



# Quick Start Guide for the specialized application "supply shortages" for human vaccines

#### Contact person Supply shortages

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## **Contents**

1	In	ntroduction	2
2	R	egistration	2
2	2.1	Specification of an email address for supply shortages	3
3	2.2 N	Authorization letter to report supply shortages for medicines from other marketing authorization holders of a supply shortage	
3	3.1	Terms of use	5
3	3.2	Further navigation steps and functionalities	5
3	3.3	"First notification" category	6
3	3.4	"Change notification" category	.10
3	3.5	"Deletion notification" category	.12
3	3.6	Notification Split - change in the expected end date or partial deletion of an existing supply shortage fo specific pack sizes	
4	S	upport	.14
4.1	Н	lelpdesk	.14
4.2		AQ	
5	Α	ppendix	.15
5.1		etter of authorization to report supply shortages for medicinal products from other marketing authorization olders (in German)	
5.2		etter of authorization to report supply shortages for medicinal products from other marketing authorization olders (in English)	









#### 1 Introduction

The Federal Institute for Drugs and Medical Devices (BfArM) gives an overview of current supply shortages for human medicinal products (excluding human vaccines) in Germany via the PharmNet.Bund portal. Shortages of human vaccines are published on the Paul-Ehrlich-Institut (PEI) https://www.pei.de/EN/medicinal-products/vaccines-human/supply-shortages/supplyshortages-node.html. Supply shortages are submitted by the pharmaceutical companies and are based on the voluntary commitment to report supply shortages for supply-relevant medicines, as set out in the Pharmadialog committee meetings.

The list of active substances considered to be supply-relevant is regularly updated by the advisory board on delivery and supply shortages. To enable the submission of supply shortage reports to BfArM, a portal with a form-based reporting system was established in 2016. In the next stage of the PharmNet.Bund portal, the BfArM and the PEI developed an online reporting portal for supply shortages. This enables quality assured submissions supported by an automated process linked to a regulatory database. The aims of the new online reporting portal are to significantly improve the flow of information in the event of impending supply shortages and to serve as support for decisions on countermeasures, thus contributing to an increase in patient safety.

#### 2 Registration

The registration portal is integrated into the PharmNet.Bund project. Registrations are handled centrally via the BfArM and make use of the RuBen Database. Access to several areas of the PharmNet.Bund, including the submission of shortages, is restricted exclusively to pharmaceutical companies, wholesalers and public authorities.

Registration for the "supply shortages" application takes place via the following website: https://portal.dimdi.de/ruben/faces/registration/RegistrationPage.xhtml





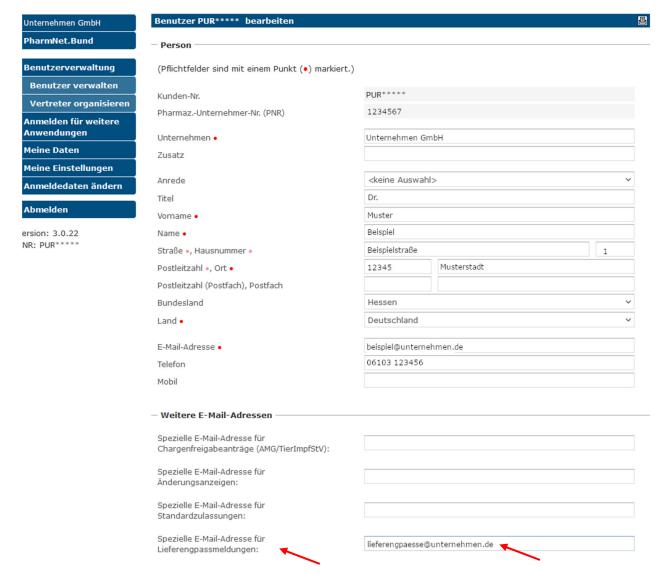






### 2.1 Specification of an email address for supply shortages

When registering in the RuBen database, make sure that a "specific email address for supply shortage reports" (*Spezielle E-Mail-Adresse für Lieferengpassmeldungen*) is assigned in the user data under "other email addresses" (*Weitere E-Mail-Adressen*). The field is not marked as a mandatory field when entering data in the system, as it only has to be filled in if supply shortage reports for human vaccines are submitted. This email address is used by the Paul-Ehrlich-Institut to send follow-up communications to the person reporting (see red arrows below). Therefore, an email address must be provided here so that the PEI can contact the correct person from the corresponding pharmaceutical company that filed a vaccine shortage.













