

Cases of excipients approved for use only in specific products or under specific conditions

6/19/2025

Excipient	Product	Route of administration	Remarks
ATX-126	Kostaive intramuscular injection	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
DLin-MC 3-DMA	Onpattro Infusion 2 mg/mL	Intravenous injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient. In the toxicity studies, increases in hepatic enzyme levels potentially attributable to LNP were observed. PMDA thus concluded that the concerned product should not be handled as a precedent for use of this excipient, although its use to ensure the formulation attributes is considered inevitable.
MATRIX-A	Nuvaxovid Intramuscular Injection	Intramuscular injection	PMDA concluded that this excipient may be used only as an adjuvant in view of the risk and benefit.
MATRIX-C	Nuvaxovid Intramuscular Injection	Intramuscular injection	PMDA concluded that this excipient may be used only as an adjuvant in view of the risk and benefit.
N-(carbonyl-methoxypolyethylene glycol-2000)-1,2-distearoyl-sn-glycero-3phosphonoethanolamine sodium salt	Onivyde I.V. Infusion 43 mg	Intravenous injection	This excipient is a component of liposomes. In patients treated with the liposomal formulation, infusion reactions such as infusion-related reactions occurred to a certain extent, and for the concerned events, a causal relationship to this excipient cannot be ruled out. In view of the seriousness of the target disease, PMDA concluded that this excipient may be used in the concerned product on the condition that its use will not be handled as a precedent.
	Doxil Injection 20 mg	Intravenous injection	
PEG2000-C-DMG	Onpattro Infusion 2 mg/mL	Intravenous injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient. In the toxicity studies, increases in hepatic enzyme levels potentially attributable to LNP were observed. PMDA thus concluded that the concerned product should not be handled as a precedent for use of this excipient, although its use to ensure the formulation attributes is considered inevitable.
PEG2000-DMG	Spikevax Intramuscular Injection (formerly COVID-19 Vaccine Moderna Intramuscular Injection)	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. PMDA, however, concluded that the concerned product should not be handled as a precedent for use of this excipient, because effects on hepatocytes were observed in the toxicity studies.
	Daichirona Intramuscular Injection	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
	Kostaive intramuscular injection	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
	mRESVIA Intramuscular Injection Syringe	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. PMDA, however, concluded that the concerned product should not be handled as a precedent for use of this excipient, because effects on hepatocytes were observed in the toxicity studies.
SM-102	Spikevax Intramuscular Injection (formerly COVID-19 Vaccine Moderna Intramuscular Injection)	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. PMDA, however, concluded that the concerned product should not be handled as a precedent for use of this excipient, because effects on hepatocytes were observed in the toxicity studies.
	mRESVIA Intramuscular Injection Syringe	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. PMDA, however, concluded that the concerned product should not be handled as a precedent for use of this excipient, because effects on hepatocytes were observed in the toxicity studies.

