Working for a healthier world℠

A submission to the Productivity Commission's Review of Regulatory Burden on Business

Submission to the Productivity Commission

About Pfizer Australia and our business priorities

Pfizer Australia is Australia's largest manufacturer of prescription medicines. We have 452 products, used chiefly for the treatment of:

- cancer
- chronic diseases—such as diabetes, arthritis and heart conditions
- factors which increase the risk of heart disease—such as high blood pressure and high cholesterol
- mental illness—including depression, schizophrenia, anxiety and panic disorders
- neurological conditions—epilepsy, Parkinson's disease and Alzheimer's disease
- eye problems—such as glaucoma
- HIV/AIDS
- osteoporosis and other bone disorders
- erectile dysfunction
- sleep disorders.

Other products include:

- medicines to help people stop smoking
- anti-inflammatory medicines to reduce pain
- anti-rejection medicines for organ transplants
- oral contraceptives
- anti-bacterial and anti-fungal medicines to treat infection
- hormone replacement therapies
- anti-coagulants to prevent blood clotting.

Our core business is centred on developing innovative, patent-protected medicines, and making them available to Australians. The bulk of these medicines are made available to Australians through the Pharmaceutical Benefits Scheme (PBS). Consequently, laws and policies affecting the registration of medicines and their listing on the PBS are our core regulatory concerns. The two agencies that we deal with most are:

- The Therapeutic Good Administration (TGA)—concerned chiefly with ensuring the safety of medicines, which it does by reviewing all of the research evidence and scientific data concerning our products and inspecting our manufacturing plants, and
- The Pharmaceutical Benefits Advisory Committee (PBAC)—which advises the Minister for Health on the cost and effectiveness of medicines, and recommends which of those medicines should be listed on the PBS to receive government funding.

Developing innovative medicines is extremely expensive and time-consuming, with an average cost of $1.2 billion per medicine and a development period of 10-15 years. The period in which we have patent protection is limited, and a strong generics medicine industry means that we lose the ability to make a profit after our patents expire. We have a strong desire to see effective and potentially life-saving medicines made available to Australians as soon as possible.

Both our business and health imperatives mean that we would like to see:

- time spent by TGA assessing our medicines minimised (while properly ensuring the safety and effectiveness of all medicines)
- time spent getting medicines listed on the PBS minimised (while properly assessing the cost-effectiveness of medicines listed on the PBS)
- certainty in the timing and outcomes of both assessment processes.

The context of this submission

The nature of the Productivity Commission's reviews is to focus on problems—and this can give an inaccurate impression of our view of regulation and regulators. Before we discuss specific areas where we would like to see improvements, we want summarise our feelings about both the TGA and PBAC.

Pfizer Australia has confidence in the TGA, and we are strong supporters of its mission. Its assessment of the safety and effectiveness of medicines is of the highest quality. It has also done good policy work: for example, its contribution to the development of a Joint Australian-New Zealand Regulatory Authority (unfortunately suspended by the New Zealand Government) was very good indeed.

We are also happy working with the PBAC, and value our dialogue with it. We—and our industry generally—are strong supporters of Australia's PBS system, and want it to continue providing access to medicines for all Australians in a sustainable way. We appreciate changes made in the PBS Reform process, as well as those introduced during the negotiation of the Australia-US Free Trade Agreement.

What follows is not an overall criticism of either body. But all organisations are capable of improvement, and it is in this spirit that we offer the following suggestions.

What Pfizer Australia is seeking through this submission

In this submission, we have given examples of where regulations and the actions of regulators impact on Pfizer Australia's business. However, in presenting this submission to the Productivity Commission, we are seeking more than just the rectification of specific problems. What we want is better implementation of a number of *principles* in the regulations and regulatory bodies that govern our business. These principles are:

- Fairness—the Australian Government should treat us in the same way as other stakeholders in comparable positions. In particular, where government provides support or incentives, all stakeholders should have equal access under the same criteria.
- Transparency—we should understand what the Australian Government expects of us and why it makes particular decisions concerning our facilities and products.
- Consistency—decisions and advice given by the Australian Government at one point in their processes should apply throughout the process.
- Accountability—where there are demonstrable errors of fact or major omissions, there should be review and rectification processes.
- A focus on outcomes—where the Australian Government offers incentives or support, it should reward the long-term goals of government and the Australian community (in

particular, universal access to safe and effective medicines). Incentives should not create perverse outcomes which frustrate these higher goals.

