

Mr M K Shah
Registration no. 63471

FITNESS TO PRACTISE AND LEGAL
AFFAIRS DIRECTORATE
Statutory Committee
Telephone: + 44 (0)20 7572 2593
Facsimile: +44 (0)20 7572 2510
e-mail: david.gomez@rpsgb.org

21 October 2005

TD/STATCOMM/285/05

RECORDED DELIVERY

Dear Mr Shah

NOTICE OF INQUIRY

On behalf of the Statutory Committee of the Royal Pharmaceutical Society of Great Britain, I give you notice that the Committee has received a complaint from the Council of the Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN which alleges that:-

1. You were first registered with the Society on 6 February 1969.
2. At the material times you were Superintendent Pharmacist and a Director of MAM International Limited, the company which owned Shah Pharmacy at 734-736 Hertford Road, Freezywater, Enfield, Middlesex EN3 6PS ("the Pharmacy") where you were regular pharmacist in charge.
3.
 - a. On or around 20 February 2004 you supplied to Patient JH in response to a prescription from her General Practitioner 28 Enalapril 2.5mg tablets in a manufacturer's box comprising three foil blister strips (7 tablets on each), one blister strip of 5 tablets and one blister strip of 2 tablets;
 - b. the expiry date on the blister strip of 2 tablets was Oct 03;
 - c. the expiry date on the box and other blister strips not referred to in 3b above was "Use before 02 2004";
 - d. patient JH consumed some of these out of date tablets;

- e. when Patient JH telephoned you on or around 9 March 2004 and drew your attention to the fact that the tablets were out of date, you told her that the tablets could be taken up to 6 months after the "Use by" date;
 - f. when Patient JH returned the tablets to you on or around 9 March 2004, you exchanged the one remaining tablet of which the use by date was October 2003 but did not offer to exchange the remaining tablets of which the use by date was February 2004; and
 - g. when you exchanged the tablet referred to in 3f above for Patient JH, you supplied an Enalapril tablet 5mg, rather than 2.5mg which had been prescribed and corrected your error only when it was pointed out to you by Patient JH.
4.
 - a. On or around 19 March 2004, in response to a further prescription from Patient JH's General Practitioner, you supplied to Patient JH 28 Enalapril tablets 2.5mg in a plain white box containing 4 blister strips;
 - b. the box had no expiry date and did not contain a patient information leaflet; and
 - c. there was no batch number or expiry date on each of the four blister strips.
 5. On 27 May 2004 the Society's Inspectors visited the Pharmacy.
 6. The Society's Inspectors found in the dispensary of the Pharmacy the out of date medicines as set out in Schedule 1 to this Notice of Inquiry.
 7. The Society's Inspectors found in the dispensary of the Pharmacy the medicines where the date of expiry and batch number were not present and/or had been removed as set out in Schedule 2 to this Notice of Inquiry.
 8. The Society's Inspectors found in the dispensary of the Pharmacy mixed batches of medicines as set out in Schedule 3 to this Notice of Inquiry.
 9.
 - a. The Society's Inspectors found in the sliding dispensary drawers of the Pharmacy the medicines labelled years previously from other pharmacies for various patients, as set out in Schedule 4 to this Notice of Inquiry; and
 - b. the medicines in 9(a) above were stored amongst the other, alphabetically arranged, current stock indicating that they might be reused.
 10. The Society's Inspectors found in the dispensary at the Pharmacy the medicines which had been removed from the manufacturer's packaging and which were unlabelled or only partially labelled as set out in Schedule 5 to this Notice of Inquiry.
 11.
 - a. The Society's Inspectors found on the first floor of the Pharmacy the European products set out in Schedule 6 to this Notice of Inquiry; and
 - b. those European products did not bear a product licence number.

In summary the Society's Council alleges that:

- the supply to Patient JH of out of date tablets;
- informing Patient JH that out of date tablets could be taken up to 6 months after the "use by" date;
- your failure to exchange all the out of date medicines for Patient JH;
- the supply of a 5mg Enalapril tablet to Patient JH, rather than 2.5mg which had been prescribed;
- the subsequent supply to Patient JH of 28 Enalapril tablets 2.5mg in a box with no expiry date, with no patient information leaflet;
- the supply to Patient JH of 4 blister strips of Enalapril tablets 2.5mg on which there was no batch number or expiry date;
- the presence of inadequately segregated out of date medicines at the Pharmacy, of which you were Superintendent Pharmacist and regular pharmacist in charge;
- your failure to implement adequate systems for the removal of out of date medicines at the Pharmacy of which you were Superintendent Pharmacist and regular pharmacist in charge;
- the presence in the dispensary of medicines where the date of expiry and batch number were not present and/or had been removed at the Pharmacy of which you were Superintendent Pharmacist and regular pharmacist in charge;
- the presence in the dispensary of mixed batches of medicines at the Pharmacy of which you were Superintendent Pharmacist and regular pharmacist in charge;
- the presence in the sliding dispensary drawers of the Pharmacy of which you were Superintendent Pharmacist and regular pharmacist in charge of medicines labelled years previously from other pharmacies for various patients which were stored amongst the other, alphabetically arranged, current stock, indicating that they might be reused;
- the presence in the dispensary of medicines which had been removed from the manufacturer's packaging and which were unlabelled or only partially labelled at the Pharmacy of which you were Superintendent Pharmacist and regular pharmacist in charge; and

- the presence of European products which did not bear a produce licence number on the first floor of the Pharmacy of which you were Superintendent Pharmacist and regular pharmacist in charge

Individually or cumulatively may demonstrate that you have been guilty of such misconduct as to render you unfit to have your name on the Register of Pharmaceutical Chemists.

And I further give you notice that on **Wednesday 23 November 2005** at **9.30am** the Committee will hold an Inquiry at the Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1, for the purpose of ascertaining the facts in relation to the matters aforesaid and, if thought fit, subject to the provisions of the Pharmacy Act 1954, and the Medicines Act 1968, directing the removal of your name from the register.

You may attend the Inquiry personally and may be represented by a solicitor or counsel. If you do not attend the Statutory Committee may proceed with the Inquiry in your absence.

Any application or other communication relating to the said matters or your answer thereto shall be addressed to me not less than ten days before the day appointed for the hearing of the case.

A copy of the Regulations which govern the procedure of the Committee is enclosed herewith, and your particular attention is directed to Regulation 14. I also enclose a copy of the Committee's Indicative Sanctions Guidance.

The name and address of the solicitor acting in this case is Ms M Timms of Field Fisher Waterhouse Solicitors, 35 Vine Street, London EC3N 2AA.

Ms Timms will shortly provide you with a draft bundle of the Council of the Society's evidence and I would be grateful if you or your solicitor could liaise with her with the aim of providing where possible any written evidence from both you and the Society's Council to the Committee about one week before the day of the Inquiry.

A form for acknowledging receipt of this Notice of Inquiry is enclosed herewith for you to sign and return to me.

Yours sincerely

David Gomez
Secretary to the Statutory Committee

Enc.

Cc: Mr D Keegan, Turner & Debenhams Solicitors