Union Register support

Public Health - Union Register of medicinal products

Union Register of medicinal products for human use

Product information

Product name:	Anoro Ellipta	✔ ACTIVE
EU number:	EU/1/14/898	
Active substance:	umeclidinium bromide / vilanterol trifenatate	
Indication:	Anoro is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)	
Marketing Authorisation Holder:	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	
ATC:	Anatomical main group: R - Respiratory system Therapeutic subgroup: R03 - Drugs for obstructive airway diseases Pharmacological subgroup: R03A - Adrenergics, inhalants Chemical subgroup: R03AL - Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids Chemical substance: R03AL03 - vilanterol and umeclidinium bromide (See WHO ATC Index)	
Links to EMA website:	EMA - Anoro Ellipta	

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 Union Register.

European Commission procedures

By clicking on the icon, it is possible to download all the linguistic versions of a specific Decision or Annex in a single package.

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Anne
13 May 2014	Centralised - Authorisation	EMEA/H/C/2751	(2014)3178 of 08 May 2014			
26 Mar 2015	Centralised - Variation	EMEA/H/C/2751/IB/22	-			
Updated with:	Decision (2016)1986 of 30 Mar 2016					
01 Oct 2015	Centralised - Variation	EMEA/H/C/2751/WS/823	-			
Updated with:	Decision (2016)1986 of 30 Mar 2016					
21 Dec 2015	Centralised - Notification	EMEA/H/C/2751/N/8	-			
Updated with:	Decision (2016)1986 of 30 Mar 2016					
14 Jan 2016	Centralised - Variation	EMEA/H/C/2751/WS/871/G	-			
Updated with:	Decision (2016)1986 of 30 Mar 2016					
01 Apr 2016	PSUSA - Modification	EMEA/H/C/2751/PSUSA/10264/201506	(2016)1986 of 30 Mar 2016			
26 Sep 2016	PSUSA - Modification	EMEA/H/C/2751/PSUSA/10264/201512	(2016) 6242 of 22 Sep 2016			
26 Jan 2017	Centralised - Variation	EMEA/H/C/2751/WS/1031	-			
Updated with:	Decision (2018) 1138 of 19 Feb 2018					
21 Apr 2017	Centralised - Variation	EMEA/H/C/2751/WS/1030	-			
Updated with:	Decision (2018) 1138 of 19 Feb 2018					

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Anne
13 Jul 2017	Centralised - Variation	EMEA/H/C/2751/WS/1189	-			
Updated with:		Decision (2018) 1138 of 19 Feb 2018				
21 Feb 2018	Centralised - Yearly update	-	(2018) 1138 of 19 Feb 2018			
10 Aug 2018	Centralised - Variation	-	-			
Updated with:		Decision (2018)8049 of 26 Nov 2018				
28 Nov 2018	Centralised - Yearly update	-	(2018)8049 of 26 Nov 2018			
10 Dec 2018	Centralised - Transfer Marketing Authorisation Holder	EMEA/H/C/2751/T/23	(2018)8621 of 06 Dec 2018			
16 Jan 2019	Centralised - Variation	EMEA/H/C/2751/IG/1016	-			
Updated with:		Decision (2019)5734 of 25 Jul 2019				
17 Jan 2019	Centralised - Renewal	EMEA/H/C/2751/R/22	(2019)267 of 15 Jan 2019			
24 Apr 2019	Centralised - Notification	EMEA/H/C/2751/N/27	-			
Updated with:		Decision (2019)5734 of 25 Jul 2019				
29 Jul 2019	Centralised - Yearly update	-	(2019)5734 of 25 Jul 2019			
19 Sep 2019	Centralised - Variation	EMEA/H/C/2751/WS/1501	-			
Updated with:		Decision (2020)8099 of 16 Nov 2020				
23 Sep 2019	PSUSA - Modification	EMEA/H/C/2751/PSUSA/00010264/201812	(2019)6891 of 19 Sep 2019			
18 Nov 2020	Centralised - Yearly update	-	(2020)8099 of 16 Nov 2020			

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Anne
09 Dec 2020	Centralised - Notification	EMEA/H/C/002751/N/0032	-			

Last updated on 12/02/2021.

EUROPEAN
COMMISSION

Brussels, 8.5.2014
C(2014) 3178 final

COMMISSION IMPLEMENTING DECISION

of 8.5.2014

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Anoro - umeclidinium bromide / vilanterol trifenatate", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 8.5.2014

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Anoro - umeclidinium bromide / vilanterol trifenatate", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by Glaxo Group Ltd, on 30 January 2013, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion of the European Medicines Agency, formulated on 28 March 2014 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The medicinal product "Anoro - umeclidinium bromide / vilanterol trifenatate" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2].

(2) It is therefore appropriate to authorise its placing on the market.

(3) The Committee for Medicinal Products for Human Use considered that "umeclidinium bromide" and "vilanterol trifenatate" were new active substances at the time of submission of the marketing authorisation application.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the medicinal product "Anoro - umeclidinium bromide / vilanterol trifenatate", the characteristics of which are summarised in Annex I to this Decision.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 311, 28.11.2001, p. 67.

"Anoro - umeclidinium bromide / vilanterol trifenatate" shall be registered in the Community register of medicinal products under number EU/1/14/898.

Article 2

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II and, in particular, with those relating to manufacture and importation, control and issue.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III.

Article 4

The period of validity of the authorisation shall be five years from the date of notification of this Decision.

Article 5

This Decision is addressed to Glaxo Group Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.

Done at Brussels, 8.5.2014

For the Commission
Paola TESTORI COGGI
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION