

## **Annex I**

***List of the names, pharmaceutical forms, strength of the medicinal products, routes of administration, marketing authorisation holders in the Member States***

| <b>Member State<br/>EU / EEA</b> | <b>Marketing authorisation<br/>holder</b>                                                 | <b>(Invented)<br/>Name</b> | <b>Strength*</b> | <b>Pharmaceutical<br/>form</b>                                                           | <b>Route of<br/>administration</b>    |
|----------------------------------|-------------------------------------------------------------------------------------------|----------------------------|------------------|------------------------------------------------------------------------------------------|---------------------------------------|
| Austria                          | GlaxoSmithKline Pharma<br>GmbH<br>Albert Schweitzer-Gasse 6<br>A-1140 Wien<br>Austria     | Priorix                    |                  | Powder and<br>solvent for<br>solution for<br>injection                                   | Subcutaneous use<br>Intramuscular use |
| Austria                          | GlaxoSmithKline Pharma<br>GmbH<br>Albert Schweitzer-Gasse 6<br>A-1140 Wien<br>Austria     | Priorix                    |                  | Powder in vials<br>and solvent in<br>prefilled-syringes<br>for solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Belgium                          | GlaxoSmithKline Biologicals<br>s.a.<br>Rue de l'Institut, 89<br>1330 Rixensart<br>Belgium | Priorix                    |                  | Powder and<br>solvent for<br>solution for<br>injection                                   | Subcutaneous use<br>Intramuscular use |
| Bulgaria                         | GlaxoSmithKline Biologicals<br>s.a.<br>Rue de l'Institut, 89<br>1330 Rixensart<br>Belgium | Priorix                    |                  | Powder and<br>solvent for<br>suspension for<br>injection                                 | Subcutaneous use<br>Intramuscular use |
| Cyprus                           | GlaxoSmithKline Biologicals<br>s.a.<br>Rue de l'Institut, 89<br>1330 Rixensart<br>Belgium | Priorix                    |                  | Powder and<br>solvent for<br>solution for<br>injection                                   | Subcutaneous use<br>Intramuscular use |

| <b>Member State<br/>EU / EEA</b> | <b>Marketing authorisation<br/>holder</b>                                                 | <b>(Invented)<br/>Name</b> | <b>Strength*</b> | <b>Pharmaceutical<br/>form</b>                         | <b>Route of<br/>administration</b>    |
|----------------------------------|-------------------------------------------------------------------------------------------|----------------------------|------------------|--------------------------------------------------------|---------------------------------------|
| Czech Republic                   | GlaxoSmithKline Biologicals<br>s.a.<br>Rue de l'Institut, 89<br>1330 Rixensart<br>Belgium | Priorix                    |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Denmark                          | GlaxoSmithKline Pharma<br>A/S<br>Nykær 68<br>DK-2605 Brøndby<br>Denmark                   | Priorix                    |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Estonia                          | GlaxoSmithKline Biologicals<br>s.a.<br>Rue de l'Institut, 89<br>1330 Rixensart<br>Belgium | Priorix                    |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Finland                          | GlaxoSmithKline Biologicals<br>SA<br>Rue de l'Institut 89<br>1330 Rixensart<br>Belgium    | Priorix                    |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |

| <b>Member State<br/>EU / EEA</b> | <b>Marketing authorisation<br/>holder</b>                                                    | <b>(Invented)<br/>Name</b>                                                                                                                             | <b>Strength*</b> | <b>Pharmaceutical<br/>form</b>                         | <b>Route of<br/>administration</b>    |
|----------------------------------|----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------------------------------------------|---------------------------------------|
| France                           | Laboratoire GlaxoSmithKline<br>100 route de Versailles<br>78163 Marly-le-Roi Cedex<br>France | Priorix<br>powder and<br>solvent for<br>solution for<br>injection in a<br>pre-filled<br>syringe<br>Measles,<br>mumps, and<br>rubella vaccine<br>(live) |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use                      |
| Germany                          | GlaxoSmithKline GmbH &<br>Co. KG<br>Theresienhöhe 11<br>D-80339 München<br>Germany           | Priorix                                                                                                                                                |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Greece                           | GlaxoSmithKline AEBE<br>266 Kifisias avenue<br>152 32 Halandri<br>Greece                     | Priorix                                                                                                                                                |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Hungary                          | GlaxoSmithKline Kft.<br>1124 Budapest<br>Csörsz u 43<br>Hungary                              | Priorix                                                                                                                                                |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Iceland                          | GlaxoSmithKline ehf.<br>Thverholt 14<br>105 Reykjavik<br>Iceland                             | Priorix                                                                                                                                                |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |

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|----------------------------------|------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|------------------|--------------------------------------------------------|---------------------------------------|
| Ireland                          | GlaxoSmithKline (Ireland)<br>Limited<br>Stonemasons Way<br>Rathfarnham<br>Dublin 16<br>Ireland | Priorix                                                                        |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Italy                            | GlaxoSmithKline S.p.A.<br>Via A. Fleming, 2<br>37135 Verona<br>Italy                           | Priorix                                                                        |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Latvia                           | GlaxoSmithKline Biologicals<br>s.a.<br>Rue de l'Institut, 89<br>1330 Rixensart<br>Belgium      | Priorix<br>pulveris un<br>šķīdinātājs<br>injekciju<br>šķīduma<br>pagatavošanai |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Lithuania                        | UAB „GlaxoSmithKline<br>Lietuva“<br>Goštauto 40A<br>LT-01112, Vilnius<br>Lithuania             | Priorix                                                                        |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Luxembourg                       | GlaxoSmithKline Biologicals<br>s.a.<br>Rue de l'Institut, 89<br>1330 Rixensart<br>Belgium      | Priorix                                                                        |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |

| <b>Member State<br/>EU / EEA</b> | <b>Marketing authorisation<br/>holder</b>                                                                                                                                                   | <b>(Invented)<br/>Name</b> | <b>Strength*</b> | <b>Pharmaceutical<br/>form</b>                         | <b>Route of<br/>administration</b>    |
|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|------------------|--------------------------------------------------------|---------------------------------------|
| Malta                            | SmithKline Beecham plc<br>Great West Road, Brentford,<br>Middlesex TW8 9GS<br>Trading as<br>GlaxoSmithKline UK<br>Stockley Park West<br>Uxbridge<br>Middlesex<br>UB11 1BT<br>United Kingdom | Priorix                    |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Netherlands                      | GlaxoSmithKline BV<br>Huis ter Heideweg 62<br>3705 LZ Zeist<br>The Netherlands                                                                                                              | Priorix                    |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use                      |
| Norway                           | GlaxoSmithKline AS<br>Forskningsveien 2a<br>Postboks 180 Vinderen<br>0319 Oslo<br>Norway                                                                                                    | Priorix                    |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Poland                           | GlaxoSmithKline Biologicals<br>s.a.<br>Rue de l'Institut, 89<br>1330 Rixensart<br>Belgium                                                                                                   | Priorix                    |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |

| <b>Member State<br/>EU / EEA</b> | <b>Marketing authorisation<br/>holder</b>                                                                                                                              | <b>(Invented)<br/>Name</b>                                        | <b>Strength*</b> | <b>Pharmaceutical<br/>form</b>                         | <b>Route of<br/>administration</b>    |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|------------------|--------------------------------------------------------|---------------------------------------|
| Portugal                         | Smith Kline & French<br>Portuguesa, Produtos<br>Farmacêuticos, Lda.<br>Rua Dr. António Loureiro<br>Borges, 3<br>Arquiparque – Miraflares<br>1495-131 Algés<br>Portugal | Priorix                                                           |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Romania                          | GlaxoSmithKline Biologicals<br>s.a.<br>Rue de l'Institut, 89<br>1330 Rixensart<br>Belgium                                                                              | Priorix                                                           |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Slovak Republic                  | GlaxoSmithKline Biologicals<br>s.a.<br>Rue de l'Institut, 89<br>1330 Rixensart<br>Belgium                                                                              | Priorix                                                           |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Slovenia                         | GSK d.o.o., Ljubljana,<br>Knezov štridon 90, 1000<br>Ljubljana<br>Slovenia                                                                                             | Priorix<br>prašek in<br>vehikel za<br>raztopino za<br>injiciranje |                  | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |

| Member State<br>EU / EEA | Marketing authorisation<br>holder                                                                                                                                                                                 | (Invented)<br>Name                                                                          | Strength* | Pharmaceutical<br>form                                 | Route of<br>administration            |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|-----------|--------------------------------------------------------|---------------------------------------|
| Spain                    | GlaxoSmithKline, S.A.<br>C/Severo Ochoa, 2<br>28760 Tres Cantos (Madrid)<br>Spain                                                                                                                                 | Priorix<br>polvo y<br>disolvente en<br>jeringa<br>precargada<br>para solución<br>inyectable |           | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| Sweden                   | GlaxoSmithKline AB, Box<br>516, 169 29 Solna<br>Sweden                                                                                                                                                            | Priorix                                                                                     |           | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |
| United Kingdom           | SmithKline Beecham plc<br>980 Great West Road,<br>Brentford, Middlesex TW8<br>9GS<br>United Kingdom<br>Trading as<br>GlaxoSmithKline UK<br>Stockley Park West<br>Uxbridge<br>Middlesex UB11 1BT<br>United Kingdom | Priorix                                                                                     |           | Powder and<br>solvent for<br>solution for<br>injection | Subcutaneous use<br>Intramuscular use |

\* Strength applicable for all countries

After reconstitution, 1 dose (0.5 ml) contains:

Live attenuated measles virus (Schwarz strain)

not less than  $10^{3.0}$  CCID<sub>50</sub>

Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain)

not less than  $10^{3.7}$  CCID<sub>50</sub>

Live attenuated rubella virus (Wistar RA 27/3 strain)

not less than  $10^{3.0}$  CCID<sub>50</sub>