

15 December 2025  
EMA/934543/2022 Rev. 7  
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-overview/marketing-authorisation/product-information-requirements/exemptions-labelling-package-leaflet-obligations#guidance-on-labelling-and-package-leaflet-exemptions-section>  
[https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/recommendations-implementation-exemptions-labelling-and-package-leaflet-obligations-centralised-procedure\\_en.pdf](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) <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/003981	Duloxetine Viatris			Omission of particulars (outer labelling)	Positive			03-Sep-25	<a href="#">Duloxetine Viatris (duloxetine) - Product information</a>	N/A
Authorised	EMA/H/C/006079	Duvyzat	Translation exemption (outer, immediate labelling and package leaflet)	Positive					07-Jul-25	<a href="#">Duvyzat (qivinostat) - Product information</a>	N/A
Authorised	EMA/H/C/005454/X/0014	Rybrevant			Omission of particulars (immediate labelling)	Positive			05-Jun-25	N/A	N/A
Authorised	EMA/H/C/003981	Duloxetine Viatris			Omission of particulars (outer labelling)	Positive			07-Mar-25	<a href="#">Duloxetine Viatris (duloxetine) - Product information</a>	N/A
Authorised	EMA/H/C/005454/X/0014	Rybrevant			Omission of particulars (immediate labelling)	Positive			07-Feb-25	<a href="#">Rybrevant (amivantamab) - Product information</a>	N/A
Authorised	EMA/H/C/005907	Aucatzyl	Translation exemption (outer and immediate labelling)	Positive	Omission of particulars (immediate labelling)	Positive			05-Mar-25	<a href="#">Aucatzyl (obecabtagene autoleucel) - Product information</a>	<a href="#">Aucatzyl (obecabtagene autoleucel) - Assessment report</a>
Authorised	EMA/H/C/005934	Yorvipath	Translation exemption (outer, intermediate and immediate labelling)	Positive					05-Mar-25	<a href="#">Yorvipath (palopegteriparatide) - Product information</a>	N/A
Authorised	EMA/H/C/006396	Tepezza			Omission of particulars (immediate labelling)	Positive			05-Mar-25	<a href="#">Tepezza (teprotumumab) - Product information</a>	<a href="#">Tepezza (teprotumumab) - Assessment report</a>
Authorised	EMA/H/C/005772	Zemcelpro	Translation exemption (outer labelling)	Positive			Translation exemption (immediate labelling and package leaflet)	Positive (partial)	05-Mar-25	<a href="#">Zemcelpro - Product information</a>	<a href="#">Zemcelpro - Assessment report</a>
Authorised	EMA/H/C/006330	Vyjuvek	Translation exemption (outer and immediate labelling)	Positive (partial)					07-Nov-24	<a href="#">Vyjuvek (beremagene geperpavec) - Product information</a>	<a href="#">Vyjuvek (beremagene geperpavec) - Assessment report</a>
Authorised	EMA/H/C/00610/X/0001	Uzpruvo			Omission of particulars (immediate labelling)	Positive			07-Nov-24	<a href="#">Uzpruvo (ustekinumab) - Product information</a>	N/A
Authorised	EMA/H/C/006370	Lynozyl			Omission of particulars (immediate labelling)	Positive			07-Nov-24	<a href="#">Lynozyl (linvoseltamab) - Product information</a>	N/A
Authorised	EMA/H/C/006380	Ziihera			Omission of particulars (immediate labelling)	Positive			07-Nov-24	<a href="#">Ziihera (zanidatamab) - Product information</a>	N/A
Authorised	EMA/H/C/006363	Romvimza	Translation exemption (intermediate labelling)	Positive (partial)	Omission of particulars (immediate labelling)	Positive			07-Nov-24	<a href="#">Romvimza (vimseltinib) - Product information</a>	N/A
Authorised	EMA/H/C/005882	Theralugand			Omission of particulars (outer and immediate labelling)	Positive (partial)			13-Sep-24	<a href="#">Theralugand (lutetium (177Lu) chloride) - Product information</a>	<a href="#">Theralugand (lutetium (177Lu) chloride) - Assessment report</a>
Authorised	EMA/H/C/005849/II/0022/G	Vyvgart	Translation exemption (immediate labelling)	Positive					23-Sep-24	<a href="#">Vyvgart (efgartigimod alfa) - Product information</a>	N/A
Authorised	EMA/H/C/006544	Otulfi			Omission of particulars (immediate labelling)	Positive			26-Jun-24	<a href="#">Otulfi (ustekinumab) - Product information</a>	<a href="#">Otulfi (ustekinumab) - Assessment report</a>

Authorised	EMA/H/C/005805	Fymkina			Omission of particulars (immediate labelling)	Positive	26-Jun-24	<a href="#">Fymkina (ustekinumab) - Product information</a>	<a href="#">Fymkina (ustekinumab) - Assessment report</a>