# 2.2 Authorization letter to report supply shortages for medicines from other marketing authorization holders

All pharmaceutical companies that are allowed to manufacture, sell and ship medicines in Germany are given a pharmaceutical company number (PNR). The Paul-Ehrlich-Institut (PEI), the Federal Institute for Drugs and Medical Devices (BfArM) and the Federal Office for Consumer Protection and Food Safety (BVL) issue PNRs as the responsible approval authorities. If a pharmaceutical company is represented at different locations by different authorization holders, each authorization holder is assigned its own PNR. Using this PNR, the reporting party can register for their authorization holder in the PharmNet.Bund portal and submit supply shortage reports for the authorized medicinal products registered under this PNR. Supply shortage reports for pharmaceuticals from other marketing authorization holders (or other locations within the same company) can only be submitted if the reporting party has received a corresponding letter of authorization from the respective marketing authorization holder (foreign or domestic). This certifies that the reporting party may also submit supply shortage reports using the PNR of the other authorization holder. This authorization letter needs to be submitted to the BfArM. The BfArM then activates the option of reporting shortages using the respective PNR of the authorization holder (foreign or domestic) for the reporting of the authorization holder (German or otherwise) in the PharmNet.Bund portal. A sample authorization letter can be found in the appendix.





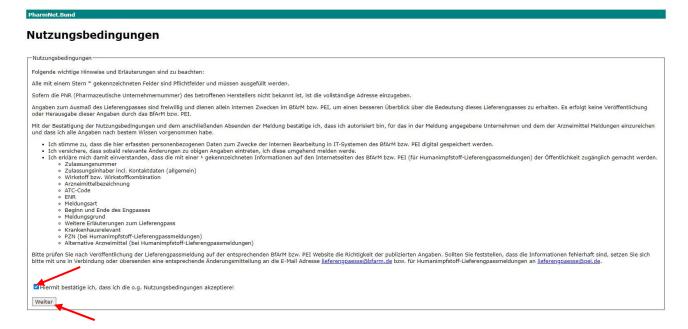




# 3 Notification of a supply shortage

#### 3.1 Terms of use

In order to be able to submit a supply shortage for medicinal products, the current version of the terms of use must first be accepted.



## 3.2 Further navigation steps and functionalities

After the terms of use have been accepted, the user receives the rights assigned to them by the main user of the company to make the submissions for one or, if necessary, several companies (field: select PNR). The main user of the company is responsible for granting the rights.

There are 3 types of notifications:

- First notification (*Erstmeldung*): The first notification is used to report a supply shortage that has not
  yet been reported or to report a supply shortage of an additional pack size in the event of an
  existing supply shortage for vaccines. Please note that in the case of an existing supply shortage,
  the notification of additional pack sizes must be made via a new first notification.
- Change notification (Änderungsmeldung): The change notification is used to make changes to a supply shortage that has already been reported, e.g. an extension of the end date of the supply shortage.
- 3. Deletion notification (*Löschmeldung*): A deletion notification indicates the end of a supply shortage.

PharmNet.Bund

#### Eingereichte LE-Meldungen LE\_01









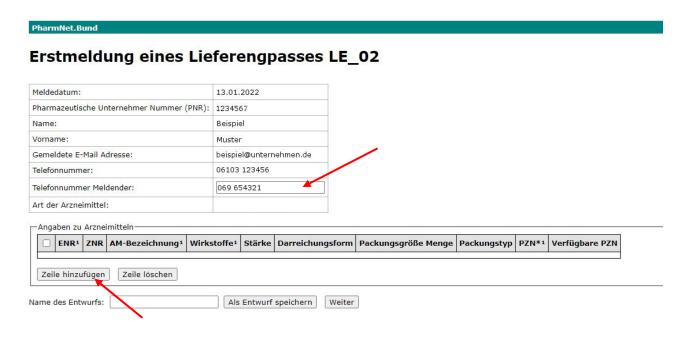




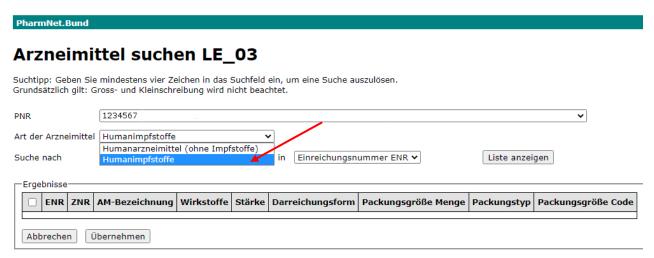
### 3.3 "First notification" category

After clicking on "first notification", a list appears containing data that was provided with the registration of the person authorized to access (name, telephone number, etc.). In the line "telephone number of reporting party" (*Telefonnummer Meldender*), the reporting party may enter an additional telephone number (e.g. if the number entered during the initial registration does not match that of the reporting party). If no telephone number was provided during the initial registration and the "telephone number" (*Telefonnummer*) field therefore remains empty, entering a telephone number is mandatory here.

For data protection purposes, only fictitious data is displayed in the images.



After clicking on "add row" (*Zeile hinzufügen*), the search form shown below opens. To report the supply shortage of a human vaccine, select "human vaccines" (*Humanimpfstoffe*) from the "type of drugs" (*Art der Arzneimittel*) drop-down menu.









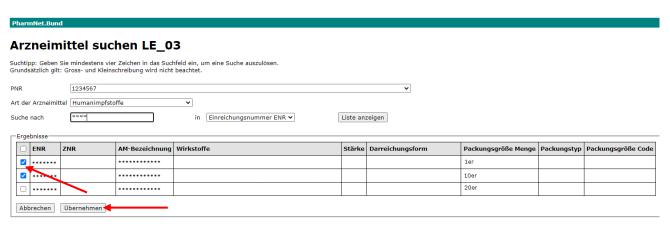




A search can be performed by using the submission number (*ENR*), the authorization number (*ZNR*) or the drug name (*AM-Bezeichnung*), which can be selected in the drop-down menu. In this example, the submission number (*ENR*) was used. A minimum of four characters has to be entered for an ENR.

PharmNet.Bund									
Arzneimittel suchen LE_03									
Suchtipp: Geben Sie Grundsätzlich gilt: Gr					m eine Suche au	szulösen.			
PNR	1234567								· ·
Art der Arzneimittel	Humanimpfstoffe		~	·					
Suche nach	****			in	Einreichungsn			Liste anzei	gen
Ergebnisse					Einreichungsnu Zulassungsnun				
				_	AM-Bezeichnur				
U ENR ZNR	AM-Bezeichnung	Wirkstoffe	Stärke	Darr	eichungsform	Packungsgrö	Be Menge	Packungstyp	Packungsgröße Code
Abbrechen Üb	pernehmen								

"Show list" (*Liste anzeigen*) shows the drug registered for the ENR submitted with all available pack sizes. All pack sizes included in the shortage are to be marked here and confirmed with "accept" (*Übernehmen*).



The 8-digit PZN (pharmacy central number) of the pack size(s) included in shortage has to be entered in the subsequent input form. If applicable, the PZN of any pack sizes still available (*Verfügbare PZN*) also have to be entered in the input field titled *Verfügbare PZN*.

