Lyrica

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
X/0127	Annex I_2.(d) Change or addition of a new pharmaceutical form	27/02/2025	23/04/2025	SmPC, Annex II, Labelling and PL	
WS/2708	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	05/09/2024	n/a		Submission of the final report from study A0081096.

[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).

	Submission of the final report from study A0081096 listed as a category 3 study in the RMP. This is a prospective randomized 12-week controlled study of visual field change in subjects with partial seizures receiving pregabalin or placebo. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
N/0137	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/08/2024	19/12/2024	PL	
IB/0130/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.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms	20/06/2024	n/a		
IB/0132/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/importer responsible for batch release	07/06/2024	19/12/2024	Annex II and PL	

	B.II.z - Quality change - Finished product - Other variation 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 B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking				
IB/0129/G	This was an application for a group of variations. B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size 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.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	24/05/2024	n/a		
WS/2520/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No	16/05/2024	19/12/2024	SmPC	Update of sections 4.4 of the SmPC in order to add information on potential abuse in recreational drug users based on final results from study A0081365.

	1234/2008. Grouped application comprising two type II as follows: C.I.4 - Update of sections 4.4 of the SmPC in order to add information on potential abuse in recreational drug users based on final results from study A0081365 "A Phase 4 Randomized Double-Blind Double-Dummy Placebo- and Active-Controlled Single-Dose Six-way Crossover Study Evaluating the Abuse Potential of Lyrica Taken Orally with Oxycodone HCl in Healthy Non-Drug Dependent Recreational Opioid Users". A.6 - To change the ATC Code from N03AX16 to N02BF02. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data A.6 - Administrative change - Change in ATC Code/ATC Vet Code				For more information, please refer to the Summary of Product Characteristics.
IAIN/0135/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.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging	14/05/2024	19/12/2024	Annex II and PL	

	site				
IG/1734	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	05/04/2024	n/a		
IAIN/0131	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	27/02/2024	19/12/2024	SmPC and PL	
IG/1690/G	This was an application for a group of variations. B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition) 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	11/01/2024	19/12/2024	Annex II and PL	
PSUSA/2511/202301	Periodic Safety Update EU Single assessment - pregabalin	12/10/2023	07/12/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2511/202301.
N/0126	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/09/2023	07/12/2023	PL	
IG/1622	B.II.b.2.a - Change to importer, batch release	31/07/2023	n/a		

	arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
N/0122	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/03/2023	07/12/2023	PL	
N/0120	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/07/2022	21/09/2022	PL	
WS/2293	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	21/07/2022	21/09/2022	SmPC and PL	To update sections 4.4 and 4.8 of the SmPC and sections 2, 3 and 4 of the PL, to implement the wording related to the cases of abuse and dependence in patients without a history of substance disorder.
IAIN/0121/G	This was an application for a group of variations. 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.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	04/07/2022	21/09/2022	Annex II and PL	

WS/2261	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of SmPC sections 4.4 and 4.8 with a warning regarding severe cutaneous adverse reactions (SJS and TEN). C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	10/06/2022	21/09/2022	SmPC and PL	
WS/2168	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	22/04/2022	21/09/2022	SmPC and PL	
N/0117	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/03/2022	21/09/2022	PL	
N/0116	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/12/2021	21/09/2022	PL	
PSUSA/2511/202101	Periodic Safety Update EU Single assessment - pregabalin	16/09/2021	12/11/2021	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2511/202101.
WS/1919	This was an application for a variation following a worksharing procedure according to Article 20 of	28/10/2021	21/09/2022	SmPC and PL	The results from the pregnancy outcomes study provided additional information concerning the risks of pregabalin

	Commission Regulation (EC) No 1234/2008. Submission of an updated RMP (version 13.2) to include results from recently completed PASS studies, namely: 1) study A0081359: a population-based cohort study of pregabalin to characterize pregnancy outcomes; 2) study A0081106: a 12-month open-label study to evaluate the safety and tolerability of pregabalin as adjunctive therapy in paediatric subjects 1 month to 16 years of age with partial onset seizures and paediatric and adult subjects 5 to 65 years of age with primary generalized tonic-clonic seizures; 3) study A0081042: a double-blind, placebo-controlled, parallel-group, multicentre study of the efficacy and safety of pregabalin as adjunctive therapy in children 1 month through <4 years of age with partial onset seizures; 4) study A0081105: a randomized, double-blind, placebo-controlled, parallel group, multicentre trial of pregabalin as adjunctive therapy in paediatric and adult subjects with primary generalized tonic-clonic seizures. In addition, information on A0081096: a prospective randomized 12-week controlled study of visual field change in subjects with partial seizures receiving pregabalin or placebo has been updated as well as A0081365: a phase 4, randomised, double-blind, double-dummy, placebo- and active-controlled, single-dose, six-way crossover study to evaluate the potential for abuse with pregabalin. However, further issues noted with the RMP should be updated at the next regulatory opportunity.				treatment during pregnancy; supporting that pregabalin should not be used during pregnancy unless clearly necessary and women of childbearing potential have to use effective contraception based on the new data on major congenital malformations. In addition, the data support that pregabalin may cross the human placenta. For more information, please refer to the Summary of Product Characteristics.

	In the light of the results from the pregnancy outcomes study, section 4.6 of the SmPC is being updated concerning the risks of pregabalin treatment during pregnancy, indicating that women of childbearing potential have to use effective contraception, pregabalin may cross the human placenta and the description of major congenital malformations (MCM). In addition, section 4.4 is updated to highlight that pregabalin should not be used during pregnancy unless clearly necessary and women of childbearing potential have to use effective contraception based on the new data on MCM. 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				
N/0115	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/10/2021	21/09/2022	PL	
N/0113	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/08/2021	12/11/2021	PL	
WS/2015	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. To update Section 5.1 of the SmPC following completion of a paediatric study (A0081105) in line	25/03/2021	12/11/2021	SmPC and PL	

	with the outcome of the Article 46 (EMEA/H/C/003880/P46/006.1 and EMEA/H/C/003880/P46/006) and Post-authorisation Measure (PAM) procedure (EMEA/H/C/000546/P46/053.1 and EMEA/H/C/003880/P46/006.1). In addition the MAH brought that annexes in line with QRD version 10.1 and a reference to the reporting of side effects that had been duplicated was removed. C.I.3.a - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Implementation of wording agreed by the competent authority				
PSUSA/2511/ 202001	Periodic Safety Update EU Single assessment - pregabalin	17/09/2020	20/11/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2511/202001.
N/0110	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/10/2020	12/11/2021	Labelling	
WS/1798	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update Section 4.8 and Section 5.1 SmPC to reflect data from study A0081106 "A 12-Month Open-Label Study to Evaluate the Safety and Tolerability of Pregabalin as Adjunctive Therapy in Pediatric Subjects 1 Month to 16 Years of Age With Partial	03/09/2020	20/11/2020	SmPC, Labelling and PL	Section 4.8 and Section 5.1 of the SmPC were updated to reflect safety results from study A0081106 "A 12-Month Open-Label Study to Evaluate the Safety and Tolerability of Pregabalin as Adjunctive Therapy in Pediatric Subjects 1 Month to 16 Years of Age With Partial Onset Seizures and Pediatric and Adult Subjects 5 to 65 Years of Age With Primary Generalized Tonic-Clonic Seizures". For more information, please refer to the Summary of Product Characteristics.

	Onset Seizures and Pediatric and Adult Subjects 5 to 65 Years of Age With Primary Generalized Tonic-Clonic Seizures". C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
T/0106	Transfer of Marketing Authorisation	03/04/2020	02/06/2020	SmPC, Labelling and PL	
IG/1245/G	This was an application for a group of variations. B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability -	29/05/2020	n/a		

	Deletion of certificates (in case multiple certificates exist per material)				
N/0105	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/03/2020	02/06/2020	PL	
IAIN/0103	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	06/03/2020	02/06/2020	Annex II and PL	
WS/1605	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Addition of a warning in section 4.4. regarding an increased risk for opioid related death in patients who took concomitant opioids. A statement on the observation of a trend for a greater risk at higher doses was also included. Section 4.5 has been updated to reflect the findings of the case-control study regarding concomitant use of pregabalin and opioids. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	14/11/2019	21/02/2020	SmPC and PL	Based on published literature and a cumulative review of cases in the MAH's safety database, there is a strong signal for an increased risk of opioid-related death in patients concomitantly receiving opioids and pregabalin compared to treatment with opioids alone. Consequently, a new warning regarding an increased risk for opioid related death in patients who took concomitant opioids has been added in SmPC section 4.4. Moreover, Section 4.5 has been updated to reflect the findings of the case-control study regarding concomitant use of pregabalin and opioids.
N/0102	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/11/2019	21/02/2020	PL	

