Planning Post-Launch Evidence Generation: Lessons from France, England and Spain

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Technological developments and innovations in regulatory pathways have meant medicinal products are increasingly associated with substantial clinical and economic uncertainties at launch. This has increased the focus on continuous evidence generation to assess the real-world value of new medicines post-launch. This paper examines Post-Launch Evidence Generation (PLEG) systems in France, Spain, and England, drawing on insights from a series of multistakeholder roundtables hosted by RWE4Decisions. These discussions provided a platform to compare national approaches to PLEG considering PLEG planning and operationalization. The roundtable events included presentations by representatives of the HTA bodies and payers in France, Spain, and England, an industry response, and multistakeholder discussions. The events highlighted that while there are differences in the products to which PLEG is applied and the way it is operationalized, there are many common challenges experienced across systems and by all stakeholders. First, there is a recognition that evidentiary needs must be anticipated earlier to avoid PLEG where possible and better plan for PLEG where needed. Second, there is a need to streamline data collection. This includes trying to make greater use of existing data sources vs. primary data collection, prioritizing collection of a small number of outcomes that directly address key uncertainties, and by improving international collaborations to streamline data collection and evidence generation across borders. Our findings suggest value in improving scientific advice processes and international collaboration to discuss key data gaps early and ensure efficient and effective evidence collection that improves the speed and quality of reimbursement and pricing decisions.

INTRODUCTION

Technological developments in medicines in areas of high unmet need have led to increased use of expedited regulatory pathways that bring medicines to market faster.[1] This creates challenges for health technology assessment (HTA) bodies who must determine the added value of these new medicines while many uncertainties remain about their short or long-term consequences and optimal use outside the controlled setting of a clinical trial. This can affect the price that Payers are willing to pay or level of reimbursement. To address these issues there is a push towards the development of evidence over a product's lifecycle, providing patient access for a limited period, or at a reduced price, subject to data collection for a specific group of patients to resolve uncertainties that are key to HTA/Payers.[2] This approach to accumulating additional evidence based on conditional reimbursement is referred to by the umbrella term Post-Launch Evidence Generation (PLEG).[3] Nationally systems may refer to such arrangements by different terms, including Outcomes/Performance Based Managed Entry Agreements,[4,5] Managed Access Agreements, (Monitoring) Registries,[6] or Post-Registration Studies. These evidence generation processes are usually led by the health system and thus differ substantially in construct, use of data sources, responsibilities of stakeholders, and use in subsequent Payer decision making. One common concern among HTA bodies is whether these PLEG processes produce sufficiently robust evidence that can be used to inform reassessments and price negotiations without placing an undue burden on stakeholders.[7]

To generate cross-country learnings of PLEG systems, RWE4Decisions, which is a multistakeholder learning network,[8] hosted a series of roundtables about operationalizing PLEG for highly innovative medicines in Europe and Canada. Previous roundtables considered the potential of using outcomes-based agreements to collect real-world evidence and inform pricing and reimbursement decisions and the possibility of aligning evidence requirements for HTA bodies and payers in the post-launch setting.[9,10] The 2021 report resulted in recommendations that emphasized the importance of planning PLEG well in advance of the pricing and reimbursement process, with iterative multistakeholder dialogues to discuss the uncertainties in clinical effectiveness that are likely, and do, emerge during clinical development. This facilitates agreement on the uncertainties that are "decision relevant" for HTA/Payers and on what evidence can be generated to fill those gaps, either by continuation of, or initiation of new clinical studies, or by collection of real-world data (RWD).[11]

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The roundtable in April 2024 focused on early planning for PLEG. It explored to what extent PLEG could be anticipated for certain types of medicines and whether better planning could improve the quality of the RWD collected and evidence generated. The roundtable involved presentations of national approaches in France, Spain, and England from national HTA representatives, an industry response and multistakeholder discussion. Approximately 40 stakeholders participated in the meeting, representing a wide range of interests and jurisdictions: 13 HTA bodies and Payers from Europe and Canada, three national health/governmental organizations, two clinicians, three patient representatives, one registry holder, two academics, and 12 health technology developers. After the roundtable, the learnings were shared with all attendees who had the opportunity to review the outcomes and provide additional responses.