Authorised	EMA/H/C/006123	Gohibic			Omission of particulars (immediate labelling)	Positive	26-Jun-24	<a href="#">Gohibic (vilobelimab) - Product information</a>	N/A
Authorised	EMA/H/C/006215	Ordspono			Omission of particulars (immediate labelling)	Positive	08-May-24	<a href="#">Ordspono (odronextamab) - Product information</a>	<a href="#">Ordspono (odronextamab) - Assessment report</a>
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/006024	Kisunla			Omission of particulars (immediate labelling)	Positive	07-Mar-24	<a href="#">Kisunla (donanemab) - Product information</a>	<a href="#">Kisunla(donanemab) - Assessment report</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/006231	Iqirvo	Translation exemption (outer and immediate labelling)	Positive			07-Mar-24	<a href="#">Edurant (rilpivirine) - Product information</a>	<a href="#">Iqirvo (elafibranor) -Assessment report</a>
Authorised	EMA/H/C/005919/II/0002	Tevimbra			Omission of particulars (immediate labelling)	Positive	27-Feb-24	<a href="#">Tevimbra (tislelizumab) - Product information</a>	N/A
Authorised	EMA/H/C/006064	Tauvid			Omission of particulars (immediate labelling)	Positive	21-Dec-23	<a href="#">Tauvid (flortaucipir (18F)) - Product information</a>	<a href="#">Tauvid (flortaucipir (18F)) - Assessment report</a>
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	<a href="#">Crysvita (burosumab) - Product information</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/002264/X/0042	Edurant			Omission of particulars (immediate labelling)	Positive	22-Dec-23	<a href="#">Edurant (rilpivirine) - Product information</a>	N/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/005036	Elahere	Translation exemption (outer and immediate labelling)	Positive (partial)	Omission of particulars (immediate labelling)	Positive	21-Nov-23	<a href="#">Elahere (mirvetuximab soravtansine) - Product information</a>	<a href="#">Elahere (mirvetuximab soravtansine) - Assessment report</a>
Authorised	EMA/H/C/006231	Iqirvo	Translation exemption (outer and immediate labelling)	Negative	Omission of particulars (immediate labelling)	Positive	21-Nov-23	<a href="#">Iqirvo (elafibranor) - Product information</a>	<a href="#">Iqirvo (elafibranor) -Assessment report</a>
Authorised	EMA/H/C/002552	Delytba	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)			21-Nov-23	<a href="#">Delytba (delamanid) - Product information</a>	N/A
Authorised	EMA/H/C/005220	Emcitate	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)			21-Nov-23	<a href="#">Emcitate (tiratricol) - Product information</a>	<a href="#">Emcitate (tiratricol) -Assessment report</a>
Authorised	EMA/H/C/005984	Tofidence			Omission of particulars (immediate labelling)	Positive	21-Nov-23	<a href="#">Tofidence (tocilizumab) - Product information</a>	<a href="#">Tofidence (tocilizumab) - Assessment report</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/004974/X/0008	Xofluza			Omission of particulars (immediate labelling)	Positive		14-Sep-22	<a href="#">Xofluza (baloxavir marboxil) - Product information</a>	N/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/005858	Akantior	Translation exemption (intermediate and immediate labelling)	Positive (partial)				14-Jun-22	<a href="#">Akantior (polihexanide) - Product information</a>	<a href="#">Akantior (polihexanide) - Assessment report</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	Kimtrak	Translation exemption (outer and immediate labelling)	Positive				16-Nov-21	<a href="#">Kimtrak (tebentafusp) - Product information</a>	<a href="#">Kimtrak (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 (artesunate) - 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	Trodelvly			Omission of particulars (immediate labelling)	Positive		17-Jun-21	<a href="#">Trodelvly (sacituzumab govitecan) - Product information</a>	<a href="#">Trodelvly (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 (Ciltacaptagene autoleucl) - Product information</a>	<a href="#">Carvykti (ciltacaptagene autoleucl) - 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 vicleucl) - Product information</a>	<a href="#">Abecma (idecabtagene vicleucl) - 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	