

## **Risk Assessment Tool for assessing the safety characteristics of medicines**

### **Purpose**

Pharmacy Voice's Patient Safety Group has worked closely with the UKMi to further develop their risk assessment tool, which is used regularly in secondary care settings, to make the tool more accessible and valuable for community pharmacy teams.

The Community Pharmacy Medication Safety Risk Assessment tool is designed as an aid in the systematic identification of potential patient safety issues associated with medicines before their introduction to clinical practice.

### **Background and definitions**

New risks may be introduced into practice when a new medicine is introduced. Such risks may cause medication errors, harm, and potentially even fatalities to patients.

A new medicine could be

- any medicine which has not been used previously in a particular healthcare organisation or area of practice (including branded medicines recently launched onto the UK market and offering a new therapeutic option for a clinical indication)
- an established licensed medicine being used for the first time in a particular setting or organisation;
- unlicensed products being used for the first time
- a new strength, formulation or presentation of an existing medicine being used in response to a medicine shortage or for some other reason.

Individuals and organisations have professional and clinical governance responsibilities to ensure that the name, packaging and labelling of a medicine are compatible with its safe use.

This tool enables full consideration of the patient safety characteristics of all medications, whether they are licensed or otherwise. The tool is designed to be as holistic as possible; considering the pharmaceutical characteristics of the product, any links between a product's regulatory status and its safety in practice, as well as practical considerations such as issues associated with the product design.

### **How to use the tool**

The tool can be used prospectively or retrospectively to assess products, their features, and how those could impact on their safe use. This will help determine whether any patient safety issues could arise in relation to a specific medicine. It can also be used as part of the learning process if any product-related incidents have arisen in a pharmacy.

The form should be completed by a pharmacy professional and any findings, particularly where the boxes next to text marked in red have been checked, should be shared with team members and the Superintendent Pharmacist if necessary.

# Community Pharmacy Medication Safety Risk Assessment Tool

Product	Strength	Pharmacy	Date
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Themes	Assessment	Details/ notes
<b>Current status</b>		
Does the product have a UK marketing authorisation?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is there a suitable product available with a marketing authorisation for the indication in question?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is the medicine a licensed generic product that is being used instead of a branded product?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is the product readily and reliably available from a recognised supplier?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>Name, packaging and labelling, and other pharmaceutical issues</b>		
Could the name of the medication be confused with those currently in existence? (Sound alike / look alike)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is the generic name clearly identifiable in English on the external packaging and internal blisters?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Are all other critical details clearly identifiable in English on the packaging (e.g. strength, form, any product specific warnings, Batch Number, Expiry Date & storage conditions)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Where the medication contains more than one active ingredient, are all constituents clearly stated on the packaging alongside the approved name?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does the packaging clearly differentiate between the various strengths of the same product (especially those which are visibly similar (e.g. 10mg and 100mg)?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is an English language Patient Information Leaflet available with the product?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>Information provided with the product</b>		
Is appropriate technical information available in English to guide calculations, preparation, and administration?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>Prescribing risks</b>		
Is the dosing and prescribing complex? Where necessary, is additional patient information available to support safe use of the medicine? For example, are steroid or lithium cards present if necessary?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is the prescribed dose consistent with the way the strength, form, and (where applicable) base salt are presented?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>Preparation, Calculation, Labelling, Information &amp; Administration</b>		
Are there current known operator safety issues with the drug?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
In the form presented, are commonly used doses easy to measure?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is the medicine supplied to the end user in a presentation that is: <ul style="list-style-type: none"> <li>▪ ready-to-use (i.e. correct volume and correct strength and is ready to draw up)? or</li> <li>▪ ready-to-administer (i.e. in a final container ready for administration to the patient)?</li> </ul>	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does the product easily enable essential labelling to be in place at point of dispensing?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is the product barcode visible and available for scanning once the dispensing label is in place?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>Storage &amp; Disposal</b>		
Are there any specific storage requirements? e.g. refrigeration, space (if bulky), secure?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does the product pose any special risks during disposal to either the user or pharmacy?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>Additional Comments</b>		
Other comments, concerns or observations		
<b>Summary &amp; Outcome</b>		
Completed by:		