

Tiered royalties

*One way to hasten
the global introduction
of new vaccines*

Issue Paper



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PROTECT A NATION**

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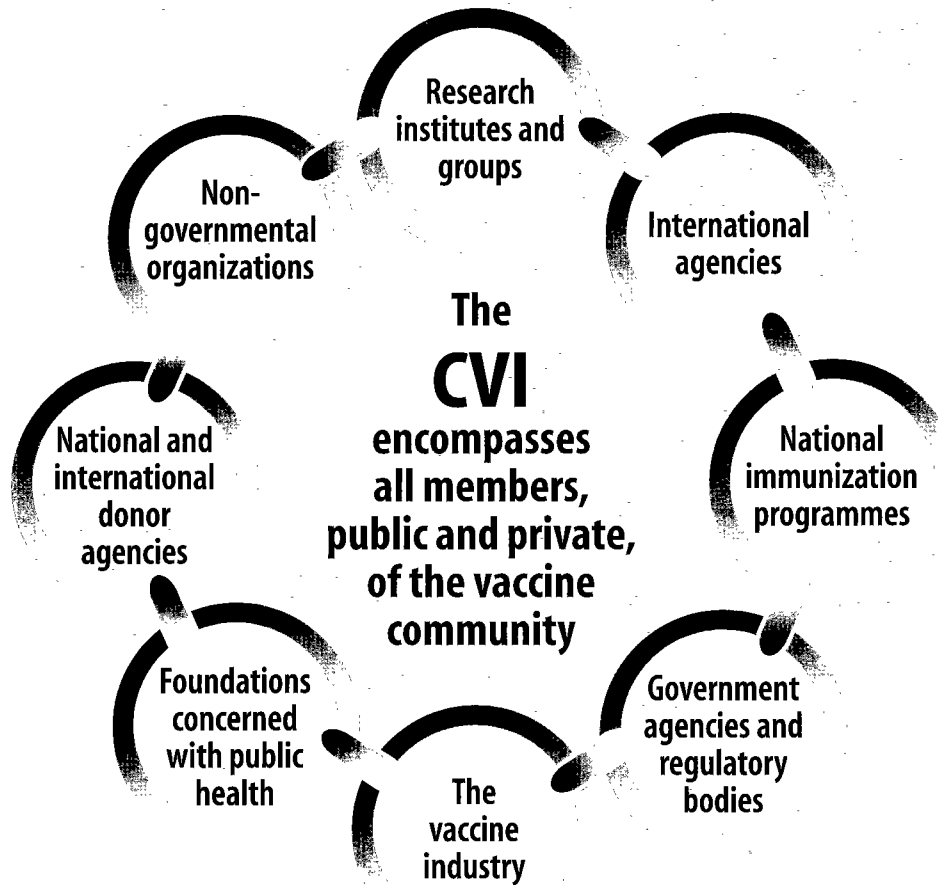
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Introduction

A royalty is compensation for the use of property. In this context, it is an ongoing fee that a licensee of intellectual property (a pharmaceutical company) pays to a licensor (a university, a biotechnology company or a licensing corporation) for the privilege of using intellectual property to manufacture and/or sell a product. Royalties are generally calculated as a fixed percentage of the receipts for the sale of the good resulting from the use of the intellectual property.

Tiered royalties are simply different royalty rates for sales in different markets.

The purpose of this document is to present one possibility for lowering, albeit slightly, the cost of vaccines purchased in bulk for the poorest countries in the world by international agencies. The idea behind tiered royalties is very simple: for new vaccines, the patent holder (licensor) would agree to accept a different royalty rate for sales in different markets, that is, it would be paid a lower royalty rate for sales made by its licensee (presumably a large vaccine manufacturer) to a UN agency for use in the world's poorest countries. A higher royalty rate would accrue for sales to the wealthier, more profitable markets.

The tiered royalty would reinforce existing tiered pricing for vaccines for different markets, with the lowest tiered price (and lowest tiered royalty) going to the poorest countries and the higher prices (and higher royalty rates) being offered to other countries. Tiered royalties would strengthen and promote tiered prices of vaccines.

The aim of this document is to present the possibility of a mechanism which could provide mutual benefit to the public and private sectors.

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Background: Tiered prices

UNICEF has historically procured vaccine for much of the developing world. It has been able to do so because large manufacturers have sold vaccine to UNICEF and other large procurement agencies at significantly tiered prices. In the absence of this very steep price tiering arrangement, national immunization programmes would not have enjoyed the successes they have achieved in the last ten years. UNICEF has been the world's largest purchaser of vaccines in terms of number of doses, purchasing annually more than one billion doses of the six traditional Expanded Programme on Immunization (EPI) antigens which, in various combinations, prevent diphtheria, pertussis, tetanus, tuberculosis, polio and measles. These are "old" vaccines.