#### PharmNet.Bund

#### Erstmeldung eines Lieferengpasses LE\_02

Meldedatum:	13.01.2022
Pharmazeutische Unternehmer Nummer (PNR):	1234567
Name:	Beispiel
Vorname:	Muster
Gemeldete E-Mail Adresse:	beispiel@unternehmen.de
Telefonnummer:	06103 123456
Telefonnummer Meldender:	069 654321
Art der Arzneimittel:	Humanimpfstoffe

<b>~</b>	ENR1	ZNR	AM- Bezeichnung <sup>1</sup>	Wirkstoffe <sup>1</sup>	Stärke	Packungsgröße Menge	Packungstyp	PZN*1	Verfügbare PZN
✓.	******		********			1er	N/A	12345678	
✓	******		********			 10er	N/A	87654321	











By clicking on "next" (Weiter), the following input form is opened. The required information has to be filled in, such as shortage type (Art des Engpasses), expected start and end dates of shortage (voraussichtlicher Beginn des Lieferengpasses, Voraussichtliches Ende des Lieferengpasses), and details on the causes of the supply shortage (Grund für den Lieferengpass).

PharmNet.Bund

## Erstmeldung eines Lieferengpasses LE\_04 Humanimpfstoffe

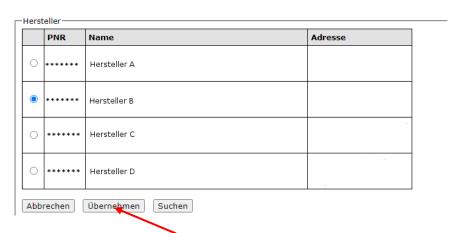
–Angaben zum Lieferengpass——		Grund für den Lieferengpass *-		
Art des Engpasses*:	Verknappung einzelner Packur ✔	Grund des Lieferengpasses*1:	Produktionsproblem	~
(Voraussichtlicher) Beginn des Lieferengpasses*1:	13.01.2022	Problem Detail*:  Betroffener Hersteller	Probleme in der Herstellung	~
Voraussichtliches Ende des	28.02.2022	Typ des Herstellers:	Wirkstoffhersteller	~
Lieferengpasses*1: Vorabinformation	□Ja	Hersteller wählen oder suchen	*	
Bereits ergriffene Maßnahmen zu Weitere geplante Maßnahmen zu	10	PNR*: Hersteller: Typ des Herstellers: Weitere Erläuterungen zum Liefe	rengpass1:	
	B	Weitere Informationen zum Liefe Veröffentlichung dieser Informati		
ame des Entwurfs:	Als Entwurf speicher	n zurück Weiter		

By clicking "select or search manufacturer" (Hersteller wählen oder suchen), the manufacturer information can be selected.

After clicking on "select or search manufacturer" the selection field shown below appears. After selection, the manufacturer is entered in the form shown above by clicking "accept" (Übernehmen). With a subsequent click on "next" (Weiter) the next input form opens.

PharmNet.Bund

# Hersteller wählen, suchen oder eingeben LE\_05













Any available information on alternative vaccine preparations can be provided in the next input form in the field "Alt. Med. Name" (Alt. AM Bezeichnung).

#### Erstmeldung eines Lieferengpasses LE\_06

ENR	ZNR	Wirkstoffe	Packungsgröße Menge		Alternativ- AM <sup>1</sup>	Alt. ZNR	Alt. Packungsgröße Menge	Alt. Packungstyp	Alt. Darreichungsform	Alt. Wirkstoff	Alt. AM- Bezeichnung	Zugelassen in
			1er	N/A	Suche			N/A		N/A		Deutschla 🗸
	1 6		10er	N/A	Suche			N/A		N/A		Deutschla N

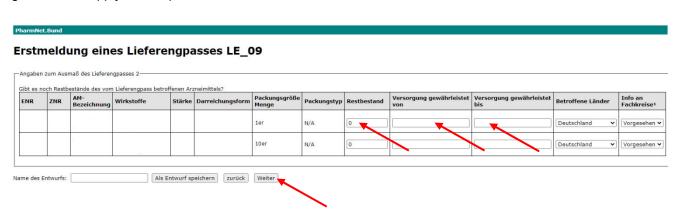
Clicking on "next" (Weiter) opens the next input form.

Here the sales volumes of the last five quarters for each pack size of the medicinal product must be reported. Please note that Q0 refers to the last completed quarter, Q1 to the quarter before that, Q2 to the quarter before Q1, etc.

#### Erstmeldung eines Lieferengpasses LE\_08 -Angaben zum Ausmaß des Lieferengpasses Angaben nach §29 Abs. 1d AMG Bitte geben sie die Absatzmengen des Arzneimittels für die letzten fünf Quartale, bezogen auf in Verkehr gebrachte Impfdosen an: AM-Bezeichnung Wirkstoffe Packungsgröße Menge Stärke Darreichungsform Packungstyp Q4 Q3 Q2 Q1 Q0 0 0 N/A 0 0 N/A 0 0 10er 0 0 Weitere Angaben zum Ausmaß des Lieferengpasses Als Entwurf speichern zurück Weiter Name des Entwurfs:

Clicking on "next" (Weiter) opens the next input form.

Information on the remaining stock (Restbestand) of the reported medicinal product and the duration of the guaranteed supply can be provided here.











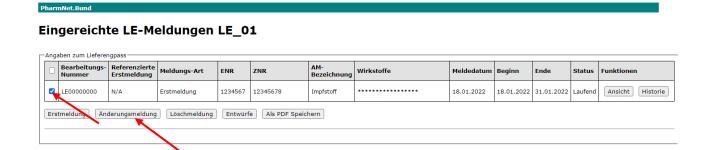


All information can be checked on the last page of the notification form. By clicking on "send" (Absenden), the report is sent to the Paul-Ehrlich-Institut. The report will be checked internally and published on http://www.pei.de/lieferengpaesse-impfstoffe-human no later than the next working day.

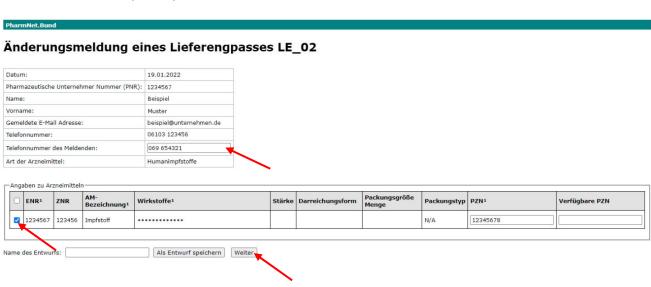


## "Change notification" category

All previously submitted supply shortage reports are shown upon logging in to the portal. Mark the report to be changed with a blue checkmark. By choosing "change notification" (Änderungsmeldung), the next input form is opened.



Here the details of the reporting company can be verified, and if necessary, the phone number of the reporting company (Telefonnummer des Meldenden) can be adjusted. The data record concerned is marked and confirmed with "next" (Weiter).











Information on the status changes of the supply shortage can be entered in the next input form. These include shortage type (Art des Engpasses), expected start and end dates of shortage (voraussichtlicher Beginn des Lieferengpasses, Voraussichtliches Ende des Lieferengpasses), and details on the causes of the supply shortage (Grund für den Lieferengpass). Once all required changes are made, the entry is confirmed with "next" (Weiter).

# PharmNet.Bund Änderungsmeldung eines Lieferengpasses LE 04 Humanimpfstoffe

Angaben zum Lieferengpass ——		Grund für den Lieferengpass *-		
Art des Engpasses*:	Verknappung einzelner Packur ✔	Grund des Lieferengpasses*1:	Produktionsproblem	~
(Voraussichtlicher) Beginn des Lieferengpasses*1:	31.01.2022	Problem Detail*: Betroffener Hersteller	Probleme in der Herstellung	~
Voraussichtliches Ende des Lieferengpasses*1:	28.02.2022	Typ des Herstellers:	Wirkstoffhersteller	~
Vorabinformation	□Ja	Hersteller wählen oder suchen*		
Bereits ergriffene Maßnahmen zu Weitere geplante Maßnahmen 20	ur Lösung des Lieferengpasses:	PNR*: Hersteller: Typ des Herstellers: Weitere Erläuterungen zum Liefer	engpass1:	
	10	Weitere Informationen zum Liefer Veröffentlichung dieser Informatio		/
				/.

