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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

6 March 2022

Dear Healthcare Professional,

NATIONAL PATIENT SAFETY ALERT - UKHSA: POTENTIAL CONTAMINATION OF ALIMENTUM AND ELECARE INFANT FORMULA FOOD PRODUCTS

Please see attached National Patient Safety alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Dieticians
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

National Patient Safety Alert

UK Health Security Agency

Title: Potential contamination of Alimentum and Elecare infant formula food products

Date of issue:	04/03/2022	Reference no:	NatPSA/2022/001/UKHSA

This alert is for action by: Acute trusts, private providers/independent treatment centres providing NHS care, healthcare commissioners, community trusts, general practice and community pharmacies.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) in collaboration with those to whom actions are directed (e.g. pharmacy, general practice, dietetics and pathology).

Explanation of identified safety issue:

On 20 February 2022 the Food Standards Agency (FSA) published a product recall information notice (PRIN), which was updated on 22 February (PRIN) for two infant formula products used for special medical purposes, due to concerns of possible contamination with *Salmonella* Newport and *Cronobacter sakazakii* (formerly known as *Enterobacter sakazakii*). This relates to products produced in one manufacturing site in the USA and imported into the UK. The recall notices provide product details and specific batch codes – these products must not be used.

Elecare Similac and Alimentum Similac are distributed UK-wide. These products are usually used for management of cow's milk protein allergy or other conditions as advised by a healthcare professional (these products are usually but not exclusively prescribed). The population at risk includes infants and young children with potentially pre-existing clinical conditions.

C. sakazakii is an opportunistic (and rarely identified) pathogen, known to occasionally cause serious infections including bacteraemia, meningitis and necrotizing enterocolitis. Premature infants and infants with underlying medical conditions are at the greatest risk for illness. *S.* Newport can cause varying severity of illness ranging from mild self-limiting gastroenteritis to severe sepsis in infants.

UKHSA are following up a small number of potentially associated cases of illness with further investigation ongoing. In the USA there are 5 epidemiologically linked infant cases (4 *Cronobacter sakazakii* and 1 *Salmonella* Newport), including two fatalities.

The FSA have published advice to parents. The MHRA has shared information on the recall and urged healthcare professionals to immediately contact all patients who have been dispensed the impacted batches.

It is crucial to ensure relevant batches of these products are removed, including from individual's homes and not prescribed. Additionally, there is need to raise awareness among healthcare professionals who might encounter potentially associated cases to inform clinical care, surveillance and public health action.

Actions required

Actions to be completed by 11 March 2022

1. Healthcare commissioners and providers to ensure their pharmacies have adhered to the instructions regarding the recall of the relevant batches of these two products
2. Pharmacists, dieticians and General Practitioners to ensure that patients who have been prescribed/dispensed Elecare Similac or Alimentum Similac since February 2021, are contacted and provided the FSA advice to parents. Instruct those in possession of affected batches not to use them and recommend to return them to a pharmacy.
3. Pharmacies to display notices containing information on the recall at the point of sale/dispensing
4. Ensure information disseminated to relevant clinicians/practitioners (primary and secondary care) for awareness:
   a. Clinicians/practitioners should have a low threshold for further monitoring and/or investigation as appropriate when encountering unwell children who have consumed these products
   b. Clinicians/practitioners should notify their relevant UKHSA Health Protection Team of confirmed cases of *Salmonella* spp. or *Cronobacter* spp. among infants and children who are known to have consumed these products
5. Diagnostic laboratories are requested to report cases of *Cronobacter* spp. or *C. sakazakii* to UKHSA either via laboratory information management systems through automated processes or by directly notifying UKHSA Health Protection Teams.
6. Laboratories should promptly refer relevant isolates (see additional information below for referral instructions).

Additional information:

In relation to diagnosis of suspected cases please note: routine diagnostic tests for detection of *Cronobacter* spp. in stool are not widely available, though selective media can aid isolation from stools, the organism can be detected from blood cultures and cerebrospinal fluid. *Salmonella* spp. can be detected from stool, blood cultures and urine.

Laboratories should promptly refer all isolates of *Salmonella* spp. to the Gastrointestinal Bacteria Reference Unit (GBRU) at Colindale. Enquiries regarding laboratory testing of *Salmonella* can be directed to GBRU@phe.gov.uk

Laboratories should promptly refer all isolates of *Cronobacter* spp., and any *Enterobacter* spp. identified via biochemical testing, that relate to infants (age <1 years), to the Opportunistic Pathogens laboratory, AMRHAI at Colindale. Enquiries regarding laboratory testing of *Cronobacter* spp. and *Enterobacter* spp. can be directed to amrhai@phe.gov.uk.

If available/recovered, these products (relevant batches) should be returned to the supplier to enable the product to be investigated.

Alternative products are available to order as below:

- Similac Alimentium alternatives include: Nutramigen 1, Nutramigen 2, Nutramigen 3, Althera, Aptamil, Pepti 1, Aptamil Pepti 2 (which are all suitable for cows milk protein allergy (CMPI). **Please refer to BNF for children for prescribing.** Please note the Nutramigen and Aptamil Pepti products are age dependent. Please note some of these products may not be suitable for infants with other allergies e.g. fish -Aptamil Pepti range contains fish oils. Please note these products are not suitable for lactose intolerance and SMA LF Lactose free or Aptamil lactose free are suitable for lactose intolerance.
- Elecare alternatives include: Neocate LCP, Alfamino, Puramino, and if child is over 1 years of age Neocate Junior may be used. **Please refer to BNF for children for prescribing.**

Both *Salmonella* and *Cronobacater* can cause mild to severe infections:

- Symptoms of Salmonellosis in babies include frequent bowel motions, watery or runny stools, vomiting, fever, refusal of feeds and irritability. Severe infections can lead to high temperature, dehydration or dry tongue/ skin, fits, slow breathing or grunting, neck stiffness and abnormal movements.
- Symptoms of *Cronobacter* in babies can present as low energy, refusal or poor feeding, excessive crying or irritability. Severe infections like meningitis and sepsis can lead to unresponsiveness, high temperature, fits, slow breathing or grunting, neck stiffness and abnormal movements.

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts.