A Comprehensive Advanced Market Commitment

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1. Introduction

This submission offers comments on the proposal of *Incentives for Global Health* to create a system in which pharmaceutical innovators may openly license their technologies in exchange for payments based on the health impact of their innovation. The proposal can be thought of as creating a Comprehensive Advance Market Commitment (CAMC), applicable to any pharmaceutical innovations, including those which could not have been predicted by the administrators. It shares many characteristics with the Advanced Market Commitment recently developed, but has much greater flexibility. It is designed to ensure access at competitive prices, while appropriately compensating innovators. My commentary assumes that the reader is familiar with AMCs. A theoretical analysis of this proposal is available in Hollis (2007).

2. Comprehensive Advanced Market Commitment (CAMC)

The essence of a CAMC is that governments (and perhaps other donors) establish a pot of money which can be used for payments every year to firms with a patented, but freely licensed, pharmaceutical product (including vaccines). The amount paid to the patentee is based on the measured QALYs saved because of the product, compared with the previous state of the art. This could, for example, be approximated as the number of units sold times the estimated incremental QALY benefit per unit.

The chief strength of this system is that it creates an incentive to develop new medicines with large measurable health impacts, where the incentive is independent of the wealth of the consumer, while enabling access at competitive prices. That is to say, the system is automatically “needs-driven”. It empowers innovators to use their private information to determine R&D investments, and does not require bureaucratic prioritization of needs or identification of research gaps. The system is intended to be optional, so that innovators can choose between it and exploitation of their patent exclusivity rights. The system might be restricted to rewarding health outcomes in a set of developing countries.

Like a standard AMC, and like the patent system, the CAMC proposals would pay out over a period of years. For example, a new pharmaceutical product might earn payments every year for its first ten years of use. An extended payment period is important since it smoothes the payment stream and offers an incentive for innovators to promote their products to ensure that they are widely used. In this respect the CAMC differs from a patent buy-out.

A CAMC would require annual committed funding at levels exceeding $1bn, and this funding would have to be committed many years into the future. It would also require an Independent Assessment Committee (IAC) to annually estimate the incremental health impact of each product.

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1 For more on AMCs see [Framework Document: Pilot AMC for Pneumococcal Vaccines](#).
3 A QALY or “Quality-Adjusted Life Year” is a standardized measure for assessing health interventions.
4 One of the important objectives is to reduce patent litigation expenses so that innovators’ profits can be re-invested or returned to shareholders. If the payments are set for a fixed period of years following registration and commercialization of the product, there will be much less benefit from frivolous patenting or from litigation.
2.1 Funding
The optimal amount of funding for the proposed CAMC has not yet been determined, and would in part depend on some important details in the plans. There are two ways of fixing the amount to be paid out under the system: either the price per incremental QALY would be fixed in advance, leaving the total budget indeterminate; or the total amount to be paid out would be fixed in advance, with the payment per QALY pro-rated.

In the case of a fixed price per QALY, firms would be justly skeptical as to the ability of the CAMC to obtain sufficient resources from donor governments to meet its commitments. Donor governments would also be understandably reluctant to enter into a commitment which created an unlimited financial liability. Therefore this approach appears improbable.

With a fixed budget, the payments could be pro-rated so that the payment per QALY would be set equal to the budget divided by the total QALYs saved. Thus, for example, if 1000 QALYs had been saved by all firms which had opted into the CAMC, with a total budget of $15,000, each firm would obtain a payment of $15 per QALY saved by its own product. This means, of course, that the payment each firm receives is dependent not only on the performance of its own product, but on the performance of all other products included in the CAMC scheme.

How large an amount is reasonable for annual disbursements from such a fund? In principle, the CAMC system could conceivably be very large, with annual payments sufficient to provide an appropriate return on several new drugs each year: perhaps $10-20bn annually. This would of course give it tremendous power. If it were smaller, say $2bn annually, it would still be able to incentivize development and commercialization of new pharmaceutical products with high health impacts but little commercial value under the patent system, though at a much lower rate. (The net cost of the CAMC system would be lower than its budget because it will include some drugs which would otherwise have had high prices.) Therefore it is not necessary to determine in advance the “theoretically correct” amount of funding. One possible strategy, in this context, is to start with a relatively modest annual commitment, and then to expand this if it appears to be successful.

