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International Payer Research: Comparing and Contrasting Payer Roles and Research Methods in Canada, Spain, and the UK

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BACKGROUND

- Global pharmaceutical companies often conduct coordinated, multicountry studies to elicit information from payers and those who influence their decisions.
- Such studies promote understanding of individual markets, influence global product value strategy, increase the likelihood of positive pricing and reimbursement (P&R) decisions, and refine market access plans.

OBJECTIVES

- Compare payer roles in three pharmaceutical markets (Canada, Spain, and the United Kingdom [UK]), taking into consideration key differences and similarities of the P&R systems across markets
- Discuss the usefulness of various qualitative research methods in eliciting information to inform a global product value strategy

METHODS

- Compared the:
  - Levels at which pricing, reimbursement, and market access decisions are made (e.g., national, regional, local, hospital)
  - Bodies influencing payer decisions (e.g., health technology assessment agencies)
  - Processes of engagement among physicians, patients, and payers.
- Conducted a review of publicly available guidance and qualitative payer research to develop a framework for comparing optimal approaches to qualitative payer research.
- Assessed effects of various qualitative and quantitative research techniques on a pharmaceutical company's ability to devise an effective global strategy.

RESULTS

Table 1. Pricing and Funding of Pharmaceuticals in Canada, Spain, and the UK

Pricing and Funding	Canada	Spain	UK
Health care management and funding decisions	Canada Health Act mandates comprehensive universal and publicly funded health care. • Funding shared between the federal and provincial/territorial governments. • Provinces/territories responsible for administration and delivery of care.	Regional governments responsible for administration and delivery of care (17 autonomous communities and 2 cities). Regional governments assume health care costs, including pharmaceuticals.	Four governments control the NHS through their respective health departments. • Parliament at Westminster: 152 PCTs responsible for administration and delivery of care with a specified budget in England. • Welsh Assembly: 22 local health boards and local authorities required to formulate and implement a "Health, Social Care and Well Being Strategy" in Wales. • Scottish Parliament: health planning carried out by 15 NHS boards. • Assembly in Northern Ireland: health planning carried out by 4 NHS boards.
Scope of pharmaceutical funding	Federal health care legislation requires only that inpatient hospital drugs must be funded in the provincial health care systems. Provincial governments have established drug plans offering outpatient drug plan coverage to seniors, the poor, and special groups. Employer-sponsored private drug plans cover much of the working population.	All prescription drugs under the SNS (National Health Service). Excluded from funding: OTCs, low therapeutic value drugs, and other few exceptions.	Once products receive market approval and a price is established, prescription drugs are generally eligible for reimbursement by the NHS.
Product pricing	Prices of all patented medicines regulated at federal level by PMPRB to ensure that patented medicines prices are not excessive. Federal price regulation plays no role in reimbursement decision making at the provincial level. Provincial drug plans negotiate the prices of reimbursed products.	Prices of reimbursed drugs regulated and established by the central government after negotiations between the Company and the DMHCP. Price of nonpatented compounds is aligned to the reference group (same compound) within the Reference Price System, updated annually. Prices identical throughout the country.	Freedom of pricing at launch for new active substance and reimbursement automatically granted. PPRS is a voluntary nonstatutory agreement between the Department of Health and the brand name pharmaceutical industry (represented by ABPI), which regulates prices and profits of branded medicines. Under the terms of the current PPRS, prices for new active substances may be set at the discretion of the company.
Pricing criteria at product launch	Internal and external reference pricing criteria. For patented drugs, new drugs categorized into 1 of 4 "levels of improvement" in clinical effectiveness, which determines the possibility for a premium price. • Prices referenced internally against other products in the same therapeutic class. • Innovative drugs referenced against price for the same product in seven reference countries (France, Germany, Italy, Spain, Switzerland, UK, US). Some provinces (notably Ontario) require that prices of generic drugs not exceed 50% of the price of the corresponding branded drug.	Internal and external referencing pricing criteria for reimbursed drugs. Full reimbursement dossiers justifying drug value must be submitted in the P&R application, referencing existing comparators and sales forecast. • For innovative drugs, external reference pricing (average of prices from the other EU countries). • Internal referencing is either done by including the product in a Reference Price System group or by comparing the cost of treatment with that of similar compounds.	In reaching a decision on the acceptability of the proposed price, the Department of Health may take into account a number of factors (i.e., (the price of other presentations of the same medicine or comparable products, forecast sales and the effect on the NHS drugs bill, the clinical need for the product, any exceptional costs). (See Table 2 for specifics on Scotland.)

