

15 July 2024  
EMA/934543/2022 Rev. 4  
Human Medicines Division

## Table of decisions of labelling exemption requests falling under article 63 of Directive 2001/83/EC examined by the Quality Review of Documents (QRD) Group

### Related information

[Exemptions to labelling and package-leaflet obligations | European Medicines Agency](#)

[Recommendations for the implementation of the exemptions to the labelling and package leaflet obligations in the centralised procedure](#)

MA status	Product number	Product name	Article 63(1) request (orphan products) <sup>2</sup>	Outcome 63(1) orphan products <sup>2</sup>	Article 63(3) request for omission of certain particulars	Outcome 63(3) omission of certain particulars	Article 63(3) request for translation exemption	Outcome 63(3) request for translation exemption	Outcome date	Product information	Assessment report
Authorised	EMA/H/C/004043/X/0039	Ocrevus			Omission of particulars (immediate labelling)	Positive			08/Apr/24	<a href="#">Ocrevus (ocrelizumab) - Product information</a>	<a href="#">Ocrevus (ocrelizumab) - Assessment report (europa.eu)</a>
Authorised	EMA/H/C/005352	Upstaza	Translation exemption (outer and immediate labelling)	Positive (partial)	Omission of particulars (immediate labelling)	Positive (partial)			07/Mar/24	<a href="#">Upstaza (eladocagene exuparvovec) - Product information</a>	N/A
Authorised	EMA/H/C/005919/II/0002	Tevimbra			Omission of particulars (immediate labelling)	Positive			27/Feb/24	N/A	N/A
Authorised	EMA/H/C/006113	Emblaveo			Omission of particulars (immediate labelling)	Positive			31/Jan/24	<a href="#">Emblaveo (aztreonam/avibactam) - Product information</a>	<a href="#">Emblaveo (aztreonam/avibactam) - Assessment report</a>
Authorised	EMA/H/C/005269/X/0033	Kaftrio	Translation exemption (outer, intermediate and immediate labelling)	Positive (partial)					21/Nov/23	<a href="#">Kaftrio (elexacaftor/tezacaftor/ivacaftor) - Product information</a>	N/A
Authorised	EMA/H/C/002552	Deltyba	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)					21/Nov/23	<a href="#">Deltyba (delamanid) - Product information</a>	N/A
Authorised	EMA/H/C/006194	Zynyz			Omission of particulars (immediate labelling)	Positive			21/Nov/23	<a href="#">Zynyz (retifanlimab) - Product information</a>	<a href="#">Zynyz (retifanlimab) - Assessment report</a>
Authorised	EMA/H/C/005900	Rezzayo			Omission of particulars (immediate labelling)	Positive			30/Aug/23	<a href="#">Rezzayo (rezafungin) - Product information</a>	N/A
Authorised	EMA/H/C/005933	Catiolanze			Omission of particulars (immediate labelling)	Positive			13/Jul/23	<a href="#">Catiolanze (latanoprost) - Product information</a>	N/A
Authorised	EMA/H/C/005756	Apretude			Omission of particulars (immediate labelling)	Positive (partial)			03/Jul/23	<a href="#">Apretude, (cabotegravir) - Product information</a>	<a href="#">Apretude (cabotegravir) - Assessment report</a>
Authorised	EMA/H/C/006185	Niapelf			Omission of particulars (immediate labelling)	Positive			14/Jun/23	<a href="#">Niapelf (paliperidone) - Product information</a>	N/A
Authorised	EMA/H/C/005985	Tepkinly	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)					14/Jun/23	<a href="#">Tepkinly (epcoritamab) - Product information</a>	<a href="#">Tepkinly (epcoritamab) - Assessment report</a>
Authorised	EMA/H/C/005849/X/0003	Vyvgart	Translation exemption (outer labelling)	Positive					10/Mar/23	<a href="#">Vyvgart (efgartigimod alfa) - Product information</a>	<a href="#">Vyvgart (efgartigimod alfa) - Assessment report</a>
Authorised	EMA/H/C/005493	Qalsody			Omission of particulars (immediate labelling)	Positive			10/Mar/23	<a href="#">Qalsody (tofersen) - Product information</a>	<a href="#">Qalsody (tofersen) - Assessment report</a>
Authorised	EMA/H/C/005122	Omvoh			Omission of particulars (immediate labelling)	Positive			04/Jan/23	<a href="#">Omvoh (mirikizumab) - Product information</a>	<a href="#">Omvoh (mirikizumab) - Assessment report</a>
Authorised	EMA/H/C/004258	Alofisel			Omission of particulars (outer labelling)	Positive (temporary)			17/Nov/22	<a href="#">Alofisel (darvadstrocel) - Product information</a>	N/A
Authorised	EMA/H/C/005343	Mvabea			Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	Positive	26/Oct/22	<a href="#">Mvabea (Ebola vaccine (MVA BN Filo [recombinant])) - Product information</a>	N/A
Authorised	EMA/H/C/005337	Zabdeno			Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	Positive	26/Oct/22	<a href="#">Zabdeno (Ad26.ZEBOV-GP [recombinant]) - Product information</a>	N/A
Authorised	EMA/H/C/005343	Mvabea			Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	Positive (partial)	13/Oct/22	<a href="#">Mvabea (Ebola vaccine (MVA BN Filo [recombinant])) - Product information</a>	N/A
Authorised	EMA/H/C/005337	Zabdeno			Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	Positive (partial)	13/Oct/22	<a href="#">Zabdeno (Ad26.ZEBOV-GP [recombinant]) - Product information</a>	N/A
Authorised	EMA/H/C/005484	Loargys	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)					13/Oct/22	<a href="#">Loargys (pegzilarginase) - Product information</a>	<a href="#">Loargys (pegzilarginase) - Assessment report</a>

Authorised	EMA/H/C/005703	Pombiliti		Omission of particulars (immediate labelling)	Positive			13/Oct/22	<a href="#">Pombiliti (cipaglucosidase alfa) - Product information</a>	<a href="#">Pombiliti (cipaglucosidase alfa) - Assessment report</a>
Authorised	EMA/H/C/005695	Opfolda		Omission of particulars (immediate labelling)	Positive			13/Oct/22	<a href="#">Opfolda (miglustat) - Product information</a>	N/A
Authorised	EMA/H/C/006016	Imjudo		Omission of particulars (immediate labelling)	Positive			13/Oct/22	<a href="#">IMJUDO - Product information</a>	<a href="#">Imjudo - Assessment report</a>
Authorised	EMA/H/C/004650	Tremelimumab AstraZeneca		Omission of particulars (immediate labelling)	Positive			13/Oct/22	<a href="#">Tremelimumab AstraZeneca - Product information</a>	<a href="#">Tremelimumab AstraZeneca - Assessment report</a>
Authorised	EMA/H/C/005776	Enjaymo				Translation exemption (outer, immediate labelling and package leaflet)	Positive	13/Sep/22	<a href="#">Enjaymo (Sutimlimab) - Product information</a>	N/A
Authorised	EMA/H/C/005035	Filsuvez		Omission of particulars (immediate labelling)	Positive			08/Aug/22	<a href="#">Filsuvez (birch bark extract) - Product information</a>	N/A
Authorised	EMA/H/C/004827	Hemgenix	Translation exemption (outer, immediate labelling and package leaflet)		Positive (partial)	Omission of particulars (outer labelling)	Negative	14/Jun/22	<a href="#">Hemgenix - Product information</a>	<a href="#">Hemgenix - Assessment report</a>
Authorised	EMA/H/C/005751	Columvi		Omission of particulars (immediate labelling)	Positive			14/Jun/22	<a href="#">Columvi, INN-glofitamab (europa.eu)</a>	N/A
Authorised	EMA/H/C/005848	Pemetrexed Baxter		Omission of particulars (immediate labelling)	Positive			14/Jun/22	<a href="#">Pemetrexed Baxter - Product information</a>	<a href="#">Pemetrexed Baxter - Assessment report</a>
Authorised	EMA/H/C/005246/X/0002	Byfavo		Omission of particulars (immediate labelling)	Negative			14/Jun/22	<a href="#">Byfavo - Product information</a>	N/A
Authorised	EMA/H/C/005815	Ertapenem SUN		Omission of particulars (immediate labelling)	Positive			11/May/22	<a href="#">Ertapenem SUN (ertapenem) - Product information</a>	<a href="#">Ertapenem SUN (ertapenem) - Assessment report</a>
Authorised	EMA/H/C/004850	Xenpozyme	Translation exemption (outer, immediate labelling and package leaflet)		Positive			12/Apr/22	<a href="#">Xenpozyme (olipudase alfa) - Product information</a>	<a href="#">Xenpozyme (olipudase alfa) - Assessment report</a>
Authorised	EMA/H/C/005769	Herwenda		Omission of particulars (immediate labelling)	Positive			10/Mar/22	<a href="#">Herwenda (trastuzumab) - Product information</a>	N/A
Authorised	EMA/H/C/005540	Pyrukynd	Translation exemption (outer, intermediate and immediate labelling)		Positive (partial)			10/Mar/22	<a href="#">Pyrukynd - Product information</a>	N/A
Authorised	EMA/H/C/005680	Lunsumio		Omission of particulars (immediate labelling)	Positive	Translation exemption (outer labelling)	Positive	10/Mar/22	<a href="#">Lunsumio (mosunetuzumab) - Product information</a>	N/A
Authorised	EMA/H/C/004577	Ebvallo	Translation exemption (outer, immediate labelling and package leaflet)		Positive (partial)	Omission of particulars (immediate labelling)	Positive (partial)	10/Mar/22	<a href="#">Ebvallo - Product information</a>	<a href="#">Ebvallo - Assessment report</a>
Authorised	EMA/H/C/004929	Kimmtrak	Translation exemption (outer and immediate labelling)		Positive			16/Nov/21	<a href="#">Kimmtrak (tebentafusp) - Product information</a>	<a href="#">Kimmtrak (tebentafusp) - Assessment report</a>
Authorised	EMA/H/C/005378	Nulibry	Translation exemption (outer and immediate labelling)		Positive (partial)			16/Nov/21	<a href="#">Nulibry - Product information</a>	N/A
Authorised	EMA/H/C/005849	Vyvgart		Omission of particulars (outer and immediate labelling)	Positive (partial)			16/Nov/21	<a href="#">Vyvgart (efgartigimod alfa) - Product information</a>	<a href="#">Vyvgart (efgartigimod alfa) - Assessment report</a>
Authorised	EMA/H/C/005973	Paxlovid		Omission of particulars (outer labelling)	Positive	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)	16/Nov/21	<a href="#">Paxlovid (nirmatrelvir + ritonavir) - Product information</a>	<a href="#">Paxlovid (nirmatrelvir + ritonavir) - Assessment report</a>
Authorised	EMA/H/C/005788	Evusheld		Omission of particulars (outer labelling)	Positive	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)	13/Oct/21	<a href="#">Evusheld (ixagevimab, cilgavimab) - Product information</a>	N/A
Authorised	EMA/H/C/005553	Aspaveli		Omission of particulars (immediate labelling)	Positive			08/Oct/21	<a href="#">Aspaveli (pegcetacoplan) - Product information</a>	<a href="#">Aspaveli (pegcetacoplan) - Assessment report</a>
Authorised	EMA/H/C/005814	Ronapreve		Omission of particulars (immediate labelling)	Positive			24/Sep/21	<a href="#">Ronapreve (casirivimab and imdevimab) - Product information</a>	<a href="#">Ronapreve (casirivimab and imdevimab) - Assessment report</a>
Authorised	EMA/H/C/005550	Artesunate Amivas	Translation exemption (outer, immediate labelling and package leaflet)		Positive (partial)			14/Sep/21	<a href="#">Artesunate Amivas (artesanate) - Product information</a>	<a href="#">Artesunate Amivas (Artesunate) - Assessment report</a>
Authorised	EMA/H/C/005854	Regkirona		Omission of particulars (outer and immediate labelling)	Positive	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)	28/Jul/21	<a href="#">Regkirona (regdanvimab) - Product information</a>	<a href="#">Regkirona (regdanvimab) - Assessment report</a>
Authorised	EMA/H/C/005676	Xevudy		Omission of particulars (outer labelling)	Positive	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)	28/Jul/21	<a href="#">Xevudy (sotrovimab) - Product information</a>	<a href="#">Xevudy (sotrovimab) - Assessment report</a>
Authorised	EMA/H/C/005182	Trodelvy		Omission of particulars (immediate labelling)	Positive			17/Jun/21	<a href="#">Trodelvy (sacituzumab govitecan) - Product information</a>	<a href="#">Trodelvy (sacituzumab govitecan) - Assessment report</a>
Authorised	EMA/H/C/005681	Pepaxti		Omission of particulars (immediate labelling)	Positive			17/Jun/21	<a href="#">Pepaxti (melphalan flufenamide) - Product information</a>	N/A

