EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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-exemptions-section
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 products2	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	EMEA/H/C/003981	Duloxetine Viatris			Omission of particulars (outer labelling)	Positive			07-Mar-25	Duloxetine Viatris (duloxetine) - Product information	N/A
Authorised	EMEA/H/C/005454/X/0014	Rybrevant			Omission of particulars (immediate labelling)	Positive			07-Feb-25	Rybrevant (amivantamab) - Product information	N/A
Authorised	EMEA/H/C/005934	Yorvipath	Translation exemption (outer, intermediate and immediate labelling)	Positive					05-Mar-25	Yorvipath (palopegteriparatide) - Product information	N/A
Authorised	EMEA/H/C/006396	Tepezza			Omission of particulars (immediate labelling)	Positive			05-Mar-25	Tepezza (teprotumumab) - Poduct information	Tepezza (teprotumumab) - Assessment report
Authorised	EMEA/H/C/006330	Vyjuvek	Translation exemption (outer and immediate labelling)	Positive (partial)					07-Nov-24	Vyjuvek (beremagene geperpavec) - Product information	Vyjuvek (beremagene geperpavec) - Assesment report
Authorised	EMEA/H/C/00610/X/0001	Uzpruvo			Omission of particulars (immediate labelling)	Positive			07-Nov-24	Uzpruvo (ustekinumab) - Product information	N/A
Authorised	EMEA/H/C/006370	Lynozyfic			Omission of particulars (immediate labelling)	Positive			07-Nov-24	Lynozyfic (linvoseltamab) - Product information	N/A
Authorised	EMEA/H/C/006380	Ziihera			Omission of particulars (immediate labelling)	Positive			07-Nov-24	Ziihera (zanidatamab) - Product information	N/A
Authorised	EMEA/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	EMEA/H/C/005849/II/0022/G	Vyvgart	Translation exemption (immediate labelling)	Positive					23-Sep-24	Vyvgart (efgartigimod alfa) - Product information	N/A
Authorised	EMEA/H/C/006544	Otulfi			Omission of particulars (immediate labelling)	Positive			26-Jun-24	Otulfi (ustekinumab) - Product information	Otulfi (ustekinumab) - Assessment report
Authorised	EMEA/H/C/005805	Fymskina			Omission of particulars (immediate labelling)	Positive			26-Jun-24	Fymskina (ustekinumab) - Product information	Fymskina (ustekinumab) - Assessment report
Authorised	EMEA/H/C/006123	Gohibic			Omission of particulars (immediate labelling)	Positive			26-Jun-24	Gohibic (vilobelimab) - Product information	N/A
Authorised	EMEA/H/C/006215	Ordspono			Omission of particulars (immediate labelling)	Positive			08-May-24	Ordspono (odronextamab) - Product information	Ordspono (odronextamab) - Assessment report
Authorised	EMEA/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	EMEA/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	EMEA/H/C/006231	Iqirvo	Translation exemption (outer and immediate labelling)	Positive					07-Mar-24	Edurant (rilpivirine) - Product information	Iqirvo (elafibranor) -Assessment report
Authorised	EMEA/H/C/005919/II/0002	Tevimbra			Omission of particulars (immediate labelling)	Positive			27-Feb-24	Tevimbra (tislelizumab) - Product information	N/A
Authorised	EMEA/H/C/006064	Tauvid			Omission of particulars (immediate labelling)	Positive			21-Dec-23	Tauvid (flortaucipir (18F)) - Product information	Tauvid (flortaucipir (18F)) - Assessment report
Authorised	EMEA/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	EMEA/H/C/006113	Emblaveo			Omission of particulars (immediate labelling)	Positive			31-Jan-24	Emblaveo (aztreonam/avibactam) - Product information	Emblaveo (aztreonam/avibactam) - Assessment report
Authorised	EMEA/H/C/002264/X/0042	Edurant			Omission of particulars (immediate labelling)	Positive			22-Dec-23	Edurant (rilpivirine) - Product information	N/A
Authorised	EMEA/H/C/005269/X/0033	Kaftrio	Translation exemption (outer, intermediate and immediate labelling)	Positive (partial)					21-Nov-23	Kaftrio (elexacaftor/tezacaftor/ivacaftor) - Product information	N/A
