P07 / How to evaluate corporate initiatives to promote access to medicines and health technologies

Topic : HEALTH POLICY

Chair : Quinn Grundy (University of Toronto)

Second Chair : Marc-Andre Gagnon (Carleton University)

GENERAL OBJECTIVES, RESEARCH QUESTIONS AND SCIENTIFIC RELEVANCE

Affordable access to safe, effective and quality medicines, health products, and other technologies is an essential aspect of Universal Health Coverage, and an unrealized goal in many parts of the world. The United Nations' Millennium, and then, Sustainable Development Goals, emphasized the role of the private and public sectors to contribute to Universal Health Coverage, including the need for industry engagement to improve access to essential medicines. Since that time, there has been an increase in the number and scope of initiatives and activities by pharmaceutical and medical device companies to facilitate access to medicines and health technologies within low- and middle-income country health systems (Rockers et al., 2017), and also higher-income countries (Prémont & Gagnon, 2014). These activities go beyond advertising and sales strategies and include: price reductions; medicines, device, and equipment donation; compassionate access programs; licensing agreements; service sponsorship; infrastructure investment; provider training; patient support programs; awareness campaigns; and regulatory and supply chain strengthening.

However, there are no global frameworks or guidelines to inform governments or health systems interfacing with corporate initiatives despite known risks, including increased health system burden and costs, such as with many drug and device donations (McDonald et al., 2019; World Health Organization, 2017). There is a bigger question around whether and to what extent initiatives serve promotional purposes to further commercial interests, which are associated with negative public health impacts. Analyses of internal industry documents has revealed the extent of corporate influence within every aspect of the pharmaceutical sector (Gagnon & Dong, 2023), including scientific research, the media, civil society, regulatory processes, and clinical practice. However, the confidential and proprietary nature of many of these initiatives poses challenges for research.

Countries continue to grapple with how to ensure affordable, equitable, and sustainable access to medicines. Pharmaceutical development is growing fastest for higher-cost, specialty medicines for chronic conditions in oncology, immunology, and diabetes; people prescribed these medicines often also require pharmacy, clinical, diagnostic, and ongoing monitoring services. In response, pharmaceutical companies have developed a suite of new promotional strategies to facilitate rapid access and uptake by directly providing such services in the form of patient support programs or funding and operating health services such as infusion clinics or diagnostic testing services. The extent to which this occurs globally is not well understood.

The objective of this panel is to bring together diverse disciplinary perspectives and research methodologies to describe, analyze, and theorize the role of corporations in promoting access to health technologies within global health systems.

The main research questions for this panel are:

1) What is the nature and range of corporate initiatives to promote access to health technologies within global health systems?

2) What frameworks or perspectives are useful in understanding how these initiatives operate to promote commercial, public health, or other interests?

3) What are the considerations for governance and what principles, frameworks, or policy tools might be, or are effective?

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Since the 1960s, the World Health Organization has sought to promote the rational use of medicines and health technologies and developed normative guidance around industry promotion. Promotion now encompasses not only traditional forms of advertising, deployment of sales representatives, and sponsorship of education or research, but increasingly, industry is involved in the funding or operating of health systems as a means to facilitate access to their products, including within low- and middle-income countries (WHO, 2017). Pharmaceutical and medical device company activities to facilitate access to health products include directly providing health systems with health products through donation, reduced prices or discounts; funding or conducting health system capacity building (e.g., training related to procurement, regulation, or continuing health professional education); providing care through patient support programs; or directly financing Ministry of Health activities (Rockers et al., 2017; WHO, 2017). However, in the context of opaque pricing and confidential procurement agreements; preferred provider networks which create exclusive distribution networks; and problematic tax incentives around donation practices, many of these initiatives are often designed to serve commercial interests to the detriment of public health.

This panel intends to bring together people from different disciplines to discuss ongoing research into and methods to study and identify medically-related industry strategies, initiatives, and activities designed to promote access to health products and technologies. We define the medically-related industry as pharmaceutical, medical device, health technology, infant formula, and medical nutrition industries and the web of commercial entities, trade associations, and lobby groups that seeks to further their corporate interests. We seek research and research approaches oriented toward informing the development of policy tools to ensure equitable, sustainable, and affordable access; promote good governance, public accountability, and transparency; and manage risks and monitor and evaluate performance.

