Urgent Field Safety Notice

Product name: Autopen Classic, Autopen 24, Densupen and Autopen 3ml for Teriparatide
FSCA identifier: FSN Autopen 08-Dec-2014 revision 1
Field Safety Corrective Action type: Voluntary Recall

Date: 08 December 2014

Attention: Customers of Autopen Classic, Autopen 24, Densupen and Autopen 3ml for Teriparatide

Details on affected devices:
A proportion of 1 and 2 unit Autopen Classic, Autopen 24 insulin delivery pens, Densupen and Autopen Classic pens used for the administration of Teriparatide from the following batches have a potential failure mode:

Only the batch LOT codes listed here are affected

Batches in the UK:

Packaging Lot Code	Production Lot Code (stamped on pen)	Country	Product Code	Product Name
7WB	7PN	UK	AN4200	Autopen 24 - 3ml 2 Unit
8CN	7PN	UK	AN4200	Autopen 24 - 3ml 2 Unit
8CP	7PN	UK	AN4200	Autopen 24 - 3ml 2 Unit
7WC	7PP	UK	AN4210	Autopen 24 - 3ml 1 Unit
8CR	7PP	UK	AN4210	Autopen 24 - 3ml 1 Unit
8JK	7PP	UK	AN4210	Autopen 24 - 3ml 1 Unit
8JP	7PP	UK	AN4210	Autopen 24 - 3ml 1 Unit
7VJ	7RT	UK	AN3810	3ml 1 Unit Autopen Classic
8EM	7RT	UK	AN3810	3ml 1 Unit Autopen Classic
8JN	7RT	UK	AN3810	3ml 1 Unit Autopen Classic
8EL	7RV	UK	AN3800	3ml 2 Unit Autopen Classic
7WD	7RV	UK	AN3800	3ml 2 Unit Autopen Classic
8JM	8KK	UK	AN3800	3ml 2 Unit Autopen Classic
8VV	8XD	UK	AN4200	Autopen 24 - 3ml 2 Unit
8VW	8XD	UK	AN4200	Autopen 24 - 3ml 2 Unit

Batches non-UK:

Packaging Lot Code	Production Lot Code (stamped on pen)	Country	Product Code	Product Name
7GA	7GA	RUSSIA	AN3801	3ml 2 Unit Autopen Classic
7JH	7JH	US	AN3800	3ml 2 Unit Autopen Classic
7LR	7LR	RUSSIA	AN3801	3ml 2 Unit Autopen Classic
7NG	7NG	THAILAND	AN3800	3ml 2 Unit Autopen Classic
7NH	7NH	INDIA	AN1281	Autopen 3ml - Teriparatide
7WA	7RT	GERMANY	AN3810	3ml 1 Unit Autopen Classic
7XT	7RV	US	AN3800	3ml 2 Unit Autopen Classic
7YH	7RV	US	AN3800	3ml 2 Unit Autopen Classic

Packaging Lot Code	Production Lot Code (stamped on pen)	Country	Product Code	Product Name
8BG	8BG	INDIA	AN1251	Autopen 3ml - Teriparatide
8JG	8JG	INDIA	AN1281	Autopen 3ml - Teriparatide
8KF	8KF	ARGENTINA	AN0960	Densupen Pen
8KH	8KH	RUSSIA	AN3800	3ml 2 Unit Autopen Classic
8KJ	8KJ	RUSSIA	AN3810	3ml 1 Unit Autopen Classic
8VN	8VN	ISRAEL	AN4200	Autopen 24 - 3ml 2 Unit
8JK	8JK	GERMANY	AN4210	Autopen 24 - 3ml 1 Unit

All other batch LOT codes of Autopen Classic, Autopen 24, Densupen and Autopen Classic 3ml for Teriparatide are not affected and can continue to be used

Autopen 24 1 unit pen

Autopen 24 2 unit pen

Autopen Classic 1 unit pen

Autopen Classic 2 unit pen

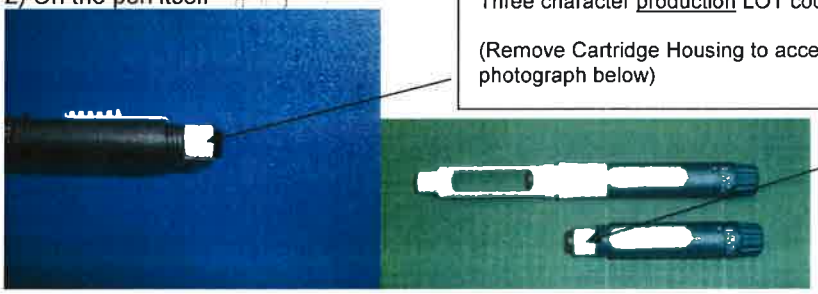
The batch LOT code can be identified either by:

1) The outer carton

Three character packaging LOT code is printed on carton label here.

Note: this LOT code may be different from the production LOT code on the pen itself (or it may be the same - see table on Page 1 of this FSN for details)

2) On the pen itself



Three character production LOT code is embossed or printed here.

