ROYAL PHARMACEUTICAL SOCIETY

A Pharmacogenomic Resource to Support the Competency Framework for all Prescribers

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This work is supported by the NHS England Genomics Programme through the pharmacogenomics and medicines optimisation genomic network of excellence, which is led by the NHS North West Genomic Medicine Service Alliance.

This resource supports prescribers to build and expand pharmacogenomics (PGx) competence, helping them to prescribe safely and effectively using PGx, ultimately improving patient outcomes through medicines optimisation. It should be used alongside the RPS prescribing competency framework as an additional resource.

The resource can be used by any prescriber, in settings across the UK, at any point in their career to underpin professional responsibility for prescribing when using PGx information. It is for all regulators, professional bodies, education providers and healthcare organisations.

Find out more about PGx - https://www.rpharms.com/development/pharmacogenomics

Introduction

Pharmacogenomics (PGx) is the study of how genetic variation influences drug response which can enable safer and more effective prescribing.[1] A PGx test is a genetic test which focuses on genes that affect drug metabolism, efficacy or risk of adverse reactions and therefore informs treatment decisions rather than predicting disease susceptibility.[1]

Across the UK, PGx is a developing strategic priority for major policy frameworks such as the Genome UK strategy,[2] NHS England 10-year plan[3] and Life Sciences Sector plan.[4] Within these plans, workforce upskilling is identified as a critical challenge to PGx implementation across all four UK nations.[5–9] National genomic workforce strategies have been developed within England[10] for individual professions and in Wales for the whole healthcare workforce to initiate progress towards embedding PGx into routine care.[11]

The routine use of PGx testing is evolving from the current use of reactive single-gene testing (e.g., DPYD gene testing for fluoropyrimidines) to the use of multi-gene panel testing within research programmes across the UK,[12–14] and further developments are predicted to include broader PGx panels for pre-emptive use.[15]

Development of this resource

In 2025, the Royal Pharmaceutical Society (RPS) was commissioned by NHS England (led by the NHSE Network of Excellence in Pharmacogenomics and Medicines Optimisation) to develop this resource. The expertise from a UK-wide multidisciplinary task and finish group and a further validation group supported and refined this resource.

Purpose

This resource supports prescribers to build and expand your PGx competence. It helps healthcare professionals (HCPs) across all disciplines prescribe safely and effectively using PGx, ultimately improving patient outcomes through medicines optimisation. It should be used alongside the RPS prescribing competency framework[16] as an additional resource to improve competence in the use of PGx.

This resource can be used by both trainee and registered prescribers (from all professions) in settings across the UK, where PGx testing is in use and in other settings where testing is not currently available or implemented.

Instances when this resource may be used:

- **Self-assessment** – for expanding or changing scope of practice or returning to practice
- **Evidence for trainees** – to demonstrate competence
- **Guidance for regulators, educators and professional bodies** – to inform standards and curriculum development
- **Organisational structure development** – to inform prescribing practice and governance systems
- **Portfolio development** – to continue education and prescriber revalidation relating to PGx.

It can be used by any prescriber at any point in your career to underpin professional responsibility for prescribing when using PGx information.

This resource is intended to support and enable prescribing practice and does not seek to disadvantage any prescribing profession.

Limitations

Prescribers are not expected to have knowledge of PGx tests beyond your individual scope of practice. It is recognised that access to PGx testing and established testing pathways may vary overtime and may not be available or commissioned across all areas of practice or geography.

To avoid duplication of the competency framework, PGx reflections have only been added to each supporting statement where there is additional context required to support the use of PGx. Meanwhile, other supporting statements from the competency framework do not require PGx context. Those competencies still apply to prescribers using PGx, and new knowledge, skills and behaviours may be required to maintain competence in these areas.

Benefits of using this resource:

- Standardises PGx education and competence across prescribing professions
- Supports design and validation of educational prescribing programmes.

Other applications for this resource:

- Provides professional organisations or specialist groups with a basis for the development of levels of prescribing competency within PGx, from 'recently qualified prescriber' through to 'experienced prescriber'
- Stimulates discussions around PGx prescribing competencies and multidisciplinary skill mix at an organisational level
- Informs the development of organisational systems and processes that support safe and effective prescribing, including the use of PGx testing, e.g., local clinical governance frameworks
- Informs the development of education curricula relating to PGx
- Informs and assures patients/carers about the competencies of a safe and effective prescriber in relation to PGx.

Scope

This resource complements A Competency Framework for all Prescribers to:

- Support any prescriber regardless of your professional background or setting and does not contain statements that relate to certain professions or clinical settings
- Is relevant for prescribing practice within all regions of the UK
- Contextualise and reflect on different areas of practice, levels of expertise and settings
- Reflect the key competencies and skills needed by all prescribers to use PGx testing in day-to-day practice. This resource is not a curriculum, nor a substitute for regulator-defined educational standards, but a shared reference that can inform, enrich and contextualise PGx content within regulated prescribing programmes
- Apply equally to independent prescribers, community practitioner nurse prescribers and supplementary prescribers, but the latter should contextualise the resource to reflect the structures imposed when entering a supplementary prescribing relationship
- Support the demonstration of prescribers' proportionate competencies aligned to prescribing scope, with baseline expectations applying to all prescribers. Advanced competencies may be required where PGx is embedded within a service or pathway.

Structure

The competencies within this resource are presented as two domains reflective of the original competency framework for all prescribers. Each competency and supporting statement is presented in a table format, with the PGx interpretation described in the corresponding box.

To explain further:

- **Domain one (the consultation)** – the PGx competencies you need relating to the consultation competencies
- **Domain two (prescribing governance)** – the PGx competencies you need relating to prescribing governance competencies
- **Case studies** – these demonstrate the PGx competencies (see appendix one).

PLEASE NOTE

Due to the nature of the resource being aligned to A Competency Framework for all Prescribers, PGx reflections have only been added to supporting statements where there is additional context to support using PGx over and above the existing statement. Competencies or supporting statements where no additional PGx reflection is required to explain the original statement have not been included in the following tables. However, all competencies and supporting statements from the prescribing competency framework still apply, and new knowledge, skills and behaviours may be required to maintain competence in these areas.

