Advance market commitment for pneumococcal vaccines: putting theory into practice

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Abstract Markets for life-saving vaccines do not often generate the most desired outcomes from a public health perspective in terms of product quantity, quality, affordability, programmatic suitability and/or sustainability for use in the lowest income countries. The perceived risks and uncertainties about sustainably funded demand from developing countries often leads to underinvestment in development and manufacturing of appropriate products. The pilot initiative Advance Market Commitment (AMC) for pneumococcal vaccines, launched in 2009, aims to remove some of these market risks by providing a legally binding forward commitment to purchase vaccines according to predetermined terms. To date, 14 countries have already introduced pneumococcal vaccines through the AMC with a further 39 countries expected to introduce before the end of 2013.

This paper describes early lessons learnt on the selection of a target disease and the core design choices for the pilot AMC. It highlights $the challenges faced with tailoring the AMC design to the specific supply situation of pneumococcal vaccines. \\ It points to the difficulty-and$ the AMC's apparent early success – in establishing a long-term, credible commitment in a constantly changing unpredictable environment. It highlights one of the inherent challenges of the AMC: its dependence on continuous donor funding to ensure long-term purchases of products. The paper examines alternative design choices and aims to provide a starting point to inform discussions and encourage debate about the potential application of the AMC concept to other fields.

Abstracts in عربی, 中文, Français, Русский and Español at the end of each article.

Introduction

The prevention of disease through vaccination with efficacious and safe vaccines is one of the most cost-effective public health interventions.1 However, often the markets for vaccines do not generate the most desired outcomes from a public health perspective in terms of product quantity, quality, affordability, programmatic suitability and/or sustainability, particularly when it comes to serving the poorest populations. Economic factors may hinder or delay the clinical development of candidate products as well as prevent manufacturing of licensed vaccines at sufficient scale to respond to these needs. Manufacturers face competing interests when making investment decisions and they perceive demand from developing countries as very uncertain. While the need for and the willingness to adopt new vaccines exist, resources to sustainably fund such products are often missing. Manufacturers thus find this market segment very risky and less attractive. An Advance Market Commitment (AMC) for vaccines aims to make the market for vaccines in developing countries more attractive through a legally binding commitment to purchase vaccines according to predetermined terms. As some of the risks are removed, the vaccine industry is encouraged to increase investments to stimulate the development and manufacture of target products.

Different models have been designed to create market-oriented incentives to support the development and introduction of appropriate health technologies for developing countries. Many have remained academic exercises, but the AMC moved from theory to practice with a pilot AMC for pneumococcal vaccines launched in 2009. While it is still early to assess the efficiency and effectiveness of this pilot, this paper discusses lessons learnt on moving from the theoretical concept to implementation. It provides a starting point to inform discussions and encourage debate about the potential applications of the AMC concept to other interventions.

The pilot AMC

An AMC for vaccines gained public attention with a report by the Center for Global Development in April 2005.² The report proposed to create incentives for commercial investments in research, development and manufacturing of vaccines for developing countries through a legally binding pledge by donors to pay a certain price for a new vaccine if it is developed and desired.2

A pilot AMC for pneumococcal vaccines was announced in February 2007 and formally launched in June 2009 with a joint pledge of 1.5 billion United States dollars (US\$) by the Governments of Canada, Italy, Norway, the Russian Federation and the United Kingdom of Great Britain and Northern Ireland, and the Bill & Melinda Gates Foundation.3 The key design features and the functioning of the AMC for pneumococcal vaccines are described in Box 1. The GAVI Alliance, a public-private partnership created to increase access to immunization in poor countries, and The World Bank co-led the design of the pilot and they implement it together with the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO). By placing the AMC on its balance sheet, The World Bank effectively guaranteed US\$ 1.5 billion in AMC funding for the purchase of pneumococcal vaccines.5 Meanwhile, the GAVI Alliance serves as the secretariat for the AMC and has committed to support eligible

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Box 1. Design and functioning of the Advance Market Commitment for pneumococcal

The pilot Advance Market Commitment (AMC) offers a legally binding commitment to support the market of targeted pneumococcal vaccines with US\$ 1.5 billion of funds for which vaccine manufacturers can bid. Interested manufacturers compete over successive tenders to supply a share of the annual forecasted demand of vaccines (which is expected to increase over time and reach around 200 million doses per year at peak). In exchange, the AMC provides a fraction of the US\$ 1.5 billion directly proportional to each manufacturer's supply share.

Each manufacturer must commit to supply its annual share of doses for 10 years at a maximum price of US\$ 3.50 per dose (i.e. "tail price cap" which was set close to the estimated marginal cost of production at the time of the AMC design) to be paid by GAVI and GAVI-eligible countries.⁴ Each manufacturer's share of AMC funds is disbursed as a subsidy per dose additional to the tail price – bringing the total price up to US\$ 7 for approximately the first 20% of vaccine doses procured from each manufacturer. This "AMC price" is set with the aim to enable companies to quickly recover incremental investment costs incurred to serve the GAVI market.

countries to purchase the product. Some of the expected benefits of the AMC are outlined here.

Assured quality

To be eligible for AMC funding, vaccines must meet minimum product specifications, as stipulated in the Target Product Profile developed by experts from WHO in 2007 for the AMC pilot. WHO guided manufacturers in their development efforts by defining additional minimal characteristics of target products suitable for immunization programmes in developing countries.6,7

Early supply

By providing some assurance of recoupment of investments, the AMC encourages manufacturers with a nearly licensed product to scale up supply capacity to serve GAVI-eligible countries faster (the historical lag between roll out of new vaccines in industrialized countries relative to low-income countries has been ≥ 10 years).8

Lower purchase price

While the AMC ensures that companies quickly receive funds to cover investment costs, beneficiary countries and their co-sponsors (in this case GAVI) pay a price close to the estimated marginal cost of production right from the start. Without an AMC, prices for new vaccines (e.g. hepatitis B vaccines) have tended to remain high in the first years following market introduction and decline only after several manufacturers enter the market.9

Incentives for competition

Unlike other "pull-funding" mechanisms (e.g. prizes) that reward the first supplier, the AMC intends to create a market of multiple manufacturers, to

provide healthy competition and sustainable supply in the long term. The terms are non-exclusive: any manufacturer with a qualifying product can bid to supply a share of the annual forecasted demand for pneumococcal vaccines. Companies compete on the long-term price offered and on product quality. Competing bids are also assessed to ensure sufficient supply to meet demand and provide supply security over time.

Donors pay for results

Donor AMC funds will be spent only if a suitable vaccine comes to market and if this product is demanded by GAVIeligible countries. A limited purchase guarantee, equivalent to 45% of one year's committed supply, is offered to each manufacturer. Thus, countries must desire the vaccines, have the health systems in place to introduce them, and must be able to pay their share of the final price, jointly with GAVI.10

Lessons learnt

The evaluation and choice of a target disease for the pilot AMC was led by an independent expert committee of internationally recognized experts in public health, epidemiology, industrial economics, vaccine development, financing and law.11 In 2006, this committee recommended pneumococcal vaccines as the most suitable candidate for a demonstration AMC mainly because of the expected magnitude of the vaccine's health impact on the target population and the ability to leverage an already existing robust pipeline of efficacious vaccines (given two candidate vaccines were in advanced stages of development). The committee also emphasized the ability to test rapidly the viability and effectiveness of the AMC concept in influencing industry and donor behaviour.12 In fact, as work progressed, it became clear that the AMC model was broad and required considerable work to be tailored to the specific characteristics of the target market, i.e. the pneumococcal vaccine market. The following examples illustrate some of the challenges faced.

Competition and early supply

The pilot AMC targeted two objectives simultaneously: (i) motivating first-generation suppliers - with nearly licensed vaccines - to increase manufacturing capacity and (ii) spurring development of new vaccines by second-generation suppliers, hence fostering competition in the long term. Yet, since both generations of suppliers compete for AMC funds on equal terms, secondgeneration suppliers may have little incentive to participate as they will require more time to enter the market and AMC funds may be depleted by the time they do. The main rationale for this design was to ensure adequate supply capacity to serve imminent demand - allowing countries to introduce these life-saving vaccines as fast as possible. In addition, setting equal conditions for all manufacturers was a way to minimize concerns of preferential treatment. In practice the pneumococcal conjugate vaccine market is currently dominated by two companies, GlaxoSmithKline and Pfizer, and the market will be truly competitive when and if additional manufacturers enter the market. Retrospectively, in similar markets, one might find ways to encourage competition more rapidly. One option could be to target first- and second-generation suppliers separately, perhaps with different simultaneous AMCs.

