

# Stage 3 of the review for medicines used in the treatment of type 2 diabetes

*Submission by the Pharmaceutical Society of Australia*

JUL  
2013

## Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission in relation to stage 3 of the Australian Government post-market review of products used in the management of diabetes. This stage relates to a review of medicines used in the treatment of type 2 diabetes mellitus (T2DM).

The clauses in the terms of reference relevant to this stage of the review are:<sup>1</sup>

- describe the utilisation and patterns of treatment of PBS listed drugs for T2DM, and compare these with PBS restrictions;
- consider if the utilisation of PBS listed drugs in current clinical practice represents expected cost effective use;
- consolidate the clinical trial evidence used to support PBS listings of diabetes medicines listed since 2002; and
- collate and evaluate any additional clinical studies or meta-analyses for drugs currently PBS listed for T2DM that the Pharmaceutical Benefits Advisory Committee (PBAC) has not seen and that would inform their consideration.

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<sup>1</sup> Australian Government Department of Health and Ageing. Post-market review of products used in the management of diabetes. Information available at: [www.pbs.gov.au/info/reviews/diabetes](http://www.pbs.gov.au/info/reviews/diabetes)

## Recommendations

PSA provides the following recommendations to this review:

- 1. The outcomes from the three stages of the diabetes review should be considered in a holistic manner and any synergies identified where possible.*
- 2. Under the leadership and guidance of the National Health and Medical Research Council, nationally accepted clinical guidelines for type 2 diabetes mellitus should be reviewed and updated immediately, and in future, according to a more frequent review cycle.*
- 3. Regular dissemination of information on updated clinical guidelines and reinforcement of key best practice messages with health practitioners should be implemented. Information on unusual patterns and unexpected trends in PBS medicine use could also be a trigger for opportunities to reinforce clinical best practice.*
- 4. Any conditions or restrictions that might be applied to PBS listings of medicines should be consistent with clinical best practice.*
- 5. Where PBS listings or restrictions do not fully reflect clinical best practice, clinicians, prescribers and pharmacists should be supported with clear and comprehensive information on the decisions and the rationale, including in a form that can be provided to and understood by consumers.*
- 6. Mechanisms to fund pharmacist-delivered medication management services which have been shown to promote the quality use of medicines, deliver benefits to the consumer and impact positively on the health care system, for consumers who are not eligible under the arrangements of the Fifth Community Pharmacy Agreement, should be explored.*
- 7. Arrangements to fund pharmacist-delivered quality use of medicines services which meet the particular needs of Indigenous Australians in a timely manner should be considered.*
- 8. Ways to enhance more appropriate and cost effective use of PBS medicines should be canvassed. For example, the inclusion of an annual Home Medicines Review in a consumer's diabetes care plan could be a requirement for eligibility for continued subsidisation of an expensive PBS medicine.*

## Holistic consideration of review outcomes

PSA notes that the four clauses of the terms of reference relevant to this review<sup>2</sup> refers or relates essentially to medicines which are currently listed on the PBS. We also note the concerns of the Drug Utilisation Sub Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee on: safety aspects of some new medicines; the evolution in complexity of PBS restrictions; growth in the proportion of use of medicines outside the PBS restrictions; and that PBS restrictions do not align with recent clinical guidelines.<sup>3</sup>

We note that when DUSC undertakes an analysis of PBS utilisation data, sponsors are notified and are provided with a copy of the report and an opportunity to comment.<sup>4</sup> As a non-sponsor stakeholder, PSA does not have access to the reports provided to sponsors. We acknowledge the expertise of DUSC but would highlight that information on patterns or trends of PBS medicine use (particularly if they are unusual or unexpected) can be useful for educational purposes and in providing information to health professionals in the context of clinical best practice. PSA would have a role in communicating such information and messages to pharmacists.

With regards to the broader review PSA has some concerns that, while it has been conducted in three stages, there does not appear to be any clear process for the outcomes from all stages to be considered in a holistic manner. While the subject matters of each stage are quite specific, we would suggest that comparing and consolidating the outcomes and identifying synergies will be important.

## Primary health care role of pharmacists

Diabetes mellitus is one of the most common non-communicable diseases globally and is the fourth or fifth leading cause of death in most high income countries.<sup>5</sup> The most common form is T2DM which accounts for a high majority of all cases.

The impact of T2DM on individuals is well established and is associated with reduced life expectancy, significant morbidity and therefore reduced quality of life. Apart from premature death, T2DM results in irreversible long term complications including myocardial infarction, stroke, retinopathy and blindness, renal disease requiring dialysis or transplantation, neuropathy, foot ulcer, amputation and erectile dysfunction.

The complexity and ongoing nature of the disease means that consideration is required of many aspects of health and coordination of appropriate health services. While general practitioners (GPs) are the central point of contact for people with diabetes, a multidisciplinary approach to care is essential in order to achieve the best possible health outcomes for the consumer.

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<sup>2</sup> Australian Government Department of Health and Ageing, op. cit.

<sup>3</sup> Drug Utilisation Sub Committee outcome statements of 7-8 June 2012, 4-5 October 2012 and 7-8 February 2013. Available at: [www.pbs.gov.au/info/industry/listing/elements/dusc-meetings/dos](http://www.pbs.gov.au/info/industry/listing/elements/dusc-meetings/dos)

<sup>4</sup> Drug Utilisation Sub Committee outcome statements of 7-8 February 2013. Available at: [www.pbs.gov.au/info/industry/listing/elements/dusc-meetings/dos](http://www.pbs.gov.au/info/industry/listing/elements/dusc-meetings/dos)

<sup>5</sup> International Diabetes Federation, [www.idf.org](http://www.idf.org)

Pharmacists have a strong primary health care role with high accessibility and regular contacts with health consumers. This means they are well placed to provide information and support to people with diabetes at all stages of the disease including, for example:

- the provision of health promotion activities to people who have yet to be diagnosed (including recognition of symptoms which may suggest the onset of diabetes);
- education and support for people in the stages immediately after initial diagnosis;
- supporting medication management;
- monitoring their risk factors (e.g. taking blood pressure measurements) and health status; and
- assisting lifestyle decisions to minimise progression of the disease and to reduce the incidence of complications.

Many community pharmacies are also Access Points for the National Diabetes Services Scheme which provides support and access to subsidised products (e.g. blood and urine testing strips, syringes and needles).

## Supporting clinical best practice

PSA supports the stated purpose of the review<sup>6</sup> and agree we should be informed by systematically evaluated bodies of clinical evidence, whether this applies to the subsidisation of medicines or recommendations to health professionals regarding the most appropriate management of diabetes in clinical practice.

## Clinical guidelines

PSA is aware that the current Australian guidelines for type 2 diabetes<sup>7</sup> are considered by clinicians and industry to be somewhat out of date. Therefore we recommend that an immediate review should be undertaken through the leadership and guidance of the National Health and Medical Research Council (NHMRC). We also believe that in order to maintain contemporary practice in the management of people with diabetes, clinical guidelines need to be updated regularly. PSA therefore recommends that a more frequent review cycle should be implemented through the NHMRC for future updates.

As the prevalence of diabetes continues to increase and new therapeutic agents are developed, it will be even more critical to consistently review and update nationally accepted guidelines by incorporating new information and evidence in a timely manner. PSA understands, for example, that the American Diabetes Association revises its standards of care document annually through

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<sup>6</sup> Australian Government Department of Health and Ageing, op. cit.

<sup>7</sup> Colagiuri S, Dickinson S, Girgis S, Colagiuri R. National evidence based guideline for blood glucose control in type 2 diabetes. Canberra: Diabetes Australia and NHMRC; 2009.

a multidisciplinary committee by incorporating new evidence.<sup>8</sup>

## **Reinforcing key messages with health professionals**

Once the national clinical guidelines are updated, it would be sensible and beneficial for health professionals to be informed of any changes as well as the up-to-date consensus position in terms of clinical best practice be reinforced. This is done to some extent already however PSA believes the need for and benefit of regular and ongoing reinforcement of best practice cannot be underestimated.

Some recent initiatives of the National Prescribing Service have included:

- type 2 diabetes *Practice review*<sup>9</sup> which focussed on key messages of quality prescribing such as: monitoring and managing multiple cardiovascular and microvascular risk factors; individualising blood glucose targets; and considering the effectiveness of glucose-lowering medicines in reducing diabetes-related complications and mortality; and
- a comparative table<sup>10</sup> outlining the advantages and disadvantages of glucose-lowering medicines for people with type 2 diabetes.