Translation exemption (outer, immediate labelling and package leaflet)	Positive	01-Mar-21	<a href="#">JCOVDEN [COVID-19 vaccine (Ad26.CO2-S [recombinant])] - Product information</a>	<a href="#">JCOVDEN [COVID-19 Vaccine Janssen (Ad26.CO2-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	Translation exemption (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	Translation exemption (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	Alymis	Omission of particulars (immediate labelling)	Positive			20-Oct-20	<a href="#">Alymis (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	Translation exemption (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	Rekamby	Omission of particulars (immediate labelling)	Positive			16-Jun-20	<a href="#">Rekamby (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 (glibenclamide) - 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, immediate labelling and package leaflet)	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 exuparvec) - Product information</a>	<a href="#">Upstaza (eladocagene exuparvec) - 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 (valoctogogene roxaparvec) - Product information</a>	<a href="#">Roctavian (valoctogogene roxaparvec) - 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 abeparvec) - Product information</a>	<a href="#">Zolgensma (Onasemnogene abeparvec) - 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 (valoctogogene roxaparvec) - Product information</a>	<a href="#">Roctavian (valoctogogene roxaparvec) - 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 (busosumab) - Product information</a>	<a href="#">Crysvita (busorumab) - Assessment report</a>
------------	----------------	----------	--	--------------------	---	----------	--------	--	--



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	EMA/H/C/006208	Apremilast Accord	Omission of particulars (immediate labelling)	Positive			05-Nov-25	<a href="#">Apremilast Accord (apremilast) - Assessment report</a>	N/A
Authorised	EMA/H/C/000697	Suboxone	Omission of particulars (outer labelling)	Positive			26-Jun-24	<a href="#">Suboxone (buprenorphine-naloxone) - Product information</a>	N/A
Authorised	EMA/H/C/004452/IB/0041	Erleada	Omission of particulars (immediate labelling)	Positive			26-Jun-24	<a href="#">Erleada (apalutamide) - Product information</a>	N/A
Authorised	EMA/H/C/006109	Anzupgo	Omission of particulars (immediate labelling)	Positive			07-Mar-24	<a href="#">Anzupgo (delgocitinib) - Product information</a>	<a href="#">Anzupgo (delgocitinib) - Assessment report</a>
Authorised	EMA/H/C/005962/X/0002	Teriflunomide Accord	Omission of particulars (immediate labelling)	Positive			07-Mar-24	<a href="#">Teriflunomide Accord (teriflunomide)</a>	N/A
Authorised	EMA/H/C/006074	Lazclule	Omission of particulars (immediate labelling)	Positive			07-Mar-24	<a href="#">Lazcluze (lazertinib) - Product information</a>	N/A
Authorised	EMA/H/C/006208	Apremilast Accord	Omission of particulars (immediate labelling)	Negative			21-Nov-23	<a href="#">Apremilast Accord (apremilast) - Product information</a>	<a href="#">Apremilast Accord (apremilast) - Assessment report</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/006050	Balversa	Omission of particulars (immediate labelling)	Positive			21-Nov-23	<a href="#">Balversa (erdafitinib) - Product information</a>	N/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/002264/X/0042	Edurant			Translation exemption (immediate labelling)	Positive	14-Jun-23	<a href="#">Edurant (rilpivirine) - 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	EMEA/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	EMEA/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	EMEA/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	EMEA/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	EMEA/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	EMEA/H/C/005208	Ayvakt	Omission of particulars (immediate labelling)	Negative			20-Jun-20	<a href="#">AYVAKYT (avapritinib) - Product information</a>	N/A
Authorised	EMEA/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	EMEA/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	EMEA/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>