We welcome diverse research designs and approaches (e.g., qualitative, ethnographic, quantitative, documentary, policy analysis and evaluation, case studies), documenting or analyzing industry initiatives in low-, middle-, and high-income countries; as well as theoretical analyses of strategies and their impacts.

The panel will be held on-site, but presenters can present via online platforms if required. Depending on the number of submissions and presenter preference, we may elect to organize an on-site and online session.

P07 / How to evaluate corporate initiatives to promote access to medicines and health technologies

Chair : Quinn Grundy (University of Toronto)

Second Chair : Marc-Andre Gagnon (Carleton University)

Session 1Understanding corporate strategies to facilitate access to medicines - Part 1

Thursday, July 3rd 08:00 to 10:00 (C4)

Discussants

Quinn Grundy (University of Toronto)

Marc-Andre Gagnon (Carleton University)

The rhetoric of rapid access to therapeutic innovation and meeting patient needs: Managed Entry Agreements in Belgium

Lucas Bechoux (Université de Liège)

Discourses among politics and pharmaceutical industry players converge on the importance of “meeting patients' needs” and the need for “early access to therapeutic innovation”. This movement is crystallized in the growing use, in Belgium and more generally in Europe and the United States, of Managed-Entry Agreements or “secret contracts” (Wenzl & Chapman, 2019). These are mechanisms that enable a company to apply for temporary reimbursement for a drug with significant innovation potential, for which the company does not yet have sufficient data to provide to the regulatory agency at the time of application. In a bid to encourage innovation, the public authorities decide to temporarily reimburse the drug by drawing up a secret contract (Neyt et al, 2020). The company, for its part, undertakes to conduct further studies and provide more conclusive data later, so that the public authorities can make a final decision. In exchange, the company also undertakes to provide a rebate for marketing the drug.

There are several problems with these procedures. Firstly, requested studies are rarely carried out, and when they are, do not provide sufficiently convincing data to inform the reimbursement body's decisions. The level of evidence derived from these ex-post studies is often weaker than that of clinical studies carried out as part of normal procedures (single arm trial, real world data, etc. when orphan drugs are involved and RCTs are not easy to set up). This reduced requirement for solid scientific evidence is likely to favour the industry. Randomized clinical trials are long, tedious and costly. In the case of an MEA, they have to make less of an effort beforehand to convince of the efficacy and safety of their molecule with a view to reimbursement. What is predominant is the desire to give patients access to innovation. Once a molecule has been reimbursed and is part of doctor's therapeutic arsenal, it is very difficult for the public authorities to withdraw reimbursement at the risk of attracting criticism from civil society (patients, etc.), the medical world and industrial players.

Finally, these secret contracts have a budgetary problem: they create more opacity in the drug reimbursement system. This opacity strengthens companies in their negotiating strategy with governments. In the absence of price transparency, companies can raise the stakes between states. The prices demanded by companies are often excessive and uncoupled from the actual realities of R&D costs. Against this backdrop, many voices are being raised to denounce the excessive prices of new drugs and the explosion in healthcare spending. Controversy also exists as to the real therapeutic advances brought about by certain new drugs, which are sometimes deemed insufficient in view of the prices charged. These mechanisms pose real problems for the sustainability of our healthcare systems. Relying on the rhetoric of early access to innovation, they undercut reimbursement procedures, they make it opaque and expensive and lower standards of scientific evidence. New drugs take up a large part of the healthcare budget, for sometimes negligible benefits in terms of patient quality of life.

(Virtual) Communicating Corporate Social Impact through Patient Reach – Opportunities for Improvement in the Biopharmaceutical Industry

Carlotta Cellini (Boston University)

Determining how many people have access to their products is a crucial step for biopharmaceutical companies in expanding access to medicines. Companies are prioritizing access to medicines through governance structures, business practices and other access approaches. A key metric used to demonstrate social impact in this context is “patient reach,” which measures the number of patients served by a company’s product(s) or initiative(s). As the healthcare space intensifies its social impact reporting, the metric has seen an uptake, but the approaches are inconsistent across companies.