They are based on technology that has passed into the public domain by virtue of its age. The patents, if any, have expired and there are, in all likelihood, no royalties payable as a result of these sales to UNICEF.

The public sector wants to ensure that new vaccines are affordable and available to developing countries as rapidly as possible.

Since the inception of EPI, however, several vaccines have been developed and licensed, for example, those against *Haemophilus influenzae* type b (Hib) and hepatitis B. There are many more to come in the near future. They are and will be more expensive than the old vaccines. The challenge presented to the public health

community is to find ways to get these "new", more expensive vaccines to children in countries that cannot afford them. The public sector wants to ensure that new vaccines are affordable and available to developing countries as rapidly as possible. Many of these new vaccines are covered by valid patents, which slightly raise the price at which they would theoretically be sold to UN agencies. The extent to which royalties add to the cost of the vaccine, and therefore, its price to UN agencies, varies significantly from vaccine to vaccine.

Manufacturers rely on the profits earned in the early years of a product's life to cover the high costs of research, development and registration (or licensing). As a result, prices of new vaccines tend to be high and manufacturers are hesitant to employ any strategy that might lower margins or decrease sales in important markets.

A system of multi-price tiering, if market segmentation could be maintained, could address these concerns. This market segmentation system, proposed several years ago by WHO and UNICEF, but not yet implemented, has met with concern on several fronts. Nevertheless, some price tiering does in fact exist for new vaccines because of different needs of different markets, and because of consolidation of orders by some procurement groups. Thus, in 1998, reported prices for Hib vaccine ranged from almost US\$40 per dose in the private market in industrialized countries to around US\$2 for public sector bulk markets. An even greater price spread, US\$45 to US\$0.41 per dose, existed for hepatitis B vaccine. Faced with the concerns expressed against an imposed system of market segmentation, yet with the reality of the need to ensure access to these new vaccines for those in the poorest donor-dependent countries, international agencies are exploring additional mechanisms to address the problem. Tiering of royalties is one of these mechanisms.

Facilitating access: Tiered royalties

UN agencies solicit bids for certain vaccines through a tender process. Tendering is generally employed only for those vaccines that have been formally recommended by WHO for inclusion in national immunization programmes. In the case of procurement by UNICEF, these vaccines are provided free of charge to some countries and on the basis of reimbursable procurement for others.

There are many factors influencing the price of a pharmaceutical product, including development, regulatory and scale-up costs; however, there is a risk that UN agencies will not be able to afford sufficient quantities of new vaccines at least in part because of the royalty cost. This is one of the reasons for a tiered royalty system. Just as manufacturers have historically tiered prices to public sector large

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volume purchasers, the licensors could tier royalties—with the lowest royalty accruing from sales to UN agencies for use in developing countries. The licensors would receive the same benefit from tiering as noted for the manufacturers, namely volume. Though the royalty rate would be lower than in other markets, the potential increase in volume is enormous. UN agencies are, in volume terms, the world's largest purchasers of vaccine.

If structured correctly, the licensors can agree to accept a lower royalty for sales to UN agencies for use in the poorest countries without incurring a loss. In fact, a licensor who tiers royalties will not lose royalty income; rather that licensor will earn more if the licensee is a successful bidder in a UN agency tender. This is because the UN agency market represents incremental volume: the market unlikely to exist in the absence of price tiering. Unless UN agencies buy the new vaccines for these poorest countries, these countries will simply not have access to them. Therefore, the manufacturer will not make the sale, and the royalties will not accrue to their licensors, unless this market is tapped. Furthermore, access by the poorest countries to a product that is also available to the wealthiest countries will likely influence middle income countries to buy it as well.

Theoretically, the UN agency would only be a third party beneficiary to the contractual arrangement between the licensor and the licensee. The licensee and licensor would agree on the royalty for their other sales. They would also agree to a lower rate for sales to the procurement agency for developing countries sales. The royalty tiering built into this arrangement would only "kick in" if the manufacturer (licensee) were the successful bidder in a UN agency tender. Often in license agreements, the percentage of sales price, or royalty rate, is indexed to the net sales volume. In the event that the royalty rate is indexed to volume of net sales, the definition of net sales could specifically exclude sales to UN agencies for use in developing countries. In this way, the manufacturer would not be penalized for a successful UN agency bid. The UN agency sale would not alter a contractual arrangement that was otherwise amenable to licensee and licensor.

