ROYAL PHARMACEUTICAL SOCIETY

1 Lambeth High Street,
London
SE1 7JN
F 020 7735 7629
www.rpharms.com

Elizabeth Evans mlx374@mhra.gsi.gov.uk
MHRA
5th Floor
151 Buckingham Palace Road
LONDON
SW1W 9SZ

Public Consultation (MLX 374): Transposition of Pharmacovigilance Directive 2010/84/EU

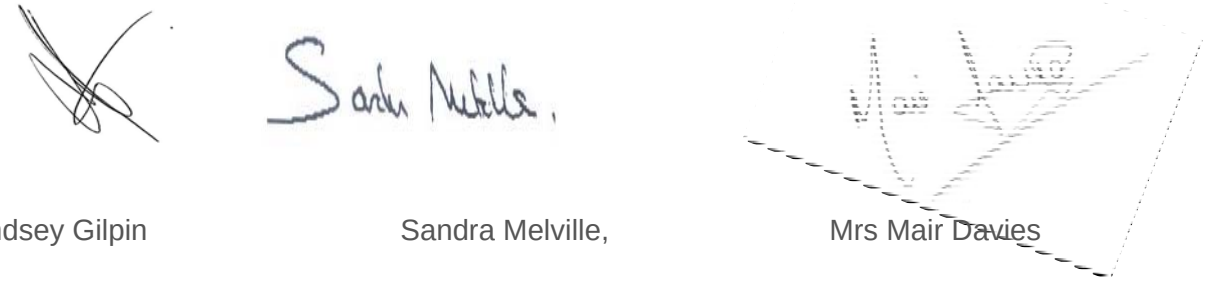
The Royal Pharmaceutical Society (RPS) welcomes the opportunity to contribute its views on the proposed changes to Pharmacovigilance in accordance with the above EU directive.

The RPS is the professional body for pharmacists across Great Britain. We are the only body that represents all sectors of pharmacy.

The RPS promotes and protects the health and well-being of the public through the professional leadership and development of the pharmacy profession. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

We would like to highlight that our response has been produced in the spirit of a professional leadership body and not by legal experts. We must therefore take in good faith the MHRA intention of not introducing any changes which will affect any sectors of pharmacy practice which have not been outlined and explained in the consultation document and accompanying annexes.

Kind regards,



Lindsey Gilpin Sandra Melville, Mrs Mair Davies

Chair, English Pharmacy Board
Chair, Scottish Pharmacy Board
Chair, Welsh Pharmacy Board

For further information or any queries you may have on our consultation response please contact Aileen Bryson *aileen.bryson@rpharms.com* 0131524200

Annex F: Response sheet for MLX 374 – Transposition of Pharmacovigilance Directive

Please return your response to: mlx374@mhra.gsi.gov.uk

Or by post: Elizabeth Evans
MHRA
Area 5-M
5th Floor
151 Buckingham Palace Road
LONDON
SW1W 9SZ

Question A – Do you agree with the approach we have take to the transposition of the Pharmacovigilance Directive? Please explain why, or why not.
We agree with the approach taken which uses the principles of reducing regulatory burden, simplifying the current system and using a risk based approach.
Question B – Do the draft regulations inadvertently introduce any unforeseen changes?
We have drafted our response focusing specifically on the questions raised and have taken in good faith the MHRA intention of not introducing any changes which will affect any sectors of pharmacy practice which have not been outlined and explained in the consultation document and accompanying annexes.
Question C – Are there any errors in the draft regulations?
Again we have taken the draft regulations in good faith and would ask that if any changes or drafting errors are found to have been introduced, that the MHRA consults again on those issues and does not view a lack of input at this stage as being compliant with the change
Question D – Are there any provisions that you do not understand or could be made clearer?
8.3 Will the MHRA have authorisation to revoke or vary a Marketing Authorisation depending on the results of any requested Post Authorisation Efficacy Studies.
Question E – Are you able to comply with the requirements of the

legislation? If not, why not?
The UK is already recognised as one of the leading member states in pharmacovigilance with patient reporting and the black triangle system in place. The proposed changes would seem to build and extend the principles of the current UK model to a European wide one We therefore do not envisage any barriers to complying, but agree that a transition period is necessary.
Question 1 – Are there any other benefits and/or costs arising from the way that we propose to transpose the Pharmacovigilance Directive?
Examination of the impact assessment would suggest a net benefit overall, despite increased costs in some areas which we believe are offset by the added patient safety benefits of a wider reporting database and more streamlined system overall.
Question 2 – Are you a micro (<10 employees), small (10-50), medium (50-250) or large (250+) business? Can you estimate the proportions of the sizes of the businesses within your sector?
As the professional body for pharmacists in England, Scotland and Wales we represent individual pharmacists working in all sectors of the profession. We are unable to estimate the proportions in each sector
Question 3 – Should the MHRA continue to allow coroners and carers to submit Yellow Card reports? Please explain why, or why not?
Patient reporting is already established and should be encouraged therefore it would seem sensible to extend this facility to carers .There may be instances where a Coroner or Procurator Fiscal obtains pertinent information which has not previously been available and this additional information could be advantageous. We would welcome this extra route of reporting.
Question 4 – Should the approach to determining the frequency of the conduct of audits by MAHs be on the basis of a documented risk assessment? Please explain why or why not?
We approve of the principle of using risk assessment to determine frequency of audit requirements. There should always be a requirement to submit a full dossier of information when any changes occur. There is

a wide spectrum of risk in medicines .This approach encourages focus on areas of high risk and reduces unnecessary burden or duplication of submissions for low risk medicines.
Question 5 – Do you agree with the introduction of an infringement notice process as proposed? Please explain why, or why not.
We agree with proposal which seems a proportionate first step to resolving any discrepancies and allowing the MAH to review procedures and improve practice. This approach should encourage transparency in the audit process and foster cooperation between all parties
Question 6 – Do you agree with the two-tier level of penalties proposed? If not, why not?
We have no objection to the two tier level of penalties but are not clear what the implications for the MA would be when a criminal offence is committed. Would suspension, revocation or variation of the MA also be applied after criminal prosecution as well as a penalty in its own right?
Question 7 – Do you agree with the level of penalty attached to the breach of an obligation? If not, why not?
It is difficult to comment on this aspect without more information. As a general principle we would be in favour of any fines or penalties imposed being proportionate to the risk to patient safety which the breach has allowed and should also reflect any potential or actual financial or commercial gain as a result of the breach.
Question 8 – Are the penalties that we have proposed proportionate?
As above
Question 9 – Can you quantify the likely costs involved in translating patient information and labelling to English?
N/A
Question 10 – Is there anything else from the Pharmacovigilance Transposition consultation that you would like to comment on?
5.4 We would ask that the system allows for appropriate changes to the patient information leaflets and summary of product characteristics to be made speedily and with minimal bureaucratic burden. This principle should apply to both emerging safety information and recognised

changes to the evidence base.

6.5 We ask the learning and experience form the established UK black triangle scheme is used to full advantage by the PRAC in setting up the new European monitoring requirements.

7.3 While we understand it would be difficult to make changes to licences already granted by requiring Risk Management Systems to be in place as proposed for new authorisations, we would however query that there be no requirement for products authorised before 21st July 2012 to have Risk Management Systems in place. We appreciate the MHRA can request this if they consider changes to risk to have occurred but suggest that this should be best practice for all MAHs regardless of when the licence was issued and should therefore be considered for all previous MAHs at their next audit .