2.2 Estimating the QALY impact
An important requirement to make such a system effective is the creation of an Independent Assessment Committee, which would be authorized to evaluate, for the purpose of determining payments, the incremental QALY impact of a given medicine. In reaching such a determination, the IAC would examine evidence presented by the patentee, as well as other independent evidence brought forward by governments and its own investigations.

There are considerable theoretical difficulties in using QALYs. For example, one must determine a discount rate to be applied when the benefits of a pharmaceutical – such as a vaccine – extend many years into the future. There are difficulties in evaluating the contribution of individual firms when two products have complementary effects on health. For example, a combination anti-retroviral therapy depends for its effectiveness on multiple drugs: in this case how is one to determine the individual contribution of each? There are also difficulties in determining the health impacts of pharmaceuticals for the case of infectious diseases, since, for example, inoculating one person makes it less likely that other people will be exposed to the
Given that the IAC will inevitably make mistakes in evaluating QALYs, the question is whether this is an impenetrable barrier to the usefulness of a CAMC. Perhaps the best way to answer this is to ask whether other schemes for rewarding pharmaceutical innovation are more accurately able to reward valuable contributions: in the patent system, it is well known that prices do not perfectly reflect the health impact of drugs. Thus, perhaps a reasonable standard is that the CAMC should do at least as well as the patent system in making rewards conditional on measurable social benefits of an innovation. If it does no worse, then there is no reason to think it an inferior system. Given that, by construction, the payments are to be conditioned on the best available measure of health impacts, the CAMC should be successful in adding value as an optional incentive mechanism to reward pharmaceutical innovation.

### 2.3 Properties of the CAMC Mechanism

The CAMC mechanism is to the greatest extent possible dependent on competition and markets rather than on arbitrary decisions. Prices to consumers are determined by competition between manufacturers; and the amount of payments due to each innovator is determined by competition for the budget of the CAMC. Innovators compete by developing and promoting drugs which improve human health.

With a limited CAMC budget whose disbursement is entirely based on the health effects of each drug, firms would have an incentive to focus their efforts on those interventions which would lead to the greatest expected health impact. Because the incentive to invest in R&D on a pharmaceutical product is proportional to its health impact under the CAMC, the limited dollars of the CAMC are automatically directed to those products of the greatest expected importance, which is a very attractive feature.

Since the CAMC is optional, firms will only submit innovations to the CAMC on which they expect to earn greater profits from CAMC payments than from unconstrained use of patent exclusivity. This considerably mitigates the risks firms face from competition for the CAMC budget: if the payment per QALY drops too low, some firms will choose to exploit their patent exclusivity, instead of accepting payment under the CAMC. In turn, this increases the payment per QALY for those firms which remain in the CAMC system. Note that this effect also works in the other direction. Thus the system automatically adjusts itself: the Independent Assessment Committee would not need to determine a rate per QALY. What is more, this automatic adjustment has the desirable property that the payment under the CAMC system is proportional to the health impact at a rate consistent with that of profits under the patent system, because of substitution by firms across the two systems.

One of the most attractive features of the CAMC approach is that it would enable many highly productive lines of R&D which are currently not attractive because the patent system does not yield effective protection from imitation or because consumers are indigent. For example, one of the serious obstacles faced by drug companies is that even when they obtain a patent for a new use of an existing drug, they may not be able to stop generic companies from selling the drug. For example, the incentives under the patent system to explore new uses of existing drugs are relatively weak. Under the CAMC approach, a firm which obtained a patent for a new use of an existing drug – perhaps one initially patented by a different firm, or one that had been

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5 It is important to note here that pharmaceutical companies trying to price their drugs under the patent system face these problems also.
generically available for many years – and could show that some proportion of sales of the drug was for the new use, would be able to receive payments on this basis. It need not prevent sales by other firms, which is the essence of the patent system, since the basis of payment would be the use of the drug. Similarly, firms could earn substantial profits by developing drugs which would mainly be consumed by poor people, a strategy which is less attractive without a CAMC.

2.4 Administrative Matters

What innovations deserve payments under a CAMC?

An important technical problem for such a system is that the IAC would need to decide what comparison to make when evaluating the QALYs saved. One possible solution is to make the reward conditional on the increase in QALYS from the prior state of the art. However, this approach may need refinement: for example, it may be desirable to compare the outcome under the innovation with the state of the art two years before the innovation was approved for commercial use, in order to allow for payments to multiple parties in case of simultaneous development of comparable products.

Preventing Gaming and Rent-Seeking

There are three ways of gaming this kind of system. The innovating firm can attempt to increase the estimate of the QALYS per unit of the product sold; it can attempt to increase the estimate of the units sold; and it can artificially increase the number of units sold. These are the only three margins on which the firm can artificially influence its payments under the CAMC scheme, and I discuss them below.

Evidently, given the difficulty of evaluating the health impacts per unit of a product, patentees will make every effort to present their product’s effectiveness in the most positive light. The best response to this is undoubtedly transparency. If data from clinical trials and other evidence on the effectiveness of pharmaceuticals in different settings is made public, the IAC will be able to benefit not only from the advice of its own experts, but from comments made by others. Since firms will compete for payments, the more X gets paid, the less there is available for Y. Thus, each will have an incentive to point out weaknesses in the claims made by other firms.

Attempting to inflate the estimate of the actual number of units sold is likely to be relatively difficult. The IAC should, however, rely on a variety of information sources to determine quantities sold, including data from pharmacies, manufacturers, wholesalers, governments, and, where available, from independent data collection agencies.

The third problem is that innovators have an incentive to inflate the actual sales of the product. If the innovator expects a CAMC payment of $10 per unit sold, it may heavily promote the product, even for off-label uses of dubious value. In such a situation, the CAMC might end up rewarding improper use of the product. The IAC can mitigate this kind of abuse by surveys of use of the products, with the payments adjusted accordingly. Another way innovators could stimulate sales volumes would be through pricing below variable cost. One obvious solution to this problem would be to restrict sales eligible for payments by the CAMC only to generic manufacturers. This would limit the role of the innovator to R&D and marketing. Since generic manufacturers would have no incentives to price below cost, and would be required to report

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6 IMS Health and perhaps other organizations conduct such surveys in developed countries: but this would clearly be a challenging task in most developing countries.
directly to the IAC the number of units sold, the problem of inflating the actual number of units sold would be mitigated.

Notably, the incentives for counterfeiting would be substantially reduced if drugs were sold at generic prices.

**Treatment of Drugs for Rare Diseases**

Because the CAMC would make payments dependent on estimated health impact in a population, the incentives would be weak for drugs for rare diseases. There are two possible responses to this. The first is that exploitation of exclusivity rights under the patent system would still be an option. Therefore the CAMC proposal, while it does nothing to assist in the treatment of rare diseases and conditions, does nothing to harm them either. An alternative response might be to set aside a portion of funding only for pharmaceutical innovations which addressed diseases and conditions with low prevalence. Thus, this approach can be used for such cases. However, one of the attractive features of the CAMC system is its simplicity. Creating special set-asides increases complexity and decreases transparency, but may sometimes be valuable.

**Funding Sources**

*Incentives for Global Health* has suggested an international treaty to form the basis of a funding arrangement between countries, where financial contributions would be based in some way on income per capita. Some of the contributions might be made up by lower health care costs and lower expenditures on pharmaceutical products – since any product under the CAMC scheme would be generically available. It is also conceivable that other charitable foundations might choose to participate, at least to kickstart the system.

**5. Summary**

The essence of the CAMC proposal is to develop a scheme in which incentives are well aligned with health needs. Under the CAMC scheme, firms would have an incentive to develop and promote products which improved health. They would have an incentive to work with public health agencies to promote their product and to ensure that it was rationally used. They would have an incentive to develop products which cured consumers, instead of maintenance products. They would have all of these incentives because the payments under the CAMC would be conditional on the measurable effects of their product on health.

The CAMC approach is guaranteed to set a reasonable rate of payment for innovative medicines, because of substitutability between the exploitation of exclusivity rights under the patent and payments under the CAMC. This possibility of substitution ensures that no matter what innovations arise, there will be a reasonable return available under the CAMC. The CAMC approach also largely solves some technical problems related to the limited protection granted by the patent system, because it is not necessary to be able to exclude imitators in order to receive payments. Most importantly, the CAMC approach can be used to create new incentives for R&D into drugs for developing countries, because it treats human lives as equal – unlike the patent system, which encourages R&D into the diseases of the rich – while enabling access.

I would be happy to address any questions the Working Group may have in relation to this brief submission.

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