This paper aims to examine patient reach metrics through the lens of sustainability-linked bonds (SLBs) issued by three pharmaceutical companies - Teva, Novartis, and Sanofi, launched between 2020 and 2022. We analyze the strengths and limitations of these metrics, their definitions and methodologies, using the companies’ annual reports and other documents describing their SLBs. We find four major challenges: lack of standardization, risk of overestimation, limited validity, and insufficient significance. For example, while patient reach is often derived from product sales volumes, this approach fails to account for stockpiling, patient adherence, or equitable access (notion of sales do not equate reach). Additionally, current metrics omit critical dimensions such as the cost-effectiveness and affordability of reaching patients.

We argue that advancing patient reach metrics requires a shift from volume-based measures to those that reflect the proportion of target populations reached, adherence to recommended care protocols, and the durability of health outcomes. Drawing on examples from pharmaceutical programs and community health initiatives, we propose actionable recommendations to improve the validity and integrity of patient reach metrics, notably patient reach as a proportion of total target population.

Our findings underscore the importance of developing standardized, meaningful metrics that align with public health goals, meet investor expectations, and drive sustainable impact. By refining patient reach measures, the pharmaceutical industry can better demonstrate its contribution to global health equity while fostering accountability and transparency in social impact investing. This is especially relevant in the growing SLB market, which offers companies an attractive mechanism to finance social goals without solely relying on internal capital - provided they can effectively demonstrate measurable impact.

Patient groups and the pharmaceutical industry: an analysis of funding and advocacy for drug reimbursement in Australia

Ashleigh Hooimeyer (University of Sydney)

Annim Mohammad (University of Sydney)

Lisa Parker (University of Sydney)

Barbara Mintzes (University of Sydney)

Background: Patient groups play an important role in research, policy, and support, and a voice for consumers is increasingly recognised as key to regulatory and reimbursement policy. However, many patient groups receive pharmaceutical industry funding, and studies have shown a link between funding and positions favourable to sponsors’ interests. The recent experience with aducanumab’s fast-tracked US approval, which has been attributed in part to strong patient group pressure, and the drug’s subsequent withdrawal, has raised additional concerns about the health and policy implications of conflicts of interest within the patient advocacy sector.

To investigate this, we analysed the extent and patterns of pharmaceutical industry funding of patient groups in Australia, and examined the proportion of groups’ income derived from the industry in 2022.

An example of advocacy in the form of submissions to the Pharmaceutical Benefits Advisory Committee (PBAC) in support of drug reimbursement has been used to explore the extent to which these activities may be aligned with funding from industry.

Methods: Medicines Australia is the trade organisation for the prescription pharmaceutical industry in Australia, and member companies are required to disclose any financial or non-financial support provided to patient groups. We downloaded the annual sponsorship reports from the Medicines Australia website over a ten-year period from 2013-2022. Data were combined into a searchable database by group and sponsor. Patient group submissions to PBAC between 2018-2022 were identified from the public summary documents published after PBAC meetings.

Results: In total, 370 groups received funding from 41 companies, though this funding was highly skewed

with the top ten groups receiving over 40% of the funding. The median funding over the 10 years was $28,764 (IQR $6,575-103,125) per group.

For the 50 groups that received the most funding in 2022, the median proportion of income being derived from industry was 9.3% (IQR 2.2-22.6%) and nine groups had over half their income from industry. The proportion of income was associated with the size of the group, with smaller groups more likely to have more of their income from industry.

These groups represent patients with a range of cancers, rare diseases, and chronic conditions such as arthritis and diabetes which are important markets for pharmaceuticals. Previous studies have shown that drug companies tend to fund patient groups that focus on diseases for which they have products under patent or in development. A preliminary analysis of PBAC patient group submissions indicates a correlation between sponsorship and positive recommendations concerning reimbursement of the drug in question.

Conclusions: This is the most comprehensive overview of national industry funding of patient groups to date. Funding was widespread but highly skewed towards a subset of heavily-funded groups. This kind of selective funding means that patient group advocacy is likely to be skewed towards conditions linked to marketed drugs and to industry friendly messaging. A broader concern is the role of industry funding in impairing patient groups' ability to be an unbiased voice for their communities.

