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MAKING SURE ORPHAN DRUGS DON'T GET LEFT BEHIND

G. Kent Fellows, Daniel J. Dutton and Aidan Hollis

SUMMARY

Orphan drugs developed to treat rare diseases are expensive, thus making it difficult for provincial governments to cover their costs and for patients to acquire them. However, a streamlined method of setting guidelines for coverage using a cost-based regulatory model could help patients get access to the drugs while ensuring manufacturers are fairly compensated.

Currently, governments can justify covering cost-effective drugs. Manufacturing costs, including research and development, typically put orphan drugs over any threshold of cost-effectiveness because so few patients use them. Thus, governments either decline coverage or end up funding the drugs under pressure from patient advocacy groups.

Without adequate compensation for their efforts, manufacturers will have no incentive to develop orphan drugs. A cost-based regulatory model, including yardstick pricing, would improve access to orphan drugs because it creates incentives for companies to lower their costs. Yardsticking means that prices are set using industry benchmarks and firms that successfully lower their costs below those of competitors can profit by it.

Under this system, the government could still apply an initial cost-effectiveness test. In cases where that threshold is not met, the cost-based regulatory model would be used to decide upon the maximum price at which the drug would be covered. This would be done through an estimated, benchmarked, capital cost based on the average cost of drug development across the pharmaceutical industry, and take into consideration the probability of success.

Such an approach would allow governments to bargain over a drug's price, yet still create incentives for companies to develop orphan drugs at the lowest possible costs.

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There is regular and continued scrutiny of Canada's pharmacare policy. Much of this discussion is focused on affordability for lower-income Canadians, the issue of private vs. public coverage and how to prioritize pharmacare spending relative to other areas of health care. In particular, a recent paper by Adams and Smith (2017) offers an overview of the political and economic issues of providing a public national pharmacare strategy for Canada. However, one critical area which has received too little attention is Canada's orphan drug policy.

Orphan drugs, those intended for the treatment of rare diseases, generally carry very high costs per patient.[1] This is a problematic issue for both private and public insurers who face a difficult question in determining the level of coverage they are willing to provide for orphan drugs: how much are they willing to pay to save or extend a life?

A recent high-profile example is the struggle the Canadian government faced trying to control the cost of Soliris, a drug used to treat a rare blood disorder, with a price tag that can exceed $500,000 a year per patient (Marowits, 2018).

Last year, the Patented Medicine Prices Review Board (PMPRB) ordered Alexion Pharmaceuticals (the Soliris patent holder) to reduce the price of Soliris to "no higher than the lowest price in the seven comparator countries set out in the Patented Medicines Regulations." Alexion Pharmaceuticals has sought judicial review and the matter is still before the courts. However, the case of Soliris is not isolated and Canada needs a reasonable policy to deal with orphan drugs (Crow, 2017).

Health Canada had been planning a formal framework for rare-disease drugs since 2012; however, those plans appear to have been abandoned late last year and references to the orphan drugs policy no longer appear as part of Health Canada's regulatory plan (Forrest, 2017).

This leaves provincial insurance plans flummoxed: Do they pay enormous prices for the treatment of rare diseases, or leave these particularly high-cost patients untreated? The usual approach for drug funding is to pay only for products with a demonstrable cost-effectiveness, where the ratio of costs to benefits is below a given threshold (Eichler et al., 2004). Orphan drugs are typically priced well above this threshold. So the cost-effectiveness decision-making approach doesn't work for orphan drugs; for these drugs, the conventional decision would always be to decline coverage (McCabe et al., 2010). Provinces therefore make ad hoc decisions on which orphan drugs to pay for, and how much. Currently, these decisions are often based on the effectiveness of advocacy by patient groups and manufacturers.

Manufacturers justify high prices for these drugs by arguing that associated R&D costs must be spread among few patients. This is a reasonable argument since the average cost per patient for these drugs is typically much higher than drugs for common diseases sold to hundreds of thousands of patients in Canada every year. It is important that manufacturers be compensated for the costs of orphan drug development to ensure that incentives exist for the development of valuable therapies for rare diseases. However, provincial drug plans should not be held to ransom by drug manufacturers setting unnecessarily high prices in search of profits.

The fact that high prices are justified by the high R&D cost per patient is important. On the one hand, insurers cannot pay less than the cost, or firms will find it unattractive to develop drugs. On the other, insurers need not pay more than the cost, since the high cost is the justification for

[1] While there is no fixed defintion of an orphan drug in Canada, the U.S.'s *Orphan Drug Act* (FDA, 1983) defines it as a drug intended to treat a condition affecting fewer than 200,000 persons in the United States. Adjusting for population differences and assuming similar disease incident rates in Canada, a consistent Canadian definition would be any drug intended to treat a condition affecting fewer than 23,000 persons in Canada.

the high price. In effect, this makes cost-based regulation a viable tool for helping to determine appropriate prices for orphan drugs.

