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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

15 March 2010

Dear Healthcare Professional,
DRUG ALERT NO 6 (Rev 1) – CLASS 3

Please find attached drug safety information from the Medicines and Healthcare products Regulatory agency (MHRA) for onward transmission (see list below).

You will see that this letter replaces an earlier version of 9 March. Due to a technical problem this did not issue in Scotland on 9 March. The problem has now been rectified and future alerts should not be affected.

1. Please could all Directors of Pharmacy forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Chief Pharmacists to forward on to Medicines Information Pharmacists

2. Please could Medical Directors forward this alert to:-

- General Practitioners
- Relevant Clinics
- Chief Executives of NHS Boards

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy Division

Safeguarding public health
Defective Medicines Report Centre
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DRUG ALERT

CLASS 3 MEDICINES RECALL

Action Within 5 Days
PHARMACY LEVEL RECALL

Date: 15 March 2010

EL (10)A/06 Rev 1

Our Ref: MDR 59-01/10

Dear Healthcare Professional,

Teva UK Limited

**Glibenclamide 5mg Tablets in Teva UK
 Limited and Generics (UK) Limited Livery**

PL 00289/0048

Product in Teva UK Limited Livery

Batch Number	Expiry Date	Pack Size	First Distributed
7T88HL	November 2010	1x28	07 April 2008
8G04HLB	June 2011	1x28	26 March 2009
8G05HL	June 2011	1x28	09 September 2008
9A06HL	January 2012	1x28	16 April 2009
9A08HL	January 2012	1x28	07 August 2009
000132	March 2012	1x28	28 September 2009

Product in Generics (UK) Limited Livery

Batch Number	Expiry Date	Pack Size	First Distributed
7T01HL	November 2010	1x28	31 March 2008
8G04HL	June 2011	1x28	22 September 2008
8G05HL	June 2011	1x28	29 September 2008
9A08HLA	January 2012	1x28	27 April 2009
000536	January 2012	1x28	09 November 2009

Please replace the Drug Alert issued on 09 March 2010 with this revised document.

MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units

Chief Pharmacists: England, Scotland, Wales, Northern Ireland

Prison Health Policy Unit (DH)

Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar

Special Hospitals

Healthcare Commission for distribution to Independent Health Care Establishments

Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency

Market Towers 1 Nine Elms Lane London SW8 5NQ

T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

An executive agency of the Department of Health

Date: 15 March 2010

EL (10)A/06 Rev 1

MDR 59-01/10

Teva UK limited has informed us that one additional batch in Teva UK Limited livery, and two additional batches in Generics (UK) Limited livery, are involved in the recall. Details have been added to the tables, above. The Company apologises for any additional inconvenience this may cause.

Teva UK Limited are recalling all remaining stock of the above batches as a precautionary measure because routine stability testing has indicated that the specification for tablet dissolution may not be met after 12 months from manufacture. All batches which may be non-compliant were manufactured using a single batch of active ingredient.

In order to avoid market shortages, batches with an expiry date of September 2012 or later will remain on the market until replacement stock is available. This is expected by the end of May. Please see details of batches remaining on the market in the table below:

Batch Number	Expiry Date	Pack Size	Livery
000537	September 2012	1x28	Teva UK Limited
000681	September 2012	1x28	Generics (UK) Limited
001315	September 2012	1x28	Teva UK Limited

For medical information enquiries, please contact Teva UK Limited on 0207 5407117

Remaining stocks of the batches which are being recalled should be returned to the original wholesaler for credit. For further stock enquiries please contact Teva UK Customer Liaison Team on 0800 590502

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary care trusts are asked to forward this to relevant clinics and to General practitioners and Community Pharmacists for information.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC.