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A White Paper To Understand The Market Structure Of Pediatric Pertussis Combination Vaccines

January 2023

A White Paper To Understand The Market Structure Of Pediatric Pertussis Combination Vaccines Landscape (2021)

Executive Summary

The objective of the present study is to understand utilization trends for acellular Pertussis (aP) based pediatric combination vaccines and to identify the market structure (volumes administered by vaccine brand) among pediatric pertussis combination vaccines. Pertussis combination vaccines include DTaP-based primary series, and preschool booster vaccines covering hexavalent, pentavalent, and tetravalent vaccines.

The research methodology includes four steps

Step-I — Finding public and private markets for the target vaccine

Step-II — Market sizing calculation of vaccine volumes for all the available public and private markets

Step-III— Filtering the countries that constitute top 95% of the vaccine market

Step-IV — Analyzing brand shares for top vaccine markets (filtered in Step-III), to find the brand leader.

Outcomes Of the Study

Sanofi was the global market leader among aP-based pediatric combination vaccines with a 74.7% share of the DTaP combination vaccines market, in 2021. Sanofi vaccine brands hold the market leader position among, hexavalent, pentavalent, and preschool booster vaccines. GSK holds the second position with 21.6% share of the market in 2021.

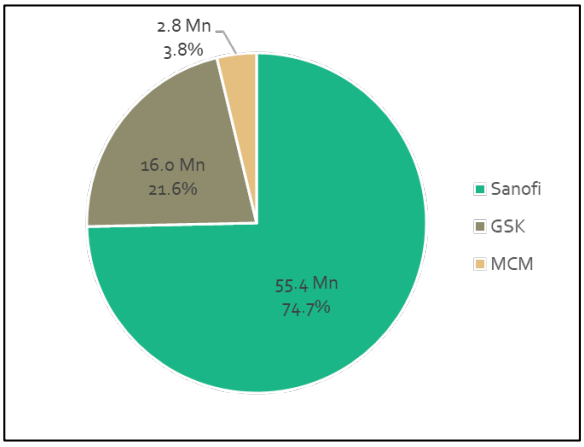

Fig 1: Global DTaP vaccines market share by manufacturer, 2021

Company	Brand Names	Brand Volume (Mn Doses)
Sanofi	Hexaxim®, Pentaxim®, Pentacel®, Pediacel®, Tetraxim®, Quadracel®, Daptacel®	55.4
GSK	Infanrix Hexa®, Infanrix Penta®, Pediarix®, Infanrix-IPV®/Kinrix®	16.0
MCM	Vaxelis®	2.8

Table 1: Global DTaP vaccines brands, volumes, by manufacturer, 2021

According to our estimates of DTaP vaccine volumes for 2021, Hexaxim® (Hexavalent vaccine), Pentaxim® (Pentavalent Vaccine), and Tetraxim® (preschool booster vaccine) hold the leading position among the hexavalent vaccines, pentavalent vaccines, and preschool booster vaccine market respectively across the globe, thus proving the dominance of Sanofi brands across aP based vaccines.

DTP Vaccine Split

As part of the study, we estimated the total market for the DTP vaccines to be around 413.3 Mn doses in 2021.The proportions of aP and wP combination vaccines for infant, toddler, and preschool booster vaccination is mentioned in the figure below (Figure 2). The wP vaccines include the primary and booster series included in the National Immunization Schedule of 119 countries from the WHO. The aP vaccines are further classified into hexavalent, pentavalent, other aP combo vaccines and copurified vaccines. Other aP combo vaccines include trivalent and tetravalent primary and booster series vaccines. The copurified vaccines marketed exclusively in China and Japan are excluded from this study.

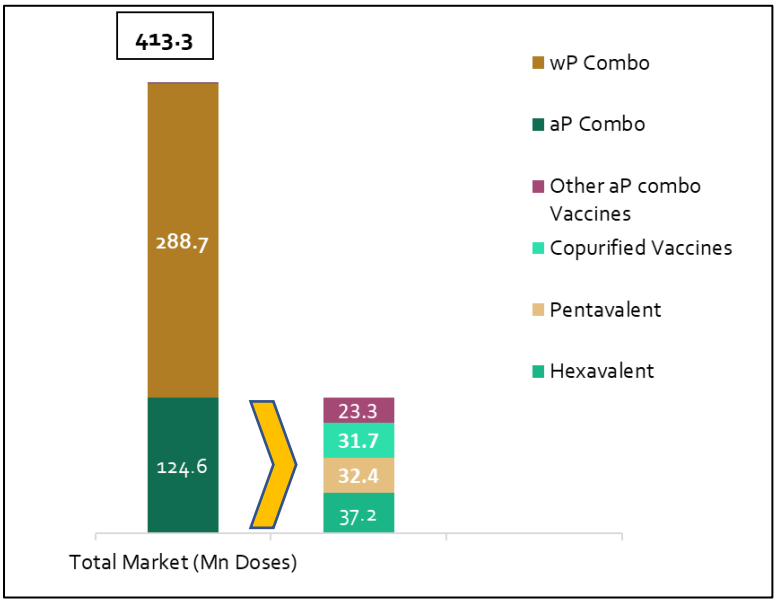

Fig 2: Global DTP vaccine split, 2021

Hexavalent Market Outcomes

In 2021, Hexaxim®, the hexavalent vaccine from Sanofi, holds the leading position in the hexavalent vaccines market with 68% of the volumes used across the globe.

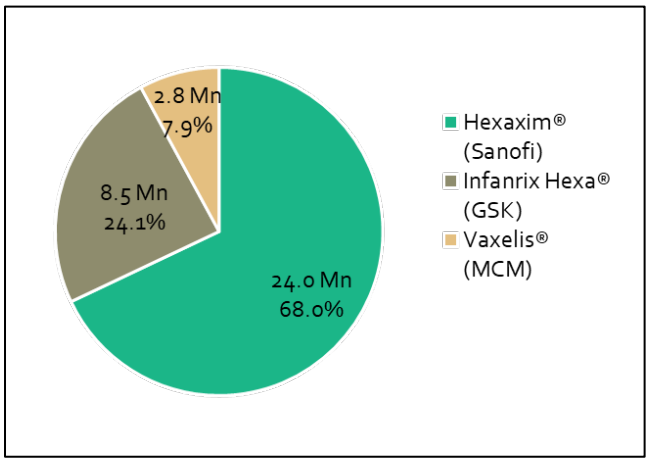

Fig 3: Global hexavalent vaccines volume, market share by manufacturer, 2021

In 2021, in the global hexavalent vaccine market, Sanofi's Hexaxim® brands contributed to a total volume of 24 Mn doses followed by GSK's Infanrix Hexa® brand to 8.5 Mn doses and MCM's Vaxelis® brand to 2.8 Mn doses.

A total number of 101 countries in the hexavalent vaccine market constitute a volume of 37.2 Mn. The top 95% (approximately) of the hexavalent vaccines constituting 41 countries have a total volume of 35.3 Mn.

The European Region (EUR) accounted for 37.1% share of the hexavalent market followed by the American Region (AMR) with a 24.1% share of the market. Among the top 41 countries, Mexico ranks number one in usage by volume in 2021 with 6.2 Mn doses followed by South Africa and Germany with 4.2 and 2.1 Mn doses, respectively.

Among the top 41 countries, 12 countries namely Mexico, South Africa, Chile, Kazakhstan, Jordan, Belgium, Sweden, Libya, Austria, Panama, Oman, and Georgia have an exclusive usage of only Hexaxim® in their market, and 11 more countries namely Germany, France, Malaysia, Saudi Arabia, Romania, Poland, Indonesia, Czech Republic, Brazil, Slovakia and Ukarine use Hexaxim® as the major brand of hexavalent vaccine.

Pentavalent Market Outcomes

In the pentavalent vaccines market, Pentaxim® and Pentacel®, from Sanofi, hold the first and second positions with 60.8%, and 20.6% respectively of the pentavalent vaccine volumes used across the globe.

The manufacturer's share of the global pentavalent vaccine volumes for 2021 is represented in below figure 4.

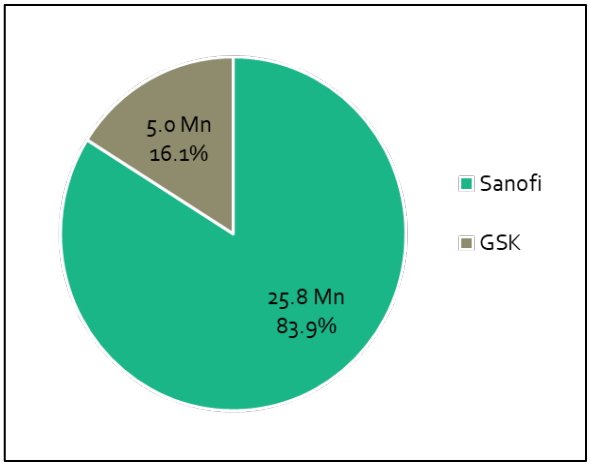

Fig 4: Global pentavalent vaccines volume, market share by manufacturer, 2021

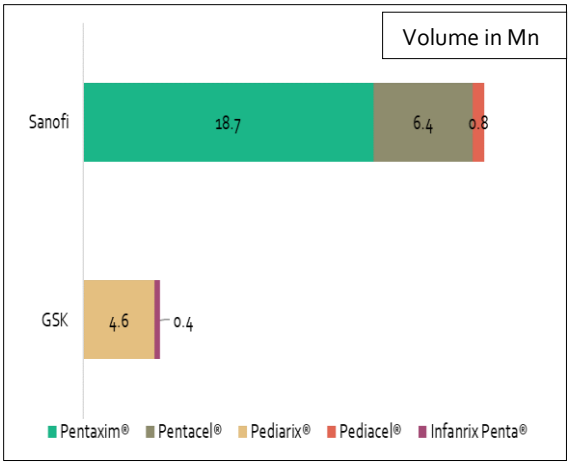

Fig 5: Global pentavalent vaccines brand volumes, by manufacturer, 2021

In 2021, in the global pentavalent vaccine market, Sanofi's brands of vaccines namely Pentaxim®, Pentacel®, and Pediacel®, contributed to a total volume of 18.7 Mn, 6.4 Mn, and 0.8 Mn doses respectively, followed by GSK's brands Pediarix® and Infanrix Penta®, contributed to 4.6 Mn and 0.4 Mn doses respectively.

In the pentavalent vaccine market, a total of 55 countries account for a volume of 32.4 Mn doses. The top 95% (approximately) of the pentavalent vaccines constituting 16 countries have a total volume of 30.8 Mn.

The AMR accounted for 38.9% of the pentavalent vaccine market followed by the EUR with a 37% share of the market. Among the top 16 countries, the USA ranks number one in usage by volume in 2021 with 11 Mn doses followed by China and Turkey with 5.2 and 5 Mn doses, respectively.

Among the top 16 countries, 10 countries namely China, Turkey, Russian Federation, Kazakhstan, Israel, Taiwan, Hungary, India, Serbia and Costa Rica have and exclusive usage of only Pentaxim® in their market, and four more countries namely Republic of Korea, Poland, Vietnam and Thailand use Pentaxim® as the major brand of pentavalent vaccine.

Preschool Booster Market Outcomes

In the preschool booster market, Tetraxim®, from Sanofi holds a leading position with 31% of the preschool booster volumes used across the globe.

In the preschool booster DTaP combination vaccines market, Tetraxim®, from Sanofi holds a leading position with 51.9% of the preschool booster volumes used across the globe.

The manufacturer's share of the global DTaP preschool booster vaccine volumes for 2021 is represented below in figure 6.

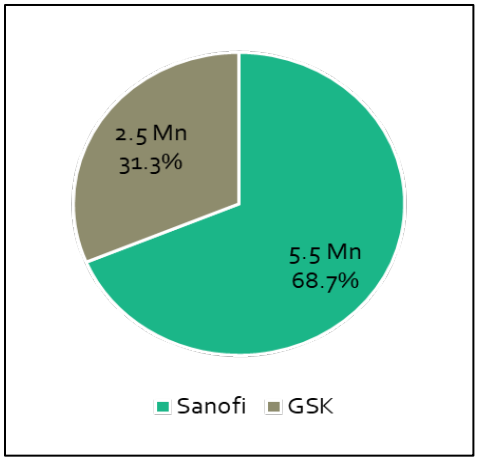

Fig 6: Global DTaP preschool booster vaccines volume, market share by manufacturer, 2021

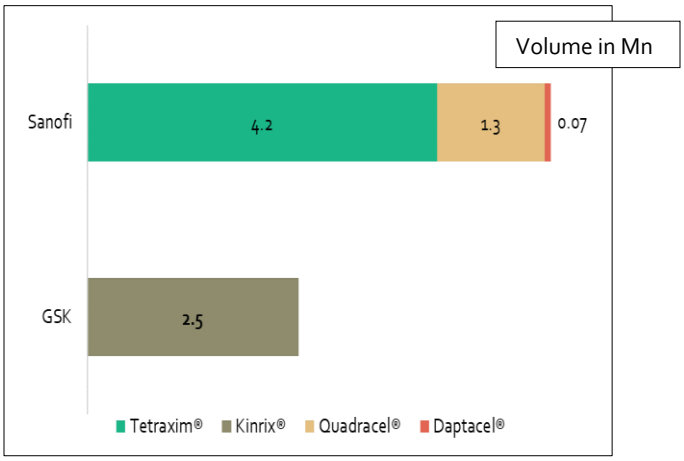

Fig 7: Global DTaP preschool booster vaccines brand volumes, by manufacturer, 2021

In 2021, in the global preschool booster DTaP combination vaccines market, Sanofi's brands of vaccines namely Tetraxim®, Quadracel®, and Daptacel®, contributed to a total volume of 4.2 Mn, 1.3 Mn, and 0.07 Mn doses, respectively followed by GSK's brands Infanrix -IPV/Kinrix®, which contributed to 2.5 Mn doses.

In 2021, according to our estimates, the total aP-based preschool vaccine volumes, including DTaP-IPV, DTaP, Tdap-IPV, and Tdap account for 13.5 Mn doses in which DTaP preschool booster vaccines volume contribute 8.0 Mn doses.

A total number of 92 countries in the preschool booster vaccine market constitute a volume of 14.1 Mn. The top 95% (approximately) of the preschool booster vaccines occur in 40 countries, having a total volume of 13.5 Mn.

The EUR accounted for 47.5% of the preschool booster vaccine volume followed by the AMR which accounted for 35.4% of the preschool booster vaccine volume. Among the top 40 countries, the USA ranks number one by volume in 2021 with 3.3 Mn doses, followed by Turkey and Germany with 1.4 and 0.7 Mn doses, respectively.

Among the top 40 countries, 11 countries namely Turkey, Poland, Romania, Belgium, Sweden, Hungary, Portugal, United Arab Emirates, Norway, Costa Rica and Ireland have an exclusive usage of Tetraxim® in their market, and five more countries namely France, Italy, Republic of Korea, Switzerland and Guatemala use Tetraxim® as the major brand of preschool booster vaccine.

Research Methodology

The study is based on the worldwide demand/usage estimates for aP combination vaccines (both primary series & preschool booster series). The copurified acellular pertussis vaccines marketed exclusively in China and Japan are excluded from this study. Three factors determine the potential size of the worldwide acellular pertussis (aP) combination vaccine market — the surviving infant population (as well as the three to seven years average target population for preschool booster vaccine), the immunization rate, and the number of doses of vaccine administered as per the recommended schedule.

The research methodology includes four steps as enumerated below

Step I — Finding public and private markets for the target vaccine

A total of 195 countries were selected (194 from WHO data + Taiwan), and public and private markets for vaccines were identified based on the inclusion of the aP-based combination vaccine in the government supply and the national immunization schedule of the country. The countries with an aP-based combination vaccine in their national immunization schedule were designated as public markets.

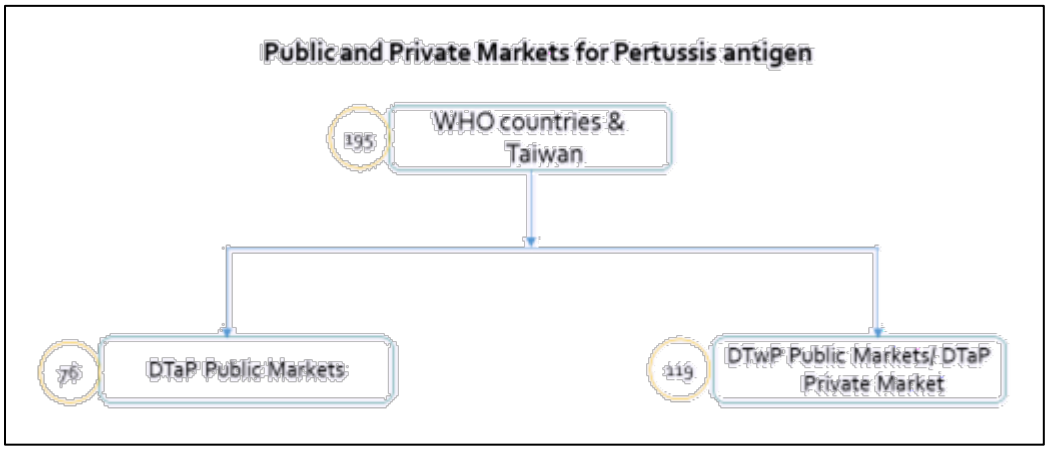

Fig 8: Public and Private markets for Pertussis antigen vaccines

Among these 195 countries, 76 countries having aP-based antigen were designated as public markets, and 119 countries using wP antigen were designated as aP private markets.

Public markets for hexavalent, pentavalent, and preschool booster vaccines were identified from the 76 public markets using aP combination vaccines.

Private markets for all three combination vaccines were calculated from 195 WHO countries + Taiwan by eliminating countries based on their income category, region, and filtering criteria specific to the individual vaccine market.

Step II — Market sizing calculation of vaccine volumes for all the available public and private markets

The volumes of the acellular pertussis combination vaccines were calculated for each of the hexavalent, pentavalent, and preschool booster markets by using three parameters — the surviving infant population (as well as the three to seven years average target population for preschool booster vaccine), the immunization rate, and the number of doses of vaccine administered as per the recommended schedule.

Step III— Filtering the countries that constitute the top 95% (approximately) of the vaccine market

The countries that constitute 95% of the market for each hexavalent, pentavalent, and preschool booster market were considered for further vaccine brand utilization analysis. The rationale for this filtering is that deducing the share of each brand of vaccine across all target countries (100%) is challenging, and hence we considered the statistically valid coverage of 95% of the market. Further, we assume that the brand that is dominant in 95% of the market will be a market leader.

The table below enumerates the total number of countries, their market size in million doses, and the number of countries constituting 95% of each market, for hexavalent, pentavalent, and preschool booster markets.

Market	Total Countries	Total Volume (Mn)	Top 95% Market Countries	Top 95% Volume (Mn)
Hexavalent	101	37.2	41	35.3
Pentavalent	55	32.4	16	30.8
Preschool Booster	92	14.1	40	13.5

Table 2: Global hexavalent, pentavalent, and preschool booster vaccine volume, 2021

Step IV — Analyzing brand shares for top vaccine markets (filtered in Step III), to find the dominant brand markets

Brand analysis was done for those countries that constitute the top 95% of the volumes for each market.

For the countries constituting the top 95% of each market brand analysis was done. The usage patterns for each brand of vaccines across the target countries are obtained through information gathered from various sources as below-

- National and Regional Tenders
- Ministry Of Health (MOH) and National Health Authorities
- Expert Interviews with key members of national immunization programs (NIP), medical advisors, university professors, UNICEF members, pediatricians, and immunization researchers.

We analyzed national tenders for available countries in each market (hexavalent, pentavalent, and preschool booster). Tendering information such as the number of doses of vaccines or the brand of vaccine procured in 2021 is used for market estimations. We also reviewed the MOH and National health authority sources in each country to obtain information on specific brands of vaccines (among hexavalent, pentavalent, and preschool booster) recommended in each country's national immunization schedules. Interviews are conducted with experts for the needed Information for some countries with limited secondary information on vaccine procurement volumes and brand usage.

Global Trends in Pediatric DTP Vaccines

Some of the key trends in pediatric DTP vaccines for 2021 include

- Global immunization rate continued to decline by 5% between 2019 and 2021 from 86% to 81% due to multiple factors such as low per capita income, mother education, lack of sanitation and prenatal care, more than five children, accessibility issues to health care services and the COVID-19 pandemic. Additionally, countries that transitioned off from GAVI support had a sharper decline in vaccination coverage than GAVI-supported countries, highlighting the fragility of LIC and LMIC. Countries with growing economies become less eligible for external funding and require increased domestic funding for immunization. In times of crisis, such as during the COVID-19 pandemic, middle-income countries (MIC), which account for an increasing share of

unprotected children, might be unable to allocate sufficient resources to immunization programs to ensure that every child receives the available vaccines.

- Various initiatives have been taken by health systems and organizations globally, to increase the immunization rate. For instance, in January 2021, WHO published strategies and guiding principles for implementing catch-up vaccination and recovering essential immunization services. To enhance the immunization rate in the coming years, WHO and GAVI have taken initiatives such as Immunization Agenda 2030 (IA2030) and GAVI 5.0. The WHO has also advised countries to ensure that their national policies and immunization programs include plans and processes for delivering catch-up vaccinations to refugees and migrants of all ages. The WHO has also set a target of achieving 90% coverage for essential vaccines given in childhood and adolescence and halving the number of children completely missing out on vaccines.[i]
- Additionally, associations such as GAVI and CDC have recommended countries to implement catch-up vaccination plans in order to prioritize routine vaccines.[ii] As a result, countries such as Mexico, Canada, and South Africa showed slightly higher DTP 3 vaccination coverage rates in 2021. In some Middle Eastern countries such as Qatar, the Ministry of Public Health launched an annual vaccination campaign against tetanus, diphtheria, and pertussis.[iii] In 2021, the DTP3 immunization rate in Qatar increased to 98% compared to 82% in 2020, and 81% global average DTP3 rate in 2021. [iv] Also, in the United Arab Emirates, the DTP3 rate increased to 96% in 2021 compared to 90% in 2020.
- Many countries are adopting to the shift in type of vaccines for improved immunization, increased safety profile, reduced adverse effects and declining side effects. For instance, countries such as Qatar in the year 2021 and Chile in the year 2019 shifted from whole cell pertussis to acellular pertussis vaccines (wP to aP), Malta in the year 2021, Malaysia in 2020 shifted to hexavalent vaccines from pentavalent vaccines and the USA and Algeria have included aP antigen based hexavalent vaccine in their National Immunization Program (NIP) in 2021. Continuing the trend of countries shifting towards aP vaccines within their public immunization programs and to curb the risk of poliomyelitis outbreak in the LATAM region, SLIPE (Latin American Society of Pediatric Infectious Diseases) commissioned experts to recommend the inclusion of either complete IPV based schedules or schedules including at least two initial doses of IPV in their NIP. SLIPE also reviewed and advocated the inclusion of aP based vaccines in the immunization scheduled of LATAM countries

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Glossary

Antigen

Any foreign substance that produces an immune response in the body.[v]

DTP Vaccine

A vaccine that produces immunity against three deadly diseases - namely diphtheria, tetanus, and pertussis (whooping cough) (DTP).[vi]

DTP$_3$ Immunization Rate

The percentage of one-year-olds who have received three doses of the combined diphtheria, tetanus toxoid, and pertussis (DTP$_3$) vaccine in a given year.[vii]

DTaP Vaccine

DTaP is a combined vaccine against diphtheria (D), tetanus (T), and pertussis (P), in which the pertussis component is acellular containing purified components of B. pertussis.[viii] DTaP vaccine is approved to provide immunity from an early age (6 weeks).

DTwP Vaccine

DTwP is a combined vaccine against diphtheria (D), tetanus (T), and pertussis(P), in which the pertussis component is a whole-cell, which is an entire B. pertussis organism that has been inactivated.[ix]

Tdap Vaccine

Tdap is a combined vaccine against diphtheria (D), tetanus (T), and pertussis(P). Tdap vaccine is approved to administered from the age of three to four years to boost the immunity.

GAVI

The Global Alliance for Vaccines and Immunizations (GAVI), is an international organization, that brings together public and private sectors with the shared goal of creating equal access to new and underused vaccines for children living in the world's poorest countries.[x]

Hexavalent Vaccine

A hexavalent vaccine (DTaP-IPV-HepB-Hib) is a six-in-one vaccine that protects babies against diphtheria (D), tetanus (T), pertussis (P), poliomyelitis (IPV), *Haemophilus influenza type b* (Hib) and hepatitis B (Hep B). All hexavalent vaccines are intended for pediatric use.[xi]

Pentavalent Vaccine

A pentavalent vaccine (DTaP-IPV-Hib) is recommended in three doses for infants and or as a fourth booster dose for a toddler to protect babies against diphtheria (D), tetanus (T), pertussis (P), poliomyelitis (IPV), and *Haemophilus influenza type b* (Hib). All pentavalent vaccines are intended for pediatric use.[xii]

Pertussis vaccines (aP and wP)

Pertussis (P), also known as whooping cough, is a highly contagious respiratory disease caused by the bacterium *Bordetella pertussis*. Pertussis vaccines are available in two forms namely acellular pertussis (aP) or whole-cell pertussis (wP).[xiii]

DTP Primary Series Vaccines

These vaccines are the initial doses of vaccines given to infants. DTP primary series vaccines are either 2 doses or 3 doses depending on individual countries' national immunization schedules.[xiv]

Public Markets (Pertussis Combination Vaccines)

Public markets include countries where pertussis combination vaccines are included under national immunization schedules and supplied to the entire nation by the government or governmental agencies. These vaccines are generally procured through tenders, and distributed to healthcare practitioners (HCPs).[xv]

Private Markets (Pertussis Combination Vaccines)

Private markets include countries where pertussis combination vaccines are given by private practitioners and not included in the national immunization schedule or countries where pertussis combination vaccines are offered through private reimbursement. The price for this vaccine may be partially or completely reimbursed by insurance companies, or be borne through out-of-pocket expenditure.[xvi]

Schedule

A vaccination schedule refers to the details of primary series and preschool booster vaccines as recommended by the national immunization program (NIP) in a country. Recommendations include the number of doses and the age at which a specific dose of vaccine is to be administered.[xvii]

aP Based Preschool Booster Vaccine

aP-based preschool booster vaccines are either trivalent (DTaP or Tdap), or tetravalent (DTaP-IPV or Tdap-IPV) and protect children against diphtheria (D), tetanus (T), pertussis (P), and poliomyelitis if containing IPV. These vaccines are used during the age of three to seven years depending on the country's national immunization schedule.

Surviving Infants

Surviving infants are the number of children reaching their first birthday during a given year.[xviii, xix]

UNICEF

The United Nations International Children's Emergency Fund (UNICEF) works in 190 countries and territories to protect the rights of every child.[xx]

WHO

The World Health Organization (WHO) is a specialized agency of the United Nations (UN) working in 194 member countries. This organization deals with issues related to public health. [xxi]

WHO Countries Income Status

WHO countries are classified based on income status into High-Income Countries (HIC), Upper Middle-Income Countries (UMIC), Lower Middle-Income Countries (LMIC), and Low-Income Countries (LIC).

WHO Regions

All regions mentioned in this report are according to the WHO countries' classification. For instance, countries under European Region (EUR) are the WHO classification of EUR, not limited to the countries which represent the European Union.

WHO Vaccine Prequalification (Prequalified vaccine)

The WHO prequalification ensures vaccines used in immunization programs are safe and effective. It provides the Member States and procurement agencies, such as GAVI and UNICEF, with the information required to purchase vaccines matching the specific needs of the program.[xxii]

SAGE

SAGE is the leading advisory group to the WHO for vaccines and immunization. It guides WHO on global policies and strategies covering vaccine and technology, research and development, immunization delivery, and its connections to other health interventions.[xxiii]

CDC

The Centers for Disease Control and Prevention (CDC) is the national public health agency of the United States. The Centers for Disease Control and Prevention promotes safe and healthy environments. It keeps track of health trends, looks for the cause of disease outbreaks and health problems, and responds to new public health threats.[xxiv]

PAHO

The Pan American Health Organization (PAHO) is the specialized international health agency for the Americas. It interacts with countries in the region to improve and safeguard public health. To tackle communicable and noncommunicable diseases and their causes, enhance health systems, and respond to emergencies and disasters, PAHO collaborates technically with its member countries.[xxv]

VCR

The Vaccination Coverage Rate (VCR) is the percent of the target population that has received the last recommended dose for each vaccine recommended in the national immunization schedule.[xxvi]

EPI

The Expanded Program on Immunization (EPI) was established in 1974 to ensure that infants/children and mothers have access to routinely recommended infant/childhood vaccines. The EPI initially included six vaccine-preventable illnesses: measles, diphtheria, tetanus, pertussis, poliomyelitis, and tuberculosis.[xxvii]**DTP5 Immunization Rate**

The percentage of three to seven years children who have received the booster dose of the combined diphtheria, tetanus toxoid, and pertussis vaccine in a given year.

CIA Factbook

The Central Intelligence Agency (CIA) provides information on the history, people, government, economy, geography, and many more aspects which are known as CIA Factbook.[xxviii]

UN Population Data

The United Nations (UN) presents population estimates from 1950 to the present for 237 countries or areas, underpinned by analyses of historical demographic trends.[xxix]

1. Research Objective

The primary goal of this white paper is to evaluate the market leader among pediatric aP-based combination vaccines. The key objectives of this study include the analysis of

- Global volumes of aP and wP-based vaccines (primary series & booster dose)
- Utilization trends for aP combination vaccines including
    - hexavalent vaccines
    - pentavalent vaccines
    - preschool booster vaccines

Pediatric aP-based combination vaccines, described as the DTaP-based hexavalent, and pentavalent vaccines are considered for analyzing the primary vaccination series. DTaP/ TdaP-based tetravalent vaccines were considered for analyzing the preschool booster vaccines market. The outcomes of the study are presented for the DTaP-based hexavalent, pentavalent, and preschool booster vaccines.

2. Introduction

This section provides an overview of the pertussis-based combination vaccines, primary vaccines, and preschool booster vaccines, the types of combination vaccines including pentavalent, hexavalent, trivalent, and tetravalent preschool booster vaccines in the market. Further information on the public and private markets for vaccines are detailed in this section.

Combination Vaccines- wP and aP, DTaP-based Vaccines

Pertussis combination vaccines can be either DTwP-based or DTaP based.

The combined diphtheria, tetanus, and pertussis (DTP) vaccine, which includes DTwP or DTaP, has already been incorporated into the national immunization schedules in most countries for pediatric vaccines.[xxx] These DTP-based vaccines serve as the backbone of several other combination vaccines such as tetravalent, pentavalent, and hexavalent vaccines.

For instance, DTaP-based tetravalent vaccines include DTaP-IPV.

Pentavalent vaccine combinations include DTaP-Hib-IPV, DTaP-HepB-IPV.

Hexavalent vaccine combinations include DTaP-Hib-HepB-IPV.

Combination Vaccines are used to overcome the problems associated with multiple administrations of monovalent vaccines. The use of combination vaccines, which include several antigens in a single administration, offers benefits such as reduced complications associated with numerous intramuscular injections, decreased costs of stocking, and a lower risk of delayed or missed vaccinations.[xxxi]

Primary and Booster Vaccines

Pediatric vaccines can be defined as primary vaccination (series) or booster vaccines based on the age at which the vaccine is administered to the infant. Primary vaccination series include vaccination to infants and toddlers from birth to the age of three years. Booster doses are administered to infants who have completed a primary vaccination series. The booster vaccination schedule varies for each country and is administered after three years until the child is eligible to receive the adult vaccine. This study considers the preschool booster vaccine administered between three to seven years of age. The objective of a booster dose is to restore vaccine effectiveness from that deemed no longer sufficient.

Inactivated polio vaccine (IPV) combinations are used for both primary and booster vaccinations. Owing to the high cost of these vaccines, they are used mainly by high-income and middle-income countries. All IPV vaccine combinations are aP-based vaccines.

The focus of this study is on DTaP-based combination vaccines.

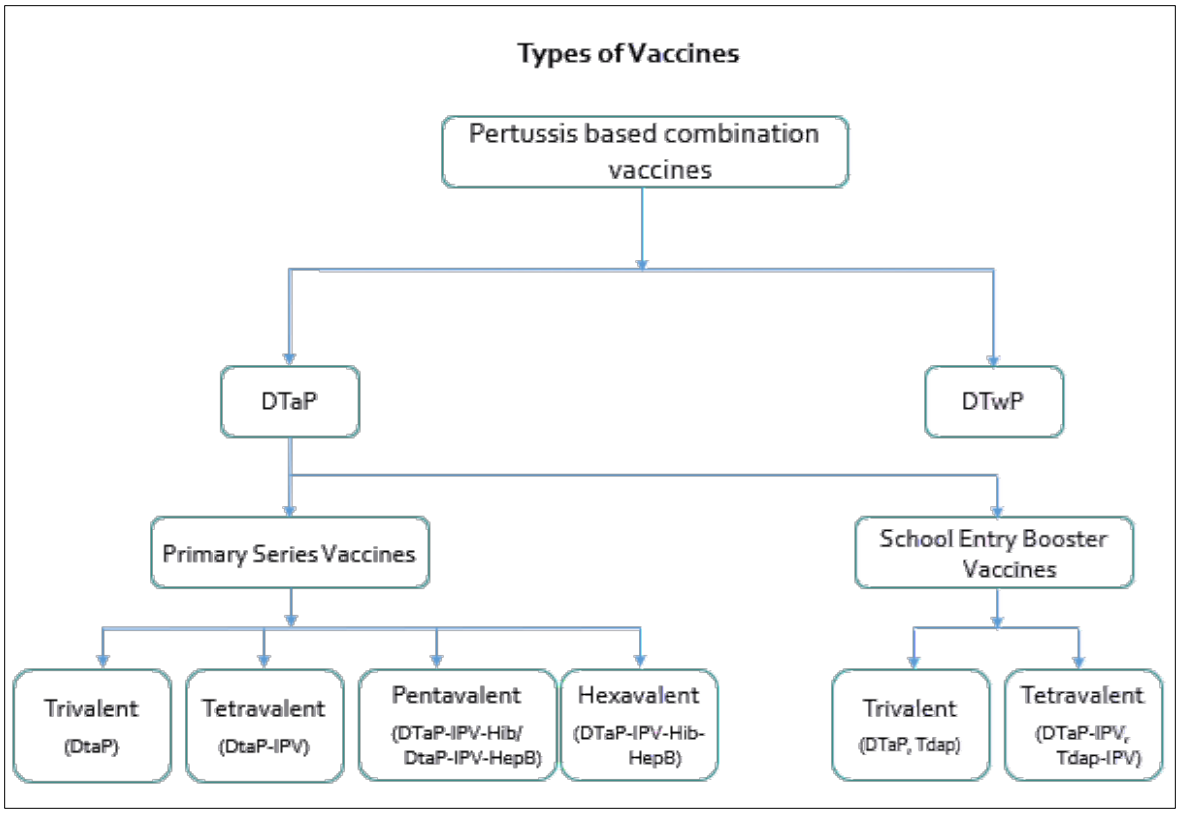

Fig 9: Types of vaccines

Countries are shifting from the DTP vaccine that include a wP antigen (DTwP) to the DTP vaccine with aP component (DTaP) due to reduced adverse events after immunization. For instance, Qatar in the year 2021 and Chile in the year 2019 have shifted from wP-based pentavalent vaccine to aP-based pentavalent vaccine.

Most countries using aP-based primary series vaccines use hexavalent or pentavalent vaccines. aP-based trivalent and tetravalent vaccines are less commonly used.

Types of Combination Vaccines and their Brands

- Hexavalent
- Pentavalent
- Preschool Booster

Hexavalent Vaccines

Hexavalent vaccines are a way to increase compliance with the entire primary schedule and the immunization rate of the six antigens: diphtheria, tetanus, pertussis (DTP), hepatitis B (Hep B), inactivated poliovirus (IPV), and *Haemophilus influenza type b* (Hib) infections, assuring simplification of administration and better control of vaccination program costs.[xxxii]

Hexavalent vaccines are the preferred vaccines in the EUR and have replaced pentavalent vaccines as primary vaccines in most European countries. In 2021, among 195 countries, around 51 countries were using "DTaP-Hib-HepB-IPV" vaccines for routine immunization. In the EUR (according to the WHO

definition), 30 of 53 countries were using hexavalent vaccines, whereas, in the AMR, only seven of 35 countries have included hexavalent vaccines in their immunization schedule.

The inclusion of hexavalent vaccines in the immunization schedule of a country is an approach to inactivated polio vaccine (IPV) access, which supports the commitment of the World Health Organization (WHO) to eradicate the poliovirus.[xxxiii]

Types Of Hexavalent Vaccines

The acellular hexavalent vaccine (DTaP-HepB-Hib-IPV) is a six-in-one (all the antigens in the same container with no reconstitution) (or 5+1, the vaccine that needs reconstitution) vaccine recommended in three or four doses schedule to help protect babies against diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenza type b*and hepatitis B.[xxxiv]

Hexavalent Vaccine Brands

There are three aP hexavalent vaccine preparations commercially available for administration to children.

Sr. No.	Brand Name	Combination	Manufacturer
1	Hexaxim®/ Hexyon®/ Hexacima®	DTaP-HepB-Hib-IPV	Sanofi
2	Infanrix Hexa®		GSK
3	Vaxelis®		MCM

Table 3: Hexavalent vaccine brands

Hexaxim® and Vaxelis® are fully-liquid formulations available in ready-to-use syringes or vials, while the Hib component in Infanrix Hexa® is supplied as a lyophilized white powder that has to be reconstituted with the components present in the pre-filled glass syringe or vials.[xxxv]

Infanrix Hexa® has three purified components of *Bordetella pertussis* namely Pertussis Toxoid (PT), filamentous haemagglutinin (FHA), and pertactin (PRN), whereas Hexaxim® includes two purified components (PT, FHA), and Vaxelis® includes five purified components s (PT, FHA, PRN, FIM (*Fimbriae*) type 2, 3)[xxxvi] (Table 16). Though the number of pertussis antigens differs by the brand of hexavalent vaccine, the WHO position paper on pertussis states, "There is no sufficient evidence to establish any significant difference in vaccine effectiveness of aP vaccines with differing numbers of pertussis antigen components."[xxxvii]

Hexaxim® is the only hexavalent vaccine with the WHO prequalification status and the only one available in both pre-filled syringes or mono-dose vial presentation.

Pentavalent Vaccines

The pentavalent vaccine is a combination vaccine that the WHO widely recommends as a substitute for prevailing vaccination practices for diphtheria, tetanus, pertussis (DTP), *Haemophilus influenza type b* (Hib) or hepatitis B (Hep B), and poliomyelitis infections (IPV).[xxxviii]

Most countries use pentavalent vaccines in their national immunization schedule. In 2021, among 195 countries, around 122 countries were using "DTwP-Hib-HepB" vaccines for routine immunization. During the same period, 28 countries were using the "DTaP-IPV-Hib" vaccine for routine immunization.

Types of Pentavalent Vaccines

Pentavalent vaccines combine five antigens in one formulation. It offers protection against diphtheria, tetanus, pertussis, hepatitis B or *Haemophilus Influenzae type b*, and poliomyelitis.[xxxix] These vaccines are of two types, either aP-based or wP-based.

aP-based pentavalent vaccines (DTaP-IPV-Hib) are mainly used for high, upper-middle and middle-income group countries. [xl] In contrast, wP-based vaccines (DTwP-HepB-Hib) are used by Low Income Countries (LIC) and Lower-Middle-Income Countries (LMIC). [xli]

wP-based pentavalent vaccines are procured by global organizations such as UNICEF and PAHO. UNICEF procures DTwP-HepB-Hib vaccines for the global alliance for vaccines and immunizations (GAVI) countries and several countries in support of expanded programs on immunization (EPI).[xlii]

Pentavalent Vaccine Brands

There are five aP-based pentavalent vaccine preparations commercially available for administration to children.

Sr. No.	Brand Name	Combination	Manufacturer
1	Pentaxim®	DTaP-IPV-Hib	Sanofi
2	Pentacel®		
3	Pediacel®		
4	Infanrix Penta®	DTaP-IPV-HepB	GSK
5	Pediarix®		

Table 4: Pentavalent vaccine brands

Pertussis-Based Preschool Booster Vaccines

Preschool booster vaccines (diphtheria & tetanus-based vaccines) are combination vaccines administered to children from three to seven years of age based on a country's national immunization schedule. These vaccines protect children against two or more of the following diseases: diphtheria, tetanus, pertussis (aP or wP), and poliomyelitis. The need for these vaccines is mainly attributed to waning immune protection conferred by vaccination i.e., after primary vaccine doses.[xliii] Children receiving preschool booster vaccines are protected against these infections until receiving an adolescent booster dose.[xliv]

Types of Preschool Booster Vaccines

Preschool booster vaccines are of two types, trivalent (DTaP, DTwP, Tdap), and tetravalent vaccines (DTaP-IPV, Tdap-IPV). Among 195 countries, around 97 countries use trivalent and tetravalent pertussis-based vaccines as preschool boosters in their national immunization schedules. Most of these countries use aP-based preschool booster vaccines in their national immunization schedules.

Trivalent preschool booster vaccines are three-in-one vaccines recommended to protect preschool children against diphtheria, tetanus, and pertussis.

Tetravalent preschool booster vaccines are four-in-one vaccines recommended to protect children against diphtheria, tetanus, pertussis, and poliomyelitis. High Income Countries (HIC) mostly use tetravalent preschool booster vaccines in their national immunization schedules.

Preschool Booster Vaccine Brands

The table below lists the DTaP and TdaP-based trivalent and tetravalent vaccines available in the market.

Sr. No.	Brand Name	Combination	Manufacturer
1	Adacel®	Tdap	Sanofi
2	Daptacel®	DTaP	
3	Tetraxim®	DTaP-IPV	
4	Quadracel®		
5	Repevax®	Tdap-IPV	
6	Revaxis®	Td-IPV	
7	Boostrix®	Tdap	GSK
8	Infanrix®	DTaP	
9	Infanrix-IPV®/Kinrix®	DTaP-IPV	
10	Boostrix-IPV®	Tdap-IPV	

Table 5: Preschool vaccine brands

Boostrix® (GSK) and Adacel® (Sanofi) are the most widely used trivalent preschool booster vaccines. These vaccines are available in single-dose prefilled syringes (Adacel® is also available as a vial) with cloudy and whitish composition with each dose of 0.5ml. They should be administered through the intramuscular route (IM), preferably into the deltoid muscle of the upper arm.[xlv]

Tetraxim® (Sanofi), Infanrix-IPV®/Kinrix® (GSK), and Quadracel® (Sanofi) are the most widely used tetravalent preschool booster vaccines. These vaccines are available in single-dose prefilled syringes with a cloudy and whitish composition (sterile suspensions) with each dose of 0.5ml. They should be administered through the intramuscular (IM) route preferably into the deltoid muscle of the upper arm.[xlvi,xlvii,xlviii] These three vaccines have a similar number of antigens for D and T, with significant differences in the number of purified pertussis (aP) antigens available.[xlix]

Public and Private Markets

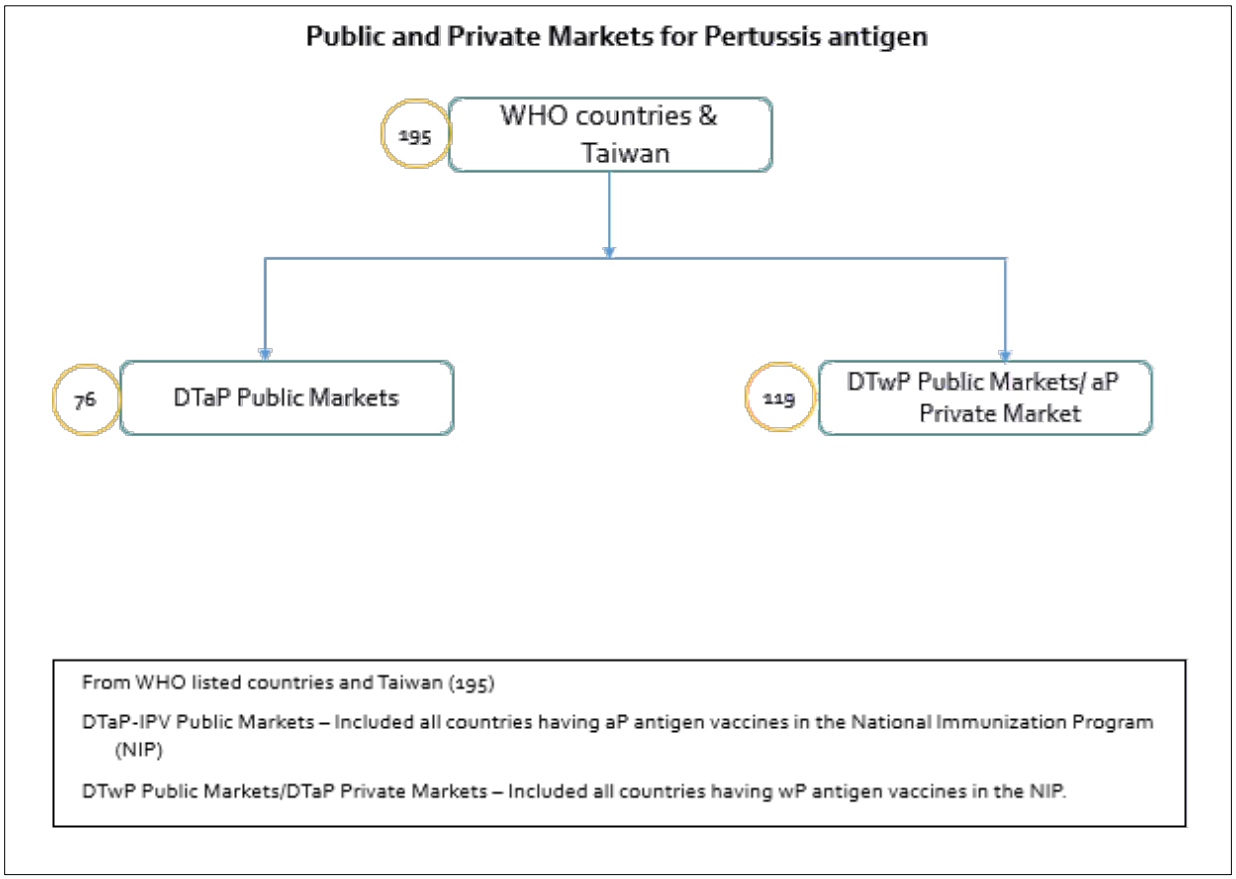

Fig 10: Public and private markets for pertussis antigen

A total of 195 countries were selected (194 from WHO Global Health Observatory (GHO) data and Taiwan). Public and private markets for vaccines are identified based on the inclusion or otherwise of the aP combination vaccine in the government supply and the national immunization schedule of the country. The countries with an aP combination vaccine in their national immunization schedule are designated public markets (76 countries) and countries with wP combination vaccine in their national immunization schedule are designated as private markets (119 countries). The government bears a part or all of the expenditure for immunization in the public markets whereas vaccine expenditure in most private markets is through out-of-pocket expenditure or reimbursement by private insurance payers.

All 195 countries selected are classified as HIC, Upper-Middle Income (UMIC), LMIC, and LIC based on the World Bank classification,[I] which is adopted by the WHO. aP-based trivalent and tetravalent vaccine markets are not considered for market analysis, as these vaccines are used only by a fraction of countries for primary series vaccination. China is included in the study, although it uses DTaP trivalent vaccine as a primary series vaccine, its private market is very large for pentavalent vaccines.

3. Research Methodology (Demand/Usage Approach)

This section includes the research methodology adopted to understand the market structure of the DTaP vaccines market. The copurified vaccines marketed in China and Japan are excluded from this study.

The study is based on the worldwide demand/usage estimates for aP combination vaccines (both primary series & preschool booster series). The methodology includes four steps as below

Step-I: Finding public and private markets for the target vaccine

The potential size of the worldwide aP combination vaccine market is calculated for the hexavalent, pentavalent, and preschool booster markets by including public and private markets

A total of 195 countries were selected (194 from WHO data + Taiwan), and public and private markets for vaccines were identified based on the inclusion of the aP-based combination vaccine the national immunization schedule, and the government supply of the country. The countries with an aP-based combination vaccine in their national immunization schedule were designated public markets.

Among these WHO countries, 76 countries were using aP-based (DTaP) combination vaccines in their national immunization schedules, which were designated public markets, whereas 119 countries using wP-based (DTwP) combination vaccines in their national immunization schedules were designated as private markets.

Among the 76 public markets using aP combination vaccines, public markets for hexavalent, pentavalent, and preschool booster vaccines were identified. The private markets for all three combination vaccines are calculated by eliminating countries based on their income category, region, and filters specific to the individual vaccine market. (All 195 countries are classified based on income categories and regions).

Step-II — Market sizing calculation of vaccine volumes for all the available public and private markets

Three factors determine the potential size of the worldwide aP combination vaccine market — the annual surviving infant population (as well as the three-seven years target population for preschool booster vaccine), the proportion of children receiving these vaccines, and the number of doses of vaccine a child receives as per the recommended schedule.

The following parameters are used for the calculation of vaccine volumes for all three markets.

a. Target population — Surviving Infants or preschool children population
b. Immunization Rate — DTP_3/DTP_5
c. Immunization Schedule — Number of doses of vaccine administered

Step-III— Filtering the countries that constitute the top 95% (approximately) of the vaccine market

The countries that constitute 95% of the market for each hexavalent, pentavalent, and preschool booster market were considered for further vaccine brand utilization analysis. The rationale for this filtering is that deducing the share of each brand of vaccine across all target countries (100%) is challenging, and hence we considered the statistically valid coverage of 95% of the market. Further, we assume that the brand that is dominant in 95% of the market will be a market leader.

Step-IV — Analyzing brand shares for top vaccine markets (filtered in Step-II), to find the dominant brand shares in the markets

For each market, brand shares were computed for the countries constituting the top 95% of the individual vaccine market.

The method by which vaccines are purchased and financed in each country influences the proportion of individual brands of vaccines used. In public markets, the government finances and procures vaccines in large quantities through tenders. In private markets, where individual consumers pay for the vaccine through out-of-pocket or private insurance, these vaccines are procured by either GP/ pediatrician's offices or by pharmacies, directly from the manufacturer and/or through wholesalers.

The proportion of each of the brands used in a country is derived through extensive secondary research and expert insights. The usage patterns for each brand of vaccines across the target countries were obtained through information gathered from various sources as below-

a) National and Regional Tenders
b) MOH and National Health Authorities
c) Expert Interviews with key members of NIP, medical advisors, university professors, UNICEF members, pediatricians, and immunization researchers.

We analyzed national tenders for available countries in the hexavalent market. Tendering information such as the number of doses of vaccines or the brand of vaccine procured in 2021 was used for market estimations. We also reviewed the MOH and National health authority sources in each country to obtain information on specific brands of vaccines (among hexavalent, pentavalent, and preschool booster) recommended in each country's national immunization schedule. Interviews were conducted with experts for the needed Information for some countries with limited secondary information on vaccine procurement volumes and brand usage.

The methodology for estimating the volumes and shares of vaccine brands among each of the hexavalent, pentavalent, and tetravalent markets is described below

Hexavalent Vaccines Methodology

Step-I: Finding public and private markets for the hexavalent vaccines

The segregation and filtering of all the WHO countries into the public and private markets for the hexavalent vaccines are described below

a. Hexavalent Public Markets - Among 195 countries (194 WHO + Taiwan) only 48 countries were using hexavalent vaccines in their National Immunization Schedule (NIP).
    - Included countries using hexavalent vaccines in their NIP (51)
    - Excluded Germany and France as they are privately reimbursed markets, and Algeria as hexavalent vaccine usage in the public market has not been implemented (3)
b. Hexavalent Private Markets - Among 195 countries (194 WHO+Taiwan) only 53 were using hexavalent vaccines in their private markets.
    - Excluded all countries considered in hexavalent public markets (48)

- Excluded LIC (29), UMIC, LMIC with surviving infants <100,000 (41), HIC with surviving infants <20,000 (9)
- Excluded all African countries (11) - These 11 countries were excluded based on the assumption that governments in these countries cannot afford the supply of hexavalent aP vaccines and that the administration of hexavalent vaccines is also limited among private markets in these countries.
- Excluded Japan, China, and Algeria as they do not have the hexavalent vaccine in their private market (3)
- Excluded Taiwan as it has no hexavalent vaccine (1)

DTaP vaccine volumes were calculated for a total of 101 countries (48 public + 53 private) in the hexavalent market.

