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ACQUIRING USER ID

Item	Slovene term	English translation
1.	Ime	Given name
2.	Priimek	Family name
3.	Delovno mesto	Position
4.	Naziv organizacije	Name of organisation
5.	Naslov organizacije	Address of organisation
6.	Telefonska številka	Telephone number
7.	Elektronski poštni naslov	Electronic mail address
8.	Vrsta organizacije	Type of organisation
	Imetnik dovoljenja za promet z zdravilom ali njegov pooblaščenec	Marketing authorisation holder or their proxy
	Imetnik začasnega dovoljenja za vnos oz. uvoz zdravila ali njegov pooblaščenec	Exceptional import license holder or their proxy
	Imetnik dovoljenja za promet s paralelno uvoženim zdravilom ali njegov pooblaščenec	Marketing authorisation holder for parallel imported medicinal product or their proxy
	Imetnik potrdila o paralelni distribuciji ali njegov pooblaščenec	Holder of notification of parallel distribution or their proxy
9.	Pripombe	Comments
10.	V primeru, da nastopate kot pooblaščenec, prosimo, pošljite vsa pooblastila v PDF obliki na elektronski poštni naslov porocanje_24clen@jazmp.si	In case you are a proxy, please provide the relevant power of attorney letter(s) in pdf form to the porocanje_24clen@jazmp.si e-mail

NOTIFICATION OF MARKETING STATUS CHANGE

Item	Slovene term	English translation
1.	Uporabniški ID (če še nimate svojega uporabniškega ID, ga lahko pridobite tukaj: https://forms.office.com/e/m0gt0VbSCH)	User ID (please register on https://forms.office.com/e/m0gt0VbSCH should you not have one)
2.	Elektronski poštni naslov	Electronic mail address
3.	Delovna šifra zdravila (pravilnost delovne šifre lahko preverite na http://www.cbz.si)	National identifier (the national identifier can be checked on http://www.cbz.si)
4.	Vrsta obvestila	Notification type
	Obvestilo o (ponovnem) prihodu zdravila na trg na debelo	Notification of (re)start of marketing
	Obvestilo o motnji v preskrbi z zdravilom	Notification of temporary supply disruption
	Obvestilo o začasnem prenehanju opravljanja prometa z zdravilom	Notification of temporary cessation of marketing
	Obvestilo o stalnem prenehanju opravljanja prometa z zdravilom	Notification of permanent cessation of marketing
	Obvestilo o preklicu napovedane motnje v preskrbi z zdravilom, začasnega ali stalnega prenehanja opravljanja prometa z zdravilom pred dogodkom	Notification of recall of notification of temporary supply disruption, temporary or permanent cessation of marketing before their start date
Icon	Naprej	Forward

NOTIFICATION OF (RE)START OF MARKETING

Item	Slovene term	English translation
5.	Vrsta prihoda zdravila na trg na debelo	Type of (re)start of marketing
	Prvi prihod zdravila na trg na debelo	First start of marketing
	Ponovni prihod zdravila na trg na debelo po predhodno priglašeni motnji v preskrbi	Restart of marketing following temporary supply disruption
	Ponovni prihod zdravila na trg na debelo po predhodno priglašenem začasnom prenehanju opravljanja prometa z zdravilom	Restart of marketing following temporary marketing cessation
	Ponovni prihod zdravila na trg na debelo po predhodno priglašenem stalnem prenehanju opravljanja prometa z zdravilom	Restart of marketing following permanent marketing cessation
6.	Datum (ponovnega) prihoda zdravila na trg na debelo	Date of (re)start of marketing
7.	Pripombe	Comments
Icon	Nazaj	Back
Icon	Pošlji	Send