If there is new information on alternative vaccine preparations, it can be entered here and confirmed with "next" (Weiter).

PharmNet Rund

Änderungsmeldung eines Lieferengpasses LE 06

#### - Alternativpräparate Alt. Packungsgröße Packungsgröße Menge Zugelassen in Alternativ-Alt. Darreichungsform ENR ZNR Wirkstoffe Packungstyp 1234567 123456 \*\*\*\*\*\*\*\* N/A Deutschla 🗸 Als Entwurf speichern zurück Weiter Name des Entwurfs:

On the following page, information on the impact of the supply shortage (pursuant to section 29 Para. 1d of the Medicinal Products Act, AMG) can be changed and confirm with "next" (Weiter).

Änderungsmeldung eines Lieferengpasses LE\_08









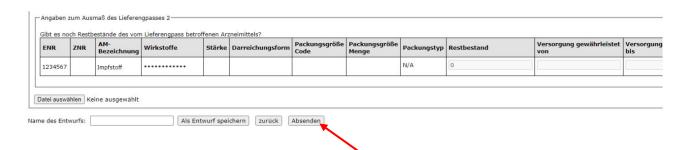




Changes on information about the remaining stock can be entered in the next input form. The entry is confirmed with "next" (Weiter).

## Änderungsmeldung eines Lieferengpasses LE\_09 Angaben zum Ausmaß des Lieferengpasses 2 ch Restbestände des vom Lieferengpass betroffenen Arzneimittels? ..... Vorgesehen **∨** Als Entwurf speichern zurück Weite Name des Entwurfs:

All information can be checked on the last page of the notification form. By clicking on "send" (Absenden), the report is sent to the Paul-Ehrlich-Institut. The report will be checked internally and published on http://www.pei.de/lieferengpaesse-impfstoffe-human no later than the next working day.



#### 3.5 "Deletion notification" category

All previously submitted supply shortage reports are shown upon logging in to the portal. Mark the report to be deleted with a blue checkmark. By choosing "deletion notification" (Löschmeldung) the following input form is opened.

#### Eingereichte LE-Meldungen LE\_01 Angaben zum Lieferengnass Referenzierte Erstmeldung AM-Bezeichnu ZNR Wirkstoffe Meldedatum Beginn Funktionen Meldungs-Art 12345678 Ansicht Historie 1234567 Impfstoff 18.01.2022 18.01.2022 31.01.2022 Laufend LE00000000 N/A Erstmeldung Erstmeldui Änderungsmeldung Löschmeldung Entwürfe Als PDF Speichern

PLEASE NOTE: Only deletion notifications with an end date corresponding to the date of deletion or earlier will be accepted. To change the expected end date, please choose "change notification" (Änderungsmeldung).





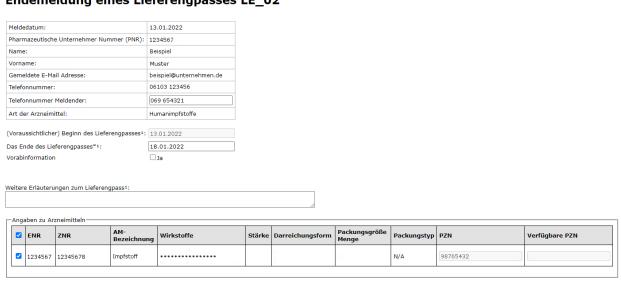




After checking the information, including PNR, name and telephone number, enter the end date of the supply shortage.

Absenden

#### Endemeldung eines Lieferengpasses LE 02



By clicking on "send" (Absenden), the report is sent to the Paul-Ehrlich-Institut. The report will be checked internally and archived on http://www.pei.de/lieferengpaesse-impfstoffe-human no later than the next working day

# Notification Split - change in the expected end date or partial deletion of an existing supply shortage for specific pack sizes

When changes are made to at least one, but not all, package sizes included in a shortage notification, either the original notification is split (case 1), or a new shortage is created (case 2).

