FOR DECISION

The decision to consider the recommendations of the October IRC after a prioritisation exercise coupled with the new eligibility/graduation policies have adversely affected the Strategic Demand Forecast (SDFs) for pneumococcal vaccines and, consequently the AMC programme in that the target demand of 200 million doses may not be reached.

The Programme and Policy Committee considered strategies for addressing this issue with the PPC recommending to the Board that it:

- Approve grandfathering of the AMC deal to include all currently GAVI eligible countries (2003 definition). These countries will be able to access pneumococcal vaccines through GAVI at the AMC terms and conditions and have access to AMC funding. However, graduated countries will need to completely self finance the vaccine price (tail price) once GAVI support has ended. Also, all countries must have achieved the DTP3 coverage above 70% in order to purchase under the AMC agreements.
- Approve channelling through the GAVI Alliance from the World Bank the AMC funding for purchase of pneumococcal vaccines for India.

It is important to highlight that, while these issues must be addressed, they are only relevant in the context where:

1. GAVI is able to raise sufficient funding to meet country demand and thus ensure maximum utilisation of the AMC funds.
2. India adopts pneumo within the expected timeframe.

Next Steps on the Pneumococcal AMC: Accounting for the New Context

When the AMC was conceived, there were certain prevailing assumptions built into the model. First, the model accounted for all countries that have been eligible for GAVI support since 2003. Second, it assumed applications that were programmatically and financially sound would be approved for funding; in other words, would not have to be vetted through a prioritisation process in a resource constrained environment.

Times have changed. The board decisions of November 2009 with regard to postponement of approval of the most recent Independent Review Committee's recommendations (October 2009) and the newly adopted eligibility/graduation policies have had an impact on the Strategic Demand Forecast for pneumococcal vaccines and, consequently on the AMC programme.

The Programme and Policy Committee along with the Policy and Performance Team within the Secretariat have discussed ways to mitigate these factors and this paper presents recommendations for the Board's consideration. The Audit and Finance Committee was also informed of the PPC's recommendations.

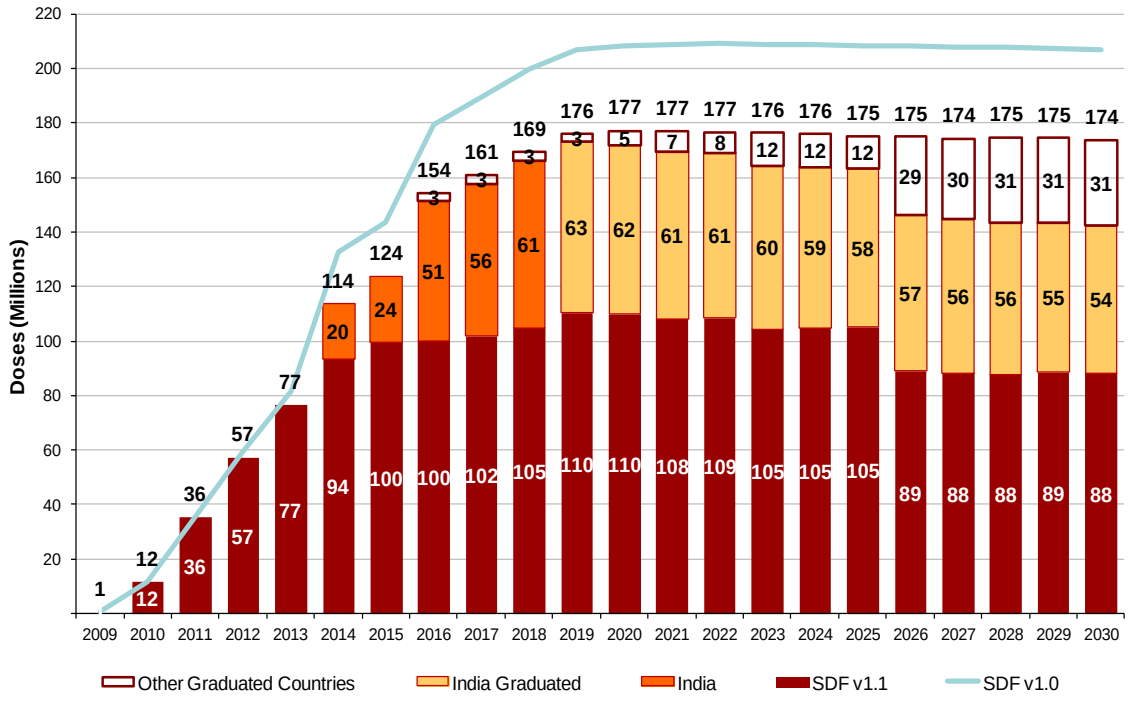
FOR DECISION

Changes in the Pneumococcal Strategic Demand Forecast

Strategic Demand Forecasts (SDFs), which predict country demand 20 years into the future, play a critical role in the implementation of the Pneumococcal AMC. UNICEF executes long-term (10-15 years) supply agreements for procurement of AMC pneumococcal vaccines, based on the strategic demand published by GAVI.