T168-1857a	Daichirona Intramuscular Injection	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
Sodium chlorite	Aiphagan Ophthalmic Solution 0.1%	Instillation	This excipient, when exposed to light or low pH, could possibly cause massive generation of chlorine dioxide, leading to oxidative damage to biological substances with its radical. PMDA concluded that this excipient may be used only under the condition that appropriately controls generation of chlorine dioxide with formulation design or a well-designed container.
	Noarl CL	Instillation	This excipient, when exposed to light or low pH, could possibly cause massive generation of chlorine dioxide, leading to oxidative damage to biological substances with its radical. PMDA concluded that this excipient may be used only under the condition that appropriately controls generation of chlorine dioxide with formulation design or a well-designed container.
2-Ethylhexyl acrylate-vinyl acetate-butyl acrylate-acrylic acid copolymer (DURO-TAK387-2051/87-2051)	Norspan Tape 5 mg/Norspan Tape 10 mg/Norspan Tape 20 mg	Transdermal patch	Because repeated applications of the product using this highly adhesive excipient at the same site would cause skin irritation, PMDA concluded that this excipient may be used only in the products that are administered by a method designed to reduce the risk of irritation, such as the concerned product, which is applied to a different site for each dose.
2-Ethylhexyl acrylate-vinyl acetate-butyl acrylate-acrylic acid copolymer (DURO-TAK387-2054/87-2054)	Norspan Tape 5 mg/Norspan Tape 10 mg/Norspan Tape 20 mg	Transdermal patch	Because repeated applications of the product using this highly adhesive excipient at the same site would cause skin irritation, PMDA concluded that this excipient may be used only in the products that are administered by a method designed to reduce the risk of irritation, such as the concerned product, which is applied to a different site for each dose.
Sodium bisulfite	Zione Injection/Lidocaine	Local injection	
L-Arginine hydrochloride	Beyfortus Intramuscular Injection 50 mg with Syringe/Beyfortus Intramuscular Injection 100 mg with Syringe	Intramuscular injection	The concerned product is usually administered once for each epidemic season of RS virus (Seasons 1 and 2). The safety in non-clinical settings was evaluated in a 1-month repeated-dose toxicity study in cynomolgus monkeys (once a week), but the safety for local tolerance at the intramuscular injection sites after long-term use has not been evaluated. PMDA thus concluded that the approval for use of this excipient should be limited to the concerned product, and it should not be handled as a precedent for use.
Aluminum hydroxyphosphate sulfate	Gardasil Aqueous Suspension for Intramuscular Injection Syringes Silgard9 Aqueous Suspension for Intramuscular Injection Syringes	Intramuscular injection	PMDA concluded that this excipient may be used only as an adjuvant in view of the risk and benefit.
Ethanol	Faslodex Intramuscular Injection 250 mg	Intramuscular injection	This excipient was suggested to have a risk of local irritation and tissue damage. PMDA concluded that this excipient may be used only in the products that are administered by a method designed to avoid accumulation of irritation such as the concerned product, which is administered intermittently.
Egg phosphatidylglycerol	Visudyne for Intravenous Injection 15 mg	Intravenous injection	
Kaolin	Barytgen HD	Oral/enema	PMDA concluded that this excipient may be used only under the condition for regular gastrointestinal contrast media, that is, a single dose is administered in the fasted state followed by rapid excretion.
Gadobutrol sodium salt	Gadovist IV Inj. 1.0 mol/L 2 mL/Gadovist IV Inj. 1.0 mol/L 7.5 mL/Gadovist IV Inj. 1.0 mol/L Syringe 5 mL/Gadovist IV Inj. 1.0 mol/L Syringe 7.5 mL/Gadovist IV Inj. 1.0 mol/L Syringe 10 mL	Intravenous injection	This excipient might have a risk of displacing biological metal ions other than gadolinium and raise safety problems when administered repeatedly for a long period of time. Its use should be approved only for the concerned product, which is basically supposed to be used as a single dose, and thus PMDA concluded that it should not be handled as a precedent for use.
Sodium citrate	Zione Injection/Lidocaine	Local injection	
Glycine	Kenketsu Venilon-I (500 mg)/Kenketsu Venilon-I (1000 mg)/Kenketsu Venilon-I (2500 mg)/Kenketsu Venilon-I (5000 mg)	Intravenous injection	Case of use in the high-dose therapy (2000 mg/kg/body weight) for acute-phase Kawasaki's disease
Glycerin	Gabapen Syrop 5%	Oral	PMDA concluded that this excipient may be used only under the condition where it is administered in appropriate divided doses, because once-daily administration of the same amount as that used through treatment with the concerned product showed a potential effect on the fecal form.
	Zione Injection/Lidocaine	Local injection	

