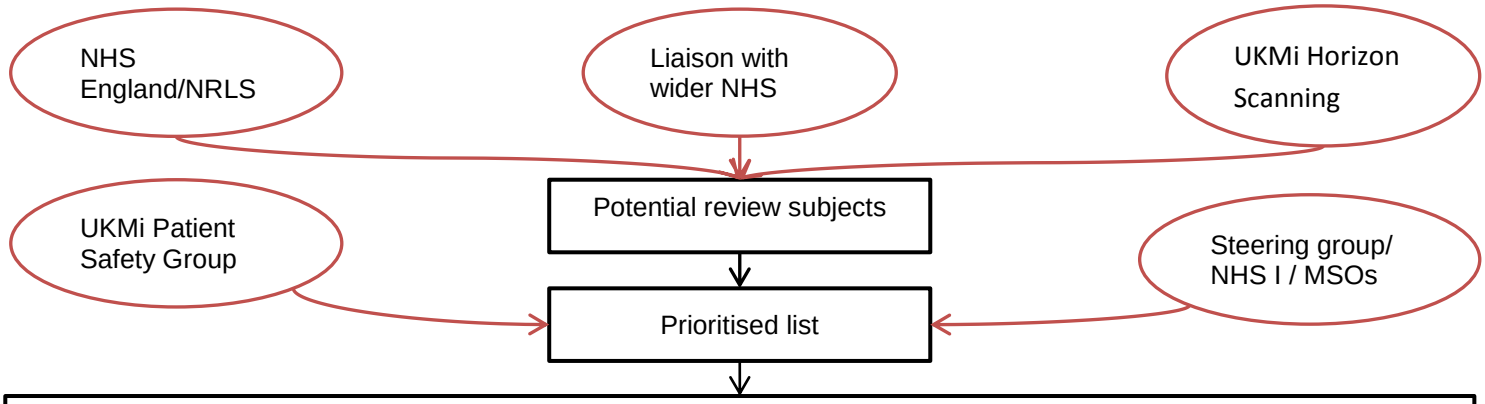
UKMi
UK Medicines Information

PROCESS FOR PRODUCTION OF UKMi MEDICINAL PRODUCT SAFETY ASSESSMENTS



- Lead UKMi centre (and individual pharmacist) and collaborating UKMi centre (and individual pharmacist) identified for each topic through the UKMi Patient Safety Group.
- Lead UKMi centre identifies other relevant input (e.g. specialist pharmacists, dispensary managers, relevant medics, specialist or other nurse input, relevant named person at the manufacturer) as deemed necessary for the type of product being reviewed. We should seek to obtain input from experts in the prescribing, supply, dispensing, and administration of the product as necessary.
- Chair of Patient Safety Group informs other SPS pharmacists, NHS I Meds Safety, and CMU as necessary of products being reviewed and expected dates of publication for reviews. This should be done monthly. Expectation is to complete reviews within 6-8 weeks of identification of need.
- Chair of Patient Safety Group ensures published reviews are included in the monthly webex presentation to MSOs.

- Lead UKMi centre works up a file of background material and shares this with collaborating centre. The file should include (as appropriate):
  - Summary of NRLS concerns (if relevant).
  - SPCs and packaging details (using the eMC, Pharma QC database, individual manufacturers, MIMS, MHRA/EMA websites, local images and the ABPI as necessary). Ideally for assessments, the product should be available in the actual physical form in which it will be presented to the NHS. If the product has been launched, physical product is the expectation. If it is not yet launched obtaining dummy versions should be pursued with the manufacturer. If physical product really cannot be obtained, high resolution images should be obtained as a minimum. A manufacturer demonstration may also be useful for products that include devices.

- Lead centre apply tool (in its full form) to each product.
- Lead centre produce draft report and liaise with collaborating centre for agreement.

- Where appropriate the draft report is shared with other relevant groups/individuals for their comments and views; include Alison Darbyshire, QA pharmacist if appropriate alison.darbyshire@rlbuht.nhs.uk.
- The comments and views of external collaborators, including manufacturers, are processed and taken account of.
- Ideally all parties should agree to the final contents of the report, including the authors and any specialists that have been involved (it should not normally be necessary to seek a second review from manufacturers, however). If, however, there is disagreement (either between contributors, commentators, or authors) then a third party from the UKMi Patient Safety group should be consulted. If disagreement persists, then final decision making rests with the UKMi Executive Group Chair, and the document would require discussion (virtually or otherwise) before release.

- The lead UKMi centre sends the final document to Varinder Rai (varinder.rai@nhs.net) for a final third-party proof read. The master list of reviews updated.
- The PDF version is then uploaded to the SPS website and arrangements made to ensure the availability of the assessment is included in Medicines Awareness Daily/Weekly.
- The lead MI centre keeps all the information on file in relation to the review for future reference as per standard UKMi practice.

Prepared by Ben Rehman/Varinder Rai. Updated January 2018. Version 4.

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Quality checklist for the production of UKMi Product Safety Assessments

	Date(s)	Completed by:
Product assigned:		
SPS pharmacists, NHS I Meds Safety and CMU informed of review		
Relevant expert input identified and contacted		
Background searches completed		
SPCs and packaging images obtained		
Physical product obtained (if product launched)		
Risk assessment conducted using full version of tool		
First draft of report completed		
Material shared with collaborating centre and first draft agreed		
Draft report sent to relevant experts		
Expert reviewer(s) comments incorporated if appropriate		
Second draft completed		
Second draft sent to manufacturers for comment		
Document approved by all parties including collaborating centre and experts consulted		
Final draft written		
Proof reading/ checking of text and references completed by collaborating centre		
Send final document to varinder.rai@nhs.net for a final third-party proof read		
Final document completed and put into PDF format by lead centre and uploaded to the SPS website		

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Quality checklist for checking the text and proof reading

Document: .....

Item to be checked		Proof read (Word document)
Standard template has been used.		
Text has been checked for:	Clarity	
	Good flow of English	
	Spellings of approved names	
	Spellings of generic names	
	Typographical and grammatical errors	
Dosages and strengths correct		
Calculations correct		
References correct and numbered in consecutive order		
Tables and diagrams labelled		
Contact details correct		

NB: Signed checklist to be kept by the lead MI centre