France and England negotiate an initial price for a medicine and have formal systems of PLEG to support reappraisals of new medicinal products, typically at around 3 to 5 years after the initial assessment, at which time the price may be re-negotiated. Spain pays a price that is dependent on the outcome for each patient and then after a defined period of time, analyses the cohort to agree a new price. In France, the Haute Autorité de Santé (HAS) has had the authority to request additional data collection since 1999 and maintains a registry of "post-registration studies."[12] In Spain, The National Health System (NHS) set up Valtermed in 2019, which is a web-based information system, to collect RWD that can inform decisions about the therapeutic value of medicines with high clinical and economic impact from all the autonomous healthcare regions in the country.[13] In England, the National Institute for Health and Care Excellence (NICE) develops Managed Access Agreements for cancer products through the Cancer Drugs Fund (reformed in 2016) and since 2022 for non-cancer products (typically orphan drugs) through the Innovative Medicines Fund (and formerly bespoke arrangements starting in 2011).[14]

In this short review, we summarize the proceedings of the 2024 RWE4Decision roundtable and supplement these with other literature. We structure the discussion around key themes that emerged during discussions of PLEG systems, namely, prioritization and key use cases, planning, data collection, and use of evidence. For each component, we describe briefly the approach used in each system, learnings from this, and comments from the industry and other stakeholders.

CROSS-COUNTRY COMPARISON OF PLEG

Which treatments are included in PLEG?

There are substantial differences across the three systems regarding the products for which PLEG is used and how decisions are made about whether PLEG is an appropriate part of the pricing and reimbursement process. NICE has specific PLEG approaches for cancer and non-cancer treatments. Treatments are eligible for managed access if they have the potential to be cost-effective but have substantial clinical or economic uncertainty that can be resolved through further data collection. Non-cancer treatments must also address a substantial unmet medical need and potentially provide large clinical benefit. The Cancer Drugs Fund has initiated 57 Managed Access Agreements since 2016, 32 of which have been completed and led to full reimbursement in all but one case. However, it has been shown that for the majority of these, continuation of ongoing clinical trials provides more evidence for re-appraisal than the collection of RWD from the national cancer registry.[7] The RWD collected was typically focused on characterizing the population receiving treatment in the NHS and use of the technology (e.g., time on treatment), whereas continuation of clinical trials provided longer-term information on clinical outcomes. Seven non-cancer drugs are currently undergoing PL.

In France and Spain, arrangements are not restricted to certain therapeutic areas. In both systems, PLEG is used to address medicinal products with high clinical or economic impact on the national health system. As of July 2024, 29 drugs across 39 indications have been part of Valtermed in Spain. The majority have been for orphan drugs with all approved Advanced Therapeutic Medicinal Products part of Valtermed, with oncology being the most common indication.

HAS recently conducted a retrospective exploratory case–control study to identify the characteristics associated with requests for "Post-Registration Studies," with the intent of improving anticipation and planning.[15] A post-registration study was requested in 103 of 600 medicines with a positive reimbursement decision between 2016 and 2021. Two distinct profiles of treatments with requests were identified: those for which clinical benefits were questionable and those where a substantial benefit may be expected or where substantial uncertainty remains. In contrast to Spain and England, such requests were less common for oncology products; the indications more likely to involve requests were neurology, pulmonology, and endocrinology. This difference may be the result of a number of factors. Firstly, the construct of the PLEG system. In England, it is only available through specific reimbursement funds for cancer and that are deemed innovative (mainly rare diseases), whereas in France, it has been considered for a wider range of products. Secondly, it may reflect greater familiarity and acceptability of uncertainty in oncology or a concern that data collection quickly becomes outdated where treatments pathways develop rapidly. In France, unlike Spain and England, companies can also voluntarily perform PLEG and submit a new dossier for reassessment.

How are PLEGs developed? Planning and feasibility assessment

All countries have processes in place to identify products, which may benefit from PLEG, and to assess the feasibility of data collection. This involves collaborations with the health technology developer, those with responsibility for data collection, and others, including healthcare professionals and patients.

In England, NICE look to anticipate products that are likely to have substantial uncertainties and could be eligible for PLEG 1 to 3 years before marketing authorization through horizon scanning and collaborations like Project Orbis,[16] Accelerated Access Collaborative,[17] or the Innovative Licensing and Access Pathway,[18] with feasibility and suitability assessments typically beginning 1 year before marketing authorization. Based on areas of uncertainty identified by academic reviewers, NICE works with NHS England, data holders, and health technology developers to consider whether clinical uncertainties are resolvable with data

collection, ongoing or planned data collection, barriers to managed access, and whether data collection would represent an undue burden on the system, the clinicians, and the patients.

Then at the time of the HTA, a managed access proposal is required from the health technology developer, which includes a list of the clinical uncertainties and the data collection required to resolve them, including its duration. Having reviewed all the clinical evidence and understood areas of greatest uncertainty, NICE's HTA committees make decisions about whether managed access is feasible. Committees can also request consideration for managed access during the HTA process but at this point feasibility assessment is often not possible.

In Spain, the Ministry of Health enters discussions with the health technology developer about the need for additional RWD and whether to include the product in Valtermed. Once agreed, a bespoke administrative resolution is created which outlines how RWD will be collected and how the evidence will be used in the pricing and reimbursement agreement. A pharmaco-clinical protocol is then designed by experts from the autonomous regions in Spain, professional societies, and the health technology developer, which usually takes several months. The Spanish Ministry of Health is trying to improve this process noting that the protocols can be quite large (10–28 pages), collecting a wide range of data and bresource consuming to develop (taking 1–6 months). Further work is ongoing to better identify and prioritize products for which data collection may be feasible and valuable through the design of a decision tree to determine the benefit vs risk of early access and potential for Valtermed to be able to collect sufficient data. Also, it has been recognized that engagement with health technology developers is needed prior to marketing authorization to enable data collection to start earlier. Subsequent to the roundtable event, a new royal decree was issued on HTA in Spain introducing new pricing and reimbursement structures.[19] This will likely have an impact on the procedures for including new medicines in Valtermed, though the exact implications are as yet unknown.

In France, reassessment is mandatory for all products and so additional data collection has been more common. Data collection is the sole responsibility of the health technology developer. HAS provides protocol assistance to support health technology developers plan data collection in their post-registration studies making use of the highly developed health data infrastructure in France.[20] HAS intends to use the results from their retrospective review of postregistration studies to better anticipate what new products might need PLEG to support earlier planning activities such as in horizon scanning and joint scientific consultations.

What evidence is collected and how does it impact assessments?

All three countries require the protocols for PLEG data collection to be published on their own websites as soon as available. These show that there is substantial overlap in the types of RWE that each country tries to generate with PLEG. These include characteristics of patients and prescribers, conditions of use, including duration and dosing, prior and subsequent treatments, and a range of uncertainties related to safety and/or effectiveness, including patient-reported outcomes.

There is limited information about how the evidence collected as part of PLEG has impacted reassessments, especially for relatively new systems like Valtermed or the Innovative Medicines Fund. Nevertheless, in Spain, the Ministry of Health has acknowledged that data collection is time consuming and that too many outcomes have been collected. There are ongoing initiatives to simplify this. Further learnings come from the Cancer Drugs Fund in England. Research noted that ongoing clinical studies have been especially influential in informing future decisions.[21] Committees have sometimes been unclear how to evaluate RWE where it conflicts with findings from trials. NICE and two academic groups are working on understanding what causes these conflicts. Four medicines that have exited the Cancer Drugs Fund have been assessed to identify what factors differ and if RWE can be consistently adjusted to match trial data. This may go some way to align evidence from these two sources.