Authorised	EMEA/H/C/005036	Elahere	Translation exemption (outer and immediate labelling)	Positive (partial)	Omission of particulars (immediate labelling)	Positive			21-Nov-23	Elahere (mirvetuximab soravtansine) - Product information	Elahere (mirvetuximab soravtansine) - Assessment report
Authorised	EMEA/H/C/006231	Iqirvo	Translation exemption (outer and immediate labelling)	Negative	Omission of particulars (immediate labelling)	Positive			21-Nov-23	Iqirvo (elafibranor) - Product information	Iqirvo (elafibranor) -Assessment report
Authorised	EMEA/H/C/002552	Deltyba	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)					21-Nov-23	Deltyba (delamanid) - Product information	N/A
Authorised	EMEA/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	EMEA/H/C/005984	Tofidence			Omission of particulars (immediate labelling)	Positive			21-Nov-23	Tofidence (tocilizumab) - Product information	Tofidence (tocilizumab) - Assessment report
Authorised	EMEA/H/C/006194	Zynyz			Omission of particulars (immediate labelling)	Positive			21-Nov-23	Zynyz (retifanlimab) - Product information	Zynyz (retifanlimab) - Assessment report
Authorised	EMEA/H/C/005900	Rezzayo			Omission of particulars (immediate labelling)	Positive			30-Aug-23	Rezzayo (rezafungin) - Product information	N/A
Authorised	EMEA/H/C/005933	Catiolanze			Omission of particulars (immediate labelling)	Positive			13-Jul-23	Catiolanze (latanoprost) - Product information	N/A
Authorised	EMEA/H/C/005756	Apretude			Omission of particulars (immediate labelling)	Positive (partial)			03-Jul-23	Apretude, (cabotegravir) - Product information	Apretude (cabotegravir) - Assessment report
Authorised	EMEA/H/C/006185	Niapelf			Omission of particulars (immediate labelling)	Positive			14-Jun-23	Niapelf (paliperidone) - Product information	N/A
Authorised	EMEA/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	EMEA/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	EMEA/H/C/005493	Qalsody			Omission of particulars (immediate labelling)	Positive			10-Mar-23	Qalsody (tofersen) - Product information	Qalsody (tofersen) - Assessment report
Authorised	EMEA/H/C/005122	Omvoh			Omission of particulars (immediate labelling)	Positive			04-Jan-23	Omvoh (mirikizumab) - Product information	Omvoh (mirikizumab) - Assessment report
Authorised	EMEA/H/C/004258	Alofisel			Omission of particulars (outer labelling)	Positive (temporary)			17-Nov-22	Alofisel (darvadstrocel) - Product information	N/A
Authorised	EMEA/H/C/005343	Mvabea			Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	Positive	26-Oct-22	Mvabea (Ebola vaccine (MVA BN Filo [recombinant]) - Product information	N/A

Authorised	EMEA/H/C/005337	Zabdeno			Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	Positive	26-Oct-22	Zabdeno (Ad26.ZEBOV-GP [recombinant]) - Product information	N/A
Authorised	EMEA/H/C/005343	Mvabea			Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	Positive (partial)	13-Oct-22	Mvabea (Ebola vaccine (MVA BN Filo [recombinant]) - Product information	N/A
Authorised	EMEA/H/C/005337	Zabdeno			Omission of particulars (outer labelling)	Positive (partial)	Translation exemption (outer and immediate labelling)	Positive (partial)	13-Oct-22	Zabdeno (Ad26.ZEBOV-GP [recombinant]) - Product information	N/A
Authorised	EMEA/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	EMEA/H/C/005703	Pombiliti			Omission of particulars (immediate labelling)	Positive			13-Oct-22	Pombiliti (cipaglucosidase alfa) - Product information	Pombiliti (cipaglucosidase alfa) - Assessment report
Authorised	EMEA/H/C/005695	Opfolda			Omission of particulars (immediate labelling)	Positive			13-Oct-22	Opfolda (miglustat) - Product information	N/A
Authorised	EMEA/H/C/006016	Imjudo			Omission of particulars (immediate labelling)	Positive			13-Oct-22	IMJUDO - Product information	Imjudo - Assessment report