Copper(II) Gluconate	Vyxeos Combination for I.V. Injection	Intravenous injection	In view of the seriousness of the target disease of the concerned product, use of this excipient in the product is considered acceptable, but the long-term use of this excipient might possibly cause accumulation of copper in the liver. PMDA concluded that the concerned product should not be handled as a precedent for use of this excipient.
Cholesterol	AmBisome 50 mg for Intravenous Drip Infusion	Intravenous injection	
	Doxil Injection 20 mg	Intravenous injection	
	Onpattro Infusion 2 mg/mL	Intravenous injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient. In the toxicity studies, increases in hepatic enzyme levels potentially attributable to LNP were observed. PMDA thus concluded that the concerned product should not be handled as a precedent for use of this excipient, although its use to ensure the formulation attributes is considered inevitable.
	Onivyde I.V. Infusion 43 mg	Intravenous injection	This excipient is a component of liposomes. In patients treated with the liposomal formulation, infusion reactions such as infusion-related reactions occurred to a certain extent, and for the concerned events, a causal relationship to this excipient cannot be ruled out. In view of the seriousness of the target disease, PMDA concluded that this excipient may be used in the concerned product on the condition that its use will not be handled as a precedent.
	Arikayce inhalation solution 590 mg	Inhalation	Deposition of inhaled substances in the respiratory tissues has been known to depend on their particle size, density, and morphology (<i>Toxicology</i> , 3rd edition. Asakura Publishing; 2018.229-32). The specifications for the product define the liposomal particle size for the liposomes comprising dipalmitoylphosphatidylcholine and this excipient and the aerodynamic particle size distribution for aerosol particles containing the liposomes. PMDA concluded that dipalmitoylphosphatidylcholine and this excipient may be used only in inhalant products with the specifications equivalent to those of the concerned product.
	Spikevax Intramuscular Injection (formerly COVID-19 Vaccine Moderna Intramuscular Injection)	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. PMDA, however, concluded that the concerned product should not be handled as a precedent for use of this excipient, because effects on hepatocytes were observed in the toxicity studies.
	Daichirona Intramuscular Injection	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
	Kostaive intramuscular injection	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
	Vyxeos Combination for I.V. Injection	Intravenous injection	This excipient is one of the components of liposomes encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
β-cyclodextrin	mRESVIA Intramuscular Injection Syringe	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. PMDA, however, concluded that the concerned product should not be handled as a precedent for use of this excipient, because effects on hepatocytes were observed in the toxicity studies.
	Patch Test Panel	Other external use	The excipient has local irritation potential, and repeated administrations at the applied concentration with the concerned product might possibly raise a problem of local irritation. Because the concerned product is supposed to be administered as a single dose, PMDA concluded that use of this excipient in the concerned product may be acceptable, but it should not be handled as a precedent for universal use.
	Baqsimi Nasal Powder 3 mg	Otolaryngologic use	

1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)	Breztri Aerosphere 56 Inhalations/Breztri Aerosphere 120 Inhalations	Inhalation	Deposition of inhaled substances in the respiratory tissues has been known to depend on their particle size, density, and morphology. In view of the safety evaluation, which was conducted using porous particles with specific powder properties, PMDA concluded that this excipient may be used only in inhalant products in which its particles have size, density, and morphology equivalent to those contained in the concerned product.
	Bevespi Aerosphere 28 Inhalations/Bevespi Aerosphere 120 Inhalations	Inhalation	Deposition of inhaled substances in the respiratory tissues has been known to depend on their particle size, density, and morphology. In view of the safety evaluation, which was conducted using porous particles with specific powder properties, PMDA concluded that this excipient may be used only in inhalant products in which its particles have size, density, and morphology equivalent to those contained in the concerned product.
	Onpattro Infusion 2 mg/mL	Intravenous injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient. In the toxicity studies, increases in hepatic enzyme levels potentially attributable to LNP were observed. PMDA thus concluded that the concerned product should not be handled as a precedent for use of this excipient, although its use to ensure the formulation attributes is considered inevitable.
	Comirnaty Intramuscular Injection	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient. In a 2-week (once every 2 weeks) intramuscular-dose toxicity study of the concerned product in rats, an effect on the liver was observed, but the long-term toxicity with daily administration has not been evaluated. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for use, although the use of this excipient in the concerned product is inevitable to ensure the formulation attributes.
	Onivyde I.V. Infusion 43 mg	Intravenous injection	This excipient is a component of liposomes. In patients treated with the liposomal formulation, infusion reactions such as infusion-related reactions occurred to a certain extent, and for the concerned events, a causal relationship to this excipient cannot be ruled out. In view of the seriousness of the target disease, PMDA concluded that this excipient may be used in the concerned product on the condition that its use will not be handled as a precedent.
	Spikevax Intramuscular Injection (formerly COVID-19 Vaccine Moderna Intramuscular Injection)	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. PMDA, however, concluded that the concerned product should not be handled as a precedent for use of this excipient, because effects on hepatocytes were observed in the toxicity studies.
	Daichirona Intramuscular Injection	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
	Kostaive intramuscular injection	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
	Vyxeos Combination for I.V. Injection	Intravenous injection	This excipient is one of the components of liposomes encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
mRESVIA Intramuscular Injection Syringe	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. PMDA, however, concluded that the concerned product should not be handled as a precedent for use of this excipient, because effects on hepatocytes were observed in the toxicity studies.	
Distearoyl phosphatidylglycerol, sodium	AmBisome 50 mg for Intravenous Drip Infusion	Intravenous injection	
	Vyxeos Combination for I.V. Injection	Intravenous injection	This excipient is one of the components of liposomes encapsulating the active ingredient and is considered as an essential ingredient to ensure the formulation attributes. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.