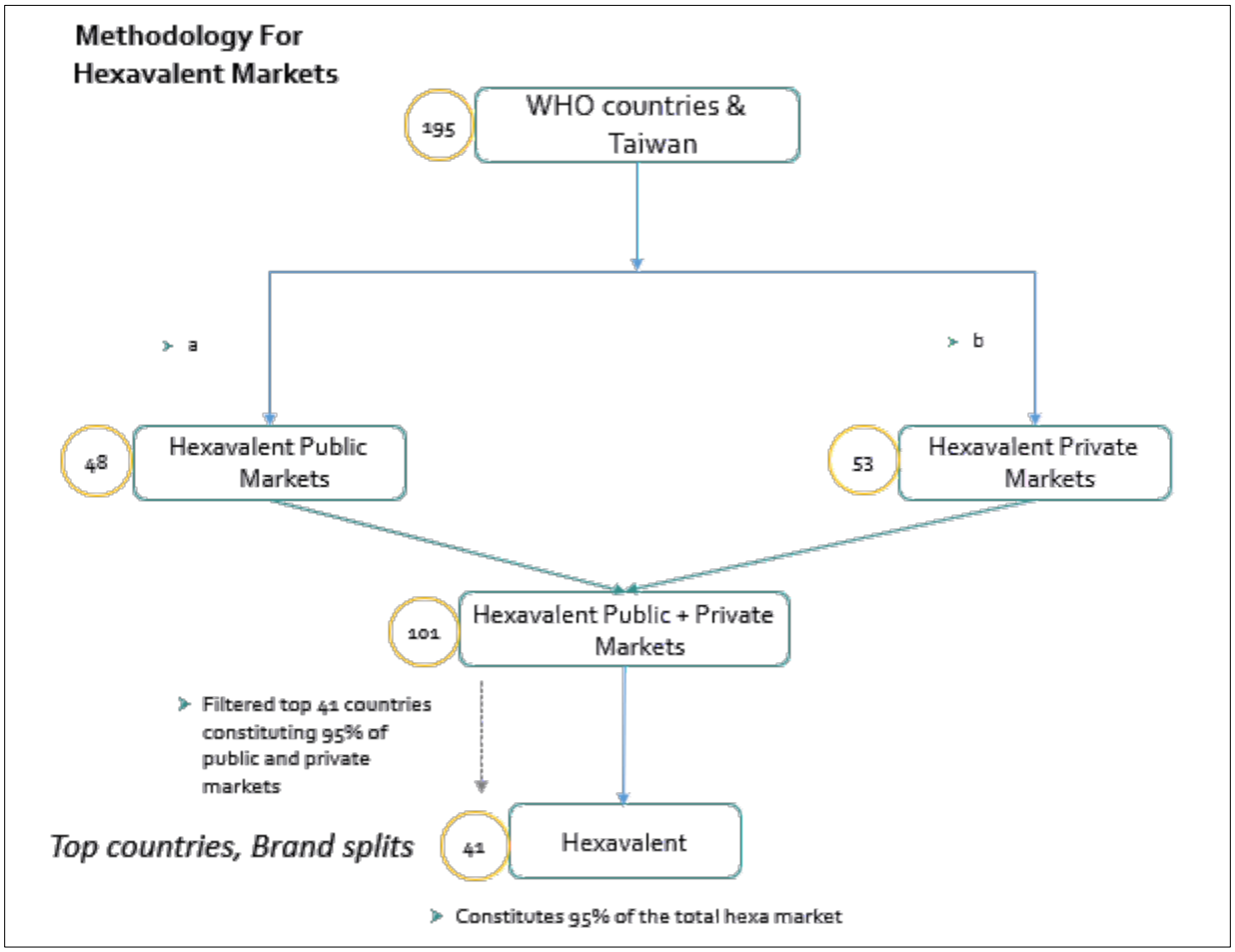

Fig 11: Methodology for hexavalent markets

Step-II: Calculation of vaccine volumes for all 101 Step-1 filtered countries

The following parameters are used for the calculation of vaccine volumes

a. Surviving Infants population

b. DTP3 Immunization Rate
c. Hexavalent Vaccine Immunization Schedule

Surviving infants

The doses of hexavalent vaccines are administered to children less than 12 months of age. Hence the surviving infant population below 12 months of age is the target population for this study. The data on the surviving children (birth cohort) is obtained from the WHO, GAVI, UNICEF, UN population data, and national statistics from CIA Factbook.

Some countries observed a significant increase or decrease in surviving infant population in 2021. For example, the Philippines, a large increase in births was reported.[li]

Due to COVID- 19 pandemic, countries such as Russia[lii], Mexico, and China faced a decline in the surviving infant population. According to preliminary Health Ministry data in Mexico, births dropped by 11% in the first six months of 2021 (compared to 2020) attributed to COVID- 19 pandemic.[liii] In 2021, China faced a decreasing trend in newborn births attributed to social changes, increasing costs of childcare and education, and an aging population.[liv]

Immunization Rate (DTP3)

DTP3 immunization rate, the third dose immunization rate for diphtheria, tetanus, and pertussis, is considered for the hexavalent vaccine immunization rate.

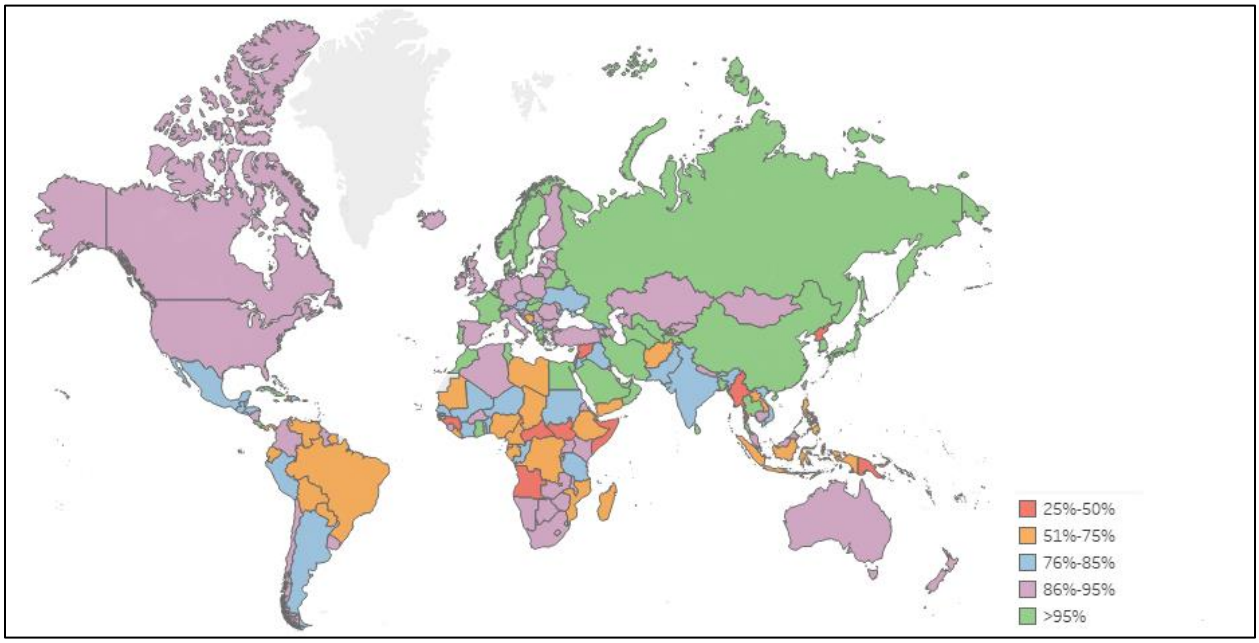

Fig 12: DTP3 immunization rate (WHO Database), 2021

Globally, hexavalent vaccines are used more in public markets than in private markets. For public markets where hexavalent is the only vaccine supplied through the national immunization schedule, the immunization rate is high, ranging from 90-99% among those countries.

For public markets where both hexavalent and pentavalent vaccines are used, the immunization rate for hexavalent and pentavalent vaccines varies by country depending on specific factors such as

geographical distribution, availability of vaccines within the country, targeted recommendations for specific populations and usage of these vaccines as a proportion of all the available multivalent vaccines.

The immunization rate for hexavalent vaccines ranges from 70-90% in most of these countries. However, USA and Canada have hexavalent vaccine immunization rates of around 4.6% and 42.0%, respectively. Although the overall immunization rate is high in USA and Canada, the use of hexavalent vaccines is low due to recommendations to limit the use of hexavalent vaccines to specific populations.

For private markets, the immunization rate for hexavalent vaccines is estimated, based on data collected from secondary sources such as WHO,[lv] and the Center for Disease Control and Prevention (CDC).[lvi] Parameters such as private healthcare vaccine trends and the income status of a country sourced from WHO were also considered for estimating private hexavalent vaccine market volumes for some countries. Private vaccine market shares obtained from WHO surveys[lvii],research publications, and from expert inputs were also used for estimating private market volumes for hexavalent vaccines.

In private markets, most HIC have hexavalent vaccine usage rates ranging from 10-20%, whereas UMIC and LMIC have hexavalent vaccine usage rates ranging from 2-6% and 1-2%, respectively.

The use of hexavalent vaccines is limited in private out-of-pocket (OOP) markets, whereas in private reimbursed markets such as France, and Germany, the usage of hexavalent vaccines is high.

In some of the UMIC and HIC, an increase in the DTP3 immunization rate was observed. For instance, in Kazakhstan, United Arab Emirates, and Qatar, the DTP3 immunization rate increased substantially in 2021 compared to 2020. In Kazakhstan, the DTP3 immunization rate increased from 88% in 2020 to 95% in 2021. In Qatar, the Ministry of Public Health launched an annual vaccination campaign against tetanus, diphtheria, and pertussis.[lviii]As a result, the DTP3 immunization rate in Qatar increased to 98% as compared to the 82% in 2020 and exceeded the 81% rate achieved in 2021 globally. [lix] Also, in the United Arab Emirates, the DTP3 rate increased from 90% in 2020 to 96% in 2021.

Immunization Schedule

The number of doses of hexavalent vaccines suggested under each country's immunization schedule is obtained from the WHO. The WHO recommends three primary doses (3p) in the vaccine immunization schedule for hexavalent vaccines. For countries under privately reimbursed markets, the standard number of doses suggested by recognized authorities (such as the European Union) was considered.

Calculation Of Volumes Of Hexavalent Vaccine:

The hexavalent market volumes were calculated using these parameters— surviving infants' population, hexavalent vaccine immunization rate, and recommended vaccine dose schedule.

Market	Type of Market	Total Countries	Total Volume (Mn)
Hexavalent	Public	48	27.3
	Private	53	9.9

Table 6: Hexavalent Market, Total Countries and Volumes

Step-III: Filtering the top 95% (approximately) markets

The total Hexavalent Vaccine market of 101 countries constitutes 37.2 Mn. Among 101 countries, 41 countries (30 Public and 11 Private) constitute 95% of the total volumes, equaling 35.3 Mn. These 41

countries were considered for further brand analysis and to understand the brand usage trends of hexavalent vaccines.

Market	Type of Market	Top 95% Countries	Top 95% Volume (Mn)
Hexavalent	Public	30	26.5
	Private	11	8.8

Table 7: Hexavalent Vaccine Market, 95% by Volume

Step-IV: Analyzing brand shares for top vaccine markets

Several brands of hexavalent vaccines exist within each of the vaccine markets. Brand preference among the hexavalent brands is estimated for the top 41 countries that constitute 95% of the hexavalent market. The brand of vaccine that is used more in these 41 countries will be a market leader in the overall hexavalent vaccine market.

The first step in analyzing brand shares is to segregate the 41 countries into countries having only one brand or having multiple brands of hexavalent vaccine in their market. Among 41 countries, 20 countries have a single brand of vaccine, and only one brand will constitute a 100% share of the market. 21 countries have more than one brand of vaccines and the share of brands in these 21 countries has been analyzed through various approaches.

Market	Top 95% Countries	Single Brand	Multiple Brand
Hexavalent	41	20	21

Table 8: Countries with only one brand of vaccine and countries with multiple brands

Single Brand – Countries with only one available brand of hexavalent vaccine in their market.

Multiple Brands – Countries with more than one available brand of hexavalent vaccine in their market.

In 20 public markets namely, Mexico, South Africa, Chile, Kazakhstan, Jordan, Netherlands, Canada, Belgium, Sweden, Libya, Austria, Panama, Ireland, Oman, Georgia, the United Kingdom, Australia, Norway, United States of America, and New Zealand only one brand of hexavalent vaccine is administered. For instance, in Mexico[lx] [lxi], South Africa[lxii] [lxiii], Chile[lxiv], Kazakhstan[lxv], Jordan[lxvi] [lxvii], Belgium[lxviii], Sweden[lxix], Libya[lxx], Austria[lxxi], Panama[lxxii], Oman, and Georgia[lxxiii], Hexaxim® is the only brand of hexavalent vaccine available and administered to all the target children. Infanrix Hexa® is the only brand of hexavalent vaccine administered in six countries, namely the United Kingdom[lxxiv], Australia[lxxv], Canada[lxxvi], New Zealand[lxxvii], Ireland[lxxviii], and Norway[lxxix] [lxxx]. In the United States of America[lxxxi] and the Netherlands[lxxxii] [lxxxiii], Vaxelis® is the only brand of hexavalent vaccine available and administered to all the target children.

National and Regional Tenders

Governmental vaccine procurement departments under the country's MOH generally procure vaccines through national or regional tenders.

National tenders procure hexavalent vaccines in Mexico, South Africa, Malaysia, the UK, the USA, the Netherlands, France, Belgium, and Germany. In Malaysia, the National Pharmaceutical

Regulatory Agency (NPRA) procures hexavalent vaccines[lxxxiv] . In Saudi Arabia, vaccines are procured through the National Unified Procurement Company (NUPCO)[lxxxv].

In Mexico, the MOH procures tenders for hexavalent vaccines. The MOH procured only Hexacima® in 2021.[lxxxvi]

In South Africa, the National Department of Health (NDoH) procures hexavalent vaccines. Hexaxim® was the only brand of vaccine included in South Africa's national immunization schedule.[lxxxvii]

In Malaysia, the NPRA procures hexavalent vaccines[lxxxviii]. Around 98% of hexavalent vaccines administered in Mexico were of Hexaxim®. Around two Mn doses of Hexaxim® were procured in 2021.[lxxxix]

In the UK, the Department of Health and Social Care procured tenders for Infanrix Hexa® among the hexavalent vaccines in 2021.

In Saudi Arabia, the NUPCO procured vaccines through annual tenders. In 2021, the tender for hexavalent vaccines was awarded to Sanofi's Hexaxim®.[xc] Around 90% of the hexavalent vaccine administered in Saudi Arabia was through the national immunization schedule and was the Hexaxim® brand.[xci]

In the USA Vaxelis® was the only brand of hexavalent vaccine available and administered in 2021.[xcii]

In the Netherlands, Vaxelis® is the only brand of hexavalent vaccine available in 2021, and the National Institute for Public Health and the environment (an agency of the Dutch Ministry of Health) procured tenders for the hexavalent vaccine.

In Belgium, Hexaxim® was the only brand of hexavalent vaccine and the Office of Birth and Childhood procured tenders for the hexavalent vaccine Hexaxim® in 2021.

In France, the various regional departments of the French government procured Hexaxim, Infanrix Hexa, and Vaxelis® vaccines in 2021. Around 67%, 26%, and 7% of the market related to Hexaxim®, Infanrix Hexa®, and Vaxelis® respectively.[xciii]

In Germany, Hexaxim, Infanrix Hexa, and Vaxelis® vaccines are procured through regional tenders from the Department of Procurement /Services in 2021. Around 48%, 37%, and 16% of the market related to Hexaxim®, Infanrix Hexa®, and Vaxelis® respectively.[xciv]

In Sweden, Hexyon® was the only brand of hexavalent vaccine available in 2021. Around 330,000 doses of Hexyon® are procured in 2021.[xcv]

Qualitative Insights from MOH/NIP Resources

The information on brands of aP-based vaccines administered in national immunization schedules in the different countries was gathered through authentic secondary sources such as the MOH sites and publications by government health authorities, among related resources.

National Registries and MOH sites provided information on the brand usage of the aP-based hexavalent vaccines in Mexico, South Africa, Australia, Netherlands, Romania, Canada, Belgium, Libya, Austria, New Zealand, Ireland, and Norway.

In the Czech Republic, the National Institute of Public Health procured both Infanrix Hexa® and Hexaxim® brands of hexavalent vaccines in 2021. Around 90% of the hexavalent vaccine doses procured are of Hexaxim® and the remaining market constitutes Infanrix Hexa®.

Romania's MOH procured both Infanrix Hexa® and Hexaxim® brands of hexavalent vaccines in 2021. Around 95% of the hexavalent vaccine doses procured are of Hexaxim® and the remaining market constitutes Infanrix Hexa®.[xcvi]

Expert Insights on Vaccine Usage Patterns

In some countries, especially in countries with private markets, data on vaccine procurement information is not publicly accessible. Expert interviews with key members of NIP, medical advisors, university professors, pediatricians, and immunization researchers were conducted for such countries to know the brand utilization.

For countries such as Poland, Indonesia, Thailand, Brazil, Greece, the Philippines, Ukraine, Vietnam, Guatemala, Brazil, and India, where the availability of secondary information was limited, expert interviews and opinions were elicited to understand the brand usage for individual markets.

Pentavalent Vaccines Methodology

Step-I: Finding public and private markets for the pentavalent vaccines

The segregation and filtering of all the WHO countries into the public and private markets for the pentavalent vaccines are described below

c. Pentavalent Public Markets - Among 195 countries (194 WHO + Taiwan) only 33 countries were using pentavalent vaccines in their national immunization schedule (NIP)

   - Included countries using pentavalent vaccines in their NIP (36)
   - Excluded countries were: Mexico, as it uses only the hexavalent vaccine in NIP, Poland, as pentavalent vaccine is used only in the risk population, and Spain, as the pentavalent vaccine is administered to school age population (6Y) as per NIP (3)

d. Pentavalent Private Markets - Among 195 countries (194 WHO + Taiwan) only 22 were using hexavalent vaccines in their private markets.

   - Removed all countries considered in pentavalent public markets (33)
   - Removed LIC (29), UMIC, LMIC with SI <100,000 (35), HIC with SI <20,000 (16)
   - Removed all African countries (11)- These 11 countries were excluded based on the assumption that governments in these countries cannot afford the supply of pentavalent aP vaccines and that the administration of pentavalent vaccines is also limited among private markets in these countries
   - Removed countries with DTaP hexavalent vaccines in NIP (25)
   - Removed countries without pentavalent vaccines in their private market (24)

DTaP vaccine volumes were calculated for a total of 55 countries (33 public + 22 private) in the pentavalent market.

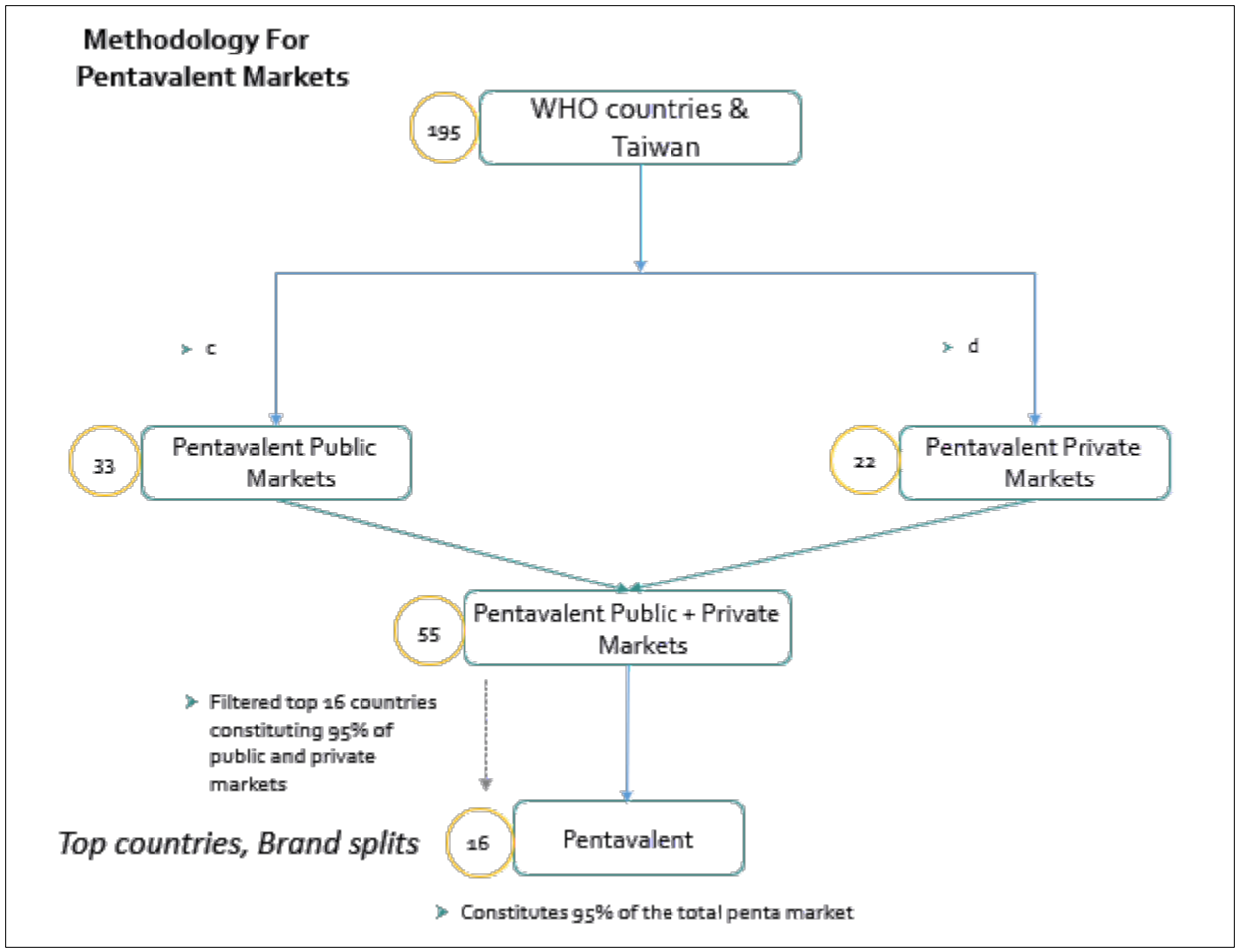

Fig 13: Methodology for pentavalent markets

Step-II: Calculation of vaccine volumes for all 55 Step-I listed countries

The following parameters are used for the calculation of vaccine volumes

a. Surviving Infants
b. Immunization Rate
c. Immunization Schedule

Surviving infants

The doses of pentavalent vaccines are administered to children less than 12 months of age. Hence the surviving infant population below 12 months of age is the target population for this study. The data on the surviving children (birth cohort) is obtained from the WHO, GAVI, UNICEF, UN population data, and national statistics from CIA Factbook.

Some countries observed a large increase and decrease in surviving infant population in 2021. In the Philippines, a significant increase in births is reported.[xcvii]

Immunization Rate (DTP_3)

DTP_3 immunization rate, the third dose immunization rate for DTP was considered for the pentavalent and hexavalent vaccine immunization rate (See figure 12).

The immunization rate for pentavalent vaccines ranges from 70-90% in most of these countries. However, USA and Canada have pentavalent vaccine immunization rates of around 74% and 50%, respectively. Although the overall immunization rate is high in USA and Canada, the immunization rate of the pentavalent vaccine is low due to recommendations for targeted use of the pentavalent vaccine in specific populations.

For private markets, the immunization rate for pentavalent vaccines is estimated, based on data collected from secondary sources such as WHO,[xcviii] and the CDC.[xcix] Parameters such as private healthcare vaccine trends and the income status of a country sourced from WHO were also considered for estimating private pentavalent vaccine market volumes for some countries. Private vaccine market shares obtained from WHO surveys[c] and research publications, and from expert inputs were also used for estimating private market volumes for pentavalent vaccines.

Immunization Schedule

The number of doses of pentavalent vaccines suggested under each country's immunization schedule was obtained from the WHO. The WHO recommends three primary doses (3p) in the vaccine immunization schedule for pentavalent vaccines. For countries under privately reimbursed markets, the standard number of doses suggested by recognized authorities and the European Union is considered.

Calculation Of Volumes Of Pentavalent Combination Vaccine:

The pentavalent market volumes were calculated using these parameters— surviving infants' population, pentavalent vaccine immunization rate, and recommended vaccine dose schedule. The objective is to find the utilization of pentavalent vaccines by region, country, and by individual brand.

Market	Type of Market	Total Countries	Total Volume (Mn)
Pentavalent	Public	33	25.7
	Private	22	6.7

Table 9: Pentavalent Market, Total Countries and Volumes

Step-III: Filtering the top 95% (approximately) markets

The total pentavalent vaccine market of 55 countries constitutes 32.4 Mn. Among 55 countries, 16 countries (11 Public and 5 Private) constitute 95% of the total volumes, equaling 30.8 Mn. These 16 countries were considered for further brand analysis and to understand the brand usage trends of pentavalent vaccines.

Market	Type of Market	Top 95% Countries	Top 95% Volume (Mn)
Pentavalent	Public	11	24.6
	Private	5	6.2

Table 10: Pentavalent Vaccine Market, 95% by Volume

Step-IV: Analyzing brand shares for top vaccine markets

Pentavalent aP combination vaccines are used for the primary vaccination series. Brand preference among the pentavalent brands is estimated for the top 16 countries having 95% share of the market. The brand of vaccine used more in these 16 countries will be a market leader in the overall pentavalent vaccine market.

The usage patterns for each brand of vaccines across the target countries were obtained through information gathered from various sources as below-

- National and Regional Tenders
- MOH and National Health Authorities
- Expert Interviews with key members of NIP, medical advisors, university professors, UNICEF members, pediatricians, and immunization researchers.

The first step in analyzing brand shares is to segregate the 16 countries into countries having only one brand or having multiple brands of pentavalent vaccine in their market. 11 countries among 16 have the single brand of vaccine, and only one brand will constitute a 100% share of the market. Five countries have more than one brand of vaccines and the share of brands in these five countries has been analyzed through various approaches.

Market	Top 95% Countries	Single Brand	Multiple Brand
Pentavalent	16	11	5

Table 11: - Countries with only one brand of vaccine and countries with multiple brands

Single Brand – Countries with only one available brand of pentavalent vaccine in their market.

Multiple Brands – Countries with more than one available bran d of pentavalent vaccine in their market.

In 11 public markets namely Turkey[ci], China[cii], Russian Federation (the)[ciii] [civ], Kazakhstan[cv], Taiwan[cvi], Israel[cvii], Hungary[cviii], India[cix], Serbia[cx], and Costa Rica[cxi] Pentaxim® is the only brand of pentavalent vaccine available and administered to all the target children. Pediacel® is the only brand of pentavalent vaccine available and administered in Canada[cxii].

In Republic of Korea, according to Korea Centers for Disease Control and Prevention, Pentaxim and Infanrix Penta® brands of pentavalent vaccines are administered. Pentaxim was the majorly used brand in Republic of Korea as in November 2021, GSK suspended domestic shipments of its vaccines and replaced with vaccines from other pharmaceutical companies. [cxiii]

National and Regional Tenders

Governmental vaccine procurement departments under the country's MOH generally procure vaccines through national or regional tenders.

