**National Lenalidomide Pregnancy Prevention Programme (PPP) - Pathfinder, Risk Management Platform: Frequently Asked Questions (FAQs) v1**

## Purpose of this document

This document has been created by an implementation subgroup to the NHS Lenalidomide Short Life Working Group (SLWG). The document aims to answer frequently asked questions (FAQ's) about the implementation of the new Pathfinder Risk Management Platform system.

This document is being circulated to all Chief Pharmacists on behalf of the NHS Lenalidomide SLWG via national pharmacy networks. Chief pharmacists are asked to share this FAQ document with their local clinical, nursing and pharmacy teams who are involved in the prescribing and supply of lenalidomide to patients.

Procurement details and information on the generic framework award in England are available in the Commercial Medicines Unit procurement briefing document which has been shared with Regional Pharmacy Procurement Specialists and local Trust procurement leads for discussion and action locally.

## Introduction

Lenalidomide (Revlimid®), originally marketed by BMS Celgene, is an anti-cancer medicine used to treat myeloma, some types of lymphoma and myelodysplastic syndromes. It is structurally related to thalidomide, a known teratogenic medicine which causes birth defects. Generic lenalidomide became available in the UK during 2022. All UK Marketing Authorisation Holders (MAH) must have a validated Pregnancy Prevention Programme (PPP), because of the teratogenic effects of lenalidomide, before a licence is granted by the Medicines & Healthcare Products Regulatory Agency (MHRA).

Generic lenalidomide has the potential to save the NHS tens of millions which can be reinvested into patient care. NHS England, working with colleagues from NHS Scotland and NHS Wales, anticipate that the generic market could be restricted if there was no single universal electronic PPP that all manufacturers could use and multiple PPPs would be very difficult for the NHS to manage. To facilitate this and to support the procurement process a UK wide NHS Lenalidomide Short Life Working Group (SLWG) was formed in October 2021

## Lenalidomide Pregnancy Prevention Programme (PPP)

The British Generics Manufacturers Association (BGMA) working in partnership with Health Beacon, PharmaCare Group and other key stakeholders have developed an electronic PPP system not linked to any single company which any manufacturer who holds a Market Authorisation for lenalidomide can sign up to use.

The system called **Pathfinder Risk Management Platform (RMP)** is in the final stages of development, which once complete will be inspected by the MHRA on the 11th/12th October 2022. If the inspection is successful, the planned launch date for this system would be later this year.

**Disclaimer**

Whilst every effort has been made to ensure the information in this document is correct at the time of publication it is recognised that there may be a need to update the FAQS as users gain experience with the Pathfinder RMP and new questions arise.

If you have any comments on the content or accuracy of this document, please contact **england.cmupharmacyteam@nhs.net** . Specific questions around Pathfinder RMP operability should be sent to **support@pharmacaregroup.co.uk**

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**What Pregnancy Prevention Programme (PPP) systems are available*?**

The list below summarises the suppliers currently awarded on the NHS England procurement framework and their PPP (where known).

- Accord (paper and own digital system- pending MHRA approval)
- Advanz/Mercury (Pathfinder RMP)
- Amarox (Pathfinder RMP)
- BMS (paper and own digital system)
- Glenmark (paper)
- Morningside (own system)
- Piramal (Pathfinder RMP)
- Ranbaxy/Sun (Pathfinder RMP)
- Sandoz (Pathfinder RMP)
- Teva (paper, own digital system will move to Pathfinder RMP)
- Thornton and Ross (Pathfinder RMP)
- Viatris/Mylan (Pathfinder RMP)
- Wockhardt (Pathfinder RMP)
- Zentiva (paper)

*Note at the time of writing this FAQ not all PPP systems had gone live and not all suppliers had confirmed their final intentions regarding their choice of PPP system, therefore we recommend readers confirm with each manufacturer directly to confirm which PPP system(s) they support.

**What is the Pathfinder Risk Management Platform (RMP) system?**

Pathfinder RMP is a digital Pregnancy Prevention Platform and controlled distribution system enabling healthcare professionals (HCPs) to register, initiate patients and complete and approve prescription authorisation forms in a seamless manner as part of the risk minimisation requirements necessary for the prescribing and dispensing of lenalidomide.

Pathfinder RMP can only be used by suppliers who sign up to this PPP system. The suppliers who had signed up to Pathfinder at the time of writing this FAQ are listed in above

*An organisation/ trust CANNOT use Pathfinder RMP for non-registered suppliers PPP– in this case you MUST use the suppliers own PPP system.*

Pathfinder RMP is managed jointly by PharmaCare Group and HealthBeacon.