These topics and resources relate directly to the quality use of diabetes medicines and should be used to support all health practitioners involved in the care of people with diabetes. Professional organisations also have an important role in promoting the use of these types of evidence-based resources and PSA certainly undertakes this role.

## **Informing subsidisation criteria through clinical best practice**

Health professionals are informed by clinical guidelines and many other stakeholders rely on such resources. It also follows that any conditions or restrictions that might be applied to PBS listings of medicines should also be consistent with clinical best practice. Where PBS listings or restrictions do not fully reflect clinical best practice, PSA believes a clear and comprehensive explanation of those decisions and the rationale underpinning them must be made available to health professionals and consumers.

Pharmacists are aware of the complexities around the PBS listing process and that negotiation of an acceptable price can impact on the extent to which the likely clinical benefits of a medicine may or may not be available to consumers. Pharmacists will attest to the difficulties they can encounter in providing a 'simple' explanation to consumers, for example, why a certain medicine may be subsidised for one indication but not another when the person is aware that the medicine "works for both conditions". Equipping prescribers and pharmacists with clear explanations and messages suitable for consumers is an essential component in ensuring the quality use of subsidised medicines.

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<sup>8</sup> American Diabetes Association. Standards of medical care in diabetes – 2013. *Diabetes Care* 2013; 36 (Supplement 1):S11–S66.

<sup>9</sup> National Prescribing Service. *Practice review: type 2 diabetes*. 2012, Sep.

<sup>10</sup> National Prescribing Service. *News: cardiovascular disease risk in type 2 diabetes. Drug table [insert]*. 2012, Aug.

It is also important to keep in mind that the range and types of diabetes medicines are likely to change further in the future and therefore the criteria or rules around PBS listing may need to adapt and evolve. For example the use of genetic testing is already flagged in providing information about subtypes of genes with the ability of prescribers to then select the most appropriate treatment.<sup>11</sup>

## Pharmacists' expertise in medication management

In Australia, there has been a gradual increase in prescriptions for diabetes medicines subsidised through the PBS and RPBS since 1992 when there were 1.6 million prescriptions. In 2011 it reached 7.2 million of which 89% (approximately 6.4 million prescriptions) were for blood glucose-lowering (BGL) medicines. Insulin accounted for 11% (or around 816,000) of prescriptions. Over 50% of all BGL medicines dispensed in 2011 was for metformin (approximately 3.2 million prescriptions).<sup>12</sup>

Pharmacists have a range of roles to fulfil in the care of people with diabetes including improving health literacy, assisting self-management and promoting lifestyle activities. However, medication management is a core area of pharmacists' expertise which is directly relevant to this review which aims to ensure the continued safe, cost effective and quality use of medicines listed on the PBS.

Given the volume of prescription medicine use (above), the reported number of people who have been diagnosed with diabetes approaching 850,000,<sup>13</sup> and the anecdotal evidence that every Australian visits a pharmacy, on average, 14 times a year, pharmacists represent a major point of regular contact for people with T2DM.

## Professional pharmacist-delivered diabetes care services

The integration of pharmacists' contribution to the care of people with diabetes is vital. The positive contribution of diabetes disease state management services delivered by pharmacists has been clearly established by research in both the clinic<sup>14,15,16</sup> and community pharmacy settings<sup>17,18,19</sup> for example in the USA and Australia. Specific services offered by pharmacists have included elements such as:

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<sup>11</sup> Shomali M. Diabetes treatment in 2025: Can scientific advances keep pace with prevalence? *Ther Adv in Endo and Metab* 2012; 3(5):163–173.

<sup>12</sup> Australian Institute of Health and Welfare, [www.aihw.gov.au/diabetes](http://www.aihw.gov.au/diabetes)

<sup>13</sup> Australian health survey 2011-12. Available at: [www.abs.gov.au](http://www.abs.gov.au)

<sup>14</sup> Irons BK, Lenz RJ, Anderson SL, Wharton BL, Habeger B, Anderson HGJ. A retrospective cohort analysis of the clinical effectiveness of a physician-pharmacist collaborative drug therapy management diabetes clinic. *Pharmacother* 2002; 22:1294–300.

