

30 June 2026
EMA/934543/2022 Rev. 8
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

<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/exemptions-labelling-package-leaflet-obligations#guidance-on-labelling-and-package-leaflet-exer>

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/recommendations-implementation-exemptions-labelling-and-package-leaflet-obligations-centralised-procedure_en.pdf

MA status	Product number	Product name	Article 63(1) request (orphan products) ²	Outcome 63(1) orphan products ²	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	Variation Type IB / EMA/VR/0000326537 (EMA/H/C/002280)	Giotrif			Omission of particulars (immediate labelling)	Positive			23-Mar-26	Giotrif (afatinib) - Product information	N/A
Authorised	Variation Type II / EMA/VR/0000312940 (EMA/H/C/004077)	Darzalex			Omission of particulars (outer labelling)	Positive			04-Mar-26	Darzalex (daratumumab) - Product information	N/A
Authorised	Notification 61(3) / EMA/N/0000348639 (EMA/H/C/004441)	Pazenir			Omission of particulars (immediate labelling)	Positive			04-Mar-26	Pazenir (paclitaxel) - Product information	N/A
Authorised	EMA/H/C/006472	mCOMBRIAX			Omission of particulars (outer labelling)	Positive			25-Dec-26	mCOMBRIAX (Influenza and COVID-19 mRNA vaccine) - Product information	mcombriax-epar-public-assessment-report_en.pdf
Authorised	EMA/H/C/006673	Zepzelca			Omission of particulars (immediate labelling)	Positive			27-Jan-26	ZEPZELCA (lurbinectedin) - Product information	Zepzelca (lurbinectedin) - Assessment report
Authorised	EMA/H/C/006583	Poherdy			Omission of particulars (immediate labelling)	Positive			12-Jan-26	Poherdy (pertuzumab) - Product information	N/A
Authorised	EMA/H/C/006428	mNEXSPIKE			Omission of particulars (outer labelling)	Positive			09-Dec-25	mNEXSPIKE (COVID-19 mRNA Vaccine) - Product information	mNEXSPIKE (COVID-19 mRNA Vaccine) - Assessment report
Authorised	EMA/H/C/006525	Waskyra	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)	Omission of particulars (immediate labelling)	Positive			05-Nov-25	Waskyra; INN: etuvetidigene autotemcel	N/A
Authorised	EMA/H/C/004974/X/0022	Xofluza			Omission of particulars (immediate labelling)	Positive	Translation exemption (immediate labelling)	Positive	05-Sep-25	Xofluza (baloxavir marboxil) - Product information	N/A
Authorised	EMA/H/C/003981	Duloxetine Viatris			Omission of particulars (outer labelling)	Positive			03-Sep-25	Duloxetine Viatris (duloxetine) - Product information	N/A
Authorised	EMA/H/C/006079	Duvyzat	Translation exemption (outer, immediate labelling and package leaflet)	Positive					07-Jul-25	Duvyzat (givinostat) - Product information	N/A
Authorised	EMA/H/C/005119	Kygevvi	Translation exemption (immediate labelling)	Positive					05-Jun-25	KYGEVVI (doxorubicin/doxorubicin) - Product information	N/A
Authorised	EMA/H/C/005454/X/0014	Rybrevant			Omission of particulars (immediate labelling)	Positive			05-Jun-25	Rybrevant (amivantamab) - Product information	N/A
Authorised	EMA/H/C/003981	Duloxetine Viatris			Omission of particulars (outer labelling)	Positive			07-Mar-25	Duloxetine Viatris (duloxetine) - Product information	N/A
Authorised	EMA/H/C/005454/X/0014	Rybrevant			Omission of particulars (immediate labelling)	Positive			07-Feb-25	Rybrevant (amivantamab) - Product information	N/A
Authorised	EMA/H/C/005907	Aucatzyl	Translation exemption (outer and immediate labelling)	Positive	Omission of particulars (immediate labelling)	Positive			05-Mar-25	Aucatzyl (obecabtagene autoleucl) - Product information	Aucatzyl (obecabtagene autoleucl) - Assessment report

Authorised	EMA/H/C/005934	Yorvipath	Translation exemption (outer, intermediate and immediate labelling)	Positive			05-Mar-25	Yorvipath (palopegteriparatide) - Product information	N/A	
Authorised	EMA/H/C/006396	Tepezza			Omission of particulars (immediate labelling)	Positive	05-Mar-25	Tepezza (teprotumumab) - Product information	Tepezza (teprotumumab) - Assessment report	
Authorised	EMA/H/C/005772	Zemcelpro	Translation exemption (outer labelling)	Positive		Translation exemption (immediate labelling and package leaflet)	Positive (partial)	05-Mar-25	Zemcelpro - Product information	Zemcelpro - Assessment report
