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

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Glossary

Antigen

Any foreign substance that produces immune response in the body.¹

DTP Vaccine

A vaccine that produces immunity against three deadly diseases - namely diphtheria, tetanus, pertussis.²

DTP₃ Immunization Rate

The percentage of one-year-olds who have received three doses of the combined diphtheria, tetanus toxoid and pertussis (DTP₃) vaccine in a given year.³

DTaP Vaccine

DTaP is a combined vaccine against Diphtheria, tetanus, and pertussis, in which the pertussis component is acellular (contains purified components of *B. pertussis*).⁴

DTwP Vaccine

DTwP is a combined vaccine against diphtheria, tetanus, and pertussis, in which the pertussis component is a whole-cell, which is an entire *B. pertussis* organism that has been inactivated.⁵

GAVI

The Global Alliance for Vaccines and Immunizations (GAVI), is an international organization, bringing 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.⁶

Hexavalent Vaccine

A hexavalent vaccine (DTaP-IPV- HepB-Hib) is a six-in-one vaccine that protect babies against diphtheria (D), tetanus (T), pertussis (whooping cough), poliomyelitis, *Haemophilus influenza type b* (Hib) and hepatitis B (Hep B). All hexavalent vaccines are intended for pediatric use.⁷

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 (whooping cough), poliomyelitis, and *Haemophilus influenza type b* (Hib). All pentavalent vaccines are intended for pediatric use.⁸

Pertussis vaccines (aP and wP)

Pertussis, 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).⁹

DTP Primary Series Vaccines

These vaccines are the initial doses of vaccines given for infants. DTP primary series vaccines are either 2 doses or 3 doses depending on individual countries national immunization schedule.¹⁰

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).¹¹

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 entirely to be borne through out-of-pocket expenditure.¹²

Schedule

A vaccination schedule refers to the details of primary series and school entry booster vaccines as recommended by the national immunization program in a country. Recommendations include the number of doses and the age at which a specific dose of vaccine to be administered.¹³

aP Based School Entry Booster Vaccine

aP-based school entry booster vaccines are either trivalent (DTaP or Tdap), or tetravalent (DTaP-IPV or Tdap-IPV) and protects children against diphtheria (D), tetanus (T), pertussis (whooping cough), and poliomyelitis if containing IPV. These vaccines are used during age of 3 to 7 years depending on an individual countries' national immunization schedule.

Statutory Insurance

Statutory health insurance is financed by funds, which are financially and organizationally independent, contributed by employees and employers through payroll taxes.¹⁴

Surviving Infants

Surviving infants is the number of children reaching their first birthday during a given year.^{15, 16}

UNICEF

The United Nations International Children's Emergency Fund works in 190 countries and territories to protect the rights of every child.¹⁷

V3P/MI4A Database

V3P/MI4A database contains information on vaccine prices, volumes, manufacturers, procurement modalities, contract length, and more as reported by over 150 countries. This database is published by the World Health Organization (WHO).¹⁸

WHO

The World Health Organization is a specialized agency of the United Nations working in 194-member countries. This organization deals with issues related to public health.¹⁹

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

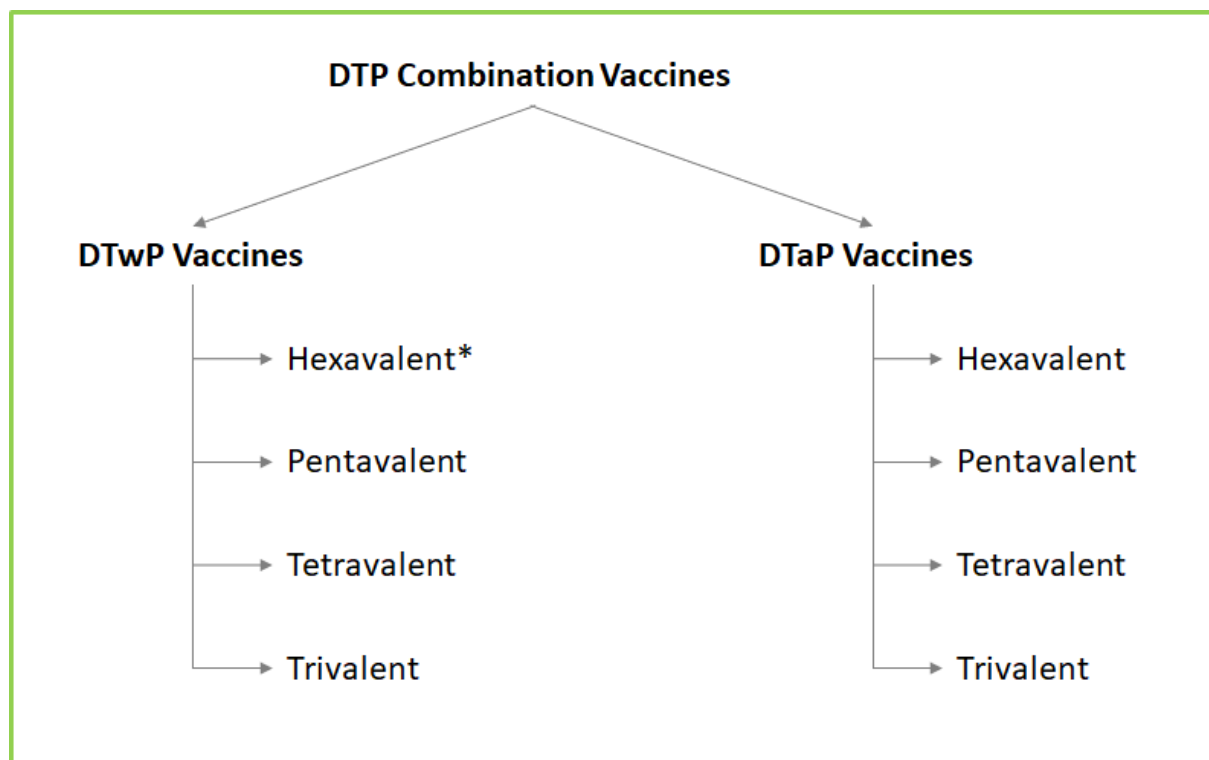
All regions mentioned in this report are according to the WHO countries' classification. For instance, countries under EUR are the WHO classification of EUR, not limited to the countries which represent the European Union.

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.²⁰

Market Structure Of the DTP Combination Vaccines

The below schematic is to give a background understanding of the DTP combination vaccines market.



*One wP hexavalent vaccine called Easy Six produced by panacea biotech but with registration and sales limited to India.

DTP combination vaccines are used for both primary series and booster vaccination. These DTP combination vaccines are based on either the whole cell pertussis component (DTwP) or acellular pertussis component (DTaP). Both DTwP and DTaP based combination vaccines include hexavalent, pentavalent, tetravalent, and trivalent vaccines.

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

Abstract

The objective of the present study is to understand usage patterns for aP (acellular pertussis) based pediatric combination vaccines and to identify the market structure (volumes administered by vaccine brand) among pediatric pertussis combination vaccines. The scope of this study includes DTaP combination vaccines for primary series; and DTaP and Tdap combination vaccines (DTaP, DTaP-IPV, Tdap, Tdap-IPV) for school entry boosters. To achieve the desired objective, we have analyzed three types of vaccines namely hexavalent vaccines, pentavalent vaccines, and aP-based school entry booster vaccines.

Immunization of infants against diphtheria, tetanus, pertussis, poliomyelitis, disease caused by *Haemophilus influenza* type b and hepatitis B are performed using pentavalent vaccines (targeting 5 of the 6 diseases above mentioned) or hexavalent vaccines (targeting the 6 diseases). These vaccines are recommended for primary vaccination and toddler booster administration in three or four doses. Hexavalent and pentavalent vaccines form a major part of the aP based pediatric combination vaccines market. DTaP vaccines together with DTwP based vaccines compose the DTP backbone combination vaccines market.

School entry booster vaccines are diphtheria and tetanus-based combination vaccines administered as a booster dose in addition to the primary vaccination series to increase immunity against diphtheria (D), tetanus (T), pertussis (Whooping cough), and poliomyelitis. Acellular pertussis-based school entry booster vaccines are of two types: trivalent (DTaP, Tdap), and tetravalent vaccines (DTaP-IPV, Tdap-IPV). These vaccines are administered to children from 3 to 7 years of age according to the country's national immunization schedule.

To meet the study objectives, we analyzed key indicators such as vaccine immunization schedules, vaccination coverage rate, and population of surviving infants and of school entry age (3-7 years), for all the target countries, across the globe, in 2020. Qualitative and quantitative data gathered through the application of these key parameters were used to estimate market volumes for hexavalent, pentavalent, tetravalent, and trivalent vaccines in each target country. We referred to UNICEF, the WHO, and other country-specific sources for data gathering.

Our methodology involves the selection of major countries from the global 196 countries (194 WHO countries, plus Taiwan and Hong Kong), that constitute at least 95% of each of the vaccine markets (primary series, toddler booster, and school entry booster). The top 40 countries (29 public markets + 11 private markets) that constitute 96% of the worldwide hexavalent market by volume, were selected for the study. Similarly, the top 22 countries (17 public markets + 5 private markets) that constitute 98% of the worldwide pentavalent vaccine market by volume, were selected for the study. For school entry booster vaccines, the top 40 markets were selected based on the fact that they represent 97% of the global school entry booster vaccine market.

As part of the study, we estimated the proportions of 'acellular pertussis' (aP) and 'whole-cell pertussis'-based (wP) combination vaccines for infant primary and toddler booster vaccination. In 2020, among the 313.2 million doses of pertussis

containing vaccines used for infant primary and toddler vaccination, 73% are wP vaccines and 27% are of aP vaccines. Hexavalent vaccines account for 46% of the DTaP primary series and toddler booster market with 37.7 million doses consumed in 2020. Pentavalent vaccines accounted for 41% of the DTaP primary series and toddler booster market with approximately 34.5 million doses consumed in 2020.

As part of the study, we have analyzed DTwP and DTaP/Tdap based school entry booster markets by volume and estimated the proportions of trivalent and tetravalent booster vaccines. DTP combination school entry booster vaccines with a whole-cell pertussis component (DTwP) is estimated to have a 60% share of the total pertussis combination school entry vaccine combination school entry vaccines market in 2020, which accounts for 19.8 million doses. DTaP or Tdap combination school entry booster vaccines (acellular pertussis) had a 40% share of the DTP combination school entry booster vaccines market, which accounts for 13.3 million doses. The study found that DTaP-IPV/Tdap-IPV tetravalent vaccines are more often utilized in high-income countries. Among aP based school entry booster vaccines 75% are tetravalent vaccines with 10 million doses distributed, whereas 25% are trivalent vaccines with 3.3 million doses distributed. By region, tetravalent vaccines are consumed more in the European region (EUR). The study found that DTaP/DTaP-IPV tetravalent vaccines are more often utilized compared to Tdap/Tdap-IPV vaccines. Among aP based school entry booster vaccines 74% are DTaP/DTaP-IPV vaccines with 9.3 million doses distributed, where as 24% are Tdap/Tdap-IPV vaccines with 3.5 million doses distributed.

As part of the study, we studied brand surveillance across infant primary series, toddler booster, and school-entry booster vaccine markets. Based on our estimations of hexavalent vaccine volumes for 2020, **Hexaxim®, the hexavalent vaccine from Sanofi Pasteur, holds the leading position in the hexavalent vaccines market with 67% of the volumes consumed across the globe.** Infanrix Hexa®, manufactured by GlaxoSmithKline (GSK) accounts for 26% of the hexavalent vaccines market, and Vaxelis®, manufactured by MCM (Partnership formed between Sanofi Pasteur and Merck & Co., Inc.) accounts for 7% of the hexavalent vaccines market. **In the public markets analyzed, Hexaxim® has a 73% market share and is the most used hexavalent vaccine.**

In the pentavalent vaccines market, **Pentaxim®, from Sanofi Pasteur, holds a leading position with 62% of the pentavalent vaccine volumes consumed across the globe.** Pentacel® and Pediacel® manufactured by Sanofi Pasteur accounts for 17% and 2% of the pentavalent vaccine market. Pediarix® and Infanrix-IPV/Hib® manufactured by GSK accounts for 16% and 3% of the pentavalent vaccine market.

In the school entry booster market, **Tetraxim®, from Sanofi Pasteur holds a leading position with 36.3% of the school entry booster volumes consumed across the globe.** Infanrix-IPV®, and Boostrix®, manufactured by GSK account for 18.6%, and 17.2% of the school entry booster vaccine market. Quadracel®, Repevax® (also called as Adacel Polio®, Triaxis Polio®), and Adacel® (also called as Covaxis®, Triaxis®) manufactured by Sanofi Pasteur account for 10.5%, 5.6%, and 3.1%, respectively.

In all the three segments, hexavalent, pentavalent, and tetravalent vaccines, Sanofi Pasteur's vaccine brands hold the market leader position. Sanofi Pasteur is thus the leading provider of aP based pediatric combination vaccines.

Key Words: aP based Combination Vaccines, Hexavalent, Pentavalent, Trivalent, Tetravalent, Hexaxim®, Infanrix Hexa®, Vaxelis®, Acellular Pertussis, Whole-cell Pertussis, Combination Vaccine, Pentaxim®, Infanrix-IPV/Hib®, Pentacel®, Pediacel®, Pre-School Booster Vaccine, Immunization, Schedule, Tetraxim®, Infanrix IPV®/Kinrix®, Boostrix®, Boostrix-IPV®, Adacel®, Repevax®, Acellular Pertussis, Whole-cell Pertussis, Combination Vaccine, Trivalent Vaccines, Tetravalent Vaccines

Research Objective

The primary goal of this white paper is to evaluate the market leader among pertussis combination vaccines. DTaP primary series and toddler booster series were considered for estimating hexavalent and pentavalent markets, whereas both DTaP and Tdap combination vaccines are considered for the school entry booster vaccines market. Our analysis includes

- *Global volumes of aP and wP based vaccines (primary series & booster dose)*
- *Utilization trends for acellular pertussis combination vaccines including*
 - *hexavalent vaccines*
 - *pentavalent vaccines*
 - *school entry booster vaccines*

1. Introduction

This introduction section provides an overview of the pertussis-based combination vaccines, including the types of primary and school entry booster vaccines and the details of various pentavalent, hexavalent and school entry booster vaccines that existed in the market.

Pertussis combination vaccines can be either DTwP (whole-cell Pertussis antigen) based or DTaP (acellular pertussis antigen) based. The focus of this study is on DTaP based combination vaccines.

DTaP based combination vaccines include primary series vaccines (Trivalent, Tetravalent, Pentavalent and Hexavalent vaccines) and school entry booster series vaccines (Trivalent and Tetravalent).

Most of the countries using aP based primary series vaccines either use the hexavalent or pentavalent vaccine. Hexavalent acellular pertussis combination vaccines are DTaP-IPV-Hib-HepB, whereas pentavalent vaccines are either DTaP-IPV-Hib or DTaP-IPV-HepB.

Acellular pertussis-based Trivalent (DTaP) and Tetravalent (DTaP-IPV) vaccines are less and less commonly used. A few countries still use these vaccines in primary series, whereas most aP using countries have shifted to either a pentavalent or a hexavalent vaccine.

Pertussis-based school entry booster vaccines are of two types: trivalent (DTaP, DTwP, Tdap), and tetravalent vaccines (DTaP-IPV, Tdap-IPV).

Combination Vaccines Overview

Combination Vaccines are used to overcome the problems associated with multiple administration 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.²¹

The combined diphtheria, tetanus, and pertussis (DTP) vaccine, which includes a whole-cell pertussis antigen (DTwP) or two or more acellular pertussis components (DTaP), has already been incorporated into the national

immunization schedules in most countries for pediatric vaccines.²² These DTP based vaccines serve as the backbone of several other combination vaccines such as tetravalent, pentavalent, and hexavalent vaccines.

Inactivated polio vaccine (IPV) combinations are used for both primary and booster vaccinations.²³ Owing to the high cost of these vaccines, these are used mainly by high income and middle-income countries. All IPV vaccine combinations are acellular pertussis (aP) based vaccines.

Pentavalent Vaccines

The pentavalent vaccine is a combination vaccine that the WHO widely recommend as a substitute for prevailing vaccination practices for diphtheria, tetanus, pertussis (DTP), *Haemophilus influenza type b* (Hib) or hepatitis B, and poliomyelitis infections.²⁴

Most of the countries use pentavalent vaccines in their national immunization schedule. In 2020, around 125 countries are using "DTwP-HepB-Hib" vaccines for routine immunization. During the same period, 30 countries are using the "DTaP-IPV-Hib" vaccine for routine immunization.²⁵

Low-income and lower-middle-income group countries are the major countries using wP pentavalent vaccines without IPV antigens (as most of these countries are still using oral polio vaccine – OPV). In contrast, high income and upper-middle-income countries have all adopted IPV containing pentavalent vaccines.²⁶

Types of Pentavalent Vaccines

Pentavalent vaccines combine five antigens in one formulation. It offers protection against Diphtheria, Tetanus, Pertussis (DTP), hepatitis B (HepB) or *Haemophilus Influenzae type b* (Hib), and poliomyelitis.²⁷ These vaccines are of two types, either acellular pertussis based or whole-cell pertussis-based.

Acellular pertussis (aP) based pentavalent vaccines (DTaP-IPV-Hib) are mainly used for high and upper middle middle-income group countries.²⁸ In contrast, whole-cell pertussis (wP) based vaccines (DTwP-HepB-Hib) are used by low and lower-middle-income countries.²⁹

Whole-cell pertussis (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 programmes on immunization (EPI).³⁰

In most of the countries, the trivalent (DTwP) and tetravalent (DTwP-HepB) vaccines for primary series have been replaced with pentavalent vaccines (DTwP-HepB-Hib).³¹

Pentavalent Vaccine Brands

There are five acellular pertussis (aP) based pentavalent vaccine preparations commercially available for administration to children; namely Pentaxim®, Pentacel®, Pediacel® (Sanofi Pasteur), Infanrix-IPV/Hib®, and Pediarix (GlaxoSmithKline, GSK). They are all DTaP-IPV-Hib vaccines except Pediarix DTaP-IPV-HepB.

Hexavalent Vaccines

Hexavalent vaccines are a way to increase compliance with the entire primary schedule and the coverage rate of the six antigens: diphtheria, tetanus, pertussis (DTP), hepatitis B, inactivated poliovirus (IPV), and *Haemophilus influenza type b* (Hib) infections, assuring simplification of administration and better control of vaccination program costs.³²

Hexavalent vaccines are the preferred vaccines in the European region and have replaced pentavalent vaccines as primary vaccines in most European countries. In Europe, 30 of 52 countries (according to WHO definition) are using hexavalent vaccines, whereas, in LATAM, only four of 30 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.³³

Middle-income group countries (MIG) are increasingly adopting hexavalent vaccines in their national immunization schedule. For instance, two upper-middle-

income countries such as South Africa and Mauritius in the AFR region, have introduced hexavalent vaccines in their national immunization program. South Africa was the first country in the AFR region to replace the pentavalent vaccine and adopt hexavalent vaccines in 2015, followed by Mauritius in 2017. Other middle-income group countries, including Mexico, Saudi Arabia, Panama, Gulf countries, and Jordan, have also included hexavalent vaccines in their national immunization program.

Types Of Hexavalent Vaccines

The acellular Hexavalent vaccine (DTaP-IPV-HepB-Hib) is a six-in-one (all the antigen in the same container with no reconstitution) (or 5+1, vaccine that needs reconstitution) vaccine recommended in three or four doses schedule to help protect babies against diphtheria (D), tetanus (T), pertussis (aP) (whooping cough), poliomyelitis, *haemophilus influenza type b* (Hib) and hepatitis B (Hep B).³⁴ To date, there is only one hexavalent vaccine with a whole-cell pertussis component available only in India.

Hexavalent Vaccine Brands

There are three hexavalent vaccine preparations commercially available for administration to children; namely Hexaxim®/Hexyon®/Hexacima® (Sanofi Pasteur), Infanrix Hexa® (GlaxoSmithKline, GSK), and Vaxelis® (MCM). 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.³⁵

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)³⁶ (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.”³⁷

Hexaxim® is the only hexavalent vaccine with the World Health Organization (WHO) prequalification status and the only one available in both pre-filled syringe or mono-dose vial presentation.

Pertussis Based School Entry Booster Vaccines

School entry booster vaccines (diphtheria & tetanus-based vaccines) are combination vaccines administered to children from 3 to 7 years of age based on a country's national immunization schedule.³⁸ These vaccines protect children against two or more of the following diseases: diphtheria (D), tetanus (T), pertussis (aP or wP) (whooping cough), and poliomyelitis (IPV). The need for these vaccines is mainly attributed to waning immune protection conferred by vaccination i.e., after primary vaccine doses.³⁹ Children receiving school entry booster vaccines are protected against these infections until receiving an adolescent booster dose.⁴⁰

Types of School Entry Booster Vaccines

School entry booster vaccines are of two types, trivalent (DTaP, DTwP, Tdap), and tetravalent vaccines (DTaP-IPV, Tdap-IPV). Around 94 countries use trivalent and tetravalent pertussis-based vaccines as school entry boosters in their national immunization schedules. Most of these countries use acellular pertussis (aP) based school entry booster vaccines in their national immunization schedules.⁴¹

Trivalent school entry booster vaccines are three-in-one vaccines recommended to protect school entry children against diphtheria (D/d), tetanus (T), and pertussis (aP) (Whooping cough).

Tetravalent school entry booster vaccines are four-in-one vaccines recommended to protect children against Diphtheria (D/d), tetanus (T), pertussis (aP) (Whooping cough), and poliomyelitis (IPV). High-income countries mostly use tetravalent school entry booster vaccines in their national immunization schedules.⁴² (Table 12)

School Entry Booster Vaccine Brands

Boostrix® (GSK) and Adacel® (Sanofi Pasteur) are the most widely used trivalent school entry booster vaccines. These vaccines are available in single-dose prefilled syringes (Adacel® is also available as 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.⁴³ (Table 19)

Tetraxim® (Sanofi Pasteur), Infanrix-IPV®/Kinrix® (GSK), and Quadracel® (Sanofi Pasteur) are the most widely used tetravalent school entry 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 route (IM) preferably into the deltoid muscle of the upper arm.^{44,45,46} 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.⁴⁷ (Table 18)

In the American region (AMR), Eastern Mediterranean Region (EMR), and South East Asia region (SEAR), trivalent vaccines are the most used school entry booster vaccines. For instance, 25 out of 33 countries use DTwP school entry booster vaccines in their national immunization schedule in AMR. In the Western Pacific Region (WPR) region, trivalent vaccines are used in 8 countries, whereas tetravalent vaccines are used in 6 countries. In EUR, tetravalent vaccines (DTaP-IPV, Tdap-IPV) are the most used vaccines.

In EUR, 35 of the total 53 countries are using aP based school entry booster vaccines, whereas in AMR only 5 countries of 35 countries are using aP based school entry booster vaccines in their national immunization schedule. In Europe, 28 countries use tetravalent vaccines for school entry booster doses, whereas in AMR three countries use tetravalent vaccines namely the USA, Canada, and Costa Rica for school entry booster doses.⁴⁸

2. Methodology

The study is based on the worldwide demand estimates for acellular pertussis combination vaccines (both primary series & school entry booster series). Three factors determine the potential size of the worldwide acellular pertussis combination vaccine market — the annual worldwide birth cohort (as well as 3-7 years target population for school entry 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 stakeholders influencing the DTaP-IPV combination vaccine demand include governments of industrialized and developing countries and the private sector.⁴⁹

2.1 Volumes of DTP vaccines by Type of Pertussis Antigens (wP and aP)

The global volumes for wP & aP DTP combination vaccines are sourced from a global market study conducted by the WHO on diphtheria and tetanus-containing vaccines.⁵⁰ The further split of aP vaccines into hexavalent, pentavalent, and others is based on the Vaccine Product, Price, and Procurement (V3P) database.⁵¹

2.2 Public And Private markets For Pertussis Antigen (wP and aP)

A total of 195 countries were selected (194 from WHO Global Health Observatory (GHO) data, Taiwan*), and public and private markets for vaccines are identified based on the inclusion or otherwise of the acellular pertussis combination vaccine in the government supply and the national immunization schedule of the country. The countries with an acellular pertussis combination vaccine in their national immunization schedule are designated public markets. 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 high income (HI), Upper middle income (UMIC), lower middle income (LMIC),

and low-income countries (LIC) based on the World Bank classification,⁵² which is adopted by the WHO.⁵³ Among these WHO countries, 72 countries are using acellular pertussis (DTaP) based combination vaccines in their national immunization schedules, which are designated public markets, whereas 121 countries using whole-cell pertussis (DTwP) combination vaccines in their national immunization schedules are designated as private markets. Acellular pertussis 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. Monaco is excluded from the analysis because it is not using IPV based pertussis combination vaccines in its immunization schedule. Monaco uses DTIPV (Diphtheria, Tetanus, IPV combination vaccine) in their immunization schedule⁵⁴. China is considered for the study (although it is using DTaP trivalent vaccine as primary series vaccine since its private market is huge for pentavalent vaccines).

2.2.1 Hexavalent Markets

Among the 72 public markets using acellular pertussis combination vaccines, 46 countries are using hexavalent vaccines. These countries are listed for estimating market volumes.