A "level playing field"

Engagement of both first-generation suppliers was considered highly desirable to ensure sufficient and secure supply in the early years of the programme. Consequently, the terms of the AMC offer (in particular the tail price cap) being equal for all manufacturers, ensured that both suppliers were sufficiently encouraged to participate. As they had different production technologies, strategic objectives and costs, it may have been more efficient to provide or negotiate tailored contracts with the two manufacturers, rather than shape a "one size fits all" contract. Although this option was discussed, AMC donors did not want to establish differential and potentially preferential terms for different suppliers.

Changing environment

One of the intrinsic difficulties of the AMC is to establish a long-term, credible commitment in a constantly changing unpredictable environment. For instance, the AMC for pneumococcal vaccines is set up to encourage development of 200 million doses of annual production capacity for target pneumococcal vaccines, an amount slightly more than the estimated peak annual demand from GAVI-eligible countries at the time of the AMC set-up. A reduction in demand would mean the AMC was not used to its full potential, which would in turn reduce the likelihood of participation by late market entrants. Also, some AMC funds would for some time lie unutilized - since disbursement of the US\$ 1.5 billion is based on the supply of 200 million doses annually for ten years. Additionally, any drop in demand for which there are existing supply contracts would lead to an inefficient use of AMC funds as suppliers would be left with paid-for and dedicated but unused production capacity.

While uncertainties about vaccine uptake at country level may be unavoidable, the AMC could potentially have done a better job at enhancing overall demand predictability. For instance, to foster demand stability and predictability, the AMC contracts could have fixed the list of eligible recipient countries over the duration of the programme, rather than allowing for changes as occurred when the GAVI Board revised the country eligibility policy in November 2009. While this decision threatened to reduce projected peak demand, the GAVI Board subsequently decided to provide continued access to pneumococcal vaccines under the AMC terms and conditions to all GAVI countries that were eligible at the time of signature of the legal agreements (although only the lowest-income countries would benefit from GAVI financial support).¹³

A second example of unpredictability is that GAVI pays a considerable proportion of the vaccine price and funds are contingent upon continuous donor contributions. Consequently, the actual level of funded demand depends on GAVI's ability to raise sufficient resources over time. This highlights one of the inherent challenges of the AMC:

while attempting to reassure industry of the viability of the developing country market for vaccines, the AMC still heavily depends on donor funding to ensure long-term purchases of available and much needed products. In future, the ability of the final buyer to purchase the target product over time may need to be considered as a central design and selection criterion when choosing a target intervention. For future AMCs, it might also be desirable to explore the coupling of an AMC with long-term and predictable donor commitments to the buyer's budget as well as innovative, less pro-cyclical sources of funding.

Discussion

While some analyses of the AMC for pneumococcal vaccines are available, 14,15 it is too early to draw any firm conclusions on its efficiency and effectiveness. For now the AMC pilot stands out as a successful collaboration between different partners. To date 37 countries have been approved for funding support from the GAVI Alliance and 14 countries have introduced pneumococcal vaccines into their national programmes. By 2013, a total of 53 countries are expected to have introduced pneumococcal vaccines through the AMC agreement and GAVI financial support. The first of these introductions happened within approximately one year of introduction of the same products in high-income countries.

Because of its innovative design, the AMC has received a tremendous amount of attention from the international community, governments, industry and academia. This has led to increased awareness and attention to vaccines in general, and specifically to pneumococcal vaccines, as a powerful prevention measure.

