

Intrinsa

Procedural steps taken and scientific information after the authorisation

| No | Scope | Opinion/ Notification ¹ issued on | Commission Decision Issued ² / amended on | Product Information affected ³ | Summary |
|--------|--|--|---|---|--|
| R/0018 | Renewal of the Marketing Authorisation | 19/05/2011 | 18/07/2011 | SPC, Annex II, Labelling, PL | <p>Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance, the CHMP is of the opinion that the quality, safety and efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Intrinsa continues to be favourable.</p> <p>The CHMP is of the opinion that one additional five-year renewal on the basis of pharmacovigilance grounds is required. The reason for an additional five-year renewal is that the off-label use is a safety risk. It is worrying that the data from the THIN (The Health Improvement Database) study suggests that approx 70% of the users are outside indication. The MAH has been asked to consider how to prevent the off-label use and present it in the next PSUR (6 month).</p> <p>Therefore based upon the safety profile of Intrinsa, which requires the submission of 6 monthly PSURs, the CHMP concluded that the MAH should submit one additional renewal application in 5 years time.</p> |

¹ Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.

² No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.

³ SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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|-----------|---|--|---|---|--|
| IA/0017/G | This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer of the manufacturer responsible for batch release, B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings | 06/12/2010 | n/a | SPC, Annex II, PL | |
| T/0016 | Transfer of Marketing Authorisation Holder | 19/04/2010 | 02/06/2010 | SPC, Labelling, PL | Transfer of the Marketing Authorisation from Warner Chilcott Pharmaceuticals UK Ltd to Warner Chilcott UK Ltd. |
| IA/0015/G | This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH, A.5.a - Administrative change - Change in the name and/or address of a manufacturer of the manufacturer responsible for batch release | 14/04/2010 | n/a | SPC, Annex II, Labelling, PL | |
| IA/0014 | 15_b_02_Submission of Ph. Eur. certificate for active substance - new manuf./other substances | 29/10/2009 | n/a | | |
| IB/0012 | 42_a_01_Change in shelf-life of finished product - as packaged for sale | 16/09/2008 | n/a | SPC | |
| II/0011 | Update of section 4.8 of the Summary of Product Characteristics and accordingly of the Package Leaflet to add the undesirable effect "abdominal pain", based on the MAH's in-house Clinical Trial database review. Moreover, inclusion of additional information on "hirsutism" as undesirable effect. Update of Summary of Product Characteristics and Package Leaflet | 19/03/2008 | 22/04/2008 | SPC, PL | Further to a review of the MAH's in-house Clinical Trial database, and particularly of an analysis of double blind data with 1,645 patients receiving testosterone and 1,455 patients receiving placebo for up to one year, it was observed that the number of adverse events reported and coded to the MedDRA PT "abdominal pain" was significantly higher in the TTS group compared with placebo (1.6% vs 0.6% p=0.0107). The MAH has applied to include "Abdominal Pain" in section 4.8 within the frequency "Common". |

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| | | | | | Moreover, following the outcome of the 2nd PSUR, more restructuring of section 4.8 of the SPC was proposed, including an update of the SPC table and the addition of information on "irritation", as undesirable effect. The Package Leaflet has been updated accordingly. |
| IA/0010 | 08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing | 12/09/2007 | n/a | Annex II, PL | |
| IA/0009 | 07_a_Replacement/add. of manufacturing site: Secondary packaging site | 09/08/2007 | n/a | | |
| IA/0005 | 38_a_Change in test procedure of finished product - minor change to approved test procedure | 09/07/2007 | n/a | | |
| IA/0007 | 38_a_Change in test procedure of finished product - minor change to approved test procedure | 09/07/2007 | n/a | | |
| IA/0006 | 38_a_Change in test procedure of finished product - minor change to approved test procedure | 09/07/2007 | n/a | | |
| IA/0002 | 15_a_Submission of Ph. Eur. certificate for active substance - approved manufacturer | 09/07/2007 | n/a | | |
| IA/0003 | 15_a_Submission of Ph. Eur. certificate for active substance - approved manufacturer | 09/07/2007 | n/a | | |
| IA/0004 | 38_a_Change in test procedure of finished product - minor change to approved test procedure | 09/07/2007 | n/a | | |
| IA/0008 | 38_a_Change in test procedure of finished product - minor change to approved test procedure | 09/07/2007 | n/a | | |
| IA/0001 | 07_a_Replacement/add. of manufacturing site: Secondary packaging site | 17/11/2006 | n/a | | |