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#### **KEY**

#### **HEXAVALENT VACCINE (Primary Course):**

**DTaP** Diphtheria, Tetanus and acellular Pertussis vaccine: paediatric formulation

IPV Inactivated Polio VaccineHBV Hepatitis B vaccine

Hib Haemophilus influenzae b vaccine
 PCV Pneumococcal conjugate vaccine
 4CMenB 4-component Meningococcal B vaccine

**RotaV** Rotavirus vaccine

MMRV Measles, Mumps, Rubella and Varicella [chickenpox] vaccine (for children

born 2016 or later)

MMRV 1: 1st dose - MMRV 2: 2nd dose

Tdap Tetanus, Diphtheria and acellular Pertussis [whooping cough] vaccine -

adult formulation

Men C Meningococcal C conjugate vaccine VAR Varicella [chickenpox] vaccine VAR 1: 1st dose - VAR 2: 2nd dose

**HPV** Human Papillomavirus vaccine

Men ACW<sub>135</sub>Y Meningococcal A, C, W<sub>135</sub> and Y conjugate vaccine

T<sub>0</sub> administration of 1<sup>st</sup> dose (Time 0)

**1 month** administration of 2<sup>nd</sup> dose 1 month after 1<sup>st</sup> dose

**6 months** administration of 3<sup>rd</sup> dose 6 months after the 1<sup>st</sup> dose

3<sup>rd</sup> month of life period between the 8<sup>th</sup> week of life and the 12<sup>th</sup> week of life.

**6<sup>th</sup> year** period between the child's 5<sup>th</sup> birthday and 6<sup>th</sup> birthday.

# CHILDREN'S VACCINATION SCHEDULE

## Vaccines offered actively and free of charge

., .	1 <sup>st</sup> Year			2 <sup>nd</sup> Year		6 <sup>th</sup> -7 <sup>th</sup> Year	After 10 <sup>th</sup> Birthday		
Vaccine	3 <sup>rd</sup> Month	5 <sup>th</sup> Month	7 <sup>th</sup> Month	11 <sup>th</sup> Month	13 <sup>th</sup> -15 <sup>th</sup> Month	15 <sup>th</sup> -18 <sup>th</sup> Month		12 <sup>th</sup> Year	12 <sup>th</sup> -17 <sup>th</sup> Year
Primary Course	Hexavalent	Hexavalent		Hexavalent			DTaP-IPV		Tdap-IPV
Pneumococcus	PCV	PCV		PCV					
Meningococcus	4CMenB	4CMenB	4CMenB		Men C	4CMenB			Men ACWY
Rotavirus	Rota	virus							
Measles Mumps Rubella Varicella					MMRV 1		MMRV 2		
Varicella [chickenpox]									VAR (2 does administered at least 4 weeks apart)
Human papillomavirus								HPV (2 doses administered at least 5/6 months apart depending on the product)	

**CHILDREN'S VACCINATIONS** 

## **CHILDREN'S VACCINATIONS**

	Vaccination is one of medicine's most important achievements. Vaccinations have made it possible to eradicate the serious disease
The Piemonte Region's Vaccination Promotion Plan	smallpox at global level and almost entirely eliminate polio.  The Piemonte Region has updated its Vaccination Promotion Plan ( <i>Piano di Promozione delle Vaccinazioni - PPPV</i> ) in accordance with the 2017-2019 National Vaccine Prevention Plan ( <i>Piano Nazionale Prevenzione vaccinale - PNPV</i> ).
What Vaccines Contain	Vaccines vary depending on the disease they are designed to combat. They may consist of killed or weakened (thus rendered innocuous) bacteria or viruses, or parts of these, or even substances produced by these rendered inactive.
How Vaccines Work	Vaccines work by stimulating a natural defence system: the immune system. This results in the production of antibodies and protective cells capable of preventing the disease from developing. During our life, we must defend ourselves against thousands of bacteria that we encounter since they are present everywhere in our surrounding environment.
Which Diseases they Combat	Vaccines combat dangerous infectious diseases for which no treatment exists (Polio and Tetanus) or whose treatment is not always effective (diphtheria, invasive diseases from Haemophilus, Meningococcus and Pneumococcus, Hepatitis B and Varicella [chickenpox], or diseases that can cause serious complications (Measles, Rubella, Mumps and Pertussis [whooping cough]). Furthermore, vaccines are now available to prevent infections caused by some viruses which can, at times, cause cancer.
Before Vaccination	For informed use of vaccinations, parents should always request information and clarification from the vaccination service and their child's GP/paediatrician. Before vaccination, the service personnel check that there are no contraindications and examine the child's healthcare documentation (e.g. "Agenda della salute" - personal health record). Parents are invited to contact the vaccination service and their child's GP/paediatrician with any queries or information they consider relevant.
False Contraindications	The following do not constitute contraindications to vaccination:  • fever <38°C or mild diarrhoea;  • current treatment with antibiotics;  • prematurity, including with low birth weight;  • crosta lactea (cradle cap);  • Down syndrome;  • HIV infection;  • recent exposure to contagion;  • pregnancy of the child's mother or another woman in the family;  • breastfeeding.
After Vaccination	In some cases, after vaccination, patients may have local reactions such as swelling, redness or soreness, which may be treated simply be applying cold packs. At times, there may be fever. If this exceeds 38°C, it must be treated by administering fever medicine. More rarely, other adverse events may occur after vaccination. In such cases, parents should promptly contact the child's GP/paediatrician and/or the vaccination service for assessment and establishment of the most appropriate treatment.
Important Information	Vaccination is a form of safe preventive healthcare practised all over the world.  It is used to control some diseases and eradicate others.  High vaccine coverage in the child population reduces the circulation of the infectious agent, thus also protecting those few subjects who, for various reasons, have not been vaccinated.

# A SINGLE VACCINE AGAINST SIX DISEASES, ONE AGAINST PNEUMOCOCCUS, ONE AGAINST MENINGOCOCCUS B and ONE AGAINST ROTAVIRUS

Four vaccines are offered in the first year of a child's life: a hexavalent vaccine and a vaccine against Pneumococcus (administered together during the same visit), a vaccine against type-B Meningococcus and one against Rotavirus infection.

#### Hexavalent Vaccine

The hexavalent vaccine, with six components, is against the following diseases:

- o diphtheria
- o tetanus
- pertussis [whooping cough]
- o polio
- o hepatitis B
- Haemophilus influenzae type b infections

#### Side Effects of the Hexavalent Vaccine

As could occur following any vaccination, local and general side effects may occur.

The following could develop at the injection site, within 24-48 hours: soreness, redness and swelling. These are generally mild reactions which last a short time only.

During the first few days after the injection, the child could also develop a fever (generally not exceeding 38°C), irritability or drowsiness. These reactions last one or two days.

On rare occasions (less than 1/10,000), the child could develop a fever exceeding 40.5°C, inconsolable crying lasting more than three hours, a "shock"-like state or convulsions, attributable to the Pertussis [whooping cough] vaccine. These reactions do not have lasting effects but it is necessary, in any case, to carefully assess the situation at the time of subsequent doses.

## Diphtheria

The disease	Diphtheria is a very severe contagious disease which is mainly transmitted via the respiratory route, is caused by a bacterium ( <i>Corynebacterium diphtheriae</i> ), and manifests itself in different ways depending on the site of the infection: pharyngitis, laryngitis, or pseudomembranes that block the airways. The most severe symptoms of diphtheria affect the heart and nervous system. Approximately 1 in 10 cases can be fatal, even if treated with antibiotics.  After the introduction of mandatory vaccination under Italian law in 1939, the last fatal childhood case was recorded in 1991 (the victim was a little girl who had not been vaccinated). In the 1990s, in Eastern European countries, due to failure to vaccinate, there was an alarming diphtheria epidemic, lasting for several years, which caused thousands of deaths. The germ is therefore still in circulation and capable of striking on a large scale among unprotected populations.  For these reasons, it is important to vaccinate children against diphtheria and continue with boosters, together with those against tetanus and pertussis, in children and adults (every 10 years).
The vaccination	The hexavalent vaccine is 95% effective against diphtheria. The recommended course is 3 doses ( $3^{rd}$ , $5^{th}$ and $11^{th}$ - $13^{th}$ months of life). Boosters are necessary in the $6^{th}$ - $7^{th}$ year and between the $12^{th}$ and $17^{th}$ year of life.
When it is necessary to postpone	Vaccination must be temporarily postponed if the child presents an acute illness with a fever or general disorders deemed clinically significant.
When vaccination should not be performed	There are no particular health conditions that prevent this vaccine from being administered, with the exception of previous severe allergic reactions to substances contained in the vaccine or to previous administrations of the same vaccine.
Side effects	See those of the hexavalent vaccine (page 7).

## **Tetanus**

The disease	Tetanus is a very serious disease caused by a bacillus ( <i>Clostridium tetani</i> ) capable of producing a substance that causes very powerful and painful spasms affecting all the muscles, starting with the face and progressing to the limbs. The germ can survive in any environment. It comes into contact with our organism through wounds which provide the right conditions for it to multiply and produce the toxin.  Tetanus is an infection that is not transmitted from person to person. Tetanus vaccination therefore serves to protect the individual, and is the only effective protection against this infection.
The vaccination	The hexavalent vaccine is 100% effective against tetanus. The recommended course is 3 doses (3 <sup>rd</sup> , 5 <sup>th</sup> and 11 <sup>th</sup> -13 <sup>th</sup> months of life). Boosters are necessary in the 6 <sup>th</sup> -7 <sup>th</sup> year and between the 12 <sup>th</sup> and 17 <sup>th</sup> years of life.
When it is necessary to postpone	Vaccination must be temporarily postponed if the child presents an acute illness with a fever or general disorders deemed clinically significant.
When vaccination should not be performed	There are no particular health conditions that prevent this vaccine from being administered, with the exception of previous severe allergic reactions to substances contained in the vaccine or to previous administrations of the same vaccine.
Side effects	See those of the hexavalent vaccine (page 7).

## Pertussis [whooping cough]

The disease	Pertussis [whooping cough] is an infectious and contagious disease caused by a bacterium ( <i>Bordetella pertussis</i> ) which is transmitted via the respiratory route. Pertussis lasts several weeks. Initially, it causes sneezing, a runny nose, mild fever and a phlegmy cough. This if followed by coughing fits (spasms), sometimes causing vomiting. Pertussis generally passes without lasting consequences. It is possible, however, in 5-6% of cases, for complications to occur such as laryngitis, pneumonia, convulsions and brain damage.  The disease is particularly serious in the first year of life: in newborns and nursing infants, it often manifests itself through genuine attacks of asphyxia, necessitating hospitalisation. Serious inflammation of the brain (encephalitis) is also common and can cause permanent damage and, in the most severe cases, even death (fatality rate in the first year of life: around 1%).  Even in the absence of complications, pertussis causes considerable disruption to the child as the coughing fits restrict them in their play and movement and disrupt their feeding and night-time rest.  In the past, pertussis epidemics occurred every 3-4 years in Italy, with thousands of cases. Currently, thanks to vaccination, the incidence is very low: 1-2 cases per 100,000 people each year.
The vaccination	The hexavalent vaccine is 85% effective against pertussis [whooping cough].  The recommended course is 3 doses (3 <sup>rd</sup> , 5 <sup>th</sup> and 11 <sup>th</sup> -13 <sup>th</sup> months of life).  Boosters are necessary in the 6 <sup>th</sup> -7 <sup>th</sup> year and between the 12 <sup>th</sup> and 17 <sup>th</sup> year of life, as immunity, both natural (from recovery from the disease) and acquired (through vaccination) has been proven to decrease over the years.
When it is necessary to postpone	Vaccination must be temporarily postponed if the child presents an acute illness with a fever or general disorders deemed clinically significant. The vaccinating doctor will also assess the advisability of postponing vaccination in cases of neurological disorders whose cause has not been sufficiently ascertained, until resolution or diagnosis of the problem.
When vaccination should not be performed	If the child has a serious neurological disease which may deteriorate over time, the vaccinating doctor will assess, on a case by case basis, whether it is advisable to proceed with vaccination. The vaccine may also be administered to children with a history of "febrile convulsions", advising the parents to monitor them in case a fever should develop. Subjects with a history of severe allergic reactions to substances contained in the vaccine or severe reactions to previous administrations of the same vaccine.
Side effects	See those of the hexavalent vaccine (page 7).