Moreover, experience with this AMC suggests that long-term donor commitments can be made credible to industry and induce manufacturers to sign long-term binding commitments themselves to supply a fixed amount of vaccines per year at a predetermined price. This is unprecedented as, historically, industry has entered only into good faith agreements of three years with no binding obligation to supply. Since the signature of the legal agreements, four manufacturers – GSK, Pfizer, the Serum Institute of India and Panacea Biotech – have publicly disclosed their formal

agreement to the AMC terms and conditions. As a result of a first tender issued in September 2009, UNICEF entered into supply agreements with GSK and Pfizer under which both manufacturers supply 30 million doses annually each for 10 years from January 2012 for GSK and from January 2013 for Pfizer. Both manufactures have also committed to supply additional doses in 2010 and 2011 while scaling up production capacity. A second tender for additional doses is currently underway.

The supply price of US\$ 3.50 per dose can also be considered a significant achievement. This is more than a 90% reduction in price compared with the European Union and the United States of America, where average public prices are 40 Euros and US\$ 96, respectively. This new reference price for the lowest-income countries may impact prices charged for other segments of the market. Some authors suggest that, given the cost structure in vaccine production, both consumers in developing countries and high-price markets may benefit from such a tiered pricing scheme. 17

Donors and policy-makers in different fields - within and beyond health - follow the implementation of this AMC to assess its value and applicability to other products affected by similar market failures. For example, the United Kingdom Department for International Development started to explore AMCs to support low-carbon technology development. 18-20 There is also ongoing work, led by Canada and the United States of America and supported by The World Bank, to develop AMCs and other pull mechanisms in the context of agriculture and food security. Whether an AMC is the most efficient and cost-effective tool compared to other push- and pull-funding options depends on the specific problem. Based on the lessons described in this paper, we can draw some tentative conclusions.

Conclusion

The AMC concept is broad and needs careful and flexible crafting to address the specific problem efficiently and effectively. The analysis of a particular technology's demand and supply landscapes must drive project designers to define an adequate AMC contract ensuring appropriate incentives for desired goals.

The AMC pilot for pneumococcal vaccines provides insights for products in a similar market. In this case, we learnt that there are trade-offs between the objectives of ensuring sufficient manufacturing capacity to serve imminent demand and establishing a competitive market in the long term. Yet, this AMC tells us little as to whether the mechanism would effectively work to encourage commercial investments in research and development for new vaccines in early stages of development or whether a similar model can be applied to other types of pharmaceutical

products. It is likely that an AMC is more easily established in markets where a single entity is in charge of pooling and purchasing large volumes of demand for a predefined set of countries and is thus able to make a credible commitment. While vaccines for the lowest-income countries are often purchased through some form of global or regional pooling mechanism, this is not typically the case for pharmaceutical products which are more often individually purchased by countries. A prominent exception is the dominant role that UNITAID

plays in purchasing a high proportion of paediatric antiretrovirals.21

This AMC pilot also shows the importance of predictability, particularly of sufficient funding commitments from donors and/or beneficiary countries to pay the long-term purchasing price of vaccines in addition to the AMC envelope. Ongoing monitoring and evaluations scheduled for the coming years will provide further information about the value of this AMC and its applicability to other interventions.

Competing interests: None declared.

ملخص

تطوير الالتزام السوقى للقاحات المكورات الرئوية: تطبيق النظريات عملياً

منها في اختيار المرض المستهدف، وتحديد اختيارات التصميم الرئيسي للمبادرة الارتيادية للالتزام بتطوير سوق اللقاحات، كما تلقي الورقة العلمية الضوء على التحديات التي تواجه مواءمة تصمّيم المبادرة الارتيادية أمام حالات محددة للإمداد بلقاحات المكورات الرئوية، وتشر الورقة إلى صعوبة تأسيس التزام طويل الأمد وله مصداقية في ظل بيئة مستمرة التغيير ولا يمكن التنبؤ بها - والنجاح المبكر الواضح للمبادرة الارتيادية في هذا المجال. وتلقى الورقة الضوء على أحد التحديات المتأصلة أمام المبادرة الارتيادية للالتزام بتطوير سوق اللقاحات وهو: اعتماد المادرة على التمويل المستمر من المانحين لضمان شراء المنتجات لأمد طويل. وتفحص الورقة العلمية اختيارات التصميم البديلة، وتهدف إلى إيجاد نقطة بداية للنقاشات المستنيرة وتشجيع الحوارات حول إيجاد تطبيق مفهوم المبادرة الارتيادية للالتزام بتطوير سوق اللقاحات في مجالات أخرى.