PSUSA/2511/201901	Periodic Safety Update EU Single assessment - pregabalin	05/09/2019	n/a		PRAC Recommendation - maintenance
IA/0101/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	30/08/2019	n/a		
N/0100	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/05/2019	21/02/2020	PL	
IG/1103	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	17/05/2019	21/02/2020	SmPC, Labelling and PL	
WS/1495	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	28/02/2019	21/02/2020	SmPC	

WS/1364	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Introduction of an updated RMP version 12.3 in order to include the changes proposed by EMEA/H/C/PSUSA/00002511/201701, updating the safety concerns and risk minimisation measures. The pharmacovigilance plan has also been updated. The protocol for non-interventional non-imposed PASS (A0081359) titled "A population-based cohort study of Pregabalin to characterize pregnancy outcomes" has been approved. 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	29/11/2018	n/a		
PSUSA/2511/ 201801	Periodic Safety Update EU Single assessment - pregabalin	06/09/2018	n/a		PRAC Recommendation - maintenance
T/0095	Transfer of Marketing Authorisation	11/07/2018	30/07/2018	SmPC, Labelling and PL	
IG/0938/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability -	13/07/2018	n/a		

	New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)				
WS/1137	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of sections 4.8 and 5.1 of the SmPC in order to reflect final results from paediatric study A0081041: "A Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of the Efficacy and Safety of Pregabalin as Adjunctive Therapy in Children 4-16 Years of Age with Partial Onset Seizures".	16/11/2017	19/02/2018	SmPC	In the 12 week placebo controlled study, paediatric patients were assigned to pregabalin 2.5 mg/kg/day (maximum, 150 mg/day), pregabalin 10 mg/kg/day (maximum, 600 mg/day), or placebo. The percentage of subjects with at least a 50% reduction in partial onset seizures as compared to baseline was 40.6% of subjects treated with pregabalin 10 mg/kg/day (p=0.0068 versus placebo), 29.1% of subjects treated with pregabalin 2.5 mg/kg/day (p=0.2600 versus placebo) and 22.6% of those receiving placebo. The most common adverse events observed in the 12 week study with pregabalin treatment were somnolence, pyrexia, upper respiratory tract infection, increased appetite, weight

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				increased, and nasopharyngitis.
WS/1213	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.c.1.z - Change in immediate packaging of the AS - Other variation	14/09/2017	n/a		
PSUSA/2511/ 201701	Periodic Safety Update EU Single assessment - pregabalin	01/09/2017	n/a		PRAC Recommendation - maintenance
IA/0091	B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	14/07/2017	n/a		
WS/1200	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/07/2017	19/02/2018	SmPC, Labelling and PL	
WS/1121	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g.	16/03/2017	19/02/2018	SmPC, Labelling and PL	

	tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes				
PSUSA/2511/ 201601	Periodic Safety Update EU Single assessment - pregabalin	15/09/2016	09/11/2016	SmPC, Annex II, Labelling and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2511/201601.
N/0084	Update of the package leaflet with revised contact details of the local representative for Germany. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/06/2016	09/11/2016	PL	
IG/0683	B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS	13/05/2016	n/a		
IA/0081/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability -	04/04/2016	n/a		

	New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)				
N/0080	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/11/2015	16/12/2015	Labelling	
IB/0079	B.I.c.1.z - Change in immediate packaging of the AS - Other variation	14/10/2015	n/a		
PSUSA/2511/ 201501	Periodic Safety Update EU Single assessment - pregabalin	10/09/2015	n/a		PRAC Recommendation - maintenance
IA/0078/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	05/08/2015	n/a		
N/0076	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/06/2015	16/12/2015	PL	