The framework is generic, and not every competency or supporting statement may be relevant to your practice or setting. However, you should still consider how you could demonstrate the supporting statement.

Domain one
The consultation

PGx testing is used to predict the risk of adverse drug reactions or response to medicines. Using this testing, HCPs can better anticipate that risk, leading to improved medicines optimisation within a consultation.

Domain one's common themes are summarised as:

- **Genetic variability** – Variations in genes which encode drug-metabolising enzymes, transporters or receptors can influence whether a medicine is effective or causes adverse effects
- **Consent aspects** – Any form of consent (often verbal is sufficient) should be documented appropriately and should ensure patients understand the implications for treatment, privacy and potential future use of their genetic data and how this differs to obtaining genetic information to diagnose genetic conditions
- **Testing limitations** – Patients should be informed of the technical and clinical limitations of PGx testing and that interpretation and treatment recommendations may change over time as evidence, guidelines and testing technologies evolve
- **Risk-benefit aspects** – PGx testing can introduce extra considerations to treatment decisions, balancing the benefits of personalised therapy against challenges such as access and limitations of testing and incidental findings. Transparent discussion of the benefit and risks with patients and other members of the multi-disciplinary team supports shared decision making
- **Testing strategy** – PGx testing models range from reactive single-gene testing in response to a prescription (including rapid point of care tests) to pre-emptive multi-gene or whole genome sequencing. Available testing models vary across healthcare settings and have different considerations including turnaround time, cost-effectiveness and commissioned status which may impact on clinical decision making
- **Analytic and clinical validity of testing** – PGx variants can be tested for using a range of different technical approaches which can impact on the analytic and clinical validity of the results, e.g., through incomplete gene panels or variants of uncertain significance
- **Relevance of family history** – Family history can indicate inherited genetic traits that affect drug response. Obtaining this information complements PGx test results and contributes towards the prediction of adverse reactions or therapeutic failure
- **Cultural competence and impact of patient understanding** – It is essential to explain PGx concepts using a culturally sensitive and accessible approach. E.g., when dealing with patients who have learning disabilities or language barriers, plain language and tailored communication should be used to ensure understanding and informed decision making
- **Variant frequency and ethnicity** – PGx variants often occur at different frequencies across ethnic and ancestral groups, which can influence drug response and safety. Historic under-representation of some groups in genomic reference datasets may limit the clinical utility of some PGx tests in individuals. Recognising these patterns helps you avoid assumptions and ensure equitable access to personalised care for all patients.

COMPETENCY ONE: **ASSESSING THE PATIENT**	
ORIGINAL SUPPORTING STATEMENT	**PGX REFLECTION ON EXISTING SUPPORTING STATEMENT**
1.1 Undertakes the consultation in an appropriate setting.	*This original supporting statement does not require additional PGx-specific action beyond standard prescribing practice.*
1.2 Considers patient dignity, capacity, consent, and confidentiality.	You should assess patients' health literacy and genomic understanding before ensuring they understand the purpose, benefits and risks of PGx testing including the potential for reuse of results and safeguarding of genetic data regardless of their current level of understanding.
1.3 Introduces self and prescribing role to the patient/carer and confirms patient/carer identity.	*These original supporting statements do not require additional PGx-specific action beyond standard prescribing practice.*
1.4 Assesses the communication needs of the patient/carer and adapts consultation appropriately.	
1.5 Demonstrates good consultation skills and builds rapport with the patient/carer.	
1.6 Takes and documents an appropriate medical, psychosocial and medication history including allergies and intolerances.	You should take a patient history that includes ethnicity or ancestry, relevant known family history, known genetic information and any known family history of adverse drug reactions or variable responses potentially linked to genetics. Where possible, document any prior PGx test results, including those from the independent sector, and note their impact on past prescribing.
1.7 Undertakes and documents an appropriate clinical assessment.	*This original supporting statement does not require additional PGx-specific action beyond standard prescribing practice.*
1.8 Identifies and addresses potential vulnerabilities that may be causing the patient/carer to seek treatment.	You should be aware that certain health conditions, symptoms or adverse drug reactions may be linked to specific PGx variants in people. During the consultation, it is equally important to explore and respect the patient's views, concerns and expectations about the use of genetic information in their care.
1.9 Accesses and interprets all available and relevant patient records to ensure knowledge of the patient's management to date.	You should review all available PGx test results (NHS and non-NHS (with care of test quality assurance)), including relevant family data. Understand the analytical and clinical validity and utility of results in context of the patient's history, considering test timing, type of laboratory source (NHS or validated provider) and relevance of variants or star alleles tested.
1.10 Requests and interprets relevant investigations necessary to inform treatment options.	You should first assess whether a PGx test is clinically indicated and then, where appropriate, consider the patients' eligibility for that test. Ensure patients understand its purpose, interpretation and limitations. Use validated sources to distinguish between actionable, non-actionable and conflicting PGx results and support clinical interpretation. Ensure evidence-based testing contributes to holistic care within local and national pathways.
1.11 Makes, confirms, or understands, and documents the working or final diagnosis by systematically considering the various possibilities (differential diagnosis).	You should have an awareness of how genetic information may contribute to and affect the patient's diagnosis relating to treatment.
1.12 Understands the condition(s) being treated, their natural progression, and how to assess their severity, deterioration, and anticipated response to treatment.	*These original supporting statements do not require additional PGx-specific action beyond standard prescribing practice.*
1.13 Reviews adherence (and non-adherence) to, and effectiveness of, current medicines.	
1.14 Refers to or seeks guidance from another member of the team, a specialist or appropriate information source when necessary.	