ABPI – Association of the British Pharmaceutical Industry; DMHCP – Directorate of Medicines and Health Care Products; EU – European Union; NHS – National Health Service; OTC – over the counter; PCT – primary care trust; PPRS – Pharmaceutical Price Regulation Scheme; SNS – Health National Service, Servicio Nacional de Salud.

Table 2. Payer Roles in Canada, Spain, and the UK

Setting Where Drugs Are Delivered to Patients	Canada	Spain	UK
Outpatient drugs (community pharmacies)	Provincial drug plans make reimbursement decisions for outpatient drugs, taking into account the CADTH/CDR recommendations. • CDR reviews all new drugs and important new indications of existing drugs (clinical and cost-effectiveness criteria). • ~50% of products reviewed by CDR recommended for reimbursement. • Analysis of CDR reviews suggests informal ICER threshold of $50K–$70K per QALY. Provincial drug plans free to accept or reject CDR recommendations. In practice: • Decisions consistent with CDR recommendations (> 90% of the time). • Provincial plans more interested in affordability (budget impact) than cost-effectiveness; several have established listing agreement policies to mitigate the financial risk. • Private plans typically reimburse most prescription drugs with certain limitations and may require prior authorization.	Regional governments responsible for administration and delivery of care (including pharmaceuticals) in and out of hospitals. • Outpatient drugs available to patients through pharmacy offices at specific copayment (40%–0%). • Regional governments implement cost control policies influencing physicians' prescriptions (conducting drug assessments and providing information, setting prescription targets and incentives) and pharmacists' dispensation of cheaper substitutes (generics). Primary care area pharmacists play significant role in prescription control. • Restricted outpatient drugs dispensed to the patient through hospital pharmacy at no patient copayment. These are accountable to the hospital pharmacy expenses (the budget allocation system varies among regions and the nature of the hospital).	Budget responsibility largely devolved to local decision-making bodies (e.g., the PCTs). In primary care, PCTs increasingly establish guidelines, and the Prescription Pricing Authority monitors performance of all prescribers. PCTs make funding decisions in the absence of NICE appraisal in England. SMC, NICE, and AWMSG appraisals and guidelines should be followed by the publicly funded health services. • SMC reviews all newly licensed medicines, all new formulations, and new indications. Negative appraisal form the SMC would limit prescribing in Scotland to very low levels. • AWMSG appraises new high-cost medicines (i.e., costing > £2000 per patient per annum), new cardiac and cancer medicines within the BNF classification, and new indications and formulations. Makes recommendations for use within NHS Wales. • NICE conducts drugs appraisals based on burden of disease, resource impact, policy importance, and whether there is inappropriate variation in practice across the country.
Inpatient drugs (hospitals/clinics)	• Hospitals fund inpatient drugs from global budget assigned by provincial government. • Hospital P&T formulary committees assess and recommend drugs for hospital use. • Contracting, rebates, discounts, and bundling (with other drugs, services) common for hospital drugs.	• Regional governments assume hospital pharmaceuticals within annual budget for hospitals. Some hospitals funded on a DRG basis. • PC decides on inclusion of new drugs on each hospital list of drugs. • Pharmacy departments evaluate drugs, including cost of treatment compared with existing alternatives. PC decides whether to include the drug. • Hospitals reduce drug prices through price negotiation with suppliers, tenders, rebates, etc. and create purchasing bodies to increase bargaining power. • For new expensive drugs, specific boards decide access to therapy on a case-by-case basis.	• NHS PCTs purchase care, including medicines, from NHS acute trusts. Some drugs excluded from agreement and separately negotiated. • Hospitals reimbursed for the medicines supplied. • DTCs evaluate treatments, make decisions on medicines use, and produce a "formulary" that is a list of necessary medicines to meet the clinical needs of patients. • DTCs expected to adhere to NICE appraisals (if existing) on the use of medicines within the NHS. Also true for the SMC and AWMSG. • For new hospital drugs, in absence of NICE appraisals, DTCs evaluations often require full business cases, including primary care impact.

