



MEDICAL SERVICES ADVISORY COMMITTEE (MSAC) MINUTES - November 2016

Sixth Community Pharmacy Agreement (6CPA) Pharmacy Practice Incentives (PPI) Programs

MSAC's advice to the Minister

MSAC concluded that there is insufficient evidence and a lack of empirical research to determine the clinical and cost-effectiveness of the following continuing Pharmacy Practice Incentive (PPI) Programs: Clinical Interventions, Dose Administration Aids, and the Staged Supply Support Allowance.

MSAC considered that it was difficult to conduct a comparative assessment of these programs as they were now primarily standard of care expected of a pharmacist. An option to address this might be to conduct a comparative assessment of an improvement to these current practices, which might justify the provision of program funding for the enhanced services.

For further evidence generation, MSAC considered that a set of principles should be developed highlighting the need for comparative data to determine whether these enhanced programs provide effective care compared to current practice. MSAC suggested that PASC could have a role in assisting this process.

Summary of consideration and rationale for MSAC's advice

The 6CPA between the Australian Government and the Pharmacy Guild of Australia (the Guild) commenced on 1 July 2015 and includes an allocation of \$1.26 billion in funding for evidence based, patient focused programs and services delivered by pharmacy and pharmacists to improve health outcomes for consumers. Under the 6CPA, all programs and services delivered need to be reviewed by a Health Technology Assessment body, such as MSAC, for clinical and cost-effectiveness and the health benefits they offer to the community.

At its March 2016 meeting, MSAC reviewed a high level synthesis of the available data and evidence to support these programs and requested a more detailed review be conducted, informed by a comprehensive literature review. The first programs to be assessed were the PPI Programs which provide a financial incentive to community pharmacies to deliver medication compliance initiatives. These include:

- Staged Supply support allowance (SS) — *'the provision of PBS medicines in instalments where requested by the prescriber'*.
- Dose Administration Aids (DAAs) — provision of *'a well-sealed, tamper-evident device that allows individual medicine doses to be organised according to the prescribed dose schedule'* to the patient.

- Clinical Interventions (CIs) — *‘any professional activity by the pharmacist directed towards improving the quality use of medicines (QUM) and resulting in a recommendation for a change in the patient’s medication therapy, means of administration or medication-taking behaviour’*. CIs may involve a recommendation for change of therapy, referral, provision of information or monitoring in relation to a drug-related problem. A drug-related problem may include drug selection, over or under dosing, compliance, under-treatment, monitoring the efficacy and adverse effects of a drug, education or information about a drug or disease and toxicity or adverse reaction to a medicine.

MSAC noted that a large number of pharmacies currently participate and receive an annual incentive payment for delivering the SS program, although there is no requirement for pharmacies to provide any patient specific data or even service delivery data, in order to receive payment. The review and evaluation of these programs did not identify any evidence to assess the impact of the SS program on improving medication adherence or health outcomes and hence no conclusions could be made regarding the program’s effectiveness or cost-effectiveness.

A large number of pharmacies also currently participate in the DAA program, which is provided to patients in the community, not in residential or aged care. They receive a quarterly incentive payment based on the number of services provided in the previous quarter, although there is no requirement for pharmacies to provide any patient specific data in order to receive payment. The evidence identified during the review and evaluation of these programs had limited applicability to Australia and was inconclusive as to whether DAAs improve medication adherence, clinical outcomes and patient satisfaction, or are cost-effective.

Evaluations of previous DAA projects were funded under the Third Community Pharmacy Agreement (3CPA). The 2004 report found DAAs were not cost-effective in the community setting. The 2006 report presented a cost-benefit analysis (based on decreasing adverse drug reactions), which reported the costs of providing DAAs in the community setting to outweigh the benefits by \$443 per year per person receiving a DAA, while a second cost-benefit analysis (based on health service use) found the costs of providing DAAs to outweigh the benefits by \$9,381 per year. It was noted that although both reports showed DAAs were not cost effective, the findings need to be interpreted with caution, due to several uncertainties attributed to methodological limitations and poor quality data. MSAC noted these uncertainties particularly related to the variability in cost of providing service between pharmacies, as the model was based on only 30 patients per pharmacy.

