Atriance

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
N/0067	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/07/2024		PL	
PSUSA/2132/ 202310	Periodic Safety Update EU Single assessment - nelarabine	13/06/2024	n/a		PRAC Recommendation - maintenance

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

IAIN/0066/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	30/04/2024		Annex II and PL	
N/0064	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/12/2023		PL	
S/0062	16th annual re-assessment	09/11/2023	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of Atriance should be maintained.
IA/0063	A.7 - Administrative change - Deletion of manufacturing sites	12/09/2023	n/a		
N/0061	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/01/2023		PL	
T/0060	Transfer of Marketing Authorisation	16/11/2022	09/12/2022	SmPC, Labelling and PL	
S/0058	Annual re-assessment.	10/11/2022	n/a		
IA/0059	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process	22/09/2022	n/a		

	of the AS				
IG/1521	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	23/06/2022	n/a		
S/0055	14th annual re-assessment	11/11/2021	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of Atriance should be maintained.
IAIN/0056/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	24/09/2021	12/11/2021	Annex II and PL	
PSUSA/2132/ 202010	Periodic Safety Update EU Single assessment - nelarabine	10/06/2021	n/a		PRAC Recommendation - maintenance

S/0051	Annual re-assessment.	12/11/2020	n/a		
IB/0053	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	30/10/2020	12/11/2021	SmPC, Annex II, Labelling and PL	
IA/0052/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	26/08/2020	n/a		
IAIN/0050/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	25/02/2020	n/a		

IAIN/0049/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	25/02/2020	27/08/2020	Annex II and PL	
S/0048	Annual re-assessment.	17/10/2019	n/a		
II/0046/G	This was an application for a group of variations. Update of Annex II to remove the existing specific obligation Study NLR506AUS02T 'Intensified	17/10/2019	27/08/2020	SmPC, Annex II and PL	Men with partners who are pregnant or could become pregnant should use condoms during treatment with nelarabine.

	methotrexate, nelarabine and augmented BFM therapy for children and young adults with newly diagnosed T-ALL and T-LBL'; a new SOB is introduced in Annex II to provide yearly updates on any new information concerning the efficacy and safety of the product in the approved indication. Additionally, section 4.6 of the SmPC is updated in order to revise information on the male and female contraception taking into consideration available non-clinical and clinical safety data as well as internal MAH's guidelines based on information from literature, health authority and working group guidelines. Minor corrections are also made to sections 4.8 and 5.3 of the SmPC. Moreover, the MAH took the opportunity to update details of the local representatives in the PL and introduce minor editorial changes in the PI. The revised RMP version 10.1 has been agreed. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
II/0047/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a	19/09/2019	27/08/2020	SmPC, Annex II, Labelling	

	manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change			and PL	

	in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.d - Change in the manufacturing process of the finished or intermediate product - Introduction of a non-standard terminal sterilisation method B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites				
II/0045/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of	31/01/2019	n/a		

	manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS				

	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
S/0044	Annual re-assessment.	15/11/2018	n/a		
IA/0043/G	This was an application for a group of variations.	31/07/2018	n/a		

	B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
IG/0950	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	18/06/2018	n/a		
PSUSA/2132/ 201710	Periodic Safety Update EU Single assessment - nelarabine	14/06/2018	n/a		PRAC Recommendation - maintenance
T/0041	Transfer of Marketing Authorisation	26/03/2018	30/04/2018	SmPC, Labelling and PL	
IB/0039	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	05/01/2018	30/04/2018	Annex II	
S/0038	Annual re-assessment.	09/11/2017	n/a		
R/0037	Renewal of the marketing authorisation.	21/04/2017	16/06/2017	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Atriance in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
S/0034	Annual re-assessment.	10/11/2016	n/a		

IB/0036	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	09/11/2016	n/a		
IA/0035	A.7 - Administrative change - Deletion of manufacturing sites	15/09/2016	n/a		
N/0033	Update of the package leaflet with revised contact details of the local representatives for France and Spain. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/07/2016	16/06/2017	PL	
IAIN/0032/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a	11/05/2016	n/a		

	manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				

	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				
S/0031	8th Annual Re-assessment.	19/11/2015	12/01/2016	Annex II	The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that Marketing Authorisation of Atriance should be maintained.
IB/0030	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	02/09/2015	n/a		
IAIN/0029/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	13/07/2015	12/01/2016	Annex II and PL	
PSUSA/2132/ 201410	Periodic Safety Update EU Single assessment - nelarabine	11/06/2015	n/a		PRAC Recommendation - maintenance

II/0027	Submission of data from a Post-Marketing Surveillance Study for Atriance in the indicated patient population under 21 years of age receiving 650 mg/m2 dose of nelarabine. This variation intends to fulfil ANX II Specific Obligation SOB 004.2 and Article 46 of the Paediatric legislation. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	21/05/2015	12/01/2016	Annex II	
T/0028	Transfer of Marketing Authorisation from Glaxo Group Ltd. to Novartis Europharm Limited. Transfer of Marketing Authorisation	30/03/2015	24/04/2015	SmPC, Labelling and PL	
II/0024/G	This was an application for a group of variations. Approved scope: B.II.e.1.a - 3 Change in quantitative composition of sterile medicinal product: to register Datwyler FM457/0 Omniflex 3G bromobutyl rubber stopper. B.II.e.7.b - Replacement of a supplier of packaging components: to register Datwyler at Industrieterrein Kolmen 1519, BE-3570, Aiken, Belgium as a rubber stoppers supplier.	20/11/2014	n/a		