أسواق اللقاحات المنقذة للحياة لا تتيح غالباً أفضل النتائج المأمولة من منظور الصحة العمومية من حيث كمية المنتج، وجودته، وسعره المتيسر، وملاءمته للبرامج، وضمان استمرار استخدامه في البلدان المنخفضة الدخل. وقد أدت المخاطر والشكوك المتصورة من عدم القدرة على تمويل طلبات اللقاح وضمان استمرارها في البلدان النامية إلى ضعف الاستثمار في تطوير وتصنيع المنتجات الملائمة. وقد انطلقت المبادرة الارتيادية للالتزام بتطوير سوق لقاحات المكورات الرئوية في عام 2009، وهي تهدف إلى إزالة بعض المخاطر السوقية عن طريق رفع مستوي الالتزام القانوني بشراء اللقاحات وفقاً للشروط المحددة مسبقاً. وقد استخدمت 14 بلداً، حتى الآن، لقاحات المكورات الرئوية لديها من خلال المبادرة الارتبادية لإلالتزام بتطوير سوق اللقاحات، ومن المتوقع أن يقوم 39 بلداً آخراً باستخدام اللقاحات قبل نهاية عام 2013. وتصف هذه الورقة العلمية الدروس المبكرة الممكن الاستفادة

摘要

针对肺炎疫苗的预付款采购保证:将理论付诸实践

从公共健康的角度来看, 最低收入国家挽救生命的疫苗市 场常常未能在产品数量、质量、可购性、规划适用性和/或 使用可持续性方面产生最期望得到的结果。发展中国家对 可持续资金需求的风险性和不确定性常常导致相关产品开 发和制造方面投资不足。2009年发起的针对肺炎疫苗的" 预付款采购保证(AMC)"旨在通过根据预先确定的条款 提供具有法律约束力的疫苗预先承付款项以消除市场风 险。迄今为止,已有14个国家通过"预付款采购保证" 引入肺炎疫苗,并且预计另外39个国家将在2013年年底 之前引入该疫苗。

本文描述了早期针对试点"预付款采购保证"选择目标 疾病以及进行核心设计选择方面的经验教训。文章强调了 使"预付款采购保证"设计适应肺炎疫苗特定供应形势所 面临的挑战。表明其难点及"预付款采购保证"的早期成 功在于在不断变化和不可预知的环境中确立长期、可信的 计划。文章还强调了"预付款采购保证"的固有挑战之一 在于依赖持续捐赠资金以确保长期产品购买。本文审查了 替代设计选择, 旨在提供切入点以鼓励有关"预付款采购 保证"在其他领域潜在应用的讨论和辩论。

Résumé

Engagement préalable relatif au marché pour les vaccins contre le pneumocoque: mettre la théorie en pratique

Les marchés des vaccins salvateurs ne génèrent souvent pas les résultats désirés du point de vue de la santé publique, en termes de quantité, de qualité et de fiabilité des produits, mais aussi d'adéquation et/ou de durabilité des programmes pour l'utilisation dans les pays aux plus faibles revenus. Les risques perçus et les incertitudes concernant une demande durablement financée, de la part des pays en voie de développement, conduisent souvent à un sous-investissement dans le développement et la fabrication des produits appropriés. L'initiative pilote Garantie de marché (AMC) pour le vaccin antipneumococcique, lancée en 2009, vise à éliminer certains de ces risques du marché en offrant un engagement préalable, juridiquement contraignant, d'acheter des vaccins selon des conditions prédéfinies. À ce jour, 14 pays ont déjà introduit les vaccins contre le pneumocoque par le biais de l'AMC. Il est prévu que 39 autres pays les introduisent avant la fin de 2013.