The change in the Pneumo SDF as a result of the November GAVI Board decisions is reflected in Graph 1 below. The new eligibility and graduation policies result in a 17% change in demand from the AMC reference of 200M. The main driver of this change is Nigeria - which is excluded from the revised forecast because the threshold of 70% DPT3 coverage is not reached until after the country has graduated - and India, which has an expected graduation in 2019.[1] Also, as shown in Graph 1 below, if one considers only the demand from countries that remain eligible, demand falls sharply from its peak in 2018 as India graduates.

Graph 1: Impact of Board Decisions on Pneumo SDF



[1] Of note, graduation has limited financial impact because GAVI financing for India ends earlier due to cap by the GAVI Board (see Annex III for more information). From the project start, demand has been captured in the SDF, but self-financing has been spelled out as an assumption for India's adoption.

FOR DECISION

Policy and Financial Implications

Reduction in projected Pneumo SDF and the fall in demand from 2018 present two main challenges for the AMC mechanism:

- New peak demand: The Pneumo AMC was designed to encourage development of 200M doses of production capacity for targeted pneumococcal vaccines. If one considers only the demand from countries that remain GAVI eligible, the new peak demand from GAVI eligible countries is now 166 M (in 2018) and thus the potential of the Pneumo AMC will not be fully exploited. As a consequence, since the allocation of shares of the AMC funds among participating firms is based on a peak demand of 200 million doses, the AMC funds will not be fully used.
- Demand drop: If one considers only the demand from countries that remain eligible, demand falls sharply from its peak in 2018 as India graduates. In view of the long-term nature of the AMC supply contracts, this situation can trigger two scenarios:
    - There is a possibility that suppliers do not offer to enter into agreements to supply in excess of around 110 million doses to avoid a situation of excess supply.[2] As a result, the objective of the Pneumococcal AMC to encourage build up of manufacturing capacity could not be fully exploited.
    - Suppliers do offer to enter into agreements to supply in excess of around 100 million doses, but as demand falls, UNICEF SD has to cut supply in the outer years. In such case, a significant share of the AMC funds (about 30%) would have been disbursed to manufacturers in exchange for a 'short term' rather than a 10-years commitment.

Issues for Decision

The GAVI Secretariat modelled options to help develop scenarios for moving forward. The PPC recommended the option below. This concurs with the views of the AMC stakeholders (UNICEF, World Bank), industry and the AMC donors.

- *Grandfathering of the AMC deal to include all currently GAVI eligible countries (2003 definition).*

According to the latest forecast, starting from 2019, a growing portion of Pneumo demand may potentially come from graduated countries - who have introduced Pneumo vaccines prior to graduating. These countries will lose access to both GAVI funding and GAVI prices as they graduate.