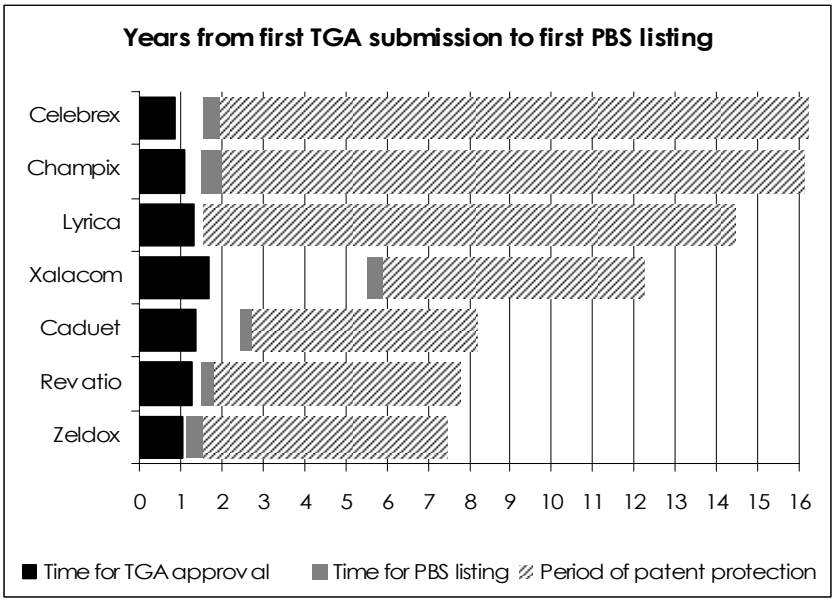
- Creating certainty for all stakeholders—manufacturers and government alike.
- Decisions about the quality, safety, efficacy and cost-effectiveness of medicines should be based on objective scientific evidence and on rigorous statistical methods.
- Duplication should be minimised and, where possible, eliminated.

The topics in this submission are arranged loosely in the order we deal with them, but these principles apply to most stages of the process of registering, listing and marketing new medicines. Specific ways that these principles can be applied are:

1. Aligning the PBAC and TGA application processes
2. Basing decisions to register new products on science—following the principles of evidence-based medicine—not on opinion
3. Eliminating duplication caused by 'regulatory creep'
4. Improving the transparency of TGA processes generally
5. Making PBAC processes fairer and more transparent
6. Improving the accountability of PBAC evaluations
7. Altering government subsidies which close markets and reduce competition.
8. Removing or amending unworkable requirements in the US Free Trade Agreement (Patent Certification).

Aligning the PBAC and TGA application processes

The following graph illustrates some of the business pressures we face. It shows the amount of time some of our recently-listed products spent being assessed by the TGA (in black) and PBAC (in grey). The hatched area shows the period of time before we lose first patent protection or exclusivity. As will be apparent, we routinely spend around two years before a product is listed on the PBS and, in some cases, we may lose half the patent protected-period waiting for listing. (In the case of Lyrica® (*Pregabalin*), for the treatment of partial epileptic seizures, the PBAC recommended the product for PBS listing, but at a price that was not commercially viable—and consequently Lyrica® is not listed on the PBS. The result is that few Australians have access to this medicine.)



The long assessment period impacts both our business objectives and our goal of making medicines available to Australians who need them. Consequently, Pfizer Australia wants to reduce the time between (1) our initial application to register a medicine with the TGA and (2) Australians' ability to access our medicines via the PBS.

One way we see to achieve this is for manufacturers to be able to make synchronised applications to the TGA and the PBAC. Each organisation is concerned with different assessment questions—the TGA with effectiveness and safety; the PBAC with cost effectiveness—so at a level of principle, there is little to impede the two evaluations happening in parallel.

At present it is technically possible for a company like Pfizer Australia to develop TGA and PBAC submissions simultaneously, and we are permitted to make a PBAC submission if we have a provisional TGA approval notice. However, the PBAC and TGA assessment periods are not synchronised at the moment, so efficiencies are fortunate rather than planned. For example, the date we receive approval from the TGA may be just after the cut-off for PBAC submissions (meaning we have to wait several months if we miss the cut-off

date), and the TGA process itself may be delayed. What we would like to see is better streamlining and synchronisation of both organisations' assessment processes.

