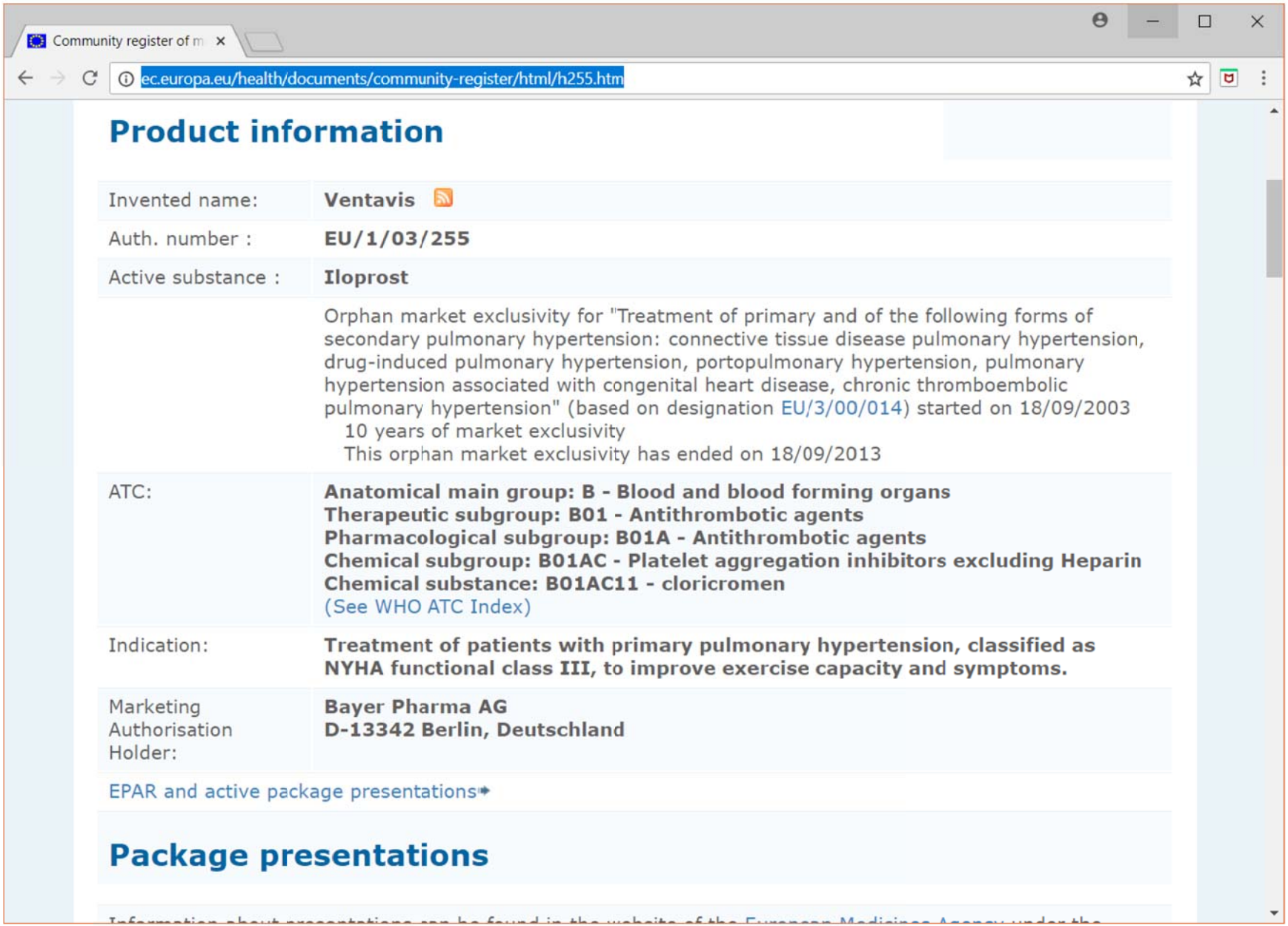
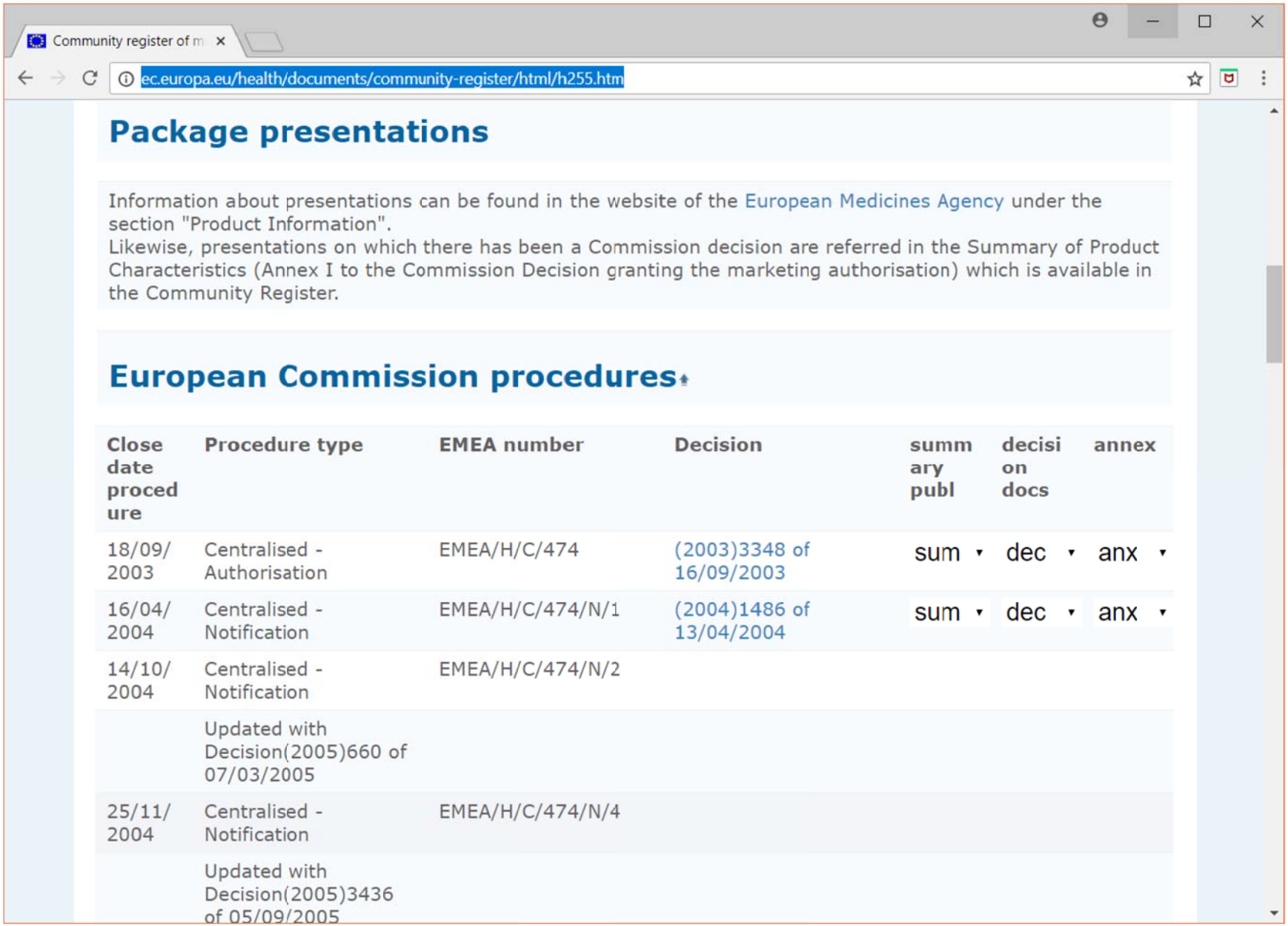