COMPETENCY TWO: **IDENTIFY EVIDENCE-BASED TREATMENT OPTIONS AVAILABLE FOR CLINICAL DECISION MAKING**	
ORIGINAL SUPPORTING STATEMENT	**PGX REFLECTION ON EXISTING SUPPORTING STATEMENT**
2.1 Considers both non-pharmacological and pharmacological treatment approaches.	You should understand how to prioritise one pharmacological and/or non-pharmacological approach over another based on the patient's genetic information available, supporting more individualised and effective care planning.
2.2 Considers all pharmacological treatment options including optimising doses as well as stopping treatment (appropriate polypharmacy and deprescribing).	*This original supporting statement does not require additional PGx-specific action beyond standard prescribing practice.*
2.3 Assesses the risks and benefits to the patient of taking or not taking a medicine or treatment.	You should understand that PGx testing can enhance risk–benefit assessment by providing patient-specific genetic insights to support informed decisions on the initiation, continuation or discontinuation of therapy. This should be balanced with any risk by delaying decision making in the absence of PGx results.
2.4 Applies understanding of the pharmacokinetics and pharmacodynamics of medicines, and how these may be altered by individual patient factors	You should be aware that patients' genetic differences (variation) affect drug response, making PGx key to optimising efficacy and reducing adverse drug reactions to ensure the safe use of prescribed medicines. Not all findings are immediately actionable, and results may need revisiting as evidence grows.
2.5 Assesses how co-morbidities, existing medicines, allergies, intolerances, contraindications, and quality of life impact on management options	
2.6 Considers any relevant patient factors and their potential impact on the choice and formulation of medicines, and the route of administration	
2.7 Accesses, critically evaluates, and uses reliable and validated sources of information.	*These original supporting statements do not require additional PGx-specific action beyond standard prescribing practice.*
2.8 Stays up to date in own area of practice and applies the principles of evidence-based practice.	
2.9 Considers the wider perspective including the public health issues related to medicines and their use and promoting health.	
2.10 Understands antimicrobial resistance and the roles of infection prevention, control, and antimicrobial stewardship measures.	You should understand how PGx data can guide antibiotic selection by predicting a patient's likelihood of experiencing adverse drug reactions or their potential response to treatment.

COMPETENCY THREE: **PRESENT OPTIONS AND REACH A SHARED DECISION**	
ORIGINAL SUPPORTING STATEMENT	**PGX REFLECTION ON EXISTING SUPPORTING STATEMENT**
3.1 Actively involves and works with the patient/carer to make informed choices and agree a plan that respects the patient's/carer's preferences	You should inform and involve patients in decision making about the potential implications of testing, including how results may influence therapeutic options. You should have an awareness of the need for the patient to share information with family members if it is relevant for them.
3.2 Considers and respects patient diversity, background, personal values and beliefs about their health, treatment, and medicines, supporting the values of equality and inclusivity, and developing cultural competence	You should demonstrate cultural competence by respecting patient diversity, values and health literacy when PGx testing. Communicate information clearly to support inclusive, shared decision-making and equity of access to testing.
3.3 Explains the material risks and benefits, and rationale behind management options in a way the patient/carer understands, so that they can make an informed choice.	PGx can inform risk–benefit discussions by offering insight into likely treatment responses. However, prescribers should be aware that results are not always definitive. Use your clinical judgement and interpret genetic data alongside other patient factors. Its permanence also underscores the need for careful, long-term consideration.

3.4 Assesses adherence in a non-judgemental way; understands the reasons for non-adherence and how best to support the patient/carer	*These original supporting statements do not require additional PGx-specific action beyond standard prescribing practice.*
3.5 Builds a relationship which encourages appropriate prescribing and not the expectation that a prescription will be supplied	
3.6 Explores the patient's/carer's understanding of a consultation and aims for a satisfactory outcome for the patient/carer and prescriber.	

COMPETENCY FOUR: **PRESCRIBE**	
ORIGINAL SUPPORTING STATEMENT	**PGX REFLECTION ON EXISTING SUPPORTING STATEMENT**
4.1 Prescribes a medicine or device with up-to-date awareness of its actions, indications, dose, contraindications, interactions, cautions and ADRs.	You should understand PGx variability as part of your knowledge of medicines. Genetic differences can affect treatment response, and summaries of product characteristics (SmPCs) increasingly include genomic guidance to support personalised prescribing, especially considering factors like ethnicity and comorbidities.
4.2 Understands the potential for adverse effects and takes steps to recognise, and manage them, whilst minimising risk	You should understand how PGx testing can help predict the risk of adverse drug reactions and its limitations when interpreting results. You should understand how in some cases, ancestry and family history may influence susceptibility and support safer, personalised prescribing.
4.3 Understands and uses relevant national, regional and local frameworks for the use of medicines	You should be aware of, and adhere to, national, regional and local prescribing frameworks within your specialty that incorporate PGx testing or recommendations.
4.4 Prescribes generic medicines where practical and safe for the patient and knows when medicines should be prescribed by branded product.	*This original supporting statement does not require additional PGx-specific action beyond standard prescribing practice.*
4.5 Accurately completes and routinely checks calculations relevant to prescribing and practical dosing.	You should apply PGx result-informed guidance to support safe and effective decision-making. This requires not only familiarity with relevant PGx resources but also the use of clinical judgement to interpret results within the holistic context of the patient case.
4.6 Prescribes appropriate quantities and at appropriate intervals necessary to reduce the risk of unnecessary waste	*These original supporting statements do not require additional PGx-specific action beyond standard prescribing practice.*
4.7 Recognises potential misuse of medicines; minimises risk and manages using appropriate processes	
4.8 Uses up-to-date information about the availability, pack sizes, storage conditions, excipients and costs of prescribed medicines.	
4.9 Electronically generates and/or writes legible, unambiguous and complete prescriptions which meet legal requirements.	
4.10 Effectively uses the systems necessary to prescribe medicines	
4.11 Prescribes unlicensed and off-label medicines where legally permitted, and unlicensed medicines only if satisfied that an alternative licensed medicine would not meet the patient's clinical needs.	

