



Department of
**Health, Social Services
and Public Safety**

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From The Chief Pharmaceutical Officer
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Date: 27 May 2011

For Action: Assistant Director Pharmacy and Medicines Management
HSC Board & BSO
Heads of Pharmacy and Medicines Management of HSC
Trusts
Regional Quality Improvement Authority

DRUG ALERT MEDICINES RECALL

Dear Healthcare Professional

Intercell AG, product distributed in Novartis livery

**Ixiaro Vaccine
(Japanese Encephalitis Vaccine, Inactivated, Adsorbed)**

EU/1/08/501/002

Batch Number	Expiry Date	Pack Size	First Distributed
JEV09L37A	Aug 2011	1 x pre-filled syringe	June 2010

Intercell AG is recalling the above batch of Ixiaro, which is distributed in Novartis livery. This is because routine stability testing has shown that this batch may be less potent than expected and may not induce a full protective immune response in recipients. This batch met all quality specifications at the time of release and complied with all the required specifications, with the exception of the potency test, at the 11 month stability time point when this issue was identified.

Healthcare Professionals are asked to quarantine any remaining stock of this batch and return it to the original supplier for credit. Please contact anyone who may have received this batch and inform them of this matter.

Healthcare professionals should consider the potential need for revaccination of individuals who may have received a dose from this batch. Available safety data does not indicate any specific safety concerns for those receiving more than two doses within a short period of time.

As a precaution, further potency testing of other batches is being conducted, in particular of those in the middle and at the end of their shelf-life. This testing has not yet been concluded.

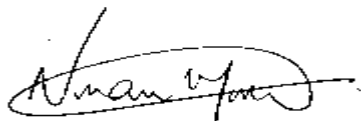
For stock enquiries, please contact Novartis Vaccines on 08457 451500.

For medical information enquiries please contact Novartis on 01748 828838.

HSC Board/RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely



DR NORMAN MORROW
Chief Pharmaceutical Officer

For information:
CMO
CNO
CDO
CSSO
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Extended nurse prescribers

Regional Medicines and Poisons Information Service
Regional Director of Supplies
RPQAS
Pharmaceutical Society of NI
Senior Prison Pharmacist
Prison Service, Dundonald House
Nursing Officer, Health Estates
Medical Officer, Castle Buildings
Regional Procurement Pharmacist
NICPLD