

Research Synthesis: Affordability

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Introduction

The literature surrounding medicines affordability could be characterized as somewhat thin*. The most relevant literature is quite recent—within about the last ten years.

Search terms

Medicines/drugs/pharmaceuticals and affordable, catastrophic expenditure, excessive price, fair price

Synthesis of the literature

The WHO's definition of an 'essential medicine'—a medicine that should be available "at a price the individual and community can afford" (World Health Organization (WHO), n.d.)—puts central emphasis on the issue of affordability. The affordability of essential medicines is supported by the WHO, the 2001 Doha Declaration on TRIPS and Public Health, the Sustainable Development Goals, and human rights norms, among others. Examining affordability for a medicine requires a shift in thinking from other types of consumer goods. That is, from both a human rights and public health perspective, the relevant concept is arguably not economic demand or willingness to pay, but rather the extent of the human need for a product.

The concept of affordability of medicines varies, but has been defined as the *"ability to purchase a necessary quantity of a product or level of a service without suffering undue financial hardship."* (italics added, as quoted in the Lancet Commission on Essential Medicines report by Wirtz et al. (2017)). As the Lancet Commission continued, however, "no agreement exists on what financial hardship means, nor how best to assess it" (Wirtz et al. 2017, 422). At the individual/household level, financial hardship could be determined by the level of income, insurance coverage and other resources available.

There are two relevant benchmarks: a maximum of 40% of a household's income after subsistence needs are met to avoid catastrophic health expenditure (Xu et al. 2003), and expenses above 7.5% of adjusted gross income being considered extraordinary by the US tax authorities (Love 2012). At the population level, financial hardship on a government would be shaped by the quantity required to meet the health needs of the population and the extent to which a government is committed or required to provide a medicine. Love has argued that empirical evidence on actual use of a medicine should also be taken into account in assessing affordability (Love 2012).

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A demand-side consideration when examining affordability is to assess the price of a medicine according to the financial resources available to the payer, rather than assessing affordability based on a single price. This is because there are different types of payers: Individuals or households paying out of pocket, private insurers, public entities (public insurance or a Ministry of Health), or international donors—each of which with varying financial resources.

The Lancet Commission concluded, “at the collective level, such as for public or third-party payers, affordability depends on the price of the product or service, the available budget, and the fiscal space (which has been defined as “the capacity of government to provide additional budgetary resources for a desired purpose without any prejudice to the sustainability of its financial position” (Heller 2006 as cited in Wirtz et al. 2017))” (Wirtz et al. 2017, 422). The implication is that affordability at government level should be determined not only by the level of government spending on medicines today but also on the possible increase in that budget up to a certain ceiling. A challenge with operationalizing the concept of fiscal space, however, is that government spending on health varies widely by country both in absolute terms and as a proportion of national budgets and GDPs (Ottersen et al. 2017). Nor are there widely-accepted benchmarks for what proportion of a society’s resources should reasonably be spent on medicines.

When examining affordability, the question of excessive price, and the regulation of such prices, emerges. In some countries, governments may intervene if prices of goods reach an ‘excessive’ level, though they may or may not regulate prices *ex-ante*. For example, excessive pricing is prohibited by competition law in China, the EU, Russia and South Africa [1]. Excessive pricing of medicines in particular is also grounds for price regulation by Canada’s Patented Medicines Price Review Board (Lexchin 2015, as cited in Abbott 2016). By definition, a price deemed to be excessive can be considered not to be fair. Abbott (2016) points out that “‘fairness’ can be equated with what reasonable people might expect from a transaction, while ‘excess’ is more suggestive of something extreme or pushing boundaries.” The boundary between fair/reasonable and excessive pricing is not clear in practice, however, nor does there appear to be an accepted methodology for drawing a line between the two.

See also the research synthesis on Competition Law.