Authorised	EMA/H/C/005035	Filsuvez	Translation exemption (outer, intermediate, immediate labelling and package leaflet)	Positive (partial)				17/Jun/21	<a href="#">Filsuvez (birch bark extract) - Product information</a>	N/A
Authorised	EMA/H/C/005095	Carvykti	Translation exemption (outer and immediate labelling)	Positive				17/Jun/21	<a href="#">Carvykti (Ciltacaptogene autoleucel) - Product information</a>	<a href="#">Carvykti (ciltacaptogene autoleucel) - Assessment report</a>
Authorised	EMA/H/C/005467	Voraxaze	Translation exemption (outer, intermediate, immediate labelling and package leaflet)	Positive (partial)				17/Jun/21	<a href="#">Voraxaze (glucarpidase) - Product information</a>	<a href="#">Voraxaze (glucarpidase) - Assessment report</a>
Authorised	EMA/H/C/005501	Nexviadyme			Omission of particulars (immediate labelling)	Positive		17/Jun/21	<a href="#">Nexviadyme (avalglucosidase alfa) - Product information</a>	<a href="#">Nexviadyme (avalglucosidase alfa) - Assessment report</a>
Authorised	EMA/H/C/004662	Abecma			Omission of particulars (outer and immediate labelling)	Positive (partial)		03/Jun/21	<a href="#">Abecma (idecabtagene vicleucel) - Product information</a>	<a href="#">Abecma (idecabtagene vicleucel) - Assessment report</a>
Authorised	EMA/H/C/004275/II/0021	Crysvita	Translation exemption (outer, immediate labelling and package leaflet)	Positive				06/May/21	<a href="#">Crysvita (burosumab) - Product information</a>	N/A
Authorised	EMA/H/C/005475	Voxzogo	Translation exemption (outer and immediate labelling)	Positive (partial)				04/Mar/21	<a href="#">Voxzogo (vosoritide) - Product information</a>	<a href="#">Voxzogo (vosoritide) - CHMP assessment report</a>
Authorised	EMA/H/C/005737	Jcovden			Omission of particulars (outer, immediate labelling and package leaflet)	Positive		01/Mar/21	<a href="#">JCOVDEN [COVID-19 vaccine (Ad26_COV2-S [recombinant])] - Product information</a>	<a href="#">JCOVDEN [COVID-19 Vaccine Janssen (Ad26_COV2-S, recombinant)] - Assessment report</a>
Authorised	EMA/H/C/005327	Abevmy			Omission of particulars (immediate labelling)	Positive		13/Jan/21	<a href="#">Abevmy (bevacizumab) - Product information</a>	<a href="#">Abevmy (bevacizumab) - Assessment report</a>
Authorised	EMA/H/C/005791	Spikevax			Omission of particulars (outer, immediate labelling and package leaflet)	Positive		01/Jan/21	<a href="#">Spikevax - Product information</a>	<a href="#">Spikevax - Assessment report</a>
Authorised	EMA/H/C/005735	Comirnaty			Omission of particulars (outer and immediate labelling)	Positive		17/Dec/20	<a href="#">Comirnaty (tozinameran, tozinameran/riltozinameran, tozinameran/famtozinameran) - Product information</a>	<a href="#">Comirnaty (tozinameran, tozinameran/riltozinameran, tozinameran/famtozinameran) - Assessment report</a>
Authorised	EMA/H/C/005286	Alymysis			Omission of particulars (immediate labelling)	Positive		20/Oct/20	<a href="#">Alymysis (bevacizumab) - Product information</a>	N/A
Authorised	EMA/H/C/005556	Oyavas			Omission of particulars (immediate labelling)	Positive		20/Oct/20	<a href="#">Oyavas (bevacizumab) - Product information</a>	N/A
Authorised	EMA/H/C/005145	Evrysdi			Omission of particulars (immediate labelling)	Negative		20/Oct/20	<a href="#">Evrysdi (risdiplam) - Product information</a>	<a href="#">Evrysdi (risdiplam) - Assessment report</a>
Authorised	EMA/H/C/005089	Imcivree	Translation exemption (outer and immediate labelling)	Positive				20/Oct/20	<a href="#">Imcivree (setmelanotide) - Product information</a>	<a href="#">Imcivree (setmelanotide) - Assessment report</a>
Authorised	EMA/H/C/004662	Abecma			Omission of particulars (outer and intermediate labelling)	Positive (partial)		20/Oct/20	<a href="#">Abecma (idecabtagene vicleucel) - Product information</a>	<a href="#">Abecma (decabtagene vicleucel) - Assessment report</a>
Authorised	EMA/H/C/004731	Breyanzi			Omission of particulars (outer and intermediate labelling)	Positive (partial)		20/Oct/20	<a href="#">Breyanzi (lisocabtagene maraleucel) - Product information</a>	N/A
Authorised	EMA/H/C/005386	Phesgo			Omission of particulars (immediate labelling)	Positive		13/Oct/20	<a href="#">Phesgo (pertuzumab/trastuzumab) - Product information</a>	<a href="#">Phesgo (pertuzumab / trastuzumab) - Assessment report</a>
Authorised	EMA/H/C/005102	Tecartus			Omission of particulars (immediate labelling)	Positive		05/Oct/20	<a href="#">Tecartus (autologous anti-CD19-transduced CD3+ cells) - Product information</a>	<a href="#">Tecartus (autologous anti-CD19-transduced CD3+ cells) - Assessment report</a>
Authorised	EMA/H/C/005675	Vaxzevria			Omission of particulars (outer and immediate labelling)	Positive		07/Jul/20	<a href="#">Vaxzevria - Product information</a>	<a href="#">Vaxzevria - Assessment report</a>
Authorised	EMA/H/C/005246	Byfavo			Omission of particulars (immediate labelling)	Positive		16/Jun/20	<a href="#">Byfavo (remimazolam) - Product information</a>	<a href="#">Byfavo (remimazolam) - Assessment report</a>
Authorised	EMA/H/C/004586	Exparel liposomal			Omission of particulars (immediate labelling)	Positive		16/Jun/20	<a href="#">Exparel liposomal (bupivacaine) - Product information</a>	<a href="#">Exparel liposomal (bupivacaine) - Assessment report</a>
Authorised	EMA/H/C/004954/X/0004/G	Ultomiris			Omission of particulars (immediate labelling)	Positive		16/Jun/20	<a href="#">Ultomiris (ravulizumab) - Product information</a>	N/A
Authorised	EMA/H/C/004976	Vocabria			Omission of particulars (immediate labelling)	Positive		16/Jun/20	<a href="#">Vocabria (cabotegravir) - Product information</a>	N/A
Authorised	EMA/H/C/005060	Rekambys			Omission of particulars (immediate labelling)	Positive		16/Jun/20	<a href="#">Rekambys (rilpivirine) - Product information</a>	N/A
Authorised	EMA/H/C/005436	Minjuvi			Omission of particulars (immediate labelling)	Positive		16/Jun/20	<a href="#">Minjuvi (tafasitamab) - Product information</a>	N/A
Authorised	EMA/H/C/005681	Pepaxti			Omission of particulars (immediate labelling)	Positive		16/Jun/20	<a href="#">Pepaxti (melphalan flufenamide) - Product information</a>	N/A
Authorised	EMA/H/C/004379	Amglicia	Translation exemption (outer, immediate labelling and package leaflet)	Negative				16/Jun/20	<a href="#">Amglicia (qilbenclamide) - Product information</a>	N/A
Authorised	EMA/H/C/005271	Zokinvy	Translation exemption (outer, immediate labelling and package leaflet)	Positive				16/Jun/20	<a href="#">Zokinvy (lonafarnib) - Product information</a>	N/A

Authorised	EMA/H/C/002393	Defitelio	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)			16/Jun/20	<a href="#">Defitelio (defibrotide) - Product information</a>	N/A
Authorised	EMA/H/C/005622	Veklury			Omission of particulars (immediate labelling)	Positive	15/May/20	<a href="#">Veklury (remdesivir) - Product information</a>	<a href="#">Veklury (remdesivir) - Assessment report</a>
Authorised	EMA/H/C/005269	Kaftrio	Translation exemption (outer, intermediate, immediate labelling and package leaflet)	Positive (partial)			22/May/20	<a href="#">Kaftrio (elxacaftor/tezacaftor/ivacaftor) - Product information</a>	N/A
Authorised	EMA/H/C/005167	Dovprela	Translation exemption (outer and immediate labelling)	Positive			27/Mar/20	<a href="#">Dovprela (pretomanid) - Product information</a>	<a href="#">Dovprela (pretomanid) - Assessment report</a>
Authorised	EMA/H/C/004077/X/0032	Darzalex			Omission of particulars (immediate labelling)	Positive	20/Mar/20	<a href="#">Darzalex (daratumumab) - Product information</a>	N/A
Authorised	EMA/H/C/002614	Sirturo	Translation exemption (outer and immediate labelling)	Positive			03/Mar/20	<a href="#">Sirturo (bedaquiline) - Product information</a>	N/A
Authorised	EMA/H/C/005321	Libmeldy	Translation exemption (outer, intermediate, immediate labelling and lot information sheet)	Positive	Omission of particulars (immediate labelling)	Positive	03/Mar/20	<a href="#">Libmeldy (atidarsagene autotemcel) - Product information</a>	<a href="#">Libmeldy (atidarsagene autotemcel) - Assessment report</a>
Authorised	EMA/H/C/004849	Idefirix	Translation exemption (outer and immediate labelling)	Positive			03/Mar/20	<a href="#">Idefirix (imlifidase) - Product information</a>	<a href="#">Idefirix (imlifidase) - Assessment report</a>
Authorised	EMA/H/C/000829/X/0122/G	Pradaxa			Omission of particulars (immediate labelling)	Positive	03/Mar/20	<a href="#">Pradaxa (dabigatran etexilate) - Product information</a>	<a href="#">Pradaxa (dabigatran etexilate) - Assessment report</a>
Authorised	EMA/H/C/003855	Coagadex	Translation exemption (outer and immediate labelling)	Positive			03/Mar/20	<a href="#">Coagadex (human coagulation factor X) - Product information</a>	N/A
Authorised	EMA/H/C/005352	Upstaza	Translation exemption (outer and immediate labelling)	Positive (partial)	Omission of particulars (immediate labelling)	Positive (partial)	03/Mar/20	<a href="#">Upstaza (eladocagene exuparvovec) - Product information</a>	<a href="#">Upstaza (eladocagene exuparvovec) - Assessment report</a>
Authorised	EMA/H/C/003855	Coagadex	Translation exemption (outer and immediate labelling)	Positive			13/Jan/20	<a href="#">Coagadex (human coagulation factor X) - Product information</a>	N/A
Authorised	EMA/H/C/004829	Fetroja			Omission of particulars (immediate labelling)	Positive	19/Nov/19	<a href="#">Fetroja (cefiderocol) - Product information</a>	<a href="#">Fetroja (cefiderocol) - Assessment report</a>