Authorised	EMA/H/C/006330	Vyjuvek	Translation exemption (outer and immediate labelling)	Positive (partial)				07-Nov-24	Vyjuvek (beremagene geperpavec) - Product information	Vyjuvek (beremagene geperpavec) - Assessment report
Authorised	EMA/H/C/00610/X/0001	Uzpruvo			Omission of particulars (immediate labelling)	Positive		07-Nov-24	Uzpruvo (ustekinumab) - Product information	N/A
Authorised	EMA/H/C/04312/X/0038	Spinraza	Translation exemption (immediate labelling)	Positive				07-Nov-24	Spinraza (nusinersen) - Assessment report	N/A
Authorised	EMA/H/C/005119	Kygevvi	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)				07-Nov-24	KYGEVVI (doxectine/doxribtimine) - Product information	N/A
Authorised	EMA/H/C/006370	Lynozytic			Omission of particulars (immediate labelling)	Positive		07-Nov-24	Lynozytic (linvoseltamab) - Product information	N/A
Authorised	EMA/H/C/006380	Ziihera			Omission of particulars (immediate labelling)	Positive		07-Nov-24	Ziihera (zanidatamab) - Product information	N/A
Authorised	EMA/H/C/006363	Romvimza	Translation exemption (intermediate labelling)	Positive (partial)	Omission of particulars (immediate labelling)	Positive		07-Nov-24	Romvimza (vimseltinib) - Product information	N/A
Authorised	EMA/H/C/005882	Theralugand			Omission of particulars (outer and immediate labelling)	Positive (partial)		13-Sep-24	Theralugand (lutetium (177Lu) chloride) - Product information	Theralugand (lutetium (177Lu) chloride) - Assessment report
Authorised	EMA/H/C/005849/II/0022/G	Vyvgart	Translation exemption (immediate labelling)	Positive				23-Sep-24	Vyvgart (efgartigimod alfa) - Product information	N/A
Authorised	EMA/H/C/006544	Otulfi			Omission of particulars (immediate labelling)	Positive		26-Jun-24	Otulfi (ustekinumab) - Product information	Otulfi (ustekinumab) - Assessment report
Authorised	EMA/H/C/005805	Fymskina			Omission of particulars (immediate labelling)	Positive		26-Jun-24	Fymskina (ustekinumab) - Product information	Fymskina (ustekinumab) - Assessment report
Authorised	EMA/H/C/006123	Gohibic			Omission of particulars (immediate labelling)	Positive		26-Jun-24	Gohibic (vilobelimab) - Product information	N/A
Authorised	EMA/H/C/006215	Ordspono			Omission of particulars (immediate labelling)	Positive		08-May-24	Ordspono (odronextamab) - Product information	Ordspono (odronextamab) - Assessment report
Authorised	EMA/H/C/004043/X/0039	Ocrevus			Omission of particulars (immediate labelling)	Positive		08-Apr-24	Ocrevus (ocrelizumab) - Product information	Ocrevus (ocrelizumab) - Assessment report (europa.eu)
Authorised	EMA/H/C/006024	Kisunla			Omission of particulars (immediate labelling)	Positive		07-Mar-24	Kisunla (donanemab) - Product information	Kisunla (donanemab) - Assessment report
Authorised	EMA/H/C/005352	Upstaza	Translation exemption (outer and immediate labelling)	Positive (partial)	Omission of particulars (immediate labelling)	Positive (partial)		07-Mar-24	Upstaza (eladocagene exuparvovec) - Product information	N/A
Authorised	EMA/H/C/006231	Iqirvo	Translation exemption (outer and immediate labelling)	Positive				07-Mar-24	Iqirvo (Elafibranor) - Product information	Iqirvo (elafibranor) - Assessment report
Authorised	EMA/H/C/005919/II/0002	Tevimbra			Omission of particulars (immediate labelling)	Positive		27-Feb-24	Tevimbra (tislelizumab) - Product information	N/A
Authorised	EMA/H/C/006064	Tauvid			Omission of particulars (immediate labelling)	Positive		21-Dec-23	Tauvid (flortaucipir (18F)) - Product information	Tauvid (flortaucipir (18F)) - Assessment report
Authorised	EMA/H/C/004275/II/0035	Crysvita	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)	Omission of particulars (outer labelling)	Positive		07-Mar-24	Crysvita (burosumab) - Product information	N/A

Authorised	EMA/H/C/006113	Emblaveo		Omission of particulars (immediate labelling)	Positive		31-Jan-24	Emblaveo (aztreonam/avibactam) - Product information	Emblaveo (aztreonam/avibactam) - Assessment report
Authorised	EMA/H/C/002264/X/0042	Edurant		Omission of particulars (immediate labelling)	Positive		22-Dec-23	Edurant (rilpivirine) - Product information	N/A
Authorised	EMA/H/C/005269/X/0033	Kafrio	Translation exemption (outer, intermediate and immediate labelling)		Positive (partial)		21-Nov-23	Kafrio (elxacaftor/tezacaftor/ivacaftor) - Product information	N/A