[1] With thanks to Paul Jones for providing the relevant information on this topic via IP-health.
For the EU: http://ec.europa.eu/competition/publications/cpn/2004_3_40.pdf; http://ec.europa.eu/competition/international/multilateral/2011_oct_excessive_prices.pdf; https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1850569
For China: <http://www.allenoverly.com/publications/en-gb/Pages/Antitrust-in-China-NDRC-v--Qualcomm-%E2%80%93-One-All.aspx>
For Russia: <http://www.lidings.com/eng/legalupdates?id=143>; <http://en.fas.gov.ru/>; <http://en.fas.gov.ru/documents/documentdetails.html?id=13913>
For South Africa: <http://www.compcom.co.za/the-competition-act/>
OECD commentary: <http://www.oecd.org/daf/competition/abuse/49604207.pdf>

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Research gaps

- Methods to measure and assess financial hardship (or resource benchmarks) for different types of payers, including both individuals/households and organizations (e.g. private or public insurers, governments)
- Use of competition policy to regulate pricing, including how to determine a line between a fair and excessive price
- Research on benchmarks and/or fiscal space for government spending on health: existing and suggested ways to determine how much of a country's health resources should (or should not) be spent on medicines

Cited papers with abstracts

Abbott, Frederick. 2016. "Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health." *UC Irvine Law Review* 6 (3): 281.

Abstract: Public health budgets and individual patients around the world struggle with high prices for pharmaceutical products. Difficulties are not limited to low income countries. Prices for newly introduced therapies to treat hepatitis C, cancer, joint disease and other medical conditions have entered the stratosphere. In the United States, state pharmaceutical acquisition budgets are at the breaking point -- or have passed it -- and treatment is effectively rationed.

Competition/antitrust law has rarely been used to address "excessive pricing" of pharmaceutical products. This is a worldwide phenomenon. In the United States, the federal courts have refused to apply excessive pricing as an antitrust doctrine, either with respect to pharmaceutical products or more generally. Courts in some other countries have been more receptive to considering the doctrine, but application in specific cases has been sporadic, including with respect to pharmaceuticals.

This remains a paradox of sorts. Competition law experts acknowledge that one of the principal objectives of competition policy is to protect consumers against the charging of excessive prices. The currently preferred alternative is to address the "structural problems" that allow the charging of excessive prices. That is, "fixing the market" so that the underlying defect by which excessive prices are enabled is remedied.

There is a fundamental problem with the "fixing the market" approach when addressing products protected by legislatively authorized market exclusivity mechanisms such as patents and regulatory marketing exclusivity. That is, mechanical aspects of the market are not broken in the conventional antitrust sense. Rather, the market has been designed without adequate control mechanisms or "limiters" that act to constrain exploitive behavior. Political institutions, such as legislatures, that might step in are constrained by political economy (e.g., lobbying), and do not respond as they should.

Competition law and policy should develop robust doctrine to address excessive pricing in markets lacking adequate control mechanisms. This article will focus specifically on the pharmaceutical sector because of its unique structure and social importance. This focus is not

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intended to exclude the possibility that development of excessive pricing doctrine would be useful in other contexts.

This article is divided into two parts. The first addresses competition policy and why it is appropriate to develop the doctrine of excessive pricing to address distortions in the pharmaceutical sector. The second addresses the technical aspect of how courts or administrative authorities may determine when prices are excessive, and potential remedies.

The policy prescription of this article is twofold: first, the United States should incorporate excessive pricing doctrine in its antitrust arsenal, and; second, other countries should maintain the status quo with respect to multilateral competition rules that allow them flexibility to develop and refine doctrine, including excessive pricing doctrine, that is best suited to their circumstances and interests.

Link: <https://scholarship.law.uci.edu/ucilr/vol6/iss3/3/>

Heller, Peter S. "The Prospects of Creating 'Fiscal Space' for the Health Sector." *Health Policy and Planning* 21, no. 2 (March 1, 2006): 75–79. <https://doi.org/10.1093/heapol/czj013>.

Abstract: Not Available

Link: <https://academic.oup.com/heapol/article/21/2/75/554947>

Lexchin, Joel. 2015. "Drug Pricing in Canada." In *Pharmaceutical Prices in the 21st Century*, 25–41. Adis, Cham. https://doi.org/10.1007/978-3-319-12169-7_2.