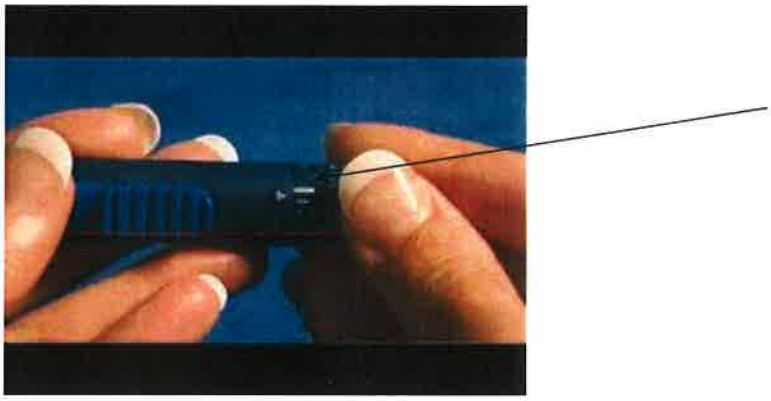
(Remove Cartridge Housing to access this LOT area as per photograph below)

Description of the problem:

A proportion of devices from the LOT codes listed above have a potential mechanical fault. The fault presents itself in the following ways:

A) A dose may be dialled-up but the dose selector will not hold that dose and instead will spin straight back to zero

B) The dose may be dialled-up and the dose selector will hold the dose momentarily, but will then spin back to zero



There have been no Adverse Incidents to date due to this potential mechanical fault of the device. This recall is being performed on a voluntary basis as a precaution to avoid the use of a faulty device and to reduce the risk that a patient may receive an under-dose or no dose of insulin or Teriparatide.

Potential risk to patient:

A) The patient will not be able to use the pen, no dose can be delivered

B) The patient may only receive a partial dose and will not know how much insulin has been delivered

There is a risk of no dose or under-dose of insulin or Teriparatide. An under-dose of insulin may lead to hyperglycaemia. There is **no** possibility of over-dose.

Action to be taken

Wholesalers, Distributors and Pharmacists:

1. Wholesalers, Distributors and Pharmacists to check stock for the listed batch numbers. If these batches are in stock, place under quarantine immediately.

2. Please initiate your procedure for **recall down to patient level within the next 7 working days**

Please return your FSN Confirmation Form by Thursday18th December 2014 to the following email:

Technical.support@owenmumford.co.uk **Please entitle any email with 'Autopen Recall'**

Or by Fax:

Fax: +44(0) 1993 813466

Even if you have none of this product left in stock, please return the **Field Safety Notice confirmation form** as this will preclude the need for further notices and we need to know. Please also sign to confirm that your procedure has been enacted for recall of the product down to patient level. Please ensure to include a copy of the **Field Safety Notice confirmation form** with the return products for our records.

When you return the Field Safety Notice confirmation form to Owen Mumford a member of our Customer Services Team will contact you to arrange the return and replacement of the product free of charge.

Actions and advice for Patients

Patients should return their affected pen to the issuing Pharmacy/Health Care Provider. The issuing Pharmacy/Health Care Provider will contact their distributor who should check for availability of replacement product from Owen Mumford Ltd.

Alternatively patients based in the UK only may return the device to the following Freepost address:

Owen Mumford Ltd
FREEPOST OF1727
Woodstock
Oxon
OX20 1BR

Where there is no Autopen variant available in stock, the patient should consult their Health Care Provider for a suitable alternative device, to enable them to maintain their insulin regime.

Patient follow-up:

A patient in possession of a pen from one of these affected batches with any concern for their blood sugar levels or their Teriparatide treatment regime should contact their healthcare professional as soon as possible.

Transmission of this Field Safety Notice (FSN):

This Field Safety Notice is being provided to all Owen Mumford Affiliates and to all customers of Owen Mumford to whom our distribution records confirm that the potentially affected batches have been sent to. Please pass on this FSN to all those who need to be aware within your organisation and transfer this notice to other organisations on which this action has impact. Please consider this notice as live until all affected pens distributed by your organisation have been returned to Owen Mumford Ltd.

Onward distribution of this Field Safety Notice

The following list of potential recipients of this device is intended as a prompt for onward communication. Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

CAS liaison officers for onward distribution to all relevant staff including:

- A&E departments
- All wards
- Clinical governance leads
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Diabetics departments
- Endocrinology units
- Endocrinology, directors of
- Health and safety managers
- Medical directors
- Nursing executive directors
- Occupational health departments
- Outpatient clinics
- Paediatric wards
- Risk managers
- Special care baby units
- Supplies managers

Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Domiciliary care providers

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Clinics
- Hospices

- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Health Protection Agency to:

Directors for onward distribution to:

- Heads of department
- Heads of health, safety and quality
- Health protection nurses
- Risk manager
- Safety officers

Primary care trusts to:

CAS liaison officers for onward distribution to all relevant staff including:

- Community children's nurses
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Community pharmacists
- District nurses
- General practitioners
- Health visitors
- NHS walk-in centres
- Occupational health departments
- Pharmaceutical advisors
- Practice managers
- Practice nurses
- School nurses
- Walk-in centres

Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)

For any questions or concerns about your pen device please contact any member of our Marketed Product Support Team on +44 (0) 1993 812021, stating to the receptionist that this is an urgent matter concerning the 'Autopen Recall' or email to: technical.support@owenmumford.co.uk

Please entitle any email with 'Autopen Recall'

Contact reference person (for the information provided in this Field Safety Notice only):

Jane Wilson, Owen Mumford Ltd, Brook Hill, Woodstock, Oxfordshire, OX20 1TU
Technical.support@owenmumford.co.uk

Please do not wait for a communication from the MHRA to enact this Field Safety Notice, MHRA are aware of this Field Safety Corrective Action.

Owen Mumford would like to thank you for your co-operation and apologise for any inconvenience caused by this action. If you require any further information regarding this matter, please do not hesitate to contact us.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

[redacted]

Jane Wilson
Regulatory Affairs & Product Safety Manager
Owen Mumford Ltd.