Authorised	EMA/H/C/005036	Elahere	Translation exemption (outer and immediate labelling)		Positive (partial)	Omission of particulars (immediate labelling)	21-Nov-23	Elahere (mirvetuximab soravtansine) - Product information	Elahere (mirvetuximab soravtansine) - Assessment report
Authorised	EMA/H/C/006231	Iqirvo	Translation exemption (outer and immediate labelling)		Negative	Omission of particulars (immediate labelling)	21-Nov-23	Iqirvo (elafibranor) - Product information	Iqirvo (elafibranor) - Assessment report
Authorised	EMA/H/C/002552	Delyba	Translation exemption (outer, immediate labelling and package leaflet)		Positive (partial)		21-Nov-23	Delyba (delamanid) - Product information	N/A
Authorised	EMA/H/C/005220	Emcitate	Translation exemption (outer, immediate labelling and package leaflet)		Positive (partial)		21-Nov-23	Emcitate (tiratricol) - Product information	Emcitate (tiratricol) - Assessment report
Authorised	EMA/H/C/005984	Tofidence		Omission of particulars (immediate labelling)	Positive		21-Nov-23	Tofidence (tocilizumab) - Product information	Tofidence (tocilizumab) - Assessment report
Authorised	EMA/H/C/006194	Zynyz		Omission of particulars (immediate labelling)	Positive		21-Nov-23	Zynyz (retifanlimab) - Product information	Zynyz (retifanlimab) - Assessment report
Authorised	EMA/H/C/005900	Rezzayo		Omission of particulars (immediate labelling)	Positive		30-Aug-23	Rezzayo (rezafungin) - Product information	N/A
Authorised	EMA/H/C/005933	Catiolanze		Omission of particulars (immediate labelling)	Positive		13-Jul-23	Catiolanze (latanoprost) - Product information	N/A
Authorised	EMA/H/C/005756	Apretude		Omission of particulars (immediate labelling)	Positive (partial)		03-Jul-23	Apretude, (cabotegravir) - Product information	Apretude (cabotegravir) - Assessment report
Authorised	EMA/H/C/006185	Niapelf		Omission of particulars (immediate labelling)	Positive		14-Jun-23	Niapelf (paliperidone) - Product information	N/A
Authorised	EMA/H/C/005985	Tepkinly	Translation exemption (outer, immediate labelling and package leaflet)		Positive (partial)		14-Jun-23	Tepkinly (epcoritamab) - Product information	Tepkinly (epcoritamab) - Assessment report
Authorised	EMA/H/C/005849/X/0003	Vyvgart	Translation exemption (outer labelling)		Positive		10-Mar-23	Vyvgart (efgartigimod alfa) - Product information	Vyvgart (efgartigimod alfa) - Assessment report
Authorised	EMA/H/C/005493	Qalsody		Omission of particulars (immediate labelling)	Positive		10-Mar-23	Qalsody (tofersen) - Product information	Qalsody (tofersen) - Assessment report
Authorised	EMA/H/C/005927	Joenja	Translation exemption (outer labelling)		Positive		20-Dec-22	Joenja (leniolisib) - Product information	Joenja (leniolisib) - Assessment report
Authorised	EMA/H/C/005122	Omvoh		Omission of particulars (immediate labelling)	Positive		04-Jan-23	Omvoh (mirikizumab) - Product information	Omvoh (mirikizumab) - Assessment report
Authorised	EMA/H/C/004258	Alofisel		Omission of particulars (outer labelling)	Positive (temporary)		17-Nov-22	Alofisel (darvadstrocel) - Product information	N/A
Authorised	EMA/H/C/005343	Mvabea		Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	26-Oct-22	Mvabea (Ebola vaccine (MVA BN Filo [recombinant])) - Product information	N/A
Authorised	EMA/H/C/005337	Zabdeno		Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	26-Oct-22	Zabdeno (Ad26.ZEBOV-GP [recombinant]) - Product information	N/A
Authorised	EMA/H/C/005343	Mvabea		Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	13-Oct-22	Mvabea (Ebola vaccine (MVA BN Filo [recombinant])) - Product information	N/A
Authorised	EMA/H/C/005337	Zabdeno		Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	13-Oct-22	Zabdeno (Ad26.ZEBOV-GP [recombinant]) - Product information	N/A

Authorised	EMA/H/C/005484	Loargys	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)				13-Oct-22	Loargys (pegzilarginase) - Product information	Loargys (pegzilarginase) - Assessment report	
Authorised	EMA/H/C/005703	Pombiliti			Omission of particulars (immediate labelling)	Positive		13-Oct-22	Pombiliti (cipaglucoosidase alfa) - Product information	Pombiliti (cipaglucoosidase alfa) - Assessment report	
Authorised	EMA/H/C/005695	Opfolda			Omission of particulars (immediate labelling)	Positive		13-Oct-22	Opfolda (miglustat) - Product information	N/A	