The Complex Dynamics of Preferred Provider Networks in Employer-Sponsored Drug Insurance Programs

Marc-Andre Gagnon (Carleton University)

Blue Miaoran Dong (Carleton University)

Quinn Grundy (University of Toronto)

The Complex Dynamics of Preferred Provider Networks in Employer-Sponsored Drug Insurance Programs

Preferred Provider Networks (PPNs) have become a prominent strategy in pharmaceutical distribution in both the United States and Canada's employer-sponsored drug insurance programs. By streamlining drug distribution and negotiating pricing advantages, PPNs claim to reduce expenses for drug plans. However, in the context of expensive specialty drugs and opaque pricing, their implementation raises critical concerns about potential long-term risks to the healthcare system that warrant closer examination (1–3). Current ongoing investigations at the Federal Trade Commission show how such PPNs often end up increasing costs for drug insurees (4).

PPNs are typically categorized into four types: closed, mandatory, open, and voluntary (1,5). Existing research predominantly focuses on their short-term cost-saving benefits, with little attention to their broader implications (6–9).
This article addresses this gap through an analysis of existing literature, government oversight of PPNs in the United States and Canada, and relevant legal cases. Our findings reveal that PPNs often distort market incentives through confidential rebate agreements and exclusive patient support programs. These practices undermine the patient-pharmacist relationship, restrict patient autonomy, and exacerbate geographic and financial barriers to care, particularly in underserved regions. Moreover, the emphasis on profit margins over therapeutic value compromises the quality and continuity of care, further entrenching inequities in access and affordability. If, in the short term, PPNs can reduce costs, they seem to drive costs up in the longer term.

Despite these challenges, different initiatives in Canada could lead to relevant pharmaceutical policy reform. By addressing systemic inefficiencies and inequities associated with PPNs, policymakers can advance a more equitable and sustainable healthcare system that prioritizes patient outcomes over short-term financial gains.

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P07 / How to evaluate corporate initiatives to promote access to medicines and health technologies

Chair : Quinn Grundy (University of Toronto)

Second Chair : Marc-Andre Gagnon (Carleton University)

Session 2Understanding corporate strategies to facilitate access to medicines - Part 2

Thursday, July 3rd 10:15 to 12:15 (C4)

Discussants

Quinn Grundy (University of Toronto)

Marc-Andre Gagnon (Carleton University)

Exploring the interactions between the community pharmacy sector and medically-related industry in Australia: case studies of professional education and patient support programs

Kellia Chiu (University of Sydney)

Ashleigh Hooimeyer (University of Sydney)

Lisa Parker (University of Sydney)

Barbara Mintzes (University of Sydney)

INTRODUCTION

Community pharmacists are medicines-use experts and are increasingly seen as an accessible health workforce that may address inequitable healthcare access and promote access to medicines. This approach has been suggested across many countries globally. Critical examination of commercial interests and industry influence in the pharmacy sector is important considering: 1) the expansion of pharmacists' scope of practice into more complex clinical activities (e.g. prescribing) which may facilitate new opportunities for commercial interests to promote their products; and 2) ongoing discussions and reform of funding/remuneration sources for pharmacist-delivered services.

To investigate these ideas, we analysed two examples of pharmacist-industry interactions: industry-sponsored pharmacist continuing professional development (CPD) education, and a patient support program case study.

METHODS

We conducted a content analysis of accredited CPD activities available through the print version of the Australian Journal of Pharmacy – a widely available source for Australian pharmacists – between November 2023 to October 2024 inclusive. We collected data on the type of CPD activity, author details (including conflicts of interest), sponsor, clinical area, and learning objectives.

We also examined an example of a patient support program in Australia — Amgen and Arrotex's joint osteoporosis patient program — and describe key features that demonstrate how industry may promote their products through pharmacy involvement.

FINDINGS

We identified 61 accredited CPD activities, of which 16 (26%) were sponsored by a pharmaceutical company, and one was sponsored by a patient advocacy group. Of these 16 activities, the most common educational focus (6/16; 38%) was on the use of vitamins/supplements/complementary medicines for various conditions, followed by dermatology (4/16; 25%). Most of the learning objectives (13/16; 81%) that related to pharmacological treatment focused on benefits only; likewise, the CPD content emphasised the

benefits of these treatments, aligning with the sponsor’s own products.

