SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
UNK	UNITED STATES		Unk		Unk	Male	Unk		AUG	2019

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Numbness in his right and left foot and numbness to face [Numbness]
The patient felt pins and needles like feeling in his body as well as eyes [Pins and needles]

Case Description: Case QLU-000159-2020 is a spontaneous report received from a consumer or non-healthcare professional via Qilu-Apotex (reference number: 1046060) and concerns a male patient of unknown age who received intravenous ceftriaxone 2 g 10x20ml injection and 1 g 10x20ml injection (NDC# 60505-6149-04 and NDC# 60505-6148-04) both infusion once daily for an unknown indication and experienced pins and needles like feeling in his

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Ceftriaxone (CEFTRIAXONE) Solution For Injection, 1 gram {Lot # RH6756; Exp.Dt. 31-MAY-2021}
#2) Ceftriaxone (CEFTRIAXONE) Solution For Injection, 2 gram {Lot # **(Continued on Additional Information Page)**

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) infusion once a day	#1) Unknown
#2) infusion once a day	#2) Unknown

17. INDICATION(S) FOR USE
#1) Drug use for unknown indication (Produ
#2) Drug use for unknown indication (Produ **(Continued on Additional Information Page)**

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown	Current Condition	Lyme disease (Lyme disease)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Qilu Pharmaceutical Co.Ltd.
No. 243, Gong Ye Bei Road,
Jinan, Shandong 250100 CHINA

26. REMARKS
Medically Confirmed: No

24b. MFR CONTROL NO.
QLU-000159-2020

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
26-MAY-2020

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
12-JUN-2020

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

body as well as eyes and numbness in his right and left foot then numbness to his face.

Current medical condition included Lyme disease.

Past medical history and concomitant medications were not reported.

On an unknown date, the patient received ceftriaxone 1 g (batch number: RH6756, expiry date: 31-May-2021) and ceftriaxone 2 g (batch number: RG4147, expiry date: 31-Mar-2021) infusions. The patient reported that he had been using this product for 1 year and that in the first 3 months he had no problems.

In Aug-2019, the patient started to experience some unusual symptom/ adverse events and he felt pins and needles like feeling in his body as well as eyes and after sometimes it went away.

In Feb-2020 (at the end), the patient experienced other symptoms numbness in his right and left foot and then numbness to his face.

The patient stated that, his doctor believed ceftriaxone was good medication and that his symptoms could be the result of his Lyme disease and his doctor does not want him to stop using the medication and worried if he stop taking the medication his Lyme disease will get worsen. The patient also mentioned this was a good product and he did not have Lot and NDC# for the previous medication. The patient declined to provide address and currently not experiencing any adverse event.

Action taken with ceftriaxone was unknown.

At the time of report, the events were resolved.

Dechallenge and rechallenge for the events were assessed as unknown as action taken with ceftriaxone was unknown.

Although the reporter did not provide a causality assessment for the events, as this report was made spontaneously a possible causal link with ceftriaxone 1 g and 2 g cannot be ruled out.

This case was considered non-serious.

Medical evaluation comment: The case was assessed as non-serious. Hypoaesthesia and paraesthesia are unexpected AEs as per ceftriaxone USPI. Based on the information received and considering a plausible temporal relation, the causality for the AEs of hypoaesthesia and paraesthesia is assessed as possibly related to the suspect drug.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Ceftriaxone (CEFTRIAXONE) Solution For Injection, 1 gram {Lot # RH6756; Exp.Dt. 31-MAY-2021}; Regimen #1	infusion once a day; Unknown	Drug use for unknown indication (Product used for unknown indication)	Unknown; Unknown
#2) Ceftriaxone (CEFTRIAXONE) Solution For Injection, 2 gram {Lot # RG4147; Exp.Dt. 31-MAR-2021}; Regimen #1	infusion once a day; Unknown	Drug use for unknown indication (Product used for unknown indication)	Unknown; Unknown