4.12 Follows appropriate safeguards if prescribing medicines that are unlicensed, off-label, or outside standard practice.	You should understand that in certain cases, PGx testing may support off-label or non-standard treatments where guidelines are limited. You must document decisions clearly, assess risks and benefits and prioritise safety using the best available evidence.
4.13 Documents accurate, legible and contemporaneous clinical records	Where available, you should make effective use of electronic health records to securely record PGx results in line with local and national standards to enable development and use of interoperable clinical decision support tools and alerts within digital systems.
4.14 Effectively and securely communicates information to other healthcare professionals involved in the patient's care, when sharing or transferring care and prescribing responsibilities, within and across all care settings	You should understand that genetic results remain constant (although interpretation may evolve) and could have relevance to other HCPs involved in the patient's current or future care.

COMPETENCY FIVE: **PROVIDE INFORMATION**

ORIGINAL SUPPORTING STATEMENT	PGX REFLECTION ON EXISTING SUPPORTING STATEMENT
5.1 Assesses health literacy of the patient/carer and adapts appropriately to provide clear, understandable and accessible information	*This original supporting statement does not require additional PGx-specific action beyond standard prescribing practice.*
5.2 Checks the patient's/carer's understanding of the discussions had, actions needed and their commitment to the management plan	You should recognise that PGx results can impact treatment plans, in some cases delaying or adjusting treatment choices. You should ensure patients understand that unlike many other clinical tests, genetic results remain constant. Interpretation of genetic results may evolve and may need revisiting over time.
5.3 Guides the patient/carer on how to identify reliable sources of information about their condition, medicines and treatment.	*These original supporting statements do not require additional PGx-specific action beyond standard prescribing practice.*
5.4 Ensures the patient/carer knows what to do if there are any concerns about the management of their condition, if the condition deteriorates or if there is no improvement in a specific timeframe	
5.5 Encourages and supports the patient/carer to take responsibility for their medicines and self-manage their condition	

COMPETENCY SIX: **MONITOR AND REVIEW**

ORIGINAL SUPPORTING STATEMENT	PGX REFLECTION ON EXISTING SUPPORTING STATEMENT
6.1 Establishes and maintains a plan for reviewing the patient's treatment	You should review treatment plans when new medicines (which could be a drug that interacts, such as enzyme inhibitors or inducers) are added, as these may affect interpretation of PGx findings. Drug–drug–gene interactions should be considered and adjusted, or more frequent review periods may be needed to maintain safe, effective therapy and appropriate clinical context over time.
6.2 Establishes and maintains a plan to monitor the effectiveness of treatment and potential unwanted effects	*These original supporting statements do not require additional PGx-specific action beyond standard prescribing practice.*
6.3 Adapts the management plan in response to on-going monitoring and review of the patient's condition and preferences.	
6.4 Recognises and reports suspected adverse events to medicines and medical devices using appropriate reporting systems	*You should be aware of pharmacovigilance initiatives and the need to include PGx test information if available, e.g., the Yellow Card biobank, which supports reporting adverse drug reactions with genetic links and helps build evidence for safer, personalised prescribing.*

Domain two Prescribing governance

PGx is an evolving field, and this resource has been developed in the context of practice today, although this position may change in the future. Traditional reference resources used for prescribing practices, such as the BNF or SmPCs, are continually updated with PGx content to support prescribers.

Within domain two, there are common themes summarised as:

- **Commissioning and regulation around PGx testing** – Each UK nation has a different approach to the commissioning and regulation of PGx testing, but all approaches include evaluating the clinical utility and cost-effectiveness of a testing approach to ensure equity of access to testing within a nation.[17,18] Development of a UK regulatory framework to support PGx testing is underway[19]
- **Digital capability to utilise PGx data** – Each UK nation is at a different stage of implementing the digital infrastructure required to integrate PGx data into routine clinical care
- **Consent and data reuse** – Verbal consent is often considered acceptable for PGx testing due to the direct impact of the test on medicines use, provided it is documented. Within research settings, consent is mandatory, especially for data reuse. Both consent and data-reuse strategies should align with local governance processes
- **Direct-to-consumer (DTC) testing** – Involves PGx tests sold directly to individuals without clinician involvement. In 2025, the British Society for Genetic Medicine (BSGM) and partners issued a statement advising that DTC testing approaches could be referred to in practice but should complement, not replace clinical services and highlighted its limitations and risks[20]
- **Sharing of PGx test results** – PGx test results may be relevant to prescribing and follow-up across different organisations and sectors of healthcare. Clear governance processes and defined communication responsibilities are needed to support appropriate information sharing between healthcare settings, recognising that digital systems and data transfer capabilities may vary within and between organisations
- **PGx-related prescribing risks** – May arise from misinterpretation of results, inappropriate reliance on genetic information in isolation, or failure to act on available findings. Awareness of this risk is required, and mitigation of this risk would involve ensuring that PGx information is interpreted alongside relevant clinical factors and applied using appropriate professional judgement and local clinical pathways
- **Accessing test results** – Prescribing decisions should consider the potential value of the PGx test results where available and how limited access to results should not unnecessarily delay treatment when timely care is clinically indicated, particularly in community, urgent or emergency care settings.

COMPETENCY SEVEN: **PRESCRIBE SAFELY**	
ORIGINAL SUPPORTING STATEMENT	**PGX REFLECTION ON EXISTING SUPPORTING STATEMENT**
7.1 Prescribes within own scope of practice and recognises the limits of own knowledge and skill.	*These original supporting statements do not require additional PGx-specific action beyond standard prescribing practice.*
7.2 Knows about common types and causes of medication and prescribing errors and knows how to minimise their risk.	
7.3 Identifies and minimises potential risks associated with prescribing via remote methods	
7.4 Recognises when safe prescribing processes are not in place and acts to minimise risks	
7.5 Keeps up to date with emerging safety concerns related to prescribing	
7.6 Reports near misses and critical incidents, as well as medication and prescribing errors using appropriate reporting systems, whilst regularly reviewing practice to prevent recurrence.	

COMPETENCY EIGHT: **PRESCRIBE PROFESSIONALLY**	
ORIGINAL SUPPORTING STATEMENT	**PGX REFLECTION ON EXISTING SUPPORTING STATEMENT**
8.1 Ensures confidence and competence to prescribe are maintained	*This original supporting statement does not require additional PGx-specific action beyond standard prescribing practice.*
8.2 Accepts personal responsibility and accountability for prescribing and clinical decisions, and understands the legal and ethical implications	You must understand the legal and ethical duties around PGx testing, especially regarding clinical and analytic validity of testing, consent and data reuse. In certain situations, reusing results without renewed consent could risk undermining accountability, governance and patient autonomy. Transparent decision making and alignment with evolving ethical standards are essential when applying genomic data in new clinical contexts.
8.3 Knows and works within legal and regulatory frameworks affecting prescribing practice.	You should be aware that the regulatory framework supporting PGx testing is currently under development. While integration into clinical practice is progressing, comprehensive regulatory structures are still being established.
8.4 Makes prescribing decisions based on the needs of patients and not the prescriber's personal views.	*This original supporting statement does not require additional PGx-specific action beyond standard prescribing practice.*
8.5 Recognises and responds to factors that might influence prescribing	You should consider factors influencing prescribing, including non-NHS and DTC testing. People may seek treatment changes based on such results, requiring careful interpretation and clinical judgement to make an informed decision. You should understand and be satisfied with the analytic and clinical validity of tests, support access to validated pathways and stay informed of evolving regulations.
8.6 Works within the NHS, organisational, regulatory and other codes of conduct when interacting with the pharmaceutical industry	*This original supporting statement does not require additional PGx-specific action beyond standard prescribing practice.*

COMPETENCY NINE: **IMPROVING PRESCRIBING PRACTICE**	
ORIGINAL SUPPORTING STATEMENT	**PGX REFLECTION ON EXISTING SUPPORTING STATEMENT**
9.1 Improves by reflecting on own and others' prescribing practice, and by acting upon feedback and discussion	*This original supporting statement does not require additional PGx-specific action beyond standard prescribing practice.*
9.2 Acts upon inappropriate or unsafe prescribing practice using appropriate processes	
9.3 Understands and uses available tools to improve prescribing practice	
9.4 Takes responsibility for own learning and continuing professional development relevant to the prescribing role	
9.5 Makes use of networks for support and learning.	
9.6 Encourages and supports others with their prescribing practice and continuing professional development.	
9.7 Considers the impact of prescribing on sustainability, as well as methods of reducing the carbon footprint and environmental impact of any medicine	

COMPETENCY TEN: **PRESCRIBE AS PART OF A TEAM**	
ORIGINAL SUPPORTING STATEMENT	**PGX REFLECTION ON EXISTING SUPPORTING STATEMENT**
10.1 Works collaboratively as part of a multidisciplinary team to ensure that the transfer and continuity of care (within and across all care settings) is developed and not compromised.	*This original supporting statement does not require additional PGx-specific action beyond standard prescribing practice.*
10.2 Establishes relationships with other professionals based on understanding, trust and respect for each other's roles in relation to the patient's care.	
10.3 Agrees the appropriate level of support and supervision for their role as a prescriber.	
10.4 Provides support and advice to other prescribers or those involved in administration of medicines where appropriate.	

Glossary of terms and abbreviations[20,21]

Adverse drug reaction (ADR) – unintended harm experienced by a patient because of medication.

Analytic validity – how well a test accurately and reliably detects if a specific genetic variant is present or absent.

British National Formulary (BNF) – a resource to obtain key information to inform the prescribing, dispensing and administration of medicines.

Centre of Excellence in Regulatory Science and Innovation in Pharmacogenomics (CERSI PGx) – a UK regulatory network that brings together academia, industry, regulators and patients to accelerate the adoption of PGx in the UK.

Clinical governance – systems and processes in place to support safe and effective PGx prescribing.

Clinical utility – how well a test improves patient outcomes and informs clinical decision-making.

Clinical validity – how well variants predict drug response.

Commissioned test status – indicates whether a PGx test is funded or approved for routine use across a healthcare system.

Clinical Pharmacogenetics Implementation Consortium (CPIC®) – an international consortium of individual volunteers and a small, dedicated staff team who are interested in facilitating use of PGx tests for patient care by developing freely available, peer-reviewed, evidence-based, updatable and detailed gene/drug clinical practice guidelines.

Cultural competence – the ability to tailor PGx communication appropriately to meet the cultural, linguistic and social needs of the patient and community.

Data re-use – the secondary use of data for additional prescribing purposes beyond the original reasons intended when collected.

Direct-to-consumer (DTC) test – any genomic test that has been sought and paid for outside routine NHS care, whether purchased online or via a commercial provider.

Deoxyribonucleic acid (DNA) – the molecule that contains/encodes genetic information.

Dutch Pharmacogenetics Working Group (DPWG) – a European organisation that produces evidence-based PGx prescribing guidelines.

Drug–drug–gene interactions – when interactions occur between multiple drugs and gene variants which may affect drug activity.

Gene – a section of DNA that contains the biological instructions to produce a polypeptide chain, usually a specific protein or component of a protein.

Genetics – the study of genes and their impact on health.

Genetic variation – differences between the DNA sequences of individuals.

Genotype – the DNA sequence of an individual, which determines (along with environmental influences) the specific characteristics (phenotype) of that individual.

Genomics – the study of the whole genome (both genes and non-coding regions).

Genomic literacy – the level of knowledge and understanding the person has regarding genomics and its application.

Healthcare professionals (HCPs) – a registered professional who provides healthcare treatment and advice based on their formal training and experience related to their profession.

Health literacy – a persons' ability to understand and use health-related information to make decisions on their care.

Medicines and Healthcare products Regulatory Agency (MHRA) – UK Government agency responsible for regulating medicines, medical devices and blood components for transfusion.

Multi-disciplinary team (MDT) – a group of HCPs working collaboratively to support patient care.

Multi-gene panel testing – testing several PGx genes at once to inform prescribing decisions.

Network of excellence in PGx and medicines optimisation (NoE) [NHS England only] – a collaborative network supporting the adoption of PGx and medicines optimisation.

National Health Service of England (NHSE) – the executive body responsible for the NHS in England only.

Prevalence – a measure of the frequency of a condition in the population at a particular point in time.

Pharmacogenomics (PGx) – testing to obtain the genetic information within the wider genome, to tailor pharmaceutical treatment to an individual including identification of new drug targets in new drug development.

Pharmacovigilance – monitoring the safety of medicines and identifying adverse effects.

Phenotype – an individual's observable physical and biochemical characteristics directly influenced by the genotype (genetic factor) and/or environment. In humans, this is often the observed signs and symptoms of a condition.

Pre-emptive testing – genetic testing performed before a prescribing decision is needed to enable future use of results.

Point-of-care testing (POCT) – rapid, near-patient PGx testing performed at the point of clinical care.

Reactive testing – genetic testing performed in response to a specific prescribing or clinical decision.

Shared decision making – a collaborative process by which the prescriber makes healthcare decisions together.

Star alleles – a system of naming genetic variants to describe gene activity (e.g., *2, *3), used in PGx.

Summary of product characteristics (SmPC) – a regulatory document for a medicine that provides information on the safe and effective use of that medicine.

Turnaround time (TAT) – time taken from requesting the test to receiving the result.

Variant – any difference between the sequence of two individuals' genomes or a reference genome.

Variant frequency – how common a genetic variant is within or across populations.

Variants of uncertain significance (VUS) – genetic variants where the impact on drug response is currently unclear.

Yellow Card biobank – a UK initiative that explores the link between the reporting of adverse drug reactions with the patient's genetic data to improve patient safety (currently in study phase).

Appendix One – PGx testing case studies

The case study examples included in this resource support and link to the PGx principles covered in domains one and two of this document. Details about whether testing has been carried out, or how test results are used in practice have been intentionally excluded due to differences in the availability of commissioned testing across the UK and the potential for these arrangements and clinical guidance to evolve over time.

CASE STUDY 1. CLOPIDOGREL AND *CYP2C19* PGX TESTING (EMERGING PRACTICE)

A 65-year-old man experiences sudden left-sided weakness after an afternoon nap. He is admitted to the local A&E and is diagnosed with a suspected acute stroke and transferred to the acute stroke unit. Following examination, the prescriber intends to start treatment with clopidogrel in 14 days' time as per national stroke guidelines.[22]

THE PRESCRIBER

Identifies the need for CYP2C19 PGx testing before clopidogrel initiation,[23,24] to determine if the patient carries a variant which could impact their ability to metabolise clopidogrel effectively, and to guide optimal antiplatelet selection. Published evidence describes that approximately 30% of the UK population are believed to carry a CYP2C19 variant which will likely predict a lack of response to clopidogrel treatment[25]

- Assesses the patient's eligibility for PGx testing, ensuring patient understands its purpose, interpretation and limitations using validated resources to support clinical interpretation
- Establishes if there has been any prior PGx testing found in the patient's medical record or within their family history and/or questions the patient on whether they or any family member has had previous testing performed
- Engages with the patient and their relatives to explain the purpose, benefits and risks of the test before requesting PGx testing
- Considers local guidelines and clinical need for interim antiplatelet management in the absence of PGx results
- Refers to relevant resources when interpreting the test result to inform the treatment decision[24,26]
- Explains the genetic result and its implications for clopidogrel when making a shared decision about antiplatelet prescribing

- Explains the relevance of the genetic result for any other medications and explains that unlike other clinical tests, genetic results remain constant, although the interpretation of results may evolve and may need revisiting over time
- Prescribes an appropriate antiplatelet for the patient
- Documents the event and treatment decisions within medical records, shares the results within the GP discharge letter and ensures result is available within electronic records where the infrastructure is available
- Documents within the patient record that other drugs metabolised by the same enzyme (e.g., citalopram) may be affected if prescribed, informing current and future treatment choices
- Reviews treatment plans when new medicines (which could potentially interact, such as enzyme inhibitors or inducers) are added, as these may affect PGx findings. Drug–drug–gene interactions and adjusted review periods may be needed to maintain safe, effective therapy and retain appropriate clinical context over time.

COMPETENCIES SHOWN

1.2, 1.6, 1.9, 1.10, 1.11, 2.4, 2.7, 2.8, 3.1, 3.3, 4.1, 4.12, 4.14, 4.15, 5.2, 6.1, 8.2, 10.1, 10.2.

CASE STUDY 2. GENTAMICIN AND *MT-RNR1* PGX TESTING (EMERGING PRACTICE)

A baby is born by C-section at the local hospital maternity ward at 32 weeks' gestation weighing 5lbs 12oz. After three days, the baby starts to show clinical signs of poor feeding, lethargy and a spiking temperature. The baby has a suspected diagnosis of early-onset neonatal sepsis and is transferred to the neonatal intensive care unit. After a thorough examination, the prescriber decides to start empirical treatment with gentamicin in combination with another antibiotic aligned with trust guidance.

THE PRESCRIBER

- Identifies the need for a *MT-RNR1* POCT prior to prescribing the gentamicin as per reference sources,[27–29] as the presence of a *MT-RNR1* gene variant can increase the risk of aminoglycoside- (gentamicin) induced hearing loss
- Uses the result to inform the selection of antibiotic for the baby, within the window for effective antibiotic prescribing. A risk–benefit decision on prescribing should be made in the event of delayed or unavailable results
- Documents the result of PGx testing within the patient record
- Explains the purpose, benefits and limitations of the test and implications of the result to the baby's parents. Ensures they have appropriate understanding of the need for the test and familial implications, while keeping communication appropriate and patient centred
- Engages the baby's parents in a discussion about the potential family history of hearing loss and how it could affect the future prescribing of aminoglycosides
- Discusses the need for the patients' parents to share information with family members if potentially relevant for them guided by clinical judgement
- Knows how to contact specialist genetics services, if appropriate

- Documents the event thoroughly within medical records and ensures the PGx test result is included in the discharge letter to the GP, with a recommendation to record it in the primary care system, ensuring continuity of care across settings and multidisciplinary working.