Dipalmitoylphosphatidylcholine	Arikayce inhalation solution 590 mg	Inhalation	Deposition of inhaled substances in the respiratory tissues has been known to depend on their particle size, density, and morphology (<i>Toxicology</i> , 3rd edition. Asakura Publishing; 2018.229-32). The specifications for the concerned product define the liposomal particle size for the liposomes comprising this excipient and cholesterol and the aerodynamic particle size distribution for aerosol particles containing the liposomes. PMDA concluded that this excipient and cholesterol may be used only in inhalant products with the specifications equivalent to those of the concerned product.
Dimyristoylphosphatidylcholine	Visudyne for Intravenous Injection 15 mg	Intravenous injection	
N,N-Dimethylacetamide	Busulfex Injection 60 mg	Intravenous injection	
Dimethylsulfoxide	Zicthoru Tapes 75 mg	Transdermal patch	For the following reasons, PMDA concluded that restrictions on the use specific to this excipient should be established and the concerned product should not be handled as a precedent for universal use of the excipient. - If the amount of use of this excipient, which is transdermally absorbed, exceeds a certain level, systemic toxicity may occur. For the products using this excipient, the daily dose should be restricted with application frequency and area, or other measures. - If a product containing this excipient is transdermally administered to humans, the safety-control measures such as avoiding repeated application at the same site should be taken to prevent skin irritation.
Aluminum hydroxide suspension	Cervarix	Intramuscular injection	PMDA concluded that this excipient may be used only as an adjuvant in view of the risk and benefit.
Hydrogenated soy phosphatidylcholine	Doxil Injection 20 mg	Intravenous injection	
Hydrogenated soybean phospholipids	AmBisome 50 mg for Intravenous Drip Infusion	Intravenous injection	
Sulfobutylether β -cyclodextrin sodium	Kyprolis for Intravenous Injection 10 mg/Kyprolis for Intravenous Injection 40 mg	Intravenous injection	Although a safety margin for nephrotoxicity cannot be adequately ensured, considering the seriousness of the target disease, PMDA permitted its use from a viewpoint of risk and benefit. PMDA, on the other hand, concluded that the concerned product should not be handled as a precedent for universal use of this excipient.
	Vfend for Intravenous Use 200 mg	Intravenous injection	
	Noxafil for Intravenous Infusion 300 mg	Intravenous injection	Because nephrotoxicity was observed in repeated intravenous dose studies in rats and dogs, and anaphylactic (anaphylactoid) reactions may occur in response to a rapid increase in blood concentrations of this excipient, its use is approved only in specific products or under specific conditions. PMDA, on the other hand, concluded that the concerned product should not be handled as a precedent for universal use of this excipient.
	Veklury for Intravenous Injection 100 mg	Intravenous injection	Because (1) nephrotoxicity was observed in a repeated intravenous dose study in rats; (2) the effect of this excipient on children younger than 2 years who have the kidneys at a developmental stage remains unknown; and (3) in patients with renal impairment, accumulation of this excipient might further worsen their renal functions, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
	Fycompa for Intravenous Infusion 2 mg	Intravenous injection	Nephrotoxicity of this excipient was observed in repeated intravenous dose studies in rats, rabbits, dogs and monkeys, and a safety margin for the nephrotoxicity cannot be ensured with the concerned product. PMDA, however, considered it inevitable to use this excipient as a solubilizer. In view of the above points, PMDA concluded that the concerned product should not be used as a precedent for universal use of this excipient.
	Mekinist Dry syrup for Pediatric 4.7 mg	Oral	This excipient contained in the pediatric product has not caused any changes suggestive of a significant risk, and in view of the seriousness of the target disease, use of this excipient in the pediatric product is considered acceptable. However, because diarrhoea, etc. occurred in clinical studies using the pediatric product, PMDA considers that the concerned product should not be handled as a precedent for use of this excipient.
Purified Quillaja saponin	Shingrix for I.M. Injection	Intramuscular injection	PMDA concluded that this excipient may be used only as an adjuvant in view of the risk and benefit.
D-Sorbitol	Venoglobulin IH (500 mg)/Venoglobulin IH (1000 mg)/Venoglobulin IH (2500 mg)/Venoglobulin IH (5000 mg)	Intravenous injection	Case of use in the high-dose therapy (2000 mg/kg/body weight) for acute-phase Kawasaki's disease