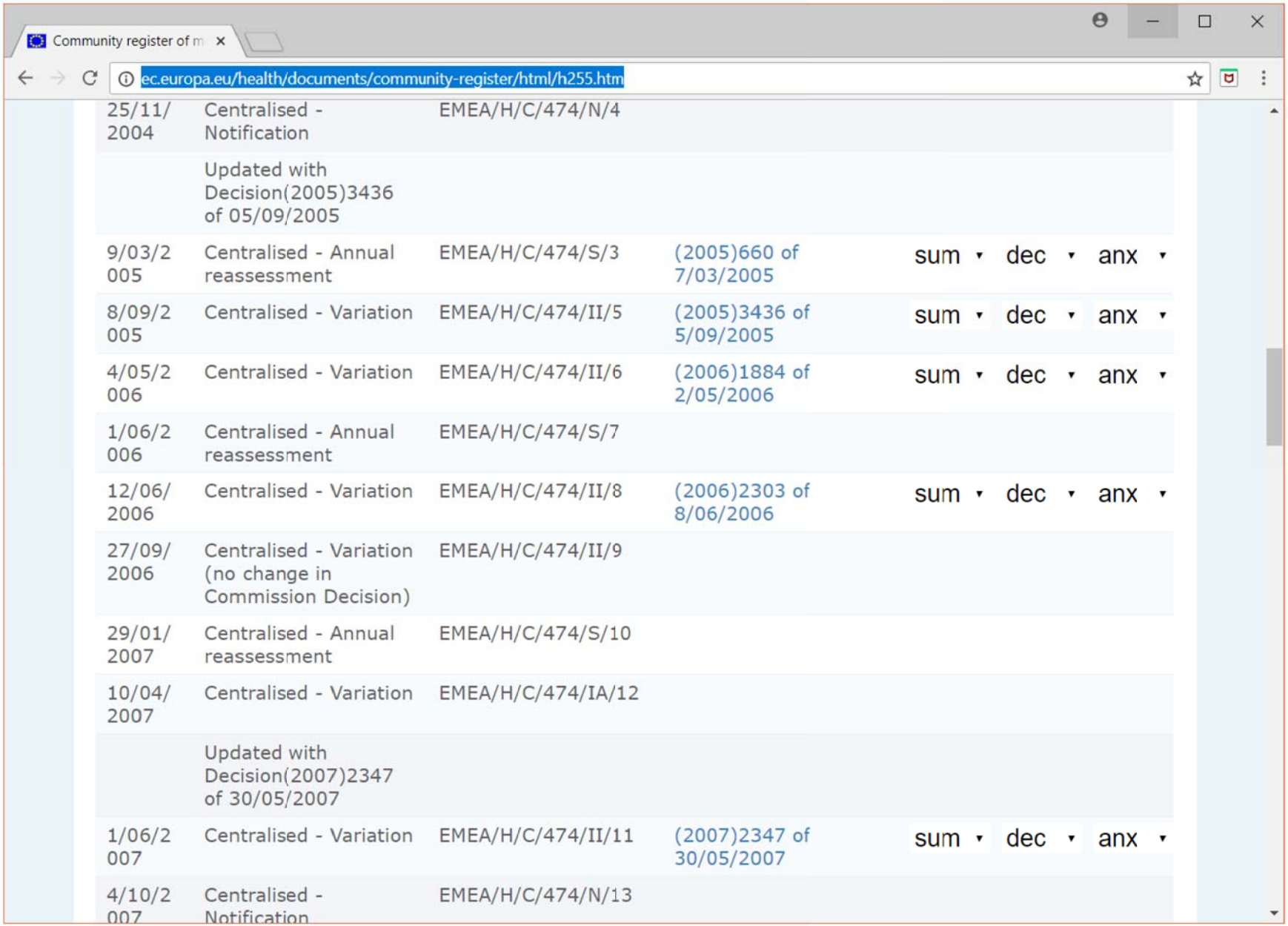



## Package presentations