COMPETENCIES SHOWN

1.2, 1.6, 1.10, 1.11, 1.14, 2.3, 2.4, 2.5, 2.6, 2.10, 3.1, 4.1, 4.2, 4.13, 4.14, 10.1.

CASE STUDY 3. **CODEINE AND PGX TESTING (ILLUSTRATIVE EXAMPLE)**

A 29-year-old, 34-week pregnant patient visits the GP practice with severe lower back pain. Despite taking paracetamol regularly, she is still suffering pain which is affecting her daily life. The local prescribing guidelines recommend codeine in this scenario. The prescriber is aware that *CYP2D6* metaboliser status can impact codeine treatment response and checks to see if they can access testing.[30–33] PGx testing is not available locally for this gene, but the prescriber takes a comprehensive medical history from the patient, including allergies and personal and family history of adverse drug reactions before proceeding with the prescription.

After 24 hours after starting codeine treatment, the patient develops excessive sedation, nausea and respiratory depression. She is admitted to the maternity unit at her local hospital and receives foetal monitoring which shows reduced movements potentially due to increased exposure of codeine. The codeine treatment is stopped immediately, and she is closely monitored for any changes in her or the baby's signs or symptoms. The patient makes a full recovery and returns to the GP practice following the birth of her baby for further back pain control. She also asks the prescriber's opinion of direct-to-consumer testing (as she has read about this online) and believes her DNA may have caused this reaction to occur.

THE PRESCRIBER

- Refers to guidance/resources around PGx testing and the prescribing of codeine treatment
- Is aware that certain health conditions, symptoms or adverse drug reactions may be linked to specific PGx variants in the patient
- Reviews the patient including hospital discharge letters to ensure knowledge of the patient's management to date including information about her possible ADRs to codeine and any testing done in hospital
- Checks that opioid risk has been recorded in the patient's (electronic) health record
- Discusses an alternative option to manage the pain with the patient, including both pharmacological and non-pharmacological options in the absence of PGx testing
- Advises the patient to avoid the use of codeine in the future and to inform other HCPs
- Submits a Yellow Card report to the MHRA for further exploration of this ADR
- Discusses considerations of DTC testing with the patient, including benefits and limitations of testing and access to treatment pathways.

COMPETENCIES SHOWN

1.6, 1.8, 1.9, 1.10, 2.1, 2.4, 2.5, 2.6, 3.3, 4.1, 4.2, 4.3, 4.10, 6.4, 8.5.

CASE STUDY 4. **CAPECITABINE AND *DPYD* PGX TESTING (ESTABLISHED UK CLINICAL PRACTICE)**

A 62-year-old woman has been referred to the cancer centre for adjuvant chemotherapy following surgery for stage III colorectal cancer. After assessment, the prescriber plans to start capecitabine chemotherapy as a first line treatment. The prescriber is aware of the MHRA safety alert,[34] recommending the use of *DPYD* gene tests to predict the likelihood of the patient experiencing adverse drug reactions from fluoropyrimidine drugs (e.g., capecitabine, 5-FU).[35,36]

THE PRESCRIBER

- Accesses the patient record to review whether *DPYD* genetic testing has already been requested and interprets any relevant history and results
- Decides that the patient will need a *DPYD* genetic test before they commence the capecitabine prescription
- Explains the purpose, benefits and limitations of the test to the patient in the context of their chemotherapy treatment, including possible impact on treatment plan and start date, considering their level of genomics understanding
- Requests the *DPYD* test along with other relevant investigations to inform treatment options
- Explains to a new staff member why the patient needs to come back to clinic next week and is not being started on the capecitabine treatment today
- Interprets the *DPYD* result and discusses this with other members of the multi-disciplinary team who have more experience in using PGx reports, before making a decision about prescribing[37]
- Ensures the *DPYD* result has been recorded in the patient's (electronic) health record
- Educates the patient on adverse effects that they may experience regardless of the outcome of the test result and establishes a plan for monitoring and patient reporting of their condition and potential unwanted effects. The prescriber should be aware that the results are not always definitive and clinical judgement is essential, as genetic data should be interpreted alongside other patient factors.

COMPETENCIES SHOWN

1.9, 1.10, 1.11, 2.3, 2.4, 2.5, 2.6, 3.1, 3.3, 5.2, 6.1, 7.1, 8.2, 8.3, 9.1, 9.2, 9.3, 9.4, 9.5, 10.3, 10.4.

CASE STUDY 5. **CARBAMAZEPINE AND PGX TESTING (EMERGING PRACTICE)**

A 42-year-old man, originally from China, now living in the UK, visits the dentist experiencing sudden, electric-shock-like pain in the right side of his face consistent with trigeminal neuralgia. After initial assessment, the prescriber considers carbamazepine as an effective first line treatment. But while referring to reference sources,[38,39] the prescriber notices there is a caution listed regarding the increased risk of Steven Johnsons Syndrome (SJS) in patients of Han Chinese or Thai descent, due to the increased likelihood of carrying the *HLA-B*15:02* allele. Patients who carry the *HLA-B*31:01* allele are also at increased risk of experiencing hypersensitivity reactions with carbamazepine.[38,39]

THE PRESCRIBER

- Takes and documents the patient history including ethnicity, ancestry and relevant family history. Explains the relevance of this to the use of the medicine, and possibility of accessing PGx testing, in a culturally competent way while considering the patient's level of genomics understanding and avoiding assumptions based on ethnicity alone
- Reviews all available PGx test results (NHS and non-NHS (with care of test quality assurance)), including relevant family history of testing
- Explores availability of testing within local services, prior to prescribing carbamazepine and the patient's eligibility within resources (e.g., NHSE NTD)
- Discusses treatment options with the patient, including pharmacological and/or non-pharmacological approaches, based on the patient's genetic information available
- Discusses with the patient the risk of starting the medicine without PGx testing due to the patient's ethnicity and potential ancestry and the severity of the adverse effects that could be experienced as a result
- Prescribes an appropriate analgesic following shared decision making with the patient.
- Documents aspects of the decision making within the patients' health record.