Tiering of royalties increases the likelihood of a successful bid by a manufacturer. A licensor who agrees to tier royalties creates incentive for the licensee to access markets that might otherwise be unattractive.

UN agency sales are unlikely to occur in the absence of some price tiering, and tiering of royalties increases the likelihood of a successful bid by a manufacturer. A licensor who agrees to tier royalties creates incentive for the licensee to access markets that might otherwise be unattractive. A tiered royalty structure would have the benefit of reducing the vaccine manufacturer's costs and thus enabling manufacturers to offer more competitive bids. Winning a UN agency contract would also provide the manufacturer with a large increase in volume. As vaccine production is highly sensitive to economies of scale, a

successful bid in a UN agency tender could make a vaccine manufacturer more competitive, even in its profitable markets.

Finally, vaccine manufacturers have been the focus of negative political pressure because of misunderstanding about tiered pricing. The countries that discourage tiering actually hamper the ability of their domestic producers to compete in the global vaccine market. In the event that the manufacturer elects to bid in a UN agency tender, then a tiered royalty structure is one way to help to defuse that pressure. If tiering is built into the actual cost of production, rather

than introduced at the end of the process, in the vaccine pricing, then production costs are different for different markets, because of packaging, because of volume, but also because of differential royalty rates. At a Conference on Global Supply of New Vaccines, co-sponsored by the Rockefeller Foundation and CVI in Bellagio, Italy in February 1997, several vaccine manufacturers expressed strong support for the maintenance of one quality standard for each vaccine they produce. If the royalty expense is tiered, then the product and its quality could be the same for all markets, but the costs for producing the product sold to the UN agency and the other markets are different. Tiered royalties would thus bolster the overall price tiering system by integrating tiering into the production process.

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Questions and answers

There are some legitimate concerns that have been expressed about tiered royalties. Among others, a general concern is that tiering royalties does not address the fundamental problem, which is that the public sector needs to raise more funds for new vaccines. This is undoubtedly true. However, when one considers how many life-saving vaccines are in the development pipeline or in the final stages of licensure, the likelihood of availability of sufficient funding becomes even lower. Some innovation will be required to make sure that children in the poorest countries have access to these life-saving products. Other more specific concerns are given below.

1. It won't save enough money.

It is true that the extent to which royalties add to the actual price of vaccine is highly variable and generally fairly low. For example, royalty rates vary from those for Hib, for which there are no royalties for at least one licensed formulation, to those for acellular pertussis, for which the royalties range from approximately 2–11% for various formulations, to recombinant hepatitis B vaccine, for which the royalty expense is from 13–15% of the cost of the vaccine. But in the arena of purchases potentially as enormous as those to be made by UN agencies, tiering can make a difference. As a hypothetical example, if recombinant hepatitis B vaccine theoretically cost US\$0.75/dose, and the UN agency had US\$30 million to spend on hepatitis B vaccine, then the agency could buy 40 million doses. If the royalty expenses (approximately 14%) were halved, then the bid would presumably be US\$0.70. At this price, the UN agency could purchase 43 million doses. Under this scenario, the UN agency could afford to buy 3 million more doses with royalty tiering than it could in its absence. With a three dose regimen, this is enough to immunize 1 million more of the poorest children per year.

2. Royalties are already tiered because they are indexed to sales price. If the UN agency price is lower, why should the licensor "give something away" by tiering the royalty even more?

Part of the success of price tiering is that it is very steep. Although there is tiering built into the standard royalty arrangement, it is also true that increased incentive is required to get new vaccines in the

public health sector. The royalty should be tiered more because it fosters entry into an untapped market, and because it is in the financial best interest of the licensor to do so. The licensor isn't giving anything away, but rather is potentially making more.

3. How will the licensor know that the manufacturer is actually lowering its bid price to the UN agency by the same differential?

The manufacturer is bidding against competitors who also want the UN agency market. It is in the manufacturer's interest to bid as competitively as possible in a non-monopoly situation. The obligation to make the differential in bid commensurate with the differential in royalty rate would theoretically be built into the contract as consideration for the licensor's agreement to accept a lower royalty rate. To violate this contractual agreement would be to endanger a

potentially large sale for what is, from the large manufacturer's perspective, an insignificant amount of money. After all, the UN agency market is appealing not because it is profitable, but because it offers economies of scale to increase profit margins in other markets.

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Conclusion

In summary, the tiering of royalties for sales to developing country markets bolsters existing tiered pricing generally, offers financial benefit to the patent holder and the vaccine producer, and makes new vaccines more accessible to the children of the world's poorest countries. It is not a panacea, but it is a mechanism which could make introduction of new vaccines one step closer.