We fully recognise that there are risks involved in parallel assessments—for both manufacturers and regulators. For example, if the TGA decides not to approve a medicine, the PBAC will have potentially invested unnecessary effort and used scarce resources (there are few external academic evaluation groups in Australia, so unnecessary work impacts in a very real way on the introduction of new medicines). For companies too, there are costs involved in an unsuccessful TGA submission. (We regard this as a relatively small risk for Pfizer Australia. We have withdrawn only two medicines from the assessment process in recent years: Exubera® (*insulin human*) and Macugen® (*pegaptarib sodium injection*).)

The key to managing risks for both sponsors and regulators is *clarity*. In particular:

- a clear demarcation between TGA and PBAC
- clear expectations of sponsors and what their submissions need to contain
- consistency of advice provided by regulators.

We do not anticipate commencing parallel submissions for every single medicine. However, we want the regulatory system to support appropriately timed patient access. We must stress, however, that any reforms to speed up access to medicines must not compromise the quality of, or undermine public confidence in, the assessment of:

- the safety of all medicines
- the effectiveness of our medicines
- the cost-effectiveness of medicines.

We need to stress that we do *not* see a complete merging of the PBAC and TGA as a way of achieving these goals. It is important that the assessment of medicines' physical properties and safety is kept quite distinct from questions of health economics. These assessments involve not only different skills but fundamentally different outlooks. In our view, it is in both Australia's interests and industry's interests to keep the TGA and PBAC separate.

Changes along the lines of those we are suggesting here are being explored in the health portfolio by the Access to Medicines Working group (AMWG), which brings together the Department of Health and Ageing with Medicines Australia. We fully support the work of this group—but we want to stress that the approach needs support within industry portfolio of government, as well as health.

Basing decisions to register new products on science, not opinion

As we noted at the beginning of this submission, we have very good relations with the TGA and we are strong supporters of its mission. However, we are concerned that there are an increasing number of assessments based their own interpretations of their own internal rules rather than strictly on scientific research. In part, this is because of ambiguities in the Act, but this has proved costly to us on several occasions.

To take a single example: Pfizer Australia has an anti-cancer medicine, Camptosar® (irinotecan hydrochloride). We originally registered this in two injectable volumes—40 mg in 2 mL and 100 mg in 5 mL—but otherwise identical formulations and equal strengths (both contain 20 mg/mL). The sole difference between these products was the volume in each vial. The reason for providing two volumes that it allows oncologists to tailor their patients' dose, while minimising costly wastage and reducing the potential exposure to hazardous waste. Typically, oncologists need to use more than one vial, and we identified a need to produce a larger third volume of 300 mg in 15 mL—but at the same strength as the other two vials. The TGA considered this third vial to be a different *strength* of Camptosar®, not just a different fill volume. (This interpretation of 'strength' is not consistent with either the scientifically or commonly understood definition of 'strength'). The consequence of this interpretation was that Pfizer Australia had to make a Category 1 application to the TGA, with a fee of $65,900. Category 1 applications typically required for entirely new medicines, or new clinical uses of existing medicines, or variations which require substantial re-evaluation of data. Our view is that the TGA should have requested a Category 3 application. This is the normal approach for variations to existing presentations which require a review of chemistry. (In fact, in this case, the TGA had already assessed the data for variations to the existing 2 mL and 5 mL presentations—all for a fee of $3,880.) Our problem with this type of decision is that it is not made on scientific evidence.

It also seems inefficient to require an evaluator to perform what is essentially an administrative task. It potentially reduces the amount of time and resources that the TGA has to review and approve new therapies which genuinely require Category 1 scrutiny. This is in no ones' interests: the TGA's, industry's, or Australian patients waiting on new medicines.

Eliminating duplication caused by regulatory creep

One of the important functions of the TGA is to inspect manufacturing plants, to ensure that medicines produced in them will be safe for human use. We support this goal very strongly.

The components of medicines—active ingredients, excipients, capsules, binders—are manufactured around the globe. One medicine can potentially have components produced in plants in several different countries—all of which need to be inspected. Furthermore, manufacturers can subcontract the production of some components to external plants.