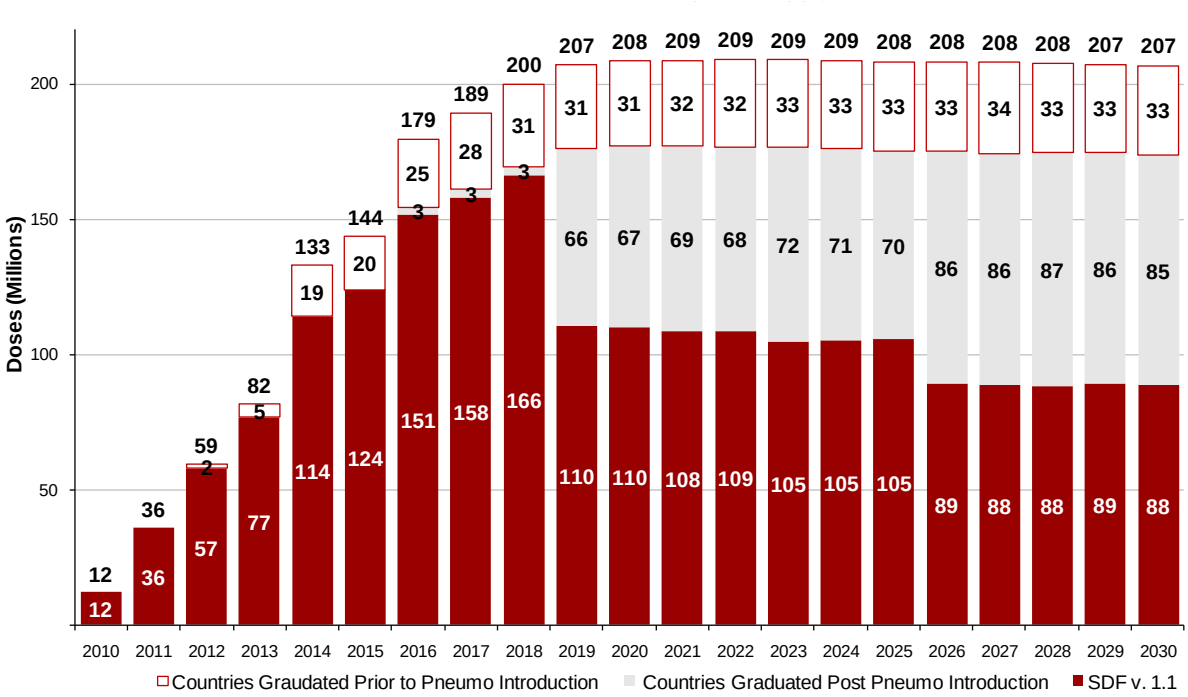
One way to address this issue is to "grandfather" currently GAVI eligible countries (2003 definition) for the AMC deal. These countries would be able to access pneumococcal vaccines through GAVI at the AMC terms and conditions and have access to AMC funding. However, graduated countries will need to completely self

[2] If, for instance, UNICEF enters into a 10 year AMC supply agreement with a manufacturer in 2016 for 50M doses in excess of 100M doses, in 2019 the manufacturer would have excess supply as demand from GAVI eligible countries diminishes as countries lose eligibility.

finance the vaccine price (tail price) once GAVI support has ended. Also, all countries must have achieved the DTP3 coverage above 70% in order to purchase under the AMC agreements.

Demand would take the following shape:

Graph 2



In this scenario, the new eligibility and graduation policies would have no impact on the Pneumo AMC as total required supply would stabilize at approximately 208 M doses (207 to 209 M doses): the AMC potential would be fully exploited, i.e. the AMC could stimulate development of manufacturing capacity to meet the original AMC demand target of 200M doses and the original targeted health impact.

In this scenario, entry into long term supply agreements with industry would not be problematic, as demand would be sustained over time. Therefore, the objective to have new market entrants get a share of the Pneumo vaccine market, i.e. developing new vaccines, could be reached.

It's important to highlight that this option would not have financial implications for GAVI as graduated countries would cover the cost of the vaccine up to $3.50. Also, this scenario would allow full use of AMC funds (assuming GAVI can raise matching funds).

Cost of pneumococcal vaccines introduction: GAVI, AMC and countries

in US$ millions	GAVI	AMC	Country
2010 – 2015	1,389.38	1,029.82	197.71
2010 – 2030	8,102.99	1,500.00	6,228.27

FOR DECISION

GAVI will address this issue in the context of graduation procedures. For AMC purposes, graduated countries could remain 'Eligible', while losing access to GAVI funding (with exception of AMC funds transiting through GAVI).[3]

While recommended this strategy for moving forward, the PPC recognised the following risks with this approach:

- This scenario assumes that graduated countries will be able to self-fund vaccines up to $3.50.
- Graduated countries whose GNI per capita surpasses the GAVI Eligibility threshold of $1,500 would access GAVI prices for pneumococcal vaccines even if they have not introduced these vaccines through GAVI's support. Contextually, countries that were never GAVI eligible and have similar GNI may be paying different prices.
- Anew 'category' of GAVI countries, i.e. 'Countries Eligible for procurement under AMC agreements.' This may be confusing to countries and will require careful communication.

➢ *Approve channelling through the GAVI Alliance from the World Bank the AMC funding for purchase of pneumococcal vaccines for India.*

$135 million is available for Indian use for Pneumo or any other GAVI support. From a legal perspective, any AMC funding used to subsidise doses for India under AMC contracts would reduce funding available to India under its cap. This is because AMC funding flows through GAVI.

Allowing this passing through of AMC funding for the purchase of $7 doses of pneumococcal vaccines for India would allow India to pay a maximum vaccine price of $3.50. Also, AMC funds would be used for their intended purpose.

