



# **An Advance Market Commitment for new vaccines**

## **The Pneumococcal Pilot**

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GAVI Alliance

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UNICEF Supply Division  
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## Objectives of the presentation

- AMC Concept & the pneumo pilot
- Terms of the deal in detail
- Progress to date



Source: UNICEF

## What is an AMC?

- An AMC creates **market conditions to stimulate private investment** in vaccine R&D and manufacturing capacity for future vaccines.
- An AMC requires donors to make **legally binding financial commitments** to support a market of a pre-agreed value.
- **Companies** participating in an AMC agreement **commit to supply** a successful vaccine at a long term price below a pre-set cap (tail price cap).

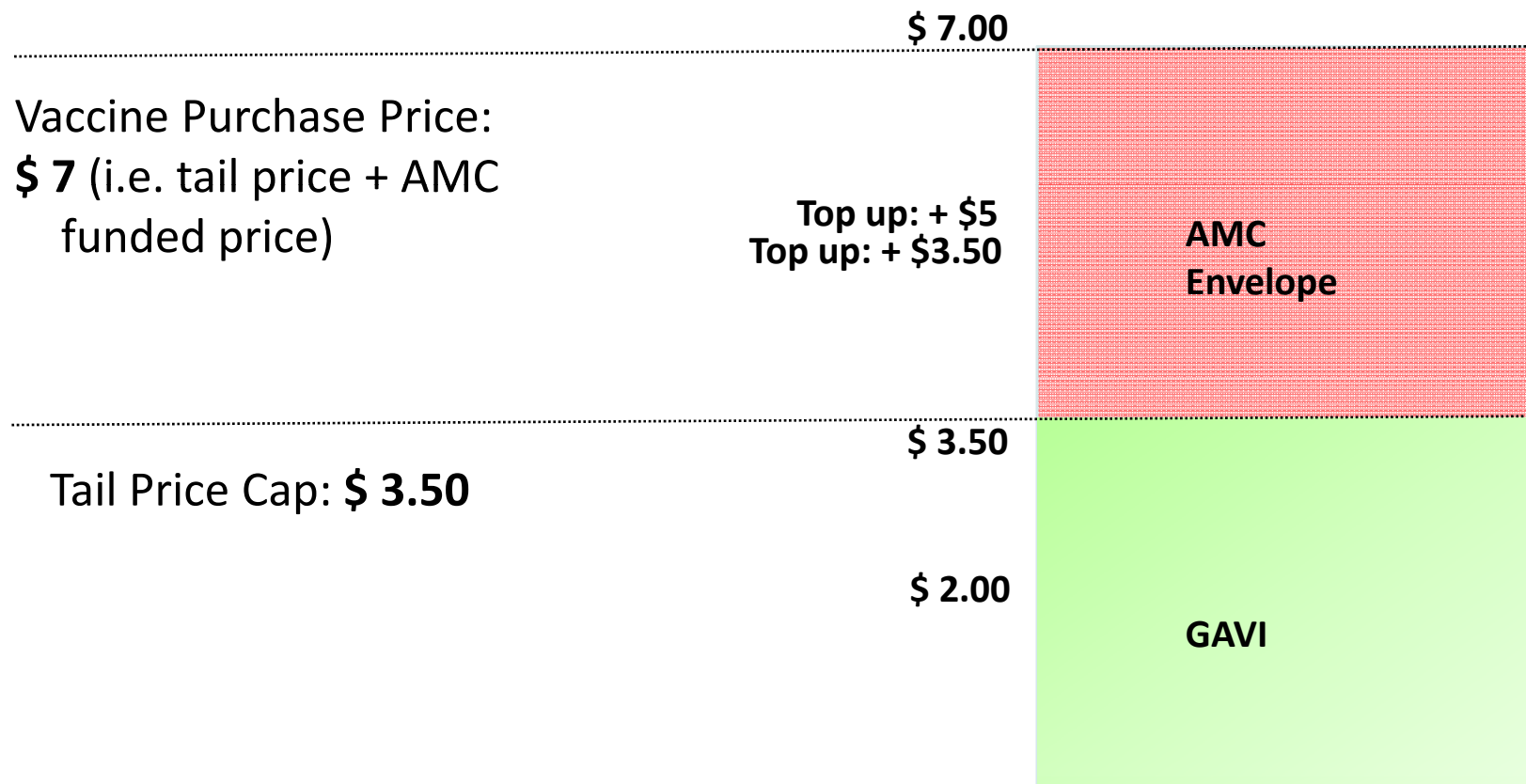
## What is an AMC? (cont.)