Authorised	EMA/H/C/006016	Imjudo			Omission of particulars (immediate labelling)	Positive		13-Oct-22	IMJUDO - Product information	Imjudo - Assessment report	
Authorised	EMA/H/C/004650	Tremelimumab AstraZeneca			Omission of particulars (immediate labelling)	Positive		13-Oct-22	Tremelimumab AstraZeneca - Product information	Tremelimumab AstraZeneca - Assessment report	
Authorised	EMA/H/C/005927	Joenja	Translation exemption (outer and immediate labelling)	Positive (partial)				13-Oct-22	Joenja (leniolisib) - Product information	Joenja (leniolisib) - Assessment report	
Authorised	EMA/H/C/004974/X/0008	Xofluza			Omission of particulars (immediate labelling)	Positive		14-Sep-22	Xofluza (baloxavir marboxil) - Product information	N/A	
Authorised	EMA/H/C/005776	Enjaymo					Translation exemption (outer, immediate labelling and package leaflet)	Positive	13-Sep-22	Enjaymo (Sutimlimab) - Product information	N/A
Authorised	EMA/H/C/005035	Filsuvez			Omission of particulars (immediate labelling)	Positive		08-Aug-22	Filsuvez (birch bark extract) - Product information	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	Hemgenix - Product information	Hemgenix - Assessment report	
Authorised	EMA/H/C/005751	Columvi			Omission of particulars (immediate labelling)	Positive		14-Jun-22	Columvi, INN-glofitamab (europa.eu)	N/A	
Authorised	EMA/H/C/005858	Akantior	Translation exemption (intermediate and immediate labelling)	Positive (partial)				14-Jun-22	Akantior (polihexanide) - Product information	Akantior (polihexanide) - Assessment report	
Authorised	EMA/H/C/005848	Pemetrexed Baxter			Omission of particulars (immediate labelling)	Positive		14-Jun-22	Pemetrexed Baxter - Product information	Pemetrexed Baxter - Assessment report	
Authorised	EMA/H/C/005246/X/0002	Byfavo			Omission of particulars (immediate labelling)	Negative		14-Jun-22	Byfavo - Product information	N/A	
Authorised	EMA/H/C/005815	Ertapenem SUN			Omission of particulars (immediate labelling)	Positive		11-May-22	Ertapenem SUN (ertapenem) - Product information	Ertapenem SUN (ertapenem) - Assessment report	
Authorised	EMA/H/C/004850	Xenpozyme	Translation exemption (outer, immediate labelling and package leaflet)	Positive				12-Apr-22	Xenpozyme (olipudase alfa) - Product information	Xenpozyme (olipudase alfa) - Assessment report	
Authorised	EMA/H/C/005769	Herwenda			Omission of particulars (immediate labelling)	Positive		10-Mar-22	Herwenda (trastuzumab) - Product information	N/A	
Authorised	EMA/H/C/005540	Pyrukynd	Translation exemption (outer, intermediate and immediate labelling)	Positive (partial)				10-Mar-22	Pyrukynd - Product information	N/A	
Authorised	EMA/H/C/005680	Lunsumio			Omission of particulars (immediate labelling)	Positive	Translation exemption (outer labelling)	Positive	10-Mar-22	Lunsumio (mosunetuzumab) - Product information	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	Ebvallo - Product information	Ebvallo - Assessment report	
Authorised	EMA/H/C/004929	Kimtrak	Translation exemption (outer and immediate labelling)	Positive				16-Nov-21	Kimtrak (tebentafusp) - Product information	Kimtrak (tebentafusp) - Assessment report	
Authorised	EMA/H/C/005378	Nulibry	Translation exemption (outer and immediate labelling)	Positive (partial)				16-Nov-21	Nulibry - Product information	N/A	
Authorised	EMA/H/C/005849	Vyvgart			Omission of particulars (outer and immediate labelling)	Positive (partial)		16-Nov-21	Vyvgart (efgartigimod alfa) - Product information	Vyvgart (efgartigimod alfa) - Assessment report	

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	Paxlovid (nirmatrelvir + ritonavir) - Product information	Paxlovid (nirmatrelvir + ritonavir) - Assessment report
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	Evusheld (ixagevimab, cilgavimab) - Product information	N/A
Authorised	EMA/H/C/005553	Aspaveli		Omission of particulars (immediate labelling)	Positive			08-Oct-21	Aspaveli (pegcetacoplan) - Product information	Aspaveli (pegcetacoplan) - Assessment report
Authorised	EMA/H/C/005814	Ronapreve		Omission of particulars (immediate labelling)	Positive			24-Sep-21	Ronapreve (casirivimab and imdevimab) - Product information	Ronapreve (casirivimab and imdevimab) - Assessment report