Cet article décrit les premières leçons tirées de la sélection d'une maladie cible et des choix du concept de base de l'AMC pilote. Il souligne les défis que suppose l'adaptation du concept d'AMC à la situation spécifique d'approvisionnement des vaccins contre le pneumocoque. Il met en exergue la difficulté – et l'apparent succès initial de l'AMC –

d'établir un engagement crédible à long terme dans un environnement imprévisible, en constante évolution. Il met l'accent sur l'un des défis inhérents de l'AMC: sa dépendance vis-à-vis du financement continu des donateurs pour garantir les achats à long terme de produits. L'article examine les choix de concept alternatifs et vise à fournir un point de départ pour préparer les discussions et encourager le débat sur l'application potentielle du concept AMC à d'autres domaines.

Резюме

Механизм предварительных обязательств по закупкам пневмококковых вакцин: воплотить теорию в практику

На рынках вакцин, спасающих жизнь, не всегда достигаются наиболее желаемые, с точки зрения общественного здоровья, долгосрочные результаты в отношении количества, качества, финансовой доступности, программной пригодности и/ или устойчивости использования препаратов в странах с самым низким доходом. Ощущаемые риски и неуверенность в отношении устойчиво финансируемого спроса со стороны развивающихся стран часто приводят к недостаточному инвестированию в разработку и производство соответствующих препаратов. Пилотная инициатива по авансированным закупкам (Advance Market Commitment, AMC) пневмококковых вакцин, осуществление которой начато в 2009 году, направлена на устранение некоторых из этих рыночных рисков путем предоставления юридически связывающих предварительных обязательств по закупке вакцин в соответствии с заранее установленными условиями. К настоящему времени 14 стран

уже применили пневмококковые вакцины в рамках АМС, а еще 39 стран, как ожидается, применят их до конца 2013 года.

В данной статье формулируются первые выводы, сделанные по результатам выбора целевого заболевания и ключевых характеристик плана пилотной инициативы АМС. В ней освещаются проблемы, возникшие при адаптации плана АМС к конкретным условиям предложения пневмококковых вакцин. Обращается внимание на трудности – и ранний успех, достигнутый благодаря АМС, – при формировании долгосрочных, надежных обязательств в постоянно меняющейся, непредсказуемой среде. Отмечается одна из проблем, присущих АМС: ее зависимость от непрерывного донорского финансирования, позволяющего обеспечить долгосрочные закупки препаратов. Рассматриваются альтернативные варианты плана. Цель статьи - определить тематику дискуссии и стимулировать обсуждение возможностей применения концепции АМС в других областях.

Resumen

Compromiso de mercado avanzado para vacunas neumocócicas: poniendo en práctica la teoría

Los mercados de vacunas que salvan vidas no suelen generar los resultados más deseados desde una perspectiva de salud pública, en términos de cantidad, calidad, viabilidad del producto, así como de idoneidad y/o sostenibilidad programática para su uso en los países con menores ingresos. Es frecuente que los riesgos e incertidumbres percibidos sobre la demanda financiada sostenible de países en desarrollo conlleven a la desinversión en el desarrollo y fabricación de los productos adecuados. La iniciativa piloto Compromiso de mercado anticipado (CAM) para vacunas neumocócicas, que se lanzó en 2009, pretende eliminar algunos de estos riesgos de mercado mediante la creación de un compromiso legalmente vinculante para la compra de vacunas de acuerdo con condiciones predeterminadas. Hasta la fecha, ya son 14 los países que han introducido vacunas neumocócicas a través del CAM y se espera que otros 39 países las introduzcan antes

de finales del 2013.

Este documento describe las lecciones anteriormente aprendidas sobre la selección de una enfermedad objetivo y las elecciones de diseño principales para el CAM piloto. Destaca los retos a los que hay que enfrentarse para adaptar el diseño CAM a la situación de suministro de vacunas neumocócicas específica. Señala la dificultad – y al aparentemente temprano éxito del CAM – de establecer un compromiso creíble, a largo plazo, en un entorno impredecible y constantemente cambiante. Destaca uno de los desafíos inherentes del CAM: su dependencia de la financiación donante continua para asegurar compras de productos a largo plazo. El documento examina las opciones de diseño alternativas y pretende proporcionar un punto inicial para informar las discusiones y promover los debates sobre la aplicación potencial del concepto CAM a otros campos.

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