National tenders procure pentavalent vaccines in the USA. In the USA, CDC procured Pentacel® and Pediarix® brands of pentavalent vaccines in 2021.[cxiv]

Qualitative insights from MOH/NIP resources

The information on brands of aP-based vaccine administered in national immunization schedules in the different countries is gathered through authentic secondary sources such as the MOH sites and publications by government health authorities, among related resources.

National Registries and MOH sites provided information on the brand usage of the aP-based pentavalent vaccines in Kazakhstan, Taiwan, Canada, India, and Thailand.

Expert insights on vaccine usage patterns

In some countries, especially in countries with private markets, data on vaccine procurement by pharmacies or clinics, and or wholesaler sales data is not publicly accessible. Expert interviews with key members of NIP, medical advisors, university professors, pediatricians, and immunization researchers were conducted for such countries to know the brand utilization.

Preschool Booster Vaccines Methodology

Step-I: Finding public and private markets for preschool booster vaccines

The segregation and filtering of all the WHO countries into the public and private markets for the preschool booster vaccines are described below

e. Preschool Booster Markets – Among 195 countries (194 WHO + Taiwan) only 97 were using preschool booster trivalent or tetravalent vaccines in their markets.
    - Removed countries without Tri or Tetravalent booster vaccines (32)
    - Removed countries with Divalent Vaccines (36)
    - Removed all countries with Booster vaccine within 3Y or above 7Y (30)
f. Preschool Booster Public and Private Markets – Among 97 countries using preschool booster tri or tetravalent vaccines, 60 and 32 countries were in the public and private markets respectively.
    - Included countries with aP vaccine (60)
    - Included all wP antigen vaccines (37)
    - Excluded countries without booster vaccines in the private market (5)

DTaP vaccine volumes were calculated for a total of 92 countries (60 public + 32 private) in the preschool booster market.

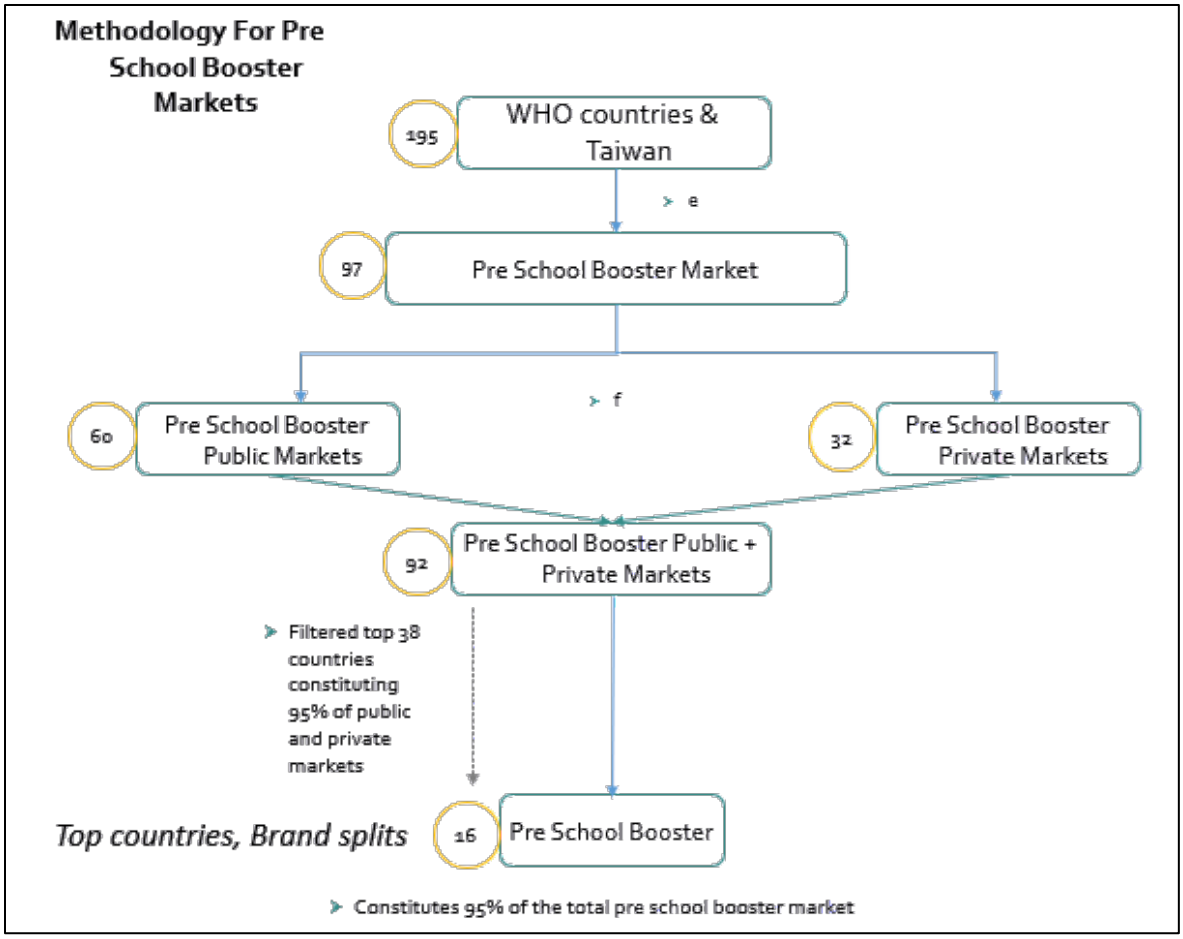

Fig 14: Methodology for preschool booster markets

Step-II: Calculation of vaccine volumes for all 92 Step-I listed countries

The following parameters are used for the calculation of vaccine volumes

a. The preschool-age children population
b. Immunization Rate
c. Immunization Schedule

Preschool-age children population:

The doses of aP-based preschool booster vaccines are administered to children aged between three to seven years, depending on each country's immunization schedule. Hence the average preschool population between three to seven years of age is the target population for this study. The data on the preschool population is obtained from the World Bank population estimates and projections database.

Immunization Rate (DTP5)

The preschool booster immunization rate (DTP5) was considered for estimating the aP-based preschool booster vaccine volumes. For public markets, the immunization rate of preschool boosters is considered for vaccine volume analysis.

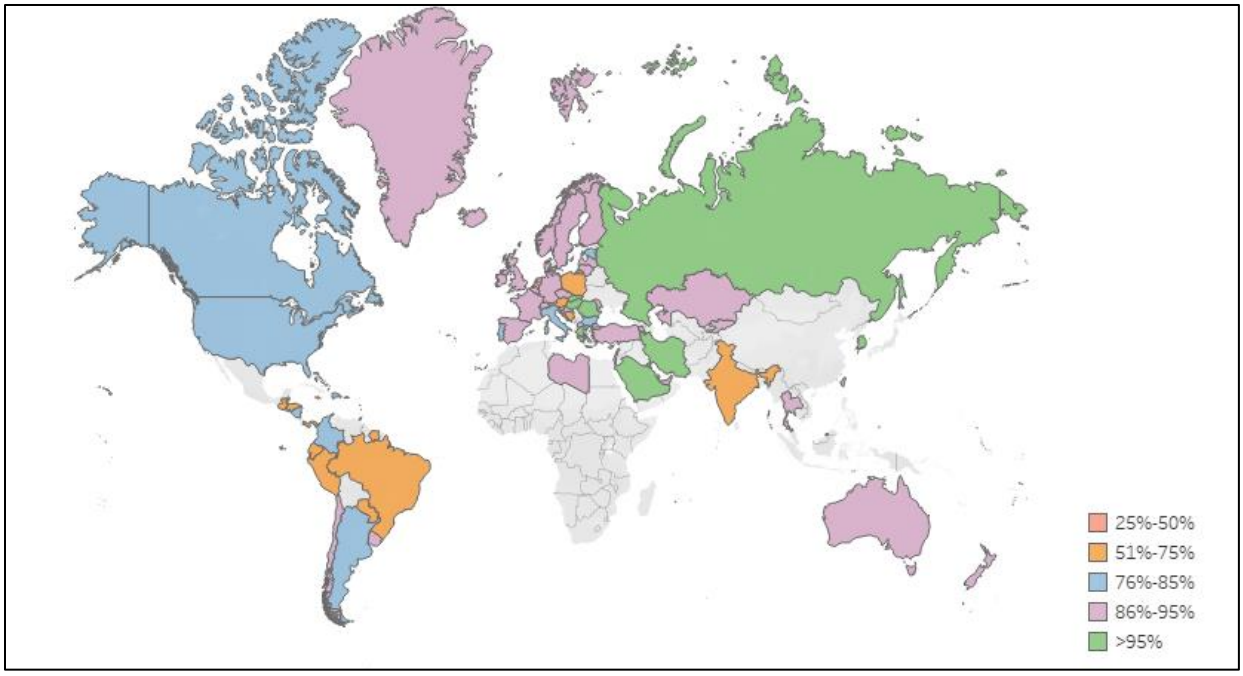

Fig 15: DTP5 immunization rate (WHO Database), 2021

Globally, aP based preschool booster vaccines were administered more in public markets than in private markets. For public markets where aP based preschool booster is supplied through the national immunization schedule, the immunization rate ranges from 75-95% in most of these countries.

For private markets, the immunization rate for aP-based preschool booster vaccines was estimated, based on inputs from expert interviews. Parameters such as private healthcare vaccine trends, and the income status of a country sourced from WHO, are also considered for estimating private aP-based preschool booster vaccine market volumes for some of the countries. The immunization rate for aP based preschool booster vaccines is low in private markets and ranges from 1-49% in most countries.

Among 195 countries, 98 countries do not use preschool booster vaccines in their immunization schedule.

A total of 97 countries are using preschool booster vaccines in their public and private market, either trivalent or tetravalent vaccines. Among these 97 countries, 53 countries are of high-income status, 33 countries are of upper-middle-income status, and 11 countries are of lower-middle-income status.

Immunization Schedule

The number of doses of aP-based preschool booster vaccines suggested under each country's immunization schedule is obtained from the WHO. The schedule is a standard one dose for booster vaccines, hence for all countries, the schedule is considered as a single dose as reported by WHO and national immunization schedules of different countries.

Calculation Of Volumes Of Preschool Vaccine:

The aP-based preschool booster vaccines market volumes were calculated using these parameters—preschool children population, aP preschool booster vaccine immunization rate, and vaccination

schedule. The objective is to find the utilization of aP preschool booster vaccines by region, country, and by individual brand.

Market	Type of Market	Total Countries	Total Volume (Mn)
Preschool Booster	Public	60	12.3
	Private	32	1.8

Table 12: Preschool Booster, Total Countries and Volumes

Step-III: Filtering the top 95% (approximately) markets

The total preschool booster vaccine market of 92 countries constitutes 14.1 Mn. Among 92 countries, 40 countries (34 Public and 6 Private) constitute 95% of the total volumes, equaling 13.5 Mn. These 40 countries are considered for further brand analysis and to understand the brand usage trends of the preschool booster market.

Market	Type of Market	Top 95% Countries	Top 95% Volume (Mn)
Preschool Booster	Public	34	11.9
	Private	6	1.6

Table 13: Preschool Booster Vaccine Market, 95% by Volume

Step-IV: Analyzing brand shares for top vaccine markets

Trivalent or tetravalent combination vaccines are used for preschool booster vaccinations. Several brands exist within each of the vaccine markets and the proportion of each of the brands used in a country is derived through extensive secondary research and studying various approaches. The brand of vaccine that is used more in these 40 countries will be a market leader in the overall aP-based preschool booster vaccine market.

The usage patterns for each brand of vaccines across the target countries are obtained through information gathered from various sources as below-

- National and Regional Tenders
- MOH and National Health Authorities
- Expert Interviews with key members of NIP, medical advisors, university professors, UNICEF members, pediatricians, and immunization researchers

The first step in analyzing brand shares is to segregate the 40 countries into countries having only one brand or having multiple brands of booster vaccines in their market. Among 40 countries, 22 countries have a single brand of vaccine, and only one brand will constitute a 100% share of the market. 18 countries have more than one brand of vaccines and the share of brands in these 18 countries has been analyzed through various approaches.

Market	Top 95% Countries	Single Brand	Multiple Brand
Preschool Booster	40	20	20

Table 14: Countries with only one brand of vaccine and countries with multiple brands

Single Brand – Counties with only one available brand of preschool booster vaccine in their market.

Multiple Brands – Countries with more than one available brand of preschool booster vaccine in their market.

In 20 public markets namely Turkey, Poland, Australia, Kazakhstan, Chile, Russian Federation, the Netherlands, Israel, Romania, Libya, Belgium, Sweden, Czech Republic, Hungary, Portugal, United Arab Emirates (the), Norway, Costa Rica, New Zealand and Ireland only one brand of preschool booster vaccine is administered. For instance, in Turkey[cxv], Poland[cxvi], Romania[cxvii], Belgium[cxviii], Sweden[cxix], Hungary[cxx], Portugal[cxxi], United Arab Emirates (the)[cxxii], Norway[cxxiii], Ireland[cxxiv], and Costa Rica[cxxv] Tetraxim® is the only brand of tetravalent vaccine available and administered. In New Zealand[cxxvi cxxvii], Infanrix-IPV®/Kinrix® is the only booster vaccine and in Australia[cxxviii], Quadracel® is the only preschool booster administered to the target children.

Repevax® is the only brand of preschool booster administered in Israel[cxxix] and Libya[cxxx cxxxi].

Boostrix-IPV® is the only brand of vaccines procured for a preschool booster dose in the Netherlands.[cxxxii cxxxiii]

In five countries namely Saudi Arabia, Spain[cxxxiv], Kazakhstan[cxxxv], and Chile[cxxxvi cxxxvii] Boostrix® is the only brand of preschool booster administered to the target children. Adacel® is the only brand of preschool booster used in Russia[cxxxviii] and the Czech Republic[cxxxix cxl cxli].

National and Regional Tenders

Governmental vaccine procurement departments under the country's MOH generally procure vaccines through national or regional tenders.

National tenders procure preschool booster vaccines (aP based) in the USA, the UK, France, Italy, Spain, Netherlands, Romania, Belgium, and Australia.

The Department of Health and Social Care and Public Health England procured tenders for booster vaccines such as Boostrix-IPV® (tetravalent) and Revaxis® (trivalent) in 2021. Around 50% of the booster vaccines procured are Boostrix-IPV® and the remaining were Revaxis®.[cxlii]

Boostrix-IPV® was the only brand of vaccines procured for a preschool booster dose in the Netherlands in 2021.[cxliii]

In Belgium, the Office of Birth and Childhood procured tenders for booster vaccines. Tetraxim® was the only preschool booster vaccine used in the immunization program in Belgium in 2021.[cxliv]

The French government procured tenders for booster vaccines such as Revaxis® (trivalent) and Tetraxim® (tetravalent). Around 85% of booster vaccines administered in France were Tetraxim® and the remaining was Revaxis® in 2021. [cxlv]

In Italy, vaccines are procured through regional tenders. In 2021 more than 95% of the booster vaccines procured were Tetraxim® (tetravalent) and the remaining was Infanrix-IPV®/Kinrix® (tetravalent).[cxlvi]

In Spain, vaccines are procured through regional tenders. In 2021 the booster vaccine market constituted of Boostrix® (trivalent) and Adacel®(trivalent). Around 80% of the booster vaccines administered in Spain were Boostrix®.[cxlvii]

In Romania, vaccines are procured through national tenders by the MOH. Tetraxim® was the only brand of vaccine procured for a preschool booster dose in Romania in 2021.[cxlviii]

In Taiwan, the MOH and Welfare procured both trivalent vaccines Boostrix® and Adacel® brands of booster vaccines in 2021. Around 65% of the booster vaccine doses procured are of Boostrix® and the remaining market constitutes Adacel®.

In Sweden, Tetraxim® was the only brand of preschool booster vaccine available in 2021. Around 120,000 doses of Tetraxim® are procured in 2021.[cxlix]

Qualitative insights from MOH/NIP resources

The information on brands of aP-based vaccine administered in national immunization schedules in different countries is gathered through authentic secondary sources such as the MOH sites and publications by government health authorities, among related resources.

National Registries and MOH sites provided information on the brand usage of the aP-based preschool booster vaccines in Russia, Poland, Kazakhstan, Taiwan, Chile, Israel, Libya, Hungary, United Arab Emirates, Norway, and New Zealand.

In the Netherlands, vaccines are procured through national tenders by the national institute for public health and the environment (an agency of the Dutch Ministry of Health).

In Canada, both Repevax® and Boostrix-IPV® brands of booster vaccines are procured for public immunization by Health Canada for 11 provinces/territories including Alberta, British Colombia, Saskatchewan, Manitoba, Ontario, New Brunswick, Prince Edward Island, Newfoundland and Labrador, Nova Scotia, Nunavut, and Yukon. Around 74% of booster vaccines administered in Canada are of Repevax® and the remaining market constitutes Boostrix-IPV® in 2021.

Expert insights on vaccine usage patterns

In some countries, especially in countries with private markets, data on vaccine procurement by pharmacies or clinics, and or wholesaler sales data is not publicly accessible. Expert interviews with key members of NIP, medical advisors, university professors, pediatricians, and immunization researchers were conducted for such countries to know the brand utilization.

4. Pediatric Vaccination Trends

Global immunization rate continued to drop in 2021

In 2021, the global immunization rate continued to drop, leaving 25 Mn babies without access to potentially life-saving vaccines. The percentage of newborns who received three doses of the DTP3 declined by 5% between 2019 and 2021. This highlights the rising number of children who face a risk of diseases that are fatal yet preventable.[cl]

Multiple factors contributed to the decline, including an increase in the number of children living in unstable and conflict-ridden environments where getting immunizations is difficult, an increase in misinformation, and COVID-19-related problems like service and supply chain disruptions. [cli] Identifying missed-out children and scheduling catch-up sessions are required to maintain the scheduled routine immunization rate over the next years.[clii]

Reasons for the recent decline in the immunization rate

The recent decline in immunization rate has some complex, multivariate, context-dependent, and even subjective maternal perception factors at effect.[cliii] Inadequate immunization coverage was attributed to some reasons, including low per capita income, mother education, lack of sanitation and prenatal care, more than five children, and accessibility issues to health care services. [cliv]

The decline can be attributed to factors in vaccination supply, such as decreased availability of health workforce, as well as factors in vaccination demand, such as public fear and transportation restrictions. The fact that countries saw more disruption in outreach services than in fixed-post immunization services, suggests that vulnerable groups were likely to have been more severely impacted.[clv]

Since 2000, GAVI has supported the distribution of vaccinations and vaccination services to LIC and LMIC, helping to improve access and reduce disparities in immunization coverage with HIC. However, from 2019 to 2021, countries that transitioned off from GAVI support had a sharper decline in vaccination coverage than GAVI-supported countries, highlighting the fragility of LIC and LMIC.[clvi]

As countries develop economically, they potentially become less eligible for external funding and require increased domestic funding for immunization. In times of crisis, such as during the COVID-19 pandemic, middle-income countries (MIC), which account for an increasing share of unprotected children, might be unable to allocate sufficient resources to immunization programs to ensure that every child receives the available vaccines.[clvii]

There have been global disruptions to routine immunization services as a result of the COVID-19 pandemic. It will take context-specific strategies to overcome immunization gaps by catching up on missed children, giving priority to important health services, and expanding immunization programs to avoid outbreaks, for immunization programs to fully recover.[clviii]

US childhood immunization rates have remained steady despite the global decrease in immunization rates

The WHO's immunization data dashboard and UNICEF's immunization profile for the United States indicated that immunization rates for the majority of immunizations in the USA have remained constant and frequently exceeded global immunization rates between 2019 and 2021, despite significant drops in childhood immunization rates all over the globe. In 2021, around 93% of children received the third dose of the DTaP vaccine, while 92% of children received the third dose of the polio-containing vaccine.[clix]

Various initiatives have been taken to increase the immunization rate

The WHO is trying to implement a variety of strategies to restore immunization programs and close immunity gaps. In January 2021 WHO published strategies and guiding principles for implementing catch-up vaccination and recovering essential immunization services. To enhance the immunization rate in the coming years, WHO and GAVI have taken initiatives such as Immunization Agenda 2030 (IA2030) and GAVI 5.0. [clx] [clxi] The IA2030 aims to identify and eliminate all direct and indirect barriers to vaccination services, including those based on the gender of caregivers and medical professionals. It strives to promote healthy lifestyles and promotes well-being for all people, regardless of age.[clxii]

The significant increase in Vaccination Coverage Rate (VCR) for Middle East Countries

In some Middle Eastern countries, the VCR has shown a significant increase. In Qatar, the Ministry of Public Health launched an annual vaccination campaign against tetanus, diphtheria, and pertussis.[clxiii] In 2021, the DTP3 immunization rate in Qatar increased to 98% compared to 82% in 2020, and 81% global average DTP3 rate in 2021. [clxiv] Also, in the United Arab Emirates, the DTP3 rate increased to 96% in 2021 compared to 90% in 2020.

Centralized Procurement of Vaccines and Medicines

The public procurement policies are being revised by countries, particularly for pharmaceuticals and biologicals. This trend is growing to enhance purchasing power, improve health outcomes, provide greater transparency, manage therapeutic freedom, encourage innovation, and reduce costs. For instance, in Canada, Quebec and Ontario have both recently announced an intention to move to a centralized procurement model for all government and broader public sector institutions.[clxv] Also, some European nations have implemented centralized procurement for vaccines and medicines.[clxvi]

Shift to Hexavalent Vaccine

HIC are completely shifting from pentavalent to hexavalent vaccines by removing pentavalent vaccines from their national immunization schedule. For instance, Switzerland, Slovenia, Malaysia and Malta have shifted completely to hexavalent vaccines. In 2019, the government of Malta decided to switch from the pentavalent to the hexavalent vaccine[clxvii] and this was implemented in 2021 in the NIP.[clxviii] By switching to the hexavalent vaccine and according to the guidelines outlined in the tender specifications, the Medical Authorities were taking the least amount of risk.[clxix] In 2020, Malaysia has implemented the usage of hexavalent vaccine to reduce side effects and considering the milder adverse effects with the usage of these vaccines.[clxx]

MIC are increasingly adopting hexavalent vaccines in their national immunization schedule. For instance, two UMIC such as South Africa and Mauritius in the AFR, have introduced hexavalent vaccines in their NIP. South Africa was the first country in the AFR to replace the pentavalent vaccine and adopt hexavalent vaccines in 2015, followed by Mauritius in 2017, and Malta in 2021. Other MIC, including

Mexico, Saudi Arabia, Panama, Gulf countries, and Jordan, have also included hexavalent vaccines in their NIP. The USA and Algeria have included the hexavalent vaccine in its national immunization program in 2021. Algeria is yet to implement the usage in the public market.

Qatar and Chile Shift from whole cell pertussis to acellular pertussis vaccine (wP to aP)

In 2021, the ministry of public health of Qatar shifted to the aP pentavalent vaccine **(**DTaP-Hib-HepB) from wP pentavalent vaccine.[clxxi] Due to the safety profile of the aP vaccine, they can be offered to wider population groups.[clxxii] Before 2018, primary DTP immunization in Chile was carried out using a pentavalent vaccine that contained a wP component. In 2019, the Chilean Ministry of Health introduced hexavalent aP vaccines for the primary vaccination series. A study showed that AEFI (adverse events following immunization) have been declining as a result of this change, achieving the lowest frequency of side effects.[clxxiii]

Increased availability of Vaxelis® in the USA

In the CDC's Recommended Child and Adolescent Immunization Schedule, Vaxelis® was added as a combination vaccination option on February 11, 2021, by the US-CDC and Prevention's Advisory Committee. FDA licensed the Hexavalent vaccine (Vaxelis®) in 2018 for use in children of age six weeks through four years.[clxxiv] Vaxelis® is the first and only hexavalent (six-in-one) combination vaccine available in the USA and can be accessed via traditional public and private channels.[clxxv] In the coming years, Vaxelis® will be readily available in many countries all across the globe.[clxxvi]

Vaccination Coverage Rate (VCR) from 2019-2021

In 2021, around 18.2 Mn infants (73%) had received no doses, and 6.8 Mn (27%) were incompletely vaccinated with DTP. Among 18.2 Mn zero-dose children in 2021, LIC accounted for 5 Mn (27%), whereas MIC had the largest number (12.8 Mn; 70%).[clxxvii]

In 2021, DTPcv1 (first dose) coverage varied from 97% in the EUR to 80% in the WHO African Region (AFR). DTPcv3 (third dose) coverage followed comparable regional patterns. The South-East Asia Region (SEAR) saw the largest decrease in first and third-dose DTPcv coverage between 2019 and 2021 (from 94-86% for DTPcv1 and from 91-82% for DTPcv3). Between 2019 and 2021, DTPcv1 and DTPcv3 coverage in the Americas declined by 3 and 4 percentage points, respectively.[clxxviii]

In 2021, of the 25 Mn infants with no access to immunization, more than 60% of these children live in 10 countries: India (2.7 Mn), Nigeria (2.2 Mn), Indonesia (1.1 Mn), Ethiopia (1.1 Mn), Philippines (1 Mn), the Democratic Republic of the Congo (0.73 Mn), Brazil (0.71 Mn), Pakistan (0.61 Mn), Angola (0.55 Mn), and Burma (0.49 Mn).[clxxix]

Approximately 12 Mn zero-dose children (69% of the global total) lived in GAVI-eligible countries. DTPcv3 coverage declined sharply in 17 countries that transitioned out of GAVI support.[clxxx]

Myanmar and Mozambique are two of the nations that saw the largest relative increases in the number of children who did not receive a single vaccine between 2019 and 2021.[clxxxi]

Every region saw a decrease in vaccination rates, but East Asia and the Pacific saw the largest decline in DTP3 coverage, dropping nine percentage points in just two years. The sharp two-year decline follows almost a decade of stagnant progress, highlighting the need to address both systematic

immunization issues as well as disruptions caused by the pandemic to ensure that every child and adult is fully vaccinated.[clxxxii]

Increased vaccinations for catch-up doses in 2021

The routine vaccination coverage rate was significantly decreased due to the pandemic. Multiple studies were conducted to understand the change in VCR before and after the pandemic.[clxxxiii] Associations such as GAVI and CDC have recommended countries to implement catch-up vaccination plans in order to prioritize routine vaccines.[clxxxiv] As a result, countries such as Mexico, Canada, and South Africa showed slightly higher DTP 3 vaccination coverage rates in 2021.[clxxxv] [clxxxvi]

Impact of covid-19 on routine vaccination for migrant babies

Migrants and refugees are particularly vulnerable to the impact of COVID-19 in the wider community.[clxxxvii] Recently, WHO released a report on "Ensuring the integration of refugees and migrants in immunization policies, planning and service delivery globally". This report provides an overview of existing policies on inclusion of refugees and migrants in vaccine national plans and their implementation across countries and regions globally.[clxxxviii] The WHO has advised countries to ensure that their national policies and immunization programs include plans and processes for delivering catch-up vaccinations to refugees and migrants of all ages, including targeted catch-up for children, adolescents, and adults throughout the migration journey.[clxxxix]

Recommendations from SLIPE in LATAM

In Latin America, to curb the risk of poliomyelitis outbreak, SLIPE (Latin American Society of Pediatric Infectious Diseases) commissioned experts to recommend the inclusion of either complete IPV based schedules or schedules including at least two initial doses of IPV in their NIP. The first Regional Experts on Infant Vaccination (REIV) meeting provided updated recommendations to improve the control of various major vaccine preventable diseases (VPD). REIV highlighted the recent changes in immunization schedules in the countries within the region and the experience of incorporating combined acellular pertussis vaccines schedules and advised immediate adoption of either complete IPV based schedules or schedules including at least two initial doses of IPV. Incorporation of combined vaccines (CV) was considered potentially advantageous.[cxc]

Recommendations from WHO

To enhance the immunization rate in the coming years, the WHO has taken initiatives such as IA2030. Expanding immunization services to reach zero-dose and incompletely vaccinated children and reducing immunization inequities are key objectives of the IA2030.[cxci]

To avoid any vaccine doses from being missed, a sustained catch-up campaign seems to be necessary, especially in LIC, as a result of the vaccination rate decrease during the COVID pandemic.

