



From The Chief Pharmaceutical Officer  
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**For Action:** Directors of Pharmaceutical Services of the Boards & CSA  
Directors of Pharmaceutical Services of HSC Trusts  
Regional Quality Improvement Authority

Our reference: PHC/21/08

Date: 12 December 2008

## **DRUG ALERT**

### **MEDICINES DEFECT INFORMATION**

Caution in use

For distribution to community and hospital pharmacists

Dear Healthcare Professional

**Merck Serono UK**

**Gonal-F 900 IU/1.5ml solution for injection in a pre-filled pen  
(follitropin alfa, recombinant human follicle stimulating hormone)  
EU/1/95/001/035**

| <b>Batch Number</b> | <b>Expiry Date</b> | <b>Pack Size</b> | <b>First Distributed</b> |
|---------------------|--------------------|------------------|--------------------------|
| Y10B0063            | 03/2010            | 1                | 06/06/2008               |
| Y10B2052            | 03/2010            | 1                | 25/07/2008               |
| Y10B4293            | 04/2010            | 1                | 18/08/2008               |
| Y10B7228            | 04/2010            | 1                | 12/09/2008               |
| Y10B8889            | 04/2010            | 1                | 17/10/2008               |
| Y11B2580            | 05/2010            | 1                | 31/10/2008               |
| Y11B3841            | 06/2010            | 1                | 11/11/2008               |

The MHRA has been informed that there is an error in the title of the package leaflet for some batches of Gonal-F 900 IU/1.5ml solution for injection in pre-filled pens. Details of the affected batches are shown above.

The actual concentration of Gonal-F in the pre-filled pen device is 900 IU/**1.5ml** and this is correctly stated on both the label of the pen injection device and the external packaging. It is also stated correctly in the body of the text of the package leaflet in section 6. However the title of the package leaflet indicates a concentration of 900 IU/**0.5ml**.

The error in the package leaflet should not affect the dosage of Gonal-F administered to the patient as the package leaflet clearly specifies that the dose on the pen should be set in IU and not by volume.

We have been asked to advise pharmacists that this information should be relayed to patients when dispensing, and should be conveyed to all pharmacists working within their pharmacy.

To avoid stock disruption, distribution of affected stock will continue, therefore further deliveries over the next few months will display this error. Corrected package leaflets are being produced but it is unlikely that these will be supplied to the market before January 2009.

It is recognised that this is not the ideal solution but necessary to maintain supplies of medication. Pharmacists should therefore reassure patients should any enquiries arise.

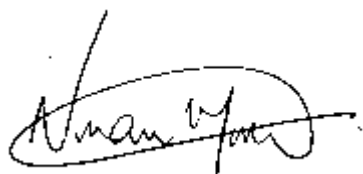
#### **Further Information**

For further enquiries, please telephone Merck Serono Medical Information on 0208 818 7373.

Area Boards/RQIA should bring this information to the attention of private hospitals/clinics registered with them, Out of Hours Centres and any other relevant care facilities.

The Central Services Agency 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  
CISSI  
SMO  
Director, Health Estates  
Public Health Branch  
DHSSPS, Library  
Extended nurse prescribers

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