#### Polio

The disease	Polio is an infectious and contagious disease caused by 3 different types of virus which usually enter the organism via the digestive tract. It is an extremely dangerous disease which can, in the most severe cases, cause paralysis of the limbs and, at times, even death. There are no medicines capable of curing polio and the only concrete possibility lies in prevention through vaccination.  The last epidemic, before adoption of vaccination which was introduced starting in 1964 (law of 1966), was in 1958.  The last case of polio was recorded in Italy in 1983, in a non-vaccinated child.  The disease is still present in many countries of the world, and it is important to continue protecting children through vaccination, also due to the increasing frequency of international travel.
The vaccination	The polio component of the hexavalent vaccine, known as the Salk vaccine (IPV), contains killed viruses. The hexavalent vaccine is 90-100% effective against polio after the second dose. The recommended course is 3 doses (3 <sup>rd</sup> , 5 <sup>th</sup> and 11 <sup>th</sup> -13 <sup>th</sup> months of life). A booster is necessary in the 6 <sup>th</sup> -7 <sup>th</sup> year of life and, from 2018, a booster will also be offered to adolescents.
When it is necessary to postpone	Polio vaccination must be temporarily postponed if the child presents an acute illness with a fever or general disorders deemed clinically significant.
When vaccination should not be performed	The Salk vaccine must not be administered if the child has a history of severe allergic reactions to substances contained in the vaccine or after previous administrations of the same vaccine.
Side effects	See those of the hexavalent vaccine (page 7).

## Hepatitis B

The disease	Hepatitis B is an infectious and contagious disease caused by a virus which attacks the liver.  In the majority of cases, infection does not present clear or specific symptoms. Only a few people (5-6%) present weakness, joint pains, nausea, vomiting, fever and a yellowish colouring of the skin and eyes (jaundice). Most people (85-100%) make a full recovery. In rare cases, particularly in adults, the disease can be fatal. In 5-6% of cases, it is possible to continue to carry the virus, and approximately half of these encounter very serious liver diseases, such as cirrhosis or liver cancer. The hepatitis B virus is transmitted by patients or carriers via the blood, sexual intercourse or contact with domestic objects such as razors, toothbrushes and manicure articles.  It is estimated that, every year, approximately 1,000 people die from hepatitis B or chronic diseases caused by the virus.  Administration of this vaccine was initiated for all newborns in Italy in 1991.  Children born from a "chronic carrier" mother have a high probability of contracting it during labour and therefore of becoming infected unless vaccinated as soon as possible.  The vaccine is, indeed, offered free of charge to people particularly at risk of contracting this infection. Children of "chronic carrier" women receive the first dose of the vaccine the day they are born, together with immunoglobulins (antibodies), and this protects them from contagion.
The vaccination	The hepatitis B vaccine currently in use contains only part of the virus and is therefore certainly not capable of transmitting the disease but merely of stimulating the body's defence against infection. The hexavalent vaccine is 98% effective against Hepatitis B. The recommended course is 3 doses (3 <sup>rd</sup> , 5 <sup>th</sup> and 11 <sup>th</sup> -13 <sup>th</sup> months of life). No boosters are necessary.
When it is necessary to postpone	Vaccination must be temporarily postponed if the child presents an acute illness with a fever or general disorders deemed clinically significant.
When vaccination should not be performed	The vaccination must not be administered to subjects with a history of severe allergic reactions to substances contained in the vaccine (e.g. brewer's yeast) or to previous administrations of the same vaccine.
Side effects	See those of the hexavalent vaccine (page 7).

## Haemophilus influenzae type b INFECTIONS

The disease	Haemophilus influenzae type b is a bacterium normally found in the throat or nose and transmitted from one person to another via the respiratory route. This bacterium does not usually cause any harm. However, in some children, it not only infects the throat but also succeeds in reaching other organs via the blood, causing very serious diseases. The most common of these is meningitis, which can, to this day, be fatal at times (in 5% of cases) and therefore cause permanent severe damage such as deafness, blindness, paralysis and intellectual disability. At other times, the bacterium attacks the throat, on rare occasions causing an infection so severe (epiglottitis) as to cause death by asphyxiation. Alternatively, it can attack the lungs (bronchopneumonia) or infect the entire organism (sepsis).  Children between the ages of 3 months and 5 years are most at risk (particularly those under the age of 2).  Following introduction of vaccination, the disease has practically disappeared, with an incidence of 0.6/100,000 per year.
The vaccination	The vaccine is the only method of preventing the most severe <i>Haemophilus influenzae</i> type b infections in children up to the age of 5. The vaccine is highly effective both in preventing the disease and in eliminating carriers, i.e. healthy children who, once infected, allow the bacterium to circulate and cases of the disease to continue. Vaccination is a priority for all children from the 3 <sup>rd</sup> month of life and is particularly important if the child is at risk. The hexavalent vaccine is 90% effective against <i>Haemophilus influenzae</i> type b infections.  The recommended course is 3 doses (3 <sup>rd</sup> , 5 <sup>th</sup> and 11 <sup>th</sup> -13 <sup>th</sup> months of life). No boosters are necessary.
When it is	This vaccination, like the others, must be temporarily postponed if the
necessary to	child presents an acute illness with a fever or general disorders deemed
postpone	clinically significant.
When	There are no particular health conditions that prevent this vaccine from
vaccination	being administered with the exception of very severe allergic reactions to
should not be performed	substances contained in the vaccine or to previous administrations of the same vaccine.
Side effects	
Side effects	See those of the hexavalent vaccine (page 7).

## The pneumococcal vaccine Streptococcus pneumoniae (pneumococcal) infections

The disease	Streptococcus pneumoniae (pneumococcus) infection can cause severe diseases. It is one of the main causes of meningitis (infection of the membranes covering the central nervous system). It can also cause other diseases such as pneumonia, otitis (chronic ear infection) and septicaemia (infection of the blood). Possible permanent consequences include deafness (15-30%) and intellectual disability (5-20%). The pneumococcus is transmitted from person to person via the respiratory route. About 3 cases of meningitis or pneumococcal sepsis per 100,000 children under the age of 5 are reported in Italy each year.  The age groups most at risk of "invasive" disease are children aged 0 to 5 and adults over the age of 64.
The vaccination	The pneumococcal conjugate vaccine prevents over 80% of pneumococcal infections. It can also prevent some forms of otitis. However, the causes of ear infection are multiple and the vaccine is only effective against a small proportion of them. The vaccine's effectiveness is 80% against invasive disease, 30% against pneumonia and 6-10% against otitis media (middle ear infections). The recommended course for newborns involves 3 doses in the first year of life (3 <sup>rd</sup> , 5 <sup>th</sup> and 11 <sup>th</sup> month of life).
When it is necessary to postpone	This vaccination, like the others, must be temporarily postponed if the child presents an acute illness with a fever or general disorders deemed clinically significant.
When vaccination should not be performed	There are no particular clinical conditions that prevent this vaccine from being administered with the exception of subjects with a history of significant allergic reactions to substances contained in the vaccine or to previous doses of the same vaccine.
Side effects	Tolerance to the pneumococcal vaccine is good. The reactions caused by the vaccine are redness, soreness and swelling at the injection site. Irritability or drowsiness may also occur, and febrile reactions are common.

## The Meningococcal B vaccine Neisseria meningitidis B (meningococcal B) infections

The disease	Meningococcal B ( <i>Neisseria meningitidis B</i> ) infection can cause severe diseases. It can manifest itself as meningitis (infection of the membranes covering the central nervous system) or as septicaemia (infection of the blood). In 10% of cases, neurological consequences persist and, in 3-7% of cases, there are more serious consequences (cognitive or motor deficits, deafness, convulsions, visual impairments and hydrocephalus). On average, approximately 150 people contract meningococcal disease each year in Italy, most of whom are children. Between 2007 and 2009, serogroup B was most prevalent (59.6% of cases of meningococcal disease). The majority of the remaining cases were due to meningococcus C. The disease mainly affects children under the age of 5, particularly in the first 12 months of life. It can occur in subjects with other, predisposing diseases and in subjects living collectively (soldiers, students in halls, etc.). Another age group affected, although less commonly, is that of adolescents and young adults. Certain people, such as patients with asplenia or immunodeficiency, are at greater risk of the disease.
The vaccination	In the Piedmont Region, the meningococcal type B vaccine is offered actively and free of charge to those born after 01/01/2017 with a course of 4 doses (3 <sup>rd</sup> , 5 <sup>th</sup> , 7 <sup>th</sup> and 15 <sup>th</sup> -18 <sup>th</sup> month). In all other situations, it is offered at cost price. The vaccination is free of charge to at-risk subjects and to those travelling to at-risk areas if under the age of 18 or volunteering on cooperation or humanitarian projects.  Meningococcal vaccines are highly recommended for subjects at risk or affected by certain pathologies, or with particular conditions:  o anatomical or functional asplenia  congenital or acquired immunodeficiencies  haemoglobinopathies  loss of cerebrospinal fluid due to congenital or acquired causes.  Vaccination is the most effective way to reduce the risk of death or permanent damage from meningococcal infection.  The meningococcal B vaccine is offered free of charge to at-risk subjects.
When it is	This vaccination, like the others, must be temporarily postponed if the child
necessary to postpone	presents an acute illness with a fever or general disorders deemed clinically significant.
When	There are no particular clinical conditions that prevent this vaccine from
vaccination should not be	being administered with the exception of subjects with a history of significant allergic reactions to substances contained in the vaccine or to
performed	previous doses of the same vaccine.
Side effects	The meningococcal B vaccine usually causes febrile reactions and local reactions such as redness, soreness and swelling at the injection site. To reduce fever and alleviate soreness, paracetamol should be administered. At times, local reactions can be particularly intense and prolonged, with soreness and swelling lasting for several days. In small children, agitation and irritability are due to local soreness: in this case, it is advisable to administer paracetamol, even in the absence of fever. As with all vaccines, allergic reactions, including severe ones, may occur in rare cases.

# The rotavirus vaccine Rotavirus infections

Rotavirus infection	io
The disease	Rotavirus is the cause of 80% of cases of viral gastroenteritis in the first 5 years of life. Every year, it is responsible for approximately 10,000 hospitalisations in Italy. In the Piedmont Region, 2090 children affected by rotavirus were hospitalised between 2001 and 2005.  All these children come into contact with the virus in the first 5 years of life. It predominantly infects children for the first time between 6 and 24 months, causing acute gastroenteritis with diarrhoea, vomiting and fever and, in the most severe cases, dehydration. Episodes of diarrhoea may recur, due to the different types of rotavirus, but with less severity. Transmission mainly occurs in the childhood community. In industrialised countries, rotavirus is believed to be the cause of 40% of cases of diarrhoea in children. It can be transmitted both via objects contaminated with faeces and via the respiratory route.
The vaccination	The vaccines currently available consist of live viruses of the types most commonly circulating in the population. It is administered orally in two or three doses (depending on the product used) starting at 6-8 weeks of life and no later than 24-32 weeks of life (depending on the product used). No boosters are proposed; indeed, the disease does not constitute a problem after 5 years of age.  Vaccination is a priority for at-risk children, namely:  • children born prematurely or small for their gestational age;  • children affected by chronic pathologies of the circulatory, nephrourinary, central nervous, respiratory and metabolic systems with diagnosis by the 3 <sup>rd</sup> month of life resulting in frequent hospitalisations,  • children travelling to areas at risk due to inadequate healthcare.  The vaccine is at least 90% effective in preventing serious forms of diarrhoea and 74-85% against any form of rotaviral diarrhoea.
When it is necessary to postpone	This vaccination, like the others, must be temporarily postponed if the child presents an acute illness with a fever or general disorders deemed clinically significant.
When vaccination should not be performed	There are no particular clinical conditions that prevent this vaccine from being administered with the exception of subjects with a history of significant allergic reactions to substances contained in the vaccine or to previous doses of the same vaccine and children affected by severe combined immunodeficiency (SCID). Precautions must be taken with children with immunodeficiencies and moderate or severe illnesses, including gastroenteritis.
Side effects	Tolerance of the vaccine is good, as demonstrated by a very large preclinical trial which excluded severe adverse reactions. The most common side effects are diarrhoea and irritability. Very rarely (less than 1 child in 10,000), during the 30 days after vaccination (and particularly within 7 days of the first dose), cases of intussusception (a serious condition in which one section of intestine is folded into another, causing obstruction) have been observed. The child's GP/paediatrician must, therefore, be contacted immediately in the event of one of the following symptoms, causing suspicion of intestinal intussusception: severe stomach or abdominal pains, persistent vomiting, blood in the faeces, abdominal bloating and/or high fever.

# Some precautions to be taken after vaccination

The virus in the vaccine is eliminated with the faeces after vaccination, with a maximum peak around the seventh day. There is therefore a theoretical risk of the virus being transmitted to the people in closest contact with the child. For this reason, people in contact with a recently vaccinated child must take especial care with regard to their personal hygiene (e.g. washing their hands after changing the child's nappies). People with severe immunodeficiencies, i.e. people affected by malignant tumours and anyone who is, for any reason, immunocompromised or taking medication that weakens the immune system, must avoid contact with the child's faeces.

#### One vaccine against four diseases and one against meningococcus C

Two vaccines are offered in the second year of the child's life: the Measles, Mumps, Rubella and Varicella [chickenpox] (MMRV) vaccine and the Meningococcal C vaccine.

#### Tetravalent Vaccine

The 2017-2019 National Vaccine Prevention Plan (*Piano Nazionale Prevenzione vaccinale - PNPV*) introduced a vaccination against varicella, offered together with those for measles, mumps and rubella in a quadrivalent vaccine.

The four-component vaccine contains the 4 viruses responsible for the infections, live but weakened, in the same vial. The advantages of this preparation are that the child receives a single injection and that the collective is better protected since the circulation of all four viruses is reduced simultaneously.

The vaccine is administered by subcutaneous injection, usually in the upper arm, and has been proven to be effective and safe. After administration of a single dose of the vaccine, over 95% of subjects develop antibodies against measles and rubella and over 90% against mumps and varicella [chickenpox].

The recommended course is 1 dose between the 13<sup>th</sup> and 15<sup>th</sup> months of life.

It is necessary to administer a second dose in the 6<sup>th</sup>-7<sup>th</sup> year of life.

Vaccination of a subject who has naturally recovered from the diseases, even without symptoms, or who has already been vaccinated against one of the diseases, is extremely well tolerated and does not expose the subject to any additional side effect.

The vast majority of people vaccinated do not present any disorders after vaccination.

Any reactions usually occur between the 5<sup>th</sup> and 12<sup>th</sup> day after vaccination.

#### Common reactions

- swelling and redness at the injection site
- fever (at least 1 case in 10)
- a rash, similar to measles or varicella [chickenpox] (less than 1 case in 10)
- swelling of the parotid gland, i.e. the gland that normally increases in size in the event of mumps (less than 1 case in 100).

#### Rare reactions

- temporary reduction in the number of blood platelets (1 case in 40,000); the same disorder is much more commonly found in children who contract measles or rubella (1 in 3,000).
- febrile convulsions (up to 1 case every 1,000 doses);
- as with all biological products, there is a possibility of allergic reactions, including severe ones (extremely rare). For this reason, it is advisable to remain in the waiting room for at least 15 minutes after vaccination.

It had been hypothesised that vaccines containing measles could cause autism. However, scientific research conducted to investigate this hypothesis proved that the development of autism is in no way linked to use of the MMR vaccine or any other vaccine.

Circumstances making it is advisable to postpone this vaccination are:

- acute illness with a fever or general disorders deemed clinically significant;
- recent administration of immunoglobins, blood or plasma, or products that may impede a good immune response to the vaccine;
- recent administration of another live virus-based vaccine.

This vaccine must not be administered in the following cases:

• severe immune deficiency due to diseases or treatments;

• severe allergic reactions to constituents of the vaccine or to previous administrations of the same vaccine.

The main purpose of the vaccine is to prevent possible complications following these four diseases (described on the following pages).

#### Measles

#### Measles is an infectious and contagious disease caused by a virus transmitted via the respiratory route. Its symptoms are a high fever, persistent cough, runny nose, conjunctivitis and a rash (appearance of small red spots on the skin). It is contagious from the appearance of the first symptoms until 4 days after the appearance of the rash. Complications are more frequent and severe in small children and in adults. These mainly consist of otitis (chronic ear infection), laryngitis and bronchopneumonia (in 3-10% of cases), convulsions and encephalitis (1 The disease case in 1000), reduction in blood platelets, deafness, intellectual disability or epilepsy (in 40% of cases). A far more severe delayed complication (which can develop years later) is subacute sclerosing panencephalitis (4/11 in 100,000 cases). In developed countries, measles can lead to death in at least 1 case in 10,000. In Italy, during the epidemic years, there were thousands of cases of the disease, with significant variations between regions due to the vaccine coverage achieved. The disease can still kill, in approximately 1 case in 1000, as occurred during the epidemic of 2002 in Italy in which thousands of cases and 8 deaths were reported.

#### Mumps

The disease	Parotitis epidemica, commonly known as mumps, is an infectious disease caused by a virus transmitted via the respiratory route. Its symptoms are painful swelling of a salivary gland located in front of and beneath the ear (the parotid gland). One or both of the parotid glands may become enlarged, as can the other (sublingual and/or submandibular) salivary glands. This is often accompanied by headaches, abdominal pains and fever. The disease is contagious from 1-2 days before swelling of the glands until 6-8 days after. Possible complications are: meningitis (3 in 1000), encephalitis (1-2 in 100,000), hearing organ damage (5 in 100,000, with 1% permanent deafness) and inflammation of the pancreas (2-4%). Death occurs in 1 case in 10,000. If the disease attacks a male during puberty, complications can arise affecting one or both of the testicles (20-30% of cases). In Italy, the incidence of the disease has decreased in the last decade thanks to vaccination.

#### Rubella

**Rubella** is an infectious disease caused by a virus transmitted via the respiratory route. It is generally a benign disease which often passes unnoticed (in 25-50% of cases).

Its symptoms are a mild fever, generalised glandular swelling (the lymph nodes, particularly those in the neck and nape) and the brief appearance of small pink spots on the skin. It is contagious during the week before and the week after the skin symptoms appear. Certainty of having had rubella is only possible through a specific blood test (the "Rubeo" test), since the same symptoms may also be caused by other viruses. Temporary joint pains may also be observed occasionally in children, and more often in adolescent girls and women. Severe complications, such as encephalitis (1 in 6,000 cases) and a reduction in blood platelets (1 in 3,000 cases) are exceptional and benign and leave no permanent damage. Rubella is most dangerous if it is contracted during the first 5 months of pregnancy by a "unprotected" woman, i.e. one who has not been vaccinated or has not previously had the infection. In this case, the virus can reach the embryo (or foetus) via the placenta and cause severe damage, such as miscarriage or congenital rubella (malformations of the heart, eyes, hearing organs or brain). In Italy, epidemics occur every 3-4 years, with thousands of cases of the disease, and several tens of cases of congenital rubella are

#### The disease

#### Varicella [chickenpox]

estimated each year.