Authorised	EMA/H/C/005550	Artesunate Amivas	Translation exemption (outer, immediate labelling and package leaflet)		Positive (partial)			14-Sep-21	Artesunate Amivas (artesunate) - Product information	Artesunate Amivas (Artesunate) - Assessment report
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	Regkirona (regdanvimab) - Product information	Regkirona (regdanvimab) - Assessment report
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	Xevudy (sotrovimab) - Product information	Xevudy (sotrovimab) - Assessment report
Authorised	EMA/H/C/005182	Trodelvy		Omission of particulars (immediate labelling)	Positive			17-Jun-21	Trodelvy (sacituzumab govitecan) - Product information	Trodelvy (sacituzumab govitecan) - Assessment report
Authorised	EMA/H/C/005681	Pepaxti		Omission of particulars (immediate labelling)	Positive			17-Jun-21	Pepaxti (melphalan flufenamide) - Product information	N/A
Authorised	EMA/H/C/005035	Filsuvez	Translation exemption (outer, intermediate, immediate labelling and package leaflet)		Positive (partial)			17-Jun-21	Filsuvez (birch bark extract) - Product information	N/A
Authorised	EMA/H/C/005095	Carvykti	Translation exemption (outer and immediate labelling)		Positive			17-Jun-21	Carvykti (Ciltacabtagene autoleucl) - Product information	Carvykti (ciltacabtagene autoleucl) - Assessment report
Authorised	EMA/H/C/005467	Voraxaze	Translation exemption (outer, intermediate, immediate labelling and package leaflet)		Positive (partial)			17-Jun-21	Voraxaze (glucarpidase) - Product information	Voraxaze (glucarpidase) - Assessment report
Authorised	EMA/H/C/005501	Nexviadyme		Omission of particulars (immediate labelling)	Positive			17-Jun-21	Nexviadyme (avalglucosidase alfa) - Product information	Nexviadyme (avalglucosidase alfa) - Assessment report
Authorised	EMA/H/C/004662	Abecma		Omission of particulars (outer and immediate labelling)	Positive (partial)			03-Jun-21	Abecma (idecabtagene vicleucl) - Product information	Abecma (idecabtagene vicleucl) - Assessment report
Authorised	EMA/H/C/004275/II/0021	Crysvita	Translation exemption (outer, immediate labelling and package leaflet)		Positive			06-May-21	Crysvita (burosumab) - Product information	N/A
Authorised	EMA/H/C/005475	Voxzogo	Translation exemption (outer and immediate labelling)		Positive (partial)			04-Mar-21	Voxzogo (vosoritide) - Product information	Voxzogo (vosoritide) - CHMP assessment report
Authorised	EMA/H/C/005737	Jcovden		Omission of particulars (outer, immediate labelling and package leaflet)	Positive	Translation exemption (outer, immediate labelling and package leaflet)	Positive	01-Mar-21	JCOVDEN [COVID-19 vaccine (Ad26.COV2-S [recombinant])] - Product information	JCOVDEN [COVID-19 Vaccine Janssen (Ad26.COV2-S, recombinant)] - Assessment report
Authorised	EMA/H/C/005327	Abevmy		Omission of particulars (immediate labelling)	Positive			13-Jan-21	Abevmy (bevacizumab) - Product information	Abevmy (bevacizumab) - Assessment report
Authorised	EMA/H/C/005791	Spikevax		Omission of particulars (outer, immediate labelling and package leaflet)	Positive	Translation exemption (outer, immediate labelling and package leaflet)	Positive	01-Jan-21	Spikevax - Product information	Spikevax - Assessment report
Authorised	EMA/H/C/005735	Comirnaty		Omission of particulars (outer and immediate labelling)	Positive	Translation exemption (outer and immediate labelling)	Positive	17-Dec-20	Comirnaty (tozinameran, tozinameran/ritozinameran, tozinameran/famtozinameran) - Product information	Comirnaty (tozinameran, tozinameran/ritozinameran, tozinameran/famtozinameran) - Assessment report
Authorised	EMA/H/C/005286	Alymsis		Omission of particulars (immediate labelling)	Positive			20-Oct-20	Alymsys (bevacizumab) - Product information	N/A
Authorised	EMA/H/C/005556	Oyavas		Omission of particulars (immediate labelling)	Positive			20-Oct-20	Oyavas (bevacizumab) - Product information	N/A
Authorised	EMA/H/C/005145	Evrysdi		Omission of particulars (immediate labelling)	Negative			20-Oct-20	Evrysdy (risdiplam) - Product information	Evrysdy (risdiplam) - Assessment report

Authorised	EMA/H/C/005089	Imcivree	Translation exemption (outer and immediate labelling)	Positive		20-Oct-20	Imcivree (setmelanotide) - Product information	Imcivree (setmelanotide) - Assessment report	