AWMSG – All Wales Medicines Strategy Group; BNF: British National Formulary, CADTH – Canadian Agency for Drugs and Technologies in Health; CDR – Common Drug Review; DRG – diagnosis-related group; DTC – Drugs and Therapeutics Committee; ICER – incremental cost-effectiveness ratio; NICE – National Institute for Health and Clinical Excellence; P&T – pharmacy and therapeutics; PC – pharmacotherapeutic committee; PMPRB – Patented Medicine Prices Review Board; QALY – quality-adjusted life-year; SMC – Scottish Medicines Consortium.

Qualitative Research Methods

The qualitative research process for conducting payer research typically involves some form of desktop research, followed by one-on-one interviews with key decision-makers and influencers. When consensus is desired, these one-on-one interviews may be followed by a group qualitative research technique, such as a Delphi panel.

Preliminary Research

- Qualitative research should be based on a deep knowledge of the country reality and existing trends.
- Health care structure, decision making, influencing mechanisms, and stakeholder roles are an essential part of the preliminary research.
- Targeted desktop research on national, regional, and local Web sites provides relevant reference information, illustrating criteria for decision makers and influencers.
- These sources may provide guidelines reflecting governmental and professional criteria, drugs assessments (by national, regional, or hospital bodies), or patients preferences/roles.
- This information allows us to better approach the specific issues that configure payer/influencer view/opinion, understand their responses, and understand the specific scenario for a new therapeutic compound in that particular country.
- This preliminary research provides relevant information for preparing the research guideline.
- Involving company local subsidiaries with experience in the therapeutic area may be extremely beneficial.

Informal Discussions

- Preliminary research must always be followed with some sort of personal interview with an appropriate key opinion leader (KOL).
- A few informal interviews with the selected KOL may be sufficient to get the desired picture.
- A semi-structured interview guide based on the project objectives and the preliminary research will encourage the KOL to freely explain his/her views, knowledge, and opinion.

Formal Interviews

- When it is necessary to get more specific results on product attributes and specific aspects of the new product or interest of the client, a more structured interview is needed.
- While physicians may accept this kind of questionnaire, payers often refuse interviews based on very structured questionnaires or respond with very low interest and involvement.

Delphi Panel

- Delphi panels are probably the richest source of information; however, they are not always feasible or justified because they require more resources.
- When considering payer/KOL involvement, the best methodology is a specific type of panel, which includes a board meeting.
- A limited number of participants (8-15) are selected, including payers and other KOLs (clinicians and other professionals).
- Participants are requested to complete and send back a structured anonymous questionnaire.
- Results of the survey will be processed and will be the basis for a slide presentation.
- A 3-4 hour board meeting is scheduled, during which all participants discuss the results of the questionnaire. The objective of the meeting is to identify missing aspects and to get a consensus on specific issues or criteria important for the research. Consensus may or may not be reached.
- Participants are requested to complete a second anonymous questionnaire.
- The results of the second survey provide a sense of the robustness of the consensus.
- For the board minutes, metaplan methodology can be used. A metaplan is a "written discussion" on paper walls. The board minutes include photography of the walls and clarifying comments.

CONCLUSIONS

- In Canada, provincial drug plans make reimbursement decisions for outpatient drugs, considering CDR recommendations. Hospital formulary committees assess drugs for hospital use.
- In Spain, treatment location (outpatient, hospital only) and type of prescriber must be considered when determining the research strategy.
- In the UK, NICE, the SMC, and the AWMSG make decisions at the national level, while PCTs make funding decisions in the absence of NICE appraisal in England.
- For multicountry payer research to be useful for devising a global value strategy, it is important to understand the P&R systems in different countries and to identify the key stakeholders who should be considered as participants for any survey.
- The most appropriate and acceptable methodology must also be chosen to engage the KOLs and encourage them to provide the most useful information.

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