## Tool for assessing the in-use patient safety characteristics of medicines and medicinal products

| Product | Assessment completed by | Date |
|---|---|---|
| | | |

| No | Themes | Assessment | Details/ notes |
|---|---|---|---|
| **A** | **Licensing status** | | |
| A1 | Does the product have a UK marketing authorisation? | Yes ☐→A2 No ☐→A3 | |
| A2 | Is it only going to be used within that marketing authorisation? | Yes ☐→B No ☐→A3 | |
| A3 | Is there a suitable product available with a marketing authorisation for the intended use? | Yes ☐ No ☐ | |
| A4 | Is the anticipated use supported by a reasonable evidence base? | Yes ☐ No ☐ | |
| A5 | Is technical and patient information available in English to support the anticipated use? | Yes ☐ No ☐ | |
| A6 | Do you have assurance of pharmaceutical quality? For example,<br>• If the medicine is unlicensed, is the supplier of the medicine suitably licensed?<br>• What type of assurance process does the manufacturer have in place? | Yes ☐ No ☐ | |
| **B** | **Name, packaging and labelling, and other pharmaceutical issues** | | |
| B1 | Could the medicine's names be confused with those currently in existence?<br>*[Is there risk of sound alike/look-alike errors?]* | Yes ☐ No ☐ | |
| B2 | Is the medicine's generic name clearly identifiable in English on the packaging? | Yes ☐ No ☐ | |
| B3 | Is other critical information also clearly identifiable in English on the packaging? (e.g. strength, form, any product specific warnings) | Yes ☐ No ☐ | |
| B4 | Is the critical information above clear on all sides of the packaging as well as on the primary (e.g. ampoule) and secondary (e.g. carton) packaging | Yes ☐ No ☐ | |
| B4 | For branded medicines, is the generic name also suitably prominent? | Yes ☐ No ☐ | |
| B5 | Is pharmaceutical information such as the batch number, expiry date, and storage conditions clear and unambiguous on the packaging? | Yes ☐ No ☐ | |
| B6 | Where medicines contain more than one active ingredient, are all generic constituents clearly stated on the packaging? | Yes ☐ No ☐ | |
| B7 | Is the expression of strength on the packaging consistent with prescribing practice? | Yes ☐ No ☐ | |
| B8 | Does the packaging encourage (or at the least not hinder) differentiation between a range of products from a single supplier, or between different products from different suppliers?<br>*[Is there risk of selection errors?]* | Yes ☐ No ☐ | |
| **C** | **Information provided with the product** | | |
| C1 | Is an English language patient information leaflet available with the product? | Yes ☐ No ☐ | |
| C2 | Is English language prescribing information available for the product? | Yes ☐ No ☐ | |
| C3 | Is appropriate technical information available in English at the point of care to guide calculations, preparation, and administration? | Yes ☐ No ☐ | |
| C4 | Does the product information only contain positive statements about use? For example "for intravenous use only" as opposed to "not for intrathecal use" | Yes ☐ No ☐ | |
| **D** | **Prescribing risks** | | |
| D1 | Is the product an additional treatment option, or is it replacing another product or drug? | | |
| D2 | Are there issues associated with non-familiarity or confusion with existing treatments? | Yes ☐ No ☐ | |
| D3 | Is the dosing and prescribing complex? | Yes ☐ No ☐ | |
| D4 | Who will prescribe the item? *[consider prescriber's scope of practice and processes involved]* | | |
| D5 | Is the prescribed dose consistent with the way the strength, form, and (where applicable) base salt are presented? | Yes ☐ No ☐ | |
| **E** | **Known risks and management** | | |
| E1 | Has the item (or any similar product) been the subject of any medicines safety alerts? *[e.g. NPSA report, description as a never event, or inclusion in a MHRA drug safety bulletin]* | Yes ☐ No ☐ | |
| E2 | Is the medicine under intensive regulatory surveillance? | Yes ☐ No ☐ | |
| E3 | Are new or amended clinical or laboratory monitoring requirements associated with the introduction of the medicinal product? | Yes ☐ No ☐ | |
| E4 | Is there potential for significant harm in deliberate or inadvertent overdose? If yes,<br>• Are suitable reversibility and antidote strategies available?<br>• Are clinical management strategies in such circumstances defined? | Yes ☐ No ☐<br>Yes ☐ No ☐<br>Yes ☐ No ☐ | |
| E5 | 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 ☐ No ☐<br>NA ☐ | |

