Obaveštenje o povlačenju serija **G09087, K09548, G10759, H08873, M04154 i K09549** leka **Rheumesser** 3 ml ampula

Kroz obaveštenje primljeno od nosioca dozvole za stavljanje leka u promet (MAH) „GL Pharma - Austrija“, Kosovska agencija za medicinske proizvode (KMAD) je obaveštena o povlačenju sa tržišta serija **G09087, K09548, G10759, H08873, M04154 i K09549** leka **Rheumesser ampula**.

Povlačenje sa tržišta je pokrenuto iz preventivnih razloga zbog sumnje na defekt u kvalitetu leka, koji je povezan sa mogućim prisustvom stranih čestica u rastvoru.

Serije **G09087 i K09548** leka **Rheumesser ampula** su uvezene u Republiku Kosovo.

Pacijentima koji su već kupili ampulu iz bilo koje od gore navedenih serija preporučuje se da je vrate u apoteku u kojoj su je kupili ili da kontaktiraju predstavnika proizvođača putem e-pošte: **E-pošta:** regulatory@provitpharmaceuticals-al.com

Savet za pacijente

Pacijenti koji koriste ili su koristili proizvod **Rheumesser 3 ml ampula**, sa bilo kojim od **gore navedenih** serijskih brojeva, a koji su primetili bilo kakve neželjene efekte ili nelagodnost nakon upotrebe proizvoda, treba da kontaktiraju svog lekara, farmaceuta ili drugog zdravstvenog radnika.

Saveti za zdravstvene radnike

Svi zdravstveni radnici koji su primili bilo kakve izveštaje o sumnji na neželjene reakcije nakon upotrebe **Rheumesser 3 ml ampule**, sa bilo kojim od **gore navedenih** brojeva serije, podstiču se da prijave slučajeve lokalnoj osobi zaduženoj za farmakovigilansu, koju je ovlastio nosilac dozvole za stavljanje leka u promet „GL Pharma - Austrija“, na sledeću adresu:

E-pošta: miniverehajdarifoniqi@gmail.com ili minapha@hotmail.com

Sumnje na neželjene reakcije/efekate mogu se prijaviti i direktno KMAD-u, koristeći standardni obrazac **CIOMS**-a za prijavljivanje sumnji na neželjene reakcije, objavljen na veb stranici KMAD-a, ili na sledeću adresu:

E-pošta: info.akppm@rks-gov.net

KMAD savetuje zdravstvenim radnicima da prilikom prijavljivanja uključe što više relevantnih informacija o pacijentu, leku, broju serije i sumnjivoj neželjenoj reakciji/efektu.

Kosovska agencija za medicinske proizvode i uređaje (KAMD)

Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Institute Surveillance
Enforcement, Medicine Shortages & Quality Defects
(EVEQ)

Defective Product Report Template for Marketing

For marketing authorisation holders to report a quality defect relating to a medicinal product
Pursuant to Section 75q of the Austrian Medicinal Products Act (*AMG*), as amended, and/or Section 42 of the Austrian Veterinary Medicinal Products Act (*TAMG*), as amended.

Contact:	Institute Surveillance Tel.: +43 (0)50555-36411, -36466, -36476, -36418

1 Origin of the Report

Information required	**Information provided**
1.1 Name of the reporting individual	Gerlinde Muster
1.2 Organisation	G.L. Pharma GmbH
1.3 Address	Schlossplatz 1 8502 Lannach
1.4 Telephone	00 43 1 / 485 35 05 – 139 00 43 664 42 83 011
1.5 Fax.	---
1.6 Email address	gerlinde.muster@gl-pharma.at
1.7 Date and time of the report	30.07.2026

Defective Product Report Template for Marketing

2 Product Details / Scope of the Defect

Remark: A separate form is to be completed for each medicinal product

Information required	Information provided
2.1 Name of the medicinal product affected	Rheumesser 3ml ampoules
2.2 Marketing authorisation number	17.397
2.3 Name and address of the MAH or importer[1]	G.L. Pharma GmbH Schlossplatz 1, 8502 Lannach, Austria
2.4 Galenic form	Parenteral ampoule
2.5 API(s) (INN)	Ketophenylbutazone Salicylamide-O-acetic acid Lidocaine Dexamethasone Cyanocobalamin
2.6 Name and address of the manufacturer (end product and finished product)	G.L. Pharma GmbH, Vienna site (1160) Arnethgasse 3, 1160 Vienna, Austria Gansterergasse 9-13, 1160 Vienna, Austria
2.7 Foreign manufacturer (end and finished product)	Which foreign regulatory authority is competent for the foreign manufacturer? Not applicable When was this body informed about the defect? Not applicable What evaluation of the defect is available from the competent regulatory authority? Not applicable

