PHARMAC and the funding of high-cost pharmaceuticals

George Laking

1 Author's Perspective

I am a medical doctor with a research interest in the economics of diagnosis, which I have applied practically in health technology assessment (HTAs) of medical diagnostics. The methods I use emphasise cost-utility analysis (CUA) and the statistical handling of uncertainty. When not working on economics I also do some clinics and research in medical oncology. Although I have not personally been involved in the kind of decisions made by PHARMAC, I have followed these with interest, particularly the technical use of CUA. My prior standpoint on funding was pretty much that of maximising QALYs. The background reading and the reports have certainly made me more sensitive to the range of moral positions.

2 Comments on the reports

Hansen is an economist from the University of Otago who has developed a computerised tool for multi-criteria decision making. Gillon is Emeritus Professor of Medical Ethics at Imperial College London and has written a standard text on his subject. Both authors have given considered, constructive responses to PHARMAC's questions. Gillon's work includes a reply to Hansen, but not vice-versa. I think it would be worth offering the authors at least another round of exchange. Both writers recommend that PHARMAC change its approach to decision making on high cost pharmaceuticals (HCPs). Although he is appropriately diffdent, Hansen would like PHARMAC to use his computer-based multicriteria decision software. Gillon would like PHARMAC to create a new advisory committee on allocation, on a par with PTAC but in the domain of social value.

2.1 Hansen

Hansen is motivated by the idea that PHARMAC should 'be more explicit and transparent' in its decision-making, and that to do this requires the use of 'technical methods'. CUA offers the technical means to describe changing costs and effects across different treatments in terms of a 'health possibilities frontier'. In figures taken from his earlier Treasury working paper, Hansen shows how various theories of distributive justice map to different points on the health possibilities frontier. This illustrates PHARMAC's finding that 'CUA [alone] cannot explicitly assist in any debate about the ethics of maximising health' (Anonymous 2004). The challenge for decision makers presented with CUA is to identify

tradeoffs between patient groups that are deemed 'equitable' or 'distributionally just'.

Hansen argues that 'there is a tendency in decision-making situations . . . for criteria that are based on so-called "hard" data . . . to overwhelm other criteria'. He suggests that this tendency may inadvertently bias decisions towards Benthamist utilitarianism. His proposed remedy is to fortify the technical means of handling value judgments. Here Hansen identifies the 'four step approach' of the Oxford Priorities Forum (Hope Reynolds and Griffths) as a starting point. Within this he recommends PHARMAC 'tighten' (i.e., specify more precisely) its decisionmaking criteria, in consultation with its constituencies. Finally, he recommends that PHARMAC consider using multi-criteria decision analysis. He declares an interest in his own computer package, 'Point*Wizard'. I will return to this below.

In summary, were Hansen's recommendations to be adopted, PHARMAC's Operating Policies and Procedures would perhaps be rewritten in Section 2 to give more detail on decision criteria, and Section 4 to describe the new technical means of handling distributional issues.

2.2 Gillon

Gillon's recurring point is that 'when agreed moral principles or values come into conflict judgement is required and unfortunately the moral approaches to carrying out such judgement are disputed'. He recommends against 'building into PHARMAC's procedures a morally contentious mathematical, computerbased, approach to moral judgement that is likely to be vigorously, vociferously, and conscientiously rejected by many'. Instead PHARMAC should 'stick with . . . a variant of implicit judgement when moral values conflict, while making explicit the moral values considered to be relevant and in conflict'.

To facilitate this Gillon recommends creation of an 'allocation committee' composed of 'conscientious people drawn from a variety of perspectives'. This committee would 'draw on such models as a clinical ethics committee, the Oxford Priorities Forum, and the nice Citizens Council. He describes its role as advisory, which suggests that it would stand outside PHARMAC's main decision-making structure. He also recommends that PHARMAC specify an explicit ethical framework within which to make allocation decisions, offering Beauchamp and Childress's formulation (autonomy, non-malevolence, beneficence, and justice), and UNESCO's Declaration on Bioethics and Human Rights as possible alternatives. Finally Gillon recommends that PHARMAC's appeal mechanisms be more clearly specified, in the pattern of Daniels and Sabin's 'accountability for reasonableness'. He has not however suggested a specific alternative to the current possibilities for informal appeals to Government via public and media opinion and a formal appeal process through the courts.