**Varicella** [chickenpox] is an infectious and highly contagious disease. It is transmitted through contact with the infected subject's lesions or via the respiratory route.

Its symptoms are moderate fever, headache and feeling unwell, followed by appearance of a rash (small, raised, red spots called papules) on the skin which turn into blisters and persist for 3-4 days. These then scab over.

The incubation period is 14-21 days. It is contagious from 5 days before the skin rash breaks out until 5 days after the blisters appear. Possible complications are: bacterial superinfection of the blisters, pneumonia (the most common complication in adults: in 20% of cases), a reduction in blood platelets, meningoencephalitis (1.7 in 100,000 cases in children and 15 in 100,000 in adults) and ataxia, a severe movement disorder (1 case in 4,000 in children under the age of 15). If contracted by a pregnant woman, the infection can harm the foetus or give varicella [chickenpox] to the newborn infant.

#### The disease

The disease is fatal in 2 in 100,000 cases (30 in 100,000 in adults), and approximately 2000 people are hospitalised each year due to its complications. Once infection has occurred, the virus persists in latent form. In some cases (10-20%), particularly in elderly and immunocompromised subjects, the virus can reactivate, causing herpes zoster, also known as shingles, characterised by "bunches" of blisters in localised areas of the body's surface, often accompanied by severe pain. Varicella [chickenpox] is currently the most widespread rash disease in Italy, with thousands of cases reported each year.

## The Meningococcal vaccine Neisseria meningitidis C (meningococcal C) infections

The disease	Meningococcal ( <i>Neisseria meningitidis</i> ) infection can cause severe diseases. It may manifest itself as meningitis (infection of the membranes covering the central nervous system), with possible permanent consequences (blindness 15-30%, hydrocephalus 2-3% and intellectual disability 5-20%), or as septicaemia (infection of the blood). On average, approximately 150 people contract meningococcal disease each year in Italy. The disease is most common in children under the age of 1 year, in subjects with other, predisposing diseases, and in subjects who living collectively (soldiers, students in halls, etc.). Another age group affected, although less commonly, is that of adolescents and young adults.
The vaccination	The meningococcal vaccine recommended for vaccination of children is the type C conjugate vaccine.  Vaccination is the most effective way to reduce the risk of death or permanent damage from meningococcal infection.  The vaccines available today do not protect against all forms of the disease.  Vaccination with the type C conjugate vaccine is offered actively and free of charge to newborns in their second year of life (specifically from the 13 <sup>th</sup> to 15 <sup>th</sup> month) and to subjects in their 16 <sup>th</sup> -17 <sup>th</sup> year of life.  The vaccine is offered free of charge to at-risk subjects, to under-18s travelling abroad and to all those working on cooperation or humanitarian projects.  The conjugate vaccine is approximately 85-90% effective.
When it is	This vaccination, like the others, must be temporarily postponed if the child
necessary to postpone	presents an acute illness with a fever or general disorders deemed clinically significant.
When vaccination should not be performed	There are no particular clinical conditions that prevent this vaccine from being administered with the exception of subjects with a history of significant allergic reactions to substances contained in the vaccine or to previous doses of the same vaccine.
Side effects	The meningococcal vaccine usually causes mild reactions such as redness, soreness and swelling at the injection site, while febrile reactions are rare.

## IN THE SIXTH-SEVENTH YEAR OF LIFE

#### **Vaccine Boosters**

At this age, a four-component formulation (tetravalent DTaP-IPV) is offered as a priority vaccine, in response to the need for boosters against the following diseases:

- o diphtheria
- o tetanus
- pertussis [whooping cough]
- o polio

This fourth dose completes the primary course begun in the first year of life, ensuring long-term protection.

The second dose of the tetravalent MMRV vaccine against the following diseases is always offered as a priority:

- o measles
- o mumps
- o rubella
- varicella [chickenpox]

#### AFTER TEN YEARS OF LIFE

The varicella [chickenpox] vaccine is offered to children who were not vaccinated in their 13<sup>th</sup>-15<sup>th</sup> month of life (the 2017-2019 PNPV introduced this vaccination from 2017), or who have not had the disease. The vaccination is recommended for children and adults who are at risk, i.e. those who, due to individual, working or environmental conditions, are most exposed to the complications of the disease.

Between the 12<sup>th</sup> and 17<sup>th</sup> year of life, the Diphtheria, Tetanus, acellular Pertussis [whooping cough] and polio booster - adult formulation (Tdap-IPV) is offered **to those who have received the primary course or had pertussis**.

Further boosters are recommended every ten years.

The meningococcal A, C,  $W_{135}$  and Y conjugate vaccine is also offered at the same time.