As part of Amgen and Arrotex’s osteoporosis program, pharmacies receive a $10 “professional service payment” per patient for enrolling patients using Amgen’s 6-monthly osteoporosis medication; for every patient returning to have this medication dispensed on time, pharmacies receive an additional $25, or $5 if the patient returns 7 or more months from the previous supply. These payments are accumulated for pharmacies to use to purchase stock within the program. Additionally, patients receive a bottle of Arrotex’s vitamin D3 for free every 4 months, text and email support/reminders, and counselling with branded consumer information.

CONCLUSIONS

These examples highlight how pharmacists and the pharmacy sector may be a conduit through which industry promote their products; the community pharmacy sector may also have an inherent familiarity and understanding of the benefits of integrating commerce and health, rendering it more amenable to interactions with medically-related industries.

Our analysis is exploratory; future research will involve conducting deeper policy analyses of stakeholders, professional pharmacy culture/attitudes towards the role of industry, pharmacy practice policy agenda setting, and existing governance structures. This may be used to inform the development of accountability mechanisms that can ensure that pharmacists’ practice and individuals’ access to healthcare is less subject to industry agendas and interests.

Securing the future through improved access to child-appropriate medicines

Margaret Siyawamwaya (University College London, University of London)

Medical products are an essential component of healthcare systems. A country cannot improve its population's health and, therefore, meet the Sustainable Development Goals (SDGs) targets without adequately addressing the medical needs of sub-populations such as children. According to UNICEF[1], in 2022, 4.9 million children under 5 years old died, meaning that 13,400 children under the age of 5 years of age died every day in 2022. Lack of adequate access to appropriate medicines contributes significantly to these sad statistics. Children are constantly growing; therefore, they have unique needs at each stage of development, warranting access to child-appropriate medicines to improve treatment outcomes and reduce mortality rates. Further, manufacturing medicines for children is often subject to more stringent regulatory oversight because of the nature of the products and the target population's vulnerability, which dissuades manufacturers from investing in product development specifically for this population.

Following experiences of severe health product shortages exacerbated by the Covid-19 pandemic, many nations globally are investing in building local pharmaceutical manufacturing capacity. Our ongoing study is analyzing initiatives of the pharmaceutical industry in Zimbabwe and the United Kingdom (UK) to improve access to medicines for children, considering the complexity and high technical and ethical demands around developing suitable medicines for this sub-population. In particular, the study critically examines the nexus of health policy and industry policy, as one important lens for evaluating any health benefits of the commercial activities of the pharmaceutical industry, particularly for an often-overlooked population segment.

We have analysed how pharmaceutical manufacturers in Zimbabwe and the UK are responding to policies related to pharmaceutical production to identify whether there are any measures in place to solve the global problem of inadequate access to child-appropriate medicines. Our findings so far highlight that health policies are focused on addressing the therapeutic demands of a population by providing treatment guidelines for medicines being supplied by the pharmaceutical industry, an industry whose commercial activities are guided by other policies outside the health sector, such as industrial policy. For example, in 2021, the Ministry of Industry and Commerce launched the Pharmaceutical Strategy for Zimbabwe (2021-2025)[2] to promote local manufacturing of medicines. Emphasis has been placed more on the industry being a priority in the Zimbabwe National Development Strategy (2021-2025)[3], which aims to achieve sustainable economic growth and socio-economic transformation rather than on meeting the public health needs in line with current disease burdens and clinical demands.

The literature and, indeed, the evidence from our ongoing research contend that there is still conflict between health policies and industrial policies, which is detrimental to sustainable health equity and access to health by different segments of the population.

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The conditions of branded care: System dependence on pharmaceutical companies for access to high-cost medicines

Quinn Grundy (University of Toronto)

Dana Hart (University of Toronto)

In an era of personalized medicine, pharmaceutical research and development is concentrated around specialty medicines for people living with chronic conditions. Specialty medicines require complex manufacturing, special handling, and complicated regimens, such as learning to self-inject the drug, and are characterized by high prices that threaten the sustainability of public and private drug plans. Pharmaceutical marketers thus face the challenge of convincing prescribers, payers, and patients that specialty medicines are worth the cost. Pharmaceutical companies routinely offer wrap-around patient support programs for people prescribed their specialty drug to provide insurance coverage navigation, financial support, treatment adherence support, and access to pharmacy, laboratory, or nursing services. We sought to understand the implications for patients, healthcare, and health policy in a system where pharmaceutical companies control access, delivery, and coordination of care for people prescribed high-cost, specialty medicines.