Cost-based regulation has been used for many years in Canada and around the world to set prices for pipeline transportation, electricity transmission, telecommunications and water services. Under cost-based regulation, the price for a good or service is set such that total revenues equal the cost of providing that good or service (including a fair return on capital invested). In this manner consumers face a price approximately equal to the firm's average cost. Regulators, such as the National Energy Board, hold public hearings in which the allowed prices are determined.

In recent years, there has been a trend toward creating incentives for cost reduction by regulated utilities. "Yardstick pricing" sets the prices charged by each firm based on industry benchmarks. Firms that are successful in reducing their costs below those of industry peers can earn extra profits. Yardsticking has a well-established history in regulation. In the U.K., OFWAT (the Water Services Regulation Authority) employs yardstick methods to control the prices of firms providing water and sewer services. The OFWAT application of yardsticking is widely considered to be among the best practices of price control regulation (Lannier, 2010). Yardstick methods have also been successfully implemented to constrain hospital costs in the Netherlands (Mikkers et al., 2008).

Fortunately, the same kinds of regulatory tools can be applied to orphan drug pricing. The most obvious difference between innovative drugs and utilities or hospitals is that investment into research and development of innovative drugs is much more speculative than investment in physical capital in the utilities sectors. That is, when a pipeline is being built, it is reasonable to predict the approximate amount of use of the pipeline over time. In contrast, most investment in drug innovation fails to produce a viable drug. The successful drugs thus need to pay for the failed ones; in effect, the firm needs to obtain a rate of return on any successful investment high enough to make the investment profitable in expectation.

Based on the speculative nature of investment in orphan drug development, we advocate the use of a cost-based model of price control with a substantial yardsticking component. In such a system, the insurer would have two tools at its disposal. The insurer could continue to use standard cost-effectiveness measures as an initial screen. If a drug failed to meet the cost-effectiveness standard, but the insurer wished to cover it despite this,[2] it could then use a cost-based regulatory model to determine the maximum price at which it would cover the drug.

The costs of providing a drug can be divided into two components: operating and capital costs. Operating costs relate to production, marketing and distribution. Capital costs include the costs of research and development and obtaining regulatory approval.

Operating costs can be assessed in the context of a regulatory hearing or through audited information requests, so that the firm can be compensated for justifiable costs. The assessment of capital costs presents more of a challenge since the actual costs of the firm relating to a specific drug are not observable and do not reflect the cost of failures. An efficient solution is to apply a benchmarked capital cost, based on the average cost of drug development in the industry, recognizing the industry-wide probability of success and the average cost of capital (i.e., the cost of financing the firm's activities). Firms have a legitimate interest in confidentiality, and assessing costs of R&D is challenging; nevertheless, it is not impossible to make reasonable estimates about

[2] In his analysis of the economic evaluation of health technologies conducted by the U.K.'s National Institute for Health and Care Excellence, Paulden (2017) asserts that the reason for insuring drugs deemed not to be cost-effective is generally that there can be political or even public pressure to meet the needs of identifiable individuals, even if that ultimately means harm to others who are anonymous.

the average cost of R&D.[3] Firms successful in developing drugs at low cost would make profits, while those that are inefficient or unlucky in the research process would make losses.

This approach creates a mechanism for deciding how much to pay when the insurer is not relying on a cost-effectiveness standard. As a rough example: It seems likely that the average new orphan drug has capital costs of no more than $1 billion.[4] Canada's share of this is approximately 2.6 per cent (its share of the global market for patented drugs). So the average drug development cost attributable to Canada is in the range of $26 million. Given 10 years of monopoly enabled by a patent, this implies that a firm would have to earn roughly $4 million per year above its operating costs to recoup its development costs on the average drug. Evidence on the profitability of companies that develop orphan drugs suggests that they perform well relative to competitors, so there could be room for prudent regulation.[5] Government could conduct periodic hearings to more accurately benchmark capital costs of drug development and approval of drugs that are covered by this policy.

How does this compare with the cost of orphan drugs? Eculizumab (trademarked Soliris), the drug previously mentioned, is a treatment for two rare diseases, one being atypical hemolytic uremic syndrome, which results in the formation of blood clots. It is difficult to diagnose but estimated to occur in one in one million births (aHUS Canada) and Soliris is the main treatment. The cost per patient depends on weight, and could be as high as $700,000 per year for the remainder of the patient's life (CADTH, 2013). If approximately 35 Canadians needed this drug per year, at a suggested average cost of $500,000 each, that would generate revenues of $17.5 million per year for Alexion Pharmaceuticals. After paying for operating costs, the net revenues from Soliris would be more than enough to pay for Canada's share of even the most expensive drug development program. As it stands, the Canadian government engaged in a costly legal dispute with Alexion culminating in a ruling from the PMPRB (2017) that Alexion repay the Canadian government for price gouging. Up-front cost regulation would avoid the kind of post-hoc legal proceedings associated with the ongoing Soliris litigation. Pharmaceutical companies see a market for orphan drugs in other jurisdictions. In the U.S. in 2016, 41 per cent of novel drugs approved by the Food and Drug Administration (FDA) were approved for the treatment of rare diseases (FDA, 2017). However, without an effective orphan drugs policy Canada cannot be assured that these same companies would even apply for marketing approval in this jurisdiction, and if they did there is no existing policy to prevent excessive pricing and a potential repeat of the Solaris litigation.