Authorised	EMEA/H/C/004650	Tremelimumab AstraZeneca			Omission of particulars (immediate labelling)	Positive			13-Oct-22	Tremelimumab AstraZeneca - Product information	Tremelimumab AstraZeneca - Assessment report
Authorised	EMEA/H/C/004974/X/0008	Xofluza			Omission of particulars (immediate labelling)	Positive			14-Sep-22	Xofluza (baloxavir marboxil) - Product information	N/A
Authorised	EMEA/H/C/005776	Enjaymo					Translation exemption (outer, immediate labelling and package leaflet)	Positive	13-Sep-22	Enjaymo (Sutimlimab) - Product information	N/A
Authorised	EMEA/H/C/005035	Filsuvez			Omission of particulars (immediate labelling)	Positive			08-Aug-22	Filsuvez (birch bark extract) - Product information	N/A
Authorised	EMEA/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	EMEA/H/C/005751	Columvi			Omission of particulars (immediate labelling)	Positive			14-Jun-22	Columvi, INN-glofitamab (europa.eu)	N/A
Authorised	EMEA/H/C/005858	Akantior	Translation exemption (intermediate and immediate labelling)	Positive (partial)					14-Jun-22	Akantior (polihexanide) - Product information	Akantior (polihexanide) - Assessment report
Authorised	EMEA/H/C/005848	Pemetrexed Baxter			Omission of particulars (immediate labelling)	Positive			14-Jun-22	Pemetrexed Baxter - Product information	Pemetrexed Baxter - Assessment report
Authorised	EMEA/H/C/005246/X/0002	Byfavo			Omission of particulars (immediate labelling)	Negative			14-Jun-22	Byfavo - Product information	N/A
Authorised	EMEA/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	EMEA/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	EMEA/H/C/005769	Herwenda			Omission of particulars (immediate labelling)	Positive			10-Mar-22	Herwenda (trastuzumab) - Product information	N/A
Authorised	EMEA/H/C/005540	Pyrukynd	Translation exemption (outer, intermediate and immediate labelling)	Positive (partial)					10-Mar-22	Pyrukynd - Product information	N/A
Authorised	EMEA/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	EMEA/H/C/004929	Kimmtrak	Translation exemption (outer and immediate labelling)	Positive					16-Nov-21	Kimmtrak (tebentafusp) - Product information	Kimmtrak (tebentafusp) - Assessment report

Authorised	EMEA/H/C/005378	Nulibry	Translation exemption (outer and immediate labelling)	Positive (partial)						16-Nov-21	Nulibry - Product information	N/A
Authorised	EMEA/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	EMEA/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 (nimatrelvir + ritonavir) - Assessment report
Authorised	EMEA/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	EMEA/H/C/005553	Aspaveli			Omission of particulars (immediate labelling)	Positive				08-Oct-21	Aspaveli (pegcetacoplan) - Product information	Aspaveli (pegcetacoplan) - Assessment report
Authorised	EMEA/H/C/005814	Ronapreve			Omission of particulars (immediate labelling)	Positive				24-Sep-21	Ronapreve (casirivimab and imdevimab) - Produt information	Ronapreve (casirivimab and imdevimab) - Assessment report
Authorised	EMEA/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	EMEA/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	EMEA/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	EMEA/H/C/005182	Trodelvy			Omission of particulars (immediate labelling)	Positive				17-Jun-21	Trodelvy (sacituzumab govitecan) - Product information	Trodelvy (sacituzumab govitecan) - Assessment report
Authorised	EMEA/H/C/005681	Pepaxti			Omission of particulars (immediate labelling)	Positive				17-Jun-21	Pepaxti (melphalan flufenamide) - Product information	N/A
Authorised	EMEA/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	EMEA/H/C/005095	Carvykti	Translation exemption (outer and immediate labelling)	Positive						17-Jun-21	Carvykti (Ciltacaptagene autoleucel) - Product information	Carvykti (ciltacabtagene autoleucel) - Assessment report