We report the findings of a critical policy ethnography within the Canadian health system that sought to describe and critically analyze the nature of branded care for people prescribed specialty medicines grounded in the experiences of those that provide, coordinate, and receive care. We draw on 43 in-depth interviews with patients enrolled in a patient support program (n=17), pharmaceutical industry employees (n=5), clinicians working within patient support programs and private infusion clinics (n=8), clinicians and leaders within the publicly-funded health system (n=7), and policymakers (n=6). We triangulated these data with critical content analysis of documents including program materials, industry reports, white papers, and news coverage.

In this paper, we discuss three realities of patient support programs. First, that patient support programs are the default way that patients are able to access specialty medicines; companies provide financial assistance to cover deductibles, out-of-pocket costs, or even free drugs, however variably, and often for undetermined periods of time. Consequently, patients felt they had to submit to the requirements of the program, including collection of their health and personal data, to mitigate the risk of losing financial support. Second, patients characterized living with a chronic illness as a part-time job and at first many welcomed the idea of working with a case manager from the patient support program. The reality for many was that in addition to the burden of managing their own health and healthcare team, having to work with multiple commercial entities including the patient support program, the specialty pharmacy, and the private infusion clinic. Third, participants from varied roles thus characterized “PSPs” as “physician support programs” with services tailored to cultivating positive relationships with prescribers and ensuring at minimum, no barriers to prescription of their product.

Manufacturer patient support programs operate as a closed, and largely separate, private healthcare system. Patients, prescribers, and payers, however, are currently dependent on pharmaceutical manufacturers to provide access to specialty medicines in terms of navigating reimbursement, bridging gaps in coverage, and delivery of essential healthcare services such as infusion care. We thus raise questions about the conditions of branded care, asking who benefits and who is placed at risk when access to medicines is dependent on commercial interest.

Under what ethical and methodological conditions can researchers become a collaborative partner with a company in digital health?

Céline Mahieu (Université Libre de Bruxelles)

Laura Solar (Université Libre de Bruxelles)

Miguel Farraj (Université Libre de Bruxelles)

Joachim Van Cant (Université Libre de Bruxelles)

In a setting characterized by the commodification of care and taking into account the challenges posed by digital health regarding care quality, the well-being of healthcare professionals, and addressing health inequalities, the Rehabilitation Sciences Research Unit (ULB) and the Research Centre on Social Approaches to Health (CRISS-ULB) have opted for a position that is both engaging and challenging, by initiating an action-research project, supported by the Brussels Region, in collaboration with moveUP, a

small business focused on developing digital monitoring tools for healthcare practitioners (HCPs) and patient applications.

The goal here is to explore whether it is feasible to merge the technological and commercial ambitions of a company (moveUP) with, firstly, the viewpoint of clinical needs concerning a prevalent condition (Anterior Knee Pain) that has low treatment efficacy and a risk of additional medical issues if left untreated; secondly, the perspective of professionals who need to establish the conditions for creating a genuine partnership based on trust (similarly to a colleague or a representative from another field); thirdly, the public viewpoint (including the most vulnerable populations and efforts to combat social health inequities); and finally, the viewpoints of public authorities aiming to enhance both public health and the competitiveness of the local companies in this domain.

Investigating the circumstances under which such a collaboration results in socio-technical innovation that successfully tackles the challenges of care quality, the well-being of health professionals, and access to health services for everyone is a core aspect of this research project that commenced a year ago and will extend until 2027.

This communication seeks to reflect on the project's design phase, the presentation to public authorities, and the initial development stages to examine, as in Science studies (Callon 1986), the various phases (*problematisation, incentivization, enrollment, mobilization of allies*, and *dissent*) in the progression, challenges, and achievements of this partnership. This seeks to enhance the comprehension of the ethical and methodological factors under which researchers can collaborate with a private firm on a digital health initiative addressing public health challenges.