[1] In the case of parallel imports

Defective Product Report Template for Marketing

2.8 Batches affected (batch number / date of manufacture / dosage strength / expiry date / batch size / number of packs)	Set up a separate list if required Refer to separate list
2.9 Bulk goods	Are the relevant batches listed under Section 2.7 from a bulk batch from which other end and/or finished products have been manufactured? ☐ Yes, ☒ No If yes, which and intended for which country?
2.10 Distribution of the batches affected (domestic and/or international / customers supplied / distribution period / inventory level)	Set up a separate list if required To be submitted at a later date
2.11 Impact on medicine shortages (domestic and/or foreign)	Are medicine shortages possible? ☒ Yes ☐ No If Yes, which markets/territories are affected? Austria, Albania, Kosovo
2.12 Marketing data (what is the market share of the relevant medicinal product in Austria?)	Under 40% market share: ☐ 40% market share and higher: ☒
2.13 Other medicinal products affected (name / marketing authorisation number)[2]	None

[2] If other medicinal products are affected, please complete a defective product report for each.

Defective Product Report Template for Marketing

3 Nature of the Defect

Information required	Information provided
3.1 Who identified the defect:	☐ Patient ☐ User ☐ Hospital ☐ Pharmacy ☒ Manufacturer ☐
3.2 Detailed description of the quality defect / problem	Particles in the ampoule solution Batch G09087 (distributed in Albania and Kosovo): Particles detected during visible inspection as per Ph. Eur.; Batches G10759, K09548, K09549, H08873, M04154 (distributed in Austria and Albania): Particles not detected during visible inspection as per Ph. Eur. but visible during APC background lighting inspection;
3.3 Is the defect related to an adverse reaction? If yes, please describe and add the in-house identification number of the PV incident	☐ Yes ☒ No
3.4 Are there indications or suspicions of a risk to public health (adverse reaction or lack of efficacy)?	A risk to patients on the grounds of parenteral use cannot be excluded
3.5 Has a risk assessment been performed?	☒ Yes (please provide details in the annex) ☐ No If No, when will this be provided? To be included in the investigation report
3.6 Has an investigation report, including corrective and preventative action, already been prepared?	☒ Yes (please provide details in the annex) ☐ No If No, when will this be provided? Deadline cannot yet be defined
3.7 Provision of the defective sample or a photo as a basis for processing and illustrating the defect identified. Provided by means of: Photo Send sample of defect by post to **BASG** **Institut Begutachtung & Analytik /** **Abteilung CPAA**	☒ ☐

Defective Product Report Template for Marketing

Spargelfeldstraße 191, 1220 Wien A sample of the defect cannot be provided: Explanation:	☐

Defective Product Report Template for Marketing

4 Action Undertaken and Planned

Information required	Information provided
4.1 Name and address of public authorities already informed	
4.2 Action already undertaken	Root cause analysis and deviation report including a risk assessment as a draft Status of affected batches changed to rejected
4.3 Is it planned to initiate a batch recall or withdraw the product? If Yes, please enclose/attach a draft of the recall notification. What is planned with the packs received back as a result of the recall?	☒ Yes ☐ No These will be destroyed once the root cause analysis has been completed
4.4 In the case of a recall: Classification of the defect (I, II or III)[3] with explanation	I: A risk to patients on the grounds of parenteral use cannot be excluded
4.5 Other planned or proposed action	Further root cause analysis at G.L. Pharma and ampoule supplier
4.6 Other relevant details	Answers missing on the form cannot currently be provided and will be made available as soon as possible.

5 List of attachments to this report

Annex 1: Batches affected; Annex 2: Photos Particles

Venue, date Vienna, 30.07.2026

Signature and name in block capitals: Dr. Gerlinde Muster

6 Submission of the signed report by means of

Email to: am-qualitaetsmangel@basg.gv.at

Fax: International: +43 50555-36408
From Austria: 050555-36408

[3] *cf.* Compilation of Union Procedures on Inspections and Exchange of Information, www.ema.europa.eu