



Importation and Distribution of Pancreatic Enzyme Replacement Therapy

Anna Larkham – Lead Community Nutritional Management Specialist Dietitian, Surrey Heartlands ICB

Julia Powell – Chief Executive Officer, Community Pharmacy Surrey & Sussex



Background

 May 2024 – NPSA alert advising of the ongoing shortage of pancreatic enzyme replacement therapies (PERT) until 2026.

Action:

"prescribe unlicensed imports of PERT only where licensed alternatives are unavailable, working with local pharmacy teams to ensure orders are placed within appropriate time frames."

- December 2024 updated alert with additional actions:
 - "To ensure that patients are not left without PERT, Integrated Care Boards (ICBs) should:
 - put in place a local mitigation plan for instances when patients are unable to obtain stock from their community pharmacy or dispensing GP.
 - cascade any local management plan to all community pharmacies and GP practices within the region, as well as local trust pharmacy teams."



Working with Oxford Pharmacy Stores

- Liaised with staff at OPS
- Identified potential product for import
- Ops.orders@oxfordhealth.nhs.uk







Pangrol

- Some specials wholesalers are now stocking on next day delivery
- 2 x 100 capsule banded packs
- English patient information leaflets
- Pangrol 10 000
- Pangrol 25 000







Process for GPs

- Pangrol is now listed on electronic systems as an unlicensed import
- Patients should be informed of the rationale for the use of an unlicensed imported product and adequate justification provided. This should also be documented in the patient's medical record as per <u>GMC requirements</u>

Prescribing support system messages may be helpful (national and local):

The DHSC National Patient Safety Alert (NatPSA/2024/013/DHSC; Dec 2024) states that Creon 10,000 and 25,000 capsules are in limited supply until 2026, Pancrex V (including Pancrex V 125mcg) capsules are also unavailable. The DHSC advises clinicians to prescribe a maximum of one month's supply of PERT for all patients at a time, prioritise available Creon 10,000 capsules for patients unable to take Creon 25,000 capsules only, prioritise Nutrizym 22 capsules for patients unable to tolerate Creon capsules and to prescribe unlicensed imports of PERT only where licensed alternatives are unavailable.

Where PERT is prescribed for indications other than cystic fibrosis, clinicians and prescribers should consider prescribing a proton pump inhibitor or H2 receptor antagonist to optimise efficacy, if a dose reduction may be suitable for patients based on severity of symptoms, where symptoms remain despite a dose of > or =10,000units lipase/kg/day or 100,000units lipase with a meal, whether other causes of the symptoms should be investigated and prescribing medication to manage symptom control. Refer patients to a specialist if the alternative options are unsuitable.

LOCAL TEXT: The Surrey Heartlands APC noted the ongoing shortages of pancreatic enzyme replacement therapies. See Surrey PAD for local guidance which has been produced to summarise current issues and information and actions for prescribers, community pharmacies and patients.



Process for pharmacy

- Attempt to order Creon
- Serious Shortage Protocols in place for prescriptions limiting supply to one month for Creon – currently to the 23rd May 2025
- If Creon is unavailable and the patient runs out in next 10 days request alternative prescription of Pangrol
- Can only set up an account with OPS when stock is required to fulfil an order
- Allow 48-72 hours to set up account with OPS
- Once account is set up products are available next day delivery when ordered before 2pm





Patient awareness and messaging

- Reassure patients that the medication has not been discontinued and that supplies are available but intermittent
- Order prescription 2 weeks in advance of needed
- Linking in with local tertiary centres and local patient groups
- Providing patient information and guidance



Comms – getting information out there

- Important to not just do once, but continuous messaging needed to all stakeholders – GP's, Community Pharmacies and Patients
- Surrey Heartlands ICB Guidance
- CPSS Guidance
- Newsletters
- Local networks
- Meeting agendas
- Direct mailings
- Tertiary centre including links to guidance with correspondence



Challenges

- IT systems prescribing and dispensing systems not listing Pangrol initially
- Getting the message out there about Pangrol to GP's, pharmacies and patients ICB supporting communications
- Patient resistance awareness and accepting Pangrol when initiated by Secondary Care and changes made in Primary Care, English PILs
- GP resistance to prescribing it lack of awareness of the product, Creon initiated in Secondary Care, cost
- Pharmacies lack of awareness of the product e-mails/newsletter, resistance to setting up a OPS account e.g. multiples follow-up with HO's
- Lead contacts for community pharmacy and GP Practices to support resolution of issues