Authorised	EMEA/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	EMEA/H/C/005501	Nexviadyme			Omission of particulars (immediate labelling)	Positive				17-Jun-21	Nexviadyme (avalglucosidase alfa) - Product information	Nexviadyme (avalglucosidase alfa) - Assessment report
Authorised	EMEA/H/C/004662	Abecma			Omission of particulars (outer and immediate labelling)	Positive (partial)				03-Jun-21	Abecma (idecabtagene vicleucel) - Product information	Abecma (idecabtagene vicleucel) - Assessment report
Authorised	EMEA/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	EMEA/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	EMEA/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	EMEA/H/C/005327	Abevmy			Omission of particulars (immediate labelling)	Positive				13-Jan-21	Abevmy (bevacizumab) - Product information	Abevmy (bevacizumab) - Assessment report
Authorised	EMEA/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	EMEA/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/riltozinameran, tozinameran/famtozinameran) - Product information	Comirnaty (tozinameran, tozinameran/riltozinamearn, tozinamearn/famtozinameran) - Assessment report
Authorised	EMEA/H/C/005286	Alymsis			Omission of particulars (immediate labelling)	Positive				20-Oct-20	Alymsys (bevacizumab) - Product information	N/A

Authorised	EMEA/H/C/005556	Oyavas			Omission of particulars (immediate labelling)	Positive			20-Oct-20	Oyavas (bevacizumab) - Product information	N/A
Authorised	EMEA/H/C/005145	Evrysdi			Omission of particulars (immediate labelling)	Negative			20-Oct-20	Evrysdy (risdiplam) - Product information	Evrysdi (risdiplam) - Assessment report
Authorised	EMEA/H/C/005089	Imcivree	Translation exemption (outer and immediate labelling)	Positive					20-Oct-20	Imcivree (setmelanotide) - Product information	Imcivree (setmelanotide) - Assessment report
Authorised	EMEA/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	EMEA/H/C/004731	Breyanzi			Omission of particulars (outer and intermediate labelling)	Positive (partial)			20-Oct-20	Breyanzi (lisocabtagene maraleucel) - Product information	N/A
Authorised	EMEA/H/C/005386	Phesgo			Omission of particulars (immediate labelling)	Positive			13-Oct-20	Phesgo (pertuzumab/trastuzumab) - Product information	Phesgo (pertuzumab / trastuzumab) - Assessment report
Authorised	EMEA/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	EMEA/H/C/005675	Vaxzevria			Omission of particulars (outer and immediate labelling)	Positive	Translation exemption (outer and immediate labelling)	Positive	07-Jul-20	Vaxzevria - Product information	Vaxzevria - Assessment report
Authorised	EMEA/H/C/005246	Byfavo			Omission of particulars (immediate labelling)	Positive			16-Jun-20	Byfavo (remimazolam) - Product information	Byfavo (remimazolam) - Assessment report
Authorised	EMEA/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	EMEA/H/C/004954/X/0004/G	Ultomiris			Omission of particulars (immediate labelling)	Positive			16-Jun-20	Ultomiris (ravulizumab) - Product information	N/A
Authorised	EMEA/H/C/004976	Vocabria			Omission of particulars (immediate labelling)	Positive			16-Jun-20	Vocabria (cabotegravir) - Product information	N/A
Authorised	EMEA/H/C/005060	Rekambys			Omission of particulars (immediate labelling)	Positive			16-Jun-20	Rekambys (rilpivirine) - Product information	N/A
Authorised	EMEA/H/C/005436	Minjuvi			Omission of particulars (immediate labelling)	Positive			16-Jun-20	Minjuvi (tafasitamab) - Product information	N/A
Authorised	EMEA/H/C/005681	Pepaxti			Omission of particulars (immediate labelling)	Positive			16-Jun-20	Pepaxti (melphalan flufenamide) - Product information	N/A
Authorised	EMEA/H/C/004379	Amglidia	Translation exemption (outer, immediate labelling and package leaflet)	Negative					16-Jun-20	Amglidia (glibenclamide) - Product information	N/A
Authorised	EMEA/H/C/005271	Zokinvy	Translation exemption (outer, immediate labelling and package leaflet)	Positive					16-Jun-20	Zokinvy (lonafarnib) - Product information	N/A