NOTIFICATION OF TEMPORARY SUPPLY DISRUPTION

Item	Slovene term	English translation
5.	Datum pričetka motnje v preskrbi z zdravilom	Start date of temporary supply disruption
6.	Datum zaključka motnje v preskrbi z zdravilom	End date of temporary supply disruption
7.	Razlog za motnjo v preskrbi z zdravilom	Root cause of temporary supply disruption
	Sum na neustrezno kakovost	Quality issues (potential quality defect or recall)
	Težave v proizvodnji (nepovezane s kakovostjo ali odpoklicem zdravila)	Manufacturing issues (not related to quality defect or recall)
	Neskladnost z regulativnimi zahtevami	Regulatory issues
	Nepričakovano povečano povpraševanje po zdravilu	Unexpected increased demand
	Težave v distribucijski verigi	Distribution issues
	Poslovni razlogi	Commercial reasons
	Drugo	Other (please specify)*
8.	Sum na neustrezno kakovost	Quality issues (potential quality defect or recall)
	Sum na neustrezno kakovost, ki preprečuje sprostitev serije	Suspected defective product preventing release of batches to the market
	Sum na neustrezno kakovost, ki zahteva odpoklic serije	Suspected defective product requiring batch recall
	Drugo	Other
8.	Težave v proizvodnji	Manufacturing issues
	Težave v proizvodnji, ki onemogočajo proizvodnjo in/ali sproščanje	Manufacturing issues preventing production/release
	Kadrovske omejitve	Restrictions on people
	Neskladnost z dobro proizvodno prakso	GMP non-compliance
	Omejene proizvodne zmogljivosti	Capacity issues
	Drugo	Other
8.	Neskladnost z regulativnimi zahtevami	Regulatory issues
	Omejitev/preklic dovoljenja za promet	Marketing authorisation restricted/suspended
	Zamuda pri regulativni odobritvi	Regulatory approval delay
	Drugo	Other
8.	Nepričakovano povečano povpraševanje po zdravilu	Unexpected increased demand
	Ustvarjanje zalog pri uporabnikih	Consumer driven stockpiling
	Ustvarjanje zalog s strani države članice	Member State driven stockpiling
	Spremenjene predpisovalne navade	Changes in prescribing behaviour
	Spremenjena uporaba zdravila (izven odobrenih indikacij ali zaradi sprememb v dovoljenju za promet)	Change in use (off-label or through changes in marketing authorisation)
	Povečano povpraševanje po zdravilu zaradi motene preskrbe z zdravilom drugega imetnika dovoljenja za promet	Increased demand due to unavailability from other marketing authorisation holders
	Drugo	Other

8.	Težave v distribucijski verigi	Distribution issues
	Letalski prevoz	Air transport
	Ladijski prevoz	Sea transport
	Izvozne omejitve	Export restrictions
	Uvozne omejitve	Import restrictions
	Drugo	Other
8.	Poslovni razlogi	Commercial reasons
	Cena in razvrstitev	Pricing and reimbursements
	Insolventnost	Insolvency
	Prednostna preskrba drugih trgov	Prioritisation of other markets
	Poslovna strategija (drugo)	Business strategy (other)
	Drugo	Other
9.	Kratek opis razlogov oz. opredelitev poslovno zaupnih informacij	Brief description of root causes / indication and explanation of inclusion of any commercially confident information
10.	Ocena vpliva motnje v preskrbi z zdravilom na javno zdravje prebivalstva RS	Assessment of impact of temporary supply disruption on public health in the republic of Slovenia
	Velik	High
	Srednji	Medium
	Majhen	Low
11.	Komentar ocene vpliva	Comment on impact assessment
12.	Opis ukrepov poročevalca za zmanjšanje vpliva motnje v preskrbi z zdravilom na javno zdravje prebivalstva RS	Mitigation/prevention plan
	Dodatni viri vhodnih surovin	Alternative sources of raw/startling materials
	Dodaten proizvajalec učinkovine	Alternative active substance manufacturer
	Dodaten proizvajalec končnega izdelka	Alternative finished product manufacturer
	Dodatno mesto kontrole proizvedenih serij	Alternative batch control site
	Dodatno mesto sproščanja proizvedenih serij	Alternative batch release site
	Dobava zdravila v tuji ovojnini	Supply of product in foreign language labelling
	Dobava nadomestnega zdravila, ki nima dovoljenja za promet	Supply of alternative unauthorised product
	Sproščanje zdravila z manjšimi odstopanjimi v kakovosti	Release of product with minor quality defects
	Povečanje proizvodnih zmogljivosti trenutnih proizvodnih mest	Increase production capacity of current site(s)
	Dobava zdravila v drugi farmacevtski oblikah ali opremljanju	Supply of other presentation(s) of the same product
	Uporaba izjemnega postopka obvladovanja sprememb (angl. exceptional change management process (ECMP))	Use of exceptional change management process (ECMP)
	Odpravljanje težav v proizvodnji ali neustrezne kakovosti izdelka	Resolve manufacturing or quality issue(s)
	Sprememba načina prevoza	Change mode of transportation
	Hitro pošiljanje in pošiljanje v času karantene zdravila	Expedited shipment and shipment under quarantine