It is advised to make the immunization process easier by reducing the wait time at the health facility, addressing parents' fears and worries about COVID infection, increasing vaccine supply, and encouraging access in distant locations. To stop future pandemics of illnesses that can be prevented by vaccination, countries should assure proper immunization.[cxcii]

Recommendations from SAGE

As vaccine supplies increase, the WHO regional offices and partner organizations are assisting countries in becoming ready to face current operational challenges and scaling up vaccination to achieve the target of 70% coverage by June 2022.

All the regions have developed or are in the process of developing action plans to implement the IA2030 in their respective regions. This will provide a chance to accelerate the recovery process and boost the resilience of vaccination campaigns.

SAGE advised the systematic gathering and use of data on BeSD ('Behavioural and social drivers of vaccine uptake) to analyze the reasons for low uptake and regular trend monitoring. [cxciii]

Recommendations from CDC

Maternal Tdap immunization helps safeguard newborns and infants, who are most at risk of developing pertussis and its potentially fatal consequences. The CDC suggests vaccinating pregnant women with both the Tdap and flu vaccines at the same time.[cxciv]

Immunization during pregnancy is a relatively new strategy where delivery of vaccines in the second or third trimester to pregnant women protects the fetus, and subsequently, to the newborn through the trans-placental transfer of maternal antibodies.

The potential role of maternal immunization in protecting newborn infants has been made evident by maternal tetanus vaccination contributing to the lower incidence rates of neonatal tetanus. To increase maternal vaccination, several measures have been implemented. For instance, the WHO's Maternal and Neonatal Tetanus Elimination (MNTE) program.[cxcv]

A study conducted in 2021 in Italy, showed that multi-professional training is essential to make Obstetricians-gynecologists and Midwives more confident in recommending TdaP maternal immunization.[cxcvi]

5. Findings and Discussions

This section enumerates the findings and provides an in-depth analysis of the DTaP global vaccine study.

DTP Vaccine Market Analysis

The global DTP-based combination vaccine market includes volume usage of the DTP vaccine. DTP vaccines include a wP (DTwP) or aP antigen (DTaP). These DTP-based vaccines serve as the backbone of several other combination vaccines such as tetravalent, pentavalent, and hexavalent vaccines.

The DTP vaccine usage volume was analyzed by estimating the three indicators, namely vaccine immunization schedules, immunization rate, and population of surviving infants and preschool age (three to seven years), for all the target countries, across the globe, in 2021.

DTP Vaccine Market and Volume

The DTP vaccines market consists of DTwP and DTaP vaccines. The figure below represents the split of the DTwP and DTaP vaccines by country.

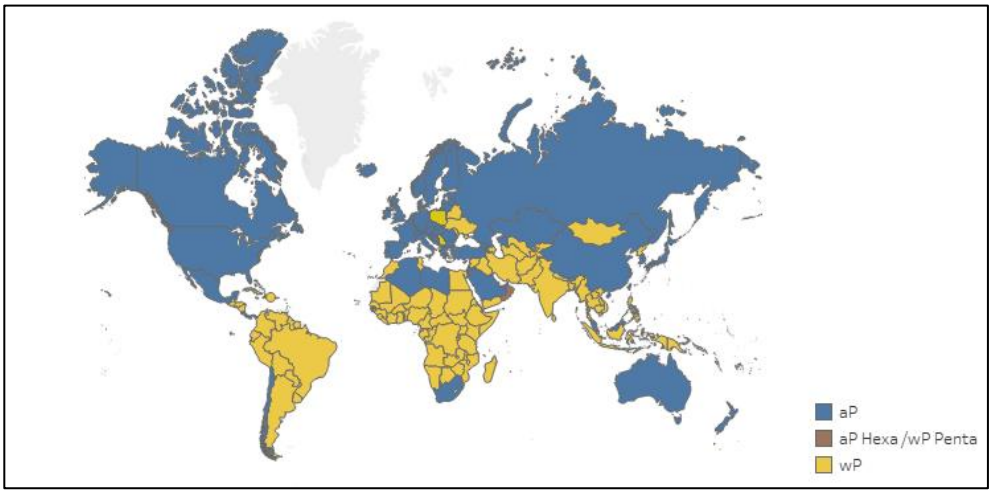

Fig 16: Countries including aP and wP vaccines in their national immunization schedule, 2021

Among the 195 countries (194 WHO countries + Taiwan), 119 countries have DTwP combination vaccines and 76 countries have DTaP combination vaccines in their national immunization schedule.

Among the 76 countries using DTaP combination vaccines, 54 are HIC. There are only three LMIC: Algeria, Bhutan, and Micronesia, using DTaP combination vaccines in their national immunization schedules. 19 UMIC are using these vaccines.

Most of the EUR countries use aP vaccines. For instance, in Europe, among 53 countries (according to WHO classification) 44 countries are using DTaP combination vaccines in their national immunization schedule. Only South Africa among the African countries, use DTaP vaccines in public immunization. Algeria has also included the DTaP vaccine in their national immunization schedule but has not yet been implemented in practice.

DTaP-based combination vaccines are more expensive than DTwP vaccines. Pooled procurement agencies such as UNICEF supported by GAVI funding procures pentavalent vaccines with wP components for supply to LIC and MIC. Also, developing countries that procure by self-financing methods procure wP-based DTP combination vaccines for supply in their countries.

DTaP vaccines are supplied to the public by governments of UMIC and HIC or administered in private markets in some HIC and MIC funded through out-of-pocket expenditure.

The above reasons explain the usage of higher volumes of DTwP vaccines than DTaP combination vaccines. There is increasing adoption of DTaP-based combination vaccines, especially hexavalent vaccines in MIC. This can be attributed to low reactogenicity and the ease of use of these vaccines.

Although, the initial cost of implementing hexavalent vaccines through NIP are high, however, there are significant cost savings through the implementation of these vaccines in NIP.

In 2021, of the total DTP combination vaccines market was estimated to be 413.3 Mn doses. The DTwP combination vaccines market was estimated for 119 WHO countries using these vaccines as primary or booster series. The volume was calculated using the demand side approach considering the three indicators namely surviving infant population, immunization rate and the number of doses of vaccine administered as per the immunization schedule of each country.

DTwP and DTaP combination vaccines had a share of 70% (288.7 Mn doses) and 30% (124.6 Mn doses) respectively.

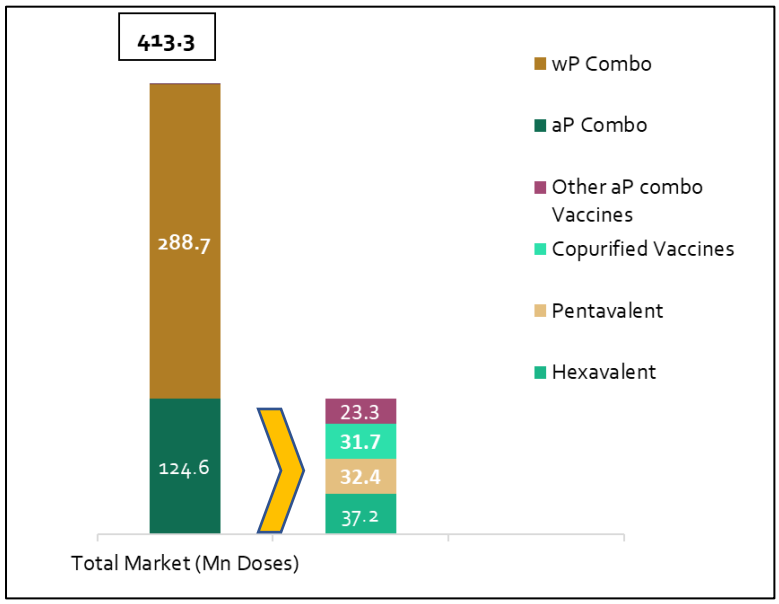

Fig 17: aP and wP Vaccine Volume Split

Among the 124.6 Mn DTaP vaccines, in 2021, the global demand for the hexavalent vaccine was 37.2 Mn doses, pentavalent vaccines were 32.4 Mn doses, other aP combination vaccines were 23.3 Mn doses and the copurified vaccines was 31.7 Mn doses. The other aP combo vaccines include trivalent and tetravalent primary and booster series vaccines. The copurified vaccines marketed exclsively in China and Japan are excluded from this study. The high share of hexavalent vaccines among DTaP-based vaccines can be attributed to the increased adoption of hexavalent vaccines by HIC, particularly European countries in their NIPs.

Hexavalent Vaccine Market Analysis

A hexavalent vaccine (DTaP-IPV- HepB-Hib) is a six-in-one vaccine that protects infants against diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenza type b and hepatitis B. The section below enumerates the findings by volume analysis and brand analysis for type of market, region, and country.

Brand Shares

The brand share of the three brands of hexavalent vaccine is given in Figure 18. In 2021, **Hexaxim® has the highest share of the hexavalent vaccines market by volume with 68% (24 Mn), followed by Infanrix Hexa® with 24.1% (8.5 Mn), and Vaxelis® with 7.9% (2.8 Mn).**

The brand share of the three brands of hexavalent vaccine for the preterm market is given in Figure 19. In 2021, Hexaxim® has the highest share of the hexavalent vaccines preterm market by volume with 73% (2.1 Mn), followed by Infanrix Hexa® with 18.5% (0.5 Mn), and Vaxelis® with 8.5% (0.2 Mn).

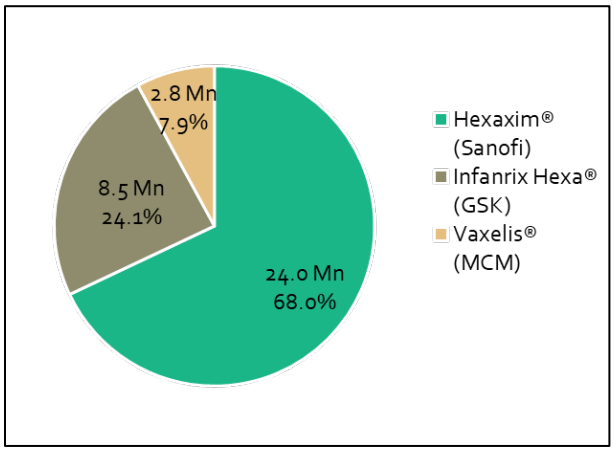

Fig 18: Brand proportion of hexavalent vaccines, 2021

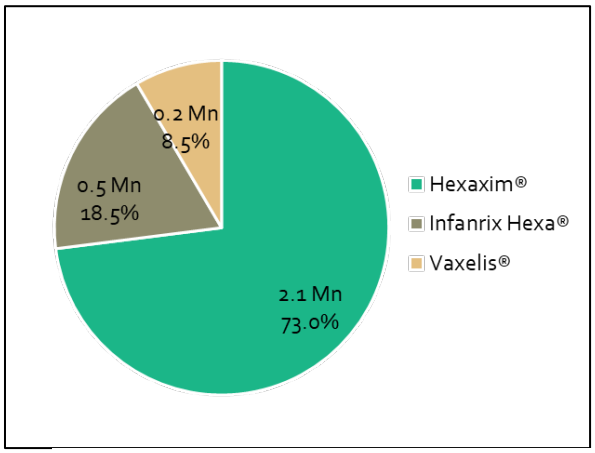

Fig 19: Brand proportion of hexavalent vaccines, preterm market, 2021

Volume Analysis

By Public And Private Markets

The administration of the hexavalent vaccines is split into public and private markets based on their inclusion in the immunization schedule of the country and government supply. The countries with an aP-based hexavalent vaccine in their national immunization schedule were designated public markets whereas countries, where hexavalent vaccines are given by private practitioners and not included in the national immunization, were designated as private markets.

Hexavalent vaccines were included in the NIP of many HIC and UMIC, due to the strong public immunization financing in these countries. The higher cost of hexavalent vaccines is a hindrance to the supply of these vaccines in LIC and MIC.

Of the 41 countries using hexavalent vaccines, 30 countries are public markets and 11 countries are private markets. **In 2021, of the 35.3 Mn doses of hexavalent vaccines administered, 26.5 Mn doses (75.1%) of hexavalent vaccines were administered in public markets and 8.8 Mn doses (24.9%) were administered in private markets.** (See Figure 20).

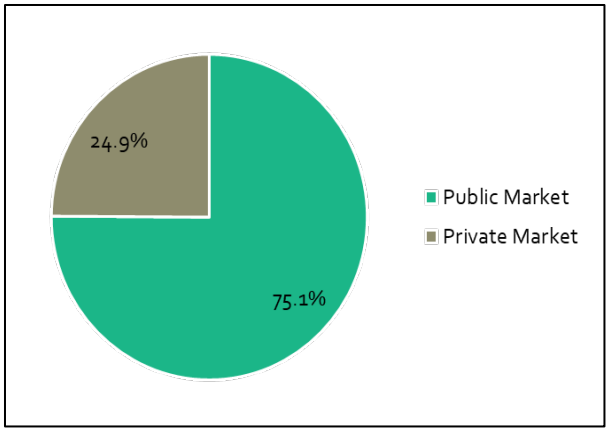

Fig 20: Volume split by public and private market, 2021

By Region

This section enumerates the vaccine volume analysis by region. Regions mentioned according to the WHO countries' classification used for analysis by region are enumerated in Table 15.

In 2021 the EUR accounted for the major share of the hexavalent vaccines market by volume at 37.1% (13.1 Mn), followed by the AMR with 24.1% (8.5 Mn), the Western Pacific Region (WPR) with 14.1% (5 Mn), the AFR with 11.8% (4.2 Mn), the Eastern Mediterranean Region (EMR) with 8.4% (3 Mn), and the SEAR with 4.6% (1.6 Mn) of the hexavalent vaccine market.

The high share of hexavalent vaccine used in the EUR can be attributed to the increased approval and adoption of these vaccines since 2001. In 2021, Germany and France each used around two million doses of the hexavalent vaccine. The UK and Italy, each used more than one million doses of the hexavalent vaccine.

Some EUR countries, such as Italy, France, and Romania, adopted policy changes and enforced mandatory vaccination to protect the community when vaccination coverage levels were at risk. In France, the use of hexavalent vaccines is mandatory for children born on January 1st, 2018.

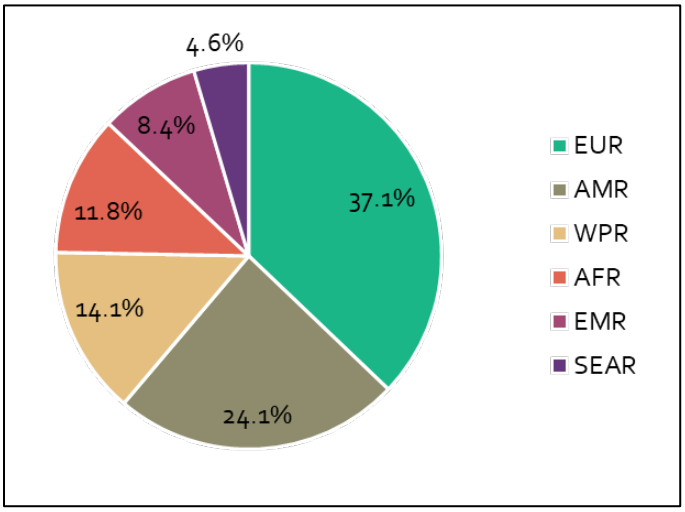

Fig 21: Hexavalent vaccine volume analysis, by region, 2021

Abbreviation	EUR	AMR	WPR	AFR	EMR	SEAR
Region	European Region	American Region	Western-Pacific Region	African Region	Eastern Mediterranean Region	South-East-Asia Region

Table 15: Abbreviations of regions classified as per WHO, 2021 (Refer to Table 33 in Appendix for countries included in each region)

In the AMR, five countries, namely Mexico, Chile, the USA, Canada, and Panama have included hexavalent vaccines in their national immunization schedules. The low use of hexavalent vaccines in the AMR compared to the EUR can be attributed to the use of hexavalent vaccines only in special situations in some countries. In 2021, 6.2 Mn doses of hexavalent vaccines were used in Mexico, while Chile and the USA used 0.9 and 0.5 Mn doses of hexavalent vaccines respectively.

In the WPR, three countries namely Malaysia, Australia, and New Zealand, have hexavalent vaccines in their immunization schedule.

In the AFR, South Africa was the first country to introduce hexavalent vaccines in its immunization schedule, replacing the pentavalent and HepB Vaccines.[cxcvii] More than 95% of hexavalent vaccine volumes used in Africa are in South Africa.

In the EMR, Saudi Arabia, Jordan, and Libya are the major countries using hexavalent vaccines. In 2021, around 1.8 Mn doses of hexavalent vaccines were used in Saudi Arabia, while Jordan and Libya used 0.6 and 0.2 Mn doses of hexavalent vaccines respectively.

By Country

In 2021, 35.3 Mn doses of hexavalent vaccines were used by 41 countries, of which Mexico had the highest usage of hexavalent vaccines 17.6% (6.2 Mn doses), while Georgia had the lowest usage of 0.4% (0.1 Mn doses).

In public markets, the top three countries with high volumes of hexavalent vaccines include Mexico, South Africa, and Malaysia.

In private markets, the top three countries with high volumes of hexavalent vaccine usage include Germany, France, and Vietnam.

Although Germany and France have high immunization rates, they are included in the private market because of the need for healthcare professional (HCP) prescriptions for administering vaccines. In Germany, the vaccines are reimbursed under the social security reimbursement program, whereas in France, the vaccines are reimbursed by the primary health insurance fund (CPAM- Caisse Primaire d'Assurances Maladie).

Brand Analysis

By Public And Private Markets

There are three hexavalent vaccine preparations commercially available for administration to infants; namely Hexaxim®/Hexyon®/Hexacima® (Sanofi), Infanrix Hexa® (GSK), and Vaxelis® (MCM). The hexavalent vaccine volumes were analyzed in both public and private markets for these three brands.

Hexaxim® (24 Mn doses) is the most-used hexavalent vaccine in public and private markets, followed by Infanrix Hexa® (8.5 Mn doses), and Vaxelis® (2.8 Mn doses) the least-used brand in the public and private market of hexavalent vaccines.

Hexavalent Vaccine	Public Market (Volume, Mn)	Private Market (Volume, Mn)
Hexaxim®	19.5	4.5
Infanrix Hexa®	4.7	3.8
Vaxelis®	2.3	0.5

Table 16: Brand analysis of hexavalent vaccines, by public and private markets, 2021

By Region

Analysis of the brand proportion by region are detailed below. Regions mentioned according to the WHO countries' classification used for analysis by region are enumerated in Table 17.

The brand proportion for Hexaxim®, Infanrix Hexa®, and Vaxelis® by region is given below in Figure 22.

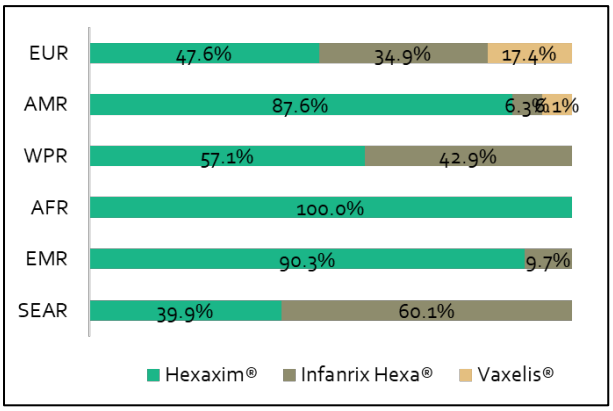

Fig 22: Brand proportion of hexavalent vaccine, by region, 2021

Abbreviation	EUR	AMR	WPR	AFR	EMR	SEAR
Region	European Region	American Region	Western-Pacific Region	African Region	Eastern Mediterranean Region	South-East-Asia Region

Table 17: Abbreviations of regions classified as per WHO, 2021 (Refer to Table 33 in Appendix for countries included in each region)

In 2021, 21 countries in the EUR used 13.1 Mn doses of hexavalent vaccines. Among these hexavalent vaccine doses, 47.6% are Hexaxim®, 34.9% are Infanrix Hexa®, and 17.4% are Vaxelis®.

In 2021, six countries in the AMR (Mexico, Chile, the USA, Canada, Brazil, and Panama) used 8.5 Mn doses of hexavalent vaccine in which Hexaxim® is the most used hexavalent vaccine (87.6%) followed by Infanrix Hexa® (6.3%), and Vaxelis® (6.1%).

In 2021, five countries in the WPR (Malaysia, Vietnam, Australia, Philippines, and New Zealand) used 5 Mn doses of hexavalent vaccines in which Hexaxim® (57.1%) is the most used vaccine followed by Infanrix Hexa® (42.9%).

In 2021, in the AFR, South Africa is the only country using the Hexavalent vaccine. The AFR used 4.2 Mn hexavalent vaccine doses in which Hexaxim® is the only vaccine being used under South Africa's national immunization schedule.

In 2021, five countries in the EMR (Saudi Arabia, Jordan, Libya, UAE, and Oman) used 3 Mn doses of the hexavalent vaccine in which Hexaxim® (90.3%) is the most used hexavalent vaccine followed by Infanrix Hexa® (9.7%).

In 2021, three countries in the SEAR (India, Indonesia, and Thailand) used 1.6 Mn doses of aP-based preschool booster vaccines of which Hexaxim® (39.9%) is the most used vaccine, followed by Infanrix Hexa® (60.1%).

By Country

This section enumerates the analysis of the vaccine brands by country.

In 12 public markets, namely Mexico, South Africa, Chile, Kazakhstan, Jordan, Belgium, Sweden, Libya, Austria, Panama, Oman, and Georgia, Hexaxim® is the only brand used in their national immunization program.

In six public markets, namely the UK, Australia, Canada, New Zealand, Ireland and Norway, Infanrix Hexa® is the only brand used in their national immunization program.

Vaxelis® was approved in the EU in 2016 and was launched in seven European countries: Germany, France, Italy, Spain, Greece, Switzerland and the Netherlands. Of the total hexavalent vaccine doses used, Vaxelis® is the only vaccine used in the USA and the Netherlands, 40% in Switzerland, 35% in Italy, 15% in Germany, 7% in France, and 10% in Greece, in 2021.

In preterm infants, Hexaxim® is the only vaccine used in 12 countries, including 5 countries in Europe: Kazakhstan, Belgium, Sweden, Austria, and Georgia. [cxcviii]

Market Share By Manufacturer

Sanofi and GSK are the major manufacturers of hexavalent vaccines. Sanofi's hexavalent vaccines include Hexaxim® Hexyon®/Hexacima® (DTaP-Hib-HepB-IPV). GSK's hexavalent vaccine is Infanrix Hexa® (DTaP-Hib-HepB-IPV), while Vaxelis® (DTaP-Hib-HepB-IPV) is manufactured by MCM.

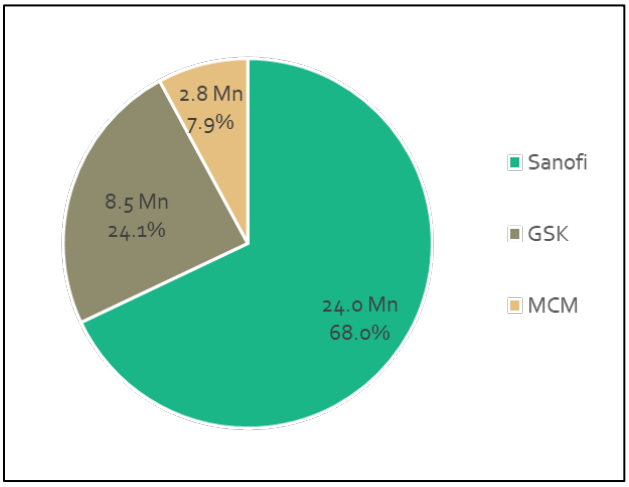

Fig 23: Hexavalent vaccine market share by manufacturer, 2021

Among the 41 countries, Sanofi has a 68% market share in the hexavalent vaccines market, whereas GSK has a 24.1% market share and MCM has an 7.9% share of the market. The high market share for Sanofi can be attributed to the sole use of Hexaxim® in many public markets.

Pentavalent Vaccine Market Analysis

A pentavalent vaccine (DTaP- IPV-Hib) is a five-in-one vaccine that protects infants against diphtheria, tetanus, pertussis, poliomyelitis, and Haemophilus influenza type b. The section below enumerates the findings by type of market, region, and country for the pentavalent vaccine volumes and brand proportions.

Brand Shares

The brand share of five brands of pentavalent vaccine is given in Figure 24. **In 2021, Pentaxim® has the highest share of the pentavalent vaccines market by volume with 60.8% (18.7 Mn), followed by Pentacel® with 20.6% (6.4 Mn), Pediarix® with 14.9% (4.6 Mn), Pediacel® with 2.5% (0.8 Mn) and Infanrix Penta® with 1.1% (0.4 Mn).**

The brand share of the five brands of pentavalent vaccine for the preterm market is given in Figure 25. In 2021, Pentacel® has the highest share of the pentavalent vaccines preterm market by volume with 53.7% (1.5 Mn), followed by Pentaxim® with 43.6% (1.2 Mn), and Pediacel® and Infanrix Penta® with 2.1% (0.06 Mn) and 0.6% (0.02 Mn) respectively.

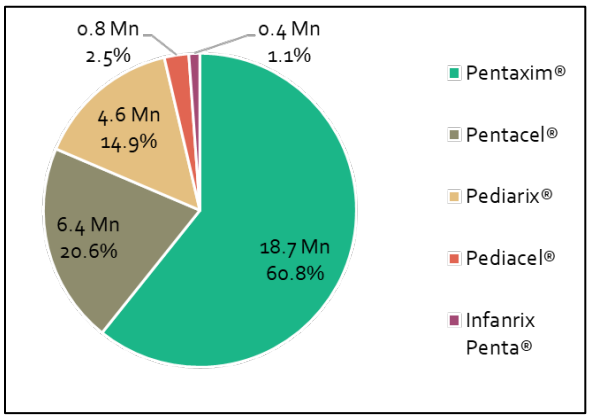

Fig 24: Brand proportion of Pentavalent vaccine, 2021

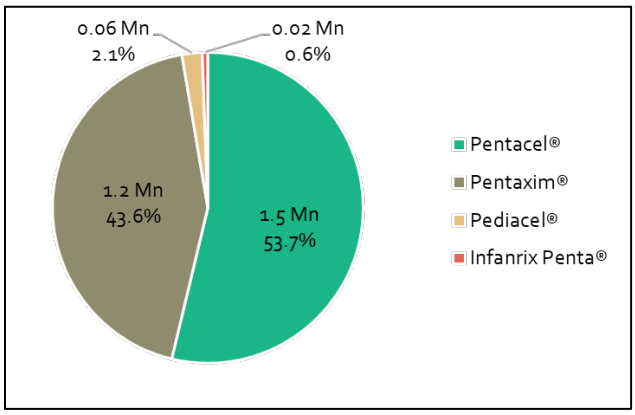

Fig 25: Brand proportion of pentavalent vaccines, preterm market, 2021

Volume Analysis

By Public And Private Markets

The usage of the pentavalent vaccines is split into public and private markets based on their inclusion in the immunization schedule of the country and government supply. The countries with an aP-based pentavalent vaccine in their national immunization schedule were designated public markets whereas countries, where pentavalent vaccines are given by private practitioners and not included in the national immunization, were designated as private markets.

Of the 16 countries using the pentavalent vaccines, 11 countries are public markets and 5 countries are private markets. **In 2021, of the 30.8 Mn doses of pentavalent vaccines administered, 79.9% (24.6 Mn**

doses) were administered in public markets, and 20.1% (6.2 Mn doses) were administered in private markets (see Figure 26).

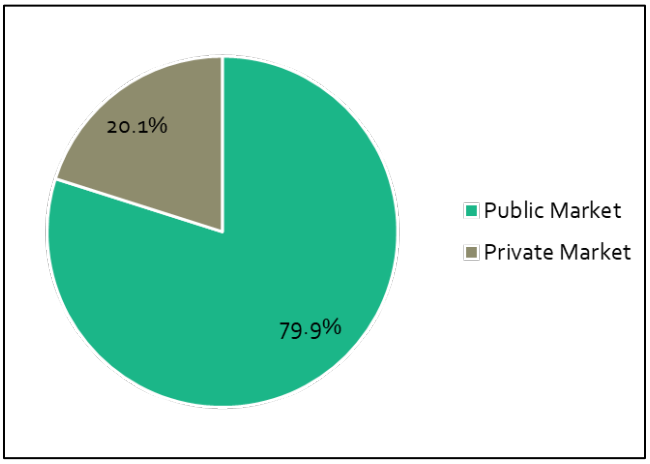

Fig 26: Volume split by public and private Markets, 2021

By Region

This section enumerates the vaccine volume analysis by region. Regions mentioned according to the WHO countries' classification used for analysis by region are enumerated in Table 18.

In 2021, the AMR accounted for the major share of the pentavalent vaccine market by volume with 38.9% (12 Mn), followed by the EUR with 37% (11.4 Mn), the WPR with 22.6% (7 Mn), and the SEAR with 1.5% (0.5 Mn). The high share in both the AMR and the EUR is due to most European and American countries' early approval and adoption of pentavalent vaccines.

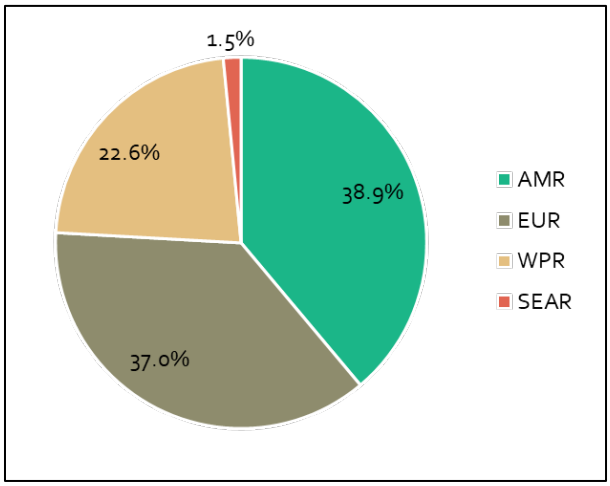

Fig 27: Pentavalent vaccine volume analysis by region, 2021

Abbreviation	AMR	EUR	WPR	SEAR
Region	American Region	European Region	Western-Pacific Region	South-East-Asia Region

Table 18: Abbreviations of regions classified as per WHO, 2021 (Refer to Table 33 in Appendix for countries included in each region)

In the AMR, the USA, Canada, and Costa Rica have included pentavalent vaccines in their national immunization schedules. The high usage of pentavalent vaccines in the AMR can be attributed to the use of aP-based pentavalent vaccines in the USA. In 2021, 11 Mn doses of pentavalent vaccines were administered in the USA.

In the EUR, 2021, Turkey, Russia, Kazakhstan, Israel, Hungary, and Serbia have included pentavalent vaccines in their national immunization schedules. Turkey and Russia each used around 5 Mn and 4 Mn doses respectively, and Kazakhstan and Israel used more than half a Mn doses of pentavalent vaccines. Hungary and Serbia used more than 0.4 Mn and 0.2 Mn doses, respectively.

In the WPR, South Korea and Taiwan have pentavalent vaccines in their immunization schedule. South Korea and Taiwan each used more than 0.7 Mn doses of the pentavalent vaccine.

In the SEAR, pentavalent vaccines are available only through private markets. Among those private markets in this region, India used 0.3 Mn doses of pentavalent vaccine in 2021.

By Country

In 2021, 30.8 Mn doses of pentavalent vaccines were used by 16 countries, of which the USA had the highest usage of pentavalent vaccines 35.6% (11 Mn doses) while Thailand had the lowest usage of (0.7%) 0.2 Mn doses of the global pentavalent vaccines used.

In public markets, the top three countries with high volumes of pentavalent vaccines include the USA, Turkey, and Russia.

The top three countries with high volumes of pentavalent vaccine usage in private markets include China, Poland, and India. Although China has an aP-based trivalent vaccine for the primary series in its immunization schedule, pentavalent vaccines have high demand in their private market. In 2021, China used 5.1 Mn doses of pentavalent vaccines through private channels.

Brand Analysis

By Public And Private Markets

There is five aP based pentavalent vaccine preparations commercially available for administration to children; namely Pentaxim®, Pentacel®, Pediacel® (Sanofi), Infanrix Penta®, and Pediarix® (GSK). They are all DTaP-IPV-Hib vaccines except Pediarix® DTaP-IPV-HepB. The pentavalent vaccine volumes are analyzed in both public and private markets for these brands.

Pentaxim® (18.7 Mn doses) is the most used pentavalent vaccine, followed by Pentacel® (6.4 Mn doses), Pediarix® (4.6 Mn doses), Pediacel® (0.8 Mn doses), and Infanrix Penta® (0.4 Mn doses). Pentacel®, Pediarix®, and Pediacel® are available only in the public market whereas Pentaxim® and Infanrix Penta® are available in both public and private markets.

Pentavalent Vaccine	Public Market (Volume, Mn)	Private Market (Volume, Mn)
Pentaxim®	12.7	6
Pentacel®	6.4	0
Pediarix®	4.6	0
Pediacel®	0.8	0

Infanrix Penta®	0.2	0.2

Table 19: Brand analysis by public and private markets, 2021

By Region

Analysis of the brand proportion by region are detailed below. Regions mentioned according to the WHO countries' classification used for analysis by region are enumerated in Table 20.

The brand proportion for Pentaxim®, Pentacel®, Pediacel®, Infanrix Penta®, and Pediarix® by regions is given in Figure 28.

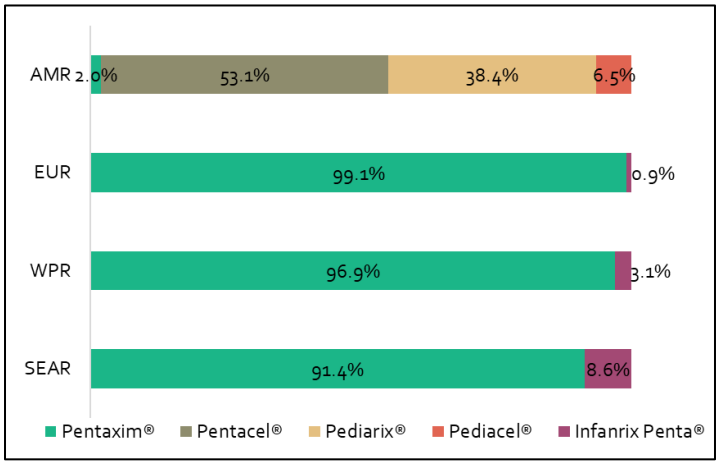

Fig 28: Brand proportion by region, 2021

Abbreviation	AMR	EUR	WPR	SEAR
Region	American Region	European Region	Western-Pacific Region	South-East-Asia Region

Table 20: Abbreviations of regions classified as per WHO, 2021 (Refer to Table 33 in Appendix for countries included in each region)

In 2021, three countries in the AMR (the USA, Canada, and Costa Rica) used 12 Mn pentavalent vaccine doses in which Pentacel® (53.1%) is the most used pentavalent vaccine, followed by Pediarix® (38.4%), Pediacel® (6.5%) and Pentaxim® (2%).

In 2021, seven countries in the EUR (Turkey, Russia, Kazakhstan, Israel, Hungary, Poland, and Serbia) used 11.4 Mn doses of pentavalent vaccines. Among these pentavalent vaccine doses, 99.1% are Pentaxim® and 0.9% are Infanrix Penta®.

In 2021, four countries in the WPR (China, South Korea, Taiwan, and Vietnam) used 7 Mn doses of pentavalent vaccines, of which Pentaxim® (96.9%) is the most used vaccine, followed by Infanrix Penta® (3.1%). The high share of Pentaxim® in this region can be attributed to China and Taiwan using only Pentaxim® in their national immunization schedule.

In 2021, two countries in the SEAR (India and Thailand) used 0.5 Mn doses of pentavalent vaccines, of which Pentaxim® (91.4%) was the most used vaccine, followed by Infanrix Penta® (8.6%). This can be attributed to India using solely Pentaxim® in their private market.

By Country

This section enumerates the analysis of the vaccine brands by country.

In 10 markets (8 public and 2 private), namely those of Turkey, Russia, Kazakhstan, Taiwan, Israel, Hungary, Serbia, Costa Rica, China, and India Pentaxim® is the only brand used in their national immunization schedule.

In Canada, Pediacel® is the only brand used in their national immunization schedule. Pentacel® and Pediarix® vaccines are used in the USA. In the USA, although Pentacel® and Pediarix® are recommended to use in term infants as per the national immunization program, only Pentacel® is used in preterm infants (according to the CDC).[cxcix]

Market Share By Manufacturer

Sanofi and GSK are the major manufacturers of pentavalent vaccines. Sanofi's pentavalent vaccines include Pentaxim® (DTaP-Hib-IPV), Pentacel® (DTaP-Hib-IPV), and Pediacel® (DTaP-Hib-IPV). GSK's pentavalent vaccines include Infanrix Penta® (DTaP-Hib B-IPV) and Pediarix® (DTaP-HepB-IPV).

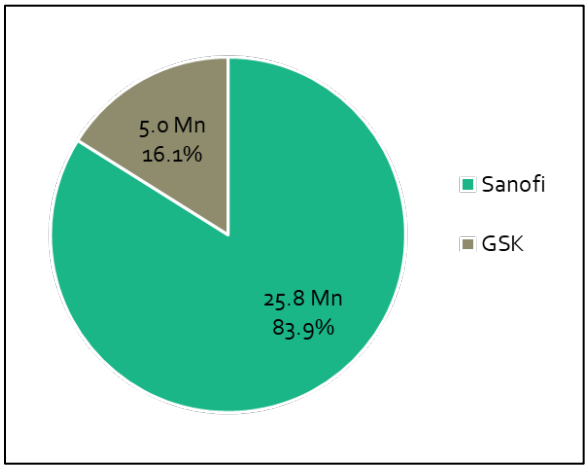

Fig 29: Pentavalent vaccine market share by manufacturer, 2021

Among the 16 countries, Sanofi has an 83.9% market share in the pentavalent vaccines market, whereas GSK has a share of 16.1%. The high market share for Sanofi can be attributed to the use of Pentaxim in many public markets.

Preschool Booster Vaccine Market Analysis

The total DTaP combination preschool booster vaccines market is split into trivalent (DTaP or Tdap) and tetravalent (DTaP-IPV or Tdap-IPV) vaccines. It protects children against diphtheria, tetanus, pertussis, and poliomyelitis if containing IPV. These vaccines are used between the age of three to seven years depending on an individual country's national immunization schedule. The section below enumerates the findings by type of market, region, and country for the preschool booster vaccine volumes and brand proportions.

Brand Shares

The brand share of preschool booster vaccine is given in Figure 30.

In 2021, Tetraxim® has the highest share of the aP-based preschool booster vaccines market by volume with 31% (4.2 Mn doses), followed by Boostrix® with 21.7% (2.9 Mn doses), Infanrix-IPV®/Kinrix® with 18.7% (2.5 Mn doses), Quadracel® with 9.6% (1.3 Mn doses), Boostrix-IPV® with 6.1% (0.8 Mn doses), Repevax® with 4.6% (0.6 Mn doses), Revaxis® with 3.3% (0.5 Mn doses), Adacel® with 4.5% (0.6 Mn doses), and Daptacel® with 0.5% (0.1 Mn doses).

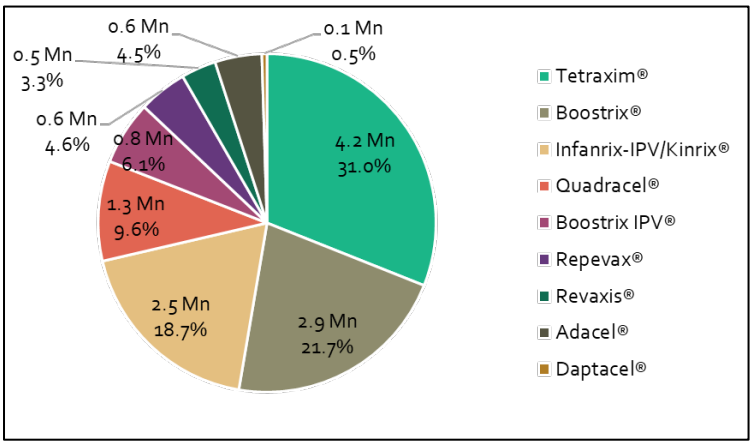

Fig 30: Brand proportions of aP-based preschool booster vaccines, 2021

Volume Analysis

By Public And Private Markets

The usage of preschool booster vaccines is split into public and private markets based on their inclusion in the immunization schedule of the country and government supply. The countries with an aP-based preschool vaccine in their national immunization schedule were designated public markets whereas countries, where preschool booster vaccines are given by private practitioners and not included in the national immunization, were designated as private markets.

Of 40 countries using preschool booster vaccines, 34 countries are public markets and 6 countries are private markets. **In 2021, 88.4% (11.9 Mn doses) of preschool booster vaccines were administered in public markets and 11.6% (1.6 Mn doses) were administered in private markets** (as shown in Figure 31).

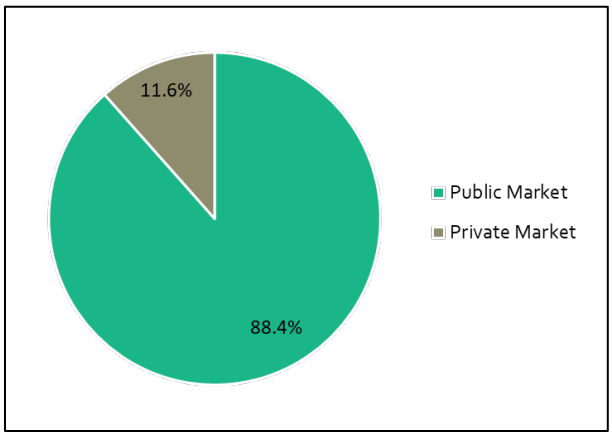

Fig 31: Volume split by public and private markets, 2021

By Region

This section enumerates the vaccine volume analysis by region. Regions mentioned according to the WHO countries' classification used for analysis by region are enumerated in Table 21.

In 2021, the EUR accounted for the major share of the aP preschool booster vaccines market by volume at 47.5% (6.4 Mn), followed by the AMR with 35.4% (4.8 Mn), the WPR with 6.6% (0.9 Mn), the EMR with 5.9% (0.8 Mn) and the SEAR with 4.6% (0.6 Mn).

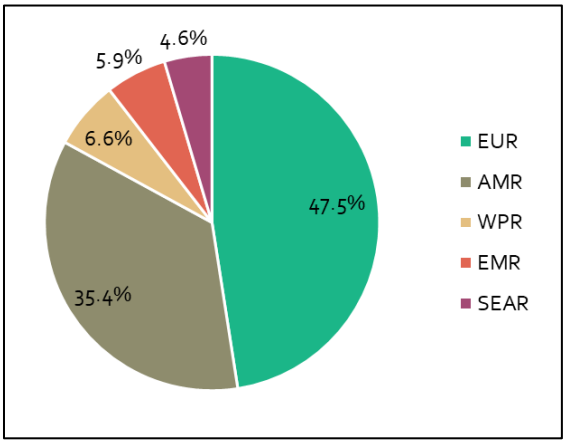

Fig 32: Preschool booster vaccine volume analysis by region, 2021

Abbreviation	EUR	AMR	WPR	EMR	SEAR
Region	European Region	American Region	Western-Pacific Region	Eastern Mediterranean Region	South-East-Asia Region

Table 21: Abbreviations of regions classified as per WHO, 2021 (Refer to Table 33 in Appendix for countries included in each region)

In the EUR, 23 countries are using aP-based preschool booster vaccines, whereas in the AMR only four countries are using aP-based preschool booster vaccines in their national immunization schedule. In Europe, 16 countries use tetravalent vaccines for preschool booster doses, whereas in AMR three countries use tetravalent vaccines namely the USA, Canada, and Costa Rica for preschool booster doses.

The high share of preschool vaccine usage in the EUR can be attributed to the increased approval and adoption of these vaccines and high vaccine coverage rates (VCR). In 2021, Turkey used 1.4 Mn doses followed by Germany and the UK each with 0.7 Mn doses of an aP-based preschool booster vaccine.

In the AMR, the USA, Canada, Chile, and Costa Rica, have included aP-based preschool booster vaccines in their national immunization schedules. In 2021, 3.3 Mn doses of aP-based booster vaccines were used in the USA, whereas Canada and Chile used 0.3 Mn and 0.2 Mn doses respectively. Costa Rica used 0.06 Mn doses of aP-based preschool booster vaccines.

In the EMR, Saudi Arabia, Libya, and United Arab Emirates have included aP-based preschool booster vaccines in their national immunization schedules. In 2021, Saudi Arabia used 0.6 Mn doses, whereas Libya used 0.1 Mn doses, and the United Arab Emirates used 0.07 Mn doses of aP-based preschool booster vaccines.

In the WPR, Australia, South Korea, Taiwan, and New Zealand have included aP-based preschool booster vaccines in their national immunization schedules. In 2021, Australia used 0.3 Mn doses, whereas South Korea used 0.3 Mn and Taiwan used 0.2 Mn doses. New Zealand used around 0.06 Mn doses of aP-based preschool booster vaccines.

In the SEAR, preschool booster vaccines are available only through private markets. Among those private markets in this region, India used 0.6 Mn doses of the preschool booster vaccine in 2021.

By Country

In 2021, 13.5 Mn doses of preschool booster vaccines were used by 40 countries of which the USA had the highest usage of preschool booster (aP) vaccines at 24.2% (3.3 Mn doses) while Ireland had the lowest usage of 0.4% (0.06 Mn doses) of the total volumes of preschool booster (aP) vaccines administered.

In public markets, the top three countries with high volumes of preschool booster (aP) vaccines include the USA, Turkey, and Germany.

In private markets, the top three countries with high volumes of preschool booster (aP) vaccine usage include India, Brazil, and Peru.

Brand Analysis

By Public And Private Markets

There are around ten aP-based trivalent and tetravalent preschool booster vaccine preparations commercially available for administration to children of age three to seven years; namely Tetraxim® (Sanofi), Infanrix-IPV®/Kinrix® (GSK), Quadracel® (Sanofi), Boostrix-IPV® (GSK), Boostrix® (GSK), Adacel® (Sanofi), Repevax® (Sanofi), Revaxis® (Sanofi), Daptacel® (Sanofi), and Infanrix® (GSK). In 2021, in tetravalent preschool booster vaccines, Tetraxim® (4.2 Mn) is the most used preschool booster vaccine, followed by Infanrix-IPV/Kinrix® (2.5 Mn), Quadracel® (1.3 Mn), and Boostrix IPV® (0.8 Mn).

In the trivalent preschool booster vaccines, Boostrix (2.9 Mn) is the most used preschool booster vaccine, followed by Repevax® (0.6 Mn), Revaxis® (0.5 Mn), Adacel (0.6 Mn), and Daptacel® (0.07 Mn).

Preschool Booster Vaccine	Public Market (Volume, Mn)	Private Market (Volume, Mn)
Tetraxim®	3.8	0.3
Infanrix-IPV/Kinrix®	2.5	0.1
Quadracel®	1.3	0.0
Boostrix IPV®	0.6	0.2
Boostrix®	2.1	0.8
Repevax®	0.6	0.0
Revaxis®	0.5	0.0
Adacel®	0.5	0.1
Daptacel®	0.0	0.1

Table 22: Brand analysis by public and private markets, 2021

By Region

Analysis of the brand proportion by region are detailed below. Regions mentioned according to the WHO countries' classification used for analysis by region are enumerated in Table 23.

The brand proportion for Tetraxim®, Infanrix-IPV®/Kinrix®, Quadracel®, Boostrix-IPV®, Boostrix®, Adacel®, Repevax®, Revaxis®, and Daptacel® by regions is given in Figure 33.

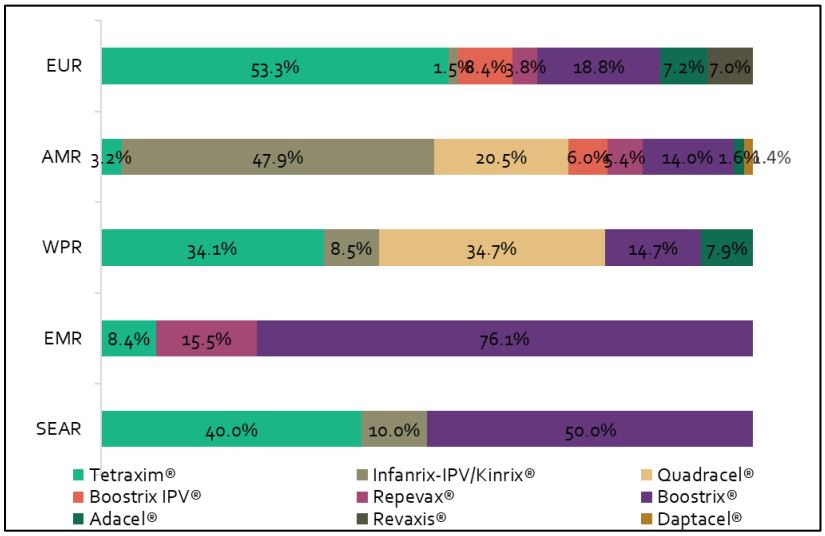

Fig 33: Brand proportion by region, 2021

Abbreviation	EUR	AMR	WPR	EMR	SEAR
Region	European Region	American Region	Western-Pacific Region	Eastern Mediterranean Region	South-East-Asia Region

Table 23: Abbreviations of regions classified as per WHO, 2021 (Refer to Table 33 in Appendix for countries included in each region)

In 2021, 23 countries in the EUR administered 6.4 Mn doses of aP-based preschool booster vaccines in which Tetraxim® (53.3%) is the most used preschool booster vaccine, followed by Boostrix® (18.8%), Boostrix-IPV® (8.4%), Revaxis® (7%), Adacel® (7.2%), Repevax® (3.8%), and Infanrix-IPV®/Kinrix® (1.5%).

In 2021, nine countries in the AMR (the USA, Brazil, Canada, Chile, Peru, Argentina, Colombia, Guatemala, and Costa Rica) consumed 4.8 Mn aP-based preschool booster vaccine doses in which Infanrix-IPV®/Kinrix® (47.9%) is the most used vaccine, followed by Quadracel® (20.5%), Boostrix® (14%), Boostrix-IPV® (6%), Repevax® (5.4%), Adacel® (1.6%), Tetraxim® (3.2%), and Daptacel® (1.4%).

In 2021, four countries in the WPR (Australia, the Republic of Korea, Taiwan, and New Zealand) used 0.9 Mn doses of aP-based preschool booster vaccines, of which Quadracel® (34.7%) is the most used vaccine, followed by Tetraxim® (34.1%), Boostrix® (14.7%), Infanrix-IPV®/Kinrix® (8.5%), and Adacel® (7.9%). This can be attributed to Australia using high volumes of Quadracel® in its national immunization schedule.

In 2021, three countries in the EMR (Saudi Arabia, Libya, and the UAE) used 0.8 Mn doses of aP-based preschool booster vaccines in which Boostrix® (76.1%) is the most used vaccine, followed by Repevax® (15.5%), and Tetraxim® (8.4%).

In 2021, only one country in the SEAR (India) used 0.6 Mn doses of aP-based preschool booster vaccines of which Boostrix® (50%) is the most used vaccine, followed by Tetraxim® (40%), and Infanrix-IPV®/Kinrix® (10%).

By Country

This section enumerates the analysis of the vaccine brands by country.

In 34 public markets, namely those of Turkey, Poland, Romania, Belgium, Sweden, Hungary, Portugal, United Arab Emirates, Norway, Costa Rica, and Ireland, Tetraxim® (Sanofi) is the only brand used in their national immunization schedule. In 2019, Tetraxim® replaced the use of DiTeKiPol Booster (by AJ Vaccines) in Denmark.[cc]

In one public market, namely New Zealand, Infanrix-IPV/Kinrix® (GSK) is the only brand used in their national immunization schedules. Boostrix-IPV® (GSK) is the only brand of vaccines used in the Netherlands' national immunization schedules. Repevax® (Sanofi) is the only brand of vaccine used in the national immunization schedules of Israel and Libya.