- An independent assessment committee (**IAC**) determines whether the vaccine meets pre-specified criteria (**TPP**).
- Then, **as long as there is effective demand** from developing countries, the company can receive the funds from the AMC as a **top up** to the long term price (AMC funded price).
- Once the AMC is exhausted, **companies** are required to **ensure the supply** of the vaccine at the lower long term price.

## Pneumo pilot

- Vaccine: pneumococcal vaccine – Technical Product Profile ([TPP](http://www.who.int/immunization/sage/target_product_profile.pdf)) - [http://www.who.int/immunization/sage/target\\_product\\_profile.pdf](http://www.who.int/immunization/sage/target_product_profile.pdf)
- Financial commitment: **\$ 1.5 billion** from Italy, UK, Canada, Norway, Russia, Bill & Melinda Gates Foundation
- Tail price cap: **\$ 3.50**
- Vaccine purchase price: **\$ 7** (i.e. tail price + AMC funded price)
- Demand forecast: reaches **200M doses** in 2020
- Stakeholders: AMC Donor Committee, GAVI, GAVI-eligible countries, suppliers, UNICEF, World Bank, WHO.

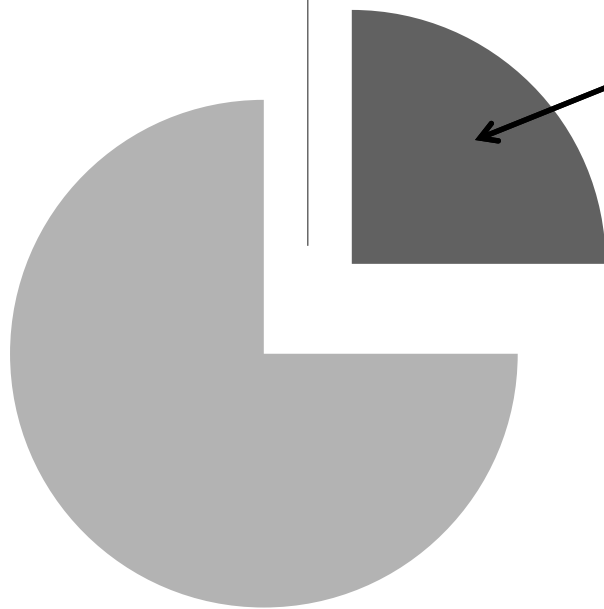
## Terms in detail: 1 - AMC Price



## 2 - Supply Commitments

10-year supply commitments by industry to build adequate capacity for GAVI countries

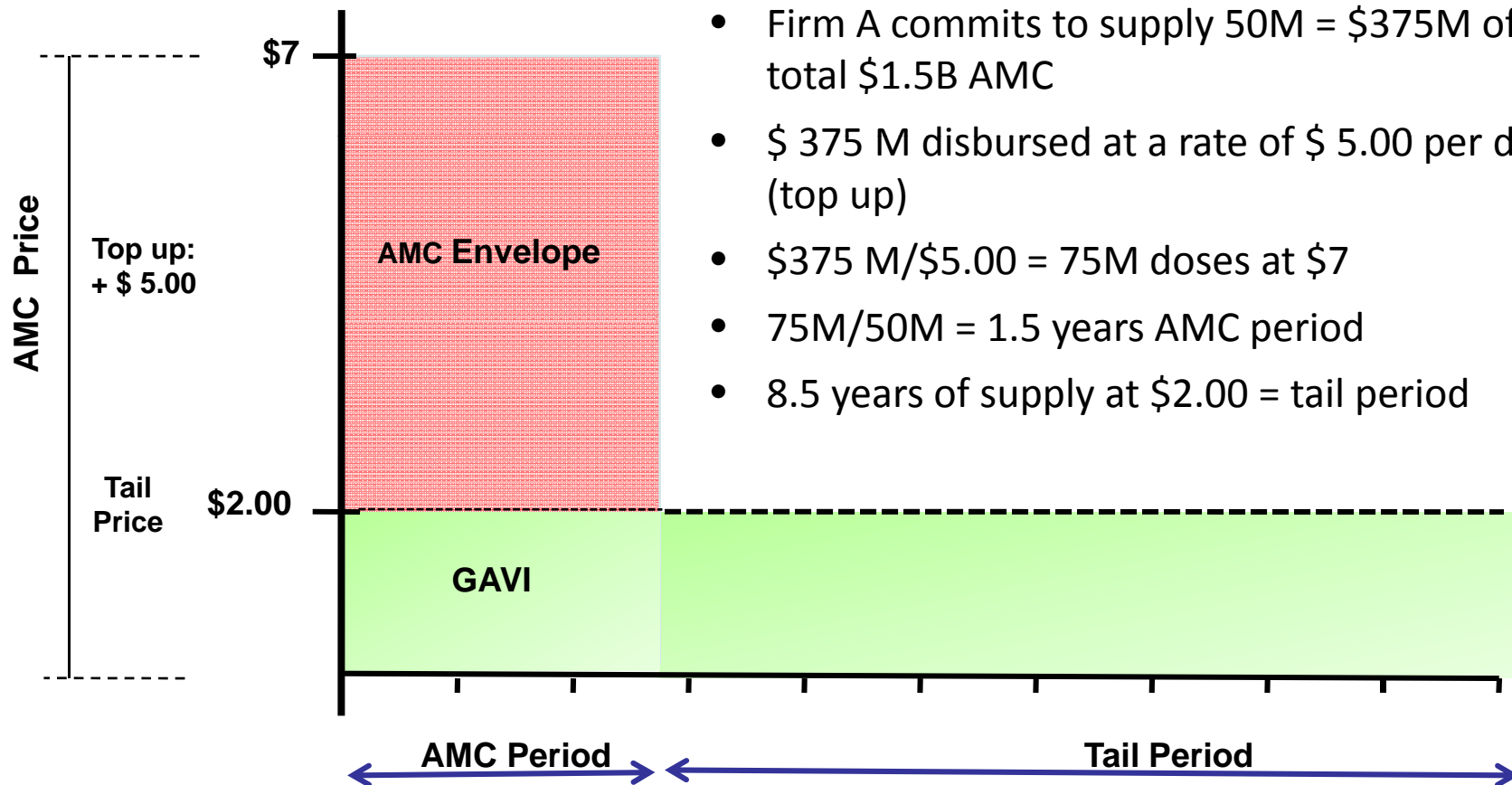
**AMC Envelope of \$1.5 B**  
**200 M annual doses**



Firm A commits to supply 50M doses per year or 25% of the total (200M) doses = \$375M of the total \$1.5B AMC

- Primary benefit: aligns AMC resources directly with desired AMC outcome
- Each supplier will have its pro rata share – improvement of sequential tendering