Authorised	EMA/H/C/004662	Abecma			Omission of particulars (outer and intermediate labelling)	Positive (partial)	20-Oct-20	Abecma (idecabtagene vicleucel) - Product information	Abecma (decabtagene vicleucel) - Assessment report
Authorised	EMA/H/C/004731	Breyanzi			Omission of particulars (outer and intermediate labelling)	Positive (partial)	20-Oct-20	Breyanzi (lisocabtagene maraleucel) - Product information	N/A
Authorised	EMA/H/C/005386	Phesgo			Omission of particulars (immediate labelling)	Positive	13-Oct-20	Phesgo (pertuzumab/trastuzumab) - Product information	Phesgo (pertuzumab / trastuzumab) - Assessment report
Authorised	EMA/H/C/005102	Tecartus			Omission of particulars (immediate labelling)	Positive	05-Oct-20	Tecartus (autologous anti-CD19-transduced CD3+ cells) - Product information	Tecartus (autologous anti-CD19-transduced CD3+ cells) - Assessment report
Authorised	EMA/H/C/005675	Vaxzevria			Omission of particulars (outer and immediate labelling)	Positive	07-Jul-20	Vaxzevria - Product information	Vaxzevria - Assessment report
Authorised	EMA/H/C/005246	Byfavo			Omission of particulars (immediate labelling)	Positive	16-Jun-20	Byfavo (remimazolam) - Product information	Byfavo (remimazolam) - Assessment report
Authorised	EMA/H/C/004586	Exparel liposomal			Omission of particulars (immediate labelling)	Positive	16-Jun-20	Exparel liposomal (bupivacaine) - Product information	Exparel liposomal (bupivacaine) - Assessment report
Authorised	EMA/H/C/004954/X/0004/G	Ultomiris			Omission of particulars (immediate labelling)	Positive	16-Jun-20	Ultomiris (ravulizumab) - Product information	N/A
Authorised	EMA/H/C/004976	Vocabria			Omission of particulars (immediate labelling)	Positive	16-Jun-20	Vocabria (cabotegravir) - Product information	N/A
Authorised	EMA/H/C/005060	Rekambyl			Omission of particulars (immediate labelling)	Positive	16-Jun-20	Rekambyl (rilpivirine) - Product information	N/A
Authorised	EMA/H/C/005436	Minjuvi			Omission of particulars (immediate labelling)	Positive	16-Jun-20	Minjuvi (tafasitamab) - Product information	N/A
Authorised	EMA/H/C/005681	Pepaxti			Omission of particulars (immediate labelling)	Positive	16-Jun-20	Pepaxti (melphalan flufenamide) - Product information	N/A
Authorised	EMA/H/C/004379	Amglicia	Translation exemption (outer, immediate labelling and package leaflet)	Negative			16-Jun-20	Amglicia (glibenclamide) - Product information	N/A
Authorised	EMA/H/C/005271	Zokinvy	Translation exemption (outer, immediate labelling and package leaflet)	Positive			16-Jun-20	Zokinvy (lonafarnib) - Product information	N/A
Authorised	EMA/H/C/002393	Defitelio	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)			16-Jun-20	Defitelio (defibrotide) - Product information	N/A
Authorised	EMA/H/C/005622	Veklury			Omission of particulars (immediate labelling)	Positive	15-May-20	Veklury (remdesivir) - Product information	Veklury (remdesivir) - Assessment report
Authorised	EMA/H/C/005269	Kaftrio	Translation exemption (outer, intermediate, immediate labelling and package leaflet)	Positive (partial)			22-May-20	Kaftrio (elexacaftor/tezacaftor/ivacaftor) - Product information	N/A
Authorised	EMA/H/C/005167	Dovprela	Translation exemption (outer and immediate labelling)	Positive			27-Mar-20	Dovprela (pretomanid) - Product information	Dovprela (pretomanid) - Assessment report
Authorised	EMA/H/C/004077/X/0032	Darzalex			Omission of particulars (immediate labelling)	Positive	20-Mar-20	Darzalex (daratumumab) - Product information	N/A
Authorised	EMA/H/C/002614	Sirturo	Translation exemption (outer and immediate labelling)	Positive			03-Mar-20	Sirturo (bedaquiline) - Product information	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	Libmeldy (atidarsagene autotemcel) - Product information	Libmeldy (atidarsagene autotemcel) - Assessment report
Authorised	EMA/H/C/004849	Idefixir	Translation exemption (outer and immediate labelling)	Positive			03-Mar-20	Idefixir (imlifidase) - Product information	Idefixir (imlifidase) - Assessment report

Authorised	EMA/H/C/000829/X/0122/G	Pradaxa			Omission of particulars (immediate labelling)	Positive	03-Mar-20	Pradaxa (dabigatran etexilate) - Product information	Pradaxa (dabigatran etexilate) - Assessment report