II/0073/G	This was an application for a group of variations. 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 C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	01/04/2015	n/a		
WS/0690	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to update paediatric information as requested after assessment of studies A0081074 & A0081075 submitted as post authorisation measure P46 045. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/03/2015	16/12/2015	SmPC	Paediatric information has been added to the SmPC after final assessment of data from two clinical studies assessed during a P46 procedure.
WS/0628	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of sections 4.6 (Fertility, pregnancy, and lactation) and 5.2 (Pharmacokinetic properties) of	18/12/2014	16/12/2015	SmPC, Annex II, Labelling and PL	This variation updated sections 4.6 (Fertility, pregnancy, and lactation) and 5.2 (Pharmacokinetic properties) of the SmPC to reflect new data available for lactation, based on the results of a recently completed study, A0081181: A multiple dose pharmacokinetic open label study of

	the SmPC to reflect new data available for lactation, based on the results of a recently completed study, A0081181: A multiple dose pharmacokinetic open label study of pregabalin (LYRICA) in healthy lactating women. Package leaflet is updated accordingly. Furthermore editorial changes have been introduced throughout the PI. In addition, the MAH took the opportunity to align the product information with the latest QRD template version 9.0. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				pregabalin (LYRICA) in healthy lactating women.
PSUV/0069	Periodic Safety Update	11/09/2014	n/a		PRAC Recommendation - maintenance
N/0072	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/08/2014	22/01/2015	PL	
IA/0070	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)	25/07/2014	n/a		
IB/0067	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	09/07/2014	22/01/2015	SmPC and PL	
IAIN/0068	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g.	16/05/2014	22/01/2015	SmPC, Labelling and	

	tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes			PL	
IA/0065	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	07/03/2014	n/a		
II/0063	Update of section 4.8 of the SmPC and Patient Leaflet in order to re-assign the frequency category for a number of Adverse Drug Reactions following a review of the clinical trial data. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	23/01/2014	22/01/2015	SmPC, Labelling and PL	The MAH conducted a review of pooled safety data from 33 clinical studies to re-assess the estimated frequencies of adverse drug reactions (ADRs) reported in the Lyrica SmPC. The majority of the labelled reactions had no modification of their frequency category, but the frequencies of a third of the currently labelled undesirable effects have been revised to estimate the previously unknown frequency or have been moved to a higher frequency category. The frequency revision is intended to provide more accurate information to the prescriber. In addition, the MAH took the opportunity to add Braille text to the bottle labels where it was previously missing.
IB/0064	C.I.3.a - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Implementation of wording agreed by the competent authority	19/11/2013	13/02/2014	SmPC and PL	Revision of Sections 4.4 and 4.8 of the SPC and section 3 of the PL to update the warning that a dose relationship may exist for either the incidence or the severity of discontinuation symptoms. The opportunity has been taken to change pregabalin to Lyrica where indicated.
IA/0062/G	This was an application for a group of variations. B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer	04/10/2013	n/a		

	B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer				
N/0061	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/07/2013	13/02/2014	PL	
IB/0060	C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH	17/04/2013	13/02/2014	SmPC and Annex II	This variation updates Section 4.9 of the SPC to remove the sentence "in overdose up to 15g no unexpected reactions were reported" and to add a reference to cases of coma. These were requested by the CHMP following assessment of PSUR 13. Annex II is also being updated.
IB/0058	C.I.3.z - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Other variation	15/02/2013	13/02/2014	SmPC, Annex II, Labelling and PL	Update of the subheading "Ethanol, lorazepam, oxycodone" to "CNS influencing medical products" in Section 4.5 of the SPC and replacement of the term "tiredness" by "drowsiness" in section 4 of the PL, as requested by CHMP during assessment of PSUR 13. In addition, the PI has been amended as per the QRD template and the contact details of the local representative have been updated.
IG/0235/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV	06/12/2012	n/a		C.I.z - To replace the Detailed Description of the Pharmacovigilance System (DDPS) with the Pharmacovigilance System Master File (PSMF).