Abstract: Not available

Link: https://link.springer.com/chapter/10.1007/978-3-319-12169-7_2

Love, James. 2012. "Affidavit: Natco Pharma Limited versus Bayer Corporation." https://www.keionline.org/sites/default/files/aff-jameslove_13Feb2012_as_Filed.pdf.

Abstract: Not available

Link: https://www.keionline.org/sites/default/files/aff-jameslove_13Feb2012_as_Filed.pdf

Ottersen, Trygve, Riku Elovainio, David B. Evans, David McCoy, Di McIntyre, Filip Meheus, Suerie Moon, Gorik Ooms, and John-Arne Røttingen. 2017. "Towards a Coherent Global Framework for Health Financing: Recommendations and Recent Developments." *Health Economics, Policy, and Law* 12 (2): 285–96. <https://doi.org/10.1017/S1744133116000505>.

Abstract: The articles in this special issue have demonstrated how unprecedented transitions have come with both challenges and opportunities for health financing. Against the background of these challenges and opportunities, the Working Group on Health Financing at the Chatham House Centre on Global Health Security laid out, in 2014, a set of policy responses encapsulated

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in 20 recommendations for how to make progress towards a coherent global framework for health financing. These recommendations pertain to domestic financing of national health systems, global public goods for health, external financing for national health systems and the cross-cutting issues of accountability and agreement on a new global framework. Since the Working Group concluded its work, multiple events have reinforced the group's recommendations. Among these are the agreement on the Addis Ababa Action Agenda, the adoption of the Sustainable Development Goals, the outbreak of Ebola in West Africa and the release of the Panama Papers. These events also represent new stepping stones towards a new global framework.

Link: <https://www.cambridge.org/core/journals/health-economics-policy-and-law/article/towards-a-coherent-global-framework-for-health-financing-recommendations-and-recent-developments/32B84686FD13D7CB340643D798832095>

Wirtz, Veronika J., Hans V. Hogerzeil, Andrew L. Gray, Maryam Bigdeli, Cornelis P. de Joncheere, Margaret A. Ewen, Martha Gyansa-Lutterodt, et al. 2017. "Essential Medicines for Universal Health Coverage." *The Lancet* 389 (10067): 403–76. [https://doi.org/10.1016/S0140-6736\(16\)31599-9](https://doi.org/10.1016/S0140-6736(16)31599-9).

Abstract: Not available

Link: <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2816%2931599-9>

World Health Organization. n.d. "Essential Medicines." WHO. http://www.who.int/medicines/services/essmedicines_def/en/.

Abstract: Not available

Link: http://www.who.int/medicines/services/essmedicines_def/en/

Xu, Ke, David B Evans, Kei Kawabata, Riadh Zeramdini, Jan Klavus, and Christopher J L Murray. 2003. "Household Catastrophic Health Expenditure: A Multicountry Analysis." *The Lancet* 362. http://www.who.int/health_financing/documents/lancet-catastrophic_expenditure.pdf.

Abstract: Not available

Link: http://www.who.int/health_financing/documents/lancet-catastrophic_expenditure.pdf

** For the purposes of this review, we have established three categories to describe the state of the literature: thin, considerable, and rich.*

- *Thin: There are relatively few papers and/or there are not many recent papers and/or there are clear gaps*
- *Considerable: There are several papers and/or there are a handful of recent papers and/or there are some clear gaps*
- *Rich: There is a wealth of papers on the topic and/or papers continue to be published that address this issue area and/or there are less obvious gaps*

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Scope: While many of these issues can touch a variety of sectors, this review focuses on medicines. The term medicines is used to cover the category of health technologies, including drugs, biologics (including vaccines), and diagnostic devices.

Disclaimer: The research syntheses aim to provide a concise, comprehensive overview of the current state of research on a specific topic. They seek to cover the main studies in the academic and grey literature, but are not systematic reviews capturing all published studies on a topic. As with any research synthesis, they also reflect the judgments of the researchers. The length and detail vary by topic. Each synthesis will undergo open peer review, and be updated periodically based on feedback received on important missing studies and/or new research. Selected topics focus on national and international-level policies, while recognizing that other determinants of access operate at sub-national level. Work is ongoing on additional topics. We welcome suggestions on the current syntheses and/or on new topics to cover.

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