| | | | |
|---|---|---|---|
| **F** | **Preparation, Calculation, Labelling & Information** | | |
| F1 | Are there current known operator safety issues with the drug?<br>• Is the medicine of a class where operator safety issues might be a concern?<br>• Is the medicine subject to COSHH regulations, for example? | Yes ☐ No ☐<br>Yes ☐ No ☐<br>Yes ☐ No ☐ | |
| F2 | Is the medicine supplied to the end user in a presentation that is<br>• ready-to-use (i.e. correct volume and correct strength and is ready to draw up) or<br>• ready-to-administer (i.e. in a final container ready for administration to the patient)? | Yes ☐ No ☐<br>Yes ☐ No ☐ | |
| F3 | In the form presented, are commonly used doses easy to measure? | Yes ☐ No ☐ | |
| F4 | If manipulation is required prior to administration,<br>• is it complex (i.e. does it have 5 or more defined steps)?<br>• does it involve any special or unusual complexities (using the contents of part ampoules or vials, complex dilution or mixing with other drugs, or need to crush preparations or make other extemporaneous products prior to administration)? | Yes ☐ No ☐<br>Yes ☐ No ☐ | |
| F5 | Is a complex calculation (i.e. has more than one step) necessary prior to preparation and/or administration? | Yes ☐ No ☐ | |
| F6 | Does the product easily enable essential labelling to be in place at point of administration? | Yes ☐ No ☐ | |
| **G** | **Administration** | | |
| G1 | Is administration of the product in any way complex? | Yes ☐ No ☐ | |
| G2 | Is the route of administration of the product intrinsically high risk (such as intrathecal)? | Yes ☐ No ☐ | |
| G3 | Does administration require the use of a device and/or disposables?<br>If yes, are there any issues related to their use? | Yes ☐ No ☐<br>Yes ☐ No ☐ | |
| G4 | For injectable medicines,<br>• is the rate of administration safety critical? If yes, what mechanisms are in place to ensure the rate is correct?<br>• is any specific monitoring required during administration? If yes, is it practical & achievable? | Yes ☐ No ☐<br>Yes ☐ No ☐ | |
| **H** | **Supply chain issues** | | |
| H1 | Is the product readily and reliably available from a recognised supplier? | Yes ☐ No ☐ | |
| H2 | Are expiry dates (both for the product in its original form, and in-use as necessary) available and clear? | Yes ☐ No ☐ | |
| H3 | Are there any specific storage requirements? e.g. refrigeration, space (if bulky) | Yes ☐ No ☐ | |
| H4 | Are there any issues relating to secure storage? e.g. is there likelihood of misappropriation? | Yes ☐ No ☐ | |
| H5 | Overall, consider whether the storage requirements can likely be met? | Yes ☐ No ☐ | |
| **I** | **Disposal** | | |
| I1 | Does the product pose any special risks during disposal to either the user or staff? | Yes ☐ No ☐ | |
| I2 | Are there any specific disposal requirements for the product? | Yes ☐ No ☐ | |
| **J** | **Impact of setting** | | |
| J1 | Is the product for use in a highly specialist environment? For example in neonates, fluid restricted patients, or those in critical care scenarios.<br>If yes, is there the potential that it will be used outside such an environment?<br>Have issues associated with such use been identified and addressed? | Yes ☐ No ☐<br>Yes ☐ No ☐<br>Yes ☐ No ☐ | |
| J2 | Is the medicine one which is likely to be used across other boundaries of care?<br>If yes, have issues associated with such use been identified and addressed? | Yes ☐ No ☐<br>Yes ☐ No ☐ | |
| J3 | Is the medicine one for which self-administration by patients is a possibility?<br>Have any issues associated with such use been identified and addressed? | Yes ☐ No ☐<br>Yes ☐ No ☐ | |
| J4 | Where the manipulation of the product is complex, is the environment in which it is to be prepared conducive to its safe use? That is, will it be as free as possible from distractions and is it an otherwise suitable environment for complex manipulation? | Yes ☐ No ☐ | |
| **K** | **Summary & Outcome** (Committees involved; whether or not approved for use in the organisation etc) | | |
| K1 | As a consequence of the product's introduction, will any changes to practice occur?<br>If yes, are those changes likely to introduce new risks?<br>Or do they have the potential to address patient safety risks known to be present currently? | Yes ☐ No ☐ | |
| K2 | Overall, when considered against the status quo, are the risks identified in relation to the product's introduction reasonable? | Yes ☐ No ☐ | |
| K3 | Where it is possible to assess, are any patient safety risks outweighed by the potential clinical benefits the product offers against available alternatives? | Yes ☐ No ☐ | |
| K4 | Other comments and actions | | |