IG/0169/G	This was an application for a group of variations. 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.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	08/06/2012	n/a		
IA/0056	B.III.1.b.2 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	29/05/2012	n/a		
IB/0054/G	This was an application for a group of variations. B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	11/05/2012	n/a		
IA/0055	A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished	13/04/2012	n/a		

	product, including quality control sites (excluding manufacturer for batch release)				
N/0053	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/01/2012	13/02/2014	PL	
II/0049	Update of section 4.8 of the Summary of Product Characteristics (SmPC) and relevant section of the PL to add "gynaecomastia" and to replace "hypertrophy breast" with the term "breast enlargement". C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	20/10/2011	22/11/2011	SmPC, Annex II and PL	A cumulative review, with data lock point 28 February 2011, identified 90 post-marketing cases reporting "gynaecomastia", "breast swelling" or "breast enlargement" with pregabalin. An analysis of treatment-related adverse events reported in placebo-controlled pregabalin clinical studies identified 2 cases of breast enlargement among the 6022 pregabalin-treated patients. Therefore, gynaecomastia was included as adverse reaction in the Product Information with frequency "not known". The term hypertrophy breast has also been replaced into breast enlargement as per the MedDRA dictionary.
IA/0051/G	This was an application for a group of variations. B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	16/11/2011	n/a		

II/0047	Update of the mechanism of action paragraph in section 5.1 of the Summary of Product Characteristics. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	22/09/2011	24/10/2011	SmPC	The mechanism of action for pregabalin described in section 5.1 has been summarised by deleting some detailed information not considered relevant for the prescriber, as per the SmPC guideline.
IA/0050	B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer	05/09/2011	n/a		
IB/0048	C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH	16/08/2011	n/a	SmPC	Following assessment study A0081046 under Article 46 of the Paediatric regulation, the CHMP, requested the addition of study A0081046 data to Section 5.1 of the Summary of Product Characteristics (SmPC).
II/0045	Update of section 4.8 of the SPC and relevant section of the PL to reclassify the frequency of headache events from not known to a common event. C.I.3.b - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under Article 45/46, or amendments to reflect a Core SPC - Change(s) with new additional data submitted by the MAH	19/05/2011	17/06/2011	SmPC and PL	As requested by CHMP during the evaluation of PSUR11, the MAH updated the Product Information to reclassify the adverse reaction headache from a postmarketing event with a frequency not known to a common event. In a pooled analysis of 32 clinical trials the incidence of headache was 7.4% with pregabalin users.
IA/0046	B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate	15/04/2011	n/a		

	from an already approved manufacturer				
IG/0044/G	This was an application for a group of variations. 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	02/03/2011	n/a	Annex II	
N/0044	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/12/2010	n/a	PL	
II/0040	Introduction of real-time release in the manufacture of 75, 100, 150, 200, 225 and 300mg Lyrica hard capsules. B.II.d.3 - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product	23/09/2010	30/09/2010		
IA/0043	B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	01/09/2010	n/a		

II/0041	The Product Information for Lyrica has been updated, as per the QRD template, to reflect that the safety and efficacy of Lyrica in children has not been established and to provide additional non-clinical and clinical data on the effects of pregabalin on fertility and pregnancy. Overall, the non-clinical effects observed are considered of no relevance to humans. However, as the potential risk for pregnant women is unknown, effective contraception is recommended. In support to this application, the MAH submitted summary data from studies investigating the effect of pregabalin on fertility in adults and juvenile rats as well as summary data from studies investigating the effect of pregabalin on fertility in humans and in paediatric patients. The Annex II has also been amended to reflect the CHMP decision on the new PSUR cycle. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/07/2010	26/08/2010	SmPC, Annex II and PL	The Product Information for Lyrica has been updated, as per the QRD template, to reflect that the safety and efficacy of Lyrica in children has not been established and to provide additional non-clinical and clinical data on the effects of pregabalin on fertility and pregnancy. Overall, the non-clinical effects observed are considered of no relevance to humans. However, as the potential risk for pregnant women is unknown, effective contraception is recommended. In support to this application, the MAH submitted summary data from studies investigating the effect of pregabalin on fertility in adults and juvenile rats as well as summary data from studies investigating the effect of pregabalin on fertility in humans and in paediatric patients. The Annex II has also been amended to reflect the CHMP decision on the new PSUR cycle.
II/0039	Update of the Product Information to include warnings regarding potential for abuse, the occurrence of convulsions and reports of encephalopathy cases following assessment of PSUR 10. In addition, the PL is also updated to fully reflect the adverse drug reactions listed in the SPC. C.I.3.b - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under Article	22/04/2010	14/06/2010	SmPC and PL	Section 4.4 of SPC and section 2 of the PL have been updated with a warning refering to abuse potential. Sections 4.4 and 4.8 of SPC and section 2 and 4 of the PL have been updated to reflect that there have been reports of convulsions when taking Lyrica or shortly after stopping Lyrica. Section 4.4 of the SPC and section 2 of the PL have been updated to reflect that there have been reports of reduction in brain function (encephalopathy) in some patients taking Lyrica when they have other conditions.

	45/46, or amendments to reflect a Core SPC - Change(s) with new additional data submitted by the MAH				In addition, section 4 of the PL has also been thoroughly reviewed to ensure its consistency with section 4.8 of the SPC.
X/0030	Addition of a new pharmaceutical form: 20 mg/ml oral solution Annex I_2.(d) Change or addition of a new pharmaceutical form	18/03/2010	08/06/2010	SmPC, Labelling and PL	The MAH submitted an extension application (EMEA/H/C/456/X/30) to add a new pharmaceutical form: 20mg/ml oral solution. Based on the CHMP review of data on quality, safety and efficacy, the CHMP considered by consensus that the risk-benefit balance of Lyrica 20 mg/ml oral solution was favourable in the treatment of: Neuropathic pain Lyrica is indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy Lyrica is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Generalised Anxiety Disorder Lyrica is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.
IA/0042/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer	19/05/2010	n/a		
II/0037	Update of Summary of Product Characteristics (SPC) and Package Leaflet (PL) to reflect the occurrence of	18/02/2010	29/04/2010	SmPC and PL	Section 4.4 and 4.8 of the SPC was updated to include anxiety as part of the withdrawal symptoms observed after

	anxiety after treatment discontinuation and to reflect a drug interaction with medicines causing constipation further to the assessment of PSUR 10. Update of Summary of Product Characteristics and Package Leaflet				discontinuation of short-term and long-term treatment with Lyrica. Section 4.4 of the SPC has also been updated to reflect that when Lyrica is taken with other medicines that may cause constipation (such as some types of pain medicines) it is possible that gastrointestinal problems may occur (e.g.,constipation, blocked or paralysed bowel). The PL was updated accordingly.
IA/0038	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	18/02/2010	n/a	Annex II and PL	
II/0035	Update of section 4.8 "Undesirable Effects" of the SPC to include 'aggression' and 'malaise' as Adverse Drug Reactions (ADRs), as requested by the CHMP following the assessment of PSURs 8 and 9. The PL was updated accordingly. Update of Summary of Product Characteristics and Package Leaflet	19/11/2009	21/12/2009	SmPC and PL	A cumulative review of 'aggression' was performed by the MAH in PSUR 8. Despite the fact that there are cases with confounding factors and taking into account the cases with a positive rechallenge and more cases with a positive dechallenge, the CHMP concluded that 'aggression' should be included in section 4.8 of the SPC for pregabalin with frequency 'unknown'. Additionally, 'malaise' was one of the most commonly reported unlisted adverse reactions, and therefore this term was also included in section 4.8 of the SPC with the same frequency.
IB/0036	IB_10_Minor change in the manufacturing process of the active substance	18/11/2009	n/a		
II/0034	Update of Summary of Product Characteristics and Package Leaflet	23/07/2009	20/08/2009	SmPC and PL	
II/0033	Update of the Detailed Description of the Pharmacovigilance System DDPS	25/06/2009	07/08/2009	Annex II	The Detailed Description of the Pharmacovigilance System (DDPS) has been updated (version 2.0) in order to reflect

	(Pharmacovigilance) Update of DDPS (Pharmacovigilance)				various organisational changes as well as the change of the global safety database. Consequently, Annex II has been updated using the standard text including the new version number of the agreed DDPS.
R/0029	Renewal of the marketing authorisation.	19/03/2009	29/05/2009	SmPC, Annex II, Labelling and PL	Based on the review of the available information the CHMP is of the opinion that the quality, the safety and the efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considers that the benefit/risk profile continues to be favourable. The CHMP was also of the opinion that the renewal can be granted with unlimited validity
II/0028	Update of section 4.4 of the Summary of Product Characteristics and section 2 of the Package Leaflet following assessment of signals of suicidal ideation and behaviour in patients treated with antiepileptics. Update of Summary of Product Characteristics and Package Leaflet	18/12/2008	13/02/2009	SmPC and PL	Due to concerns over the potential risk of suicidal thoughts and behaviour in association with the use of antiepileptics, available data from randomized placebo controlled trials and from the post-marketing phase for this class of medicines was considered by the CHMP. Overall, despite the small number of events seen in the clinical trials and the lack of a statistically significant increased risk of suicidal behaviour, the analysis of randomized placebo controlled trials of antiepileptic drugs did not exclude the possibility of an increased risk. Therefore, the CHMP considered it necessary to update section 4.4 of the SPC and section 2 of the PL with information regarding suicidal ideation and behaviour.
IA/0032	IA_05_Change in the name and/or address of a manufacturer of the finished product	05/02/2009	n/a	Annex II and PL	
IA/0031	IA_09_Deletion of manufacturing site	05/02/2009	n/a		

II/0027	Update of sections 4.4 and 4.8 of the Summary of Product Characteristics (SPC), to add a warning statement regarding vision loss observed during treatment with Lyrica, as requested by the CHMP following assessment of PSUR 7. Sections 2 and 4 of the Package Leaflet (PL) were updated accordingly. The MAH took the opportunity to implement a typographical correction and update the details of the German local representative in the PL. Update of Summary of Product Characteristics and Package Leaflet	20/11/2008	22/12/2008	SmPC and PL	Following the assessment of PSUR 7 (1 August 2007 to 31 January 2008), the MAH updated section 4.4 of the SPC with a warning regarding reported cases of vision loss, as requested by the CHMP. Consequently, the term 'vision loss' was also added to section 4.8 of the SPC. Relevant sections of the PL were updated accordingly.
IB/0026	IB_10_Minor change in the manufacturing process of the active substance	30/09/2008	n/a		
IA/0025	IA_22_a_Submission of TSE Ph. Eur. certificate for exc. - Approved/new manufacturer	11/04/2008	n/a		
II/0023	Update of sections 4.4, 5.1 (new statements for vision related changes and angioedema) and 4.8 (listing of the terms keratitis and angioedema) of the SPC, and accordingly relevant sections of the PL, in accordance with the conclusions of the CHMP assessment of PSUR 5 (September 2007) and the expert panel review meeting on visual events (October 2007). Update of Summary of Product Characteristics and Package Leaflet	21/02/2008	27/03/2008	SmPC and PL	Further to the CHMP conclusions on PSUR 5 (1/8/06 - 31/1/07), the MAH has included a warning in section 4.4 of the SPC regarding visual disturbances in patients treated with pregabalin. In addition, as a result of an internal review, the MAH included an additional warning statement regarding angioedema. As a result of the changes to section 4.4, additional terms have been introduced in section 4.8. The package information leaflet has been updated accordingly.

					Finally, further to the external expert panel meeting of ophtalmologists convened by Pfizer on 27-28th October 07, the term keratitis was included in section 4.8 Undesirable effects.
II/0022	Update section 4.8 of the SPC and accordingly relevant sections of the PL to include the Stevens Johnson syndrome (SJS) in accordance with the conclusions of FUM 12.3 reached during the November 2007 CHMP. Update of Summary of Product Characteristics and Package Leaflet	24/01/2008	29/02/2008	SmPC and PL	Further to the assessment of a cumulative review of pregabalin post-marketing cases reporting Stevens Johnson Syndrome (SJS) and related events, the MAH has included SJS in section 4.8 of the SPC and accordingly in the PL, as recommended by the CHMP.
II/0021	Update to sections 4.4 and 4.8 of the Summary of Product Characteristics and the relevant sections of the Package Leaflet (PL) following the assessment of the 5th PSUR in relation to congestive heart failure and urinary retention respectively. The MAH took the opportunity to amend the contact number of the Slovakian local representative in the section 6 of the PL. Update of Summary of Product Characteristics and Package Leaflet	15/11/2007	18/12/2007	SmPC and PL	Further to the CHMP assessment of the 5th PSUR, the urinary retention and the Stevens Johnson syndrome were identified as new safety issues; the MAH was requested to update the SPC accordingly through a type II variation. Furthermore, the CHMP considered that oedema and cardiovascular and respiratory disorders remains a concern and the warning in section 4.4 of congestive heart failure should be strengthened. The MAH therefore submitted on 10 September 2007 the present variation which includes amendements to the sections 4.4 and 4.8 of the SPC with regards to the congestive heart failure and urinary retention respectively. The relevant section of the Package Leaflet were updated accordingly.
IB/0020	IB_18_Replacement of an excipient with a comparable excipient	25/07/2007	n/a		
IB/0019	IB_17_a_Change in re-test period of the active substance	09/07/2007	n/a		