	Prednostna dobava kritičnim uporabnikom in trgom	Prioritisation of supplies to critical customers
	Drugo	Other (please specify)
13.	Pripombe oz. opredelitev poslovno zaupnih informacij	Comments / indication and explanation of inclusion of any commercially confident information
Icon	Nazaj	Back
Icon	Pošlji	Send

* If »Other« is selected in Item 7., the order number of the following items decreases for one as additional detail required if any other option is selected (Item 8) is not required for obvious reasons.

NOTIFICATION OF TEMPORARY CESSATION OF MARKETING

Item	Slovene term	English translation
5.	Datum pričetka začasnega prenehanja opravljanja prometa z zdravilom	Start date of temporary cessation of marketing
6.	Datum zaključka začasnega prenehanja opravljanja prometa z zdravilom	End date of temporary cessation of marketing
7.	Razlog za začasno prenehanje opravljanja prometa z zdravilom	Root cause of temporary cessation of marketing
	Nezmožnost zagotavljanja ustrezne kakovosti zdravila	Inability to ensure adequate quality of medicinal product
	Težave v proizvodnji (nepovezane s kakovostjo ali odpoklicem zdravila)	Manufacturing issues (not related to quality defect or recall)
	Nezmožnost izpolnjevanja regulativnih zahtev	Inability to meet regulatory requirements
	Zaključek proizvodnje učinkovine ali drugih sestavin izdelka	Termination of production of active ingredient or other components of medicinal product
	Težave v distribucijski verigi	Distribution issues
	Poslovni razlogi	Commercial reasons
	Drugo	Other (please specify)
8.	Ocena vpliva začasnega prenehanja opravljanja prometa z zdravilom na javno zdravje prebivalstva RS	Assessment of impact of temporary cessation of marketing on public health in the Republic of Slovenia
	Velik	High
	Srednji	Medium
	Majhen	Low
9.	Komentar ocene vpliva	Comment on impact assessment
10.	Opis ukrepov poročevalca za zmanjšanje vpliva začasnega prenehanja opravljanja prometa z zdravilom na javno zdravje prebivalstva RS	Mitigation/prevention plan
	Ukrepi niso potrebni	No measure required
	Ukrep	Measure implemented
11.	Ukrepi niso potrebni	No measure required
	Na trgu so na voljo druga pakiranja zdravila	Alternative packaging of the product remains available
	Na trgu so na voljo druga primerna zdravila	Adequate alternative product(s) available on the market
	Zdravljenje z zdravilom se nadomešča z novejšimi načini zdravljenja	Treatment with the medicinal product is being replaced by novel treatment modalities
	Drugo	Other
12.	Komentar, zakaj ukrepi niso potrebni	Comment on why no measure is required
13.	Pripombe oz. opredelitev poslovno zaupnih informacij	Comments / indication and explanation of inclusion of any commercially confidential information
Icon	Nazaj	Back
Icon	Pošlji	Send