How is data collection organized?

PLEG can involve (ongoing) clinical studies or RWD collection. Here we focus on the RWD collection only.

NICE has distinct approaches for PLEG for cancer and non-cancer drugs. Data on cancer drugs is collected through the Systemic Anti-Cancer Registry, a comprehensive national registry of systemic cancer treatments in England, and BlueTeq, a software system for the management of high-cost drugs in the NHS.[22] Together, these sources enable capture of patient baseline demographic and clinical characteristics, treatment duration, previous and subsequent treatments, and by linkage to the national death registry, overall survival. For non-cancer drugs, bespoke arrangements are made through collaborations with existing disease registries, with no mandated data collection, from the NHS (National Haemoglobinopathy Register), academic networks (NorthStar, Spinal Muscular Atrophy Reach UK), patient networks (Cystic Fibrosis Trust), and company commissioned registries. Due to the variability in registries and indications, the data collected also differ substantially.

In France, the appraisal document can provide recommendations on the data sources to be used for data collection. HAS recently initiated a census to identify relevant sources which currently lists 26 data sources, including patient registries, electronic health record systems, and administrative health records.[23] The health technology developer is responsible for data collection and data analysis.

In Spain, there is greater focus on bespoke data collection although this is supplemented with linkage to electronic health systems. Data collection forms are developed from the clinical protocol within Valtermed and healthcare professionals from autonomous regions across Spain must enter the required data manually. The Spanish Ministry of Health noted challenges arising from delays in contracts with vendors and of coordination across regions who have different needs and capabilities. The Spanish Ministry of Health has noted that currently too many outcomes are collected; it is taking action to better select outcomes with a checklist (in development) indicating relevant uncertainties (risk of bias, indirect evidence, imprecision, inconsistency, and insufficient follow-up). The Valtermed information system is also being improved and will include a module to enable patients to complete EQ-5D-5L and reporting of progress.

STAKEHOLDER COMMENTS

Health technology developers argued that PLEG introduces additional complexity into access pathways. It was noted that there is a real opportunity and urgent need to better anticipate the uncertainties at an earlier stage. As well as helping plan for PLEG where still required, better anticipation should enable some uncertainties to be addressed in clinical development and the initial HTA thereby avoiding PLEG and the burdens it places on all stakeholders. Interestingly the need to better anticipate uncertainties at an early stage was noted by representatives from France, England, and Spain, where initiatives are ongoing to improve anticipation of evidentiary needs. It was hoped that the new EU Health Technology Assessment Regulation[24] would offer opportunities in its Joint Scientific Consultation process to provide advice that would inform PLEG planning. Furthermore, it has been suggested that PLEG could be an early priority for "voluntary cooperation" among selected Member States.

A substantial component of the RWE4Decisions roundtable discussion with stakeholders was focused on data collection. All stakeholders stressed that data collection can impose a substantial burden on healthcare providers and patients. Efforts should therefore be made to limit additional data collection and instead try to make more and better use of existing data (secondary use). Relatedly, there was widespread consensus that data collection should be more targeted to address key areas of uncertainty only.

Greater reuse of secondary data may be supported by emerging technologies that allow for better extraction of unstructured data, such as free text. However, many argued that legal and technological developments would be necessary to realize the potential of these data sources. For instance, there is an urgent need to improve the availability of the data and ability to link between disparate data sources to achieve a complete picture of the patient journey, while respecting privacy concerns. Some participants noted the potential value of European data initiatives such as European Health Data Space[25] and DARWIN EU[26] in enhancing secondary data use.