To arrive at the list of hexavalent private markets, we have excluded all African countries and low-income countries from the list of 121 private markets. These countries were excluded based on the assumption that governments in these countries cannot afford the supply of hexavalent aP vaccines and that the consumption of hexavalent vaccines is also limited among private markets in these countries. Also, LMIC and UMIC countries with less than 100,000 surviving infants and high-income countries with <20,000 surviving infants are excluded. Finally, 44 countries using hexavalent vaccines in their private markets are selected for market estimations.

Top 30 hexavalent public markets were selected for brand analysis from 46 hexavalent public markets, which constitute 97% of the global hexavalent public markets. Top 11 hexavalent private markets were chosen for brand

analysis from 44 hexavalent private markets, which constitute 90% of the global hexavalent private markets.

The top 40 hexavalent markets considered (30 from public and 10 from private hexavalent markets) constitute 96% of the global hexavalent market by volume.

2.2.2 Pentavalent Markets

Among the 72 public markets using acellular pertussis combination vaccines, 34 countries are using the pentavalent vaccine in their national immunization schedule. These countries are considered for estimating the market volumes for pentavalent public markets (the sum of hexavalent and pentavalent countries seems to be higher than the total of 72 countries because few countries are using both hexavalent and pentavalent vaccines in their national immunization schedule).

To arrive at the list of pentavalent private markets, we have excluded all low-income countries from the list of 121 private markets. These countries were excluded based on the assumption that governments in these countries cannot afford the supply of pentavalent aP vaccines.

The consumption of pentavalent vaccines is limited among private markets in these countries.

Also, LMIC and UMIC countries with less than 100,000 surviving infants are excluded. The resultant list of 63 countries was analyzed for pentavalent vaccine approvals, procurement information, and usage trends. Finally, 20 pentavalent vaccine private markets were considered for further analysis.

The top 15 pentavalent markets were selected for brand analysis from 34 pentavalent public markets, which constitute 98% of the global public pentavalent market. The top 5 pentavalent private markets were selected for brand analysis from 20 pentavalent private markets, which constitute 90% of the global private pentavalent market by volume.

Finally, 20 pentavalent markets were considered (15 from public and 5 from private pentavalent markets) which constitute 98% of the global pentavalent market by volume

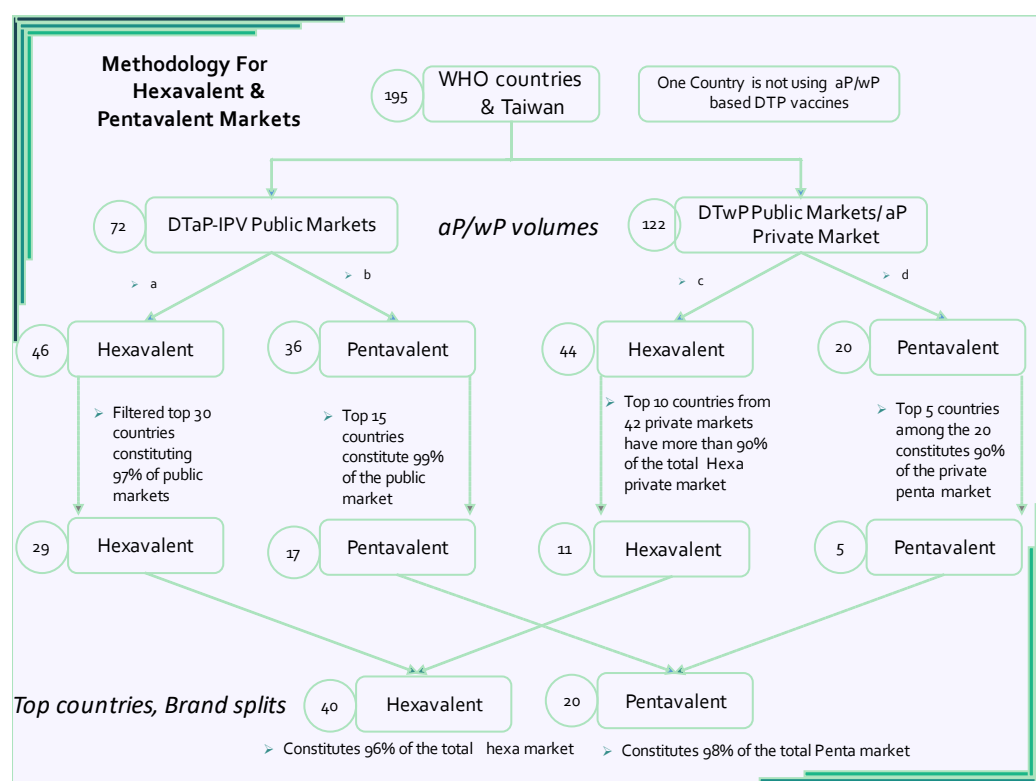


Fig 1: Methodology for selecting top countries for hexavalent & pentavalent vaccine market evaluation

- Among 72 countries, only 46 countries are using hexavalent vaccines in their national immunization schedule;
- Among 72 countries, only 36 countries are using pentavalent vaccines in their national immunization schedule
- Removed low-income countries, UMIC, LMIC with surviving infants (SI) <100,000, HIC with SI <20,000, Removed all African countries (most of these countries do not have hexavalent vaccines even in private markets)
- Removed low-income countries, removed all UMIC & LMIC with SI <100,000; The resulting 63 countries all were checked for pentavalent vaccine approvals, any procurement information, and usage trends, and finally found that only 20 countries are actively using aP based pentavalent vaccines in the private market.

2.2.3 School Entry Booster Vaccines Market

A total of 196 countries were selected (194 from the WHO Global Health Observatory (GHO) data, plus Taiwan & Hong Kong). Public and private markets for aP based school entry booster vaccines are identified based on the inclusion or otherwise of the aP based school entry booster vaccines in the government supply in the country's national immunization schedule. The countries with aP based school entry booster vaccines in their national immunization schedule are designated public markets. The government bears a part or all of the expenditure for immunization in the public markets whereas vaccine expenditure in private markets is through out-of-pocket expenditure or reimbursement by private insurance payers.

All 196 countries are classified as high income, upper middle income, lower middle income, and low-income countries based on the World Bank classification,⁵⁵ which is adopted by the WHO.⁵⁶ Around 59 countries that do not use booster vaccines for school entry children (booster vaccines for school entry children are not included in their national immunization schedule) are excluded in this analysis, based on the assumption that the private market for these vaccines will be very low.

Countries that only use bivalent or combination vaccines for school entry booster doses (DT/TT/Td/DTIPV) are also excluded from the study (43 countries). The exclusion of these countries can be attributed to their low-income status (around half of the countries being low and lower-middle-income countries), and their private market share for trivalent and tetravalent school entry booster vaccines also being low. Countries such as Taiwan and Hong Kong are included in the study despite the reason that these countries are not WHO listed. The reasons for having these countries in this study are the high use of tetravalent and pentavalent vaccines in their immunization schedules and the public availability of these vaccine procurement volumes.⁵⁷

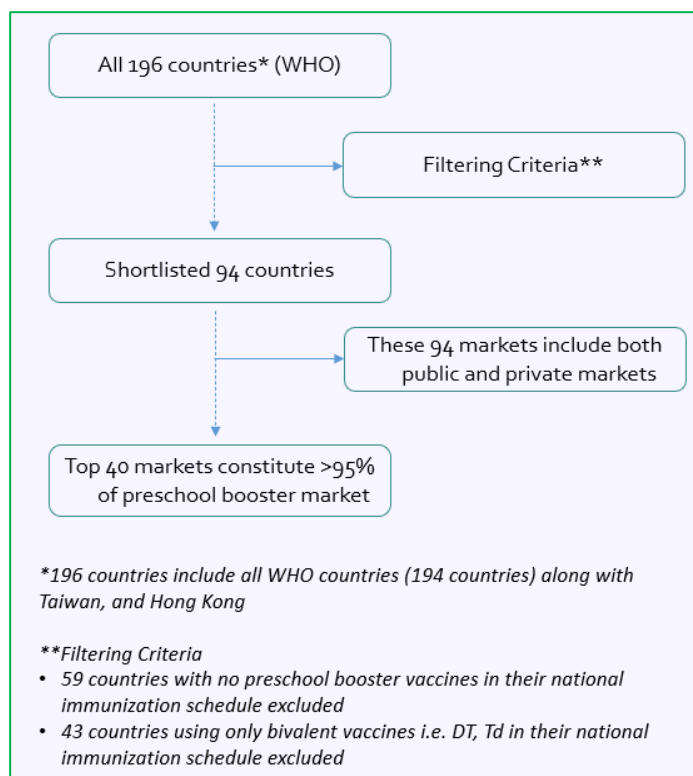


Fig 2: Methodology for selecting top countries for school entry booster market evaluation

A total of 94 countries are considered for the current study, which includes 53 countries with public markets for aP based school entry booster vaccines and 41 countries with aP based school entry booster vaccines administered through private markets.

Finally, 40 school entry booster markets were considered which constitute 96% of the global school entry booster market by volume

2.3 Indicators For calculating DTaP-IPV Combination Vaccine Volumes

2.3.1 Surviving Infants: The doses of hexavalent and pentavalent vaccines are administered to children less than 12 months of age.⁵⁸ 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 (Table 4 & Table 5).

2.3.2 School Entry Children Population: The doses of aP based school entry booster vaccines are administered to children aged between 3 to 7 years, depending on each country's immunization schedule. Hence the school entry population between 3 to 7 years of age is the target population for this study. The data on the school entry population is obtained from the World Bank population estimates and projections database.

2.3.3 Immunization Rate: The DTP₃ vaccine immunization rate was considered to estimate the hexavalent and pentavalent vaccine immunization rates. For public markets with only a hexavalent or a pentavalent vaccine supplied through a national schedule, the total immunization rate of DTP₃ is considered as the immunization rate of that vaccine (Table 4).

For public markets having both hexavalent and pentavalent vaccines, the immunization rate is estimated based on the consumption of these vaccines as a proportion of all the available multivalent vaccines (Table 4).

For private markets, the immunization rate for hexavalent and pentavalent vaccines is estimated, based on data collected from secondary sources such as WHO,⁵⁹ and the Center for Disease Control and Prevention (CDC).⁶⁰ Parameters such as private healthcare vaccine trends and the income status of a country sourced from WHO are also considered for estimating private hexavalent vaccine market volumes for some countries. Private vaccines market shares obtained from WHO surveys⁶¹ and research publications, and from primary inputs are also used for estimating private market volumes for hexavalent vaccines. (Table 5)

The school entry booster immunization rate (DTP₅/DTP₄) was considered for estimating the aP based school entry booster vaccine volumes. For public markets, the total immunization rate of school entry boosters is considered for vaccine volume analysis.

For private markets, the immunization rate for aP based school entry booster vaccines is estimated, based on inputs from primary respondents. 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 school entry booster vaccine market volumes for some of the countries.

2.3.4 Schedule: The number of doses of hexavalent and pentavalent vaccines suggested under each country's immunization schedule is obtained from the WHO (Table 4). For countries under private reimbursed markets, the standard number of doses suggested by recognized authorities and the European Union is considered (Table 5).

The number of doses of aP based school entry booster vaccines suggested under each country's immunization schedule is obtained from the WHO (Table 12 & Table 13). 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.

2.4 Calculation Of Volumes Of DTaP-IPV Combination Vaccine:

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

The aP based school entry booster vaccines market volumes are calculated using these parameters—school entry children population, aP school entry booster vaccine immunization rate, and vaccination schedule. The objective is to find the utilization of aP school entry booster vaccines by region, country, and by individual brand.

2.5 Brand Analysis of Acellular Pertussis Combination Vaccines

Hexavalent or pentavalent acellular combination vaccines are used for primary vaccination series while trivalent or tetravalent combination vaccines are used for school

entry booster vaccinations. Several brands exist within each of the vaccine markets and the proportion of each of the brands consumed in a country is derived through extensive secondary research and studying various approaches.

Brand preference among the hexavalent brands is estimated for the top 40 countries having high sales volumes for the hexavalent vaccines.

Brand preference among the pentavalent brands is estimated for the top 20 countries with high sales volumes for pentavalent vaccines.

Our criterion for identifying the top 40 for hexavalent and top 20 countries for pentavalent is that these countries account for more than 95% of the hexavalent and pentavalent vaccines market by volume. On average, the brand of vaccine that is consumed more in these 40 countries will be a market leader in the overall hexavalent vaccine market, whereas the brand of vaccine consumed more in these 20 countries will be a market leader in the overall pentavalent vaccine market. (Table 6 & Table 11)

Our criterion for identifying the top 40 countries for school entry booster vaccines is that these countries account for more than 95% of the aP based school entry booster vaccines market by volume.

The volumes of aP based school entry booster vaccines administered for all 94 countries were estimated. The top countries that constitute more than 95% of the aP based school entry booster vaccine market are considered for further market analysis. On average, the brand of vaccine that is consumed more in these 40 countries will be a market leader in the overall aP based school entry booster vaccine market.

The method by which vaccines are purchased and financed in each country influences the proportion of individual brands of vaccines consumed. In public markets (hexavalent, pentavalent, school entry booster), 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 consumption patterns for each brand of vaccines across the target countries is obtained through information gathered by various sources as below-

2.5.1 National and Regional Tenders

2.5.2 Ministry Of Health (MOH) and National Health Authorities

2.5.3 Primary Interviews with key members in national immunization programs, medical advisors, university professors, UNICEF members, pediatricians, and immunization researchers.

We analyzed national tenders for available countries in each market (hexavalent, pentavalent, and school entry booster). Tendering information such as the number of doses of vaccines or the brand of vaccine procured in 2020 is used for market estimations. We also reviewed the ministry of health (MOH) and National health authority sources in each country to obtain information on particular brands of vaccines (among hexavalent, pentavalent, and school entry 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 consumption.

Details of the information gathered from each of the above sources is exemplified below.

2.5.1 National and Regional Tenders

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

National tenders procure hexavalent vaccines in Mexico, Australia, South Africa, Romania, Netherlands, Chile, Libya, Jordan, Kazakhstan, Croatia, Norway, Austria, and Bulgaria. Canada, Italy and Spain procure vaccines through regional tenders. In Saudi Arabia, vaccines are procured through the national unified procurement company (NUPCO).

National tenders procured Pentavalent vaccines in the USA, Russia, Malaysia, Canada, South Korea, Israel, Hungary, Taiwan and Switzerland.

National tenders procure school entry booster vaccines (aP based) in Chile, Italy, the UK, South Korea, Romania, Czech Republic, Sweden, Bulgaria, Belgium, and Australia.

Tendering information details and their outcomes in terms of brands purchased are as below-

- In Mexico, the Ministry of Health (MOH) procures tenders for hexavalent vaccines. The MOH procures only Hexaxim® in 2020.⁶² Around 99% of hexavalent vaccines administered in Mexico are of Hexaxim®.⁶³
- In South Africa, the national department of health (NDoH) procures hexavalent vaccines.⁶⁴ Hexaxim® is the only brand of vaccine included in South Africa's national immunization schedule. Around three million doses of Hexaxim® were procured during 2019.^{65,66,67}
- In the UK, Infanrix Hexa® among hexavalent vaccines, Boostrix-IPV® and Repevax® among tetravalent vaccines are centrally procured to be included in the national immunization schedule. The UK is a national tender market, where Infanrix Hexa® was the awarded vaccine in 2020.⁶⁸ Among school entry booster vaccines, Boostrix-IPV, and Repevax were the distributed vaccines in 2020.⁶⁹
- In Saudi Arabia, the national unified procurement company (NUPCO) procures vaccines through annual tenders. In 2020, the tender for hexavalent vaccines is awarded to Sanofi's Hexaxim®.⁷⁰ More than 90% of the hexavalent vaccine administered in Saudi Arabia is through the national immunization schedule and is of the 'Hexaxim®' brand.⁷¹
- In Australia, Infanrix Hexa® is the only brand of hexavalent vaccine procured by the Department of Health through national tenders.⁷² Around one million doses of Infanrix Hexa® vaccine are procured in 2020.⁷³ In Australia, both Infanrix-IPV® and Quadracel® are procured by the Department of Health through national tenders.⁷⁴ Around 300,000 doses of both Infanrix-IPV® and Quadracel® vaccines are procured in 2020.⁷⁵
- In Chile, The National Health Service System (CENABAST), under the Ministry of Health, procures vaccines, and it procured the 'Hexaxim®' vaccine for public immunization in 2020.⁷⁶
- Romania's Ministry of Health procured both Infanrix Hexa® and Hexaxim® brands of hexavalent vaccines in 2020.⁷⁷ Around 60% of the hexavalent vaccine doses procured are of Hexaxim®⁷⁸ and the remaining market constitutes Infanrix Hexa®.
- 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).⁷⁹ Vaxelis® has replaced Infanrix Hexa® in 2019.⁸⁰ Boostrix-IPV® is the only brand of vaccines procured for a school entry booster dose in the Netherlands.⁸¹
- In Italy and Spain, vaccines are procured through regional tenders. In 2020, Hexaxim®,⁸² and Infanrix hexa®,⁸³ and Vaxelis® are procured by regional tenders in both countries.
- In Canada, Infanrix Hexa® is procured for public immunization by Health Canada for only 5 provinces/territories, including British Columbia, Alberta, Quebec, Prince Edward Island, and Yukon.⁸⁴ In 2020, around 0.5 million doses of Infanrix Hexa® were procured by the Government of Canada.⁸⁵ Pediacel® is the only pentavalent vaccine procured for public immunization by

Health Canada, whereas Repevax® and Boostrix-IPV® are procured for school entry booster doses.⁸⁶

- In Libya, vaccines are procured through national tenders by the ministry of health supreme committee for the supervision of tender.⁸⁷ Hexaxim® is the only hexavalent vaccine included in its national immunization schedule for public immunization.⁸⁸ According to Libya's National center for disease control, Repevax® is the only school entry booster vaccine being used in the country.⁸⁹
- In Austria, vaccines are procured through national tenders by the Federal Ministry of Labour, Social Affairs, Health, and Consumer Protection.⁹⁰ Hexaxim® is the only hexavalent vaccine included in the free children's vaccination program⁹¹ whereas Repevax® is the only school entry booster vaccine offered under national immunization.⁹²
- In Panama, vaccines are procured through PAHO.⁹³ Hexaxim® is the only hexavalent vaccine included in the national immunization schedule for public immunization.⁹⁴
- In Bulgaria, vaccines are procured through national tenders by the Ministry of health. Tetraxim® is the only school entry booster vaccine included in the immunization schedule for public immunization in 2020.⁹⁵ Every year Bulgaria MOH procures around 60,000 doses of Tetraxim®.
- In Norway, vaccines are procured through national contract open tenders through the Norwegian Institute of Public Health.⁹⁶ Infanrix-Hexa® is the only hexavalent vaccine used in the national immunization program in Norway in 2020.⁹⁷
- In Belgium, vaccines are procured solely by each Belgian community.⁹⁸ Pharmacies directly procure vaccines from manufacturers or wholesalers.⁹⁹ Hexaxim® is the only vaccine used in the immunization program in Belgium in 2020.¹⁰⁰ Tetraxim® is the only school entry booster vaccine used in the immunization program in Belgium in 2020.¹⁰¹

- In Sweden, vaccines are procured through centralized regional public tenders.¹⁰² Hexaxim® is the only vaccine used (Infanrix Hexa® replaced with Hexaxim® in September 2019) in the immunization program in Sweden in 2020.¹⁰³

2.5.2 Ministry Of Health (MOH) and National Health Authorities

The information on brands of acellular pertussis-based vaccine administered in national immunization schedules in the different countries is gathered through authentic secondary sources such as the Ministry of Health (MOH) sites and publications by government health authorities, among related resources. For instance, the Swedish public health authority publishes information on the hexavalent brands and the volumes consumed in the country. In 2019, the Sweden government has replaced Infanrix Hexa® with Hexaxim®.¹⁰⁴

In 23 public markets namely, the UK, Chile, Netherlands, Belgium, Sweden, Canada, Australia, New Zealand, Ireland, Russia, Libya, Oman, South Africa, Saudi Arabia, Mexico, Jordan, Panama, Kazakhstan, Austria, Norway, Romania, Portugal, and Croatia only one brand of hexavalent vaccine is administered (the entire public market consists of this brand of vaccine). For instance, in the UK¹⁰⁵, and Canada¹⁰⁶, Infanrix Hexa® is the only brand of hexavalent vaccine available and administered to all the target children. 'Hexaxim®' is the only brand of hexavalent vaccine administered in 14 countries, for instance in Mexico¹⁰⁷, South Africa¹⁰⁸, Kazakhstan¹⁰⁹, and Belgium¹¹⁰ use only 'Hexaxim®' in their national immunization schedule. The National Center for Disease Control (NCDC) provides medical supplies and vaccines in Libya.

According to the United Nations Industrial Development Organization (UNIDO), South Africa, has allocated around 40% of its vaccine supplies budget for the procurement of the hexavalent vaccine from Sanofi (Hexaxim® brand).¹¹¹ The vaccinator's manual published by the National Department of Health, recommends only Hexaxim® under hexavalent vaccines, to be administered to children.¹¹² The reasons for South Africa including the

hexavalent vaccine in its national immunization schedule are¹¹³ lower healthcare provider costs by simplifying logistics and delivery infrastructure, reduced visits to clinics, lower vaccination errors, fewer injections compared to individual vaccines, and reduction in vaccine adverse events.¹¹⁴

In 21 markets including Turkey, Russia, Kazakhstan, Hungary, Serbia, Costa Rica, Portugal, Lithuania, , Finland, and Canada only one brand of pentavalent vaccine is administered (India and China are private markets using only one brand of vaccine). Pentavac® is the only brand of vaccine available in Finland.¹¹⁵ Canada uses Pediacel® as the only pentavalent vaccine for immunization.¹¹⁶

In 24 public markets namely Turkey, Poland, South Korea, Taiwan, Romania, Sweden, Belgium, Hungary, Portugal, Hong Kong, United Arab Emirates, Costa Rica, Denmark, Bulgaria, Norway, Ireland, New Zealand, Saudi Arabia, Kazakhstan, Chile, Netherlands, Czech Republic, Libya, and Austria only one brand of school entry booster vaccine is administered (the entire public market consists of this brand of vaccine). **For instance, in Poland¹¹⁷, Romania¹¹⁸, Sweden¹¹⁹, Belgium¹²⁰, Turkey¹²¹, and South Korea¹²², Tetraxim® is the only brand of vaccine available and administered to all the target children.** In New Zealand¹²³, Infanrix-IPV® is the only tetravalent vaccine administered to the target children.

2.5.3 Primary Interviews

In some of the countries, especially in countries with private markets (for hexavalent, pentavalent, and school entry booster), data on vaccine procurement by pharmacies or clinics, and or wholesaler sales data is not publicly accessible. Primary interviews with key members in national immunization programs, medical advisors, university professors, pediatricians, and immunization researchers were conducted for such countries to know the brand utilization.

3. Findings & Discussion

In this section pertussis-based combination vaccines are analyzed to understand the share of acellular (aP) and whole-cell (wP) pertussis vaccines. Acellular pertussis (aP) vaccines are then further segmented into hexavalent, pentavalent, and school entry booster vaccine markets and each market is analysed in turn. In each section vaccine volumes consumed in each market are estimated and analyzed by region, country, and brand.

3.1 DTP Combination Vaccines by Type of Pertussis Antigens (wP and aP)

In 2020, the global demand for DTP-based combination vaccines was 313.2 million doses.^{124,125} This is a 4.2% decrease compared to global demand for DTP based combination vaccines in 2019. The decrease in the global immunization rate for DTP combination vaccines is attributed to the COVID-19 pandemic and measures taken to reduce SARS-CoV-2 transmission substantially, which affected health services worldwide.¹²⁶ DTP combination vaccines with a whole-cell pertussis component (DTwP) had a 73% share of the total DTP combination vaccines market in 2020, accounting for 230 million doses. DTaP combination vaccines (acellular pertussis) had a 27% share of the DTP combination vaccines market, accounting for 83.2 million doses.

The global DTP-based combination vaccine market in this study excludes DTaP vaccines consumed in China public market. In the public market, China uses DTaP vaccine, which is prepared through the co-purification process as opposed to component vaccine preparation (WHO states co-purification process as “two or more pertussis antigens that have been isolated and purified using combinations of several physicochemical separations.”)¹²⁷

However, the private market for China which includes pentavalent and tetravalent vaccines is included for estimating the global DTaP combination vaccines market. In China, the USA, and Japan no hexavalent vaccines were commercialized at the time of the study. In China, only the trivalent DTaP vaccine is being used in the national immunization schedule, whereas in the USA, pentavalent

vaccines are used and the market is shared between Sanofi Pasteur and GSK.

The total DTaP combination vaccine market (shown in Figure-3) is split into hexavalent, pentavalent, and tetravalent vaccines (added as other vaccines in Fig 3).

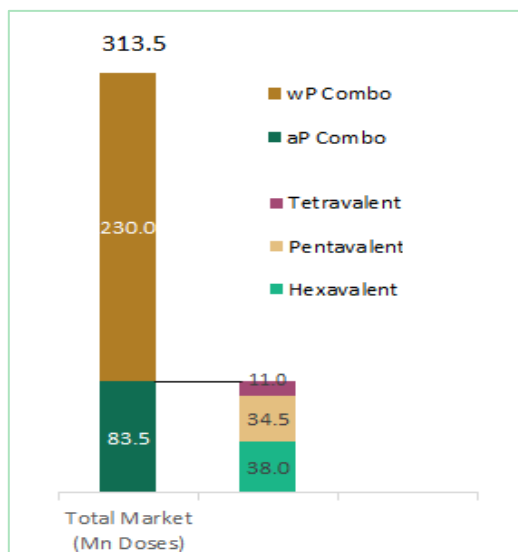


Fig 3: aP and wP Vaccine Split,

Decimal values are rounded off in the chart

Global DTP combination market volumes excluding China public market.