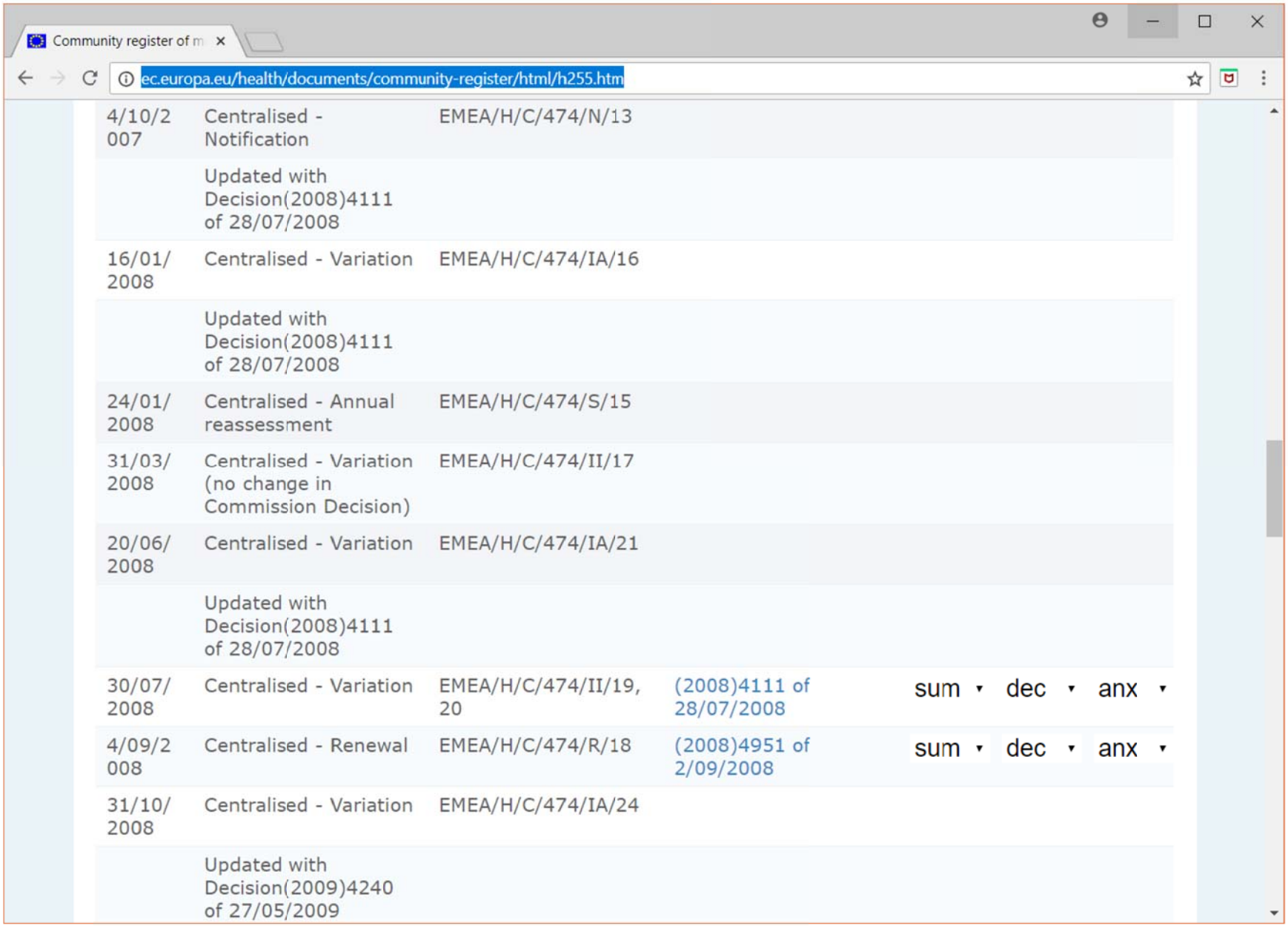
Information about presentations can be found in the website of the European Medicines Agency under the section "Product Information".