In case "Measure implemented" is selected in Item 10 the following alternative Items 11 and 12 appear:

11.	Opis izvedenih ukrepov	Description of measures implemented
12.	Pripombe oz. opredelitev poslovno zaupnih informacij	Comments / indication and explanation of inclusion of any commercially confidential information

NOTIFICATION OF PERMANENT CESSATION OF MARKETING

Item	Slovene term	English translation
5.	Datum pričetka stalnega prenehanja opravljanja prometa z zdravilom	Start date of permanent cessation of marketing
6.	Razlog za stalno prenehanje opravljanja prometa z zdravilom	Root cause of permanent cessation of marketing
	Nezmožnost zagotavljanja ustrezne kakovosti zdravila	Inability to ensure adequate quality of medicinal product
	Težave v proizvodnji (nepovezane s kakovostjo ali odpoklicem zdravila)	Manufacturing issues (not related to quality defect or recall)
	Nezmožnost izpolnjevanja regulativnih zahtev	Inability to meet regulatory requirements
	Zaključek proizvodnje učinkovine ali drugih sestavin izdelka	Termination of production of active ingredient or other components of medicinal product
	Težave v distribucijski verigi	Distribution issues
	Poslovni razlogi	Commercial reasons
	Drugo	Other (please specify)
7.	Ocena vpliva stalnega prenehanja opravljanja prometa z zdravilom na javno zdravje prebivalstva RS	Assessment of impact of permanent cessation of marketing on public health in the Republic of Slovenia
	Velik	High
	Srednji	Medium
	Majhen	Low
8.	Komentar ocene vpliva	Comment on impact assessment
9.	Opis ukrepov poročevalca za zmanjšanje vpliva stalnega prenehanja opravljanja prometa z zdravilom na javno zdravje prebivalstva RS	Mitigation/prevention plan
	Ukrepi niso potrebni	No measure required
	Ukrep	Measure implemented
10.	Ukrepi niso potrebni	No measure required
	Na trgu so na voljo druga pakiranja zdravila	Alternative packaging of the product remains available
	Na trgu so na voljo druga primerna zdravila	Adequate alternative product(s) available on the market
	Zdravljenje z zdravilom se nadomešča z novejšimi načini zdravljenja	Treatment with the medicinal product is being replaced by novel treatment modalities
	Drugo	Other
11.	Komentar, zakaj ukrepi niso potrebni	Comment on why no measure is required
12.	Pripombe oz. opredelitev poslovno zaupnih informacij	Comments / indication and explanation of inclusion of any commercially confidential information
Icon	Nazaj	Back
Icon	Pošlji	Send

In case "Measure implemented" is selected in Item 9 the following alternative Items 10 and 11 appear:

10.	Opis izvedenih ukrepov	Description of measures implemented
11.	Pripombe oz. opredelitev poslovno zaupnih informacij	Comments / indication and explanation of inclusion of any commercially confidential information

NOTIFICATION OF RECALL OF NOTIFICATION OF TEMPORARY SUPPLY DISRUPTION, TEMPORARY OR PERMANENT CESSATION OF MARKETING BEFORE THEIR RESPECTIVE START DATE

Item	Slovene term	English translation
5.	Vrsta preklica	Type of recall
	Preklic napovedane motnje v preskrbi z zdravilom pred dogodkom	Recall of notification of temporary supply disruption
	Preklic napovedanega začasnega prenehanja opravljanja prometa z zdravilom pred dogodkom	Recall of notification of temporary cessation of marketing
	Preklic napovedanega stalnega prenehanja opravljanja prometa z zdravilom pred dogodkom	Recall of notification of permanent cessation of marketing
6.	Pripombe	Comments
Icon	Nazaj	Back
Icon	Pošlji	Send