Two of the authors conducted an extensive review of potential pharmaceutical prices control regulations (Fellows and Hollis, 2013). Following from that assessment we propose that provincial governments could adopt a multi-step approval process (Figure 1).

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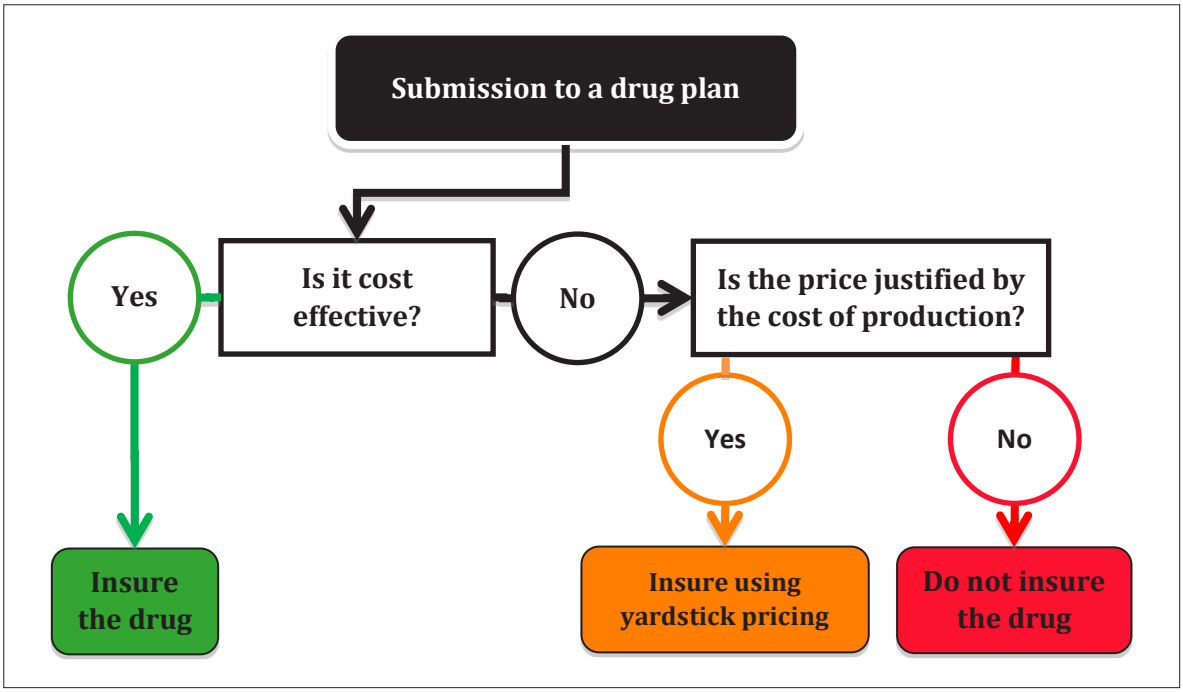
[3] For an example using public data, see Chit, Ayman, et al., (2013).

[4] It seems likely that orphan drugs have lower capital costs on average, since they aren't developed for mass audiences. See Morgan et al., (2011).

[5] The evidence is somewhat mixed about how much more profitable a company becomes by successfully developing orphan drugs. Consider Morel et al.,'s (2014) position that high research and development costs more than offset the slightly higher than average revenue of orphan drug companies. Meekings et al., (2012) suggest that factoring in government financial subsidies drives profitability in orphan drug development; others counter Morel et al.,'s claim directly and show orphan drug companies are more profitable than comparison companies (Hughes and Poletti-Hughes, 2016). Finally, other research shows that orphan cancer drug prices are not related to patient populations, implying that companies are able to set their own profitability (Jaroslawski et al., 2017).

FIGURE 1 A MULTI-STEP APPROVAL PROCESS FOR ORPHAN DRUGS



As a first step, governments could use cost-effectiveness analysis as a screen to determine what they wanted to cover. If the drug failed the cost-effectiveness test, but if the government strongly desired to ensure the drug's availability, provincial governments could use cost-based regulation: compensation (the drug price) should be set such that the firm covers its actual operating costs and is compensated for the benchmarked capital costs.

While the present process is a simple accept-or-reject system, we are proposing a streamlined third alternative to be incorporated into it. The proposed approach offers governments a tool to determine how much to pay for drugs that they wish to cover even if the drug fails the ordinary cost-effectiveness test. At the very least, this would give insurers a basis for bargaining over price, while maintaining incentives for firms to develop valuable drugs at the lowest development cost and enabling patient access to needed drugs.

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