MSAC also noted that a large number of pharmacies currently participate in the CI program and receive a quarterly incentive payment based on a mixed model of the number of services provided and number of prescriptions dispensed. The review of the evidence was constrained by:

- the broad definition and general usage of the term ‘clinical intervention’ in the literature
- a lack of empirical research on the clinical and economic value of the CIs undertaken as part of the service because they are routinely undertaken by community pharmacists as part of standard practice
- assumptions that the consequences of a given CI will result in the same level of disability and health resource utilisation in every patient, regardless of age and co-morbidities.

Work funded by the Department of Health produced the only studies identified that assessed the clinical and/or cost effectiveness of providing funding incentives to community pharmacists to deliver CI services:

- Using data from 1997, Benrimoj SI et al (2000) calculated that the cost of providing a CI intervention in terms of pharmacist time and telephone calls ranged from \$2.50 to \$3.16 per

proactive CI. This study did not directly address clinical effectiveness or cost effectiveness of CIs.

- The PROMISE III study (Peterson G et al 2009) examined the number and nature of CIs performed, over a 3-month period in 531 community pharmacies in three states, covering 2,013,923 prescriptions. Rather than basing the assessment of cost-effectiveness on observed patient follow up, expert opinion was used to surmise the consequences of CIs for patient outcomes in a subset of 200 of the total 6,230 CIs. The study concluded that CIs saved health resources and improved quality of life (i.e. dominated). These findings should be considered in the context of the significant limitations of the study.

The limitations to these studies meant no clear determinations regarding the cost-effectiveness of the CI service could be made.

Overall, based on the comprehensive review and evaluation of these programs, MSAC concluded that there was a lack of evidence to determine the clinical and cost-effectiveness of SS, DAAs, and CIs. MSAC questioned the funding of these programs given the lack of evidence. MSAC queried whether there was a need for such funding given these programs are considered to be part of standard professional practice for community pharmacists in Australia. MSAC stated that, should such funding continue, it would need to be more transparent with clear auditing requirements and reporting/data collection requirements to demonstrate the value of the continuing expenditure. MSAC also noted that it would be helpful if current data sources for the PPI programs were made readily available.

MSAC considered that it was important to fund pharmacy programs that provide value for money and stressed the need for evidence as a key step to inform future funding of such programs. MSAC suggested that it was the responsibility of the pharmacy sector to generate the evidence to support any future programs.

MSAC cautioned against collecting poor quality and/or non-comparative data as this type of data is rarely sufficient to support a recommendation for public funding. However, MSAC suggested that conducting a randomised controlled trial of the current programs against not providing these services was likely to be unethical given these services are now part of routine care. While MSAC explored the option of investigating historical data to determine if there had been any impact upon patient outcomes after the introduction of the current services, it concluded that such data would be too unreliable. MSAC suggested that identification of ways to enhance current services and test these enhancements against the currently implemented programs may be a way forward for the sector.

MSAC recommended that the pharmacy sector propose novel ways to enhance these services, given that the current services are largely standard care at this point of time. Protocols to determine the effectiveness of enhanced services compared to current practice could then be developed and implemented by the pharmacy sector. MSAC advised that these protocols should be reviewed by PASC (to confirm the PICO question) and ESC (to consider the methods proposed to address the PICO question) and approved by MSAC before the enhanced services were trialled to ensure that they provide useful evidence for later decision making. MSAC emphasised that the research studies would need a proper study design, a comparator arm and mandatory reporting/data collection of relevant consequences as well as services delivered.

MSAC highlighted that the lack of existing data linking the interventions undertaken by community pharmacists as part of these programs with patient outcome data limits the ability to measure the clinical effectiveness of these programs. MSAC noted that it would be important that any study design involve engagement of community pharmacists with GPs and potentially with consumers.

Finally, MSAC suggested that funding for the current PPI programs (SS, DAAs and CIs) could continue while these protocols for novel ways to enhance services were developed by the pharmacy sector.