Authorised	EMEA/H/C/002393	Defitelio	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)					16-Jun-20	Defitelio (defibrotide) - Product information	N/A
Authorised	EMEA/H/C/005622	Veklury			Omission of particulars (immediate labelling)	Positive			15-May-20	Veklury (remdesivir) - Product information	Veklury (remdesivir) - Assessment report
Authorised	EMEA/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	EMEA/H/C/005167	Dovprela	Translation exemption (outer and immediate labelling)	Positive					27-Mar-20	Dovprela (pretomanid) - Product information	Dovprela (pretomanid) - Assessment report
Authorised	EMEA/H/C/004077/X/0032	Darzalex			Omission of particulars (immediate labelling)	Positive			20-Mar-20	Darzalex (daratumumab) - Product information	N/A
Authorised	EMEA/H/C/002614	Sirturo	Translation exemption (outer and immediate labelling)	Positive					03-Mar-20	Sirturo (bedaquiline) - Product information	N/A

Authorised	EMEA/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	EMEA/H/C/004849	Idefirix	Translation exemption (outer and immediate labelling)	Positive			03-Mar-20	Idefirix (imlifidase) - Product information	Idefirix (imlifidase) - Assessment report
Authorised	EMEA/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	EMEA/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	EMEA/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	EMEA/H/C/003855	Coagadex	Translation exemption (outer and immediate labelling)	Positive			13-Jan-20	Coagadex (human coagulation factor X) - Product information	N/A
Authorised	EMEA/H/C/004829	Fetcroja			Omission of particulars (immediate labelling)	Positive	19-Nov-19	Fetcroja (cefiderocol) - Product information	Fetcroja (cefiderocol) - Assessment report
Authorised	EMEA/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	EMEA/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	EMEA/H/C/005205	Zynrelef			Omission of particulars (immediate labelling)	Positive	08-Oct-19	Zynrelef (bupivacaine/meloxicam) - Product information	Zynrelef (bupivacaine/meloxicam) - Assessment report
Authorised	EMEA/H/C/003860/N/0027	Nucala			Omission of particulars (immediate labelling)	Positive	08-Oct-19	Nucala (mepolizumab) - Product information	N/A
Authorised	EMEA/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	EMEA/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	EMEA/H/C/005407	Sibnayal	Translation exemption (outer and immediate labelling)	Positive			26-Mar-19	Sibnayal (potassium citrate and potassium hydrogen carbonate) - Product information	Sibnayal (potassium citrate and potassium hydrogen carbonate) - Assessment report
Authorised	EMEA/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	EMEA/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	EMEA/H/C/005407	Sibnayal	Translation exemption (outer and immediate labelling)	Positive			09-Oct-18	Sibnayal (potassium citrate and potassium hydrogen carbonate) - Product information	Sibnayal (potassium citrate and potassium hydrogen carbonate) - Assessment report
Authorised	EMEA/H/C/004275	Crysvita	Translation exemption (outer, immediate labelling and package leaflet)	Positive (partial)	Omission of particulars (outer labelling)	Positive	Oct-17	Crysvita (burosumab) - Product information	Crysvita (busorumab) - Assessment report

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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	EMEA/H/C/000697	Suboxone	Omission of particulars (outer labelling)	Positive			26-Jun-24	Suboxone (buprenorphine-naloxone) - Product information	N/A
Authorised	EMEA/H/C/004452/IB/0041	Erleada	Omission of particulars (immediate labelling)	Positive			26-Jun-24	Erleada (apalutamide) - Product information	N/A
Authorised	EMEA/H/C/006109	Anzupgo	Omission of particulars (immediate labelling)	Positive			07-Mar-24	Anzupgo (delgocitinib) - Product information	Anzupgo (delgocitinib) - Assessment report
Authorised	EMEA/H/C/005962/X/0002	Teriflunomide Accord	Omission of particulars (immediate labelling)	Positive			07-Mar-24	Teriflunomide Accord (teriflunomide)	N/A
Authorised	EMEA/H/C/006074	Lazclule	Omission of particulars (immediate labelling)	Positive			07-Mar-24	Lazcluze (lazertinib) - Product information	N/A
Authorised	EMEA/H/C/006208	Apremilast Accord	Omission of particulars (immediate labelling)	Negative			21-Nov-23	Apremilast Accord (apremilast) - Assessment report	Apremilast Accord (apremilast) - Product information
Authorised	EMEA/H/C/004936/X/0017	Rozlytrek			Translation exemption (immediate labelling)	Positive	21-Nov-23	Rozlytrek (entrectinib) - Product information	Rozlytrek (entrectinib) - Assessment report
Authorised	EMEA/H/C/006050	Balversa	Omission of particulars (immediate labelling)	Positive			21-Nov-23	Balversa (erdafitinib) - Product information	N/A
Authorised	EMEA/H/C/000378/N/0086	Axura	Omission of particulars (immediate labelling)	Positive			21-Nov-23	Axura (memantine hydrochloride) - Product information	N/A
Authorised	EMEA/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	EMEA/H/C/005107/N/0022	Roclanda	Omission of particulars (immediate labelling)	Positive			21-Nov-23	Roclanda (netarsudil mesylate/latanoprost) - Product information	N/A
Authorised	EMEA/H/C/002264/X/0042	Edurant			Translation exemption (immediate labelling)	Positive	14-Jun-23	Edurant (rilpivirine) - Product information	N/A
Authorised	EMEA/H/C/004904/IB/0016	Miglustat Dipharma			Translation exemption (immediate labelling)	Positive	14-Jun-23	Miglustat Dipharma (miglustat) - Product information	N/A
Authorised	EMEA/H/C/005517	Voydeya	Omission of particulars (immediate labelling)	Positive			14-Jun-23	Voydeya (danicopan) - Product information	Voydeya (danicopan) - Assessment report
Authorised	EMEA/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	EMEA/H/C/000697	Suboxone	Omission of particulars (immediate labelling)	Positive			13-Oct-22	Suboxone (naloxone) - Product information	N/A
Authorised	EMEA/H/C/005843	Opzelura	Omission of particulars (immediate labelling)	Positive (partial)			13-Oct-22	Opzelura (ruxolitinib) - Product information	Opzelura (Ruxolitinib) - Assessment report
Authorised	EMEA/H/C/005361	Akeega	Omission of particulars (immediate labelling)	Positive			14-Jun-22	Akeega (niraparib/abiraterone acetate) - Product information	N/A

Authorised	EMEA/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	EMEA/H/C/005367	Skytrofa	Omission of particulars (immediate labelling)	Positive (partial)			17-Jun-21	Skytrofa (lonapegsomatropin) - Product information	Skytrofa (lonapegsomatropin) - Assessment report
Authorised	EMEA/H/C/000610/X/0063	Noxafil	Omission of particulars (immediate labelling)	Positive			17-Jun-21	Noxafil (posaconazole) - Product information	N/A
Authorised	EMEA/H/C/005267	Ryeqo	Omission of particulars (immediate labelling)	Positive			04-Mar-21	Ryeqo (Relugolix/Estradiol/Norethisterone acetate) - Product information	N/A
Authorised	EMEA/H/C/005117	Ozawade	Omission of particulars (outer and immediate labelling)	Positive			04-Mar-21	Ozawade (Pitolisant) - Product information	Ozawade (Pitolisant) - Assessment report
Authorised	EMEA/H/C/005208	Ayvakyt	Omission of particulars (immediate labelling)	Negative			20-Jun-20	AYVAKYT (avapritinib) - Product information	N/A
Authorised	EMEA/H/C/004835	Zeposia	Omission of particulars (immediate labelling)	Positive (partial)			08-Oct-19	Zeposia (ozanimod) - Product information	Zeposia (ozanimod) - Public assessment report
Authorised	EMEA/H/C/005243	Lacosamide UCB	Omission of particulars (immediate labelling)	Positive			08-Oct-19	Lacosamide UCB (lacosamide) - Product information	N/A
Authorised	EMEA/H/C/004452	Erleada	Omission of particulars (immediate labelling)	Positive			09-Oct-18	Erleada (apalutamide) - Product information	Erleada (apalutamide) - Public assessment report