drugs should be covered.[128]	No.	Yes.	• NICE Independent Committees include people with lived experience.[129] • Patient organizations can be selected to participate by NICE or by a consultee organization.[130] Invited experts can share written evidence, clarify questions in evidence, and participate in committee meetings.[131] Selected experts participate through an evaluation process and can clarify issues raised by the technical team and NICE staff throughout the assessment.[132] • NICE invites other "registered" stakeholders to participate in the evaluation through comments which can include national patient and caregiver organizations and organizations representing health care providers.[133] These stakeholder groups can also submit evidence and nominate clinical, patient and commissioning experts.[134] • Members of the public can submit comments and apply to be observers.[135]	• The Committee is not required to include members with lived experience or patient backgrounds.	• There are clear pathways for patient organizations to engage. • Reports summarize patient feedback and indicate that certain considerations are "noted," and others are "concluded" based on committee discussions.[136]

[xxxviii] Federal Office of Public Health [xxxiv] The National Institute of Health and Care Excellence

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