This would <u>not</u> require an increase in GAVI's core funding for Pneumo (as India would self finance the tail price of vaccines), nor require an increase in AMC funding. Rather, this will ensure AMC funds can be used for their purpose.

Timing

The above mentioned challenges need to be addressed as:

- UNICEF SD's decisions around allocation of supply in future tender rounds are dependent on the above issues.[4]
- Vaccine manufactures need a clear indication on the way forward as soon as possible as product development decisions and manufacturing capacity investments. In particular late market entrants (especially emerging

[3] I.e. countries would pay the price of the vaccine up to the tail price and would benefit of the AMC subsidy during the AMC period. Ability to access the AMC terms could be limited by time or other valuable criteria, e.g. GNI.
[4] Among other procurement objectives, UNICEF SD aims at i) ensuring supply security (i.e. multiple manufacturers, potentially from different countries); ii) encouraging development of new products from late market entrants. Both objectives require allocation of supply among multiple manufacturers. A clear vision of demand evolution over the long term is therefore crucial: UNICEF SD enters into supply agreements to serve demand over a 15-year time horizon (as per Pneumo AMC terms and conditions).

manufacturers), may be influenced by this uncertainty and the likelihood of their participation reduced.

- Some of the already approved countries may graduate while purchasing under currently signed AMC contracts (Congo, Cameroon, Guyana, Honduras).

Consultations

To review potential options for moving forward, an informal AMC stakeholders meeting was organised on 26 March 2010 in The Hague, Netherlands. At this meeting and in follow up via email, the AMC donors and partners provided feedback and a recommendation to the PPC. The PPC concurred with this recommendation.

Subsequently, consultation with industry on the recommended option was initiated and is ongoing as industry consent will be required to procure AMC vaccines to graduated countries.

Financial Contingency and India

It is important to highlight that, while the challenges discussed in this paper must be addressed, they are only relevant in the context where:

- GAVI is able to raise sufficient funding to meet country demand and thus ensure maximum utilisation of AMC funds. The AMC is intended to provide an additional source of funding for vaccine purchase. To this end, AMC funds are designed primarily to cover investment costs, thereby acting as stimulus for vaccine development and capacity scale-up. The vaccine purchasers (GAVI and GAVI-eligible countries) will need to continue their functions as buyers of the final product at manufacturing cost. The success of the AMC is intricately tied to the ability of GAVI to secure significant additional funding towards the GAVI 2.6 billion additional funding challenge (of which pneumo represents $ 1 billion).

  At present, GAVI has sufficient funding only to cover its approved and endorsed commitments as well as any required extension up to 2015. GAVI thus needs to continue to raise funds for the purchase of AMC pneumococcal vaccines to meet expected demand over the period 2010-2015. This challenge was highlighted in the March 2010 High Level Meeting on Financing Country Demand and is now under consideration by donor countries. The pneumo funding gap amounts to approximately $ 1 billion. If these funds are not raised, country demand will not be met, the majority of the AMC potential will not be exploited and the AMC funds would lie unutilized at the IBRD (AMC funds are contingent to GAVI funds being raised).

  There is a strong case for donors to ensure GAVI's financial ability to roll out pneumococcal vaccine as planned, especially given the innovative nature of the AMC, and the tremendous potential of the pneumococcal vaccine.

- India adopts pneumo within the expected timeframe. India represents approximately 1/3 of the demand for pneumo vaccines. Should India not

adopt, the AMC could not be used to its full potential and a material proportion of the AMC funds would lie unutilized at the IBRD. In this case, the use of AMC funds would have to be re-thought. GAVI and AVI are working closely with India on new vaccine introduction and routinely updating demand forecasts to reflect the best available information.

Conclusions

On the recommendation of the Programme and Policy Committee and after informing the Audit and Finance Committee, the Board is requested to:

- Approve grandfathering of the Pneumo AMC deal to include all currently GAVI eligible countries (2003 definition). These countries will be able to access pneumococcal vaccines through GAVI at the AMC terms and conditions and have access to AMC funding. However, graduated countries will need to completely self finance the vaccine price (tail price) once GAVI support has ended. Also, all countries must have achieved the DTP3 coverage above 70% in order to purchase under the AMC agreements.

- Approve channelling through the GAVI Alliance from the World Bank the AMC funding for purchase of pneumococcal vaccines for India.

Next Steps

If the Board approves grandfathering of the AMC, implementation will proceed on this basis. Written consent from GSK and Pfizer, already signatories of AMC Supply Agreement will be requested from UNICEF Supply Division prior to shipment of these companies' vaccines to graduated countries.