Authorised	EMA/H/C/005169	Obiltoxaximab SFL	Translation exemption (outer labelling and package leaflet)	Positive (partial)			08/Oct/19	<a href="#">Obiltoxaximab SFL (obiltoxaximab) - Product information</a>	<a href="#">Obiltoxaximab SFL (obiltoxaximab) - Assessment report</a>
Authorised	EMA/H/C/005830	Roctavian	Translation exemption (outer labelling and package leaflet)	Positive (partial)			08/Oct/19	<a href="#">ROCTAVIAN (valoctocogene roxaparvovec) - Product information</a>	<a href="#">Roctavian (valoctocogene roxaparvovec) - Assessment report</a>
Authorised	EMA/H/C/005205	Zynrelef			Omission of particulars (immediate labelling)	Positive	08/Oct/19	<a href="#">Zynrelef (bupivacaine/meloxicam) - Product information</a>	<a href="#">Zynrelef (bupivacaine/meloxicam) - Assessment report</a>
Authorised	EMA/H/C/003860/N/0027	Nucala			Omission of particulars (immediate labelling)	Positive	08/Oct/19	<a href="#">Nucala (mepolizumab) - Product information</a>	N/A
Authorised	EMA/H/C/004808	Recarbrio			Omission of particulars (immediate labelling)	Positive	08/Oct/19	<a href="#">Recarbrio (imipenem/cilastatin/relebactam) - Product information</a>	<a href="#">Recarbrio (imipenem/cilastatin/relebactam) - Assessment report</a>
Authorised	EMA/H/C/004750	Zolgensma	Translation exemption (outer and immediate labelling)	Positive (partial)			26/Mar/19	<a href="#">Zolgensma (Onasemnogene abeparvovec) - Product information</a>	<a href="#">Zolgensma (Onasemnogene abeparvovec) - Assessment report</a>
Authorised	EMA/H/C/005407	Sibnaya	Translation exemption (outer and immediate labelling)	Positive			26/Mar/19	<a href="#">Sibnaya (potassium citrate and potassium hydrogen carbonate) - Product information</a>	<a href="#">Sibnaya (potassium citrate and potassium hydrogen carbonate) - Assessment report</a>
Authorised	EMA/H/C/005830	Roctavian	Translation exemption (outer and immediate labelling)	Positive (partial)	Omission of particulars (immediate labelling)	Negative	26/Mar/19	<a href="#">ROCTAVIAN (valoctocogene roxaparvovec) - Product information</a>	<a href="#">Roctavian (valoctocogene roxaparvovec) - Assessment report</a>
Authorised	EMA/H/C/004282	Vyxeos liposomal	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)			09/Oct/18	<a href="#">Vyxeos liposomal (daunorubicin/cytarabine) - Product information</a>	N/A
Authorised	EMA/H/C/005407	Sibnaya	Translation exemption (outer and immediate labelling)	Positive			09/Oct/18	<a href="#">Sibnaya (potassium citrate and potassium hydrogen carbonate) - Product information</a>	<a href="#">Sibnaya (potassium citrate and potassium hydrogen carbonate) - Assessment report</a>
Authorised	EMA/H/C/004275	Crysvita	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)	Omission of particulars (outer labelling)	Positive	Oct/17	<a href="#">Crysvita (busurumab) - Product information</a>	<a href="#">Crysvita (busurumab) - Assessment report</a>



15 July 2024  
EMA/934543/2022 Rev. 4  
Human Medicines Division

## Table of decisions of labelling exemption requested with the aim to create multilingual packages and examined by the Quality Review of Documents (QRD) Group

### Related information

[Exemptions to labelling and package-leaflet obligations | European Medicines Agency](#)

[Recommendations for the implementation of the exemptions to the labelling and package leaflet obligations in the centralised procedure](#)

MA status	Product number	Product name	Request for omission of particulars	Outcome request for omission of particulars	Request for translation exemption	Outcome translation exemption	Outcome date	Product information	Assessment report
Authorised	EMA/H/C/005962/X/0002	Teriflunomide Accord	Omission of particulars (immediate labelling)	Positive			07/Mar/24	N/A	<a href="#">Teriflunomide Accord (teriflunomide)</a>
Authorised	EMA/H/C/006208	Apremilast Accord	Omission of particulars (immediate labelling)	Negative			21/Nov/23	<a href="#">Apremilast Accord (apremilast) - Assessment report</a>	<a href="#">Apremilast Accord (apremilast) - Product information</a>
Authorised	EMA/H/C/004936/X/0017	Rozlytrek			Translation exemption (immediate labelling)	Positive	21/Nov/23	<a href="#">Rozlytrek (entrectinib) - Product information</a>	<a href="#">Rozlytrek (entrectinib) - Assessment report</a>
Authorised	EMA/H/C/000378/N/0086	Axura	Omission of particulars (immediate labelling)	Positive			21/Nov/23	<a href="#">Axura (memantine hydrochloride) - Product information</a>	N/A
Authorised	EMA/H/C/002711/N/0021	Memantine Merz	Omission of particulars (immediate labelling)	Positive			21/Nov/23	<a href="#">Memantine Merz (memantine hydrochloride) - Product information</a>	N/A
Authorised	EMA/H/C/005107/N/0022	Roclanda	Omission of particulars (immediate labelling)	Positive			21/Nov/23	<a href="#">Roclanda (netarsudil mesylate/latanoprost) - Product information</a>	N/A
Authorised	EMA/H/C/004904/IB/0016	Miglustat Dipharma			Translation exemption (immediate labelling)	Positive	14/Jun/23	<a href="#">Miglustat Dipharma (miglustat) - Product information</a>	N/A
Authorised	EMA/H/C/005517	Voydeya	Omission of particulars (immediate labelling)	Positive			14/Jun/23	<a href="#">Voydeya (danicopan) - Product information</a>	<a href="#">Voydeya (danicopan) - Assessment report</a>
Authorised	EMA/H/C/004452/X/0028	Erleada	Omission of particulars (immediate labelling)	Positive			10/Mar/23	<a href="#">Erleada, INN - apalutamide (europa.eu)</a>	<a href="#">Erleada (apalutamide) - Assessment report</a>
Authorised	EMA/H/C/000697	Suboxone	Omission of particulars (immediate labelling)	Positive			13/Oct/22	<a href="#">Suboxone (naloxone) - Product information</a>	N/A
Authorised	EMA/H/C/005843	Opzelura	Omission of particulars (immediate labelling)	Positive (partial)			13/Oct/22	<a href="#">Opzelura (ruxolitinib) - Product information</a>	<a href="#">Opzelura (Ruxolitinib) - Assessment report</a>
Authorised	EMA/H/C/005361	Akeega	Omission of particulars (immediate labelling)	Positive			14/Jun/22	<a href="#">Akeega (niraparib/abiraterone acetate) - Product information</a>	N/A
Authorised	EMA/H/C/002465/X/0035	Procysbi	Omission of particulars (immediate labelling)	Positive	Translation exemption (immediate labelling)	Positive	16/Nov/21	<a href="#">Procysbi (mercaptamine bitartrate) - Product information</a>	N/A
Authorised	EMA/H/C/005367	Skytrofa	Omission of particulars (immediate labelling)	Positive (partial)			17/Jun/21	<a href="#">Skytrofa (lonapegsomatropin) - Product information</a>	<a href="#">Skytrofa (lonapegsomatropin) - Assessment report</a>
Authorised	EMA/H/C/000610/X/0063	Noxafil	Omission of particulars (immediate labelling)	Positive			17/Jun/21	<a href="#">Noxafil (posaconazole) - Product information</a>	N/A
Authorised	EMA/H/C/005267	Ryeqo	Omission of particulars (immediate labelling)	Positive			04/Mar/21	<a href="#">Ryeqo (Relugolix/Estradiol/Norethisterone acetate) - Product information</a>	N/A
Authorised	EMA/H/C/005117	Ozawade	Omission of particulars (outer and immediate labelling)	Positive			04/Mar/21	<a href="#">Ozawade (Pitolisant) - Product information</a>	<a href="#">Ozawade (Pitolisant) - Assessment report</a>
Authorised	EMA/H/C/005208	Ayvakyt	Omission of particulars (immediate labelling)	Negative			20/Jun/20	<a href="#">AYVAKYT (avapritinib) - Product information</a>	N/A

Authorised	EMA/H/C/004835	Zeposia	Omission of particulars (immediate labelling)	Positive (partial)	08/Oct/19	<a href="#">Zeposia (ozanimod) - Product information</a>	<a href="#">Zeposia (ozanimod) - Public assessment report</a>
Authorised	EMA/H/C/005243	Lacosamide UCB	Omission of particulars (immediate labelling)	Positive	08/Oct/19	<a href="#">Lacosamide UCB (lacosamide) - Product information</a>	N/A
Authorised	EMA/H/C/004452	Erleada	Omission of particulars (immediate labelling)	Positive	09/Oct/18	<a href="#">Erleada (apalutamide) - Product information</a>	<a href="#">Erleada (apalutamide) - Public assessment report</a>