Vaccines included in Law no. 119/2017 and meningococcal A, C, W, Y vaccines: checks on the immediate packaging and absence of latex

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AIFA has published information on the absence of latex/natural rubber from the different components of the immediate packaging (pre-filled syringes: e.g. cylinder, piston and seal, tip cover, protective needle cover cap, etc.; glass vials: e.g. stopper, cap; oral tubes and applicators) of mandatory and free vaccines as well as of non-mandatory, free and actively offered vaccines provided for in Law no. 119/2017 and authorised in Italy. This follows the necessary checks with marketing authorisation holders (MAHs).
This information is extremely important for those people who are allergic to natural rubber latex and need to receive a vaccine. In fact, the presence of latex, even in traces, in the vaccine would expose such people to the risk of allergic reactions.
The European Commission guideline on excipients in the labelling and package leaflet of medicinal products for human use provides for the inclusion of a warning ('The container of this medicinal product contains latex rubber. May cause severe allergic reactions') in the package leaflet (PL), should latex/natural rubber be present in any quantity, regardless of the route of administration of the medicinal product.
If latex/natural rubber is not present, the inclusion of a specific warning in the PL is not required.
In addition to these provisions, AIFA has considered it appropriate to contact the MAHs of the above-mentioned vaccines, asking to confirm the absence of latex/natural rubber from the different components of the immediate packaging, in case no specific warning is included in the Summary of Product Characteristics (SmPC) and Patient Leaflet.
Based on the statements made by the MAHs and on the information included in the SmPC/PL of these vaccines, AIFA provides the following summary information.
Please note that not all vaccines (and/or their packs and formulations) may be currently marketed in Italy.

The asterisk (*****) indicates those vaccines for which the presence of latex/natural rubber cannot be excluded.

Marketing Authorisation Holder	Vaccine trade name Disease / pathogen	Latex/natural rubber
Free and mandatory vaccines (Law no. 119 of 31 July 2017)		
Monovalent vaccines		
Sanofi Pasteur Europe	IMOVAX POLIO Poliomyelitis	Declaration by the MAH: Latex is not used in the manufacturing process and therefore it is not present in the composition of the vaccine or in the secondary and in the immediate packaging (pre-filled glass syringe).
GSK Vaccines S.r.l.	ANATETALL***** Tetanus	Warning included in the package leaflet (paragraph 2): Individuals with hypersensitivity to latex. The needle cover [*of the pre-filled glass syringe*] contains latex which may cause severe allergic reactions. Talk to your doctor before you are given ANATETALL if you are allergic to latex.
Sanofi Pasteur Europe	IMOVAX TETANO Tetanus	Declaration by the MAH: Latex is not used in the manufacturing process and therefore it is not present in the composition of the vaccine or in the immediate packaging (pre-filled glass syringe).
GLAXOSMITHKLINE BIOLOGICALS S.A.	ENGERIX B Hepatitis B	Declaration by the MAH: Pre-filled glass syringe piston seal and glass vial stopper: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process.

		Syringe tip cover: the material used in the manufacturing is chemically distinct from and does not contain dried natural rubber.
MSD VACCINS	HBVAXPRO ***** Hepatitis B	Warning included in the package leaflet (paragraph 2): The container of this vaccine *[vial stopper, pre-filled glass syringe piston seal and needle cover]* contains latex rubber. Latex rubber may cause severe allergic reactions.
Sanofi Pasteur Europe	ACTHIB Haemophilus type b conjugate vaccine	Declaration by the MAH: Latex is not used in the manufacturing process and therefore it is not present in the composition of the vaccine or in the secondary and in the immediate packaging (glass vial and pre-filled glass syringe).
GLAXOSMITHKLINE BIOLOGICALS S.A.	HIBERIX Haemophilus type b conjugate vaccine	Declaration by the MAH: Glass vial stopper (powder) and pre-filled glass syringe piston seal (solvent): neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process. Syringe tip cover: the material used in the manufacturing is chemically distinct from and does not contain dried natural rubber.
GLAXOSMITHKLINE BIOLOGICALS S.A.	VARILRIX Varicella	Declaration by the MAH: Pre-filled glass syringe piston seal and glass vial stopper: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process. Syringe tip cover: the material used in the manufacturing is chemically distinct from and does not contain dried natural rubber.
MSD Italia S.r.l.	VARIVAX Varicella	Declaration by the MAH: No raw materials containing latex are used during the whole manufacturing process. Additionally, materials of the immediate packaging of powder (glass vial) and solvent (pre-filled glass syringe) do not contain latex.