Authorised	EMA/H/C/003855	Coagadex	Translation exemption (outer, immediate labelling and package leaflet)	Positive			03-Mar-20	Coagadex (human coagulation factor X) - Product information	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	Upstaza (eladocagene exuparvovec) - Product information	Upstaza (eladocagene exuparvovec) - Assessment report
Authorised	EMA/H/C/003855	Coagadex	Translation exemption (outer and immediate labelling)	Positive			13-Jan-20	Coagadex (human coagulation factor X) - Product information	N/A
Authorised	EMA/H/C/004829	Fetroja			Omission of particulars (immediate labelling)	Positive	19-Nov-19	Fetroja (cefiderocol) - Product information	Fetroja (cefiderocol) - Assessment report
Authorised	EMA/H/C/005169	Obiltoxaximab SFL	Translation exemption (outer labelling and package leaflet)	Positive (partial)			08-Oct-19	Obiltoxaximab SFL (obiltoxaximab) - Product information	Obiltoxaximab SFL (obiltoxaximab) - Assessment report
Authorised	EMA/H/C/005830	Roctavian	Translation exemption (outer labelling and package leaflet)	Positive (partial)			08-Oct-19	ROCTAVIAN (valoctocogene roxaparvovec) - Product information	Roctavian (valoctocogene roxaparvovec) - Assessment report
Authorised	EMA/H/C/005205	Zynrelef			Omission of particulars (immediate labelling)	Positive	08-Oct-19	Zynrelef (bupivacaine/meloxicam) - Product information	Zynrelef (bupivacaine/meloxicam) - Assessment report
Authorised	EMA/H/C/003860/N/0027	Nucala			Omission of particulars (immediate labelling)	Positive	08-Oct-19	Nucala (mepolizumab) - Product information	N/A
Authorised	EMA/H/C/004808	Recarbrio			Omission of particulars (immediate labelling)	Positive	08-Oct-19	Recarbrio (imipenem/cilastatin/relebactam) - Product information	Recarbrio (imipenem/cilastatin/relebactam) - Assessment report
Authorised	EMA/H/C/004750	Zolgensma	Translation exemption (outer and immediate labelling)	Positive (partial)			26-Mar-19	Zolgensma (Onasemnogene abeparvovec) - Product information	Zolgensma (Onasemnogene abeparvovec) - Assessment report
Authorised	EMA/H/C/005407	Sibnaya	Translation exemption (outer and immediate labelling)	Positive			26-Mar-19	Sibnaya (potassium citrate and potassium hydrogen carbonate) - Product information	Sibnaya (potassium citrate and potassium hydrogen carbonate) - Assessment report
Authorised	EMA/H/C/005830	Roctavian	Translation exemption (outer and immediate labelling)	Positive (partial)	Omission of particulars (immediate labelling)	Negative	26-Mar-19	ROCTAVIAN (valoctocogene roxaparvovec) - Product information	Roctavian (valoctocogene roxaparvovec) - Assessment report
Authorised	EMA/H/C/004282	Vyxeos liposomal	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)			09-Oct-18	Vyxeos liposomal (daunorubicin/cytarabine) - Product information	N/A
Authorised	EMA/H/C/005407	Sibnaya	Translation exemption (outer and immediate labelling)	Positive			09-Oct-18	Sibnaya (potassium citrate and potassium hydrogen carbonate) - Product information	Sibnaya (potassium citrate and potassium hydrogen carbonate) - Assessment report
Authorised	EMA/H/C/004275	Crysvita	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)	Omission of particulars (outer labelling)	Positive	Oct-17	Crysvita (busosumab) - Product information	Crysvita (busosumab) - Assessment report



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

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	Extension of marketing authorisation / EMA/X/0000257923 (EMA/H/C/004085)	Olumiant	Omission of particulars (immediate labelling)	Positive			05-Nov-25	Olumiant (baricitinib) - Product information	N/A
Authorised	EMA/H/C/006208	Apremilast Accord	Omission of particulars (immediate labelling)	Positive			05-Nov-25	Apremilast Accord (apremilast) - Assessment report	N/A
Authorised	EMA/H/C/000371	Austedo	Omission of particulars (intermediate labelling)	Positive			07-Nov-24	Austedo (deutetrabenazine) - Product information	N/A
Authorised	EMA/H/C/000697	Suboxone	Omission of particulars (outer labelling)	Positive			26-Jun-24	Suboxone (buprenorphine-naloxone) - Product information	N/A
Authorised	EMA/H/C/004452/IB/0041	Erleada	Omission of particulars (immediate labelling)	Positive			26-Jun-24	Erleada (apalutamide) - Product information	N/A
Authorised	EMA/H/C/006109	Anzupgo	Omission of particulars (immediate labelling)	Positive			07-Mar-24	Anzupgo (delgocitinib) - Product information	Anzupgo (delgocitinib) - Assessment report
Authorised	EMA/H/C/005962/X/0002	Teriflunomide Accord	Omission of particulars (immediate labelling)	Positive			07-Mar-24	Teriflunomide Accord (teriflunomide)	N/A
Authorised	EMA/H/C/006074	Lazclule	Omission of particulars (immediate labelling)	Positive			07-Mar-24	Lazclule (lazertinib) - Product information	N/A
Authorised	EMA/H/C/006208	Apremilast Accord	Omission of particulars (immediate labelling)	Negative			21-Nov-23	Apremilast Accord (apremilast) - Product information	Apremilast Accord (apremilast) - Assessment report
Authorised	EMA/H/C/004936/X/0017	Rozlytrek			Translation exemption (immediate labelling)	Positive	21-Nov-23	Rozlytrek (entrectinib) - Product information	Rozlytrek (entrectinib) - Assessment report
Authorised	EMA/H/C/006050	Balversa	Omission of particulars (immediate labelling)	Positive			21-Nov-23	Balversa (erdafitinib) - Product information	N/A
Authorised	EMA/H/C/000378/N/0086	Axura	Omission of particulars (immediate labelling)	Positive			21-Nov-23	Axura (memantine hydrochloride) - Product information	N/A
Authorised	EMA/H/C/002711/N/0021	Memantine Merz	Omission of particulars (immediate labelling)	Positive			21-Nov-23	Memantine Merz (memantine hydrochloride) - Product information	N/A
Authorised	EMA/H/C/005107/N/0022	Roclanda	Omission of particulars (immediate labelling)	Positive			21-Nov-23	Roclanda (netarsudil mesylate/latanoprost) - Product information	N/A
Authorised	EMA/H/C/002264/X/0042	Edurant			Translation exemption (immediate labelling)	Positive	14-Jun-23	Edurant (rilpivirine) - Product information	N/A
Authorised	EMA/H/C/004904/IB/0016	Miglustat Dipharma			Translation exemption (immediate labelling)	Positive	14-Jun-23	Miglustat Dipharma (miglustat) - Product information	N/A

Authorised	EMA/H/C/005517	Voydeya	Omission of particulars (immediate labelling)	Positive			14-Jun-23	Voydeya (danicopan) - Product information	Voydeya (danicopan) - Assessment report
Authorised	EMA/H/C/004452/X/0028	Erleada	Omission of particulars (immediate labelling)	Positive			10-Mar-23	Erleada, INN - apalutamide (europa.eu)	Erleada (apalutamide) - Assessment report
Authorised	EMA/H/C/000697	Suboxone	Omission of particulars (immediate labelling)	Positive			13-Oct-22	Suboxone (naloxone) - Product information	N/A
Authorised	EMA/H/C/005843	Opzelura	Omission of particulars (immediate labelling)	Positive (partial)			13-Oct-22	Opzelura (ruxolitinib) - Product information	Opzelura (Ruxolitinib) - Assessment report
Authorised	EMA/H/C/005361	Akeega	Omission of particulars (immediate labelling)	Positive			14-Jun-22	Akeega (niraparib/abiraterone acetate) - Product information	N/A
Authorised	EMA/H/C/002465/X/0035	Procysbi	Omission of particulars (immediate labelling)	Positive	Translation exemption (immediate labelling)	Positive	16-Nov-21	Procysbi (mercaptamine bitartrate) - Product information	N/A
Authorised	EMA/H/C/005367	Skytrofa	Omission of particulars (immediate labelling)	Positive (partial)			17-Jun-21	Skytrofa (lonapegsomatropin) - Product information	Skytrofa (lonapegsomatropin) - Assessment report
Authorised	EMA/H/C/000610/X/0063	Noxafil	Omission of particulars (immediate labelling)	Positive			17-Jun-21	Noxafil (posaconazole) - Product information	N/A
Authorised	EMA/H/C/005267	Ryego	Omission of particulars (immediate labelling)	Positive			04-Mar-21	Ryego (Relugolix/Estradiol/Norethisterone acetate) - Product information	N/A
Authorised	EMA/H/C/005117	Ozawade	Omission of particulars (outer and immediate labelling)	Positive			04-Mar-21	Ozawade (Pitolisant) - Product information	Ozawade (Pitolisant) - Assessment report
Authorised	EMA/H/C/005208	Ayvakyt	Omission of particulars (immediate labelling)	Negative			20-Jun-20	AYVAKYT (avapritinib) - Product information	N/A
Authorised	EMA/H/C/004835	Zeposia	Omission of particulars (immediate labelling)	Positive (partial)			08-Oct-19	Zeposia (ozanimod) - Product information	Zeposia (ozanimod) - Public assessment report
Authorised	EMA/H/C/005243	Lacosamide UCB	Omission of particulars (immediate labelling)	Positive			08-Oct-19	Lacosamide UCB (lacosamide) - Product information	N/A
Authorised	EMA/H/C/004452	Erleada	Omission of particulars (immediate labelling)	Positive			09-Oct-18	Erleada (apalutamide) - Product information	Erleada (apalutamide) - Public assessment report