II/0017	Update to sections 4.4, 4.5, 4.8 and 4.9 of the Summary of Product Characteristics and the relevant sections of the Package Leaflet accordingly, further to the assessment of the 4th PSUR. Update of Summary of Product Characteristics and Package Leaflet	24/05/2007	29/06/2007	SmPC and PL	Further to the CHMP assessment of the 4th PSUR, the MAH reviewed their safety database (spontaneous reports, clinical trials, literature) in relation to injury, loss of consciousness, confusion, mental impairment, paralysis, respiratory failure, renal failure, overdose and coma. A reference to reports of loss of consciousness and mental confusion are now included in section 4.4 and 4.8 of the SPC. Information on cases of renal failure reversible upon discontinuation of Lyrica is also now included in section 4.4 of the SPC. A reference to reports of respiratory failure and coma in patients taking pregabalin with other CNS depressant medication is now included in section 4.5 of the SPC. Finally, section 4.9 of the SPC has been updated to include most commonly reported adverse events (somnolence, confusional state, agitation, restlessness) in post-marketing experience. The package leaflet was amended accordingly.
IA/0018	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	13/06/2007	13/06/2007	SmPC, Labelling and PL	
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/05/2007	n/a	PL	
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/05/2007	n/a	Labelling	
IA/0014	IA_22_a_Submission of TSE Ph. Eur. certificate for exc. - Approved/new manufacturer	16/02/2007	n/a		

II/0013	This variation refers to the update of the sections 4.4, 4.8, 6.6 of the Summary of Product Characteristics further to the assessment of PSUR 3. The sections 2, 4 and 6 of the Package Leaflet have been amended accordingly and the local representatives for Bulgaria and Romania have been added. Update of Summary of Product Characteristics and Package Leaflet	14/12/2006	17/01/2007	SmPC and PL	A new warning is added regarding the use of Lyrica in patients who are cardiovascular compromised and the potential risk for development (aggravation of) congestive heart failure. In addition, congestive heart failure is included to the list of adverse reactions. Finally, the MAH also took this opportunity to better distinguish in section 4.8 those adverse reactions that arose from clinical trials from those that arose post-marketing experience. The sections 2, 4 and 6 of the Package Leaflet have been amended accordingly.
II/0011	This variation refers to an update of section 5.3 "Preclinical safety data" of the Summary of Product Characteristics (SPC), further to a request from the CHMP following evaluation of Follow Up Measure (FUM) 002.1. Update of Summary of Product Characteristics	21/09/2006	30/10/2006	SmPC	Further to their conclusions of the assessment of the study concerning oral toxicity of pregabalin in Juvenile Wistar rats (FUM 002.1), the CHMP requested a variation to change the section 5.3 "Preclinical safety data".
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/09/2006	n/a	Labelling	
II/0007	Extension of Indication to include 'treatment of central neuropathic pain in adults' for Lyrica. Extension of Indication	27/07/2006	07/09/2006	SmPC, Labelling and PL	The CHMP variation assessment report will be published as part of the EPAR, following review/deletion of confidential information.
IA/0012	IA_08_a_Change in BR/QC testing - repl./add. of batch control/testing site	05/09/2006	n/a		
II/0009	Change(s) to the manufacturing process for the active substance	27/07/2006	03/08/2006		

II/0008	Update of Summary of Product Characteristics and Package Leaflet	01/06/2006	04/07/2006	SmPC and PL	
X/0005	Annex I_2.(c) Change or addition of a new strength/potency	23/02/2006	15/05/2006	SmPC, Labelling and PL	
II/0004	Extension of Indication	26/01/2006	20/03/2006	SmPC, Labelling and PL	
II/0006	Update of Summary of Product Characteristics and Package Leaflet	13/10/2005	17/11/2005	SmPC and PL	
II/0002	New presentation(s)	26/05/2005	08/07/2005	SmPC, Labelling and PL	
IB/0003	IB_14_a_Change in manuf. of active substance without Ph. Eur. certificate - change in manuf. site	11/04/2005	n/a		
IB/0001	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	17/09/2004	17/09/2004	SmPC, Labelling and PL	