Soy lecithin	Stelues Suspension Liquid for Intramuscular Injection 600,000 Units/Stelues Suspension Liquid for Intramuscular Injection 2,400,000 Units	Intramuscular injection	Because the safety with intramuscular administration is evaluated based on clinical experience with the concerned product outside Japan, PMDA concluded that use of this excipient may be accepted only when it falls within the range of the dosage and administration of the concerned product.
3-Desacylation-4'-monophosphoryl lipid A	Cervarix	Intramuscular injection	PMDA concluded that this excipient may be used only as an adjuvant in view of the risk and benefit.
Tyloxapol	Inavir for Inhalation Suspension 160 mg Set	Inhalation	Because a safety margin with the long-term inhalation use cannot be ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of this excipient.
Dextran 40	Zione Injection/Lidocaine	Local injection	
Tocopherol	AmBisome 50 mg for Intravenous Drip Infusion	Intravenous injection	
Dodecylphosphocholine	Baqsimi Nasal Powder 3 mg	Otolaryngologic use	
Treprostinil sodium	Lyumjev Cart/Lyumjev MirioPen/Lyumjev MirioPen HD/Lyumjev Injection 100 units/mL	Subcutaneous injection	Treprostinil sodium is known to be potentially accompanied by local injection site reactions when administered intravenously or subcutaneously, and the incidence of events related to injection site reactions was higher in the concerned product group than in the other groups in clinical studies of the concerned product. Although events related to injection site reactions with the concerned product are unlikely to raise clinical problems, for the events, a causal relationship to treprostinil sodium cannot be ruled out. PMDA thus concluded that the concerned product should not be handled as a precedent for universal use of this excipient.
Ascorbyl Palmitate	Visudyne for Intravenous Injection 15 mg	Intravenous injection	
L-histidine hydrochloride hydrate	Beyfortus Intramuscular Injection 50 mg with Syringe/Beyfortus Intramuscular Injection 100 mg with Syringe	Intramuscular injection	The concerned product is usually administered once for each epidemic season of RS virus (Seasons 1 and 2). The safety in non-clinical settings was evaluated in a 1-month repeated-dose toxicity study in cynomolgus monkeys (once a week), but the safety for local tolerance at the intramuscular injection sites after long-term use has not been evaluated. PMDA thus concluded that the approval for use of this excipient should be limited to the concerned product, and it should not be handled as a precedent for use.
Human serum albumin	Kenketsu Venilon-I (500 mg)/Kenketsu Venilon-I (1000 mg)/Kenketsu Venilon-I (2500 mg)/Kenketsu Venilon-I (5000 mg)	Intravenous injection	Case of use in the high-dose therapy (2000 mg/kg/body weight) for acute-phase Kawasaki's disease
[4-(hydroxybutyl)azanediy]bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	Comirnaty Intramuscular Injection	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient. In a 2-week (once every 2 weeks) intramuscular-dose toxicity study of the concerned product in rats, an effect on the liver was observed, but the long-term toxicity with daily administration has not been evaluated. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for use, although the use of this excipient in the concerned product is inevitable to ensure the formulation attributes.
Hydroxypropyl-β-cyclodextrin	Itrazole Injection 1% [200 mg]	Intravenous injection	
	Itrazole Oral Solution 1%	Oral	
	Prevymis Intravenous Infusion 240 mg	Intravenous injection	Although a safety margin for hepatotoxicity and nephrotoxicity cannot be adequately ensured, considering seriousness of the target disease, PMDA approved its use from a viewpoint of risk and benefit. PMDA, on the other hand, concluded that the concerned product should not be handled as a precedent for universal use of this excipient.
Castor oil	Faslodex Intramuscular Injection 250 mg	Intramuscular injection	This excipient was suggested to have a risk of local irritation and tissue damage. PMDA concluded that this excipient may be used only in the products that are administered by a method designed to avoid accumulation of irritation, such as the concerned product, which is administered intermittently.
L-proline	Privigen 10% I.V. Drip Infusion 5 g/50 mL/Privigen 10% I.V. Drip Infusion 10 g/100 mL/Privigen 10% I.V. Drip Infusion 20 g/200 mL	Intravenous injection	Although the amount of L-proline in a clinical dose of the concerned product is not considered large enough to contribute to the treatment of the target disease, it exceeds the amount in a clinical dose of the other products using L-proline as the active ingredient. PMDA thus concluded that the concerned product should not be handled as a precedent for use of this excipient.
Maltitol powder	Barytgen-Deluxe	Oral/enema	PMDA concluded that this excipient may be used only under the condition for regular gastrointestinal contrast media, that is, a single dose is administered in the fasted state followed by rapid excretion.

Benzyl alcohol	Faslodex Intramuscular Injection 250 mg	Intramuscular injection	This excipient was suggested to have a risk of local irritation and tissue damage. PMDA concluded that this excipient may be used only in the products that are administered by a method designed to avoid accumulation of irritation such as the concerned product, which is administered intermittently.
Bentonite	Barytgen	Oral/enema	PMDA concluded that this excipient may be used only under the condition for regular gastrointestinal contrast media, that is, a single dose is administered in the fasted state followed by rapid excretion.
Povidone	Stelues Suspension Liquid for Intramuscular Injection 600,000 Units/Stelues Suspension Liquid for Intramuscular Injection 2,400,000 Units	Intramuscular injection	Because the safety with intramuscular administration is evaluated based on clinical experience with the concerned product outside Japan, PMDA concluded that use of this excipient may be accepted only when it falls within the range of the dosage and administration of the concerned product.
Povidone (K value = 17)	Istodax Injection 10 mg	Intravenous injection	Although a risk of hypersensitivity cannot be ruled out, PMDA approved use of this excipient in view of the seriousness of the target disease. PMDA, on the other hand, concluded that the concerned product should not be handled as a precedent for universal use of this excipient.
Povidone K12	Alkeran for injection 50 mg	Intravenous injection	
Polyethylene glycol 400	Busulfex Injection 60 mg	Intravenous injection	
	Rethio 100 mg for Intravenous Infusion	Intravenous injection	In view of the seriousness of the target disease of the concerned product, use of this excipient in the product is considered acceptable, but clinical use of the product may lead to toxicity in the liver and kidney. PMDA thus concluded that the concerned product should not be handled as a precedent for use of this excipient.
2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	Comirnaty Intramuscular Injection	Intramuscular injection	This excipient is one of the components of lipid nanoparticles (LNP) encapsulating the active ingredient. In a 2-week (once every 2 weeks) intramuscular-dose toxicity study of the concerned product in rats, an effect on the liver was observed, but the long-term toxicity with daily administration has not been evaluated. Because this excipient is used without an expiration date specified but the safety of such use has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for use, although the use of this excipient in the concerned product is inevitable to ensure the formulation attributes.
Polyoxyethylene octylphenyl ether	Efluelda intramuscular injection	Intramuscular injection	Because this excipient is used without an expiration date specified but the safety of this excipient intramuscularly administered has not been ensured, PMDA concluded that the concerned product should not be handled as a precedent for universal use of the excipient.
Polydimethylsiloxane cured elastomer M	Mirena 52 mg	Intrauterine	
Polysorbate 80	Taxotere 20 mg for I.V. Infusion/Taxotere 80 mg for I.V. Infusion	Intravenous injection	
	Onetaxotere I.V. Infusion 20 mg/1 mL/Onetaxotere I.V. Infusion 80 mg/4 mL	Intravenous injection	
net-poly[(1,2,6-hexantriol)-alt-(methylenebiscyclohexyl-4,4'-diyl diisocyanate)-block-(polyethylene glycol)]	Propess vaginal inserts 10 mg	Intravaginal	
Maltose	Nisseki Polyglobin-N 5% I.V. 0.5 g/10 mL/Nisseki Polyglobin-N 5% I.V. 2.5 g/50 mL/Nisseki Polyglobin-N 5% I.V. 5 g/100 mL	Intravenous injection	Case of use in the high-dose therapy (2000 mg/kg/body weight) for acute-phase Kawasaki's disease
D-mannitol	acelio Bag for Intravenous Injection 1000 mg	Intravenous injection	The dosage and administration of the concerned product are considered unlikely to lead to development of the pharmacological effect of this excipient, but a bolus of the other products containing D-mannitol might potentially lead to development of its pharmacological effect. PMDA thus concluded that the concerned product should not be handled as a precedent for use of this excipient.
	Kenketu Glovenin-I-Nichiyaku	Intravenous injection	Case of use in the high-dose therapy (2000 mg/kg/body weight) for acute-phase Kawasaki's disease
	Kenketsu Venilon-I (500 mg)/Kenketsu Venilon-I (1000 mg)/Kenketsu Venilon-I (2500 mg)/Kenketsu Venilon-I (5000 mg)	Intravenous injection	Case of use in the high-dose therapy (2000 mg/kg/body weight) for acute-phase Kawasaki's disease
	Dantrium 20 mg for Intravenous Injection	Intravenous injection	
2-(N-morpholino)ethanesulfonic acid	Trodely for Injection 200 mg	Intravenous injection	In view of results from toxicity studies using this excipient as the control or test article, use of this excipient in the proposed product is considered acceptable. PMDA, however, concluded that the concerned product should not be handled as a precedent for use of this excipient, because the information about reproductive and developmental toxicity of the excipients is limited, and use of the concerned product in clinical studies and clinical settings outside Japan is limited to specific patient populations and conditions.

Sodium lauryl sulfate	Alecensa Capsule 150 mg	Oral	No adverse effects attributable to exposure to this excipient have been observed in clinical use results of the foreign-approved product containing this excipient (identical to the Japan-approved product) (US-approved in 2015) or results from the clinical study (Study ALINA). Use of this excipient in the proposed product is considered acceptable. PMDA, however, concluded that the concerned product should not be handled as a precedent for use of this excipient for its maximum daily amount of use, because use of the concerned product in clinical studies and clinical settings outside Japan is limited to specific patient populations and conditions.
	Augtyro capsules 40 mg	Oral	Use of this excipient in the proposed product is considered acceptable, because (1) the maximum daily amount of use of this excipient is below the no-observed-adverse-effect level (NOAEL) in the non-clinical studies; and (2) no adverse effects attributable to exposure to this excipient have been observed in results from clinical studies or post-marketing experience outside Japan using the product in the same formula as that of the proposed product or clinical use results of the other products outside Japan. PMDA, however, concluded that the maximum daily amount of use of this excipient should not be handed as a precedent, because (1) the maximum daily amount of use of this excipient calculated based on the proposed dosage and administration does not have an adequate safety margin ensured in view of the human dose equivalent to the NOAEL of this excipient in rats and dogs; and (2) use of the product in the clinical studies and clinical settings outside Japan is limited to specific patient populations and conditions.
D,l-lactide/glycolide copolymer (50:50)	Bydureon for Subcutaneous Injection 2 mg	Subcutaneous injection	This excipient was suggested to have a risk of local irritation. PMDA concluded that use of this excipient should be accepted only in the products that are administered under the special conditions to reduce a risk of irritation, such as the dosage regimen of the concerned product, which is administered to a different site for each dose.
Lidocaine	Zione Injection/Lidocaine	Local injection	
Aluminum potassium sulfate	Tosuflo Ophthalmic Solution 0.3%/Ozex Ophthalmic Solution 0.3%	Instillation	
Ammonium sulfate	Doxil Injection 20 mg	Intravenous injection	
Aluminum phosphate	Prevenar 20 Suspension Liquid for Injection	Subcutaneous injection	PMDA concluded that this excipient may be used only as an adjuvant in view of the risk and benefit.
	Prevenar 13 Suspension Liquid for Injection	Intramuscular injection	
Lecithin	Stelues Suspension Liquid for Intramuscular Injection 600,000 Units/Stelues Suspension Liquid for Intramuscular Injection 2,400,000 Units	Intramuscular injection	Because the safety with intramuscular administration is evaluated based on clinical experience with the concerned product outside Japan, PMDA concluded that use of this excipient may be accepted only when it falls within the range of the dosage and administration of the concerned product.

(others)

Uses of the excipients in generic drugs of the products listed in the above table should be handled as done for the original drugs in principle, although they are not included in the table.

For excipients used in HIV treatment drugs, please consult us individually.