Polyvalent vaccines		
ASTRO-PHARMA VERTRIEB UND HANDEL VON PHARMAZEUTISCHEN PRODUKTEN GMBH	DIFTETALL ***** Diphtheria/Tetanus	Warning included in the package leaflet (paragraph 2): Latex-sensitive individuals: the needle cap *[of the pre-filled glass syringe]* contains latex. This can cause severe allergic reactions. If you are allergic to latex, talk to your doctor before you are given DIFTETALL.
GLAXOSMITHKLINE S.P.A.	BOOSTRIX Diphtheria/Tetanus/Pertussis	Declaration by the MAH: Pre-filled glass syringe piston seal: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process. Syringe tip cover: the material used in the manufacturing is chemically distinct from and does not contain dried natural rubber.
GLAXOSMITHKLINE S.P.A.	INFANRIX Diphtheria/Tetanus/Pertussis	Declaration by the MAH: Pre-filled glass syringe piston seal: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process. Syringe tip cover: the material used in the manufacturing is chemically distinct from and does not contain dried natural rubber.
AJ VACCINES A/S	TRIBACCINE Diphtheria/Tetanus/Pertussis	Declaration by the MAH: The vaccine and all elements of the pre-filled glass syringe, including the tip cover, are latex-free.
Sanofi Pasteur Europe	TRIAXIS ***** Diphtheria/Tetanus/Pertussis	Warning included in the package leaflet (paragraph 2): Tell your doctor, pharmacist or nurse before you are given Triaxis if you or your child: have ever had allergic reactions to latex. Pre-filled syringe caps contain a derivative of natural rubber latex that can cause an allergic reaction.
Sanofi Pasteur Europe	REVAXIS	Declaration by the MAH:

	Diphtheria/Tetanus/ Poliomyelitis	Latex is not used in the manufacturing process of the vaccine and therefore it is not present in the composition of the vaccine or in the immediate packaging (pre-filled glass syringe).
GLAXOSMITHKLINE S.P.A.	POLIOBOOSTRIX Diphtheria/Tetanus/Pertussis/ Poliomyelitis	Declaration by the MAH: Pre-filled glass syringe piston seal: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process. Syringe tip cover: the material used in the manufacturing is chemically distinct from and does not contain dried natural rubber.
GLAXOSMITHKLINE S.P.A.	POLIOINFANRIX Diphtheria/Tetanus/Pertussis/ Poliomyelitis	Declaration by the MAH: Pre-filled glass syringe piston seal: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process. Syringe tip cover: the material used in the manufacturing is chemically distinct from and does not contain dried natural rubber.
Sanofi Pasteur Europe	TETRAVAC Diphtheria/Tetanus/Pertussis/ Poliomyelitis	Declaration by the MAH: Latex is not used in the manufacturing process of the vaccine and therefore it is not present in the composition of the vaccine or in the immediate packaging (pre-filled glass syringe).
Sanofi Pasteur Europe	TRIAXIS POLIO Diphtheria/Tetanus/Pertussis/ Poliomyelitis	Declaration by the MAH: All elements of the pre-filled glass syringe, including the tip cover and the piston seal, are free from natural rubber latex.
GLAXOSMITHKLINE BIOLOGICALS S.A.	INFANRIX HEXA Diphtheria/Tetanus/Pertussis (DTPa)/Hepatitis B (HBV)/Poliomyelitis (IPV)/ Haemophilus type b (HiB)	Declaration by the MAH: Pre-filled glass syringe piston seal (DTPa/HBV/IPV) and glass vial stopper (HiB): neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process of the packaging. Syringe tip cover: the material used in the manufacturing is chemically distinct from and does not contain dried natural rubber.

Sanofi Pasteur Europe	HEXYON Diphtheria/Tetanus/Pertussis/Hepatitis B/Poliomyelitis/Haemophilus type b	Declaration by the MAH: Latex is not used in the manufacturing process of the vaccine and therefore it is not present in the composition of the vaccine or in the immediate packaging (pre-filled glass syringe and vial).
MCM VACCINE B.V.	VAXELIS Diphtheria/Tetanus/Pertussis/Hepatitis B/Poliomyelitis/Haemophilus type b	Declaration by the MAH: No materials containing latex are used during the whole manufacturing process of the vaccine. There is no latex in the vaccine (suspension) and in the materials of the immediate packaging (pre-filled glass syringe and vial).
MSD VACCINS	MMRVAXPRO Measles, parotitis, rubella	Declaration by the MAH: No raw materials containing latex are used during the whole manufacturing process. Additionally, materials of the immediate packaging of powder (glass vial) and solvent (glass vial or pre-filled glass syringe without needle) do not contain latex.
GLAXOSMITHKLINE BIOLOGICALS S.A.	PRIORIX Measles, parotitis, rubella	Declaration by the MAH: Pre-filled glass syringe piston seal and glass vial stopper: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process. Syringe tip cover: the material used in the manufacturing is chemically distinct from and does not contain dried natural rubber.
MSD VACCINS	PROQUAD Measles, parotitis, rubella, varicella	Declaration by the MAH: No raw materials containing latex are used during the whole manufacturing process. Additionally, materials of the immediate packaging of powder (glass vial) and solvent (glass vial or pre-filled glass syringe without needle) do not contain latex.
GLAXOSMITHKLINE BIOLOGICALS S.A.	PRIORIX TETRA Measles, parotitis, rubella, varicella	Declaration by the MAH:

		Pre-filled glass syringe piston seal and glass vial stopper: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process. Syringe tip cover: the material used in the manufacturing is chemically distinct from and does not contain dried natural rubber.
Recommended and free vaccines (Law no. 119 of 31 July 2017)		
GSK Vaccines S.r.l.	BEXSERO ***** Meningococcal group B	Warning included in the package leaflet (paragraph 2): Tell your doctor or nurse if you know that you or your child is allergic to latex. The tip cap of the *[pre-filled glass]* syringe may contain natural rubber latex. The risk for developing an allergic reaction is very small, but your doctor or nurse needs to be aware of your allergy when deciding if you or your child should receive Bexsero.
Pfizer Europe MA EEIG	TRUMENBA Meningococcal group B	Declaration by the MAH: All elements of the pre-filled glass syringe are free from natural rubber latex.
GSK Vaccines S.r.l.	MENJUGATE ***** Meningococcal group C	Warning included in the package leaflet (paragraph 2): Latex-sensitive individuals for the *[pre-filled glass]* syringe formulation: Although no natural rubber latex is detected in the syringe tip cap, the safe use of Menjugate in latex-sensitive individuals has not been established.
Pfizer S.r.l.	NEISVAC C Meningococcal group C	Declaration by the MAH: All elements of the pre-filled glass syringe are free from natural rubber latex. Information included in the package leaflet (paragraph 6): The pack of 1 may include up to two needles of different sizes. Where two needles are provided it is recommended to use the

		smaller needle for injection in children and the larger needle for vaccination in adults. The primary packaging is latex-free.
GLAXOSMITHKLINE BIOLOGICALS S.A.	SYNFLORIX Pneumococcal polysaccharide 10-valent conjugate vaccine	Declaration by the MAH: Vial stopper: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process. Pre-filled glass syringe piston seal: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process. Syringe tip cover: the material used in the manufacturing is chemically distinct from and does not contain dried natural rubber.
MSD Italia S.r.l.	PNEUMOVAX Pneumococcal polysaccharide 23-valent vaccine	Declaration by the MAH: No raw materials containing latex are used during the whole manufacturing process. Additionally, materials of the immediate packaging (glass vial and pre-filled glass syringe) do not contain latex.
Pfizer Europe MA EEIG	PREVENAR 13 Pneumococcal polysaccharide 13-valent conjugate vaccine	Declaration by the MAH: All elements of the pre-filled glass syringe, including the tip cover and the rubber seal of the piston, are free from dried natural rubber.
GLAXOSMITHKLINE BIOLOGICALS S.A.	ROTARIX Rotavirus	Declaration by the MAH: Piston seal of the pre-filled oral applicator and protective cap: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process.
MSD VACCINS	ROTATEQ Rotavirus	Declaration by the MAH: No raw materials containing latex are used during the whole manufacturing process. Additionally, materials of the immediate packaging (pre-filled tube for oral use) do not contain latex.

Marketing Authorisation Holder	Vaccine trade name Pathogen	Latex/natural rubber
Meningococcal vaccines not envisaged by Law no. 119/2017		
GSK Vaccines S.r.l.	MENVEO Meningococcal groups A,C,W,Y	Declaration by the MAH: Natural rubber latex is not used in the manufacturing process of active ingredients or as an excipient for the production of the vaccine. Neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process of glass vial stoppers (one containing group A and another containing groups C, W, Y).
Pfizer Europe MA EEIG	NIMENRIX Meningococcal groups A,C,W,Y	Declaration by the MAH: Pre-filled glass syringe and glass vial stopper: neither natural rubber latex nor dried natural rubber and its derivatives are used in the manufacturing process. Syringe tip cover: although a denatured derivative of natural rubber latex is used, no antigenic latex protein is found.