	Refused scope: B.II.f.1.d - Change in storage conditions of the finished product: to register storage conditions of 'store below 25 ºC'. B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product				
S/0025	7th Annual Re-assessment.	23/10/2014	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that Marketing Authorisation of Atriance should be maintained.
IB/0023	To extend the due date for an annex II condition from Oct. 2014 to January 2015. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	10/09/2014	24/04/2015	Annex II	
IA/0022	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished	17/01/2014	n/a		

	product formulation - Change that does not affect the product information				
S/0021	6th Annual Re-assessment	24/10/2013	20/12/2013	Annex II	
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/09/2013	20/12/2013	Labelling	
IAIN/0020	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	01/07/2013	20/12/2013	SmPC and PL	
IG/0279	A.1 - Administrative change - Change in the name and/or address of the MAH	18/04/2013	20/12/2013	SmPC, Labelling and PL	
IG/0275	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/03/2013	n/a		
S/0016	"5th Annual Re-assessment"	20/09/2012	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations submitted by the MAH and having re-assessed the benefit/risk profile of the medicinal product, concluded that the benefit/risk balance for the product remains favourable.
R/0013	Renewal of the marketing authorisation.	19/04/2012	18/06/2012	Annex II, Labelling and PL	
IB/0014	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time	11/05/2012	n/a		

	data				
IG/0150/G	This was an application for a group of variations. C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	05/04/2012	n/a		
II/0012	Update of section 4.8 of the SmPC in order to add rhabdomyolysis and blood creatine phosphokinase increased as rare adverse reactions. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to make minor editorial changes. Furthermore, the MAH proposed to bring the product information in line with the latest QRD template (version 8, revision 1). C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	16/02/2012	21/03/2012	SmPC, Annex II, Labelling and PL	A cumulative review cases of rhabdomyolysis and/or creatine phosphokinase (CPK) increased was conducted and retrieved 16 cases, as of 16 August 2011. Although most of the 16 cases were confounded due to concurrent disease(s) and/or concomitant medications, there were five reports which suggest a potential causal relationship to nelarabine was considered possible. As a consequence, rhabdomyolysis and elevated creatine phosphokinases in the blood were added to the product information as adverse reactions with a rare frequency.
S/0010	Annual re-assessment.	22/09/2011	24/11/2011	Annex II	4th Annual Re-assessment The CHMP, having reviewed the evidence of compliance with the specific obligations submitted by the MAH and having re-assessed the benefit/risk profile of the medicinal product, concluded that the benefit/risk balance for the

					product remains favourable.
IB/0009/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	18/05/2011	n/a		
IB/0008/G	This was an application for a group of variations. B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling	18/05/2011	n/a		
IG/0034/G	This was an application for a group of variations. C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV	06/01/2011	n/a	Annex II	

	C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system				
S/0007	Annual re-assessment.	23/09/2010	29/11/2010	SmPC, Annex II, Labelling and PL	3rd Annual Re-assessment The CHMP, having reviewed the evidence of compliance with the specific obligations submitted by the MAH and having re-assessed the benefit/risk profile of the medicinal product, concluded that the benefit/risk balance for the product remains favourable.

II/0006	Update of the Detailed Description of the Pharmacovigilance System (DDPS) including change of the Qualified Person for Pharmacovigilance (QPPV). Consequently, Annex II has been updated with the new version number. Changes to QPPV Update of DDPS (Pharmacovigilance)	17/12/2009	20/01/2010	Annex II	The DDPS has been updated (version 7.2) to reflect the change of the QPPV as well as to notify other changes to the DDPS performed since the last approved version. Consequently, Annex II has been updated using the standard text including the new version number of the agreed DDPS. The CHMP considers that the Pharmacovigilance System as described by the MAH fulfils the requirements.
IB/0005	IB_17_a_Change in re-test period of the active substance	14/10/2009	n/a		
S/0004	Annual re-assessment.	24/09/2009	24/09/2009		2nd Annual Re-assessment The CHMP, having reviewed the evidence of compliance with the specific obligations submitted by the Marketing Authorisation Holder and having re-assessed the benefit/risk profile of Atriance, recommended no amendments to Annexes of the Commission Decision, and that the marketing authorisation remains under exceptional circumstances.
II/0003	Changes to QPPV Update of DDPS (Pharmacovigilance)	19/02/2009	18/03/2009	Annex II	The DDPS has been updated (version 6.2) to reflect the change of the Qualified Person for Pharmacovigilance (QPPV) as well as to notify other changes to the DDPS performed since the last approved version. Consequently, Annex II has been updated using the standard text including the new version number of the agreed DDPS.
S/0001	Annual re-assessment.	25/09/2008	19/11/2008	SmPC, Annex II, Labelling and PL	1st Annual Reassessment The CHMP, having reviewed the evidence of compliance with the specific obligations submitted by the Marketing Authorisation Holder and having re-assessed the benefit/risk profile of Atriance, recommended the

					amendments of Annexes I, II and III of the Commission Decision, and that the marketing authorisation remains under exceptional circumstances.
IB/0002	IB_42_a_01_Change in shelf-life of finished product - as packaged for sale	05/08/2008	n/a	SmPC	