

Pancreatic Cancer UK's five point plan to influence the UK Government and NHS to address PERT shortages

The purpose of this brief is to inform PCUK senior leadership team and other patient charities of our five-point plan which we want to see decision makers take to address and resolve PERT shortages in the UK, based on the work undertaken by Incisive Health and our understanding of the wider context we're operating within.

The five points outlined in this plan will serve as the solutions we advocate for when influencing decision-makers.

We also summarise the influencing tactics we will adopt to push key decisionmakers in this space to make the required changes in the short-to-medium term.

Background and causes of PERT shortages

There are currently intermittent shortages of the most used form of Pancreatic Enzyme Replacement Therapy (PERT):- Creon®. Other brands of PERT are now also experiencing shortages, due to their inability to fill the gap in demand for PERT.

Several factors are causing PERT shortages including:

- Lack of availability of raw materials (pig enzymes) needed to make PERT
- Lack of manufacturing capacity
- Increased demand for treatment
- Lack of diversity of suppliers to the UK market

We have heard through our Specialist Nurse Support Line and our engagement with health care professionals, that the PERT shortages are having a significant impact on people affected by pancreatic cancer. Some of the ways people have been managing during PERT shortages include:

- Travelling back and forth between pharmacies, GP and hospital to get PERT
- Reducing their dose and their food intake
- Replacing food with prescribed 'sip feeds' to minimise symptoms when they have run out of PERT
- Going without PERT
- Being sent left over PERT by people who no longer need it
- Sourcing PERT from underground markets
- Asking family and friends who live in other countries to source PERT and send it to them
- Buying unlicensed products that claim to support digestion , online and from other countries

As a charity, we know that access to PERT is incredibly important for people affected by pancreatic cancer, and crucial to managing symptoms and maintaining a good quality of life. We also know that having trouble accessing PERT is incredibly stressful and worrying.

We want key decision-makers with the power to resolve this issue, including the UK Department of Health and Social Care, the Medicines and Healthcare products Regulatory Agency (MHRA) and national NHS bodies to commit to the actions we have identified and outlined in this brief. Ultimately, this could mean that everyone who needs PERT gets it.

Our five point plan for addressing PERT shortages

We have worked with an agency to develop a five-point plan of the actions we want key stakeholders such as the UK Government Department of Health and Social Care (DHSC), the Medicines and Healthcare products Regulatory Agency (MHRA), and national NHS bodies, to take to address shortages in PERT in both the short and long-term.

We believe that actioning the five points outlined below could mean that everyone who needs PERT gets it.

1. The UK Government must develop a national action plan to proactively address and resolve PERT shortages

In order to resolve PERT shortages, key stakeholders need to develop a plan that considers and addresses this issue.

To achieve this, the UK government must immediately:

- Conduct a **high-level meeting** between Viatrix, key patient advocacy groups, and government stakeholders including the Minister with responsibility for medicines supply within the Department of Health and Social Care (DHSC) to develop an understanding of the issues and the full scope of possible solutions.

Following this, the UK Government must:

- Establish a Vaccines Taskforce style group bringing together key stakeholders across industry, manufacturing, pharmacy, NHS, the Medicines and Healthcare products Regulatory Agency (MHRA) and the UK Government to respond to the rise of medicine shortages, with an immediate focus on PERT.
- This group should develop a national action plan to address PERT shortages and agree on responsibilities for delivering this plan.

In the longer term, suppliers and the DHSC must:

- Work together to reintroduce a higher-strength PERT capsule into the NHS. This would improve the quality of life for people with pancreatic cancer who require a higher PERT dosage as they would be able to take fewer capsules.

2. The UK Government must ensure that the UK's PERT market share matches the demand for PERT in the UK. This includes ensuring alternative brands of PERT are imported, when needed.

During shortages, prescribers can buy other brands of PERT from abroad if they cannot get PERT from UK suppliers. However, this is a time consuming process with significant costs involved and there is a lack of national effort to ensure that this is routinely happening, and the cost associated. The UK Government must ensure that access to alternative brands of PERT are easily available to prescribers during shortages.

To achieve this, DHSC and national NHS bodies must immediately:

- Centralise the purchasing of alternative PERT products, so that they can be rapidly made available in times of shortages in a way that minimises the burden on patients, pharmacists and other clinicians.
- Provide guidance and support to community pharmacies, to ensure they are empowered to access alternative PERT products during shortages.

In the longer-term, DHSC and national NHS bodies must:

- NHS bodies across the UK should also consider whether processes to support surety of supply should be incorporated in its Commercial Framework.

3. DHSC must conduct a 360-degree supply and demand forecast for PERT to scale up manufacturing where needed

There is currently no data on the demand and potential future demand for PERT across the UK. A better understanding of the supply and demand will help stakeholders to identify the changes needed to ensure that everyone who needs PERT can get it.

To achieve this, the UK government must:

- Undertake a robust supply and demand forecasting exercise for PERT.
- Establish real-time communication channels with suppliers, patients and health professionals to better understand the scope of the supply and demand and mitigate disruptions.

4. NHS organisations across the UK must provide clear information and support to patients and health professionals during PERT shortages

We are hearing through our Specialist Nurse Support Line that patients are experiencing high levels of stress and worry about getting PERT. We are also hearing from health care professionals that this is placing significant pressure on an already under resourced service as health care professionals try to access PERT for patients during shortages. National NHS bodies must take responsibility and action to ensure that patients are supported and informed during this challenging time.

To achieve this, national NHS bodies must immediately:

- Work with patient groups to improve content and disseminate existing patient information about what to do if they are struggling to get PERT.
- Ensure all patient-facing staff are sufficiently informed of changes to PERT availability so that they can support and provide accurate information to patients.
- Work with pharmacy leaders to explore prescribing flexibilities that could be adopted during PERT shortages.
- Integrate and embed real-time stock information across NHS digital infrastructure so that health professionals know which brands of PERT are being stocked across large pharmacy brands at any given time.

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6. The MHRA and UK Government must increase the resilience of the supply of raw materials for PERT

The underlying cause of PERT shortages is the lack of enzymes from pigs' pancreas - the raw material - due to changes in diet and the production of leaner pigs. Supply of raw material could be further threatened by a swine flu outbreak. A more stable supply of raw materials used to make PERT is needed to ensure stable supplies of PERT.

To achieve this, the UK government must:

- Incentivise greater investment in research into alternative, non-porcine materials to produce PERT.