COMPETENCIES SHOWN

1.6, 1.9, 1.10, 2.1, 2.3, 2.4, 2.5, 2.6, 3.1, 3.3, 4.1, 4.2, 4.13, 4.15, 8.2.

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Supporting resources

Useful resources and links to support development of PGx competence. This list is not exhaustive and other relevant resources are available.

MEDICATION SAFETY, GOVERNANCE AND IMPLEMENTATION OF PGX

Medicines safety and pharmacovigilance

- **MHRA guidance on PGx**
  www.gov.uk/mhra
  UK regulatory information, safety updates and guidance on genomics and medicine
- **MHRA Yellow Card biobank**
  yellowcard.mhra.gov.uk/biobank
  A developing collaboration between the MHRA and Genomics England to explore links between adverse drug reactions and genomic data.

Regulation, licensing and commissioning of testing

- **Electronic Medicines Compendium**
  www.medicines.org.uk/emc
  Provides access to SmPCs which can include pharmacogenomic-related information
- **NHS England National Test Directory**
  www.england.nhs.uk/publication/national-genomic-test-directories
  A directory of the genomic tests commissioned in NHS England and due to a specialist service specification agreement, NHS Wales also aligns its commissioning to this directory
- **NHS Scotland Genomic Test Directory**
  www.genomics.nhs.scot/test-directories
  A directory of the genomic tests commissioned in NHS Scotland.

Professional and policy position statements

- **British Pharmacological Society/Royal College of Physicians**
  Personalise Prescribing document: Using pharmacogenomics to improve patient outcomes
  www.bps.ac.uk/fileadmin/uploads/bps/Reports/Personalised-prescribing_main_report_2022.pdf
- **British Society for Genetic Medicine**
  Direct to Consumer Genomic testing Position statement
  bsgm.org.uk/media/12844/direct-to-consumer-genomic-testing-joint-position-statement-2025.pdf
- **Royal College of General Practitioners**
  Genomics CYP2C19 Position statement
  www.rcgp.org.uk/representing-you/policy-areas/genomic-position-statement
- **Royal Pharmaceutical Society**
  The Role of Pharmacy in Pharmacogenomics (Position Statement)
  www.rpharms.com/development/pharmacogenomics/pgx-position-statement
  Pharmacy Professionals and Genomic Medicine (Position statement)
  www.rpharms.com/development/pharmacogenomics/genomic-statement.

CLINICAL GUIDANCE RESOURCES

- **CERSI-PGx guidelines**
  Clopidogrel CYP2C19 testing
  cersi-pgx.org/new-cersi-pgx-clinical-guidelines-universal-cyp2c19-genotyping-for-clopidogrel-prescribing
  UK guidelines to help prescribers integrate PGx testing into standard care
- **Clinical Pharmacogenetics Implementation Consortium (CPIC)**
  cpicpgx.org
  International (USA led) peer-reviewed, evidence-based guidelines for implementing PGx testing in clinical practice (N.B. CPIC guidance will be incorporated into the ClinPGx resource in March 2026)

- **ClinPGx webpage**
  www.clinpgx.org
  A comprehensive (USA-led) clinical PGx resource created to support and expand PGx knowledge, implementation and education
- **Dutch Pharmacogenetics Working Group (DPWG)**
  www.knmp.nl
  Internationally recognised PGx dosing guidance based on genotype.

PGX AND GENOMIC EDUCATIONAL RESOURCES AVAILABLE TO ALL PRESCRIBERS

- **CERSI-PGx education resource**
  portal.bpsassessment.com/cersi-pgx-elearning-portal
  Provides targeted, bite-sized learning in a modern, user-friendly digital environment supporting the real-world implementation of PGx in clinical practice
- **FutureLearn education packages**
  www.futurelearn.com
  A collection of genomic and personalised education virtual courses suitable for prescribers
- **GeNotes resource**
  www.genomicseducation.hee.nhs.uk/about-us/genotes-genomic-notes-for-clinicians
  A 'just in time' educational resource for HCPs, designed to be used in a clinical setting
- **NHSE Genomic Education Programme (GEP)**
  www.genomicseducation.hee.nhs.uk
  Guidance and educational resources on genomic medicine aspects
- **NHSE Specialist Pharmacy Service (SPS)**
  www.sps.nhs.uk/articles/pharmacogenomics-resources-to-support-answering-questions
  A resource hub to support HCPs in answering questions about PGx
- **NHS Scotland**
  www.hcstraining.nhs.scot/cpd-resources/genomics-cpd-and-education-resources
  An NHS Scotland webpage to support Scottish HCPs (access to NHS Scotland employees)
- **NHS Wales Health Education and Improvement Wales (HEIW)**
  heiw.nhs.wales/our-work/genomics
  An NHS Wales webpage to support HCPs with introductory module resources.

ORGANISATIONS

This list is not exhaustive and some include restrictions related to certain professions or geographical areas.

- **Centre of Pharmacy Postgraduate Education (CPPE)**
  www.cppe.ac.uk
- **Royal Pharmaceutical Society (RPS)**
  www.rpharms.com/development/pharmacogenomics
- **Royal College of General Practitioners (RCGP)**
  www.rcgp.org.uk/your-career/gp-extended-roles/clinical-genetics-genomics-resources
- **Royal College of Physicians (RCP)**
  www.rcp.ac.uk/improving-care/resources/pharmacogenomics-in-the-nhs-a-users-guide
- **NHS Scotland**
  www.hcstraining.nhs.scot/cpd-resources/genomics-cpd-and-education-resources
- **UK Clinical Pharmacy Association (UKCPA)**
  ukclinicalpharmacy.org.

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