RBI Consultation
Room 17-102
Medicines and Healthcare products Regulatory Agency
Market Towers
1, Nine Elms Lane
Vauxhall
London
SW8 5NQ

FITNESS TO PRACTISE AND LEGAL AFFAIRS DIRECTORATE
Inspectorate
Telephone: 020 7572 2311
Facsimile: 020 7572 2510
e-mail: jackie.giltrow@rpsgb.org

Ref: G0624AAA

10 January 2008

Dear Sirs

Re: Consultation Letter MLX 345

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation. The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society welcomes the opportunity to comment on the proposals set out in the consultation letter, particularly in view of the many areas of overlap between the jurisdiction and inspections conducted by MHRA and the RPSGB.

The RPSGB supports the move towards a more risk based inspection programme to ensure that resources are allocated where most needed. There are a number of general comments that the RPSGB would wish to make in relation to the proposals set out in the consultation letter as follows:

- Whilst the principle of self assessment is used by many inspection/enforcement agencies, the requirement for verification of information submitted should not be under estimated. It is not clear from the proposals how verification of information is to be achieved. Triangulated oversight of inspection processes is a requirement for successful regulation. This requires information to be obtained from multiple sources e.g. other relevant inspection, enforcement agencies or regulatory bodies and used for verification of information provided by regulatees.
- The proposals indicate that changes within an organisation e.g. new premises, staff, reorganisation etc will be captured and fed into the risk assessment, but it is not clear whether there are any duties on organisations to feed in these changes to MHRA. If this is not the case, then it is unclear how these changes will be captured in a timely and accurate fashion to ensure that an appropriate risk assessment can be achieved.
- The model for risk assessment and inspection planning does not indicate how the MHRA will co-ordinate with other inspection agencies to avoid duplicate/multiple inspection visits to the same site. In particular, the RPSGB is aware of a number of

owners of registered pharmacy premises who also hold licences issued by MHRA. In a number of instances, the same site is inspected by both the RPSGB and MHRA inspection teams. The RPSGB would welcome recognition of the need to co-ordinate inspection activities to reduce the regulatory burden where appropriate to do so. This may include a planned programme of joint inspection visits. In view of this the RPSGB recommends that a Memorandum of Understanding is agreed between the relevant agencies in an attempt to co-ordinate activities wherever possible.

- One area of activity that does not appear to be adequately covered by the MHRA risk based inspection is the unlicensed aseptic units (mainly in hospitals), which operate under the exemptions provided under s10 of the Medicines Act 1968. These units represent a potential high risk. These activities are not currently routinely inspected by MHRA or the RPSGB (current RPSGB inspection activities are restricted to registered retail pharmacies) and it is unclear whether these and similar units should be incorporated into the inspection activities of MHRA.
- The risk factors indicated in the consultation letter should take into account regulatory action taken by other authorities and a method for capturing this information should be built into the risk assessment process.
- It is not clear how changes to personnel such as company directors are handled with respect to ensuring that only 'fit and proper' persons are permitted to involved with licensed activities e.g. are Criminal Record Bureau checks requested and/or declarations in relation to civil, criminal or regulatory action required?

Finally, on a slightly tangential issue, the RPSGB would be interested in any proposals by MHRA to inspect/licence medicine distribution (cf wholesaling) sites. Due to a lacuna in the legislation, such sites are not currently subject to routine inspection either by the RPSGB or MHRA, although medicines can be stored for long periods of time within distribution sites without any regulatory checks being made on storage conditions and/or security of medicines. This appears to be a potential risk area, which requires further consideration to identify the nature and extent of the risks involved. This may be an area that is, or can, be incorporated into the self assessment information provided by organisations inspected by MHRA in order to understand the risk profile more clearly.

The RPSGB response to the individual questions posed within the consultation letter are attached at Annex 1. The contents of this response and covering letter may be made freely available.

I hope that these comments are useful

Yours sincerely

J T Giltrow (Mrs)
Chief Inspector

G0624AAA

Annex 1

Consultation letter MLX 345: Consultation questions on the risk based inspection model

Question 1

In principle the RPSGB agrees with this proposal, although the inspection requirements should be based on general public risk rather than the narrower concept of public health. When adopting this approach to regulatory inspection regimes, it is of paramount importance to ensure that the approach to inspection and non compliance is consistent across the inspection areas.

Question 2

The background and proposals are reasonably clear, although see comments below on self assessment and the need for verification of information and how this will be achieved. The post verification process is an important part of the process and would need to be considered in order to ensure the underpinning of the self assessment. There is no mention of the frequency, depth or scope of the self assessments. This makes it difficult to assess the regulatory burden on the regulatees. There needs to be a balance between over burdensome self assessments and the need to ensure that inspection frequencies are truly maintained on the basis of risk.

One area that would benefit from clarification is how MHRA is going to ensure triangulation of inspection activities (see covering letter). Is intelligence/information going to be proactively sought from other inspection, enforcement and regulatory agencies prior to visits and, if so, what impact will this have on those other agencies?

Question 3

The RPSGB would recommend that recognition is given to the possibility of inspection sites being dual registered and the need to co-ordinate inspection activities wherever this is a possibility in order to reduce regulatory burden.

Question 4

If the risk is accurately assessed then this will lead to prioritisation of inspection activities. It is, therefore, important that the methods of assessing the risks are comprehensive and incorporate sufficient information to allow an accurate assessment. There is also a need to ensure that up to date information is maintained. There should be comprehensive methods to ensure that any changes that affect the risk assessment e.g. regulatory action taken by other authorities, change of activities, change of company directors etc are captured.

Question 5

See comments above in relation to dual registration and inspection of premises. In addition, it is one of the principles of risk based inspections that resources are targeted where the risk is highest. This will mean that for some poorly complying, high risk activity organisations, it must be anticipated that the burden of regulation may increase.

Question 6

N/A

Question 7

The RPSGB believes that there is no substitute for on site inspections to ensure that activities are being appropriately carried out *in situ.* Provided that the risk based inspection model ensures the balance between relying on self assessment and/or intelligence and inspection visits, then the RPSGB would agree that there is an adequate degree of regulatory compliance and protection of public health.

Question 8

Whilst the principle of self assessment is used by many inspection/enforcement agencies, the requirement for verification of information submitted should not be under estimated. It is not clear from the proposals how verification of information is to be achieved. Triangulated oversight of inspection processes is a requirement for successful regulation. This requires information to be obtained from multiple sources e.g. other relevant inspection, enforcement agencies or regulatory bodies and used for verification of information provided by organisations.

Whether or not the use of self assessment regulatory compliance will be effective in maintaining patient safety, public health and environmental safety will depend on the information required in the self assessment form and the methods of verification of information required.

It the view of the RPSGB that self assessment alone will not be a sufficient safeguard against public health, patient safety and environmental safety and that other methods of ensuring compliance would need to complement the self assessment process. Self assessment is but one tool in the box to be used to assess risk and compliance and ensure that appropriate safeguards are in place.

Question 9

N/A.

Question 10

No comments.

Question 11

See comments above in relation to accuracy of assessing risk.

Question 12

No comments.

Question 13

Any regulatory impact on the RPSGB is likely to be minimal.

Question 14

Please see covering letter.