Based on our assumptions, in 2020, the global hexavalent vaccine demand was 38 million doses (decimal values rounded off in Fig 3), which is 46% of the total DTaP combination vaccine market.

The demand for pentavalent vaccines and tetravalent vaccine was 34.5 million doses and 11 million doses, respectively. The high share of hexavalent vaccines among DTaP based vaccines can be attributed to a shift to hexavalent vaccines by high-income countries, particularly European countries.

3.1.1 Countries Using DTwP and DTaP Combination Vaccine

Among the 195 countries (194 WHO countries, plus Taiwan), around 121 countries have DTwP combination vaccines and 72 countries have DTaP combination vaccines in their national immunization schedule.¹²⁸ One country, which is not using DTP combination vaccines is excluded from this study. This country is Monaco which uses DTIPV (Diphtheria, Tetanus, IPV combination

vaccine) vaccine in their immunization schedule. Although China uses trivalent vaccine (DTaP) in its immunization schedule¹²⁹, it is included in the study. This is because millions of doses of pentavalent vaccines are administered in China. The high consumption of pentavalent vaccines in China is due to a significant reduction in the number of vaccine doses needed compared to other combination vaccines. (The need for 8 vaccine shots using DTaP, IPV, and Hib as separate vaccines can be reduced to 4 shots with a pentavalent vaccine). The non-availability of hexavalent vaccines is also a reason for the penetration of the pentavalent brand in the Chinese private market.

Among the 72 countries using DTaP combination vaccines, 51 are of high-income status. There are only three lower-middle-income countries: Bosnia-Herzegovina, Bhutan, and Micronesia, using DTaP combination vaccines in their national immunization schedules. There are 18 upper-middle-income countries using acellular pertussis component vaccines.¹³⁰

Most of the EUR countries use aP vaccines, for instance, in Europe, among 52 countries (according to WHO classification) 41 countries are using DTaP combination vaccines in their national immunization schedule. Only two African countries, namely Mauritius, and South Africa, use DTaP vaccines in public immunization.¹³¹

DTaP based combination vaccines are more expensive than DTwP vaccines. Pooled procurement agencies such as UNICEF supported by GAVI funding procures pentavalent vaccines with whole-cell pertussis (wP) components for supply to low- and middle-income countries.

Also, developing countries that procure by self-financing methods procure wP based DTP combination vaccines for the supply in their countries.¹³²

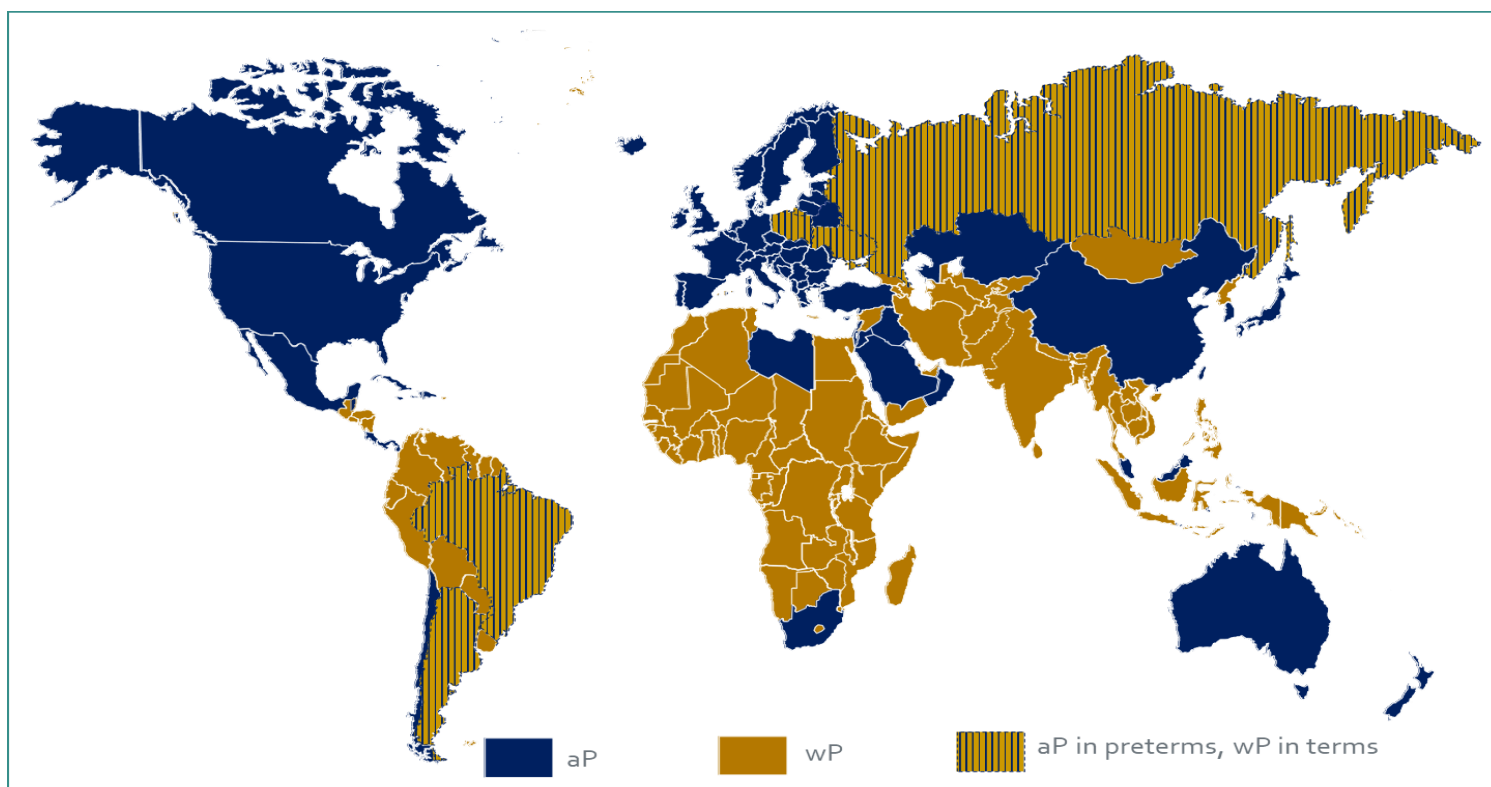


Fig 4: Countries using aP vaccines in their national immunization schedule, 2020

Acellular component (aP) based DTP vaccines are supplied to the public by governments of upper-middle-income and high-income countries or consumed in private markets in some high- and middle-income countries through out-of-pocket expenditures.¹³³

The above reasons explain the consumption of higher volumes of DTwP vaccines than DTap combination vaccines. There is an increasing adoption of DTap based combination vaccines, especially hexavalent vaccines in middle income countries. This can be attributed to low reactogenicity and the ease of use of these vaccines

The initial cost of implementing hexavalent vaccines through public immunization programs is high compared to whole-cell pertussis vaccines such as pentavalent vaccines. However, there are significant cost savings by the implementation of hexavalent vaccines in national immunization schedules.

According to a study conducted by Demarteau N et.al. in Slovenia the implementation of a hexavalent 2+1 immunization schedule with co-administration of 4th dose MMR or Tdap/MMR at 7 years old leads to annual budget

saving of €259,776 and €470,950 as compared to the budget associated with the pentavalent vaccine schedule.¹³⁴

Another study conducted by M. Mogale et.al. in South Africa estimates the cost savings of implementing hexavalent vaccines to be \$0.5 to \$1.5, compared to administering pentavalent vaccines.

These cost savings are attributed to reduced cold storage space, reduced hazardous waste disposal, and a reduced number of vaccines administered.¹³⁵

According to the WHO's MI4A database (market information for vaccines), most of the wP vaccines are manufactured in developing countries, including India, Brazil, Venezuela, Indonesia, Iran, and Serbia.¹³⁶ In contrast, most of the aP vaccines are manufactured in developed countries (high-income groups), including the USA, France, Belgium, and Denmark.¹³⁷

Hexaxim® is manufactured in France,¹³⁸ Infanrix Hexa® is manufactured in Belgium,¹³⁹ and Vaxelis® is manufactured in Canada.¹⁴⁰

3.1.2 Pediatric Pertussis Vaccine Trends

The EUR region is one of the first regions in the world to use hexavalent vaccines.^{141, 142, 143} This region has high adoption of hexavalent vaccines, and more EU countries are shifting toward these vaccines. The pediatric pertussis vaccine trends in the European region are described below.

EU Countries Shifting From Mixed Vaccination Schedules To Full Hexavalent Vaccine Schedule

Some European countries have been using hexavalent vaccines and pentavalent vaccines in their national immunization schedule for primary vaccinations. A trend toward shifting to a full hexavalent vaccine schedule from mixed vaccine schedules (using Hexa/Penta) is observed in European countries. For instance, a few countries such as France (shifted to full hexavalent schedule in 2016) and Spain (shifted to full hexavalent schedule in 2016) have shifted entirely to Hexavalent vaccines.

During 2018 and 2019, some European countries have made changes to their national immunization schedules pertaining to hexavalent vaccines. Countries including Greece¹⁴⁴ and Sweden¹⁴⁵ are progressively replacing pentavalent vaccines with hexavalent vaccines in their immunization schedule.

High Adoption of Hexavalent Vaccines Among High-Income European Countries

Among 52 EUR countries, 28 countries have adopted hexavalent vaccines in their national immunization schedules of which 22 countries belong to high-income status, 6 countries belong to the upper-middle-income status, including Russia, Kazakhstan, Bulgaria, Georgia, Armenia, and Macedonia. The adoption of the hexavalent vaccine in the EU is high in high-income status countries compared to upper middle income and lower-middle-income countries.

Preference Towards Fully Liquid Hexavalent Vaccine

European countries, including Germany, France, Italy, Spain, and Belgium, prefer a fully liquid hexavalent vaccine compared to a reconstituted hexavalent vaccine.^{146, 147} This trend might be explained by a combination of factors, including the willingness of healthcare professionals to reduce reconstitution errors, reduced vaccine preparation time, and ease of use.

In the Netherlands, the National Institute for Public Health and the Environment (RIVM) has replaced Infanrix Hexa® with Vaxelis® starting from 2019.¹⁴⁸ All children born from December 2018 are being administered with Vaxelis® according to the immunization vaccine schedule.¹⁴⁹

According to a survey conducted by Ilse De Coster et.al. in Belgium, the average preparation time for a fully-liquid hexavalent vaccine is 38 seconds, whereas it is 70.5 seconds for a non-fully liquid hexavalent vaccine. The research also reports that the time saved using fully liquid hexavalent vaccines was 34.5 seconds.¹⁵⁰

A study conducted by Mathijssen DAR et.al. in the UK demonstrated that the introduction of a fully liquid vaccine in the UK's immunization schedule for infants can save £1.17 million to £1.21 million per year, compared to using a vaccine requiring reconstitution.¹⁵¹

According to a survey conducted by Pierre Bakhache et.al. in France, 28% of pediatricians and general practitioners reported occasionally omitting to reconstitute a pentavalent or hexavalent vaccine in error, and 60% of respondents not fully reconstituting the vaccine. According to this study, vaccine reconstitution as a complicating factor is reported by 70% of pediatricians, and 57% of general practitioners.¹⁵²

According to a study conducted in Germany by Lloyd et.al. on patient preference and adherence to the hexavalent vaccine, healthcare providers prefer a fully liquid hexavalent vaccine compared to a reconstituted hexavalent vaccine.¹⁵³ This preference is due to reduced preparation time and low probability of administration errors with fully reconstituted vaccines.¹⁵⁴

According to an open-label randomized Belgian study conducted by I. De Coster et al., the preparation time and immunization errors were lower in a fully liquid hexavalent vaccine than a non-fully liquid vaccine. The same study reported that around 98% of healthcare professionals preferred a fully -liquid hexavalent vaccine (this study samples 96 health care professionals).¹⁵⁵

Georgia Transitioned To Fully Self-Financing Hexavalent Vaccines

Georgia procures many vaccines through the UNICEF supply division. During 2018 – 2019, Georgia introduced hexavalent vaccines in their national immunization schedule. As hexavalent vaccines are not available through UNICEF procurement, the country shifted to self-financing to procure this vaccine.¹⁵⁶ Georgia was able to procure hexavalent vaccines at a competitive and affordable price despite its market size (smaller market compared to other European countries using hexavalent vaccines). The country has evaluated several reasons for introducing hexavalent vaccines which include, reduction in vaccine rejections, high trust and acceptance of hexavalent vaccine in Georgia's private sector, and can overcome the potential global supply shortage of IPV vaccine.¹⁵⁷

Low Adoption of Hexavalent Vaccine In LATAM Countries

LATAM countries have low adoption of hexavalent vaccines. Among 30 LATAM countries only 4 countries namely Mexico, Chile, Panama, and Argentina (only for preterm babies), have adopted hexavalent vaccines in their immunization schedule.

In Mexico, the hexavalent vaccine was approved in 2018 for inclusion in the national immunization schedule. In 2020, Mexico has completely transitioned to hexavalent vaccines in its immunization schedule.¹⁵⁸ The reasons for introducing the hexavalent vaccine in Mexico are attributed to increased vaccine protection and the reduced number of multiple vaccine doses.¹⁵⁹

According to WHO-SAGE recommendations, Chile introduced one dose of IPV vaccine to replace the 2-month OPV dose. As a continuation, the country introduced a hexavalent vaccine (which contains IPV dose) in 2018 for 2- and 4-months intervals, and had 2 OPV doses along with a pentavalent vaccine at 6 and 12 months.¹⁶⁰ Starting from 2019, the Chilean Ministry of health recommended hexavalent vaccines to provide polio vaccine doses at 2, 4, 6, and 18 months replacing both OPV and pentavalent vaccines.¹⁶¹ The reason for Chile's shifting to the hexavalent vaccine is to overcome the supply shortages of the IPV vaccine and to reduce the adverse events related to wP pentavalent vaccine in the immunization schedule.¹⁶²

Panama was the first country in the LATAM region to introduce hexavalent vaccines in its immunization schedule. Unlike other LATAM countries, Panama offers only a hexavalent vaccine for infants. According to the Panama ministry of health at least 50,000 children out of 70,000 births, a year benefit from this immunization.¹⁶³

Argentina uses hexavalent vaccines only for risk infants, for instance, preterm newborns weighing less than 1500 grams at birth and <6 months.¹⁶⁴ According to the Center for Fetoneonatal Studies, Argentina has around 1.1% of annual pre-term births, or 8,400 are born per year weighing less than 1,500 grams.¹⁶⁵

Malaysia Shifts To Hexavalent Vaccine

In 2020, Malaysia introduced hexavalent vaccines in its national immunization schedule. Previously the country was using four doses of pentavalent vaccine schedule for the primary vaccine series. According to the Malaysian Ministry of Health (MOH), the hexavalent vaccine schedule is conducted in stages that started from 2020 and will ultimately replace the pentavalent vaccine in the next few years.¹⁶⁶ Ministry of health states the benefits of introducing the hexavalent vaccines, such as fewer vaccine doses than the pentavalent vaccine schedule and fewer immunization visits to health clinics.^{167, 168}

High Penetration of Pentavalent Vaccines In Chinese Private Market

Pentavalent vaccines in China are available in the private market through out-of-pocket expenditure. More than 35% of immunization in China (for DTP primary series) is consumed in the private market using pentavalent vaccines.

ACVIP Recommends Tetravalent Booster Vaccine In India

The Advisory Committee on Vaccines and Immunization Practices (ACVIP) of the Indian Academy of Pediatrics has recommended a booster dose of injectable polio vaccine (IPV) at 4-6 years for children who have received the initial IPV doses. The committee has also approved the use of Tetraxim for the second booster of DPT-IPV at 4-6 years of age.¹⁶⁹ Sanofi has recently launched Tetraxim, a four-in-one (DTaP-IPV) vaccine in India private out-of pocket market.¹⁷⁰

3.2 Global Market For Hexavalent Vaccines

The global market for the hexavalent vaccines section describes the use of hexavalent vaccines in public and private markets and hexavalent vaccine utilization trends.

3.2.1 Public & Private Markets For Hexavalent Vaccines

The countries are split into public and private markets based on government supply and the inclusion of hexavalent vaccines in the immunization schedule. Out of 89 countries considered for the study, 46 countries are public markets for hexavalent vaccines, and the remaining 44 countries are private markets, as shown in Figure 5.

The hexavalent vaccines are used in 46 public markets, which include 33 high-income countries, 13 upper-middle-income countries. The government spending ability of high-income countries explains the reasons for the increased use of hexavalent vaccines in these public markets.

Hexavalent vaccines are provided by private reimbursed and private out of pocket (OOP) services in 44 countries,

of which 9 are high income, 15 are upper middle income, 20 are lower-middle-income countries.¹⁷¹

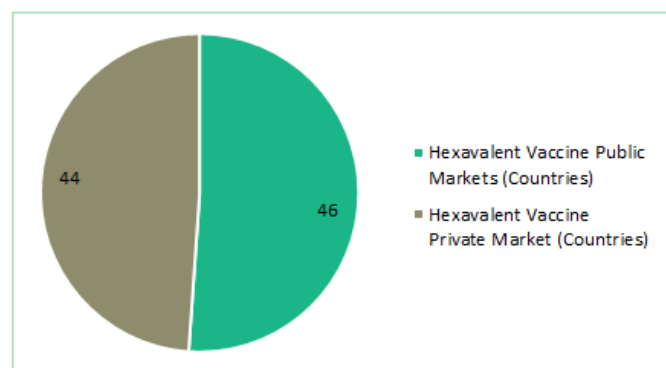


Fig 5: Hexavalent public & private markets (number of countries), 2020, (Refer to Table 4 & Table 5 in appendix)

3.2.2 Analysis Of Indicators For Calculating DTaP-IPV Containing Vaccine Volumes In Public And Private Markets

Three indicators used to estimate the hexavalent vaccine market in each target country are the annual birth cohort (surviving infants), the vaccine schedule, and the proportion of children receiving the hexavalent vaccine (vaccine coverage rate).

3.2.2.1 Surviving Infants

Hexavalent vaccine demand (in number of doses) is directly linked to the size of the birth cohort of the country. Some hexavalent public markets, namely those of Mexico, South Africa, and the UK have a high surviving infant population. In 2020, Mexico had a surviving infant population of around two million, whereas South Africa and the UK had around one million, and 0.7 million respectively. The consumption of hexavalent vaccines is high in these public market countries, due to the supply of free or subsidized hexavalent vaccines by government agencies to the sizable target population (Table 4).

Private markets with a high surviving infant population include India, Nigeria, Pakistan, and Indonesia. In 2020, while having a birth cohort of 23 million and four million in India and Indonesia, around three million in Brazil, and two million in the Philippines (Table 5) only a small

proportion of infants are vaccinated through the private market channel.

3.2.2.2 Vaccine Schedule

Most of the countries with hexavalent public markets have implemented the three-dose primary series hexavalent vaccine schedule. Only seven countries including Kazakhstan, Oman, United Arab Emirates, Portugal, Qatar, Macedonia, and Bahrain have recommended two doses of hexavalent vaccine in their immunization schedule. In these seven countries, a dose of the pentavalent vaccine is administered instead of a third dose of the hexavalent vaccine (Table 2).

Four doses of hexavalent vaccines are recommended in few public markets. The public markets in which national immunization programs recommend three dose primary series and toddler booster doses of hexavalent vaccines include Mexico, South Africa, Chile, Belgium, Malaysia, Russia (for risk groups), Latvia, Malta, Estonia, and Mauritius.

3.2.2.3 DTP3 Immunization Rate For Hexavalent Vaccine Market

DTP3 immunization rate, the third dose immunization rate for Diphtheria, Tetanus, and Pertussis, is considered for the hexavalent vaccine immunization rate

Globally, hexavalent vaccines by volume 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% to 99% among those countries.

For public markets where both hexavalent and pentavalent vaccines are used, the immunization rate for hexavalent vaccines varies by country depending on specific factors such as geographical distribution and availability of vaccines within the country and targeted recommendations for a specific population.

The immunization rate for hexavalent vaccines ranges from 70%-90% in most of these countries. However,

Argentina and Canada have hexavalent vaccine use rates of around 1.1% and 45%, respectively (Table 5).

Even though the overall immunization rate is high in Argentina and Canada, the coverage rate for the hexavalent vaccine is low due to targeted recommendations for specific population. In Argentina, hexavalent vaccines are only administered to children weighing less than 1500 grams (or pre-term born infants). In Argentina's public market, Hexaxim® is the only Hexavalent vaccine used for pre-term born infants (in 2020), about 1.1% of the total infant population.¹⁷² In Canada, hexavalent vaccines are available only in six provinces out of the ten provinces.¹⁷³ These reasons explain the limited use rates of the hexavalent vaccine in both countries.

The use of hexavalent vaccines (by volume) is limited in private out-of-pocket (OOP) markets, whereas in private reimbursed markets (such as France, Germany, and Slovakia) the use of hexavalent vaccines is high (almost all vaccinations are performed with hexavalent vaccines).

In private markets, most high-income countries have hexavalent vaccine use rates ranging from 10-20%, whereas upper-middle-income countries and lower-middle-income countries have hexavalent vaccine use rates ranging from 2-5% and 1-2%, respectively.

Owing to the high levels (over 90%) of private reimbursement for administering vaccines in France and Germany, immunization rates are high. In France, implementation of mandatory vaccination for 11 diseases (including the six diseases targeted by the hexavalent vaccine) for all children born from January 1st 2018, has led to a further increase of vaccine coverage rate (VCR) for the six diseases.

In these countries, the vaccines are reimbursed through social security (la Sécurité Sociale) and private health insurance policies making them free of charge.¹⁷⁴ (Table 5).

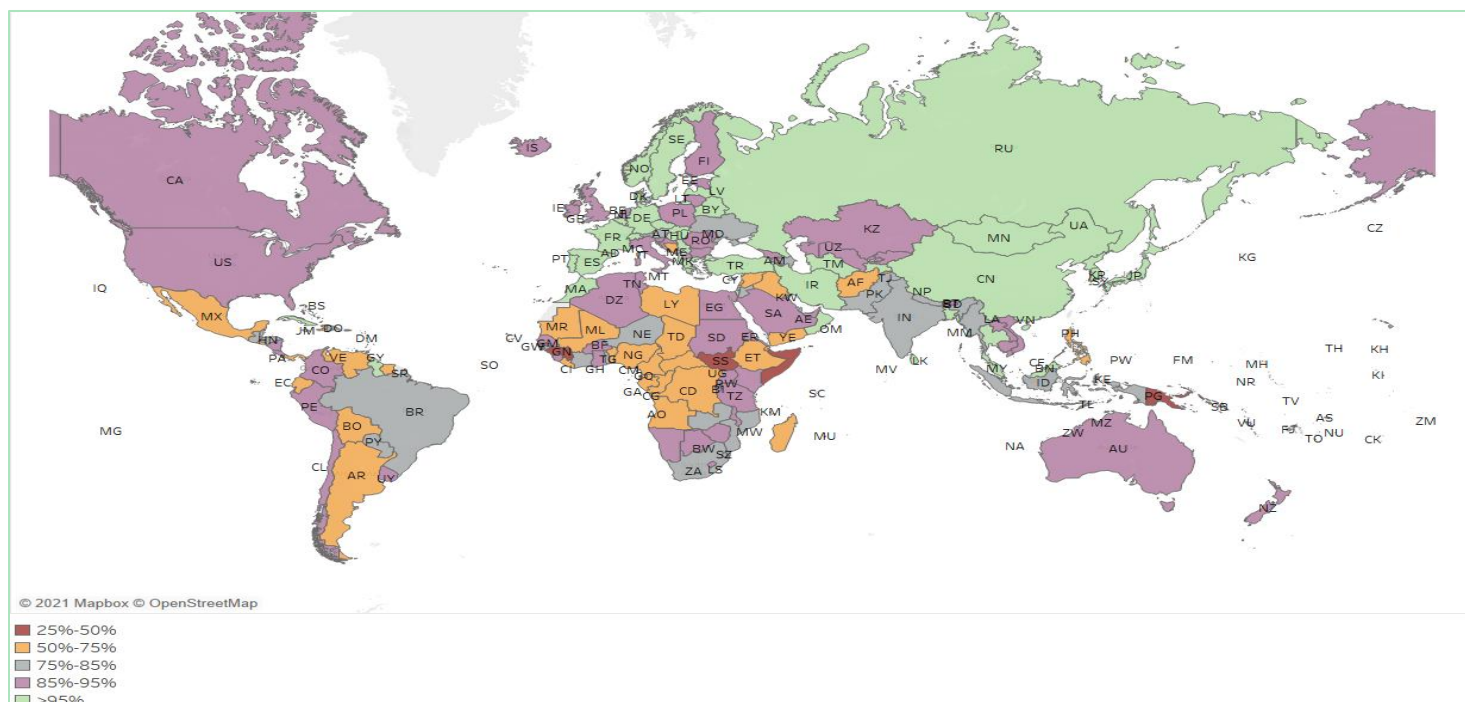


Fig 6: DTP3 immunization coverage (WHO Database)¹⁷⁵, 2020

3.2.3 Volumes Of Hexavalent Vaccines:

In 2020, among 38 million hexavalent vaccines doses used, 27.7 million doses (73%) of hexavalent vaccines were administered in public markets through national immunization programs (NIPs), and 10.2 million doses (27%) were administered to infants in private markets (see Figure 7).