Health technology developers also noted the variation in the quality of data collection from national health systems, for instance across regions of a country (such as Valtermed), and registries. Quality can vary in terms of the completeness or accuracy of the data collection. There is a need for greater clarity and agreement on data standards for decision making which should be reflected in feasibility assessments. Given the nature of global evidence generation and the considerable overlap in uncertainties identified across countries, developers noted the possibility of improving the efficiency and reducing the burden of data collection by better sharing of data and evidence across borders. This was noted to be especially important in the context of rare diseases where there will usually be insufficient data from a single jurisdiction. Several participants also noted the importance of improving collaboration with different countries to streamline data collection and decision making through joint scientific consultations and other scientific advice initiatives.[27]

Finally, as has been evidenced elsewhere, some stakeholders fear that the link between data collection, evidence generation and subsequent decisions or recommendations is unclear. Some argue that greater efforts should be made upfront to agree on data and evidentiary standards and how the results will inform the reassessment. Relatedly some participants noted the need for greater transparency around PLEG arguing that private and publicly funded data analysis must face equal scrutiny.

All stakeholders agree that there is potential to improve the planning and conduct of PLEG to generate better RWE to inform decision making with better anticipation and planning, streamlining data collection and enhanced collaboration (Figure 1).

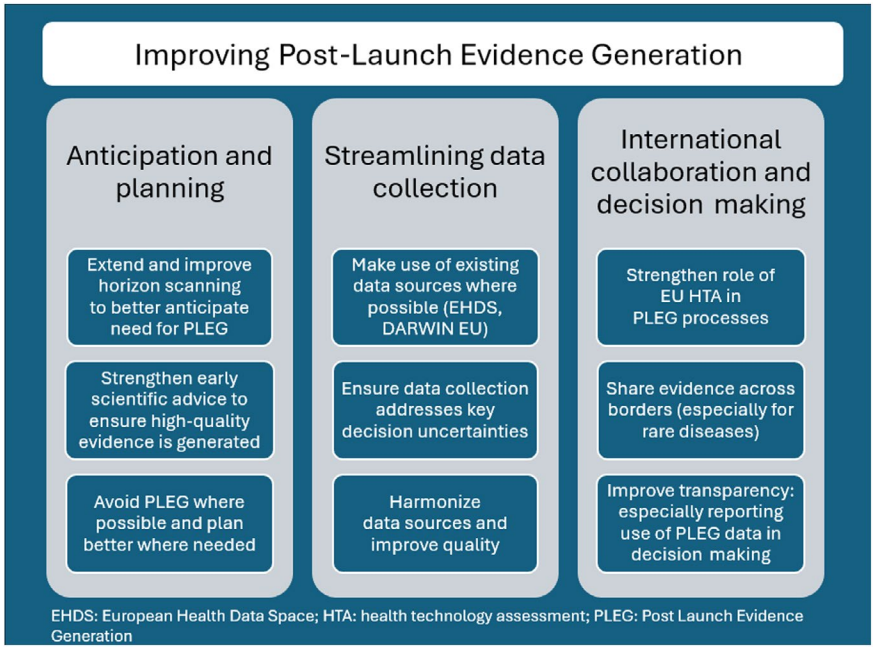

Figure 1 RWE4Decisions stakeholders recommendations on improving Post-Launch Evidence Generation.

CONCLUSIONS

RWE4Decisions hosted a series of multistakeholder roundtable events on the operationalization of PLEG. In 2024, learnings were shared around the development of PLEG systems in England, France, and Spain with substantial stakeholder discussion. The roundtable events identified several important similarities in PLEG systems across countries as well as in the challenges they face. While all systems involve similar elements in terms of prioritization, identification of evidentiary uncertainties, feasibility assessments, and multistakeholder engagement, there were significant differences in terms of the products covered, the timing of feasibility assessments and the use of the evidence generated. Key challenges noted by all stakeholders included better anticipation and planning of PLEG, streamlining data collection, and improving the clarity of decision making based on the evidence collected.

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CONFLICTS OF INTEREST

Francois Meyer is an independent consultant who has received fees from various pharmaceutical companies or consultancies to provide advice regarding the development of pharmaceutical and HTA processes. Karen Facey is an independent consultant who has received fees from various pharmaceutical companies and HTA bodies to provide advice about the use of real-world data and implementation and development of HTA. The other authors declared no competing interests for this work. All other authors declared no competing interests for this work.

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