<sup>15</sup> Jaber LA, Halapy H, Fernet M, Tummalapalli S, Diwakaran H. Evaluation of a pharmaceutical care model on diabetes management [comment]. *Ann Pharmacother* 1996; 30:238–43.

<sup>16</sup> Clifford RM, Davis WA, Batty KT, Davis TME. Effect of a pharmaceutical care program on vascular risk factors in type 2 diabetes: The Fremantle Diabetes Study. *Diabetes Care* 2005; 28:771–6.

<sup>17</sup> Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc* 2003; 43:173–84.

- providing diabetes education and coaching to assist in empowerment of the consumer;
- monitoring and promoting adherence with medication and other components of self-management;
- ensuring evidence-based use of medications in the complete management of the consumer's diabetes, including the prevention of diabetic complications;
- assisting with monitoring and documenting key clinical indicators such as BG levels, HbA<sub>1c</sub>, blood pressure, urinary albumin excretion and lipid levels; and
- reinforcing with consumers the importance of regular examinations (e.g. of eyes and feet) for the presence of any diabetic complications.

### **Diabetes MedsCheck service**

In Australia, building on research outcomes and a pilot program a diabetes medication management service, known as Diabetes MedsCheck, is currently funded through the Fifth Community Pharmacy Agreement (5CPA).<sup>20</sup> This service provides an in-pharmacy review of medications with a focus on the consumer's type 2 diabetes medicines management, monitoring devices, education and self-management. The service is targeted at consumers who are unable to gain timely access to other diabetes education or health services in their community and aims to:

- optimise a consumer's effective use of medicine through improving understanding of, and compliance with, their diabetes medication therapy;
- improve a consumer's effective use of BG monitoring devices through training and education;
- improve BG control; and
- reduce the risk of the consumer developing complications associated with type 2 diabetes.

The capped and limited period of funding through the 5CPA requires the Diabetes MedsCheck services to be made available within the parameters of a defined and targeted list of criteria for consumer eligibility<sup>21</sup>. While PSA supports this as one mechanism of service delivery, we are concerned that some consumers with T2DM who may benefit clinically from a Diabetes MedsCheck may not currently be eligible to be considered for this service.

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<sup>18</sup> Armour C, Taylor S, Hourihan F, Smith C, Krass I. Implementation and evaluation of Australian pharmacists' diabetes care services. *J Am Pharm Assoc* 2004; 44:455–66.

<sup>19</sup> Krass I, Armour C, Taylor S, Hughes J, Peterson G, Stewart K, Clark P. The Pharmacy Diabetes Care Program. Final report, April 2005.

<sup>20</sup> Further information is available at:  
[www.5cpa.com.au/sites/5CPA/Initiatives/Medication\\_Management/MedsCheck\\_and\\_Diabetes\\_MedsCheck/About%20MedsCheck.page](http://www.5cpa.com.au/sites/5CPA/Initiatives/Medication_Management/MedsCheck_and_Diabetes_MedsCheck/About%20MedsCheck.page)

<sup>21</sup> Further information is available at:  
[www.5cpa.com.au/sites/5CPA/Initiatives/Medication\\_Management/MedsCheck\\_and\\_Diabetes\\_MedsCheck/Eligibility.page](http://www.5cpa.com.au/sites/5CPA/Initiatives/Medication_Management/MedsCheck_and_Diabetes_MedsCheck/Eligibility.page)

## Medication management reviews

The 5CPA also provides the means and funds for other medication management services to be delivered by pharmacists in collaboration with GPs, such as Home Medicines Reviews (HMRs; for people living in the community)<sup>22</sup> and Residential Medication Management Reviews (RMMRs; for residents of aged care facilities).<sup>23</sup> These are not specifically targeted for people with T2DM but are designed to enhance the quality use of medicines by maximising the benefits of medicines and ensuring adverse events are prevented or reduced. The GP provides a request to the pharmacist based on the consumer's/resident's clinical need.