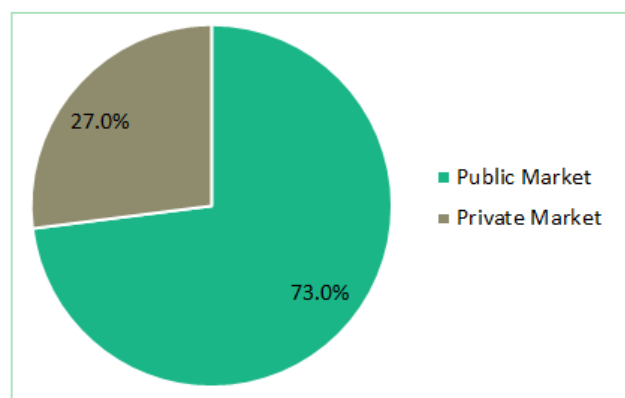


Fig 7: Public and Private Hexavalent Market Share, 2020

Hexavalent vaccines were included in the national immunization programs of many high-income and upper-middle-income countries, 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 low- and middle-income countries.

3.2.3.1 Hexavalent Vaccines Volume Analysis, By Region

As shown in Figure 8, in 2020 Europe accounted for the major share of the hexavalent vaccines market by volume at 38%, followed by American Region (AMR) with 29%, African Region (AFR) and Western Pacific Region (WPR) regions accounted for 11% and 9% respectively, Eastern Mediterranean Region (EMR) with 8%, followed by Southeast Asian Region (SEAR) with the lowest share at 5% of the hexavalent vaccine market.

The high share for EUR is due to most European countries' approval and adoption of hexavalent vaccines since 2001. In 2020, the major European countries such as Germany, the UK, and France each used more than two million doses of hexavalent vaccine in line with their birth cohort (surviving infants of 0.84 million in Germany, 0.75 million in the UK, and 0.69 million in France). Spain and Italy each

use more than one million doses of hexavalent vaccine (0.4 million surviving infants in both Spain and Italy).

In France, the use of hexavalent vaccines is mandatory for children born from January 1st, 2018. Some EU 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.

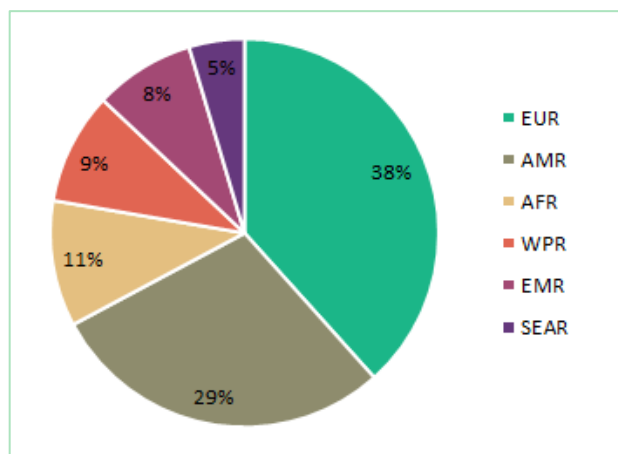


Fig 8: Hexavalent vaccine volume analysis by region, 2020

In EMR, Saudi Arabia, Jordan, and Libya are the major countries using hexavalent vaccines. In 2020, around 2 million doses of hexavalent vaccines were used in Saudi Arabia, while Jordan and Libya used 0.5 and 0.2 million doses of hexavalent vaccines.

In AMR, only five countries, namely Mexico, Canada, Argentina, Chile, and Panama have included hexavalent vaccines in their national immunization schedules. The low use of hexavalent vaccines in the AMR region compared to the EUR region can be attributed to the use of hexavalent vaccines only in special situations in some countries, as well as no availability of hexavalent vaccines in the USA until 2021.

In AFR, South Africa was the first to introduce hexavalent vaccines in its immunization schedule, replacing the pentavalent and HepB Vaccines.¹⁷⁶ More than 90% of hexavalent vaccine volumes used in Africa are in South Africa.

In the WPR region, only five countries, namely Australia, New Zealand, Malaysia, Brunei Darussalam, and Niue, have hexavalent vaccines in their immunization schedule.

In SEAR, hexavalent vaccines are available only through private markets and are not included in the countries' immunization schedules.

3.2.3.2 Hexavalent Vaccine Volume Analysis, By Country

In 2020, the top 40 countries represented 36.1 million doses of hexavalent vaccines which are 96% of the hexavalent vaccine global use (see Table 1).

Country Name	Type of Market	Hexavalent Vaccine (Volume, Million)	(% Share among top 40 markets)
Mexico	Public	8.79	24.1%
South Africa	Public	3.84	10.5%
Germany	Private	2.38	6.5%
United Kingdom	Public	2.07	5.7%
France	Private	2.04	5.6%
Saudi Arabia	Public	2.00	5.5%
Vietnam	Private	1.87	5.1%
Italy	Public	1.21	3.2%
Spain	Public	1.16	2.9%
India	Private	1.05	2.6%
Australia	Public	0.96	2.2%
Chile	Public	0.79	1.7%
Kazakhstan	Public	0.62	1.5%
Canada	Public	0.54	1.4%
Poland	Private	0.53	1.4%
Romania	Public	0.52	1.3%
Belgium	Public	0.48	1.3%
Netherlands	Public	0.47	1.2%
Jordan	Public	0.45	1.1%
Malaysia	Public	0.41	1.0%

Sweden	Public	0.36	0.9%
Czech Republic	Public	0.34	0.9%
Indonesia	Private	0.33	0.9%
Thailand	Private	0.31	0.9%
Brazil	Private	0.26	0.7%
Switzerland	Public	0.26	0.7%
Libya	Public	0.25	0.7%
Greece	Private	0.24	0.7%
Austria	Public	0.23	0.7%
Russian	Public	0.21	0.6%
Oman	Public	0.19	0.6%
Norway	Public	0.17	0.5%
Panama	Public	0.17	0.5%
Slovakia	Private	0.17	0.5%
United Arab Emirates	Public	0.17	0.5%
Ukraine	Private	0.17	0.5%
New Zealand	Public	0.16	0.5%
Ireland	Public	0.16	0.4%
Portugal	Public	0.15	0.4%
Croatia	Public	0.12	0.3%

Table 1: Hexavalent vaccine volumes for the top 40 countries, 2020

Of these 40 countries, 30 have hexavalent public markets, and 10 have private hexavalent markets. In 2020, of the top 40 countries, Mexico had the highest consumption of hexavalent vaccines at 8.79 million doses which is 24% of the total volumes of hexavalent vaccines used, while Croatia had the lowest consumption of 0.12 million doses which is 0.3% of the global hexavalent vaccines used.

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

In private markets, the top three countries with high volumes of hexavalent vaccine consumption include Germany, France, and Greece. Although Germany and

France have high immunization rates, they are included in the private market category because of the need for health care 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).

3.2.3.3 Preterm Hexavalent Vaccine Volume Analysis

In 2020, there are 13.8 million preterm births across the world, which is 10% of the total surviving infant population.¹⁷⁷

Among the global preterm births in 2020, the SEAR region had a high preterm birth rate of 32%, followed by AFR, WPR, EMR, AMR, and EUR regions. Countries with the highest number of preterm births include India, China, Nigeria, Bangladesh, and Pakistan. In 2020, India and China had 3 million and one million preterm births respectively, followed by Nigeria, Bangladesh, and Pakistan each reaching 0.5 million preterm births.

In 2020, around 3.8 million doses of hexavalent vaccines were used for preterm infants in the top 33 markets (private markets among the top 40 countries are excluded for pre-term analysis, except for the private reimbursed markets of Germany, France, and Greece; this exclusion is because private markets do not include the hexavalent vaccine in their immunization schedule, and they are not reimbursed.) (Table 8). Most of the hexavalent vaccine markets are using the same brands of hexavalent vaccines for both pre-term and term infants. In the Czech Republic, although Hexaxim® (actual brand name is Hexacima®) is recommended for use in term infants as per the national immunization program, only Infanrix Hexa® is used in preterm infants.¹⁷⁸ In the Czech Republic, approximately 26,000 doses of Infanrix Hexa® were given for preterm infants in 2020.

Hexaxim® is the only vaccine used in the preterms among 16 countries (Table 9), including 5 countries in Europe: Austria, Belgium, Croatia, Macedonia, and Norway.¹⁷⁹

Argentina uses hexavalent vaccines only for preterm infants weighing less than 1,500 grams at birth and <6 months of age.

Brazil uses hexavalent vaccine in extreme preterm infants weighing less than 1,000 grams or 31 weeks of gestation.

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Among the 33 markets analyzed for pre-term infants, Hexaxim® is the most used vaccine with a share of 60% (2.3 million doses) of the pre-term hexavalent vaccine market, followed by Infanrix Hexa® with 35% (1.3 million doses) and Vaxelis® with 5% share (0.2 million doses) of the market.

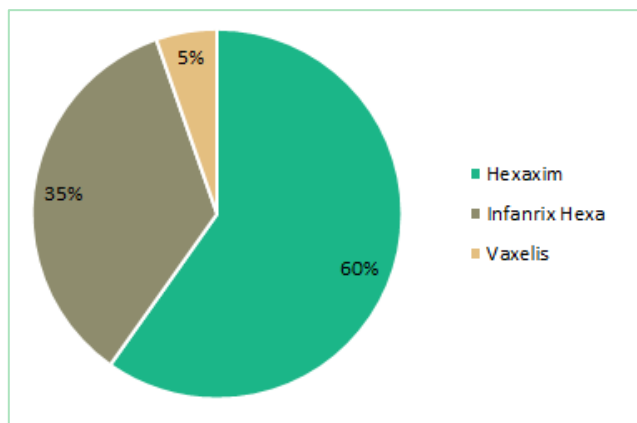


Fig 9: Pre-term infants hexavalent vaccine market by brand, 2020

In an analysis considering only EU countries with periods of exclusive use Hexyon®/Hexacima® (public market with central procurement of vaccines by authorities) from launch (in 2013) to December 2019, it was estimated that 164,000 preterm infants received Hexyon in 9 EU countries (Austria, Belgium, Bulgaria, Croatia, Denmark, Italy, Macedonia, Norway, and Romania)¹⁸¹

3.2.4 Brand Analysis of Hexavalent Vaccines

In 2020, Hexaxim® has the highest share of the hexavalent vaccines market by volume with 67%, followed by Infanrix Hexa® with 26%, and Vaxelis® with 7% (see Figure 10). In 2020, around 24.7 million doses of Hexaxim® were distributed followed by Infanrix Hexa® with 9.4 million doses and Vaxelis® with 2.4 million doses.

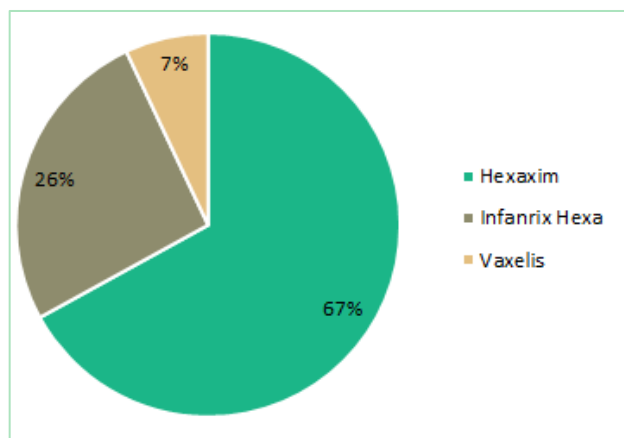


Fig 10: Share of different hexavalent vaccine brands in the top 40 countries, 2020

Brand Analysis In Public Markets

There are 30 public markets among the top 40 countries for hexavalent vaccines. These 30 public markets account for a 98% share of the global hexavalent vaccine public market.

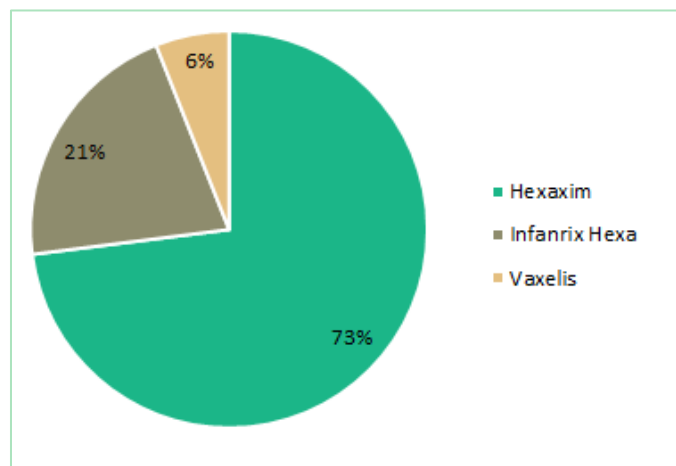


Fig 11: Share of different hexavalent vaccine brands in the top 40 countries among public markets, 2020

In public markets, Hexaxim® is the most used hexavalent vaccine with a 73% market share, followed by Infanrix Hexa® with 21%, and Vaxelis® with a 6% market share.

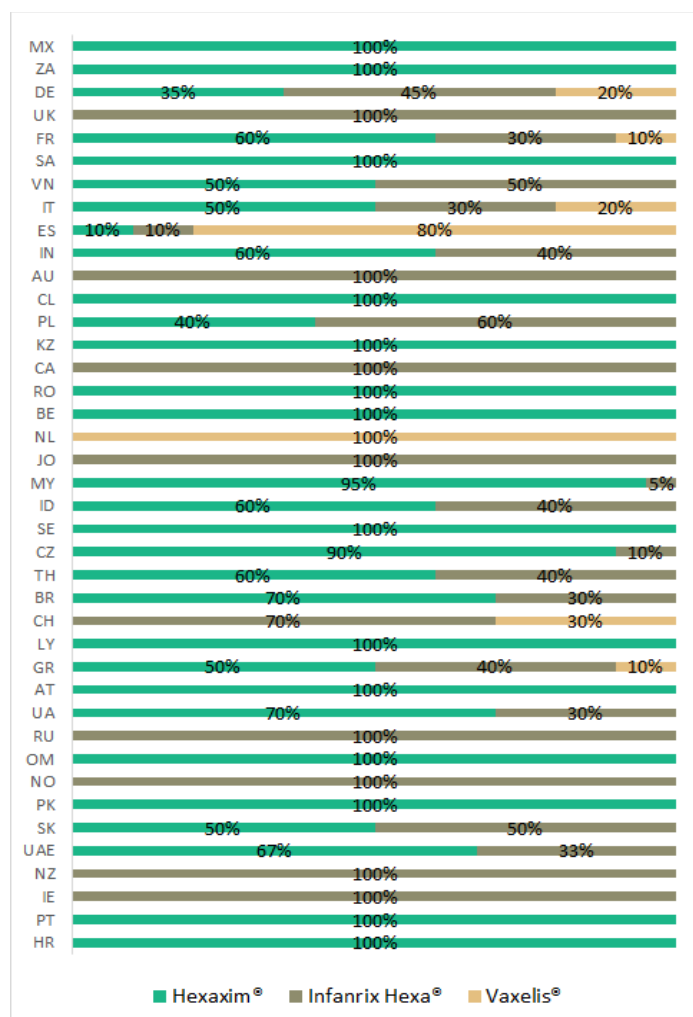


Fig 12: Volume share of hexavalent vaccines by brand (2020), detailed description is given in Table 6 in the Appendix

In 14 public markets, namely those of South Africa, Saudi Arabia, Mexico, Chile, Romania, Belgium, Sweden, Austria, Romania, Portugal, Croatia, Libya, Panama, Kazakhstan, Hexaxim® is the only brand used in their national immunization program.

In eight public markets, namely those of the UK, Australia, Canada, Jordan, Russia, Norway, New Zealand, and Ireland, 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: the UK, Germany, France, Italy, Spain, Greece, and the Netherlands.

Of the total hexavalent vaccine doses used, Vaxelis® is the only vaccine used in the Netherlands, 80% of those used

in Spain, 20% in Italy, 20% in Germany, 30% in Switzerland, and 10% in France, in 2020.

Brand Analysis By Region

Among the top 40 countries which constitute 96% of the global hexavalent vaccine market, 22 markets (countries) are of EUR, 5 markets each of AMR, and EMR followed by 4 WPR, 3 SEAR and one AFR markets.

In the 22 EUR markets (EUR markets that are among the top 40 countries in Table-1) 14 million doses of hexavalent vaccines were consumed in 2020. Among these hexavalent vaccine doses, 43% are of Hexaxim®, 40% are of Infanrix Hexa®, and 17% are of Vaxelis®.

Among the top 40 countries, only 5 countries, namely Mexico, Chile, Brazil, Panama, and Canada, use hexavalent vaccines in the AMR region. These countries consumed 10.5 million hexavalent vaccine doses in 2020. In the AMR region, Hexaxim® is the most used vaccine with a 94% share of the market followed by Infanrix Hexa® with an 6% share of the hexavalent vaccine market.

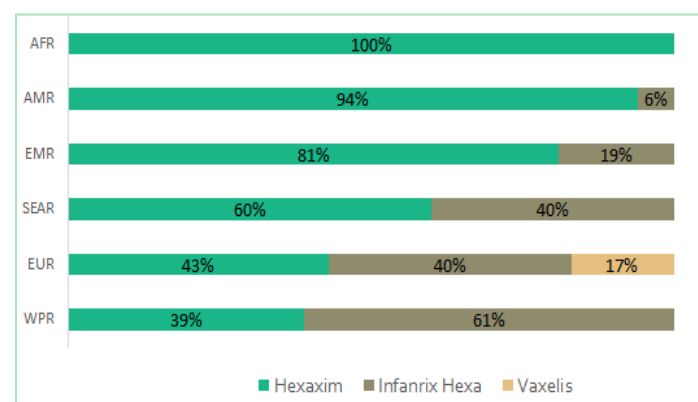


Fig 13: Volume share of hexavalent vaccine brands by regions (top 40 markets), 2020

In the EMR region, only 5 countries namely Saudi Arabia, Jordan, Libya, Oman, and UAE (among the top 40 countries) have consumed 2.7 million doses of hexavalent vaccine in 2020. In this region, Hexaxim® and Infanrix Hexa® are used at a proportion of 81% and 19% respectively.

In the WPR region, only 4 countries, namely Australia, New Zealand, Malaysia, and Vietnam, use hexavalent vaccines (among the top 40 countries). In 2020, these countries consumed 3.4 million doses of hexavalent vaccines of which Infanrix Hexa® being the most used vaccine with 61% of the market share in the WPR region. This can be attributed to Australia and New Zealand using Infanrix Hexa® solely in their national immunization schedule.

In the AFR region, South Africa is the major country using the Hexavalent vaccine (among the top 40 countries). In 2020, around 3.7 million hexavalent vaccine doses were consumed of which Hexaxim® is the only vaccine being used under South Africa's national immunization schedule.

3.3. Global Market For Pentavalent Vaccines

The global market for the pentavalent vaccines section describes the use of pentavalent vaccines in public and private markets.

3.3.1 Public & Private Markets For Pentavalent Vaccines

Based on government supply and inclusion of acellular pertussis (aP) based pentavalent vaccines (hereafter referred to as pentavalent vaccines) in the immunization schedule, the countries are split into public and private markets. Out of 54 countries considered for the study, 36 countries are public markets for pentavalent vaccines and the remaining 20 countries are private markets, as shown in Figure 14.

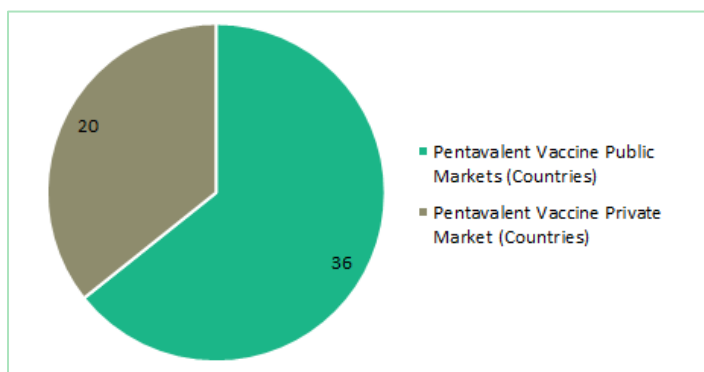


Fig 14: Pentavalent public & private markets, 2020
(refer to Table 9 & Table 10 in appendix)

The pentavalent vaccines are used in 36 countries for public programs, including 22 high-income countries, 11 upper-middle-income countries, and three lower middle-income countries. The high proportion of high-income countries among these public markets is due to the affordability of the aP based pentavalent vaccines by the governments of these countries.

Pentavalent vaccines are provided by private services in 20 countries, of which one is high income, 10 are upper middle income, 9 are lower-middle-income countries.

3.3.2 Analysis of Indicators For Calculating Pentavalent Vaccine Volumes In Public And Private Markets

Three indicators used to estimate the pentavalent vaccine market in each target country are the annual worldwide birth cohort (surviving infants), the proportion of children receiving the pentavalent vaccine (vaccine coverage rate), and the vaccine schedule.

3.3.2.1 Surviving Infants

The countries with high surviving infant populations demand more volume of pentavalent vaccine doses. Some pentavalent public markets, namely those of the USA, Turkey, Russia, and Malaysia have high levels of surviving infant population. In 2020, the USA had a surviving infant population of around four million, Russia had around 2 million, Turkey had around one million, and Malaysia had a surviving infant population of 0.5 million. The consumption of pentavalent vaccines is high in these public market countries, due to the supply of free or subsidized pentavalent vaccines by government agencies to the target population (Table 9).

Countries such as China, India, and Vietnam have a high surviving infant population. In 2020, India and China had surviving infant populations of 23 million and 16 million respectively, whereas Vietnam had 1.5 million. (Table 5). But only a tiny fraction of the population in these countries have access to private vaccination.

3.3.2.2 Vaccine Schedule

The WHO recommends 3 primary doses (3p) in the vaccine immunization schedule for pentavalent vaccines.¹⁸² Most of the WHO countries with pentavalent public markets have implemented a four-dose pentavalent vaccine schedule (which includes a booster dose). Nine countries have recommended three doses of pentavalent vaccine (major countries include the USA, Denmark, and Finland), six countries (Kazakhstan, South Korea, Portugal, Singapore, Macedonia, Palau) have recommended two doses of pentavalent vaccine in their immunization schedule, and four countries (Libya, UAE, Croatia, and Luxembourg) have recommended one dose of pentavalent vaccine in their immunization schedule. In these countries (using one or two or three doses of pentavalent vaccine), a dose of hexavalent vaccine is administered instead of other pentavalent vaccine doses (Table 9).

3.3.2.3 DTP₃ Immunization Rate For Pentavalent Vaccine Market

DTP₃ immunization rate., the third dose immunization rate for Diphtheria, Tetanus, and Pertussis, is considered for the pentavalent vaccine immunization rate.

Globally, pentavalent vaccines (by volume) are consumed more in public markets than in private markets. For public markets where hexavalent is the only vaccine supplied through the national immunization schedule, the rate of immunization is high, ranging from 90% to 99% among those countries.

For public markets where both pentavalent and other multivalent vaccines are used, the immunization rate for pentavalent vaccines varies by country depending on specific factors such as geographical distribution and availability of vaccines within the country, or particular conditions under which pentavalent vaccines are administered. The immunization rate for pentavalent vaccines ranges from 70%-90% in most of these countries.

The immunization rate for pentavalent vaccines is low in private markets and ranges from 1-50%. In private markets, most of the high-income countries have

pentavalent vaccine immunization rates around 30%, whereas upper-middle-income countries and lower-middle-income countries have pentavalent vaccine immunization rates ranging from 2-5% and 1-2%, respectively. China, an upper-middle-income country, has a 35% immunization rate for pentavalent vaccines.¹⁸³

3.3.3 Volumes of Pentavalent Vaccines

In 2020, among 34.5 million pentavalent vaccines doses used, 27.6 million doses (80%) of pentavalent vaccines were administered in public markets through national immunization programs (NIPs), and 6.9 million doses (20%) were administered to infants in private markets (see Figure 15).

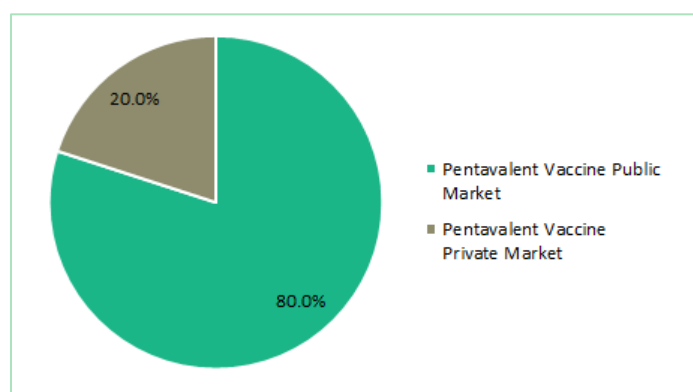


Fig 15: Public and Private Pentavalent Market Share

Pentavalent vaccines (aP based) were included in the national immunization schedules of many high-income and upper-middle-income countries due to these countries' strong public immunization financing. The higher cost of pentavalent vaccines is a hindrance to the supply of these vaccines in low- and middle-income countries.

3.3.3.1 Pentavalent Vaccines Volume Analysis, By Region

As shown in Figure 16, in 2020, American Region (AMR) accounted for the major share of the pentavalent vaccine market by volume at 36%, followed by Europe Region (AMR) with 35%, Southeast Asian Region (SEAR) with 18%, Western Pacific Region (WPR) and Eastern Mediterranean Region (EMR) accounted for 9% and 3% respectively.

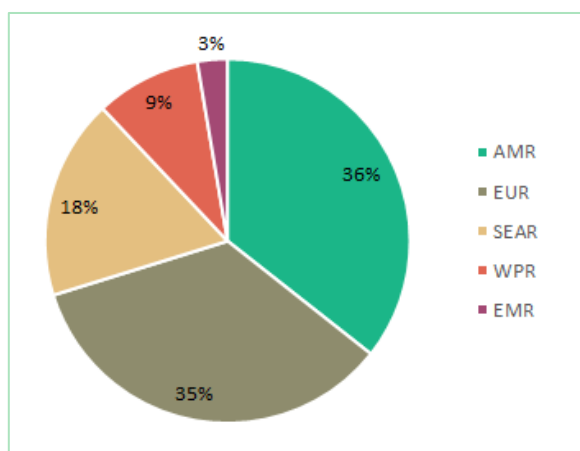


Fig 16: Pentavalent vaccine volume analysis by region, 2020

The high share in both AMR and EUR regions is due to most European and American countries' early approval and adoption of pentavalent vaccines.

In AMR, only three countries, namely the USA, Canada, and Costa Rica have included pentavalent vaccines in their national immunization schedules. The high consumption of pentavalent vaccines in the AMR region, comparable to EUR, can be attributed to the use of aP based pentavalent vaccines in the USA. In 2020, more than 11 million doses of pentavalent vaccines were consumed in the USA.

In 2020, the major European countries (according to WHO) such as Turkey, Russia, each consumed more than four million doses of pentavalent vaccines, Kazakhstan consumed more than half a million doses of pentavalent vaccines. In contrast, Hungary, and Poland each consumed more than 0.3 million doses of pentavalent vaccine.

In SEAR, pentavalent vaccines are available only in one country; namely, Bhutan, which has the pentavalent vaccine in its immunization schedule.

In the WPR region, eight countries, namely Malaysia, Taiwan, South Korea, Singapore, Micronesia, Marshall Islands, Cook Islands, and Palau, have pentavalent vaccines in their immunization schedule.

In EMR, only three countries, namely Israel, Libya, and UAE, have included pentavalent vaccines in the national immunization schedule. In 2020, more than half a million doses of pentavalent vaccines were used in Israel.

3.3.3.2 Pentavalent Vaccine Volume Analysis, By Country

In 2020, the top 22 countries consumed 33.8 million doses of pentavalent vaccines which is 98% of the pentavalent vaccine global consumption (see Table 2).

Country Name	Type of Market	Pentavalent Vaccine (Volume, mn)	(% Share among top 21 markets)
USA	Public	11.1	32.8%
China	Private	5.6	16.5%
Turkey	Public	4.9	14.4%
Russian	Public	4.6	13.7%
Malaysia	Public	1.5	4.6%
Israel	Public	0.9	2.7%
Taiwan	Public	0.7	2.1%
Kazakhstan	Public	0.6	1.9%
South Korea	Public	0.6	1.8%
Hungary	Public	0.4	1.8%
Canada	Public	0.4	1.1%
Poland	Public	0.4	1.0%
Serbia	Public	0.3	1.0%
India	Private	0.3	0.8%
Costa Rica	Public	0.3	0.8%
Thailand	Private	0.3	0.7%
Vietnam	Private	0.2	0.7%
Portugal	Public	0.2	0.5%
Finland	Public	0.1	0.4%
Singapore	Public	0.1	0.3%
Indonesia	Private	0.1	0.3%
Lithuania	Public	0.1	0.2%

Table 2: Pentavalent vaccine volumes for the top 22 countries, 2020

Of these 22 countries, 17 have pentavalent public markets, and 5 have private pentavalent markets. In 2020, of the top 22 countries, the USA had the highest

consumption of pentavalent vaccines at 11.1 million doses which is 32.8% of the total volumes of pentavalent vaccines consumed, while Lithuania had the lowest consumption of 0.1 million doses which is 0.2% of the global pentavalent vaccines consumed.

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

The top three countries with high volumes of pentavalent vaccine consumption in private markets include China, India, and Thailand. Although China has aP based trivalent vaccine for primary series in its immunization schedule, pentavalent vaccines have huge demand in their private market. In 2020, China consumed 5.6 million doses of pentavalent vaccines through private channels.

3.3.3.3 Preterm Pentavalent Vaccine Volume Analysis

In 2020, around 3.1 million doses of pentavalent vaccines were consumed by preterm infants in the top 17 markets (private markets among the top 20 countries are excluded for pre-term analysis) (Table 20). Among these top markets except for the USA, all other countries are using the same brand of pentavalent vaccine for both pre-term and term infants. 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 Center for Disease Control & Prevention-CDC).¹⁸⁴ In Brazil, Pentaxim is used for extreme preterm infants, weighing less than 1,000 grams or 31 weeks of gestation.¹⁸⁵

Among the top 17 markets analyzed for pre-term infants, Pentaxim® is the most used vaccine with a share of 57% (1.8 million doses) of the pre-term hexavalent vaccine market, Pentacel® with 37% (1.1 million doses), followed by Pediacel® and Infanrix-IPV/Hib® with 4% share (0.1 million doses), and 2% share (0.08 million doses) respectively.

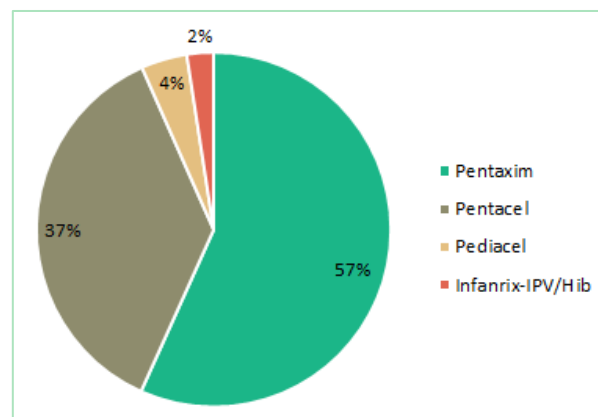


Fig 17: Pre-term infants pentavalent vaccine market by brand, 2020

Both Pentaxim® and Pentacel® are the vaccine brands manufactured by Sanofi Pasteur. Together these two brands have more than 90% share of the pentavalent preterm vaccine market (17 markets among top 22)

3.3.4 Brand Analysis of Pentavalent Vaccines

In 2020, Pentaxim® has the highest share of the pentavalent vaccines market by volume with 62%, followed by Pentacel® and Pediarix® with 17% and 16%, respectively. Infanrix-IPV/Hib® and Pediacel® have a low market share of 3% and 2%, respectively. In 2020, around 21 million doses of Pentaxim® were distributed followed by Pentacel® with 5.7 million doses, Pediarix® with 5.5 million doses, Infanrix-IPV-Hib® and Pediacel® with 0.93 and 0.9 million doses respectively.

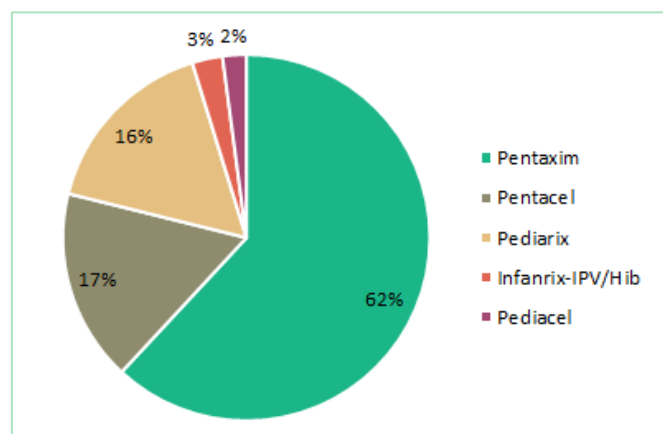


Fig 18: Share of different pentavalent vaccine brands in the top 22 countries, 2020

Brand Analysis In Public Markets

There are 17 public markets among the top 22 countries for pentavalent vaccines. These 17 public markets account for a 99% share of the global pentavalent vaccine public market.

In public markets, **Pentaxim®** is the most used hexavalent vaccine with **54% of market share**, followed by **Pentacel®** with 21%, **Pediarix®** with 20%, **Pediacel®**, and **Infanrix-IPV-Hib®** with 3% and 2% of market share.

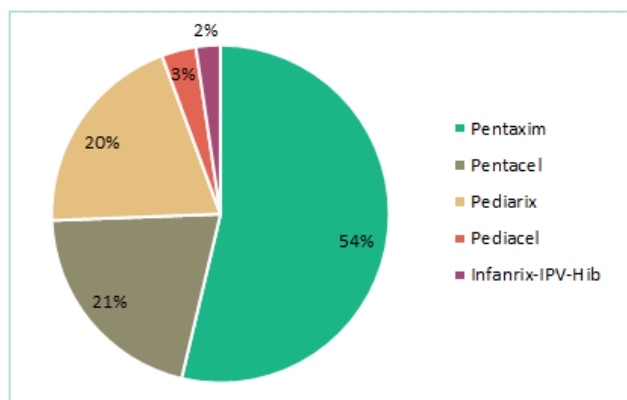


Fig 19: Share of different pentavalent vaccine brands in the top 22 countries among public markets, 2020

In 11 markets (9 public markets; along with 2 private markets), namely those of Turkey, Russian, Taiwan, Kazakhstan, Hungary, Serbia, Costa Rica, Portugal, Lithuania, China, and India (private markets) **Pentaxim®** is the only brand used in their national immunization schedule.

In Finland, **Pentaxim®** is the only brand whereas, in Canada, **Pediacel®** is the only brand used in their national immunization schedule. **Pediarix®** vaccine is only used in the USA, along with **Pentacel®** which are consumed in equal brand proportions.

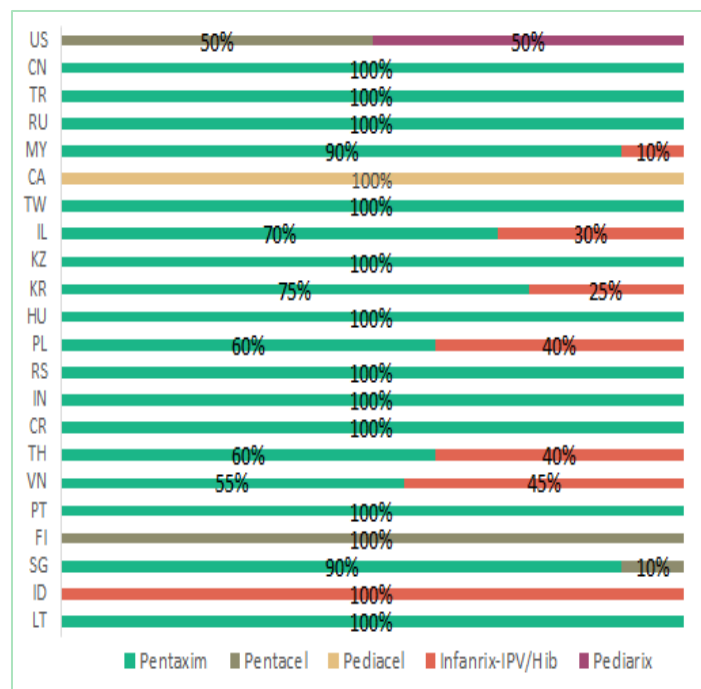


Fig 20: Volume share of pentavalent vaccines by brand (2020), detailed description is given in Table 11 in the Appendix

Brand Analysis By Region

Among the top 22 countries, which constitute 97% of the global pentavalent vaccine market, ten markets (countries) are of EUR, five markets are of SEAR, followed by four WPR and three AMR markets.

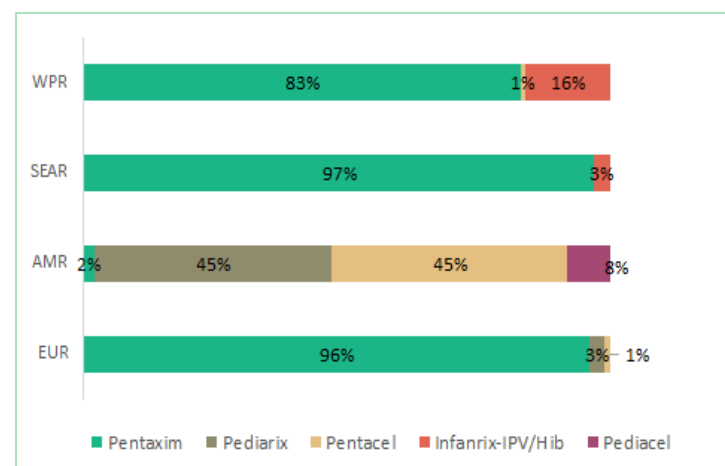


Fig 21: Volume share of pentavalent vaccine brands by regions (top 22 markets), 2020

In the top 10 EUR markets (all EUR markets are among the top 22 countries), 12.3 million doses of pentavalent vaccines were consumed in 2020. Among these pentavalent vaccine doses, 96% are of Pentaxim®, 3% are Infanrix-IPV-Hib®, and 1% are of Pentacel®.

Among the top 22 countries, only 3 countries, namely the USA, Canada, and Costa Rica, use pentavalent vaccines in the AMR region. These countries consumed 12.2 million pentavalent vaccine doses in 2020. In the AMR region, Pentacel® and Pediarix® are the most used vaccines with a 90.5% share of the market, followed by Pediacel® and Pentaxim® with an 7.4%, and 2.1% share of the pentavalent vaccine market respectively.

In the SEAR region, only five countries, namely China, Taiwan, India, Thailand, and Indonesia, use pentavalent vaccines (among the top 22 countries). In 2020, these countries consumed 6.9 million doses of pentavalent vaccines, of which Pentaxim® was the most used vaccine with 97% of the market share in the SEAR region. This can be attributed to China using solely Pentaxim® in their private market.

In the WPR region, only 4 countries, namely Malaysia, South Korea, Vietnam, and Singapore, use pentavalent vaccines (among the top 22 countries). In 2020, these countries consumed 2.5 million doses of pentavalent vaccines, of which Pentaxim® being the most used vaccine with 83% of the market share in the WPR region. This can be attributed to Malaysia and South Korea using 90% and 75% of the Pentaxim® brand vaccine in their national immunization schedule.

3.4 School Entry Booster Vaccines by Type of Pertussis Antigens (wP and aP)

The global demand for DTP combination school entry booster vaccines was 33.1 million doses. DTP combination school entry booster vaccines with a whole-cell pertussis component (DTwP) had a 60% share of the total DTP combination school entry vaccines market in 2020, accounting for 19.8 million doses. DTaP combination school entry booster vaccines (acellular pertussis) had only a 40% share of the DTP combination school entry

booster vaccines market, accounting for 13.3 million doses.

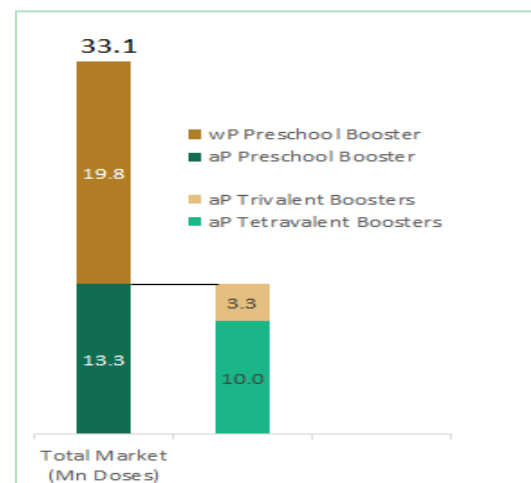


Fig 22: aP and wP school entry Booster Vaccine split, 2020

The total DTaP combination school entry booster vaccines market (as shown in Figure-21) is split into trivalent and tetravalent vaccines. Based on our estimations, in 2020, the global trivalent (aP) school entry booster vaccine demand was 3.3 million doses, which is 25% of the total DTaP school entry booster vaccines market. The demand for tetravalent (aP) school entry booster vaccines was 10 million doses, 75% of the DTaP school entry booster vaccine market (refer to Figure 21). The high share of the tetravalent vaccines among DTaP school entry booster vaccines can be attributed to the increased adoption of these vaccines, spanning the USA, Canada, and most European countries.

3.4.1. Countries Using School Entry Booster Vaccines

Among 196 countries (194 WHO countries, plus Taiwan, and Hong Kong), 59 countries do not use school entry booster vaccines in their immunization schedule. Among these 59 countries, 52 countries belong to low income and lower-middle-income status. In Africa, 38 countries are not using any school entry booster vaccines in their national immunization schedule.¹⁸⁶

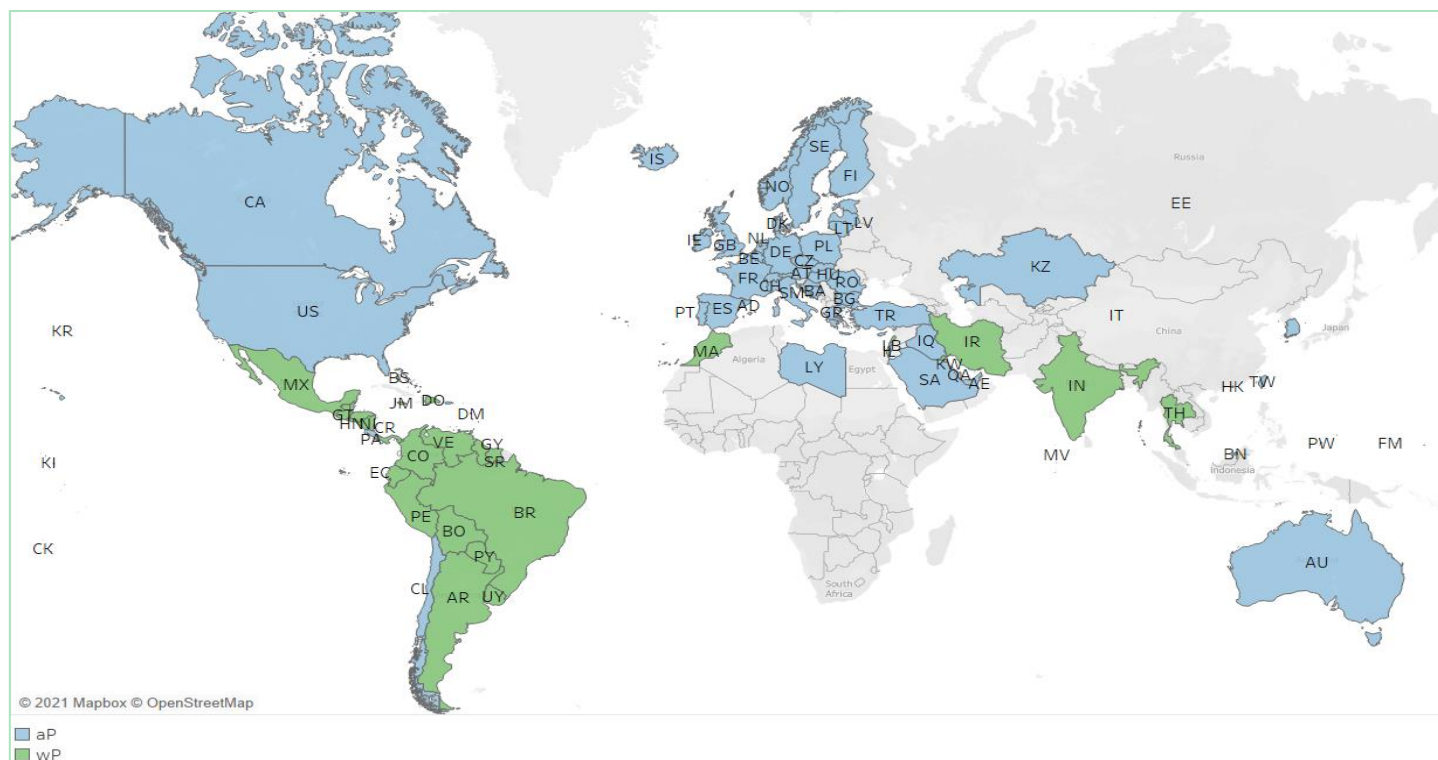


Figure 23: DTP School Entry Booster Vaccines (aP & wP), 2020

Excluding these 59 countries, there are 137 countries using school entry booster vaccines in their national immunization schedule, either bivalent, trivalent, or tetravalent vaccines. Among these 137 countries, 43 countries are using bivalent school entry booster vaccines.

More than half of the countries using bivalent vaccines belong to lower-middle-income, and upper-middle-income status, i.e., out of 43 countries, 15 belong to lower-middle-income groups, and 21 countries belong to upper-middle-income groups.

EUR, AFR, and WPR are the major regions using bivalent school entry booster vaccines in their national immunization schedule. In EUR, 15 countries use bivalent school entry booster vaccines, whereas seven countries in AFR and eight countries in WPR, use bivalent school entry booster vaccines.

Pertussis (aP) based school entry booster vaccines are used in 94 countries. Among these 94 countries, 54 countries are of high-income status, 31 countries are of upper-middle-income status, and 9 countries are of lower-middle-income status.

3.4.2 Global Markets For Acellular Pertussis (aP) Based School Entry Booster Vaccines

Based on government supply and inclusion of aP based school entry booster vaccines in the immunization schedule, the countries are split into public and private markets.

Out of 94 countries considered for the study, 53 countries are public markets for aP based school entry booster vaccines, and the remaining 41 countries are private markets, as shown in Figure 23.

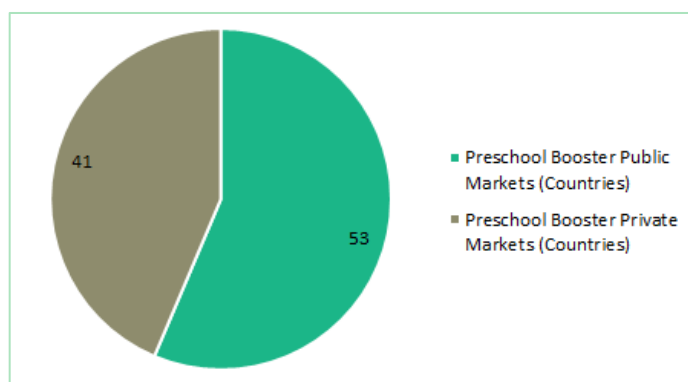


Fig 24: School entry Boosters public & private markets, 2020
(refer to Table 12 & Table 13 in appendix)

Among 41 private markets, except for Germany, France, Greece, and Slovakia, all other countries use DTWP school entry booster vaccines as recommended by their national immunization schedule. Germany uses the Tdap vaccine, whereas France, Greece, and Slovakia use DTaP-IPV vaccines in their national immunization schedule for school entry boosters. Among the 37 countries (excluding Germany, France, Greece, Slovakia), 31 countries are of lower middle income and upper-middle-income status.

There are only six high-income countries, namely Kuwait, Uruguay, Trinidad and Tobago, Barbados, and the Bahamas use DTWP school entry booster vaccines in their national immunization schedule.¹⁸⁷ Most of the wP school entry booster vaccines are being used in AMR regions, with 24 out of 35 countries (according to WHO classification) using these vaccines in their national immunization schedule.¹⁸⁸

Among 53 public markets using DTaP/Tdap combination school entry booster vaccines, 44 are of high-income status. There are eight upper-middle-income countries: Turkey, Kazakhstan, Libya, Bulgaria, Costa Rica, Bosnia-Herzegovina, Marshall Islands, and Niue, using acellular pertussis (aP) based school entry booster vaccines.¹⁸⁹

Most of the EUR countries are using aP based school entry booster vaccines; for instance, in Europe, among 53 countries (according to WHO classification) 36 countries are using either trivalent or tetravalent (DTaP/Tdap, DTaP-IPV/Tdap-IPV) combination school entry booster vaccines in their national immunization schedule.

Only two Asian countries, namely, Taiwan and Hong Kong, use DTaP combination school entry booster vaccines in their public schedule.¹⁹⁰ DTaP/Tdap combination vaccines are more expensive than DTWP vaccines. Pooled procurement agencies such as UNICEF procure DTP vaccines with whole-cell pertussis (wP) components to supply to low- and middle-income countries.

Acellular component (aP) based DTP vaccines are supplied to the public by governments of upper-middle-income and high-income countries or consumed in private markets in some high- and middle-income countries through out-of-pocket expenditures.¹⁹¹ The high cost of the aP vaccines can be attributed to their higher development and production costs compared to wP vaccines.¹⁹²

3.4.3 Indicators For calculating aP School Entry Booster Vaccine Volumes

Three indicators that are used for the estimation of the aP based school entry booster vaccine market in each target country are the annual worldwide school children age 3-7 years, the proportion of children receiving aP based school entry booster vaccine (vaccine coverage rate), and the schedule.

3.4.3.1 Target Population

The countries with a high population of pre-school children demand higher volumes of aP based school entry booster vaccine doses. Some aP based school entry booster vaccines public markets, namely those of the USA, Turkey, and the UK, have a high school entry children population. In 2020, the USA had a school entry children population of around four million, whereas Turkey and the UK had school entry children's populations of 1.5 million and 1 million, respectively. The consumption of aP based school entry booster vaccines is high in these public market countries due to the supply of free or subsidized aP based school entry booster vaccines by government agencies to the target population (Table 12).

Countries such as India, Brazil, Germany, and France are private markets having high school entry children

population. In 2020, India and Brazil had school entry children's populations of 23 million and three million respectively, whereas France and Germany had a school entry population of 0.7 million each. (Table 13).

Except for Germany, France, Greece, and Slovakia, where the vaccines are privately reimbursed, only a tiny fraction of the population has access to vaccination in private markets (due to lack of reimbursement for private market vaccines and need for out-of-pocket expenditure).

3.4.3.2 Schedule

In both public and private markets, the aP based school entry booster vaccines are recommended as a single dose. These school entry doses are administered to children age 3-7 years as either the fourth or fifth dose of the DTP vaccine.

3.4.3.3 School Entry Booster Immunization Rate For aP Based School Entry Booster Vaccine Market

School entry booster immunization rate is either the fourth (DTP₄) or the fifth dose (DTP₅) immunization rate for Diphtheria, Tetanus, and Pertussis.

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

The immunization rate for aP based school entry booster vaccines is low in private markets and ranges from 1-49% in most countries. In private markets, most high-income countries have aP based school entry booster vaccine immunization rates ranging from 15-20%, whereas upper-middle-income countries and lower-middle-income countries have aP based school entry booster vaccine immunization rates ranging from 2-15% and 3-5%, respectively. In Germany and France, the immunization rates for aP based school entry booster vaccines are 70%^{193, 194} and 90%^{195, 196} respectively.

3.4.4 Volumes Of aP Based School Entry Booster Vaccines:

The aP based school entry booster vaccines market contains both trivalent and tetravalent school entry booster vaccines. In 2020, among the 13.3 million aP based school entry booster doses, 10.8 million doses (80%) of aP based school entry booster vaccines were administered in public markets through national immunization programs (NIPs), and 2.5 million doses (20%) were administered to school entry children in private markets (as shown in Figure 25).

The global school entry booster vaccine market for trivalent (DTaP/Tdap) vaccines was 3.3 million doses in 2020. In contrast, the global school entry booster vaccine market for tetravalent (DTaP-IPV/Tdap-IPV) vaccines was 10 million doses in 2020.

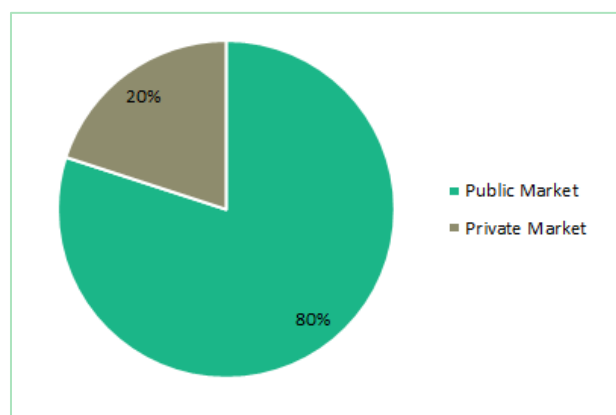


Fig 25: Public and Private aP Based school entry Boosters Market Share, 2020

Acellular pertussis (aP) based trivalent school entry booster vaccines were administered in 14 public markets, whereas tetravalent school entry booster vaccines were administered in 41 public markets.

3.4.4.1 Acellular Pertussis (aP) School Entry Booster Vaccines Volumes Analysis, By Region

As shown in Figure 25, in 2020, Europe accounted for the major share of the aP school entry booster vaccines market by volume at 48%, the American region (AMR) with 33%, South-East Asian Region (SEAR) with 7%, Western Pacific Region (WPR) and Eastern Mediterranean Region (EMR) with 6% each.

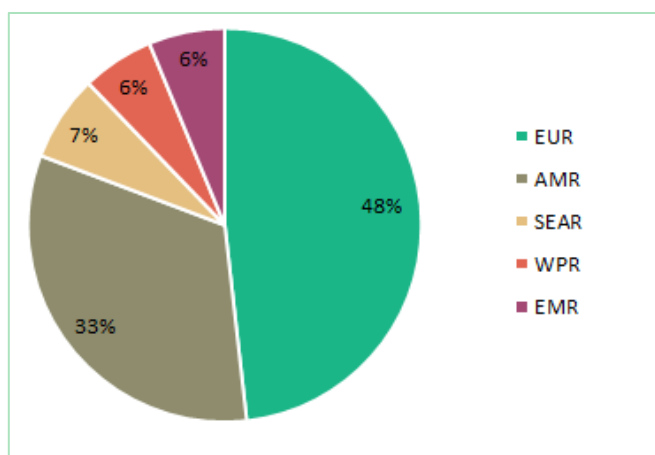


Fig 26: aP Based School entry Booster vaccine volume analysis by region, 2020

The high share for EUR is due to most European countries' early approval and adoption of aP based school entry vaccines and high vaccine coverage rates (VCR). In 2020, Turkey (WHO classified Turkey under EUR) consumed around 1.4 million doses of aP based school entry booster vaccine. France, and the UK each consumed 0.7 million doses of aP based school entry booster vaccine.

Only five countries, namely the USA, Chile, Canada, Costa Rica, and Panama, have included aP based booster vaccines in their national immunization schedules in AMR. In 2020, around 3.4 million doses of aP based booster vaccines were used in the USA, whereas Canada and Chile consumed 0.3 million and 0.2 million doses. Costa Rica consumed around 0.1 million doses of aP based school entry booster vaccines.

In SEAR, only two countries, Hong Kong and Taiwan have included aP based school entry booster vaccines in their national immunization schedules. In 2020, Taiwan consumed around 0.2 million doses of aP based school entry booster vaccines, whereas Hong Kong consumed 0.05 million doses of aP based school entry booster vaccines.

In the WPR region, South Korea and Australia are the two major countries that consumed 0.4 and 0.3 million doses of aP based school entry booster vaccines.

In the EMR, Saudi Arabia, and Libya are the top countries in aP based school entry booster vaccine consumption. In

2020, Saudi Arabia consumed 0.4 million doses of aP based school entry booster vaccines, whereas Libya consumed 0.1 million doses each of aP based school entry booster vaccines.

In AFR, aP based school entry booster vaccines are available only in the private market.

3.4.4.2 School Entry Booster (aP) Vaccine Volume Analysis, By Country

In 2020, the top 40 countries consumed 12.8 million doses of aP school entry booster vaccines which are 96% of the aP school entry booster vaccine global consumption (see Table 3).

Country Name	Type of Market	aP School Entry Booster Vaccine (Volume, '000)	(% Share Among Top 40 Markets)
USA	Public	3403	26.5%
Turkey	Public	1404	10.9%
United Kingdom	Public	729	5.7%
France	Private	697	5.4%
India	Private	589	4.6%
Germany	Private	541	4.2%
Saudi Arabia	Public	454	3.5%
Spain	Public	413	3.2%
South Korea	Public	399	3.1%
Italy	Public	354	2.8%
Poland	Public	352	2.7%
Kazakhstan	Public	335	2.6%
Australia	Public	321	2.5%
Canada	Public	316	2.5%
Chile	Public	211	1.6%
Taiwan	Public	189	1.5%
Romania	Public	160	1.2%
Netherlands	Public	151	1.2%
Israel	Public	148	1.2%

Argentina	Private	138	1.1%
Libya	Public	112	0.9%
Belgium	Public	111	0.9%
Sweden	Public	111	0.9%
Thailand	Private	108	0.8%
Iraq	Private	99	0.8%
Czech Republic	Public	94	0.7%
Hungary	Public	92	0.7%
Greece	Private	76	0.6%
Portugal	Public	75	0.6%
Switzerland	Public	73	0.6%
United Arab Emirates	Public	73	0.6%
Austria	Public	65	0.5%
Costa Rica	Public	62	0.5%
Ireland	Public	61	0.5%
Hong Kong	Public	56	0.4%
Norway	Public	56	0.4%
Bulgaria	Public	55	0.4%
New Zealand	Public	53	0.4%
Slovakia	Private	51	0.4%
Denmark	Public	49	0.4%

Table 3: aP based school entry booster vaccine volumes for the top 40 countries, 2020

Among the top 40 countries, 33 have public school entry boosters (aP) markets, and 7 have private school entry boosters (aP) markets. In 2020, the USA had the highest consumption of school entry booster (aP) vaccines at 3.4 million doses, 26.5% of the total volumes of school entry booster (aP) vaccines consumed, while Denmark had the lowest consumption of 0.05 million doses, 0.4% of the global school entry booster (aP) vaccines.

The top three countries with high volumes of school entry booster (aP) vaccines in public markets include the USA, Turkey, and the UK.

In private markets, France, India, and Germany are the top three countries with high volumes of school entry booster (aP) vaccine consumption.

3.4.5 Brand Analysis of aP Based School Entry Booster Vaccines

In 2020, Tetraxim® (Sanofi Pasteur) has the highest share of the aP based school entry booster vaccines market by volume with 36.3% (4.7 million doses), followed by Infanrix-IPV®/Kinrix® (GSK) with 18.6% (2.4 million doses), Boostrix® (GSK) with 17.2% (2.2 million doses), Quadricel® (Sanofi Pasteur) with 10.5% (1.4 million doses), Boostrix-IPV® (GSK) with 6.1% (0.8 million doses), Repevax® (Sanofi Pasteur) with 5.6% (0.7 million doses), Adacel® (Sanofi Pasteur) and others with 3.1% (0.4 million doses) and 2.4% (0.3 million doses) respectively. (see Figure 27).

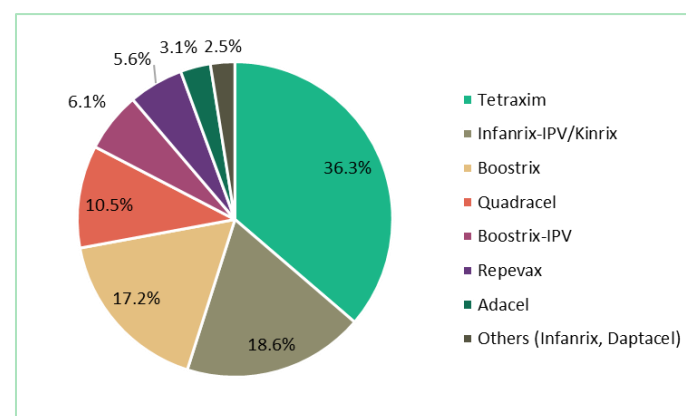


Fig 27: Brand proportions of aP based school entry booster vaccines, 2020

In 16 public markets, namely those of Turkey, Poland, South Korea, Romania, Sweden, Belgium, Hungary, Portugal, Taiwan, Hong Kong, United Arab Emirates, Costa Rica, Denmark, Bulgaria, Norway, and Ireland, Tetraxim® (Sanofi Pasteur) is the only brand used in their national immunization schedule. In 2019, Tetraxim replaced the use of DiTeKiPol Booster (by AJ Vaccines) in Denmark.¹⁹⁷

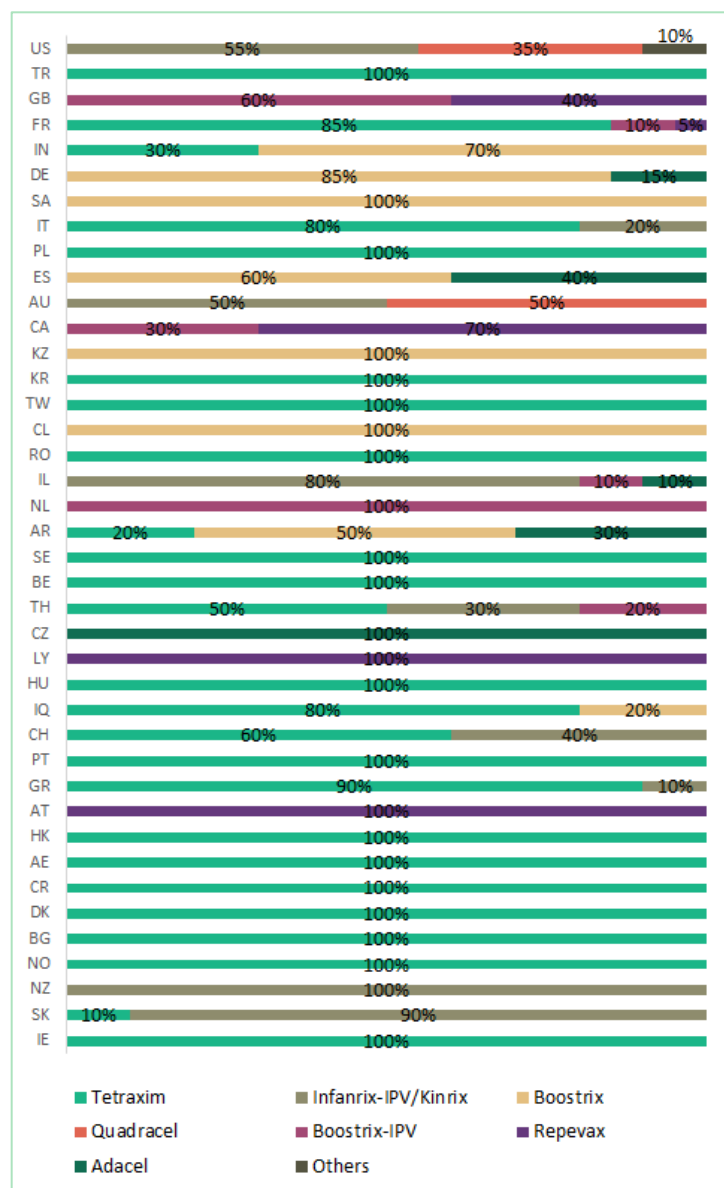


Fig 28: Volume share of aP based school entry booster vaccines by brand, 2020; Others include Daptacel & Infanrix

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 Pasteur) is the only brand of vaccines used in the national immunization schedules of Libya and Austria.

Boostrix® (GSK) is the only brand of vaccine used in Saudi Arabia's, Kazakhstan's and Chile's national immunization schedules. India is a private market for Boostrix® (GSK), and Adacel® (Sanofi Pasteur) is the only brand of vaccine

used in the Czech Republic's national immunization schedule.

In the USA, four brands of school entry booster vaccines are in use, namely Kinrix®, Quadracel®, Daptacel®, and Infanrix®. Kinrix® has a 55% market share in the USA school entry booster vaccines market, followed by Quadracel® with a 35% market share. Other brands of vaccines, namely Daptacel® and Infanrix®, hold not more than 10% of the school entry booster vaccines market share.

Brand Analysis By Region

Among the top 40 countries, which constitute 96% of the global aP based school entry booster vaccine market, 24 markets (countries) are of EUR; five markets are of AMR, four markets each for EMR and SEAR, and three WPR markets.

In the top 24 EUR markets (EUR markets here refer to those EUR countries among the top 40 markets), 6.3 million doses of aP based school entry booster vaccines are consumed in 2020.

Among 6.3 million aP based school entry booster vaccine doses, 58.8% (3.5 million doses) are of Tetraxim® (Sanofi Pasteur), 17.4% (1 million doses) are of Boostrix® (GSK), 11.3% (0.7 million doses) are of Boostrix-IPV® (GSK), 6.5% (0.4 million doses) are of Repevax® (Sanofi Pasteur), 5.9% (0.4 million doses) are of Adacel® (Sanofi Pasteur), and 4.5% (0.3 million doses) are of Infanrix-IPV®/Kinrix® (GSK).

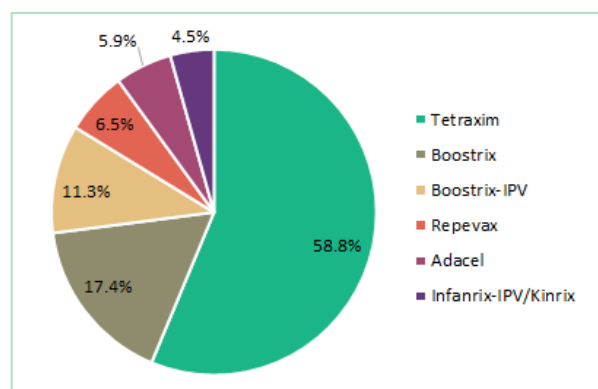


Fig 29: Brand proportions of aP based school entry booster vaccines in EUR (EUR among top 40 countries), 2020

Among the top 40 countries, only five countries, namely the USA, Canada, Chile, Argentina, and Costa Rica, are using aP based school entry booster vaccines in the AMR region. These countries consumed 4.1 million aP based school entry booster vaccine doses in 2020. In the AMR region, **Infanrix-IPV®** (GSK) is the most used vaccine with a 45% share of the market, followed by **Quadracel®** (Sanofi Pasteur) with a 29% share of the school entry booster vaccine market.

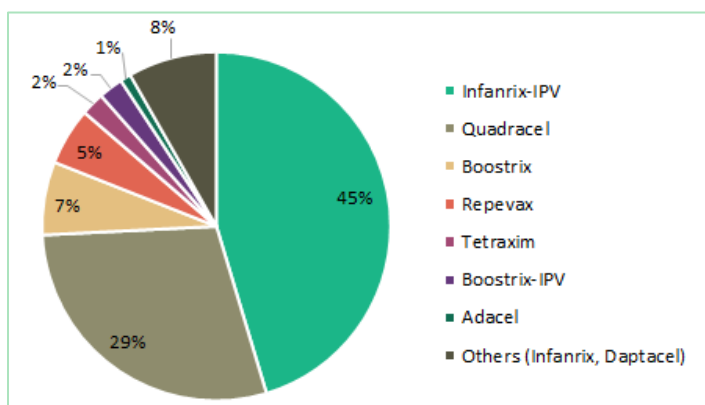


Fig 30: Brand proportions of aP based school entry booster vaccines in AMR (AMR among top 40 countries), 2020

In the EMR region, only four countries, Saudi Arabia, Libya, Iraq, and the UAE (among the top 40 countries), have consumed 0.7 million doses of aP based school entry booster vaccines in 2019. In this region, **Boostrix®** (GSK), **Tetraxim®** (Sanofi Pasteur), and **Repevax®** (Sanofi Pasteur) are used at a proportion of 64%, 20%, and 16%, respectively.

In the WPR region, only three countries, namely Australia, South Korea, and New Zealand, are using aP based school entry booster vaccines (among the top 40 countries). In 2019, these countries consumed 0.8 million doses of aP based school entry booster vaccines, of which **Tetraxim®** (Sanofi Pasteur) being the most used vaccine with 52% of the market share in the WPR region. This can be attributed to South Korea using high volumes of **Tetraxim®** (Sanofi Pasteur) doses (~0.4 million **Tetraxim** doses) in their national immunization schedule.

In the SEAR region, only 4 countries namely Hong Kong, Taiwan, India, and Thailand are using aP based school entry booster vaccines (among the top 40 countries). In

2020, these countries consumed one million doses of aP based school entry booster vaccines of which **Tetraxim®** (GSK) is the most used with 51% of the market share in the WPR region. This can be attributed to Taiwan mostly using the **Tetraxim®** vaccine.

aP School Entry Booster Vaccine Split By Vaccine Type (Tetavalent, and Trivalent Vaccines)

Among the top 40 countries, **DTaP-IPV** is the most used school entry booster vaccine. In 2020, 9 million doses of **DTaP-IPV** (71%), 2.2 million doses of **Tdap** (17%), and 1.3 million doses of **Tdap-IPV** (10%), 0.3 million doses of **DTaP** (3%) school entry boosters are distributed. **DTaP-IPV** has a 68% share of aP based school entry booster vaccines.

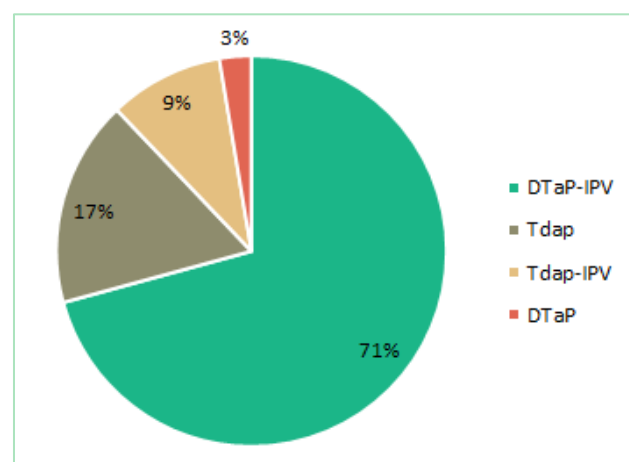


Fig 31: aP school entry booster vaccines by type of vaccine (among top 40 markets), 2020

Among the top 40 markets for aP based school entry booster vaccines 25 countries (markets) are using only the **DTaP-IPV** tetavalent vaccine, 4 countries are using only **Tdap-IPV** tetavalent vaccine, and 5 countries are using **Tdap** trivalent vaccine. Only 5 countries namely United States, India, Argentina, Thailand, Iraq are using both trivalent and tetavalent vaccines for school entry booster immunization.

Tetavalent School Entry Booster Vaccines Market

Among the top 40 aP based school entry booster markets, 35 countries use tetavalent vaccines, either **DTaP-IPV** or **Tdap-IPV**. At least 10 million doses of tetavalent vaccines were distributed among these countries, with **DTaP-IPV** vaccines having an 88% share of the tetavalent school

entry booster vaccines market compared to 12% of Tdap-IPV school entry booster vaccines.

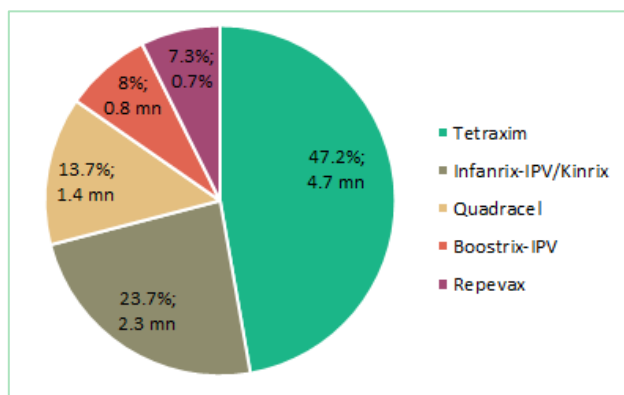


Fig 32: Tetravalent school entry booster vaccines by brand, 2020

In 2020, Tetraxim® (Sanofi Pasteur) had the highest share among the tetravalent school entry booster vaccines market by volume with 47.2% (4.7 million doses), followed by Infanrix-IPV/Kinrix® (GSK) with 23.7% (2.3 million doses), Quadacel® (Sanofi) with 13.7% (1.4 million doses), Boostrix-IPV® (GSK) and Repevax® (Sanofi Pasteur) with 8% (0.8 million doses) and 7.3% (0.7 million doses) respectively.

DTaP-IPV School Entry Booster Vaccines Market

Among the top 40 aP based school entry booster markets, 25 countries are using DTaP-IPV vaccines. At least 8.4 million doses of DTaP-IPV vaccines were distributed among these countries.

Among the 25 countries using only DTaP-IPV vaccines, 16 countries are using only Tetraxim in their immunization schedule, whereas only one country, namely New Zealand is using only Infanrix-IPV in their immunization schedule.

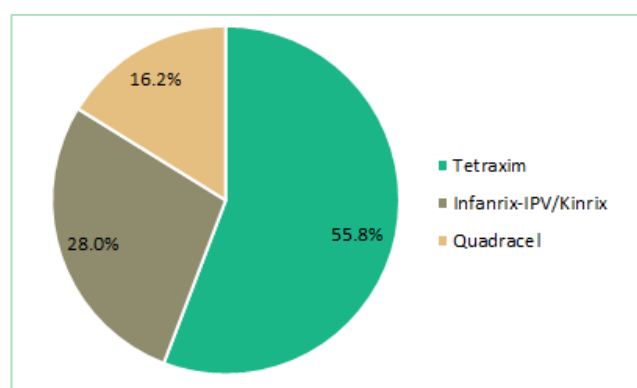


Fig 33: DTaP-IPV school entry booster vaccines by brand, 2020

In 2020, Tetraxim® (Sanofi Pasteur) had the highest share among the DTaP-IPV school entry booster vaccines market by volume with 55.8% (4.7 million doses), followed by Infanrix-IPV/Kinrix® (GSK) with 28% (2.3 million doses), and Quadacel® (Sanofi Pasteur) with 16.2% (1.4 million doses).

School Entry Booster Vaccines Market By Manufacturer

Sanofi Pasteur and GSK are the major manufacturers of school entry booster vaccines. Few vaccine manufacturers, including AJ Vaccines in Denmark and Boryung Pharm in South Korea, have a local presence but are not leading players compared to Sanofi Pasteur or GSK.

Sanofi Pasteur's school entry booster vaccines include Tetraxim® (DTaP-IPV), Quadacel® (only for the US market; DTaP-IPV), Repevax® (Tdap-IPV), Adacel® (Tdap), and Daptacel® (DTaP). GSK's school entry booster vaccines include Infanrix-IPV®/Kinrix® (DTaP-IPV), Boostrix-IPV® (Tdap-IPV), Boostrix® (Tdap), and Infanrix® (DTaP).

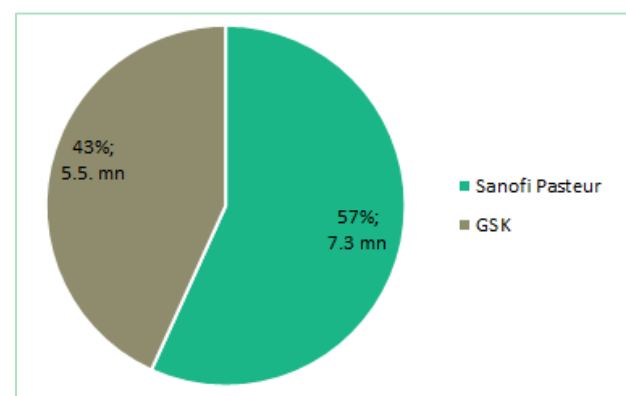


Fig 34: School entry booster vaccine manufacturers, market share among the top 40 markets, 2020

Among the top 40 countries, Sanofi Pasteur has a 57% market share (7.3 million doses) in the school entry booster vaccines market, whereas GSK has a 43% (5.5 million doses) market share. The high market share for Sanofi Pasteur can be attributed to the sole use of Tetraxim in many public markets.

4 aP Based Combination Vaccine Market Dominance

Our analysis shows that aP based vaccine brands offered by Sanofi for both primary and school entry booster series are market leaders.

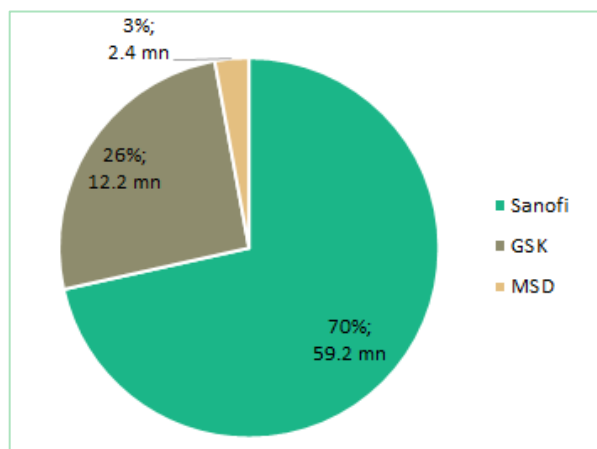


Fig 35: Sanofi Share In aP Based Combination Vaccine Market, 2020

In 2020, around 59 million doses of Sanofi's pertussis based vaccines were consumed (Hexaxim®, Pentaxim®, Pentacel®, Pediacel®, Tetraxim®, Quadracel®, Adacel®, and Repevax®) whereas 12.2 million doses of GSK's pertussis based vaccines were consumed (Infanrix-Hexa®, Pediarix®, Infanrix-IPV/Hib®, Infanrix-IPV®/Kinrix®, Boostrix-IPV®, Boostrix®, and Vaxelis®).



Fig 36: aP based primary & school entry booster series vaccine volumes consumed (million doses), 2020

In 2020, Sanofi's Hexaxim® and Pentaxim® are the major brands with consumption of more than 20 million doses each. During the same period around 10 million doses of GSK's Infanrix-Hexa®, and 5 million doses of Pediarix® were consumed.

5 Value Of the Study

The current study evaluates the volumes of aP based combination vaccines (primary series & school entry 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 School entry boosters) by region, by country, and by the individual brands are also analyzed as one of the major objectives of the study (for hexavalent vaccines not all countries were included also missing the USA, China, and Japan, but those are the countries where no hexavalent were available at the time of the study).

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

6 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/school entry booster (trivalent or tetravalent) vaccine in the immunization schedule drive the vaccine consumption in public markets, whereas availability and affordability of the vaccines drive the vaccine consumption in private markets.

In 2020, DTaP combination vaccines accounted for a 23% share of the DTP combination vaccines market for primary vaccination (excluding China), with 83 million doses of the 313 million DTP vaccine doses distributed.

Most public markets occur in high and upper-middle-income countries and most private markets in lower-middle- and low-income countries. The study summarizes that aP based combination vaccines were consumed more in public markets than in private markets in 2020.

Europe accounts for the major share of the aP based combination vaccines market by volume at 38% for hexavalent vaccines, 36% for pentavalent vaccines, and 48% for school entry booster vaccines. In 2020, the top 40 countries consumed 36.1 million doses of hexavalent vaccines, which are 96% of global consumption. During the same period top 20 pentavalent markets and top 40 school entry booster vaccine markets consumed around 33.7 million doses (97% of the global pentavalent vaccine market), and 12.8 million doses respectively (95% of the global school entry 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 2020, around 22 million doses of Hexaxim, and 21 million doses of Pentaxim were consumed.

Among hexavalent vaccines, Hexaxim® (Sanofi Pasteur) has a market share of 67%, followed by Infanrix Hexa with a market share of 26% (GSK). Among pentavalent vaccines, Pentaxim® (Sanofi Pasteur) has a market share of 62%, followed by Pentacel® (Sanofi Pasteur) and Pediarix® (GSK) with 17% and 16%, respectively. Among school entry booster vaccines, Tetraxim® (Sanofi Pasteur) has a market share of 36.3%, followed by Infanrix-IPV/Kinrix (GSK) with 18.6%.

Sanofi's vaccine brands are market leaders in each market category, namely hexavalent vaccines, pentavalent vaccines, and school entry booster vaccines. The research concludes Sanofi as the market leader in the aP based pediatric combination vaccines market.

Appendix

Table 4-Hexavalent Vaccine Public Markets

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

S.No	Country Name	Income Status ¹	Region	Hexavalent Vaccine Immunization Rate ³	Surviving Infants Population ⁴	Schedule
1	Mexico	UMIC	AMR	80%	2,745,991	4
2	Russia	UMIC	EUR	3%	1,742,692	4
3	South Africa	UMIC	AFR	84%	1,143,695	4
4	United Kingdom	HIC	EUR	93%	769,352	3
5	Argentina	UMIC	AMR	1.1%	732,596	3
6	Saudi Arabia	HIC	EMR	95%	588,314	3
7	Malaysia	UMIC	WPR	98%	529,506	4
8	Italy	HIC	EUR	94%	428,808	3
9	Canada	HIC	AMR	45%	399,628	3
10	Spain	HIC	EUR	98%	393,854	3
11	Kazakhstan	UMIC	EUR	88%	375,176	2
12	Australia	HIC	WPR	95%	337,468	3
13	Chile	HIC	AMR	93%	225,337	4
14	Jordan	UMIC	EMR	77%	205,778	3
15	Romania	HIC	EUR	87%	190,648	3
16	Netherlands	HIC	EUR	89%	168,093	3
17	Sweden	HIC	EUR	97%	122,204	3
18	Belgium	HIC	EUR	92%	121,939	4
19	Libya	UMIC	EMR	73%	121,693	3
20	Czech Republic	HIC	EUR	90%	113,304	3
21	United Arab Emirates	HIC	EMR	90%	97,587	2
22	Oman	HIC	EMR	85%	94,306	2
23	Austria	HIC	EUR	85%	91,691	3
24	Switzerland	HIC	EUR	96%	89,848	3
25	Portugal	HIC	EUR	93%	77,987	2
26	Panama	HIC	AMR	74%	76,082	3
27	Bulgaria	UMIC	EUR	75%	64,016	3
28	Ireland	HIC	EUR	94%	60,181	3
29	New Zealand	HIC	WPR	92%	59,446	3
30	Norway	HIC	EUR	97%	59,443	3
31	Georgia	UMIC	EUR	88%	51,898	3
32	Armenia	UMIC	EUR	86%	38,269	1

33	Croatia	HIC	EUR	88%	35,437	4
34	Qatar	HIC	EMR	82%	25,880	2
35	Latvia	HIC	EUR	89%	24,496	4
36	Macedonia (North)	UMIC	EUR	84%	21,953	2
37	Bahrain	HIC	EMR	98%	20,965	2
38	Slovenia	HIC	EUR	95%	19,727	3
39	Estonia	HIC	EUR	91%	13,462	4
40	Mauritius	HIC	AFR	93%	12,762	4
41	Luxembourg	HIC	EUR	99%	6,490	3
42	Brunei Darussalam	HIC	WPR	99%	6,014	3
43	Malta	HIC	EUR	98%	4,223	3
44	Andorra	HIC	EUR	94%	1,000	3
45	San Marino	HIC	EUR	84%	250	3
46	Niue	UMIC	WPR	97%	15	3

1. Income Status: Data for the type of country income classification, such as High Income (HI), Upper middle income (UMIC), Lower middle income (LMIC) country were collected from World Bank (WHO follows World Bank classification).
2. #Vaccines: Number of DTP vaccine 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 immunization schedule). From 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 5-Hexavalent Vaccine Private Markets

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

S.No	Country Name	Income Status ¹	Region	Hexavalent Vaccine Private Share in the market ²	Surviving Infants Population ³	Schedule
1	India	LMIC	SEAR	1.5%	23,303,290	3
2	Pakistan	LMIC	EMR	0%	5,424,160	3
3	Indonesia	UMIC	SEAR	2.5%	4,465,733	3
4	Brazil	UMIC	AMR	3.1%	2,831,050	3
5	Bangladesh	LMIC	SEAR	0%	2,766,692	3
6	Egypt	LMIC	EMR	0.5%	2,486,021	3
7	Philippines	LMIC	WPR	2.8%	2,061,080	3
8	Vietnam	LMIC	WPR	40.0%	1,562,463	3
9	Iran	UMIC	EMR	2%	1,555,677	3
10	Kenya	LMIC	EMR	5%	1,418,464	2
11	Iraq	UMIC	EMR	1%	1,067,525	3
12	Myanmar (Burma)	LMIC	SEAR	0%	892,607	3
13	Germany	HIC	EUR	95%	835,509	3
14	Colombia	UMIC	AMR	3%	740,264	3
15	France	HIC	EUR	96%	710,000	3
16	Thailand	UMIC	SEAR	15%	695,602	3
17	Uzbekistan	LMIC	EUR	0%	666,988	3
18	Morocco	LMIC	EMR	2%	650,110	3
19	Peru	UMIC	AMR	2%	585,551	3
20	Venezuela	UMIC	AMR	6%	458,000	3
21	Guatemala	UMIC	AMR	1%	409,888	3
22	Poland	HIC	EUR	45%	380,325	3
23	Ukraine	LMIC	EUR	15%	370,262	3
24	Cambodia	LMIC	WPR	1%	344,445	3
25	Ecuador	UMIC	AMR	1%	330,999	3
26	Sri Lanka	LMIC	SEAR	0%	330,319	3
27	Bolivia	LMIC	AMR	1%	236,870	3
28	Papua New Guinea	LMIC	WPR	6%	224,530	3
29	Honduras	LMIC	AMR	0%	207,576	3
30	Tunisia	LMIC	EMR	9%	195,619	3
31	Dominican Republic	UMIC	AMR	2%	194,646	3
32	Azerbaijan	UMIC	EUR	4%	158,115	3
33	Lao People's Democratic Republic	LMIC	WPR	5%	157,035	3
34	Kyrgyzstan	LMIC	EUR	3%	146,889	3

35	Paraguay	UMIC	AMR	1%	140,242	3
36	Turkmenistan	UMIC	EUR	2%	127,113	3
37	Nicaragua	LMIC	AMR	1%	127,001	3
38	El Salvador	LMIC	AMR	1%	114,850	3
39	Lebanon	UMIC	EMR	9%	110,946	3
40	Greece	HIC	EUR	75%	80,250	4
41	Denmark	HIC	EUR	0%	63,686	3
42	Slovakia	HIC	EUR	97%	57,193	3
43	Kuwait	HIC	EMR	5%	54,440	3
44	Uruguay	HIC	AMR	14.5%	46,163	3

1. Income Status: Data for the type of country income classification, such as High Income, Upper middle income, Lower middle income & Low-income country were collected from World Bank (WHO follows 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, primary 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 (SDG), United Nations (UN) Population data.

Table 6-Hexavalent Vaccines Brand Consumption in Top 40 Countries

The table below shows the volumes of hexavalent vaccines consumed in the top 40 countries by brand

S.No	Country Name	Country Code	Type of Market	Volumes (Million doses)	Hexaxim®	Infanrix Hexa®	Vaxelis®
1	Mexico ¹	MX	Public	8.79	8,787,170	NA	NA
2	South Africa ²	ZA	Public	3.84	3,842,815	NA	NA
3	Germany ^P	DE	Private	2.38	833,420	1,071,541	476,240
4	United Kingdom ³	UK	Public	2.07	NA	2,066,438	-
5	France ^P	FR	Private	2.04	1,226,880	613,440	204,480
6	Saudi Arabia ⁴	SA	Public	2.00	2,000,000	NA	NA
7	Vietnam ⁵	VN	Private	1.87	937,478	937,478	NA
8	Italy ^{6, P}	IT	Public	1.21	604,619	362,772	241,848
9	Spain ⁷	ES	Public	1.16	115,793	115,793	926,343
10	India ^{8, P}	IN	Private	1.05	629,189	419,459	NA
11	Australia ⁹	AU	Public	0.96	NA	961,784	NA
12	Chile ¹⁰	CL	Public	0.79	790,456	NA	NA
13	Kazakhstan ¹¹	KZ	Public	0.62	621,811	NA	NA
14	Canada ¹²	CA	Public	0.54	NA	539,498	NA
15	Poland ^P	PL	Private	0.53	210,506	315,759	NA
16	Romania ¹³	RO	Public	0.52	518,066	NA	NA
17	Belgium ^{14, P}	BE	Public	0.48	477,999	NA	NA
18	Netherlands ¹⁵	NL	Public	0.47	NA	NA	468,979
19	Jordan ^P	JO	Public	0.45	NA	449,541	NA
20	Malaysia ¹⁶	MY	Public	0.41	391,696	20,616	NA
21	Sweden ¹⁷	SE	Public	0.36	355,612	NA	NA
22	Czech Republic ¹⁸	CZ	Public	0.34	306,853	34,095	NA
23	Indonesia ^{19, P}	ID	Private	0.33	197,036	131,357	NA
24	Thailand ^{20, P}	TH	Private	0.31	187,813	125,208	NA
25	Brazil ^{21, P}	BR	Private	0.26	184,301	78,986	NA
26	Switzerland ^{22, P}	CH	Public	0.26	NA	181,134	77,629
27	Libya ²³	LY	Public	0.25	252,195	NA	NA
28	Greece	GR	Private	0.24	62,086	49,669	12,417
29	Austria ²⁴	AT	Public	0.23	233,811	NA	NA
30	Russia ²⁵	RU	Public	0.21	NA	207,797	NA
31	Oman ^P	OM	Public	0.19	194,386	NA	NA
32	Norway ²⁶	NO	Public	0.17	NA	172,980	NA
33	Panama ²⁷	PA	Public	0.17	168,903	NA	NA
34	Slovakia ^P	SK	Private	0.17	83,216	83,216	NA
35	United Arab Emirates ^{28, P}	AE	Public	0.17	111,490	54,913	NA

36	Ukraine ^P	UA	Private	0.17	115,726	49,597	NA
37	New Zealand ²⁹	NZ	Public	0.16	NA	164,072	NA
38	Ireland ³⁰	IE	Public	0.16	NA	159,815	NA
39	Portugal ³¹	PT	Public	0.15	145,055	NA	NA
40	Croatia ³²	HR	Public	0.12	124,173	NA	NA

1. Secretaria de Salud, LOTES DE VACUNAS LIBERADAS 2020
2. National Department of Health, Tender Procurement, 2020
3. NHS Immunization Schedule, 2020
4. Saudi Arabia, National Immunization Schedule 2020
5. Vietnam – Drug Administration Ministry of Health, DTP Immunization Services 2020
6. Agenzia Italiana Del Farmaco, Vaccini. Dati e analisi su consumi e spesa
7. Spain Regional Health Tenders, TED Tender Electronic Daily
8. IDBI Capital Market Report (Includes Hexaxim®), 2018, 2019
9. Australia Department of Health, Immunization Schedule; AusTender-Department of Health (2020)
10. National Health Service System (CENBAST), Mercado Público - La plataforma de compras públicas
11. Kazakhstan National Drug Formulary, Only Hexaxim Approval
12. Public Works and Government Services Canada, Tender 2020
13. Ministry of Public Health Tender Contract 2020
14. Belgium Flemish Government, Care & Health, 2020
15. National Institute for Public Health and the Environment (an agency of the Dutch Ministry of Health), National Immunization Program
16. Malaysia National Pharmaceutical Regulatory Agency, 2020
17. Regional Health Tenders, National Vaccine Procurement Sweden 2020
18. Ministry of Health of the Czech Republic Vaccination Calendar 2020,
19. Ministry of Health, Republic of Indonesia Directorate General of Health Services, 2020
20. Thailand Department of Disease Control, Vaccine Procurement
21. Leader in vaccine in Brazil, GSK expands operation 2019
22. Eidgenössische Kommission für Impffragen, 2020
23. Ministry of Health – Supreme Committee for Supervision of Tenders 2019
24. Federal Ministry of Labour, Social Affairs, Health, and Consumer Protection
25. Russia Ministry of Health (Allows hexavalent and pentavalent only for risk population)
26. Norwegian Institute of Public Health (CTM-KGV portal)
27. Panama National Institute of Statistics & Census (Instituto Nacional de Estadística y Censo) 2014 – 2018
28. UAE Pharma Retail Chains (Nextdoormed & Others), 2020
29. New Zealand, National Immunization Schedule, 2020
30. Ireland National Immunization Schedule, 2020
31. Portugal Ministry of Health Services, 2020
32. Croatia Department of Public Health

Table 7-Estimated Global Preterm Births

The table below shows the estimated global preterm births

S.No	Country Name	Country Code	Preterm Births, 2020
1	India	IN	3,171,578
2	China	CN	1,106,492
3	Nigeria	NG	745,634
4	Bangladesh	BD	529,822
5	Pakistan	PK	455,087
6	Indonesia	ID	454,463
7	Ethiopia	ET	397,557
8	United States	US	379,142
9	United Republic of Tanzania	TZ	325,072
10	Brazil	BR	316,511
11	Egypt	EG	306,567
12	Democratic Republic of the Congo (the)	CD	302,394
13	Philippines	PH	253,451
14	Sudan (the)	SD	167,853
15	Turkey	TR	154,263
16	Russia	RU	149,267
17	Mexico	MX	148,564
18	South Africa	ZA	135,695
19	Angola	AO	135,022
20	Algeria	DZ	132,478
21	Mozambique	MZ	122,038
24	Kenya	KE	117,554
22	Niger (the)	NE	115,351
23	Afghanistan	AF	114,538
25	Colombia	CO	107,708
26	Iraq	IQ	105,070
27	Viet Nam	VN	102,029
28	Uganda	UG	100,922
29	Madagascar	MG	100,358
30	Ivory Coast	CI	96,754
31	Cameroon	CM	94,807
32	Iran	IR	94,335
33	Myanmar (Burma)	MM	92,831
34	Thailand	TH	88,341
35	Mali	ML	84,015
36	Burkina Faso	BF	81,618

37	Yemen	YE	81,596
38	Morocco	MA	81,274
39	France	FR	78,690
40	Germany	DE	74,110
41	Germany	DE	73,859
42	Uzbekistan	UZ	69,367
43	Zambia	ZM	68,504
44	Chad	TD	67,566
45	Somalia	SO	67,043
46	Argentina	AR	61,392
47	Senegal	SN	61,005
48	Malawi	MW	60,655
49	France	FR	58,018
50	Malaysia	MY	55,069
51	Peru	PE	53,782
52	United Kingdom of Great Britain and Northern Ireland (the)	GB	52,216
53	Guinea	GN	49,657
54	Japan	JP	49,179
55	Syrian Arab Republic (the)	SY	43,598
56	Zimbabwe	ZW	43,185
57	Guatemala	GT	40,292
58	South Sudan	SS	39,321
59	Venezuela (Bolivarian Republic of)	VE	38,797
60	Democratic People's Republic of Korea (the)	KP	36,115
61	Cambodia	KH	35,822
62	Jordan	JO	34,582
63	Italy	IT	33,404
64	Canada	CA	32,570
65	Ukraine	UA	32,036
66	Australia	AU	29,022
67	Poland	PL	28,262
68	Nepal	NP	27,958
69	Tajikistan	TJ	27,318
70	Ecuador	EC	26,546
71	Sierra Leone	SL	26,294
72	Spain	ES	25,482
73	Tunisia	TN	24,230
74	Sri Lanka	LK	23,056
75	Saudi Arabia	SA	22,467

76	Bolivia	BO	22,391
77	Papua New Guinea	PG	21,754
78	South Korea	KR	21,116
79	Honduras	HN	20,405
80	Congo (the)	CG	19,144
81	Dominican Republic	DO	19,134
82	Kazakhstan	KZ	18,301
83	Liberia	LR	17,309
84	Romania	RO	17,309
85	Chile	CL	16,850
86	Central African Republic (the)	CF	16,535
87	Lao People's Democratic Republic (the)	LA	16,332
88	Mauritania	MR	15,971
89	Libya	LY	15,443
90	Azerbaijan	AZ	14,509
91	Kyrgyzstan	KG	13,762
92	Netherlands	NL	12,506
93	Nicaragua	NI	12,484
94	Eritrea	ER	12,306
95	Belgium	BE	12,279
96	Turkmenistan	TM	11,390
97	Paraguay	PY	11,318
98	Serbia	RS	10,223
99	Greece	GR	9,157
100	Oman	OM	9,062
101	Czech Republic	CZ	8,916
102	Hungary	HU	8,671
103	Namibia	NA	7,721
104	Sweden	SE	7,711
105	Gabon	GA	7,589
106	Panama	PA	7,479
107	Austria	AT	7,271
108	Mongolia	ME	7,151
109	Guinea-Bissau	GW	7,003
110	Costa Rica	CR	6,584
111	Switzerland	CH	6,460
112	Cuba	CU	6,029
113	Portugal	PT	6,028
114	Lesotho	LS	5,949
115	Bulgaria	BG	5,768

116	Slovakia	SK	5,187
117	United Arab Emirates (the)	AE	5,085
118	Georgia	GE	5,006
119	Denmark	DK	4,888
120	Equatorial Guinea	GQ	4,639
121	New Zealand	NZ	4,441
122	Uruguay	UY	4,141
123	Armenia	AM	3,980
124	Belarus	BY	3,865
125	Ireland	IE	3,604
126	Norway	NO	3,460
127	Republic of Moldova (the)	MD	3,217
128	Finland	FI	2,732
129	Albania	AL	2,692
130	Macedonia	MK	1,817
131	Croatia	HR	1,768
132	Bosnia-Herzegovina	BA	1,657
133	Latvia	LV	1,482
134	Slovenia	SI	1,372
135	Bhutan	BT	1,362
136	Guyana	GY	1,362
137	Lithuania	LT	1,256
138	Suriname	SR	992
139	Estonia	EE	761
140	Luxembourg	LU	626
141	Iceland	IS	336

*Estimated based on WHO 2014 preterm birth rate (value), HEXYON/HEXACIMA – Use in preterm infants in EU countries with exclusive use (up to end DEC-2020)

Table 8- Preterm Hexavalent Vaccine Volumes

The table below shows the estimated preterm hexavalent vaccine volumes in the top 32 countries

S.No	Country Name	Country Code	Preterm Births, 2020	Preterm Hexavalent Vaccine Volumes
1	Russia	RU	149,267	597,069
2	Mexico	MX	148,564	594,257
3	South Africa	ZA	135,695	542,779
4	France	FR	78,690	236,070
5	Germany	DE	73,859	221,577
6	Malaysia	MY	55,069	220,274
7	United Kingdom	GB	52,216	156,649
8	Jordan	JO	34,582	103,745
9	Italy	IT	33,404	100,212
10	Canada	CA	32,570	97,709
11	Australia	AU	29,022	87,067
12	Spain	ES	25,482	76,447
13	Saudi Arabia	SA	22,467	67,401
14	Kazakhstan	KZ	18,301	36,602
15	Romania	RO	17,309	51,926
16	Chile	CL	16,850	67,401
17	Libya	LY	15,443	46,328
18	Netherlands	NL	12,506	37,518
19	Belgium	BE	12,279	49,117
20	Greece	GR	9,149	27,446
21	Oman	OM	9,062	18,123
22	Czech Republic	CZ	8,916	26,749
23	Sweden	SE	7,711	23,133
24	Panama	PA	7,479	22,437
25	Austria	AT	7,271	21,813
26	Switzerland	CH	6,460	19,380
27	Portugal	PT	6,028	12,057
28	Slovakia	SK	5,187	15,562
29	United Arab Emirates	AE	5,085	10,169
30	New Zealand	NZ	4,441	13,322
31	Ireland	IE	3,604	10,813
32	Norway	NO	3,460	10,379
33	Croatia	HR	1,768	7,073

*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 9-Pentavalent Vaccine Public Markets

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

S.No	Country Name	Income Status ¹	Region	Pentavalent Vaccine Immunization Rate ³	Surviving Infants Population ⁴	Schedule
1	USA	HIC	AMR	93.0%	3,965,926	3
2	Russia	UMIC	EUR	67.0%	1,731,639	4
3	Turkey	UMIC	EUR	98.0%	1,243,054	4
4	Malaysia	UMIC	WPR	73.0%	529,506	4
5	Canada	HIC	AMR	91.0%	399,628	1
6	Poland	HIC	EUR	30.0%	389,826	
7	Kazakhstan	UMIC	EUR	88.0%	353,302	2
8	South Korea	HIC	WPR	98.0%	316,114	2
9	Taiwan	HIC	WPR	96.0%	189,000	4
10	Israel	HIC	EMR	98.0%	165,525	4
11	Libya	UMIC	EMR	73.0%	115,157	1
12	Hungary	HIC	EUR	99.0%	98,085	4
13	United Arab Emirates	HIC	EMR	90.0%	92,446	1
14	Switzerland	HIC	EUR	5.0%	89,848	4
15	Serbia	UMIC	EUR	97.0%	85,404	4
16	Portugal	HIC	EUR	99.0%	77,987	2
17	Denmark	HIC	EUR	97.0%	67,796	3
18	Costa Rica	UMIC	AMR	95.0%	66,981	4
19	Bulgaria	UMIC	EUR	30.0%	64,016	4
20	Singapore	HIC	WPR	96.0%	59,011	3
21	Finland	HIC	EUR	91.0%	47,347	3
22	Croatia	HIC	EUR	94.0%	35,437	1
23	Latvia	HIC	EUR	1.0%	27,451	3
24	Bosnia-Herzegovina	LMIC	EUR	73.0%	24,622	3
25	Lithuania	HIC	EUR	91.0%	23,167	4
26	Macedonia	UMIC	EUR	93.0%	20,837	2
27	Slovenia	HIC	EUR	30.0%	18,902	4
28	Bhutan	LMIC	SEAR	95.0%	13,099	3
29	Montenegro	UMIC	EUR	84.0%	7,617	4
30	Luxembourg	HIC	EUR	99.0%	6,490	1
31	Malta	HIC	EUR	98.0%	4,223	4

32	Iceland	HIC	EUR	91.0%	3,853	3
33	Micronesia (Federated States of)	LMIC	WPR	83.0%	2,479	3
34	Marshall Islands (the)	UMIC	WPR	5.0%	1,000	4
35	Cook Islands	HIC	WPR	10.0%	500	3
36	Palau	HIC	WPR	10.0%	500	2

1. Income Status: Data for the type of country income classification, such as High Income (HI), Upper middle income (UMIC), Lower middle income (LMIC) countries were collected from World Bank (WHO follows World Bank classification).
2. #Vaccines: Number of DTP vaccine 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 10-Pentavalent Vaccine Private Markets

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

S.No	Country Name	Income Status ¹	Region	Pentavalent Vaccine Private Share in the market ²	Surviving Infants Population ³	Schedule
1	India	LMIC	SEAR	0.4%	23,303,290	3
2	China	UMIC	SEAR	34.9%	15,943,682	3
3	Pakistan	LMIC	EMR	0.3%	5,424,160	3
4	Indonesia	UMIC	SEAR	0.5%	4,369,841	4
5	Brazil	UMIC	AMR	2.0%	2,831,050	3
6	Bangladesh	LMIC	SEAR	0.2%	2,766,692	3
7	Philippines	LMIC	WPR	0.5%	1,909,954	3
8	Viet Nam	LMIC	WPR	5.0%	1,562,463	3
9	Myanmar (Burma)	LMIC	SEAR	1.0%	892,607	3
10	Colombia	UMIC	AMR	1.2%	740,264	3
11	Thailand	UMIC	SEAR	16.0%	695,602	
12	Peru	UMIC	AMR	1.1%	611,855	3
13	Morocco	LMIC	EMR	0.5%	606,067	3
14	Guatemala	UMIC	AMR	1.5%	409,888	3
15	Ukraine	LMIC	EUR	3.5%	367,385	2
16	Ecuador	UMIC	AMR	1.3%	330,999	3
17	Dominican Republic	UMIC	AMR	0.5%	194,646	3
18	Tunisia	LMIC	EMR	5.0%	180,683	3
19	Lebanon	UMIC	EMR	5.0%	105,242	3
20	Kuwait	HIC	EMR	6.0%	54,440	3

1. Income Status: Data for the type of country income classification, such as High Income (HI), Upper middle income (UMIC), Lower middle income (LMIC) countries were collected from World Bank (WHO follows 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, primary 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 11-Pentavalent Vaccines Brand Consumption in Top 22 Countries

The table below shows the volumes of pentavalent vaccines consumed in the top 22 countries by brand

S.No	Country Name	Type of Market	Volumes (Million doses)	Pentaxim	Pentacel	Pediacel	Infanrix-IPV/Hib	Pediarix
1	USA ¹	Public	11.06	NA	5,532,466	NA	NA	5,532,466
2	China ²	Private	5.56	5,560,000	NA	NA	NA	NA
3	Turkey ³	Public	4.87	4,872,770	NA	NA	NA	NA
4	Russia ⁴	Public	4.64	4,640,791	NA	NA	NA	NA
5	Malaysia ⁵	Public	1.55	1,391,540	NA	NA	154,616	NA
6	Canada ⁶	Public	0.74	NA	NA	735,315	NA	NA
7	Taiwan ⁷	Public	0.73	725,760	NA	NA	NA	NA
8	Israel ⁸	Public	0.65	454,201	NA	NA	194,657	NA
9	Kazakhstan ⁹	Public	0.62	621,811	NA	NA	NA	NA
10	South Korea ¹⁰	Public	0.62	464,687	NA	NA	154,896	NA
11	Hungary ¹¹	Public	0.39	388,416	NA	NA	NA	NA
12	Poland ^P	Public	0.35	210,506	NA	NA	140,337	NA
13	Serbia ¹²	Public	0.33	331,368	NA	NA	NA	NA
14	India ¹³	Private	0.28	279,639	NA	NA	NA	NA
15	Costa Rica ¹⁴	Public	0.25	254,526	NA	NA	NA	NA
16	Thailand ^P	Private	0.25	150,250	NA	NA	100,167	NA
17	Vietnam ^P	Private	0.23	128,903	NA	NA	105,466	NA
18	Portugal ^P	Public	0.15	154,413	NA	NA	NA	NA
19	Finland ¹⁵	Public	0.13	129,257	129,257	NA	NA	NA
20	Singapore ^P	Public	0.11	101,971	11,330	NA	NA	NA
21	Indonesia ^P	Private	0.09	8,740	NA	NA	78,657	NA
22	Lithuania ¹⁶	Public	0.08	84,327	NA	NA	NA	NA

1. USA Federal Agency Tenders, GOVTRIBE
2. China Medical Health Research Center, Vaccine Consumption
3. Turkish Medical Association
4. Nanolek, Sanofi's Pentavac Manufacturing & Supply Partner
5. Malaysia Ministry of Health
6. Public Works and Government Services Canada, Tender 2020
7. Taiwan Health And Welfare Report
8. Israel Ministry of Health, Vaccine Consumption
9. Ministry of Health, Vaccine Orders
10. Korea Disease Control & Prevention Agency, Vaccine Procurement
11. Hungary Ministry of Health
12. Serbia Ministry of Health, Vaccine Procurement
13. Central Drugs Standard Control Organisation (CDSCO), Vaccine Procurement
14. Costa Rica Social Security Fund, Expanded Immunization Program
15. Finnish Institute For Health & Welfare (FHI)
16. Lithuania Ministry of Health

Table 12-aP Based School Entry Booster Vaccine Public Markets

The table below shows the parameters considered for aP based school entry booster vaccine volume estimation in the public market

S.No	Country Name	Income Status ¹	Region	School Entry Booster Vaccine Immunization Rate ²	Target Population ³	Age ⁴
1	United States of America	HIC	AMR	86%	3,965,926	4 years
2	Turkey	UMIC	EUR	90%	1,560,000	6 years
3	UK	HIC	EUR	90%	810,321	3 years and 4 months;
4	Saudi Arabia	HIC	EMR	75%	608,794	4-6 years
5	South Korea	HIC	WPR	88%	439,471	4-6 years
6	Spain	HIC	EUR	95%	434,623	6 years
7	Italy	HIC	EUR	83%	428,808	5-6 years
8	Canada	HIC	AMR	79%	399,628	4-6 years
9	Kazakhstan	UMIC	EUR	84%	399,183	6 years
10	Poland	HIC	EUR	90%	389,826	6 years
11	Australia	HIC	WPR	95%	337,468	4 years
12	Chile	HIC	AMR	83%	252,947	6 years
13	Taiwan	HIC	SEAR	95%	200,000	5 years
14	Romania	HIC	EUR	80%	198,493	6 years
15	Netherlands	HIC	EUR	87%	174,743	4 years
16	Israel	HIC	EUR	90%	165,525	7 years
17	Libya	UMIC	EMR	84%	132,998	6 years
18	Belgium	HIC	EUR	84%	132,608	5-6 years
19	Sweden	HIC	EUR	91%	122,204	5 years
20	Czech Republic	HIC	EUR	87%	108,722	5 years
21	UAE	HIC	EMR	70%	104,499	5-6 years
22	Hungary	HIC	EUR	94%	98,085	6 years
23	Switzerland	HIC	EUR	81%	89,848	4-7 years
24	Austria	HIC	EUR	75%	85,696	6 years
25	Portugal	HIC	EUR	89%	84,241	5 years
26	Panama	HIC	AMR	16%	78,031	4 years
27	Costa Rica	UMIC	AMR	88%	71,132	4 years
28	Ireland	HIC	EUR	88%	69,723	4-5 years
29	Bulgaria	UMIC	EUR	84%	65,337	6 years
30	Hong Kong	HIC	SEAR	89%	63,059	5 years
31	Norway	HIC	EUR	89%	62,532	7 years
32	New Zealand	HIC	WPR	86%	61,065	4 years
33	Denmark	HIC	EUR	86%	57,480	5 years
34	Finland	HIC	EUR	86%	57,426	4 years

35	Croatia	HIC	EUR	79%	39,688	6 years
36	Lithuania	HIC	EUR	76%	31,954	6-7 years
37	Bosnia-Herzegovina	UMIC	EUR	70%	30,021	5 years
38	Qatar	HIC	EMR	77%	27,539	4-6 years
39	Bahrain	HIC	EMR	86%	22,953	4 years
40	Latvia	HIC	EUR	90%	18,520	7 years
41	Estonia	HIC	EUR	79%	14,828	6-7 years
42	Cyprus	HIC	EUR	80%	13,484	4-6 years
43	Brunei Darussalam	HIC	WPR	92%	7,076	5 years
44	Luxembourg	HIC	EUR	85%	6,490	5-6 years
45	Iceland	HIC	EUR	86%	4,302	4 years
46	Micronesia (Federated States of)	LMIC	WPR	48%	2,381	4 years
47	Niue	UMIC	WPR	97%	1,000	4 years
48	Andorra	HIC	EUR	94%	1,000	5 years
49	Cook Islands	HIC	WPR	93%	1,000	4 years
50	Nauru	HIC	WPR	93%	1,000	4 years
51	San Marino	HIC	EUR	74%	1,000	5 years
52	Palau	HIC	WPR	58%	1,000	4-6 years
53	Marshall Islands	UMIC	WPR	48%	1,000	4-5 years

1. Income Status: Data for the type of country income classification, such as High Income (HI), Upper middle income (UMIC), Lower middle income (LMIC) countries were collected from World Bank (WHO follows 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. School entry Booster Vaccination age is taken from UN population forecast and World Bank population forecast databases

Table 13-aP Based School Entry Booster Vaccine Private Markets

The table below shows the parameters considered for aP based school entry booster vaccine volume estimation in the private market

S.No	Country Name	Income Status ¹	Region	School Entry Booster Vaccine Private Share in the market ²	Target Population ³	Age ⁴
1	India	LMIC	SEAR	2.5%	23,303,290	5-6 years
2	Brazil	UMIC	AMR	1.0%	2,911,002	4 years
3	Mexico	UMIC	AMR	1.0%	2,745,991	4 years
4	Iran	UMIC	EMR	0.5%	1,561,834	6 years
5	Iraq	UMIC	EMR	9.1%	1,083,704	4-6 years
6	France	HIC	EUR	90%	774,806	6 years
7	Germany	HIC	EUR	70%	773,459	5-6 years
8	Argentina	UMIC	AMR	18.5%	746,218	6 years
9	Colombia	UMIC	AMR	4.7%	740,264	5 years
10	Thailand	UMIC	SEAR	14.6%	737,829	4 years
11	Morocco	LMIC	EMR	4.0%	698,033	5 years
12	Peru	UMIC	AMR	3.4%	527,823	4 years
13	Guatemala	UMIC	AMR	4.8%	409,888	4 years
14	Venezuela	UMIC	AMR	0.5%	398,740	5 years
15	Ecuador	UMIC	AMR	4.7%	330,999	5 years
16	Bolivia	LMIC	AMR	0.4%	227,787	4 years
17	Honduras	LMIC	AMR	4.9%	197,745	4 years
18	Dominican Republic	UMIC	AMR	4.5%	194,646	4 years
19	Paraguay	UMIC	AMR	5.0%	140,242	4 years
20	Nicaragua	LMIC	AMR	4.8%	127,001	6 years
21	Lebanon	UMIC	EMR	8.8%	118,183	4-5 years
22	El Salvador	LMIC	AMR	3.6%	114,850	4 years
23	Greece	HIC	EUR	86%	87,851	4-6 years
24	Kuwait	HIC	EMR	17%	59,505	3.6 years
25	Slovakia	HIC	EUR	88%	57,193	5 years
26	Uruguay	HIC	AMR	20%	47,657	5 years
27	Jamaica	UMIC	AMR	4.7%	47,243	4-6 years
28	Trinidad and Tobago	HIC	AMR	20%	18,691	4-5 years
29	Guyana	UMIC	AMR	0.5%	13,856	45 Months
30	Suriname	UMIC	AMR	4.6%	10,087	5-7 years, 4 years
31	Belize	UMIC	AMR	4.5%	7,770	4 years
32	Maldives	UMIC	SEAR	14.9%	7,488	4 years
33	Bahamas	HIC	AMR	19%	5,056	4-5 years
34	Samoa	UMIC	WPR	9.8%	4,962	5 years
35	Barbados	HIC	AMR	17%	3,117	4.5 years

36	Kiribati	LMIC	WPR	4.9%	3,030	6 years
37	Tonga	UMIC	WPR	9.8%	2,354	5 years
38	Saint Lucia	UMIC	AMR	5.0%	2,211	5 years
39	Tuvalu	UMIC	WPR	9.8%	1,000	5-6 years
40	Dominica	UMIC	AMR	5.0%	1,000	3 years
41	Monaco	HIC	EUR	1%	1,000	6 years

1. Income Status: Data for the type of country income classification, such as High Income (HI), Upper middle income (UMIC), Lower middle income (LMIC) countries were collected from World Bank (WHO follows World Bank classification).
2. School entry Booster (aP) Vaccine Private Market Share: The share of aP school entry booster vaccine in these countries of total DTP immunization rate. Data taken from UNICEF Immunization database, primary 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. School entry Booster Vaccination age is taken from WHO vaccine-preventable diseases: monitoring system. 2020 global summary

Table 14-aP Based School Entry Booster Vaccines Brand Consumption in Top 40 Countries

The table below shows the volumes of aP based school entry booster vaccines consumed in the top 35 countries by brand

S.No	Country Name	Country Code	Type of Market	Volumes (doses)	Tetrixim®	Infanrix IPV®/Kinrix®	Quadracel®	Boostrix®	Boostrix -IPV®	Adacel®	Repevax®
1	USA	US	Public	3,402,764	-	1,871,520	1,190,967	-	-	-	-
2	Turkey	TR	Public	1,404,000	1,404,000	-	-	-	-	-	-
3	United Kingdom	GB	Public	729,289	-	-	-	-	437,573	-	291,716
4	France	FR	Public	697,325	592,727	-	-	-	69,733	-	34,866
5	India	IN	Private	588,641	176,592	-	-	412,049	-	-	-
6	Germany	DE	Public	541,421	-	-	-	460,208	-	81,213	-
7	Saudi Arabia	SA	Public	454,160	-	-	-	454,160	-	-	-
8	Spain	ES	Public	412,892	-	-	-	247,735	-	165,157	-
9	South Korea	KR	Public	405,754	405,754	-	-	-	-	-	-
10	Italy	IT	Public	354,196	283,356	70,839	-	-	-	-	-
11	Poland	PL	Public	352,402	352,402	-	-	-	-	-	-
12	Kazakhstan	KZ	Public	334,515	-	-	-	334,515	-	-	-
13	Australia	AU	Public	320,662	-	160,331	160,331	-	-	-	-
14	Canada	CA	Public	316,106	-	-	-	-	94,832	-	221,274
15	Chile	CL	Public	210,958	-	-	-	210,958	-	-	-
16	Taiwan	TW	Public	204,469	204,469	-	-	-	-	-	-
17	Romania	RO	Public	159,588	159,588	-	-	-	-	-	-
18	Netherlands	NL	Public	151,327	-	-	-	-	151,327	-	-
19	Israel	IL	Public	148,310	-	118,648	-	-	14,831	14,831	-
20	Argentina	AR	Private	138,349	27,670	-	-	69,174	-	41,505	-
21	Libya	LY	Public	112,117	-	-	-	-	-	-	112,117
24	Belgium	BE	Public	111,391	111,391	-	-	-	-	-	-
22	Sweden	SE	Public	110,716	110,716	-	-	-	-	-	-
23	Thailand	TH	Private	107,907	53,954	32,372	-	-	21,581	-	-
25	Iraq	IQ	Private	98,617	78,894	-	-	19,723	-	-	-
26	Czech Republic	CZ	Public	94,153	-	-	-	-	-	94,153	-
27	Hungary	HU	Public	92,102	92,102	-	-	-	-	-	-
28	Greece	GR	Public	75,728	68,155	7,573	-	-	-	-	-
29	Portugal	PT	Public	75,059	75,059	-	-	-	-	-	-
30	Switzerland	CH	Public	73,047	43,828	29,219	-	-	-	-	-
31	United Arab Emirates	AE	Public	72,836	72,836	-	-	-	-	-	-
32	Austria	AT	Public	64,529	-	-	-	-	-	-	64,529
33	Costa Rica	CR	Public	62,241	62,241	-	-	-	-	-	-
34	Ireland	IE	Public	61,008	61,008	-	-	-	-	-	-
35	Hong Kong	HK	Public	55,807	55,807	-	-	-	-	-	-
36	Norway	NO	Public	55,716	55,716	-	-	-	-	-	-

37	Bulgaria	BG	Public	54,687	54,687	-	-	-	-	-	-
38	New Zealand	NZ	Public	52,760	-	52,760	-	-	-	-	-
39	Slovakia	SK	Private	50,501	5,050	45,451	-	-	-	-	-
40	Denmark	DK	Public	49,203	49,203	-	-	-	-	-	-

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 23. Pharmaceutical Management Agency (PHARMAC), Vaccine Funding (Infanrix-IPV® in Procured)
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- P. Primary Inputs

Table 15-Primary Inputs

The table below shows the primary respondents' information

S.No	Designation	University/Organization	Country
1	Chief of Pediatrics/ OIC of Immunization/ PD of PALS	Weed Army Community Hospital	USA
2	Pediatrician	Christ Muguerza Hospital and Health Care	Mexico
3	"Commercial Director (Current), International Business Development and Partnership Manager (Past)	Levicta Medical (Current) Instituto Butantan (Government Agency) (Past)	Brazil
4	Public policy Health care	ImpulsoGov	Brazil
5	Technical Director (Past- Pediatrician)	Salute Clinica Médica Ltd	Brazil
6	Data verification Clerk for vaccination clinic	City of Ottawa (Ottawa public health)	Canada
7	Doctor & Pediatrician -Vaccines Expert	Stamboulia Health Services	Argentina
8	Pediatrician, Director of the Department of Pediatrics	GMH	Greece
9	General Practitioner	Irish Prison Service	Ireland
10	Medical Doctor- Pediatrician & Consultant	Medicina/ Atheneum	Spain
11	Vaccination Nurse	Catalan Institute of Health	Spain
12	Pediatrician	Niño Jesus University Hospital	Spain
13	Senior Consultant - Vaccinology	Global Health Consulting	Spain
14	Pediatrician	Hospital Universitari General de Catalunya	Spain
15	Associate Physician in Pediatrics	Athena Clinic	Spain
16	Pediatrician and Endocrinologist	Fundacja Medcover	Poland
17	Pediatrician	VUL Santaros klinikos	Lithuania
18	Pediatrician (Past- Junior Resident of Pediatrics)	Klaipeda Children 's Hospital	Lithuania
19	Doctor for childhood and adolescent medicine	Independent pediatrician	Germany
20	Pediatrician, PhD (Past- District Doctor)	A. Getlik Clinic for Children and Adolescents	Slovakia
21	Epidemiologist Public health researcher	National Health Institute Doctor Ricardo Jorge, Ministry of Health, Lisbon, Portugal	Portugal
22	Project Manager for Health	Fundacao Calouste Gulbenkian	Portugal
23	Pediatrician, Medical Director Incharge of Pediatrics SSD	Azienda USL di Reggio Emilia, IRCCS	Italy
24	Emergency Physician	International Committee of the Red Cross - ICRC	Italy
25	Pediatrician	San Gerardo Hospital	Italy
26	Medical Doctor (SIEC Member)	Arma dei Carabinieri	Italy
27	Pediatrician, Registered Dietitian, Consultant	The National Children's Specialized Hospital	Ukraine
28	Pediatrician	Remiremont Hospital	France
29	Medical doctor General practitioner	Multidisciplinary Health Centre	France
30	Paediatric drug safety and pharmacovigilance physician	AP-HP	France
31	Medical Head	Medic Integral Pediatrics	Switzerland
32	Pediatric and Adolescent Medicine Specialist	Global Journal of Pediatrics	Switzerland
33	Nurse (Past: Critical Care Nurse)	Nottingham University Hospital	United Kingdom
34	Health Centre Nurse	Public Health Nurse, Iran	Iran

35	Associate Professor (Past: Head of Pediatric Department)	Golestan University of Medical Sciences (GOUMS)	Iran
36	Professional Nurse	Government Agencies	Iraq
37	Pediatrician	Ministry Of Health	Oman
38	Pediatrician	Saint Joseph Hospital	Lebanon
39	Assistant Professor	Ministry of Health Bangladesh	Bangladesh
40	Assistant CEO	Public Health Authority of Saudi Arabia	Saudi Arabia
41	Pediatric Emergency Consultant	Rambam Health Care Campus	Israel
42	Specialist Pediatrics	Prime Healthcare Group LLC	UAE
43	Family Medicine Specialist	Karama Medical Centre	UAE
44	Pediatrician (Past- Member of Programme Committee)	Pofeng Lee Clinic	Taiwan
45	Consultant Pediatrician, Head of Pediatric Ambulance Department	University Hospital, Tripoli	Libya
46	Consultant Specialist-pediatrics and pediatric cardiology	St. Peter Specialized Hospital	Ethiopia
47	National Monitoring and Evaluation Officer	Immunization Technical Support Unit (ITSU) - JSI	India
48	Pediatrician	Medical Center Manila	Philippines
49	Professor of Pediatrics at Faculty of Medicine	Chulalongkorn University, Bangkok	Thailand
50	Pharmaceutical Medicine, Vaccinologist, Pediatrician	Enzychem Lifesciences	South Korea
51	Research Scientist	Pharm CADD	South Korea
52	General Pediatrician	Sentra Medika Hospital Group	Indonesia
53	Public Health Specialist	Credos Institute	Indonesia
54	General Practitioner	Mayapada Hospital	Indonesia
55	Pediatrician	Children's Hospital No.2	Vietnam
56	General Practitioner	FV Clinic	Vietnam
57	Western medicine and Traditional Chinese Medicine Doctor	Can Tho University of Medicine and Pharmacy	Vietnam
58	Pharmacist	Hanoi University of Pharmacy	Vietnam
59	Pediatrician	International Medical Clinic	Singapore
60	Public Health Interventions Manager	UNFPA (United Nations Population Fund)	Nigeria
61	Neuropediatrician- Pediatric Neurology Expert	Cabinet casablanca de pediatrie	Morocco
62	Public Health Specialist, Orphans and Vulnerable Children Expert	CDC (Centers for Disease Control and Prevention)	Republic of Congo
63	Course Coordinator Immunization (Nurse Immunizer)	Melbourne Medical School	Australia
64	Director of the Department of Pediatrics		Greece

Table 16-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	-	PRN 3 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 17-Characteristics of Pentavalent Vaccine Brands

The table below shows the characteristics of different pentavalent brands

Vaccine Characteristics	Pentaxim®	Pentacel®	Pediacel®	Infanrix-IPV/Hib®	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 18-Characteristics of Tetravalent School Entry Booster Vaccine Brands

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

Vaccine Characteristics	Tetraxim®	Infanrix-IPV/Kinrix®	Qudaracel®
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 19-Acellular Pertussis (aP) Vaccine Brands For School Entry Booster Vaccines

The table below shows different brands of aP school entry booster vaccines used across countries

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

Table 20- Preterm Pentavalent Vaccine Volumes

The table below shows the estimated preterm Pentavalent vaccine volumes in the top 17 countries

S.No	Country Name	Country Code	Preterm Births, 2020	Preterm Pentavalent Vaccine Volumes
1	United States of America	US	379,142	1,137,427
2	Turkey	TR	154,263	617,052
3	Russia	RU	149,267	597,069
4	Malaysia	MY	55,069	220,274
5	Canada	CA	32,570	130,279
6	Poland	PL	28,262	84,787
7	Taiwan	TW	18,900	75,600
8	South Korea	KR	21,116	42,233
9	Serbia	RS	10,223	40,892
10	Kazakhstan	KZ	18,301	36,602
11	Hungary	HU	8,671	34,683
12	Israel	IL	7,614	30,457
13	Costa Rica	CR	6,584	26,337
14	Portugal	PT	6,028	12,057
15	Finland	FI	2,732	8,196
16	Singapore	SG	3,500	7,000
17	Lithuania	LT	1,256	5,023

*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.

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