

# **Cefazolin Sodium**

## **Details of Supply Issue**

# Cefazolin Sodium Injection



Manufactured from sterilized cefazolin sodium API under sterile environment.

# Details of Supply Issue

## Cause 1) Foreign Object Inclusion

From end of year 2018, owing to sudden increase of foreign objection in API purchasing from Company A(Italy), we stopped manufacturing product.

## Cause 2) Outage of “TAA” Material

TAA(Tetrazole Acetic Acid), one of the starting materials of Cefazolin Sodium API is produced only in Chinese TAA company. However, because of China authorities suggestion, TAA manufacturing stopped in whole world.

No inventory stock in Company B(Italy)



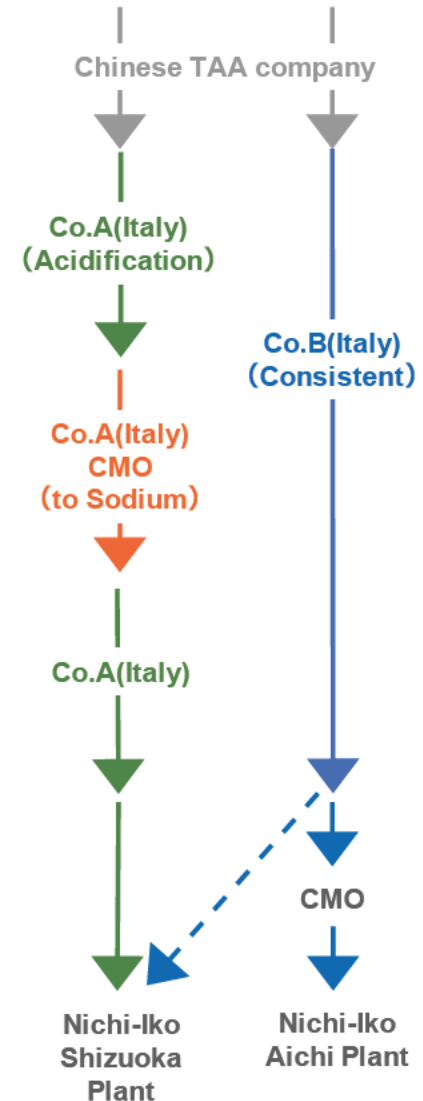
Through association report, discussion & conference report



Feb 28<sup>th</sup>,2019

Outage Guide Announcement has started against all medical institutions

## Starting material~manufacture flow



## Countermeasure of “TAA” Material outage

1. “TAA” supply restarted from Mar, 2019
2. Enhance API Manufacturing Supply Chain
  - Considering “TAA” supplier as new option

## Countermeasure of API Manufacturing

1. (Result of “TAA” supply restart)  
**Restart supply route of Company B in Italy**
2. (Result of “TAA” supply restart & changing CMO of Sodiumization)  
**Restart supply route of Company A in Italy**