Were Gillon's recommendations to be adopted, PHARMAC's Operating Policies and Procedures would perhaps be rewritten in Section 1 to introduce the Allocations Committee (on a par with PTAC) and state the ethics framework (maybe after the paragraph on the Treaty of Waitangi). Overall, Gillon's recommendations are broadly compatible with those of Hansen, if only because they are pitched at a different level of PHARMAC's operation.

2.3 A Synthesis

As I have suggested above, the basic difference between the two authors is that Hansen defends technical methods while Gillon defends judgement. Gillon has elaborated his thinking in this respect further than Hansen (noting that Hansen was not writing a reply). For example Hansen dismisses 'nontechnical' approaches in just a line, saying that they 'tend to rely on political expediency and lobbying by interest groups and ad hoc decision-making that often favours the status quo'. Gillon by contrast is positive about the political process, describing PHARMAC as 'respecting the autonomy of the people of New Zealand collectively, to the extent that democratically elected governments respect such autonomy'. Gillon defends 'vigorous appeal, often with media amplification . . . and . . ."shroud-waving"[as] valid components of both the democratic process and of an acceptable substantive theory of justice'.

I think few people would want all pharmaceutical funding to be decided in 'trial by media' or trial by court. It could be helpful if Hansen or a similarly-minded person were to develop the distinction between technical and non-technical approaches in a way that engages with rather than rejects political expediencies. Technical approaches to pharmaceutical funding still need to be politically palatable.

Hansen has suggested that his computer program Point*Wizard be used as a technical means to resolve value judgements in pharmaceutical allocation. I think Gillon is right to recommend caution. Although there is experience with points systems in other areas of life, Hansen has not given an example of their use to decide the across-the-board funding of HCPs. None of the literature he cites has 'critical review' or 'systematic review' in its title. Hadorn found that points systems were 'as a rule, more accurate than human predictors' for medical diagnosis, but these data must be of limited applicability to the just allocation of pharmaceuticals, given the lack of a 'gold standard' for justice. These things all lead me to view the use of a points system in the present setting as experimental.

Hansen's account of points would benefit from further development more generally. For example he says that the systems have been 'near-universally found to out-perform purely intuitive decision-making approaches'. Yet he also

says that 'points systems are not a replacement for human decision making'. I would like him to clarify the dimensions on which point systems out-perform intuition. I would like him to clarify the salient features of settings in which point systems would simply attenuate the need for implicit judgement (in the parlance of our times, features that tell us when a decision is a 'no-brainer'). I would certainly hope to see these kinds of issues addressed in any more formal research proposal.

3 Some Comments on Technical Approaches

I will finish with some thoughts of my own on the relative roles of technical approaches and moral judgement in deciding pharmaceutical funding. Hansen has identified explicitness, transparency, and consistency as the aims of technical approaches to decision making. Strictly speaking these are 'process aims' that relate to the way in which decisions are made, in contrast to the ultimate aim of making the right decisions.

These aims head up a longer list of what I see as virtues of technical approaches, and to which I would like to add at least three more items. First, there is a virtue of procedural effciency which follows from having worked out in advance a method that can be applied in a timely way to real-world decisions by appropriately trained workers. Although good judgement is important, it takes time, and technical approaches may offer workable interim solutions while philosophers deliberate.

Secondly, there is a reputation for procedural impartiality that derives from use of methods external to the decision-maker or analyst's psyche. Although this reputation is in many ways a consequence of explicitness and transparency, it has value in its own right in any public institution. It means that workers can be trusted to divorce the application of the method from their own self-interest.

Closely related to procedural impartiality is a virtue of dispassionate implementation. Although I agree that 'all approaches to deciding which pharmaceuticals to fund, including high cost ones, are inherently normative', it is worth distinguishing between an approach and the instruments it uses. In technical approaches, little extra normative content is introduced after the initial design of the instruments. Therefore much of the attraction of technical approaches is to take the moral heat out of decisions about health funding[1]. The

1An example with a little too much moral heat is Williams' 'story of Jim and Pedro', said to demonstrate the 'moral contentiousness of the mathematical approach to moral judgement' (Williams 1973). Pedro offers Jim the botanist the 'privilege' of shooting an indigenous Indian pour encourager les autres, but if Jim declines, Pedro will shoot twenty. It is clear that Pedro does not like Indians; it is not as clear why he wants to bring mathematicians into disrepute. Although I agree that this is one possible argument against an ethic of maximising utility, I cannot see that it is a general argument against the use of mathematics in moral reasoning. For example, we can change the numbers so that Pedro will shoot only one Indian. However let us

approach is normative, in that it entails values, but the overarching values and the freedom of moral action are determined elsewhere. In the case of a government agency such as PHARMAC, elsewhere means the democratic institutions making public law.

To me personally the scope of morality to decide the funding of the New Zealand Pharmaceutical Schedule seems a little constrained, so long as the country continues to restrict eligibility mainly to its own nationals. The moral arguments that make most sense to me are those that might be used in deciding claims policies for an insurance scheme (on reflection this is probably still only a minor constraint on the scope for morality). One subject on which I have found accounts of distributive justice in health care to be relatively quiet is how to get it wrong. Not only does fair allocation of resources pose an intractable problem, it must be decided under severe constraint of time. Moral error is inevitable – one of the more egregious examples being the death of the child Coby Howard from leukaemia in a window of time between reversals of decisions on state funding of bone marrow treatment in Oregon (Hadorn 1991).

Moral thinkers of all grades have given advice on this subject, from Luther ('as long as we are here . . . we have to sin') to Lenin ('if you are going to make an omelette you have to break eggs'). Here at least Benthamist utilitarianism could both justify a practical mode of action (maximise QALYs), and absolve the agent from responsibility for error (transmuted into decision uncertainty or QALY tradeoffs).

I will finish by suggesting a mode of action that could accommodate both Hansen and Gillon's recommendations with those of an unreconstructed costper-QALY optimiser. The QALY optimiser's preferences are strongest at the extremes of cost-effectiveness; dominant and low cost-per-QALY interventions are strongly 'in', and dominated and high cost-per-QALY interventions are strongly 'out'. The QALY optimiser is maximally indifferent about cases at the margin. It does not really matter economically if these cases are in or out. Yet it is the cases at the margin that matter most in human terms, because these are the people who lose, having almost won, or who win, having almost lost (Metcalfe, Dougherty, Brougham and Moodie 2003).

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say that Pedro has neurosyphilis, cannot aim straight, and his shot guarantees an agonising death, while Jim is a former US Marine sniper who kills instantly. Now the choice for Jim is similarly odious, but this time it is qualitative and not mathematical. My position on mathematics is that it is simply amoral, a dispassionate, value-free instrument that can be brought in to assist with some forms of reasoning. Although it is hard to see how the kind of mathematics used in deciding health care allocation could help Jim or the Indians, no one would criticise a screwdriver for failing to disarm a nuclear warhead. Issues of health care allocation are a small and relatively genteel subset of all moral possibility. The story of Jim and Pedro does not rule out the existence of defined areas of the moral landscape within which mathematics might be a wholly proper tool to use.

Therefore apart from the philosophical and ethical oversight of the process as a whole, it seems there is a special need for this expertise to scrutinise the margins. But there are neither enough philosophers, ethicists, or time to cover everything. Here multicriteria decision analysis could screen for conflicts of values, in practice those cases where the cost-per-QALY is high but there are important competing considerations. In some cases, multicriteria methods might clarify things enough for a decision to be made. Otherwise the case could be referred to the allocation committee. I would like to see the allocation committee itself working within a fiscally neutral framework such as PBMA. The requirement for fiscal neutrality is one of the admirable things about PHARMAC, in contrast to other agencies such as NICE.

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