## Indigenous Australians

Given the high rates of diabetes and its complications in Indigenous Australians, PSA believes additional attention is warranted in the design and delivery of medication management services by pharmacists to this population group. The programs under 5CPA such as Diabetes MedsCheck and HMRs are available to Aboriginal peoples. However, as the program funding arrangements are not targeted or tailored specifically for Aboriginal peoples, they can often experience greater barriers in terms of gaining access to timely care. These may be due to their regional or remote locations, or preference to receive care outside of their home (e.g. in an Aboriginal Health Centre) or in the presence of an Aboriginal Health Worker. It is clear that there is a need to consider how quality of use medicines services can be better implemented for this high priority group of Australians.

## PSA's Budget submission

The quality use of subsidised medicines generally is a core focus of PSA and pharmacists. Recognising the need for improved coordination and management of chronic conditions, and partly in response to the draft report of the review of blood glucose test strips (stage 1 of the diabetes review), PSA's pre-Budget submission<sup>24</sup> this year included a proposal for Pharmacist Diabetes Management Services. The two key areas identified where pharmacists would add value to the care of people with diabetes were a blood glucose monitoring service and a diabetes medication management service. The main components of these services are pharmacists providing consumer education to improve health literacy, supporting and assessing medication adherence, enhancing self-management and monitoring outcomes. A summary of PSA's proposal is provided at Appendix 1.

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<sup>22</sup> Further information is available at:  
[www.5cpa.com.au/5CPA/Initiatives/Medication\\_Management/Home\\_Medicines\\_Review/About+HMR.page?](http://www.5cpa.com.au/5CPA/Initiatives/Medication_Management/Home_Medicines_Review/About+HMR.page?)

<sup>23</sup> Further information is available at:  
[www.5cpa.com.au/5CPA/Initiatives/Medication\\_Management/RMMR/About+RMMR.page?](http://www.5cpa.com.au/5CPA/Initiatives/Medication_Management/RMMR/About+RMMR.page?)

<sup>24</sup> Pharmaceutical Society of Australia. Australians stay healthier: quality use of subsidised medicines [submission]. 2013, Jan. Available at: [www.psa.org.au/archives/20155](http://www.psa.org.au/archives/20155)

## Optimising treatment for consumers

Due to the complex nature of diabetes, it is consistently recommended that treatment options and goals for consumers need to be individualised for best outcomes.<sup>25,26,27</sup> Pharmacists have a core role in this regard in promoting health literacy, supporting medication management issues including adherence, encouraging self-management, and assisting with lifestyle activities. Where a consumer has a diabetes care plan, the pharmacist can work with, monitor and assist the consumer to achieve the goals they have agreed to with their GP.

Many of the activities in a care plan may not be directly relevant to the considerations of PBS listing of medicines. However, more appropriate and judicious use of medicines clearly impact on better overall health outcomes and therefore a holistic approach is necessary.

The pharmacist-delivered services mentioned above are also not a direct component of the terms of reference of this review. However, once again, PSA would stress that these medication management services deliver better health outcomes and quality of life for consumers. While the mechanisms of funding for PBS medicines and for the medication management services are different and do not dovetail well, PSA strongly believes consideration of linkages in the future should not be out of the question. For example, there may be opportunities to integrate an annual HMR as an essential component of a diabetes care plan for the consumer to be eligible to receive continued subsidy for an expensive PBS-subsidised medicine.

## Conclusion

Subsidisation of medicines through the PBS and RPBS is fundamental for Australian consumers with diabetes to access and afford quality care and treatment in a timely manner. These subsidies not only contribute to the current 'regular' care of people with diabetes, in the longer term they also help to lower costs associated with hospitalisation from diabetic complications and treatment needed from avoidable progression of the disease.

From PSA's perspective, pharmacists with their medication management expertise can make an important contribution to the health outcomes of people with diabetes. A better quality of life of individuals and their carers and a reduction of the possibility of irreversible complications will benefit the individual as well as the Australian health system.

Pharmacists can also make a difference in supporting busy prescribers with information that can assist quality prescribing. As a team member, pharmacists will complement the regular care provided by the GP, specialist, diabetes educator and other health practitioners.

These activities will lead to better use of PBS-listed medicines, in a way that appropriately reflects clinical best practice while providing flexibility to individualise therapy for optimal health outcomes for the consumer.

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<sup>25</sup> National Institute for Health and Clinical Excellence. Key therapeutic topics: Type 2 diabetes mellitus. 2013, Jan.

<sup>26</sup> American Association of Clinical Endocrinologists. Comprehensive diabetes management algorithm 2013. *Endocr Pract* 2013; 19(2):327–36.