Annex I: Summary of all options explored

Options	Brief Explanation	Benfits	Risks
Graduated countries - which have introduced Pneumo prior to graduating - can procure under AMC supply agreements and have access to AMC funding	One way to address this issue is to allow those countries which will have introduced Pneumo prior to graduation (including India) to procure under the AMC contracts, at the AMC prices: self-funding vaccines up to the tail price and, as necessary, accessing the AMC subsidy during the AMC period.	In this scenario, we can expect a total required supply to stabilize at approximately 175m doses (174-177 M doses), i.e. only about 12% less than the 200M doses target. AMC potential almost fully exploited. AMC funds almost fully spent. No issues with long term supply contracting. In line with GAVI policies.	Need to consider risks to tiered pricing concept. Potential negative impact on industry as established 200M doses target is not reached. Different treatment of countries graduating after introduction of pnuemo through GAVI and countries graduation prior to introduction of Pneumo.
All currently GAVI Eligible Countries (72) can procure under AMC supply agreements and have access to AMC funding	This option is the same as option 1 except that it would allow access to procurement under the AMC contracts (at AMC terms) and access to AMC funding for $7 doses to all currently GAVI Eligible countries (72), whether they access Pneumo vaccines through the AMC or not prior to their graduation.	In this scenario total required supply would stabilize at approximately 208 M doses (207=209 M doses), i.e. the AMC demand target of 200M doses could be reached (and surpassed). AMC potential fully exploited. AMC funds almost spent. No issues with long term supply contracting. Equal treatment of countries graduating after introduction of pnuemo through GAVI and countries graduation prior to introduction of Pneumo. More deaths averted.	Concept of tiered pricing even more at risk. Not in line with GAVI current policies. Need to create AMC specific procedures for countries graduating prior to introducing Pneumo.
Post-graduation financial support from GAVI & Access to AMC Terms and Funding	This option entails post graduation financial support from GAVI to assist countries to self-fund Pneumo vaccines at a tail price of $3.50 after multi-year financial support is concluded. It also allows access to procurement under the AMC contracts (at AMC terms) and access to AMC funding for $7 doses to GAVI countries which graduate after having introduced Pneumo.	Would enhance the possibility for graduated countries to sustain introduction. As India's support from GAVI is capped, post graduation support would only benefit 18 other countries who introduce Pneumo prior to graduating. These countries account for 3 doses yearly from 2016-2019, 5-12 M doses yearly from 2020-2025, 29-31 M doses yearly from 2026-2030.	Potentially complex for countries if not applied to the entire GAVI portfolio
Future commitments to eligible countries run for 10 years for AMC purposes & Access to AMC Terms and Funding	Once a country is approved for Pneumo introduction, continuity in financial support from GAVI would be granted for a period of 10 years rather than 5 years. It also allows access to procurement under the AMC contracts (at AMC terms) and access to AMC funding for $7 doses to GAVI countries which graduate after having introduced Pneumo.	This option would enhance the sustainability of the programs of immunization for Pneumo in countries adopting with GAVI support and then graduating. As GAVI's support to India is capped, this additional support would benefit the 18 other graduated countries accounting for 3 M doses yearly from 2016-2019, 5-12 M doses yearly from 2020-2025, 29-31 M doses yearly from 2026-2030.	Potentially complex for countries as they would be entitled to receive long term/10 years funding for pneumococcal vaccines while only 5 years funding for other vaccines. May create long term restriction affecting other potential investments
New GAVI eligibility and graduation policies do not apply to the Pneumo AMC programme	This option excludes the Pneumo AMC from the new GAVI eligibility and graduation policies.	The AMC is a long term forward commitment that has created expectations to industry, both through long term demand forecasts and through the AMC terms, of a sustainable demand that would stabilize around 200M doses. Allowing the exclusion of the Pneumo AMC from the application of GAVI's new Eligibility and Graduation policies will partially allow addressing the issue of reduced long term demand for a total of 28 countries (10 who would not introduce Pneumo prior to graduation; 18 who would introduce Pneumo prior to graduating), accounting for 19-33 M doses yearly from 2016-2019, 36-45 M doses yearly from 2020-2025, about 62-64 M doses yearly from 2026-2030.	Excluding Pneumo from the application of the new eligibility and graduation policies would not be in line with GAVI Board policy. In addition, this option risks creating confusion at country level as countries would graduate for all GAVI support other than Pneumo.