Boostrix® (GSK) is the only brand of vaccine used in Germany, Saudi Arabia, Kazakhstan, and Chile's national immunization schedules. Adacel® (Sanofi) is the only brand of vaccine used in the Russia and Czech Republic's national immunization schedule.

In the USA, two brands of preschool booster vaccines are in use, namely Infanrix-IPV/Kinrix®, and Quadracel®. Infanrix-IPV/Kinrix® has a 70% market share in the USA preschool booster vaccines market, followed by Quadracel® with a 30% market share.

Market Share By Manufacturer

Sanofi and GSK are the major manufacturers of preschool booster vaccines. Few vaccine manufacturers, including AJ Vaccines in Denmark and Boryung Pharm in South Korea, have a local presence but their presence in the market is not significant.

Sanofi's preschool booster vaccines include Tetraxim® (DTaP-IPV), Quadracel® (DTaP-IPV), Repevax® (Tdap-IPV), Adacel® (Tdap), and Daptacel® (DTaP). GSK's preschool booster vaccines include Infanrix-IPV®/Kinrix® (DTaP-IPV), Boostrix-IPV® (Tdap-IPV), Boostrix® (Tdap), and Infanrix® (DTaP).

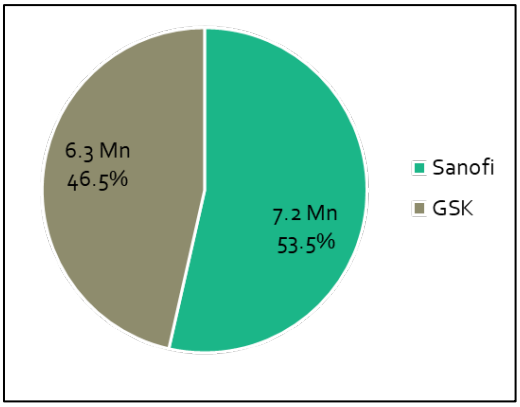

Fig 34: Preschool booster vaccine market share by manufacturer, 2021

Among the 40 countries, Sanofi has a 53.5% market share (7.2 Mn doses) in the preschool booster vaccines market, whereas GSK has a 46.5% (6.3 Mn doses) market share. The high market share for Sanofi can be attributed to the sole use of Tetraxim® in many public markets.

Preschool Booster Vaccine Split By Vaccine Type (Tetravalent, and Trivalent Vaccines)

The aP-based preschool booster vaccines are either tetravalent or trivalent. Among the top 40 countries, DTaP-IPV is the most used preschool booster vaccine. In 2021, 8 Mn doses of DTaP-IPV (59.3%), 3.5 Mn doses of Tdap (26.1%), 1.4 Mn doses of Tdap-IPV (10.7%), 0.5 Mn doses of Td- IPV (3.3%), and 0.1 Mn doses of DTaP (0.5%) preschool boosters were administered.

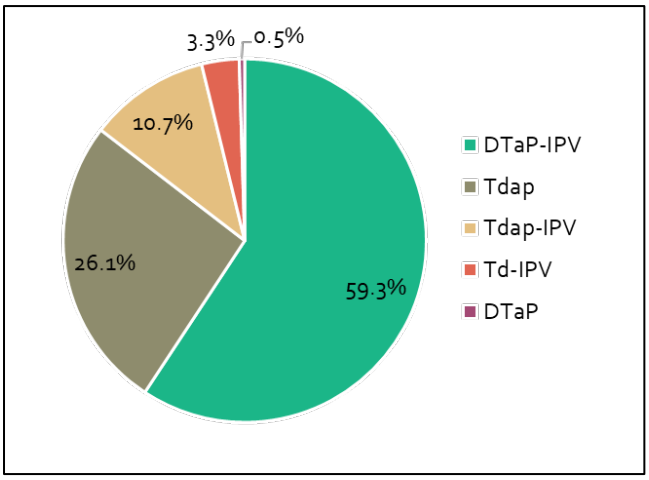

Fig 35: Preschool booster vaccines split by type, 2021

Among the 40 markets for preschool booster vaccines, 15 countries are using only the DTaP-IPV tetravalent vaccine, 5 countries are using only the Tdap-IPV tetravalent vaccine, and 8 countries are using Tdap trivalent vaccine. Only 6 countries namely the UK, France, India, Brazil, Colombia, and Guatemala are using both trivalent and tetravalent vaccines for preschool booster immunization.

DTaP-IPV Preschool Booster Vaccines Market

Brand Shares

Among the top 40 preschool booster markets, 22 countries used 8.1 Mn doses of DTaP-IPV vaccines. Among these, 11 countries are using only Tetraxim® in their immunization schedule, whereas New Zealand is using only Infanrix-IPV®/Kinrix® and Australia is using only Quadracel® in their immunization schedule.

In 2021, Tetraxim® has the highest share of 52.3% (4.2 Mn doses) in the DTaP-IPV preschool booster vaccines market, followed by Infanrix-IPV/Kinrix® with 31.5% (2.5 Mn doses), and Quadracel® with 16.1% (1.3 Mn doses).

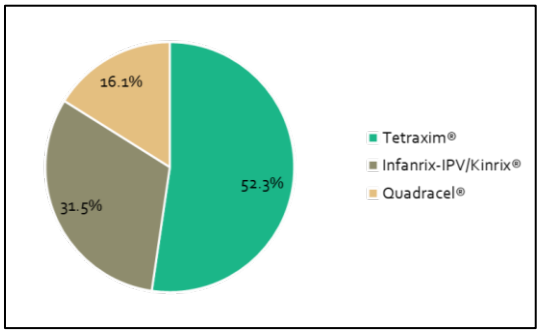

Fig 36: Brand proportion of DTaP-IPV preschool booster vaccines, 2021

Market Share By Manufacturer

Sanofi and GSK are the major manufacturers of DTaP-IPV preschool booster vaccines.

Sanofi's DTaP-IPV preschool booster vaccines include Tetraxim® and Quadracel®. GSK's DTaP-IPV preschool booster vaccines include Infanrix-IPV®/Kinrix®.

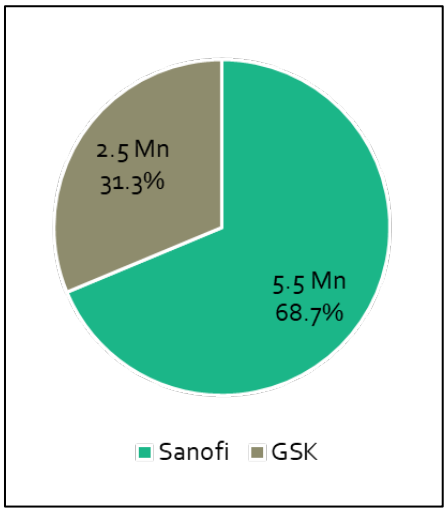

Fig 37: DTaP-IPV Preschool booster vaccines market share by manufacturer, 2021

Among the top 40 countries, Sanofi has a 68.7% market share (5.5 Mn doses) in the DTaP-IPV preschool booster vaccines market, whereas GSK has a 31.3% (2.5 Mn doses) market share.

6. aP Based Combination Vaccine Market Dominance

Our analysis shows that aP-based vaccine brands offered by Sanofi for both primary and preschool booster series are market leaders in the DTaP combination vaccines market.

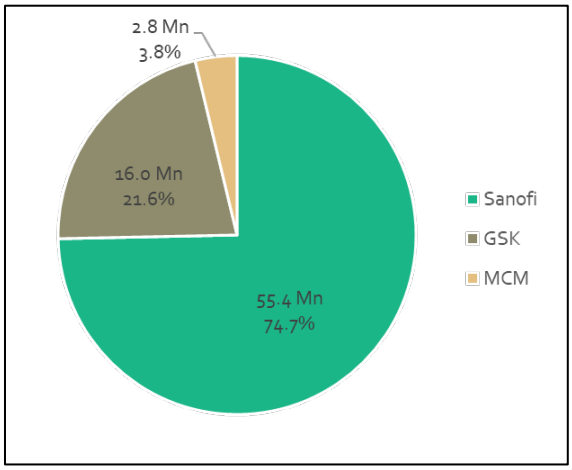

Fig 38: Sanofi Share In aP Based Combination Vaccine Market, 2021

In 2021, around 55.4 Mn doses of Sanofi's pertussis-based vaccines were used (Hexaxim®, Pentaxim®, Pentacel®, Pediacel®, Tetraxim®, Quadracel®, and Daptacel®) whereas 16 Mn doses of GSK's pertussis-based vaccines were used (Infanrix-Hexa®, Pediarix®, Infanrix-Penta®, Infanrix-IPV®/Kinrix®, Infanrix®).

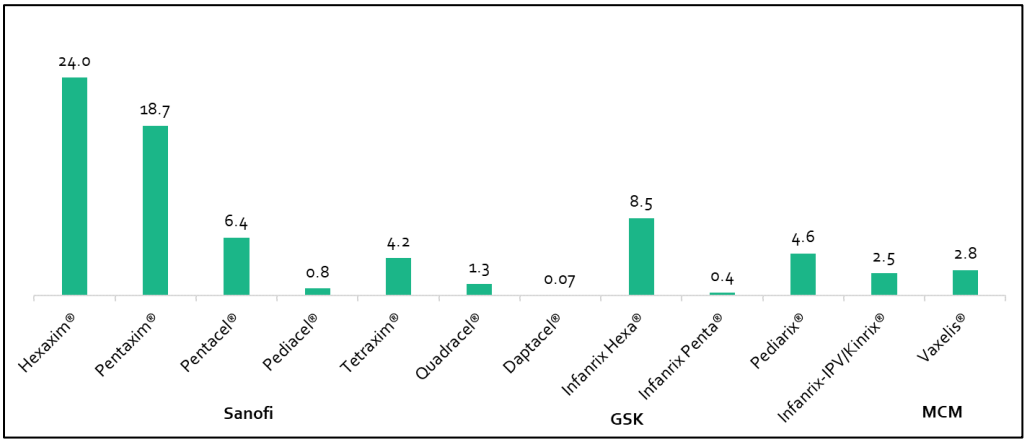

Fig 39: aP based primary & preschool booster series vaccine volumes used (Mn doses), 2021

In 2021, Sanofi's Hexaxim® and Pentaxim® are the major brands with usage of more than 15 Mn doses each. During the same period around 8 Mn doses of GSK's Infanrix-Hexa®, and 4 Mn doses of Pediarix® were used.

7. Value of the Study

The current study evaluates the volumes of aP-based combination vaccines (primary series & preschool booster series) administered across the globe. The proportion of aP-based combination vaccines administered among the other DTP-based multivalent vaccines is also analyzed. Utilization trends of aP-based combination vaccines (including Hexavalent, Pentavalent, and preschool boosters) by region, by country, and by individual brands were also analyzed indicating market leadership by the manufacturer.

Major indicators that drive the demand for aP-based combination vaccines, such as immunization rate, surviving infants' population/target population, and the immunization schedule, were studied. The correlation between these indicators and the vaccine volumes is described. These indicators directly affect the volumes of aP-based combination vaccines administered.

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8. Conclusions

Different factors drive the demand for aP-based combination vaccines among the public and private markets. Government financing and inclusion of the hexavalent/pentavalent/preschool booster (trivalent or tetravalent) vaccine in the immunization schedule drive vaccine usage in public markets, whereas availability and affordability of the vaccines drive the vaccine usage in private markets.

In 2021, DTaP combination vaccines accounted for a 30% (124.6 Mn doses) share of the DTP combination vaccines market (413.3 Mn doses) for primary and booster vaccination.

Most public markets occur in HIC and UMIC and most private markets in LMIC and LIC. The study summarizes that aP-based combination vaccines were administered more in public markets than in private markets in 2021.

Europe accounts for the major share of the aP-based combination vaccines market by volume at 37.1% for hexavalent vaccines, 37% for pentavalent vaccines, and 47.5% for preschool booster vaccines. In 2021, the top 41 countries used 35.3 Mn doses of hexavalent vaccines, which is 95% of global usage. During the same period top 16 pentavalent markets and the top 40 preschool booster vaccine markets used around 30.8 Mn doses (95% of the global pentavalent vaccine market), and 13.5 Mn doses respectively (95% of the global preschool booster vaccine market).

Among the commercially available brands of aP combination vaccines, Hexaxim® is most administered among hexavalent vaccines, followed by Pentaxim® in pentavalent vaccine markets. In 2021, around 24 Mn doses of Hexaxim®, and 18.7 Mn doses of Pentaxim® were administered.

Among hexavalent vaccines, Hexaxim® (Sanofi) had a market share of 68%, followed by Infanrix Hexa® with a market share of 24.1% (GSK). Among pentavalent vaccines, Pentaxim® (Sanofi) had a market share of 60.8%, followed by Pentacel® (Sanofi) and Pediarix® (GSK) with 20.6% and 14.9%, respectively. Among preschool booster vaccines, Tetraxim® (Sanofi) had a market share of 31%, followed by Infanrix-IPV®/Kinrix® (GSK) with 18.7%.

Sanofi's vaccine brands were market leaders in each market category, namely hexavalent vaccines, pentavalent vaccines, and preschool booster vaccines. **The research concludes Sanofi as the market leader in the aP-based pediatric combination vaccines market with a global share of 74.7% in 2021.**

Appendix

Table 24 - Abbreviations

The table below shows abbreviations across the report

S. No	Abbreviation	Description
1	DTP	Diphtheria Tetanus Pertussis
2	IPV	Poliomyelitis
3	Hib	Haemophilus influenza type b
4	Hep B	Hepatitis B
5	aP	Acellular Pertussis Antigen
6	Wp	Whole-cell Pertussis Antigen
7	NIP	National Immunization Program
8	MOH	Ministry of Health
9	NPRA	National Pharmaceutical Regulatory Agency
10	NUPCO	National Unified Procurement Company
11	NDoH	National Department of Health
12	CIA	Central Intelligence Agency
13	WHO	World Health Organization
14	CDC	Center for Disease Control and Prevention
15	GAVI	Global Alliance for Vaccine and Immunization
16	UNICEF	United Nations Children's Fund
17	UN	United Nations
18	HIC	HIC- High Income Countries
19	UMIC	UMIC- Upper middle income
20	LMIC	LMIC- Lower middle income
21	SAGE	Strategic Advisory Group of Experts
22	PAHO	Pan American Health Organization
23	VCR	Vaccination Coverage Rate
24	GHO	Global Health Observatory
25	AEFI	Adverse Events Following Immunization
26	MNTE	Maternal and Neonatal Tetanus Elimination Program
27	EUR	European Region
28	AMR	American Region
29	AFR	African Region
30	WPR	Western Pacific Region
31	EMR	Eastern Mediterranean Region
32	SEAR	South-East Asia Region
33	SLIPE	Latin American Society of Pediatric Infectious Diseases

Table 25 - Hexavalent Vaccine Public Markets

The table below shows the parameters considered for hexavalent vaccine volume estimation in the public market

Sr. No.	Country Name	Income Status	Region	Hexavalent Vaccine Immunization Rate	Surviving Infant Population	Schedule
1	United States of America	HIC	AMR	4.65%	37,05,532	3
2	Mexico	UMIC	AMR	78%	19,97,100	4
3	Russian Federation (the)	UMIC	EUR	3%	13,92,819	3
4	South Africa	UMIC	AFR	86%	12,06,723	4
5	United Kingdom	HIC	EUR	93%	6,75,119	3
6	Saudi Arabia	HIC	EMR	97%	6,26,222	3
7	Malaysia	UMIC	WPR	95%	5,33,471	4
8	Kazakhstan	UMIC	EUR	95%	4,10,302	2
9	Italy	HIC	EUR	94%	4,09,696	3
10	Canada	HIC	AMR	42%	3,72,355	3
11	Spain	HIC	EUR	92%	3,56,895	3
12	Australia	HIC	WPR	95%	2,97,762	3
13	Jordan	UMIC	EMR	77%	2,41,764	3
14	Chile	HIC	AMR	95%	2,28,192	4
15	Romania	HIC	EUR	86%	1,94,454	3
16	Netherlands	HIC	EUR	95%	1,79,730	3
17	Libya	UMIC	EMR	66%	1,19,101	3
18	Belgium	HIC	EUR	98%	1,16,101	4
19	Sweden	HIC	EUR	98%	1,13,135	3
20	Czech Republic	HIC	EUR	94%	1,03,737	3
21	United Arab Emirates	HIC	EMR	90%	96,086	2
22	Switzerland	HIC	EUR	96%	86,846	3
23	Austria	HIC	EUR	85%	84,439	3
24	Oman	HIC	EMR	99%	82,817	2
25	Portugal	HIC	EUR	93%	80,296	2
26	Panama	HIC	AMR	74%	76,053	3
27	New Zealand	HIC	WPR	90%	63,341	3
28	Ireland	HIC	EUR	94%	58,438	3
29	Bulgaria	UMIC	EUR	71%	57,855	3
30	Slovakia	HIC	EUR	97%	54,129	3
31	Norway	HIC	EUR	97%	53,777	3
32	Georgia	UMIC	EUR	85%	50,077	3
33	Croatia	HIC	EUR	74%	34,617	4
34	Armenia	UMIC	EUR	93%	33,426	3
35	Qatar	HIC	EMR	65%	26,425	2
36	Macedonia (North)	UMIC	EUR	84%	20,028	2
37	Slovenia	HIC	EUR	86%	19,115	3

38	Bahrain	HIC	EMR	98%	17,417	2
39	Latvia	HIC	EUR	89%	16,978	4
40	Estonia	HIC	EUR	90%	13,622	3
41	Luxembourg	HIC	EUR	99%	6,564	3
42	Brunei Darussalam	HIC	WPR	99%	6,098	3
43	Malta	HIC	EUR	99%	4,649	4
44	Bahamas	HIC	AMR	75%	4,624	3
45	Barbados	HIC	AMR	82%	3,017	3
46	Andorra	HIC	EUR	99%	564	3
47	San Marino	HIC	EUR	90%	202	3
48	Niue	HIC	WPR	99%	27	3

1. Income Status: Data for the type of country income classification, such as High Income (HI), Upper middle income (UMIC), and Lower middle income (LMIC) country were collected from World Bank (WHO follows World Bank classification).
2. #Vaccines: Number of DTP vaccines within the national immunization schedule followed in each country
3. The immunization rates for the public market are taken from WHO (having only hexavalent in the immunization schedule). In some countries, the immunization rates are taken from sources such as country-specific MOH sites, News articles, and other secondary sources. For instance, in Argentina, children weighing <1500 grams should be administered a hexavalent vaccine, these children are around 1.1% of the total surviving infant population. Hence the hexavalent immunization rate is considered 1.1% for Argentina. In Canada, hexavalent vaccines are used only in 6 provinces out of 10 provinces. In Latvia infants who receive HepB mono vaccine due to HepB risk exposure from mothers will use the pentavalent vaccine, all others are given Hexavalent vaccines.
4. WHO vaccine-preventable diseases: monitoring system (Global summary 2020), GAVI-Country Hub, The World Factbook 2020, UNICEF child survival, and sustainable development goals (SGD), United Nations (UN) Population data.

Table 26 - Hexavalent Vaccine Private Markets

The table below shows the parameters considered for hexavalent vaccine volume estimation in the private market.

Sr. No.	Country Name	Income Status[1]	Region	Hexavalent Vaccine Immunization Rate in Private Market	Surviving Infants Population[3]	Schedule
1	India	LMIC	SEAR	1%	2,25,91,299	3
2	Pakistan	LMIC	EMR	0%	61,05,641	3
3	Indonesia	LMIC	SEAR	2%	44,22,245	3
4	Bangladesh	LMIC	SEAR	0%	29,57,723	3
5	Brazil	UMIC	AMR	3%	27,29,876	3
6	Philippines	LMIC	WPR	3%	24,37,200	3
7	Egypt	LMIC	EMR	0%	24,30,330	3
8	Viet Nam	LMIC	WPR	40%	14,40,888	3
9	Turkey	UMIC	EUR	0%	12,36,527	3
10	Iran (Islamic Republic of)	LMIC	EMR	2%	11,92,886	3
11	Iraq	UMIC	EMR	1%	11,70,541	3
12	Myanmar	LMIC	SEAR	1%	8,93,712	3
13	Uzbekistan	LMIC	EUR	0%	7,94,642	3
14	Germany	HIC	EUR	91%	7,61,164	3
15	Colombia	UMIC	AMR	3%	7,23,229	3
16	France	HIC	EUR	96%	7,08,967	3
17	Morocco	LMIC	EMR	2%	6,41,736	3
18	Thailand	UMIC	SEAR	15%	6,40,380	3
19	Argentina	UMIC	AMR	3%	6,24,312	3
20	Nepal	LMIC	SEAR	0%	5,97,369	3
21	Peru	UMIC	AMR	2%	5,88,365	3
22	Venezuela (Bolivarian Republic of)	UMIC	AMR	6%	4,45,578	3
23	Guatemala	UMIC	AMR	1%	3,65,842	3
24	Poland	HIC	EUR	45%	3,62,344	3
25	Ukraine	LMIC	EUR	15%	3,34,489	3
26	Cambodia	LMIC	WPR	1%	3,14,929	3
27	Sri Lanka	LMIC	SEAR	0%	3,04,378	3
28	Ecuador	UMIC	AMR	1%	2,96,230	3
29	Republic of Korea	HIC	WPR	7%	2,88,419	3
30	Haiti	LMIC	AMR	1%	2,59,152	3
31	Bolivia (Plurinational State of)	LMIC	AMR	1%	2,57,599	3
32	Tajikistan	LMIC	EUR	2%	2,54,611	3
33	Papua New Guinea	LMIC	WPR	6%	2,46,340	3
34	Honduras	LMIC	AMR	0%	2,14,096	3
35	Dominican Republic	UMIC	AMR	2%	2,00,195	3

36	Tunisia	LMIC	EMR	9%	1,94,998	3
37	Israel	HIC	EUR	6%	1,73,883	3
38	Lao People's Democratic Republic	LMIC	WPR	5%	1,58,442	3
39	Kyrgyzstan	LMIC	EUR	3%	1,55,579	3
40	Nicaragua	LMIC	AMR	1%	1,38,979	3
41	Paraguay	UMIC	AMR	1%	1,36,478	3
42	Turkmenistan	UMIC	EUR	2%	1,32,864	3
43	Azerbaijan	UMIC	EUR	4%	1,25,236	3
44	El Salvador	LMIC	AMR	1%	1,00,463	3
45	Cuba	UMIC	AMR	3%	1,00,100	3
46	Hungary	HIC	EUR	1%	91,627	3
47	Greece	HIC	EUR	75%	78,837	4
48	Denmark	HIC	EUR	20%	62,994	3
49	Finland	HIC	EUR	91%	46,814	3
50	Kuwait	HIC	EMR	5%	44,119	3
51	Singapore	HIC	WPR	25%	42,161	3
52	Uruguay	HIC	AMR	14%	35,747	3
53	Lithuania	HIC	EUR	10%	26,793	3

1. Income Status: Data for the type of country income classification, such as High Income, Upper middle income, Lower middle income & Low-income countries were collected from World Bank (WHO follows the World Bank classification).
2. Hexavalent Vaccine Private Market Share: The share of hexavalent vaccine in these countries of total DTP immunization rate. Data taken from WHO private vaccine shares, expert interviews
3. WHO vaccine-preventable diseases: monitoring system (Global summary 2020), GAVI-Country Hub, The World Factbook 2020, UNICEF child survival, and sustainable development goals (SGD), United Nations (UN) Population data.

Table 27 - Preterm Hexavalent Vaccine Volumes

The table below shows the estimated preterm hexavalent vaccine volumes in the top 33 countries

Sr. No.	Country Name	Preterm Births, 2021	Preterm Hexavalent Vaccine Volumes
1	South Africa	171,066	588,466
2	Mexico	148,894	464,548
3	Malaysia	63,992	243,168
4	Germany	59,977	218,316
5	United Kingdom	60,685	169,312
6	France	55,231	159,066
7	Saudi Arabia	36,065	104,950
8	Australia	27,062	77,127
9	Jordan	33,343	77,022
10	United States of America	517,400	72,177
11	Spain	25,015	69,042
12	Chile	17,754	67,464
13	Italy	22,483	63,403
14	Kazakhstan	21,687	41,205
15	Romania	15,488	39,960
16	Belgium	9,941	38,968
17	Canada	29,998	37,797
18	Netherlands	12,318	35,107
19	Libya	15,600	30,748
20	Greece	8,425	25,276
21	Czech Republic	7,905	22,292
22	Sweden	7,088	20,839
23	Panama	8,620	19,137
24	Switzerland	6,314	18,183
25	Oman	8,013	15,867
26	Austria	5,602	14,285
27	Georgia	5,159	13,155
28	Ireland	4,500	12,690
29	New Zealand	4,670	12,610
30	Portugal	6,158	11,453
31	United Arab Emirates	6,250	11,249
32	Slovakia	3,757	10,933
33	Norway	3,498	10,179

*The estimation of these preterm volumes is not robust but based on multiple parameters such as WHO preterm birth rate, surviving infant's population, similar immunization rates used for term babies, private market share of hexavalent vaccines used

for term infants. However, we did extensive secondary research to find specific countries that use different brands of vaccines for preterm to estimate the brand proportions split.

1) Global preterm birth estimates - WHO
2) World Bank/UN Population Estimates and Projections
3) WHO vaccine-preventable diseases: monitoring system. 2020 global summary
4) HEXYON/HEXACIMA – Use in preterm infants in EU countries with exclusive use (up to end DEC-2020)

Table 28 - Pentavalent Vaccine Public Markets

The table below shows the parameters considered for pentavalent vaccine volume estimation in the public market.

