



Community Pharmacy Roadmap Program Development Template

Program/Service	Pharmacogenomics
Quadrant	C – In-pharmacy Health Services and Programs
1. Program/Service Description	
a) Background	<p>Pharmacogenomics is the study of how an individual’s genetic makeup affects the body’s response to particular medicines. Pharmacogenomics combines traditional pharmaceutical sciences, such as biochemistry, with annotated knowledge of genes, proteins and single nucleotide polymorphisms.¹ The term is often used interchangeably with pharmacogenetics, although there are subtle differences. Pharmacogenomics provides an opportunity to individualise drug therapy to maximise efficacy and minimise toxicity, based on patients’ genetic data.</p> <p>Individualised drug therapy is an important aspect of contemporary pharmacy practice.² Inter-patient variability in response to a drug is common, with 35% of patients using beta-blockers, 30% with schizophrenia treated with antipsychotics and 33% on interferon-beta for multiple sclerosis not responding satisfactorily³. Even when a drug is effective, the optimal dose varies between individuals, for example the required daily doses of warfarin and propranolol vary 20-fold and 40-fold respectively.⁴</p> <p>Pharmacogenomics has so far not been widely adopted, but has the potential to substantially change health practice and the expectations of consumers, health professionals and governments. Conditions where specific genetic differences are detectable and drugs where the effects can vary significantly according to genetic profiles, have potential for pharmacogenomic screening programs. Examples include⁵:</p> <ul style="list-style-type: none"> • statin-induced myopathy • carbohydrate sensitivity • lipid sensitivity • caffeine metabolism • folate metabolism • warfarin • omeprazole • tricyclic antidepressants • codeine <p>Pharmacogenomics is already being used to assist in the treatment of some diseases such as breast cancer, where a person’s genetic makeup informs the prescribing of the drug trastuzumab (Herceptin®).⁶</p>
b) Brief Description	<p>Community pharmacists have the capacity to raise the awareness of pharmacogenomics with consumers and other health professionals. Community pharmacies are also ideally placed to introduce a point-of-care testing service for specific medicines and conditions for which testing exists, and to coordinate information sharing back to patients and between relevant health care providers and the consumer to facilitate the most effective use and dosing of</p>

¹ Human Genome Project Information; September 2008.

http://www.ornl.gov/sci/techresources/Human_Genome/medicine/pharma.shtml

² Toy AC, Anderson BA, McKinnon RA, Gilbert AL. Possible role for clinical pharmacist in identifying pharmacogenomic interventions. J Pharm Pract Res 2006, 36: 35-9

³ Akhtar S. Pharmacogenomics: are pharmacists ready for genotyped prescribing? Pharm J 2002; 268: 296-9

⁴ Destenaves B, Thomas F. New advances in pharmacogenomics. Curr Opin Chem Biol2000: 4, 440-4

⁵ The Royal Society Study on Pharmacogenetics – Response by the RPSGB; Nov 2008

⁶ Personalised medicine and genetics; www.nhmrc.gov.au

	relevant medicines. An in-pharmacy pharmacogenomic service would involve the provision of advice and counselling, taking samples, conducting tests, interpreting results, collaborating with prescribers to develop prescribing plans and then monitoring and reviewing treatment with feedback to the prescriber. Information gathered could be recorded on person-controlled electronic health records.
c) Alignment with Government Policy	<p>Recommendations from the National Health and Hospitals Reform Commission (NHMRC) and Primary Health Care Strategy promote team care support for patients with chronic conditions. Utilising the expertise and accessibility of community pharmacists as part of a patient's health support team is consistent with these recommendations.</p> <p>Supporting prescribers and consumers in using medicines that are safe and effective is also consistent with the Australian Government's National Medicines Policy⁷, incorporating the National Strategy for the Quality Use of Medicines.</p>
d) Expected Outcomes for Government and Community Pharmacy	<p>From a Government perspective, pharmacogenomics brings a number of benefits. Instead of the standard 'trial-and-error' method of prescribing, a patient's genetic profile could inform whether a particular medicine will be effective and whether they are likely to suffer an adverse reaction. Improving drug efficacy, reducing the likelihood of adverse effects and minimising recovery time, can have a significant impact on health expenditure, including the Pharmaceutical Benefits Scheme (PBS).</p> <p>From a pharmacy perspective, there will be a greater recognition of the role of community pharmacists as a member of the primary health care team. Community pharmacy will have the opportunity to develop a viable business involving service provision as an adjunct to product supply and will have a greater capacity to effectively utilise the increased number of new pharmacy graduates in a manner that benefits both pharmacy practice and the community. Pharmacy graduates will continue to have a positive outlook for community pharmacy as a career, supporting the viability of pharmacy education providers.</p>
e) Consumer Benefits	Consumers would benefit from using medicines that are individually tailored, leading to improved efficacy and fewer adverse effects. They will potentially have access to more effective and more targeted drug therapy. Knowing their genetic code will allow consumers to make adequate lifestyle and environmental adjustments at an early age so as to avoid or lessen the severity of a genetic disease. Advance knowledge of a particular disease will also allow careful monitoring, facilitating drug intervention at a more appropriate time.
f) Who Performs the Service?	Pharmacists, with pharmacy assistant support.
g) Collaboration with Other Health Care Professionals	<p><i>Will service delivery require any formal collaboration with any other health care professionals?</i></p> <p>Yes.</p> <p>Depending on the level of service intervention, the pharmacist could work collaboratively with prescribers, providing recommendations and feedback on particular prescribing plans.</p>
2. Implementation and Enablers	
a) Stakeholder Consultation	<p><i>Representative bodies from the following areas will need to be consulted in order to fully develop and implement a program:</i></p> <ul style="list-style-type: none"> • Consumer organisations • Disease management organisations • Funders • Government and regulatory bodies • GP and prescriber organisations • Pathology organisations • Pharmacy organisations

⁷ <http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1>

	<ul style="list-style-type: none"> • Pharmacy software vendors • Product manufacturers • Professional insurers • Relevant allied health professional bodies • Privacy Commissioner
b) IT Requirements	<p><i>Is pharmacy software required to deliver this program?</i> Yes. Pharmacy software should have an integrated recording system for service consultation. With the development of e-Health records, there is the opportunity for relevant information to be recorded for access by other health professionals as required. Documentation and claiming software needs to be available for programs that support subsidised services and it is essential that systems are streamlined for ease of use and to maximise pharmacy workflow. There is also the opportunity for de-identified information to feed into population-based drug analyses.</p>
c) Infrastructure and Staffing	<p><i>Is a private consultation area required to deliver this program?</i> To be determined. Any requirement for a consultation area or additional equipment will be determined by the level of intervention required as part of the professional service.</p> <p><i>Is the program within the pharmacist's/pharmacy assistant's normal scope of practice?</i> Yes – noting that some additional training would be required/beneficial.</p> <p><i>Will an additional pharmacist likely to be needed?</i> In developing professional services that require an extended pharmacist consultation, consideration needs to be given to staffing resources. There may be a need for another pharmacist to manage other professional activities within the pharmacy at the time of consultation, such as dispensing or the supply of Pharmacist Only Medicines.</p>
d) Training	<p><i>What additional formal training is likely?</i> Undergraduate pharmacists should be provided with a general understanding of pharmacogenomics and its practice utilisation. An understanding of privacy issues is particularly important for this service. This would be complemented by ongoing Continuing Professional Development (CPD) training for registered pharmacists to ensure services remain aligned with current clinical guidelines. Training for pharmacists and pharmacy assistants should include on-line training where possible to maximise participation.</p> <p><i>Does any suitable training exist?</i> No.</p>
e) Supporting Standards, Procedures and Templates/ Checklists	<p><i>Will a QCPP standard be required?</i> Yes. Adherence to professional protocols set out in an auditable standard would ensure the public receives a standardised, quality-assured professional support service. Generic standards for professional support services are available as part of QCPP 2nd edition. As services are developed, the need for supporting templates and procedures will be assessed.</p> <p><i>Will professional guidelines and/or standards for pharmacists be required?</i> Yes.</p> <p><i>Are there any other national guidelines that need to be taken into account in developing the program to ensure consistency with best practice?</i> As pharmacogenomics develops, there are likely to be relevant national guidelines to consider. Currently, the NHMRC⁸ has some guidelines that have some relevance, such as Guidelines for Genetic registers and Associated Genetic Material 1999.</p>

⁸ www.nhmrc.gov.au

f) Legislation/ Regulation Implications	It will be necessary to ensure that all elements comply with relevant legislation.
3. Funding	
Funding Options	<p>Possible funding options include:</p> <ul style="list-style-type: none"> • Alternative Commonwealth Program (e.g. Preventative Health) • User-pays (requires review of GST implications) • Health Insurers <p><i>Has any funding for this program been secured?</i> No.</p>
4. Timelines	
Timelines	<input type="checkbox"/> Established community pharmacy practice <input checked="" type="checkbox"/> Immediate to short-term implementation (< 30 June 2015) <input type="checkbox"/> Medium-term implementation (1 July 2015 to 30 June 2020) <input type="checkbox"/> Longer-term implementation (> 1 July 2020)