**Who are HealthBeacon and PharmaCare Group?**

HealthBeacon plc is a digital health company that develops tools to manage medication. With clients in 15 countries, HealthBeacon operates in highly regulated environments around the globe working with Marketing Authorisation Holders and health systems. HealthBeacon is providing the Pathfinder IT platform.

PharmaCare Group (PCG) is a pharmaceutical service provider specialised in risk minimisation activities for medicines with teratogenic side effects and other medicinal products which require a complex Risk Management Programme. PCG has a deep knowledge of pharmacovigilance responsibilities in both branded and generic sectors. The company has experience with lenalidomide and related compounds. PCG will be responsible for the administration of the system.

**What are the benefits of the Pathfinder Risk Management Platform?**

The Pathfinder Risk Management Platform (RMP) is a user-friendly, electronic Pregnancy Prevention Programme system which any supplier can use following registration /subscription.

The NHS wide lenalidomide short life working group believes the creation of one electronic PPP system will drive standardisation, compliance and therefore improve patient safety. One system will support organisations with the training and education of staff and support the implementation of future contracts and any subsequent switching between products that might be necessary (no re-registration of patients will be necessary).

The Pathfinder RMP allows nurse and pharmacist independent prescribers to complete the Prescription Authorisation Form (PAF) at each consultation, which may improve the workflow in clinics and improve compliance.

**How does Pathfinder differ from current PPP systems?**

Pathfinder RMP has been developed in partnership with the NHS and the BGMA to support multiple suppliers sharing the same system which means Trusts do not need to re-register patients when switching medicine suppliers if both use Pathfinder RMP.

On the dispensing page, healthcare professionals will be able to select which supplier they are dispensing the product from which will support robust medicine reconciliation.

**My trust is choosing to use a supplier who is registered with Pathfinder RMP, what should my Trust do?**

1. **Review supporting materials:**

   Pharmacy, working with the wider haematology multi-disciplinary team, should review all supporting materials and create a project plan for managing the switch from the incumbent supplier's PPP to the new Pathfinder RMP.

2. **Registration of Premises:**

   The Chief Pharmacist at your organisation must register its premises thereby agreeing to implement and ensure compliance to the risk minimisation measures of the Pathfinder RMP PPP. The Chief Pharmacist must register any premises which will receipt and /or dispense lenalidomide.

3. **Training and registration of Healthcare Professionals HCPs**:

   Education and training of healthcare professionals (HCPs) will be carried out by PharmaCare Group (PCG) or by self-training via the materials provided on the Pathfinder RMP.

   All HCPs must access training through PCG or self-training on the portal before they can sign up. Once they have completed training, they can register in system and PCG will review their application. Once approved they can login to Pathfinder RMP. This usually happens within 24 hours but is not instantaneous so needs to be completed before seeing a patient.

4. **Contact Patients**

   Provide patients with information on the Pathfinder RMP and the generic switch (see FAQ on what I need to tell patients? – details below)

5. **Inventory management**

   Chief Pharmacists need to consider the management of stock remaining in dispensaries, if the incumbent supplier is not using Pathfinder RMP, to minimise waste. Any stock dispensed

MUST be registered in the PPP applicable to that brand of lenalidomide. Therefore, any Prescription Authorisation Forms generated will need to be for the correct PPP, which will require close communication between pharmacy and the wider MDT. For example, provider Trust teams could create a table of patients, doses, and what stock is available in order to plan a switch date which ensures stock is used up.

**6. Reconciliation**

All stock must be reconciled quarterly by PharmaCare Group pharmacovigilance team to pharmacy level; therefore, Chief Pharmacists are advised to minimise internal transfer of medicines within Trusts and consider all dispensaries order stock directly from wholesalers/suppliers (where possible).

**What do we need to tell patients about the Pathfinder System, what is my Trust required to do?**

Inform patients about the new PPP platform (as it will hold information about patients) and the possible switch in brand of their medicine (where applicable).

A draft patient template letter will be provided to Chief Pharmacists through Regional Pharmacy Networks that Trusts can adapt and use to inform their patients about the changes.

Engage with any out-sourced pharmacies /homecare service partners to agree implementation plan, including when you will be contacting patients and dates for planned switches.