# Example



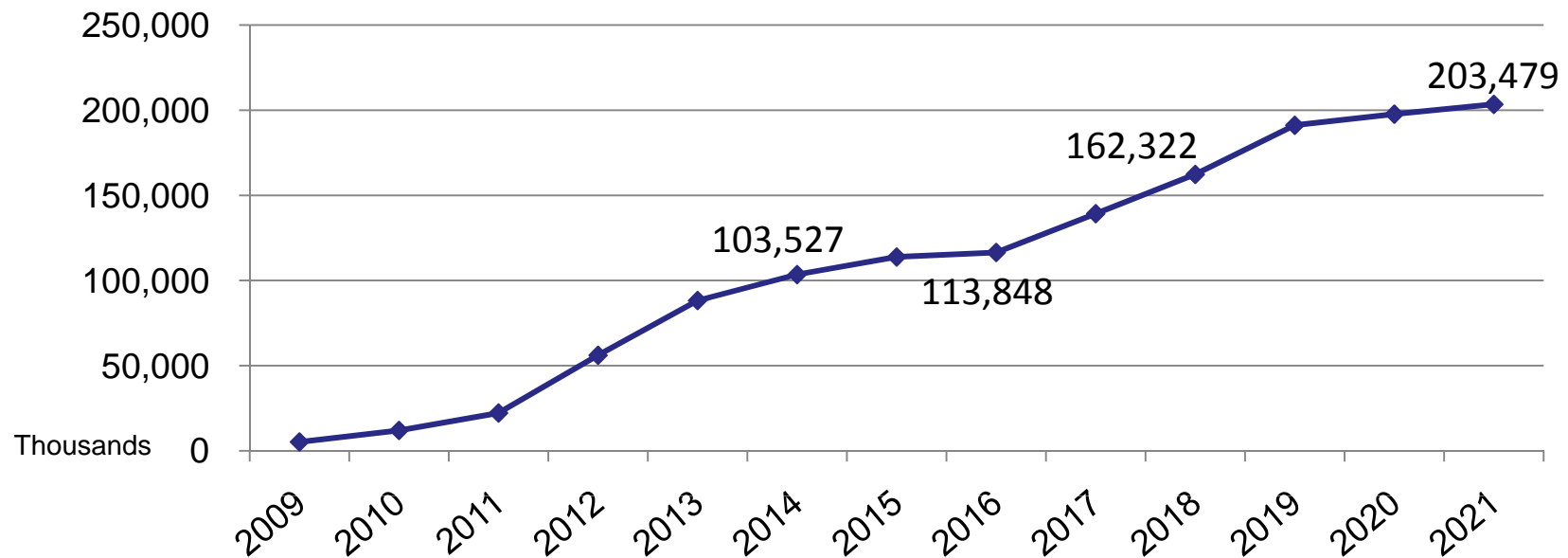
Example:

- Firm A commits to supply 50M = \$375M of the total \$1.5B AMC
- \$ 375 M disbursed at a rate of \$ 5.00 per dose (top up)
- $\$375 \text{ M} / \$5.00 = 75\text{M}$  doses at \$7
- $75\text{M} / 50\text{M} = 1.5$  years AMC period
- 8.5 years of supply at \$2.00 = tail period

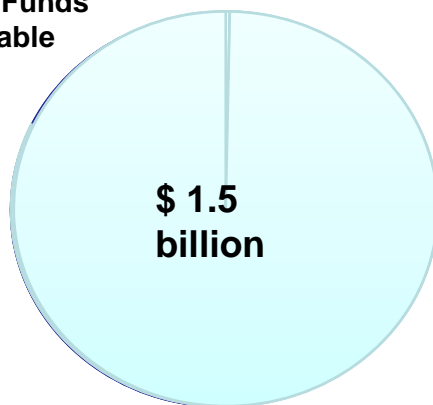
## 3 - Matching capacity to demand

- The entire \$1.5 billion aggregate AMC contribution is on offer at the launch of the pneumo-AMC
- Bids must have an estimated start date no more than 5 years into the future (meanwhile suppliers can sell existing manufacturing headroom)
- The bid cannot be higher than the forecasted demand for the start date
- Once projected demand for a given year is met, commitments would no longer be accepted for that year

## Example



AMC Funds Available



Example:

- Firm A makes a bid in 2009 for the 100M doses = \$750M of the total \$1.5B AMC
- In 2013 Firm A makes a bid for an additional 60 M doses = +\$ 450 M
- In 2015 Firm B makes a bid for an additional 40 M doses = \$ 300 M

## 4 - Mitigate risk for companies

Two incentives will help ensure dedicated capacity

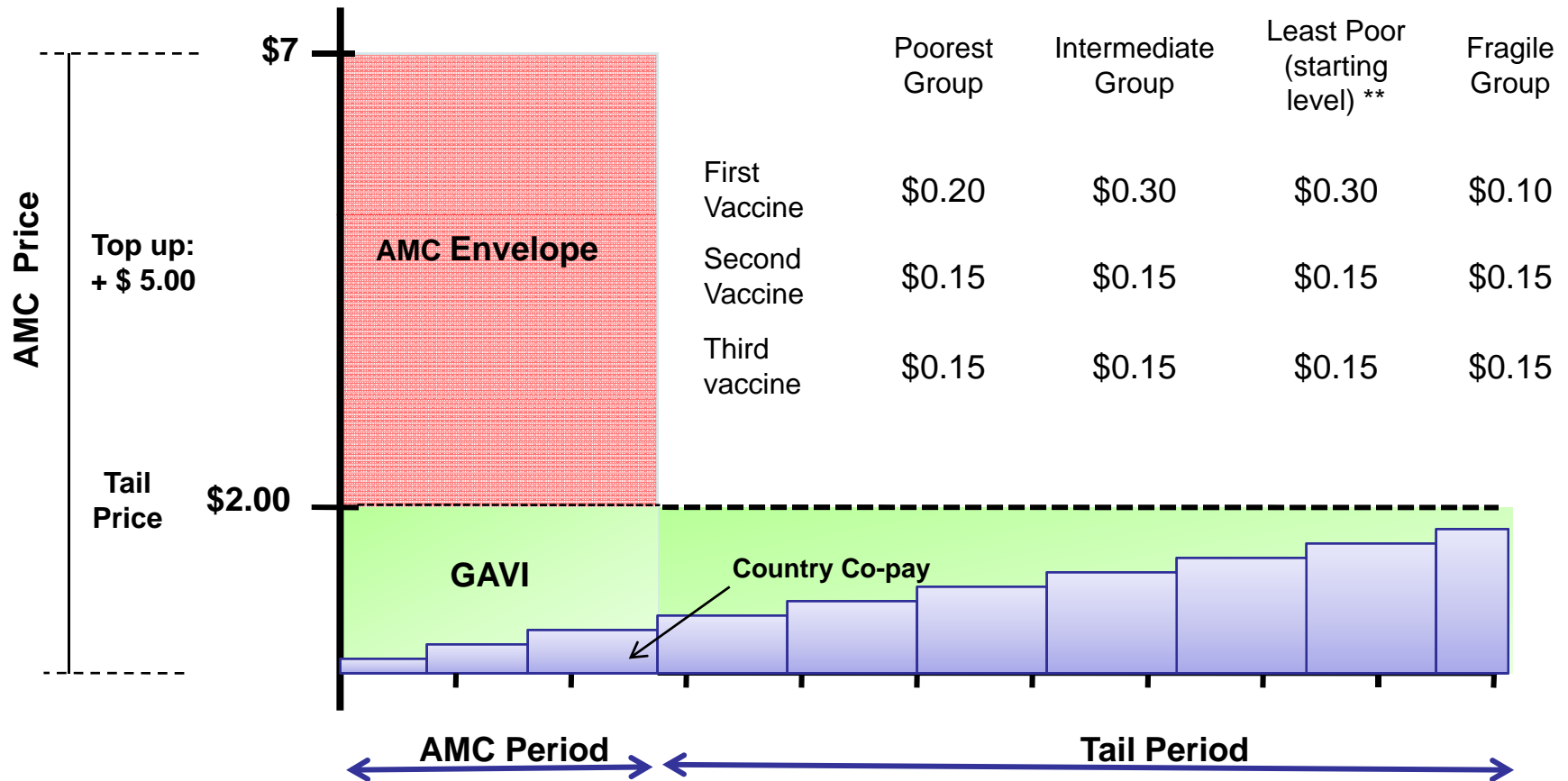
1. Frontloading by making initial “AMC price” sufficiently high
2. Provide limited demand assurance (firm order timing) :

At the time of signature of the supply agreement, the AMC donors & GAVI will make a legally binding commitment to buy 20, 15 and 10 % of the supplier’s dedicated capacity in years 1, 2 & 3, respectively

