



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

10 September 2015  
EMA/590690/2015  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: tetanus vaccines

Procedure no.: PSUSA/00002910/201501



| Product Name (in authorisation country)                                          | MRP/DCP Authorisation number | National Authorisation Number | MAH of product in the member state       | Member State where product is authorised |
|----------------------------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------------|------------------------------------------|
| Anatetall                                                                        |                              | 002238018                     | Novartis Vaccines And Diagnostics S.R.L. | IT                                       |
| Anatetall                                                                        |                              | 002238044                     | Novartis Vaccines And Diagnostics S.R.L. | IT                                       |
| Anatetall                                                                        |                              | 002238057                     | Novartis Vaccines And Diagnostics S.R.L. | IT                                       |
| Cjepivo Protiv Tetanusa, Adsorbirano vaccinum Tetani Adsorbatum Imunološki Zavod |                              | UP/I-530-09/11-02/186         | Imunološki Zavod D.D.                    | HR                                       |
| Cjepivo Protiv Tetanusa, Adsorbirano vaccinum Tetani Adsorbatum Imunološki Zavod |                              | UP/I-530-09/11-02/187         | Imunološki Zavod D.D.                    | HR                                       |
| Imovax Tetano                                                                    |                              | 026171013                     | Sanofi Pasteur Msd S.P.A.                | IT                                       |
| Tetanol Pur                                                                      |                              | 2-00079                       | Novartis Vaccines And Diagnostics Gmbh   | AT                                       |
| Tetanol Pur                                                                      |                              | 5363-I-108/10                 | Novartis Vaccines And Diagnostics Gmbh   | SI                                       |
| Tetanol Pur                                                                      |                              | OGYI-T-9451/01                | Novartis Vaccines And Diagnostics Gmbh   | HU                                       |
| Tetanol Pur                                                                      |                              | OGYI-T-9451/02                | Novartis Vaccines And Diagnostics Gmbh   | HU                                       |
| Tetanol Pur                                                                      |                              | OGYI-T-9451/03                | Novartis Vaccines And Diagnostics Gmbh   | HU                                       |
| Tetanol Pur                                                                      |                              | OGYI-T-9451/04                | Novartis Vaccines And Diagnostics Gmbh   | HU                                       |
| Tetanol Pur                                                                      |                              | OGYI-T-9451/05                | Novartis Vaccines And Diagnostics Gmbh   | HU                                       |
| Tetanol Pur                                                                      |                              | OGYI-T-9451/06                | Novartis Vaccines And Diagnostics Gmbh   | HU                                       |

|                                    |     |                       |                                        |    |
|------------------------------------|-----|-----------------------|----------------------------------------|----|
| Tetanol Pur                        |     | PEI.H.01804.01.1      | Novartis Vaccines And Diagnostics Gmbh | DE |
| Tetanus-Adsorbat-Impfstoff Mérieux |     | 2-00087               | Sanofi Pasteur Msd Snc                 | AT |
| Tetanus-Adsorbat-Impfstoff Mérieux |     | 61A/83                | Sanofi Pasteur Msd Gmbh                | DE |
| Tetanusvaccine                     | N/A | 14828                 | Statens Serum Institut                 | DK |
| Tetavax                            |     | 12123                 | Sanofi Pasteur Sa                      | CY |
| Tetavax                            |     | 186397                | Sanofi Pasteur Sa                      | EE |
| Tetavax                            |     | 4593/2012/01-04       | Sanofi Pasteur Sa                      | RO |
| Tetavax                            |     | 59/0291/95-S          | Sanofi Pasteur Sa                      | SK |
| Tetavax                            |     | 59/1026/94-C          | Sanofi Pasteur Sa                      | CZ |
| Tetavax                            |     | 95-1156               | Sanofi Pasteur Msd                     | NO |
| Tetavax                            |     | MA573/00401           | Sanofi Pasteur Sa                      | MT |
| Tetavax                            |     | MA573/00402           | Sanofi Pasteur Sa                      | MT |
| Tetavax                            |     | NL 6274-1             | Sanofi Pasteur Sa                      | FR |
| Tetavax                            |     | NL 6274-2             | Sanofi Pasteur Sa                      | FR |
| Tetavax                            |     | NL 6274-3             | Sanofi Pasteur Sa                      | FR |
| Tetavax                            |     | UP/I-530-09/12-01/381 | Sanofi Pasteur Sa                      | HR |
| Vaccin Tetanique Pasteur           |     | NL 9155-3             | Sanofi Pasteur Msd Snc                 | FR |