Sr. No.	Country Name	Income Status[1]	Region	Pentavalent Vaccine Immunization Rate[3]	Surviving Infants Population[4]	Schedule
1	USA	HIC	AMR	74.00%	37,05,532	4
2	Russia	UMIC	EUR	67.00%	14,88,946	4
3	Turkey	UMIC	EUR	95.00%	13,07,504	4
4	Kazakhstan	UMIC	EUR	95.00%	4,10,302	2
5	Canada	HIC	AMR	49.68%	3,90,973	4
6	Republic of Korea	HIC	WPR	98.00%	2,88,419	3
7	Taiwan	HIC	WPR	96.00%	1,86,239	4
8	Israel	HIC	EUR	98.00%	1,83,380	4
9	Libya	UMIC	EMR	7.30%	1,19,101	1
10	United Arab Emirates	HIC	EMR	90.00%	96,086	1
11	Hungary	HIC	EUR	99.00%	91,627	4
12	Portugal	HIC	EUR	99.00%	80,296	2
13	Serbia	UMIC	EUR	92.00%	67,352	4
14	Denmark	HIC	EUR	97.00%	62,994	3
15	Costa Rica	UMIC	AMR	99.00%	60,831	4
16	Bulgaria	UMIC	EUR	17.80%	57,855	4
17	Finland	HIC	EUR	89.00%	46,814	3
18	Singapore	HIC	WPR	96.00%	42,161	4
19	Croatia	HIC	EUR	18.40%	34,617	1
20	Bosnia-Herzegovina	UMIC	EUR	73.00%	27,530	3
21	Lithuania	HIC	EUR	90.00%	26,793	4
22	Qatar	HIC	EMR	32.34%	26,425	1
23	Macedonia (North)	UMIC	EUR	93.00%	20,028	2
24	Latvia	HIC	EUR	1.00%	16,978	3
25	Bhutan	LMIC	SEAR	98.00%	9,507	3
26	Montenegro	UMIC	EUR	83.00%	6,960	4
27	Luxembourg	HIC	EUR	99.00%	6,564	1
28	Iceland	HIC	EUR	92.00%	4,568	3
29	Micronesia (Federated States of)	LMIC	WPR	72.00%	2,315	3
30	Marshall Islands	UMIC	WPR	86.00%	811	3
31	Monaco	HIC	EUR	99.00%	321	3
32	Cook Islands	HIC	WPR	98.00%	276	3
33	Palau	UMIC	WPR	95.00%	269	2

1. Income Status: Data for the type of country income classification, such as High Income (HI), Upper middle income (UMIC), and Lower middle income (LMIC) countries were collected from World Bank (WHO follows the World Bank classification).
2. #Vaccines: Number of DTP vaccines within the national immunization schedule followed in each country
3. The immunization rates are taken from WHO, country-specific MOH sites, News articles, and other secondary sources. In Latvia infants who receive HepB mono vaccine due to HepB risk exposure from mothers will use the pentavalent vaccine, all others are given Hexavalent vaccines.
4. WHO vaccine-preventable diseases: monitoring system (Global summary 2020), GAVI-Country Hub, The World Factbook 2019, UNICEF child survival, and sustainable development goals (SGD), United Nations (UN) Population data.

Table 29 - Pentavalent Vaccine Private Markets

The table below shows the parameters considered for pentavalent vaccine volume estimation in the private market.

Sr. No	Country Name	Income Status[1]	Region	Pentavalent Vaccine Immunization Rate in Private Market[2]	Surviving Infants Population[3]	Schedule
1	China	UMIC	WPR	15.00%	1,15,01,936	3
2	Poland	HIC	EUR	30.00%	3,62,344	3
3	India	LMIC	SEAR	0.40%	2,25,91,299	3
4	Viet Nam	LMIC	WPR	4.99%	14,40,888	3
5	Thailand	UMIC	SEAR	15.92%	6,40,380	2
6	Brazil	UMIC	AMR	2.00%	27,29,876	3
7	Indonesia	LMIC	SEAR	0.40%	44,22,245	4
8	Pakistan	LMIC	EMR	0.30%	61,05,641	3
9	Bangladesh	LMIC	SEAR	0.50%	29,57,723	3
10	Philippines	LMIC	WPR	0.50%	24,37,200	3
11	Tunisia	LMIC	EMR	4.99%	1,94,998	3
12	Myanmar	LMIC	SEAR	1.00%	8,93,712	3
13	Colombia	UMIC	AMR	1.00%	7,23,229	3
14	Peru	UMIC	AMR	1.00%	5,88,365	3
15	Guatemala	UMIC	AMR	1.25%	3,65,842	3
16	Japan	HIC	WPR	0.50%	8,17,283	3
17	Ukraine	LMIC	EUR	3.49%	3,34,489	1
18	Kuwait	HIC	EMR	5.99%	44,119	4
19	Nepal	LMIC	SEAR	0.50%	5,97,369	3
20	Uzbekistan	LMIC	EUR	0.25%	7,94,642	3
21	Ecuador	UMIC	AMR	0.50%	2,96,230	3
22	Paraguay	UMIC	AMR	0.50%	1,36,478	3

1. Income Status: Data for the type of country income classification, such as High Income (HI), Upper middle income (UMIC), and Lower middle income (LMIC) countries were collected from World Bank (WHO follows the World Bank classification).
2. Hexavalent Vaccine Private Market Share: The share of hexavalent vaccine in these countries of total DTP immunization rate. Data taken from WHO private vaccine shares, expert interviews
3. WHO vaccine-preventable diseases: monitoring system (Global summary 2020), GAVI-Country Hub, The World Factbook 2019, UNICEF child survival, and sustainable development goals (SGD), United Nations (UN) Population data.

Table 30 - Preterm Pentavalent Vaccine Volumes

The table below shows the estimated preterm pentavalent vaccine volumes in the top 11 countries

Sr. No.	Country Name	Preterm Births, 2021	Preterm pentavalent Vaccine Volumes
1	United States of America	517,400	1,531,504
2	Turkey	195,403	742,533
3	Russian Federation (the)	99,131	199,254
4	Republic of Korea	28,021	82,381
5	Taiwan	20,014	76,855
6	Canada	29,998	59,996
7	Kazakhstan	21,687	41,205
8	Israel	8,095	31,731
9	Hungary	7,965	31,540
10	Serbia	7,419	27,302
11	Costa Rica	6,414	25,398

*The estimation of these preterm volumes is not robust but based on multiple parameters such as WHO preterm birth rate, surviving infant's population, similar immunization rates used for term babies, private market share of hexavalent vaccines used for term infants. However, we did extensive secondary research to find specific countries that use different brands of vaccines for preterm to estimate the brand proportions split.

1) Global preterm birth estimates - WHO

2) World Bank/UN Population Estimates and Projections

3) WHO vaccine-preventable diseases: monitoring system. 2020 global summary

Table 31 - Preschool Booster Vaccine Public Markets

The table below shows the parameters considered for preschool booster vaccine volume estimation in the public market.

Sr. No	Country Name	Income Status[1]	Region	Preschool Booster Vaccine Immunization Rate[2]	Target Population[3]	Age[4]
1	United States of America	HIC	AMR	81.6%	34,10,696	4 years
2	Turkey	UMIC	EUR	94.3%	14,41,191	3 years
3	Russian	UMIC	EUR	96.1%	13,92,819	6-7 years
4	United Kingdom	HIC	EUR	86.4%	6,66,593	3 years
5	France	HIC	EUR	89.0%	6,13,257	6 years
6	Germany	HIC	EUR	91.5%	5,84,856	5-6 years
7	Saudi Arabia	HIC	EMR	97.0%	4,25,511	4-6 years
8	Italy	HIC	EUR	79.0%	3,55,911	6 years
9	Poland	HIC	EUR	55.3%	3,50,843	6 Years
10	Spain	HIC	EUR	85.8%	3,42,653	6 years
11	Australia	HIC	WPR	94.5%	3,20,595	4 years
12	Canada	HIC	AMR	78.0%	3,15,706	4 to 6 years
13	Kazakhstan	UMIC	EUR	91.1%	2,96,774	6 years
14	Republic of Korea	HIC	WPR	96.1%	2,88,419	4-6 years
15	Chile	HIC	AMR	86.0%	1,76,365	6 Years
16	Romania	HIC	EUR	97.3%	1,58,794	6 years
17	Israel	HIC	EUR	93.9%	1,48,973	7 years
18	Netherlands	HIC	EUR	48.9%	1,46,241	4 years
19	Libya	UMIC	EMR	94.8%	1,19,101	6 years
20	Sweden	HIC	EUR	95.0%	1,11,206	5 years
21	Belgium	HIC	EUR	93.9%	1,02,428	5-6 years
22	Czech Republic	HIC	EUR	87.0%	1,01,933	5 years
23	Hungary	HIC	EUR	99.5%	92,200	6 years
24	Switzerland	HIC	EUR	95.0%	72,777	4-7 years
25	Portugal	HIC	EUR	83.5%	69,408	5 years
26	Greece	HIC	EUR	95.8%	69,015	4-6 years
27	Austria	HIC	EUR	75.0%	68,768	6-8 years
28	United Arab Emirates	HIC	EMR	88.3%	64,712	5-6 years
29	Denmark	HIC	EUR	87.2%	58,305	5 years
30	Bulgaria	UMIC	EUR	81.4%	53,773	6 years
31	Norway	HIC	EUR	89.0%	52,904	7 years
32	New Zealand	HIC	WPR	92.0%	51,124	4 years
33	Slovakia	HIC	EUR	96.2%	50,330	5 years
34	Ireland	HIC	EUR	88.0%	49,871	4 years
35	Finland	HIC	EUR	90%	46,814	4 years
36	Slovenia	HIC	EUR	92.10%	19,115	9 years
37	Cyprus	HIC	EUR	85.00%	12,795	4 to 6 years

38	Luxembourg	HIC	EUR	90.0%	6,564	5-6 years
39	Marshall Islands	UMIC	WPR	83.8%	811	4-5 years
40	Andorra	HIC	EUR	97.6%	564	5 years
41	Monaco	HIC	EUR	85.2%	321	6 years
42	Cook Islands	HIC	WPR	95.00%	276	4 years
43	Niue	HIC	WPR	106.1%	27	4 years
44	Taiwan	HIC	WPR	95%	NA	5 years
45	Costa Rica	UMIC	AMR	NA	NA	4 years
46	Georgia	UMIC	EUR	NA	NA	5 years
47	Armenia	UMIC	EUR	91.5%	NA	6 years
48	Croatia	HIC	EUR	86.9%	NA	6 Years
49	Lithuania	HIC	EUR	87.4%	NA	6-7 years
50	Qatar	HIC	EMR	95.5%	NA	4-6 years
51	Bahrain	HIC	EMR	97.7%	NA	4-5 years
52	Latvia	HIC	EUR	92.9%	NA	7 years
53	Bosnia-Herzegovina	UMIC	EUR	60.1%	NA	5-6 years
54	Macedonia (North)	UMIC	EUR	89.2%	NA	7 years
55	Estonia	HIC	EUR	83.7%	NA	6-7 Years
56	Brunei Darussalam	HIC	WPR	97.6%	NA	5 years
57	Iceland	HIC	EUR	91.4%	NA	4 years
58	Palau	UMIC	WPR	95.1%	NA	4-6 years
59	San Marino	HIC	EUR	84.8%	NA	5 years
60	Nauru	HIC	WPR	NA	NA	4 years

1. Income Status: Data for the type of country income classification, such as High Income (HI), Upper middle income (UMIC), and Lower middle income (LMIC) countries were collected from World Bank (WHO follows the World Bank classification).
2. The immunization rates are taken from national vaccine procurement databases, national public health institutes, WHO, country-specific MOH sites, News articles, and other secondary sources.
3. World Bank population forecast database, United Nations (UN) Population data, National census statistics, and The World Factbook 2020
4. Preschool Booster Vaccination age is taken from the UN population forecast and World Bank population forecast databases

Table 32 - Preschool Booster Vaccine Private Markets

The table below shows the parameters considered for preschool booster vaccine volume estimation in the private market.

Sr. No.	Country Name	Income Status[1]	Region	Preschool Booster Vaccine Immunization Rate in the Private Market[2]	Target Population[3]	Age[4]
1	India	LMIC	SEAR	2.60%	2,25,91,299	5-6 Years
2	Brazil	UMIC	AMR	20.35%	27,29,876	4 years
3	Iran (Islamic Republic of)	LMIC	EMR	1.99%	11,92,886	6 years
4	Colombia	UMIC	AMR	9.31%	7,23,229	5 years
5	Thailand	UMIC	SEAR	6.59%	6,40,380	4 years
6	Argentina	UMIC	AMR	11.72%	6,24,312	6 years
7	Peru	UMIC	AMR	23.90%	5,88,365	4 years
8	Guatemala	UMIC	AMR	14.64%	3,65,842	4 years
9	Ecuador	UMIC	AMR	14.57%	2,96,230	5 years
10	Honduras	LMIC	AMR	13.72%	2,14,096	4 years
11	Dominican Republic	UMIC	AMR	10.90%	2,00,195	4 years
12	Kyrgyzstan	LMIC	EUR	2.58%	1,55,579	2 years
13	Nicaragua	LMIC	AMR	8.92%	1,38,979	6 years
14	Paraguay	UMIC	AMR	23.89%	1,36,478	4 years
15	El Salvador	LMIC	AMR	11.06%	1,00,463	4 years
16	Panama	HIC	AMR	19.50%	76,053	4 years
17	Kuwait	HIC	EMR	1.93%	44,119	3 years
18	Uruguay	HIC	AMR	4.17%	35,747	5 years
19	Trinidad and Tobago	HIC	AMR	12.57%	17,585	4-5 years
20	Bahamas	HIC	AMR	19.00%	4,624	4-5 years
21	Lebanon	LMIC	EMR	18.95%	NA	4-5 years
22	Jamaica	LMIC	AMR	13.11%	NA	4-6 years
23	Suriname	UMIC	AMR	23.81%	NA	4 to 5 years
24	Mauritius	UMIC	AFR	18.50%	NA	5 years
25	Belize	UMIC	AMR	15.62%	NA	4 years
26	Republic of Moldova	UMIC	EUR	2.59%	NA	2 years
27	Maldives	UMIC	SEAR	13.13%	NA	4 years
28	Kiribati	LMIC	WPR	26.22%	NA	6 years
29	Samoa	LMIC	WPR	7.64%	NA	5 years
30	Saint Lucia	UMIC	AMR	12.57%	NA	5 years
31	Dominica	UMIC	AMR	10.20%	NA	3 years
32	Tonga	UMIC	WPR	0.35%	NA	5 years

1. Income Status: Data for the type of country income classification, such as High Income (HI), Upper middle income (UMIC), and Lower middle income (LMIC) countries were collected from World Bank (WHO follows the World Bank classification).
2. Preschool Booster (aP) Vaccine Private Market Share: The share of a preschool booster vaccine in these countries of total DTP immunization rate. Data were taken from the UNICEF Immunization database, expert interviews
3. WHO vaccine-preventable diseases: monitoring system (Global summary 2020), GAVI-Country Hub, The World Factbook 2020, World Bank population forecast, and, United Nations (UN) Population data.
4. Preschool Booster Vaccination age is taken from the WHO vaccine-preventable diseases: monitoring system. 2020 global summary

Table 33- WHO countries classification by region

Sr. No	Region	Abbreviation	Countries
1	EUR	European Region	United Kingdom, Italy, Spain, Kazakhstan, Netherlands, Romania, Poland, Belgium, Sweden, Czech Republic, Switzerland, Greece, Austria, Ireland, Slovakia, Norway, Ukraine, Portugal, Georgia, Turkey, Serbia, Israel, Hungary, Russian Federation (the), Germany, France,
2	AMR	American Region	Mexico, Chile, United States of America, Canada, Brazil, Panama, Costa Rica, Peru, Argentina, Colombia, Guatemala
3	WPR	Western Pacific Region	Malaysia, Viet Nam, Australia, Philippines, New Zealand, China, Republic of Korea, Taiwan
4	AFR	African Region	South Africa
5	EMR	Eastern Mediterranean Region	Saudi Arabia, Jordan, Libya, United Arab Emirates (the), Oman
6	SEAR	South-East-Asia Region	India, Indonesia, Thailand

Table 34 - Expert Inputs

The table below shows the expert respondents' information.

Sr. No	Designation	University/ Organization	Country
1	Pediatrician (Specialist training in family medicine)	Individual Medical Practice (Past- Clinic Bajka Promedica)	Poland
2	Pediatric Endocrinologist and Diabetologist	Medicover	Poland
3	Medical Director	Intersono IVF clinic	Ukraine
4	Clinical director, Pediatrician, Child infection disease specialist	Medical Centre Friendlic	Ukraine
5	Chief Consultant in Pediatrics	Athens Pediatric Center	Greece
6	Pediatric Resident	Agia Sofia pediatric hospital	Greece
7	Pediatrician, Director of the Department of Pediatric	University of Crete	Greece
8	Pediatrician	REA Maternity Hospital	Greece
9	National Immunization and Child Health Information System (NICIS) Project Support	HSE National Immunization Office	Ireland
10	Senior Health Officer	World Health Organization	Switzerland
11	Medical Doctor	Hausarztpraxis Huttwil GmbH (Reviewer Board Member- Global Journal of Pediatrics	Switzerland
12	Medical Head	Medic Integral Pediatrics	Switzerland
13	Doctor MD, pediatrician	Medicine University of Lausanne	Switzerland
14	Pediatrician	Geneva Perinatal Center	Switzerland
15	Senior Physician in Neonatology (Senior Researcher)	University Hospital Zurich	Switzerland
16	Attending Pediatrician	Centro Hospitalar Tondela-Viseu	Portugal
17	Public Health Researcher	National Health Institute Doctor Ricardo Jorge, Ministry of Health, Lisbon.	Portugal
18	Pediatrician	Regina Maria, The Private Healthcare Network	Romania
19	General Pediatrician (Associate Professor of Pediatrics at the University of Georgia)	REDMED	Georgia
20	Pediatrician	Iashvili Children's Central Hospital	Georgia
21	Pediatrician	EKO-MED	Slovakia
22	Pediatrician	Medped, S. R. O	Slovakia
23	Pediatrician & Pediatric Cardiologist	Klinikum Rohrbach	Slovakia
24	Pediatrician	Noorderhart Hospital	Belgium
25	Public Health Expert, APVAX	Immunization Division, Ministry of Health & Family Welfare, GoI	India
26	Specialist medical officer	Guru Gobind Singh hospital Patna City	India
27	Director Of Operations	Ministry of Health & Population - Egypt	Egypt
28	Young Child Survival and Development Health Officer	UNICEF	Egypt
29	General Pediatrician	Dawi Clinics	Egypt
30	Consultant Pediatrician (Lecturer of pediatrics Zagazig university)	Zagazig University children's hospital	Egypt
31	Nurse, Pediatric Division	Children's Urgent Care Centre - The Portland Hospital - UK	United Kingdom
32	Medica Staff Pediatria	Sanatorio La Trinidad Ramos Mejia	Argentina
33	Pediatrician	Government of the Province of Santa Fe	Argentina
34	MD Pediatrician	Mutual Nikkai	Argentina
35	Medical Pediatrician	Hospital Houssay Vicente Lopez	Argentina
36	Pediatrician	Medicus	Argentina
37	Medical Pediatrician	Palmares Medical Center, Pediatric San Luis, Hospital H Notti	Argentina
38	Neonatology- Pediatrician (Asrem medical director)	Asrem	Italy
39	Pediatric Allergy and Immunology Director and Immunology Professor	Children's University Hospital of San Jose Bogota Colombia	Colombia
40	Pediatric infectious diseases specialist	Hospital Universitario Erasmo Meo	Colombia

41	Pediatrician	Sanitas	Colombia
42	Pediatric Resident	University Clinic for Pediatric	Colombia
43	Pediatrics, Clinical Fellow	AP-HP, Assistance Publique – Hospital of Paris (Greater Paris University Hospitals)	Norway
44	Pediatrician	Private clinic	France
45	Pediatric Resident	Bellevue Medical Center - Lebanon	France
46	Pediatrician	Nuestra Senora Del Pilar Santorium	Guatemala
47	Medico Pediatra (Consultant)	Atheneum	Guatemala
48	Nurse (Pediatric Division)	Catalan Institute of Health	Spain
49	Pediatrician Clinical Immunologist	National Children's Hospital	Costa Rica
50	Senior Clinical Researcher (Medical Doctor)	Woolcock Institute of Medical Research	Vietnam
51	Pediatrician	Children's Hospital 2	Vietnam
52	General Practitioner (Medical Doctor)	FV clinic Saigon	Vietnam
53	Pediatric Cardiac Interventionist (Clinical Specialist)	Children Hospital 1	Vietnam
54	National Immunization Program Specialist	Pfizer	Saudi Arabia
55	Pediatrician	Pofeng Lee Clinic	Taiwan
56	Pediatrician	Ohana Specialist Hospital	Malaysia
57	Pediatrician	Columbia Asia Malaysia	Malaysia
58	Pediatrician (National Project Coordinator)	Eka Hospital	Indonesia
59	Pediatrician	Pantai Indah Kapuk Hospital	Indonesia
60	Pediatric Allergy and Immunology	Ankara Sehir Hastanesi	Turkey
61	Sr. Market Research Manager& Business Development	Diyalog Arastırma	Turkey
62	Deputy Director (Faculty of Medicine Ramathibodi Hospital, Mahidol University)	National Institute for Child and Family Development	Thailand
63	Developmental and Behavioral Pediatrician	Faculty of Medicine Siriraj Hospital, Mahidol University	Thailand
64	Nurse Practitioner, Founder, and Director	Highgate Health · Self-employed	Australia
65	General Practitioner	Shafa hospital	Australia
66	General Practitioner	University of Melbourne, Shepperton Medical Centre	Australia
67	Pediatrician	The Islamic Hospital -Aqapa	Jordan
68	General Pediatrician	Reinhold Jansen MVZ Kinder Clinic	Germany
69	Technical Director Health Clinical Medicine and Pediatrician	Salute Clinica Médica Ltd	Brazil
70	Pediatrician (Medical Specialist)	The Medical City Satellite Clinics	Philippines
71	Pediatric OPD c/w ER officer	Hwacheon Public health center	Republic of Korea
72	Managing Director, Chief Executive Officer		
	AyurvedaDoc	Austria	
73	Pediatrician	Burjeel Oasis Medical Centre	UAE
74	Pediatric Specialist	Emirates Healthcare	UAE
75	Hematologist Pediatrician	San Borja Child Health National Institute	Peru
76	GCP inspector (Pediatrician / Clinical Trials Evaluator)	National Institute of Health Peru	Peru
77	Head of the Pediatric Intensive Care Service and Associate Professor	Hospital Cayetano Heredia	Peru
78	Pediatrician	Clinical Hospital Center	Serbia
79	Pediatrician	Medi Group Serbia	Serbia
80	Pediatrician	Médecins Sans Frontiers (MSF)	Mexico
81	ER Pediatrician	St Joseph's Hospital and Medical Center	United States
82	Medical Director (Pediatrician)	Blue Cross and Blue Shield of Illinois, Montana, New Mexico, Oklahoma & Texas	United States
83	Primary Care Pediatrician	Orlando Medical Health Care	United States
84	Pediatrician	Port Pediatrics	United States
85	Pediatrician	Lifeline Healthcare Group	Oman

Table 35 - Characteristics of Hexavalent Vaccine Brands

The table below shows the characteristics of different hexavalent brands

Vaccine Characteristics	Infanrix Hexa®	Hexaxim®	Vaxelis®
Diphtheria toxoid	Not less than 30 UI	Not less than 20 UI	Not less than 20 UI
Tetanus toxoid	Not less than 40 UI	Not less than 40 UI	Not less than 40 UI
Pertussis	PT 25 µg	PT 25 µg	PT 20 µg
	FHA 25 µg	FHA 25 µg	FHA 20 µg;
	PRN 8 µg	-	PRN3 µg
	-	-	FIM type 2,3: 5 µg
Hepatitis B – HbsAg	Saccharomyces cerevisiae	Hansenula polymorpha	Saccharomyces cerevisiae
Hib -PRP	10 µg Conjugated to Tetanus toxoid	12 µg Conjugated to Tetanus toxoid	3 µg Conjugated to Meningococcal protein
IPV Polio	Poliovirus inactivated type 1, 2, 3	Poliovirus inactivated type 1, 2, 3	Poliovirus inactivated type 1, 2, 3

Table 36 - Characteristics of Pentavalent Vaccine Brands

The table below shows the characteristics of different pentavalent brands

Vaccine Characteristics	Pentaxim®	Pentacel®	Pediacel®	Infanrix Penta®	Pediarix®
Diphtheria toxoid	Greater than 30 UI	15Lf	15Lf	Not less than 30 UI	25 Lf
Tetanus toxoid	Greater than 40 UI	5Lf	5Lf	Not less than 40 UI	10 Lf
Pertussis	PT 25 µg	PT 20 µg	PT 20 µg	PT 25 µg	PT 25 µg
	FHA 25 µg	FHA 20 µg	FHA 20 µg	FHA 25 µg	FHA 25 µg
	-	PRN 3 µg	PRN 3 µg	PRN 8 µg	PRN 8 µg
	-	FIM 5 µg	FIM 5 µg	-	-
Hepatitis B – HbsAg	-	-	-	Saccharomyces cerevisiae	Saccharomyces cerevisiae
Hib -PRP	10 µg Conjugated to Tetanus toxoid	10 µg Conjugated to Tetanus toxoid	10 µg Conjugated to Tetanus toxoid	-	-
IPV Polio	Poliovirus inactivated type 1, 2, 3	Poliovirus inactivated type 1, 2, 3	Poliovirus inactivated type 1, 2, 3	Poliovirus inactivated type 1, 2, 3	Poliovirus inactivated type 1, 2, 3

Table 37 - Characteristics of Tetravalent Preschool Booster Vaccine Brands

The table below shows the characteristics of different tetravalent preschool booster vaccine brands

Vaccine Characteristics	Tetraxim®	Infanrix-IPV/Kinrix®	Quadracel®
Diphtheria toxoid	Not less than 30 UI	Not less than 25 Lf	Not less than 15 Lf
Tetanus toxoid	Not less than 40 UI	Not less than 10 Lf	Not less than 5 Lf
Pertussis	PT 25 µg	PT 25 µg	PT 20 µg
	FHA 25 µg	FHA 25 µg	FHA 20 µg;
	-	Pertactin (PRN) 8 µg	PRN 3 µg
	-	-	FIM type 2,3: 5 µg
IPV Polio	Poliovirus inactivated type 1, 2, 3	Poliovirus inactivated type 1, 2, 3	Poliovirus inactivated type 1, 2, 3

Table 38 - Vaccine Brands For Preschool Booster Vaccines

The table below shows different brands of preschool booster vaccines used across countries

Sr. No	Vaccine Type	Vaccine Representation	Vaccine Brand/Manufacturer
1	Trivalent Vaccine	Tdap	Boostrix® (GSK)
2	Trivalent Vaccine	Tdap	Adacel® (Sanofi)
3	Tetravalent Vaccine	DTaP-IPV	Tetraxim® (Sanofi)
4	Tetravalent Vaccine	DTaP-IPV	Infanrix-IPV®/Kinrix® (GSK)
5	Tetravalent Vaccine	DTaP-IPV	Quadracel® (Sanofi)
6	Tetravalent Vaccine	Tdap-IPV	Boostrix-IPV® (GSK)
7	Tetravalent Vaccine	Tdap-IPV	Repevax® (Sanofi)

[i] Explaining the Immunization Agenda 2030 (who.int)

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[v] National Cancer Institute Dictionary of Terms
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[vi] WHO Global Market Study Of Diphtheria & Tetanus Containing Vaccines
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