Likewise, presentations on which there has been a Commission decision are referred in the Summary of Product Characteristics (Annex I to the Commission Decision granting the marketing authorisation) which is available in the Community Register.

## European Commission procedures

| Close date procedure | Procedure type | EMEA number | Decision | summary publ | decision docs | annex |
|---|---|---|---|---|---|---|
| 18/09/2003 | Centralised - Authorisation | EMEA/H/C/474 | (2003)3348 of 16/09/2003 | sum | dec | anx |
| 16/04/2004 | Centralised - Notification | EMEA/H/C/474/N/1 | (2004)1486 of 13/04/2004 | sum | dec | anx |
| 14/10/2004 | Centralised - Notification | EMEA/H/C/474/N/2 | | | | |
| | Updated with Decision(2005)660 of 07/03/2005 | | | | | |
| 25/11/2004 | Centralised - Notification | EMEA/H/C/474/N/4 | | | | |
| | Updated with Decision(2005)3436 of 05/09/2005 | | | | | |




| | | | | |
|---|---|---|---|---|
| 25/11/2004 | Centralised - Notification | EMEA/H/C/474/N/4 | | |
| | Updated with Decision(2005)3436 of 05/09/2005 | | | |
| 9/03/2005 | Centralised - Annual reassessment | EMEA/H/C/474/S/3 | (2005)660 of 7/03/2005 | sum dec anx |
| 8/09/2005 | Centralised - Variation | EMEA/H/C/474/II/5 | (2005)3436 of 5/09/2005 | sum dec anx |
| 4/05/2006 | Centralised - Variation | EMEA/H/C/474/II/6 | (2006)1884 of 2/05/2006 | sum dec anx |
| 1/06/2006 | Centralised - Annual reassessment | EMEA/H/C/474/S/7 | | |
| 12/06/2006 | Centralised - Variation | EMEA/H/C/474/II/8 | (2006)2303 of 8/06/2006 | sum dec anx |
| 27/09/2006 | Centralised - Variation (no change in Commission Decision) | EMEA/H/C/474/II/9 | | |
| 29/01/2007 | Centralised - Annual reassessment | EMEA/H/C/474/S/10 | | |
| 10/04/2007 | Centralised - Variation | EMEA/H/C/474/IA/12 | | |
| | Updated with Decision(2007)2347 of 30/05/2007 | | | |
| 1/06/2007 | Centralised - Variation | EMEA/H/C/474/II/11 | (2007)2347 of 30/05/2007 | sum dec anx |
| 4/10/2007 | Centralised - Notification | EMEA/H/C/474/N/13 | | |




| | | | | | | |
|---|---|---|---|---|---|---|
| 4/10/2007 | Centralised - Notification | EMEA/H/C/474/N/13 | | | | |
| | Updated with Decision(2008)4111 of 28/07/2008 | | | | | |
| 16/01/2008 | Centralised - Variation | EMEA/H/C/474/IA/16 | | | | |
| | Updated with Decision(2008)4111 of 28/07/2008 | | | | | |
| 24/01/2008 | Centralised - Annual reassessment | EMEA/H/C/474/S/15 | | | | |
| 31/03/2008 | Centralised - Variation (no change in Commission Decision) | EMEA/H/C/474/II/17 | | | | |
| 20/06/2008 | Centralised - Variation | EMEA/H/C/474/IA/21 | | | | |
| | Updated with Decision(2008)4111 of 28/07/2008 | | | | | |
| 30/07/2008 | Centralised - Variation | EMEA/H/C/474/II/19, 20 | (2008)4111 of 28/07/2008 | sum | dec | anx |
| 4/09/2008 | Centralised - Renewal | EMEA/H/C/474/R/18 | (2008)4951 of 2/09/2008 | sum | dec | anx |
| 31/10/2008 | Centralised - Variation | EMEA/H/C/474/IA/24 | | | | |
| | Updated with Decision(2009)4240 of 27/05/2009 | | | | | |

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