## AFTER TEN YEARS OF LIFE

## Varicella [chickenpox]

The disease	Varicella [chickenpox] is an infectious and highly contagious disease. It is transmitted through contact with the infected subject's lesions or via the respiratory route.  Its symptoms are moderate fever, headache and feeling unwell, followed by appearance of a rash (small, raised, red spots called papules) on the skin which turn into blisters and persist for 3-4 days. These then scab over.  The incubation period is 14-21 days. It is contagious from 5 days before the skin rash breaks out until 5 days after the blisters appear. Possible complications are: bacterial superinfection of the blisters, pneumonia (the most common complication in adults: in 20% of cases), a reduction in blood platelets, and meningoencephalitis (1.7 in 100,000 cases in children and 15 in 100,000 in adults). If contracted by a pregnant woman, the infection can harm the foetus or give varicella [chickenpox] to the newborn infant.  Varicella [chickenpox] is fatal in 2 in 100,000 cases (30 in 100,000 in adults).  Once infection has occurred, the virus persists in latent form. In some cases (10-20%), particularly in elderly and immunocompromised subjects, the virus can reactivate, causing herpes zoster, also known as shingles, characterised by "bunches" of blisters in localised areas of the body's surface, often accompanied by severe pain. Varicella [chickenpox] is currently the most widespread rash disease in Italy, with thousands of cases reported each year.
The vaccination	The varicella [chickenpox] vaccine consists of the live, weakened virus. Vaccination against varicella [chickenpox] is offered at 11 years to children who have not had the disease or who were not vaccinated in their 13 <sup>th</sup> -15 <sup>th</sup> month of life (susceptible subjects). 2 doses are necessary, administered at least 4 weeks apart.  Vaccination is a priority for children belonging to categories at risk of contracting varicella [chickenpox] and of encountering complications. These are children who are affected by leukaemia, immunocompromised or transplant candidates or have undergone transplant, for whom the clinical course of varicella [chickenpox] would be particularly severe or fatal.  The effectiveness of the vaccine is 70-85% in preventing the mild forms and 95% in preventing the more severe forms.  Vaccination of children living with a pregnant mother is also recommended, since the (weakened) vaccine virus does cause the disease in cohabitants.
When it is necessary to postpone	Circumstances making it is advisable to postpone vaccination are:  • acute illness with a fever or general disorders deemed clinically significant;  • recent administration of immunoglobins, blood or plasma, or products that may impede a good immune response to the vaccine;  • recent administration of another live, attenuated virus-based vaccine.
When vaccination should not be performed	The varicella [chickenpox] vaccine must not be administered under the following circumstances:  • severe immune deficiency due to diseases or treatments;  • severe allergic reactions to constituents of the vaccine or to previous administrations of the same vaccine.
Side effects	Tolerance of the varicella [chickenpox] vaccine is good. In approximately 20% of cases, redness and swelling may occur at the site where the injection is performed. These very quickly disappear. From 5 to 26 days after vaccination, the child may develop a fever, which is generally mild and lasts a short time (1-2 days). In approximately 6% of cases, attenuated varicella [chickenpox] symptoms may occur.

## Human papillomavirus (HPV) infections

The disease	Human papillomavirus (HPV) is a virus that infects the cells of the reproductive organs. There are 100 known types, 16 of which are considered at high risk of causing cancer; some of these, in particular, can cause cervical cancer. HPV types 16 and 18 are present in 70% of cases of cancer of the genital area. Types 6 and 11 and others are at low risk of cancer and can give rise to benign lesions such as condylomas. The vaccine has proven to offer protection against other types of cancer (vulvar, vaginal and anal). 75% of the sexually active population come into contact with HPV during the course of their lives, and approximately half of these become infected with a type of HPV that can cause cancer. HPV infection, which is most common sexually transmitted infection and can cause cancer, may also be contracted through incomplete sexual intercourse.  In the majority of cases (80-90%), HPV is eliminated spontaneously. In a small percentage of cases, the virus remains in the cells of the reproductive organs, transforming them into abnormal cells which can evolve into cancer. This evolution is very slow, and manifestation of cancer is predominantly observed after the age of 35.  Since the 1990s, screening to identify early lesions, at a stage when they may be successfully treated, has been offered free of charge in the Piedmont Region to women from the age of 25.  Unfortunately, approximately 3,500 cases of cervical cancer and 1,000 deaths from it occur every year in Italy. These must be added to other cases of cancer (vulvar, vaginal and anal) caused by HPV.
The vaccination	Three vaccines are available in Italy (a bivalent one, a quadrivalent one and a 9-valent one), consisting of virus surface proteins which immunise against the two HPV types 16 and 18. The quadrivalent one is also capable of immunising against HPV types 6 and 11, responsible for condylomas. The 9-valent one protects against HPV types 16, 18, 6, 11, 31, 33, 45, 52 and 58. Vaccination is more effective if administered before sexual activity begins. It is less effective in women who have already had sexual intercourse as they could already be infected. Vaccination serves to prevent infections but does not cure already existing ones.  The vaccine is administered through two intramuscular injections in the upper arm. The duration of its protection is not yet known, but no boosters are currently proposed.  The vaccine is offered actively and free of charge to adolescent boys and girls from the 11 <sup>th</sup> year of life while, for all those not eligible for the active and free offering, it is available at cost price at Local Health Authority (ASL) vaccination clinics.  Women over the age of 25, both vaccinated and non-vaccinated, must, in any case, continue to go for screening tests for diagnosis of precancerous lesions, not all of which can be prevented by the vaccine.
When it is necessary to postpone	This vaccination, like the others, must be temporarily postponed in the event of acute illness with a fever or general disorders deemed clinically significant.
When vaccination should not be performed	There are no particular clinical conditions that prevent this vaccine from being administered with the exception of subjects with a history of very severe allergic reactions to substances contained in the vaccine or to previous doses of the same vaccine.
Side effects	The human papillomavirus vaccine is safe and effective. The most common side effects experienced after this vaccination are: soreness, swelling and redness at the injection site, headaches, fever, nausea and other gastrointestinal disorders, hives, and joint and muscle pain.

# Neisseria meningitidis A, C, $W_{135}$ and Y (meningococcal ACWY) infections

The disease	Meningococcus is a bacterium that can cause two types of disease: septicaemia (infection of the blood) and meningitis (inflammation of the membranes covering the brain and spinal cord).  Meningococcal diseases are relatively rare in Italy. Human beings are infected by five types of meningococcus, called serogroups, which are identified using letters of the alphabet: A, B, C, Y and W <sub>135</sub> .  Serogroups C and B are the most common in Italy, while the remaining serogroups (A, Y and W) are currently more widespread in other nations, both in Europe and elsewhere.  Children, adolescents and young adults are most affected by the disease. The disease becomes increasingly rare as people get older.  Anyone can contract a meningococcal infection, although those most at risk are people with:  • Severely decreased immune defences caused by a disease (e.g. HIV infection) or a treatment (chemotherapy for cancer, radiotherapy, prolonged use of high-dosage cortisone),  • reduced function or surgical removal of the spleen.  Meningococcus, similarly to many other germs, is transmitted through coughing, sneezing or, in any case, close contact between people. It establishes itself on the internal surface of the nose and throat, where it can live for as long as months without causing any harm. Sometimes, for reasons not yet entirely known, it can pass into the blood. Through the blood, it can reach the meninges (membranes covering the brain and spinal cord).
The vaccination	Two meningococcal ACWY vaccines are available in Italy. One is recommended for active immunisation of subjects from the age of 6 weeks and the other from 24 months.  The vaccines are inactive (i.e. made from fragments of the bacterium) and conjugate (i.e. attached to a particular protein to render them more effective). As with any other vaccine, their effectiveness is high but not absolute. The vaccine is administered through an intramuscular injection in the upper arm. Only one dose is necessary. The vaccine is offered actively and free of charge to adolescents between the 12 <sup>th</sup> and 17 <sup>th</sup> years of life.
When it is necessary to postpone	This vaccination, like the others, must be temporarily postponed in the event of acute illness with a fever or general disorders deemed clinically significant.
When vaccination should not be performed	There are no particular clinical conditions that prevent this vaccine from being administered with the exception of subjects with a history of very severe allergic reactions to substances contained in the vaccine or to previous doses of the same vaccine.
Side effects	The level of safety of this vaccine is comparable to that of other routine vaccines.  The following side effects may occur:  local reaction with swelling, redness and soreness  fever  irritability and prolonged crying (in very small children)  headache (less common in small children)  tiredness and drowsiness

Vaccines Offered to At-Risk Children

#### Influenza

The disease	Influenza ("the flu") is an infectious and contagious disease caused by an influenza virus. It is transmitted by an infected person via the respiratory route.  The main symptoms are: fever, cough, sore throat, headache, muscle pains and shivering.  The disease affects all age groups, all over the world, every year. Many people contract it for a few days only while, in others, the disease can have a much more severe course resulting in hospitalisation. Influenza causes thousands of deaths each year, mainly in elderly people.  The viruses that cause influenza often change, and it is necessary to prepare a new influenza vaccine each year to ensure its effectiveness.
The vaccination	The protection provided by the vaccine develops two weeks after vaccination. Some vaccinated people may contract influenza, usually in milder form.  The vaccine does not protect against respiratory viruses other than those contained in the vaccine.  Vaccination is a priority for children (from 6 months of life) who are affected by:  • chronic diseases of the respiratory, circulatory or urinary system;  • diseases of the blood;  • diabetes or other metabolic diseases;  • intestinal malabsorption syndromes;  • cystic fibrosis;  • congenital or acquired diseases resulting in insufficient antibody production; pathologies for which major surgical procedures are planned;  • rheumatic diseases under chronic treatment with acetylsalicylic acid;  • neurological diseases.  The vaccine is 59% effective in healthy children over 2 years of age.  Vaccination involves two doses administered at least 4 weeks apart up to 9 years of age, if it is the first vaccination, or a single dose after the age of 9.
When it is necessary to postpone	People currently presenting a severe or moderate acute illness must wait for clinical improvement or recovery before receiving the vaccine.
When vaccination should not be performed	Vaccination is not recommended for anyone who is allergic to one of the components of the vaccine.
Side effects	The most common side effects are: soreness, redness and swelling at the injection site, feeling unwell and fever beginning 6-12 hours after vaccination and lasting 1-2 days.  Neurological disorders are rare (1-2 cases per million people vaccinated), and this risk is, in fact, far lower than that associated with severe influenza [flu].

## Hepatitis A

The disease	Hepatitis A is an acute febrile disease that affects the liver and resolves spontaneously with fever, anorexia (loss of appetite), nausea, feeling unwell and abdominal pains, followed, a few days later, by jaundice (a yellowish colouring of the skin). Asymptomatic forms also exist, particularly during epidemics and in children.  It is caused by a virus transmitted from person to person through consumption of water or certain raw (not sufficiently cooked) foods, particularly shellfish farmed in water contaminated by sewerage containing the virus. Infection is also common among subjects who travel to countries where the disease is endemic, among homosexuals and among intravenous drug users. Mother-child transmission is rare, as is transmission through transfusion.  Hepatitis A is widespread all over the world, both in sporadic and endemic form. In developing countries with poor health and hygiene conditions, infection is quickly transmitted between children, in whom the disease is often asymptomatic, so that many adults are already immune to the disease.
The vaccination	The vaccine is 94-100% effective after two doses. The hepatitis A vaccine must be administered through intramuscular injection. Two different vaccines are available in Italy, providing protection from infection after just 14-21 days. The vaccination is offered free of charge to subjects of all ages working on cooperation/humanitarian projects and to all subjects under the age of 18, with particular focus on children travelling to countries where the disease is endemic or belonging to certain at-risk groups. General hygiene standards (personal hygiene, washing and cooking of vegetables, shellfish, etc.) are also very important in preventing faecal-oral infection, as is monitoring of the farming and marketing of seafood. There are no contraindications to use in immunocompromised subjects.
When it is necessary to postpone	As with any other vaccine, vaccination must be postponed in subjects with acute and severe infections. However, the presence of mild infections does not constitute a contraindication to vaccination.
When vaccination should not be performed	The vaccine must not be administered to people with hypersensitivity to any component of the vaccine. No data is available on safety during pregnancy, but the risk is considered low or inexistent.
Side effects	Adverse effects are moderate and include local soreness and, less commonly, hardening at the vaccination site.

## **Rotavirus infections**

Please see the table on page 15.

Neisseria meningitidis (meningococcal) infections

Please see the relevant tables.

Vaccines Offered at Cost Price

For birth cohorts not included in the free, active offer, the Piemonte Region makes all vaccines available at cost price.

The term "cost price" refers to the purchase price of the product (including VAT) plus the cost of administering the product (16 euros). The 16-euro payment applies to the first vaccination visit, regardless of the number of vaccines administered, and is not payable for subsequent visits necessary to complete the vaccination course initiated or for vaccination postponed for any reason until a later vaccination visit.

## Other Useful Information

The doctors, healthcare assistants and professional nurses of the Vaccination Service of your Local Health Authority (ASL) and your child's GP/paediatrician will assist you with any queries and updates you may require.

#### For further information:

- Regional Epidemiological Services for the Monitoring, Prevention and Control of Infectious Diseases (SeREMI) - Alessandria Local Health Authority (ASL AL): <a href="http://www.seremi.it/">http://www.seremi.it/</a>
- GenitoriPiù informative website for parents: <u>www.genitoripiu.it</u>
- The epidemiology public health portal: www.epicentro.iss.it
- The Italian Society of Hygiene (SITI) medical and scientific portal on vaccinations: <u>www.vaccinarsi.org</u>
- "Vaccinazioni pediatriche: le domande difficili" (Children's Vaccinations: The Difficult Questions)
   <a href="http://www.seremi.it/content/vaccinazioni-pediatriche-le-domande-difficili">http://www.seremi.it/content/vaccinazioni-pediatriche-le-domande-difficili</a>