<sup>27</sup> NPS MedicineWise. Pharmacy practice review: Type 2 diabetes – enhancing patient care. Clinical guidance: Glucose-lowering medicines. 2012, Sep.

**Submitted by:**

Pharmaceutical Society of Australia  
PO Box 42  
Deakin West ACT 2600  
Tel: 02 6283 4777  
[www.psa.org.au](http://www.psa.org.au)

**Contacts:**

Liesel Wett  
Chief Executive Officer

Kay Sorimachi  
Director Policy and Regulatory Affairs  
[kay.sorimachi@psa.org.au](mailto:kay.sorimachi@psa.org.au)

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## Appendix 1: PSA's 2013-14 Federal Budget Submission – Summary points

### **Funding:**

A total of \$7.93 million is requested over two years to conduct and evaluate a pharmacist diabetes management service (PDMS), to deliver better health outcomes to consumers with diabetes and savings to Federal Government expenditure on medicines and other associated health costs.

### **Broad description of service:**

The PDMS described in this proposal consists of two component services, each of which is designed to meet specific clinical needs of the consumer. The two services will contribute to overall better management of Australian consumers with diabetes.

**1. Blood glucose monitoring service.** Consumers with Type 2 diabetes can benefit from individualised education and information on self-monitoring. Pharmacists will provide this service in the community pharmacy at the time of supply of blood glucose test strips to consumers registered on the National Diabetes Services Scheme (NDSS) database.

**2. Diabetes medication management service.** This service will assist consumers in the self-management of their diabetes, with a focus on medication adherence. Pharmacists will work in collaboration with the consumer's GP to review the consumer's medication as part of their Annual Diabetes Cycle of Care.

### **Expected core outcomes:**

The following outcomes are expected through the implementation of a PDMS:

- Optimisation of the quality use of blood glucose test strips. The Federal Government spent \$143.5 million in 2011-12 subsidising blood glucose test strips for people with diabetes<sup>i</sup>, with total utilisation growing at a rate of approximately 6.3% per annum.<sup>ii</sup>
- Improved blood glucose control as a result of improved consumer understanding and medication management, including adherence.
- A flow-on reduction in the rate of associated complications and consequential savings to costs associated with hospitalisation and recovery.
- Improvement in the rate of completion of Annual Diabetes Cycles of Care. Optimised care coordination and management of chronic (long-term) conditions results in improved utilisation of resources, leading to a reduction in overall health care costs. Annual health care costs for T2DM are predicted to increase from \$1.4 to \$7 billion by 2023.<sup>iii</sup>

### **Associated benefits:**

The following associated benefits are expected through the implementation of a PDMS:

- Consumers have timely and seamless access to information about blood-glucose self-monitoring which is tailored to their health status and health care needs.
- Consumers have an additional choice of health care provider where this is appropriate in the context of their health care needs.
- Consumers have greater access to the expertise of pharmacists to receive earlier intervention and resolution of all medicine-related problems.
- Consumers have support and opportunities to improve their understanding of their own health, integrate self-management skills and improve their quality of life.
- Greater productivity through healthier consumers.
- Increased efficiency of use of expertise of health care professionals.

- GPs are able to refer medication management related decisions to the pharmacist<sup>iv</sup> while maintaining provision of overall ‘whole-person’ care for the consumer.
- GPs are less burdened by routine tasks which may be unnecessarily time-consuming.
- Pharmacists are able to contribute their core medication management expertise more effectively and work closely with the consumer’s GP.
- Pharmacists are able to consider the consumer’s medication management issues more holistically.
- Pharmacists can make an impact as a liaison person by coordinating, assisting and delivering seamless care.

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<sup>i</sup> Department of Health and Ageing. Draft Report of the Post-Market Review: Pharmaceutical Benefits Scheme Products used in the Treatment of Diabetes. Canberra: Department of Health and Ageing, 2012.

<sup>ii</sup> Ibid.

<sup>iii</sup> National Preventive Health Taskforce 2008. Australia: The Healthiest Country by 2020. A discussion paper.

<sup>iv</sup> For example, this could assist GPs in meeting requirements under criterion 1.6.1 *Engaging with other services* of the RACGP *Standards for general practices* (4th ed., 2010).