**Insulin Preparations**

**Safety factors checklist for local formulary decision making**

The Regional Medicines Optimisation Committee has published [guidance](https://www.sps.nhs.uk/articles/insulin-preparations-rmoc-recommendations-of-safety-considerations-for-formulary-decision-making/) to formulary committees/ Area Prescribing Committees on safety factors to consider when adding a new insulin preparation to a local formulary.

This checklist should be completed as part of the evidence gathering process for each new insulin product being considered for the formulary. These principles should be given equal significance as clinical and cost-effectiveness data. A plan of action should be developed if completion of this checklist identifies areas where more work is needed before introducing the new product into the formulary.

|  |  |  |
| --- | --- | --- |
| **Product** | **Assessment Completed by** | **Date** |

|  |  |  |
| --- | --- | --- |
|  | Assessment | Details / Notes |
| 1. **General**
 |
| Is adequate representation available on the Committee to consider these issues? For example diabetologists and community nurses. | Yes No |  |
| 1. **Presentation**
 |  |  |
| Is it clear which presentations are being considered? | Yes No |  |
| Is it necessary for all presentations of the product to be endorsed? | Yes No |  |
| Give details of only those presentations which **are** being endorsed. |  |  |
| If different presentations are being endorsed, are there clear criteria in which circumstances each presentation will be used? | Yes No |  |
| If a vial has been requested, have restrictions for use been defined, e.g. special circumstances or appropriate care settings? | Yes No |  |
| 1. **Risk Assessment**
 |  |  |
| Has a risk assessment of the product been conducted? | Yes No |  |
| Confirm which assessment tool has been used:* UKMi Product Safety Assessment (check [here](https://www.sps.nhs.uk/articles/ukmi-product-safety-assessments-2/) ).
 |  |  |
| * UKMi Product Safety Assessment template tool ([here](https://www.sps.nhs.uk/articles/ukmi-product-assessment-tool/)).
 |  |  |
| * Local risk assessment.
 |  |  |
| 1. **Device**
 |  |  |
| Is the proposed device already available on the formulary for use with other insulin products? | Yes No |  |
| If not, confirm that introducing an additional device into the local community is absolutely necessary | Yes No |  |
| 1. **Product Usability**
 |  |  |
| Is the product easy to use on a day-to-day basis in practice? | Yes No |  |
| Considering in particular patients with poor vision:* Can the packaging be read easily?
 | Yes No |  |
| * Can the device be read easily?
 | Yes No |  |
| * Can the dial be read easily?
 | Yes No |  |
| Considering in particular patients with poor dexterity:* Is the dial easy to manipulate?
 | Yes No |  |
| * Can the activation button be depressed easily?
 | Yes No |  |
| 1. **Training**
 |  |  |
| If the device is new to the formulary: |
| Is training available for patients? | Yes No |  |
| Confirm the training can be given before the product is dispensed | Yes No |  |
| Is training available for all healthcare professionals who may use the device (include secondary care staff such as nurses, doctors and pharmacists, and primary care staff such as GPs, practice nurses, community nurses, community pharmacists and care home staff)? | Yes No |  |
| Will this training be available on an ongoing basis? | Yes No |  |
| Is training available for carers? | Yes No |  |
| Has consideration been given to the impact of adding a new product to neighbouring Trusts and other providers out of catchment? | Yes No |  |
| 1. **Supply**
 |  |  |
| Are arrangements in place to provide timely supply of all elements of the new preparation (e.g. the device, needles, re-fills) | Yes No |  |
| Is it clear which needles should be used? | Yes No |  |
| Is there are reliable supply to both primary and secondary care? | Yes No |  |
| Are Safer Sharps available to healthcare workers, especially those administering outside of a clinical setting with no sharps bin access?  | Yes No |  |
| Have the additional costs associated with the insulin product been considered, e.g. the device and the needles? | Yes No |  |
| 1. **Implementation**
 |  |  |
| Have practical implementation issues been considered? | Yes No |  |
| Will community services, e.g. local pharmacies, be made aware?  | Yes No |  |
| **For high strength insulins, consider the following:** |
| Will the product be isolated/identified locally? | Yes No |  |
| Do separate storage arrangements need to be mandated? | Yes No |  |
| Can warnings be added to the following: |  |  |
| * electronic prescribing systems
 | Yes No |  |
| * paper prescribing processes
 | Yes No |  |
| * pharmacy dispensing systems
 | Yes No |  |
| 1. **Support**
 |  |  |
| Where patients are unable to self-administer, is immediate support/resources available to help advise/treat patients? | Yes No |  |
| If so, please provide details |  |
| Is this support available out-of-hours? | Yes No |  |
| Is this support available to primary and secondary care staff? | Yes No |  |
| 1. **Errors due to insulin withdrawal from devices.** See [NPSA alert](https://improvement.nhs.uk/news-alerts/risk-severe-harm-and-death-withdrawing-insulin-pen-devices/)
 |  |  |
| Are systems in place to avoid insulin withdrawal from pen devices? | Yes No |  |
| Are there mechanisms in place to ensure that patients will have the necessary needles and devices should they be:  |  |  |
| * admitted to hospital
 | Yes No |  |
| * transferred
 | Yes No |  |
| * discharged
 | Yes No |  |
| Are Safer Sharps available to avoid re-sheathing of insulin needles | Yes No |  |
| 1. **Prescribing**
 |  |  |
| Are systems in place to ensure that insulin prescribing: |
| * is by brand name
 | Yes No |  |
| * includes the strength
 | Yes No |  |
| * includes the device required
 | Yes No |  |
| Is there on going education/training for the above requirements? | Yes No |  |
| Are systems in place to ensure pharmacy personnel clarify the insulin product and presentation during medicines reconciliation? | Yes No |  |
| Is a specific check on this mandated? | Yes No |  |
| 1. **Rationalisation**
 |  |  |
| Will any current products be removed from the formulary? | Yes No |  |
| If so, will patients be switched to a suitable alternative? | Yes No |  |
| Are systems in place to allow such switching to occur? | Yes No |  |
| Will stocks of current products be used up to reduce wastage? | Yes No |  |
| Will community pharmacies be informed, so stocks can be rationalised? | Yes No |  |