**What is the deadline for moving patients to the Pathfinder?**

The decision on which supplier a Trust will use and therefore the PPP system they will need to use will be made locally. Supporting information will be available from the Commercial Medicines Unit /Regional Pharmacy Procurement Specialists in September 2022. There is no deadline for moving patients to the new Pathfinder RMP system. Patients can be moved or added at any point following MHRA approval and launch of the system

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| When a trust is dispensing a new brand of lenalidomide, they MUST use the PPP which applies to that brand. See comments on inventory management above. |

**We have decided to switch to a medicine supported by the Pathfinder system. Can our Revlimid® patients be automatically transferred to the new system?**

No. the short life working group did explore this in some depth. Good data governance should include a manual Quality Control check on data transfer and validation, ideally, of every patient record. This would be a time-consuming process. This would be complicated by the need to transfer different patients at different times to ensure previous stock was used up.

Registration of a patient in Pathfinder RMP when they first receive a new supply of lenalidomide is a much quicker option than the data transfer and the quality control check. Our simulations show that it takes less than two minutes to register a new patient on the system and complete the patient authorization form.

**Can existing patients on Lenalidomide Teva®, registered on the patientsafetyhub.co.uk be automatically transferred to the Pathfinder system?**

See answer above regarding Revlimid®. It is not recommended to electronically transfer patient data between PPP systems, it does not save time and required time consuming data validation.

**How long does it take to register each patient on Pathfinder?**

It will take less than two minutes per patient to register existing patients on Pathfinder RMP.

The MHRA now supports the Prescription Authorisation Form (PAF) being completed by a Non-Medical Prescriber. This means all existing patients can be registered on Pathfinder RMP by their Doctor or Non-Medical Prescriber.

Note: The initial registration and initiation of **new patients** starting on lenalidomide must still be completed by the doctor.

**When should the patient be registered on Pathfinder RMP?**

The registration and Prescription Authorisation Form (PAF) is directly linked with a prescription. It is recommended to register each patient when they are prescribed their first new supply of lenalidomide.

Please also refer to the flow chart

**What are the different roles/registrations on Pathfinder RMP?**

Please also refer to the flow chart in appendix one this describes the role below:

- Premise/Trust
- Chief pharmacist or delegated pharmacist
- Prescribers, which includes doctors, nurses and pharmacists
- Dispensing pharmacist or technician, which can be a Homecare provider or community pharmacist. Pharmacy technicians can only dispense on the system they cannot approve

**Who can I contact for training?**

Training will be completed by PharmaCare Group, and this can be organised by contacting **support@pharmacaregroup.co.uk** or telephone: **0330 043 0908**.There will be a user guide and training videos available on the Pathfinder RMP website in which users can watch and read in order to learn the functionality of Pathfinder RMP.

**How can I reset my password?**

The password can be reset through the main login page. The user will click “Forgot Password” in which they then must insert their email. Once they have submitted their email and if they have an account on the system, they will get emailed a password reset link. When they click on the link, they will be redirected to create a new password and to confirm their password. Once this is complete, they can login to their account.

**What happens if I change to a different supplier in the future?**

If the supplier is registered with Pathfinder RMP, then nothing needs to be done. The dispensing pharmacy simply needs to select the correct supplier at the point of dispensing on the dispensing page in portal.

If the supplier is not registered with the Pathfinder RMP, then the Trust needs to comply with the specific Pregnancy Prevention Programme of the supplier, which will require re-registration of the premises, HCPs and patients.

**How do I comply with the pregnancy prevention programme for thalidomide and pomalidomide?**

PharmaCare Group and Health Beacon are currently road mapping the Pathfinder RMP to include both thalidomide and pomalidomide into the system. Further information to follow regarding these drugs. At the current time, the existing PPP for these will still apply.

**Who deals with non-compliance?**

PharmaCare Group will be responsible for both compliant and non-compliant PAFs. PCG will be reaching out to Healthcare Professionals regarding any non-compliance that has occurred and taking forward remedial actions as appropriate

**Side effect reporting**

Pathfinder RMP provides a link to the Yellow Card (MHRA) system and contact details for the relevant Marketing Authorisation Holder to report any side effects that have occurred using the relevant Marketing Authorisation Holder's drug. Any exposure during pregnancy (whether confirm or suspected) must be reported.

**How long is patient data kept on Pathfinder?**

The patient data is kept for a minimum of 10 years.

**Can Pathfinder be integrated with electronic SACT prescribing systems?**

Health Beacon will be working in integrating Pathfinder into SACT prescribing systems in phase 2.

**ENDS**

**Appendix One: Flow chart for Pathfinder system**