## 5- Integrate AMC with GAVI procedures

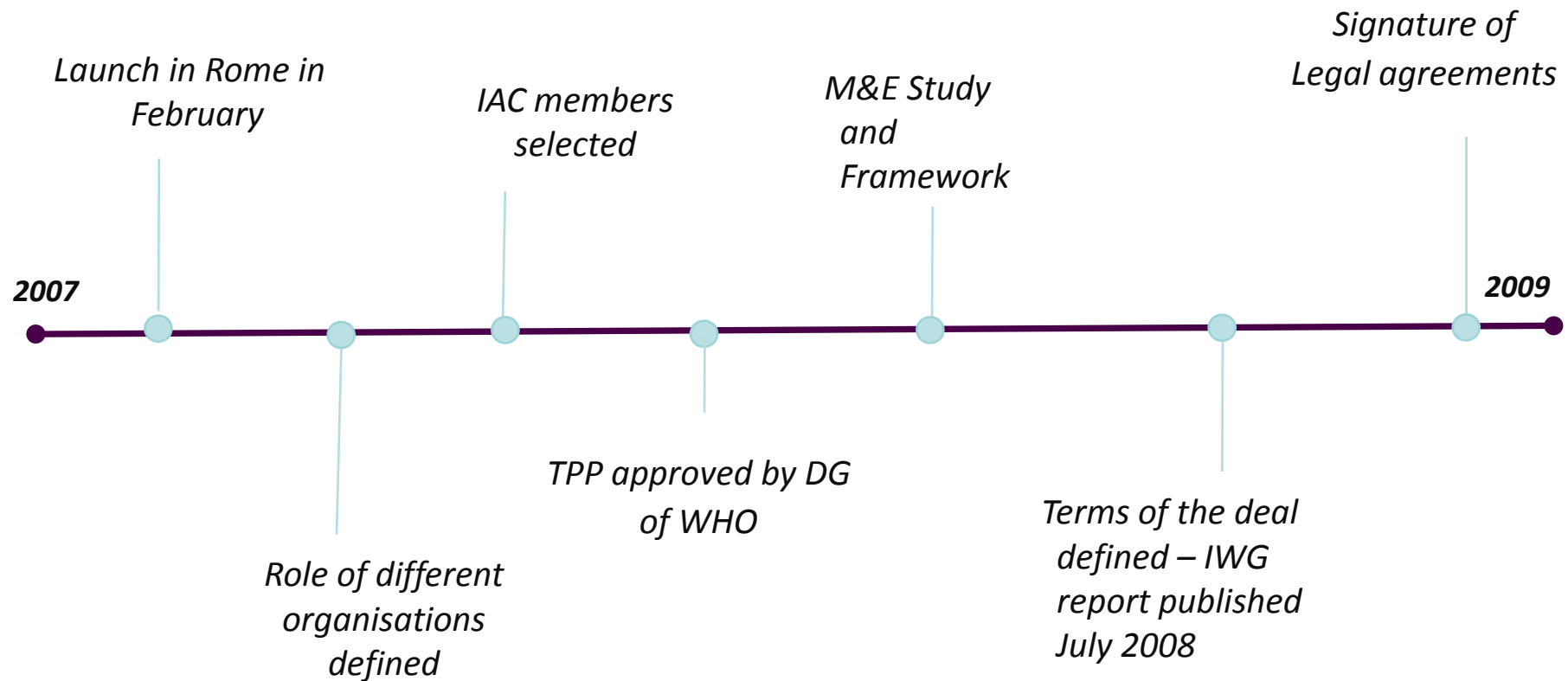
- Pneumococcal vaccine introduction and delivery systems aligned with other GAVI support
  
- Example: using existing co-financing mechanism provides predictability for countries
  - Recognition of differing ability to pay
  - Follow GAVI default policy

# Example: GAVI co-financing policy



\*\* Will be requested to increase payment 15% annually

## Progress to date



**Thank you!**



Source: GAVI

# Target Product Profile

Attribute	Minimally Acceptable Profile
Vaccines serotypes	<ul style="list-style-type: none"> <li>• Must cover at least <b>60% of invasive disease isolates in target region</b></li> <li>• <b>Must include 1,5,14</b></li> </ul>
Immunogenicity	In accordance with WHO criteria: non inferiority to a licensed pneumo vaccine
Target population	Prevent disease among children < 5, in particular < 2
Safety, reactogenicity	Similar to currently licensed vaccine
Dosage and schedule	Compatible with national infant immunisation programmes and no more than 3 doses in first year of life
Interference	No significant interaction or interference with currently administered vaccines
Routes of administration	Intramuscular or subcutaneous
Product presentation	<b>Mono-dose or low multi-dose</b>
Product formulation	<b>Liquid formulation</b>
Storage and cold chain	Stable at 2-8 ° C with shelf life of at least 24 months
Packaging and labelling	In accordance with WHO recommendations
Product registration and pre-qualification	<b>WHO pre-qualified</b>
Post marketing surveillance	In accordance with national regulatory authorities and WHO prequalification requirements

# Legal structure

