**Letter from hospital/specialist clinic who initiated unlicensed medicine to patient named GP to indicate clinical need when prescribing an unlicensed medicine**

Dear GP,

Re Patient: ……………………………………………………………………………………………………………………………………………….

The SEL Paediatric Formulary carefully considers and assesses the suitability of a product before making a recommendation on the most appropriate formulation. We have initiated an unlicensed medicine instead of a licensed medicine to meet the special clinical need(s) of this child. The reason for recommending the unlicensed medicine is due to the presence of undesirable or harmful excipients in the licensed product.

Listed below are those medicines for which an unlicensed preparation is recommended instead of a licensed preparation in SEL. This child has been prescribed the following:

[ ]  Chloral Hydrate 500mg/5ml oral liquid

[ ]  Melatonin (Kidmel®) 1mg/1ml oral liquid

[ ]  Midazolam 2.5mg/1ml oral liquid

[ ]  Omeprazole 20mg/5ml oral liquid

As the prescribing responsibility for this medicine will be transferred to you, please ensure you are provided with adequate clinical information to continue safe prescribing. Further detail on clinical indications, dosing and administration guidance may be found in the SEL Paediatric Formulary. Please be assured that the patient/parent/carer has been made aware of the rationale for prescribing an unlicensed medicine.

**Supporting Information**

The Medicines and Healthcare Regulatory Agency (MHRA) has produced guidance on the supply of unlicensed medicinal products (“specials”) which essentially recommends that:

1. An unlicensed medicinal product may only be supplied in order to meet the special needs of an individual patient.
2. An unlicensed medicinal product should not be supplied where an equivalent licensed medicinal product can meet the special needs of the patient.
3. Anyone supplying an unlicensed medicinal product, where an equivalent licensed medicinal product is available must be satisfied as to the existence of a special need for the unlicensed medicinal product
4. MHRA expects that documentary evidence of this special need should be obtained by manufacturers, importers or distributors and that this evidence should be made available on request of the Licensing Authority. This may take the form of a prescriber’s letter, however an alternative fully documented audit trail through the supply chain confirming special need may be acceptable.

The full document can be accessed here: <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf>

Please share the following letter (page 2) for prescription requests with the patient’s community pharmacy to ensure that the specific product can be sourced from an unlicensed manufacturer/supplier for proof of clinical need.

**Letter from patient named GP to community pharmacy to request specific brand of unlicensed specials due to clinical need or excipients**

Dear community pharmacy colleague,

We are aware that there is a licensed pharmaceutical preparation available, however; we are requesting supplies of an unlicensed preparation for this patient to best meet their clinical needs. The special clinical need in this case relates to an unacceptable excipient profile in the licensed product, and is recommended by the South East London Paediatric Formulary.

Request for use of:

[ ]  Chloral Hydrate 500mg/5ml oral liquid

[ ]  Melatonin (Kidmel®) 1mg/1ml oral liquid

[ ]  Midazolam 2.5mg/1ml oral liquid

[ ]  Omeprazole 20mg/5ml oral liquid

Doctor name:………………………………………………….

GMC number:…………………………………………………

Date:…………………………………………………