Case 1: The expected end date of the supply shortage for at least one, but not all, of the reported pack sizes is changed.

Case 2: The shortage report for at least one, but not all, of the pack sizes is deleted, because the respective pack sizes are available again.

In case 1, the original notification will be split into two partial notifications (technical change notification and change notification).

In case 2, a new technical change notification is created in addition to the original first notification.

In both cases, the "technical change notification" (technische Änderungsmeldung) includes all pack sizes whose status has not changed. The "change notification" in case 1 includes all pack sizes for which a change has been reported.

By clicking on "history" (Historie) you can call up the history for each first report, which then is displayed below the submitted reports.

#### Eingereichte LE-Meldungen LE\_01











# 4 Support

### 4.1 Helpdesk

Questions about the application can be sent to the email address lieferengpaesse@pei.de.

In order for the supply shortage team to be able to the best possible assistance, the following information should be submitted:

- 1. Name of the requesting party including relevant contact details (e.g. telephone number)
- ENR of the medicinal products concerned 2.
- 3. Exact description and screenshots of the issue (if possible).
- 4. In the case of technical issues, information such as which browser (incl. version) is being used, etc.

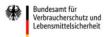
#### 4.2 FAQ

Question	Answer
In the list of medicinal products, several entries with	This indicates different dosage forms of the
identical information but different pack size codes	medicine, e.g. with regard to the medical products
for one pack size are shown. What does that mean?	contained in the packaging. If you do not have the
	relevant information, please contact + 49 6103
	773739 or send a screenshot of the corresponding
	medicine entries in the list to
	lieferengpaesse@pei.de. You will receive an answer
	no later than the next working day.

A German-language FAQ document regarding further questions on the supply shortage notification in the PharmNet.Bund portal can be found on the website

https://www.pharmnet-bund.de/static/.content/.galleries/downloads/de/le-faq.pdf.

If your question about the supply shortage report is not answered there, please send an email to lieferengpaesse@pei.de.







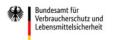




# 5 Appendix

# 5.1 Letter of authorization to report supply shortages for medicinal products from other marketing authorization holders (in German)

		Vollmacht*	
Im Auftrag des Zulas Firmensitz sich in		<i>Firmenname</i> indet,	(PNR xxxxxxxx), dessen eingetragene
berechtige ich, der/di	e Unterzeichnende, ł	hiermit den/die Mitarbe	eitende
Vorname Name	·		
des Unternehmens_ <u>Adresse</u> befind		e (PNR yyyyy	yyy), dessen eingetragener Firmensitz sich i
erhalten, diesem Ko	onto weitere Funktio lie Anwendung Pharr	onen und Rechte nac mNet.Bund im Namen	<u>menname</u> ) zu erhalten und das Recht z ch eigenem Ermessen zuzuweisen und z der ( <u>Firmenname</u> ) Lieferengpäss
Für und im Auftrag vo	on <i>Firmenname</i>	9	
Unterschrift des Repi	räsentanten des Unte	ernehmens	











<sup>\*</sup>Bitte beachten Sie, dass das Autorisierungsschreiben auf Firmenpapier erstellt wird, aus dem eindeutig die Herkunft des Schreibens ersichtlich wird.

# 5.2 Letter of authorization to report supply shortages for medicinal products from other marketing authorization holders (in English)

#### Power of attorney\*

On behalf of the Marketing office is located atA			(PNR xxxxxxx), whose registered
I, the undersigned, entitle			
Name Surname	,		
Employee of <u>Company</u>	Name (PNR yyyyyyy),	whose registered office	e is located at <u>Address</u> ,
right to assign other funct	ions and rights for this ac rder to submit supply sh	count at his/her own d nortage notifications t	pany Name ), and to have the iscretion and to administrate those the BfArM and the PEI via the
For and on behalf ofC	Company Name		
Signature of the represen	tative of the company		









<sup>\*</sup>Please note that the authorization letter must be prepared on company paper clearly showing the origin of the letter.