Because of the international nature of medicine production, there are international quality standards that apply to production, Good Manufacturing Practice (GMP), which are coupled with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (known collectively as PIC/S). Currently, 33 regulatory agencies internationally are PIC/S signatories.

Although the TGA is a member of PIC/S, it has decided that inspection reports from other regulatory agencies are no longer sufficient for its needs.

For example, until recently, the TGA respected the acceptability ratings produced by the USA's Food and Drug Administration (FDA) and would grant GMP Clearance based on

the FDA inspection ratings on the FDA database. This is no longer the case. The TGA now insists on reviewing the full inspection report, and requires manufacturers like Pfizer Australia to provide these. These inspection reports, called EIRs, are often issued many months after the inspection dates and are very difficult to obtain—which makes providing timely advice to the TGA almost impossible. Many subcontracting plants also insist on edited the report before issuing it to the manufacturer. However, the TGA will not accept a edited EIR. Another new requirement imposed by the TGA is that EIRs must now specify dosage forms and specific active pharmaceutical ingredients (APIs). These additional requirements make using the FDA database difficult, because the FDA itself generally limits the scope of its inspection to products and processes which impact drugs approved and marketed in the US—not those intended for other markets. Also, neither the manufacturer nor the subcontracted plants can influence what the FDA audits or the frequency of FDA inspections—again making it difficult to meet the TGA's requirements of EIRs.

In addition to these changes, the TGA now requires a variety of key documents from each plant, in addition to the full inspection report. Some subcontracting plants regard these documents as confidential, and consequently the plant may forward these documents directly to the TGA—without showing them to the contracting manufacturer. This has caused concern for both TGA and contracting manufacturers. The TGA itself has told industry that 20% of the documentation it receives is either poor or unacceptable. Because of this, we expect that some applications to register medicines in Australia may be severely delayed or even rejected.

In certain circumstances—mostly where an ingredient or a product involves a high risk active pharmaceutical ingredient—the TGA can *still* regard an inspection report and supporting key documents as insufficient. In such cases, the only way the TGA will grant GMP Clearance is if it inspects the plant itself. It appears that the TGA no longer has confidence in inspections conducted by the FDA or a PIC/S regulator outside their own country. While we agree with the TGA in the importance of safeguarding the health and safety of medicine users, we do not believe that conducting inspections that parallel those done by European and American authorities adds any value.

For Pfizer, as a major international manufacturer, all of these additional requirements create significant duplication of effort. Plants now spend a great deal of time preparing for and participating in GMP audits. Currently, plants may currently be inspected by a European Union authority and a USA authority—and now the TGA can insist on inspecting the same site for exactly the same processes.

These changes by the TGA have also created considerable uncertainty for us. Previously, a GMP Clearance for an API or finished product would expire three years from the date of the last inspection. Now the TGA has indicated that it will calculate expiry dates using a risk matrix. However, the TGA will not make this risk matrix available to industry, and manufacturers like Pfizer Australia have no way of determining what length of clearance they will receive for subcontracted plants overseas. We expect that the clearance periods

will significantly reduced, which will create the need for more frequent applications. And the number of TGA inspections will definitely increase.

Our core concern—beyond the cost and inconvenience and uncertainty of multiple inspections—is that the *principle* of inspection has been lost. We have a duplication of effort and an increase in uncertainty for no increase in outcome (that is, safety and quality).

While we appreciate that the TGA's intention was to create a level playing field by imposing the same GMP restrictions on overseas plants as they do on local manufacturers, it has had exactly the opposite effect. Australian manufacturers have a harder time registering overseas plants than pharmaceutical manufacturers anywhere else in the world.

Improving the transparency of TGA processes generally

The previous two sections outline specific problems in our dealings with the TGA. But an issue common to both these and other situations is that we are not certain how or why the TGA makes decisions. That is, it lacks transparency. And this creates uncertainty for us.

Even if specific TGA processes cannot be changed, we would find our work easier if the TGA explained when and how and why it makes decisions. We would have more time to prepare what the TGA requires, give and get useful advice, and contribute more constructively.

For instance, when the TGA prepares new guidelines, we rarely have advance warning that we will be asked to give advice, and the time provided for comment is usually short. A better model for policy-making is the process used by the European Medicines Evaluation Agency (EMEA): the *Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework* (EMEA/P/24143/2004). This is a highly-structured, five-step process for the development of new legislation and guidelines. It covers the issuing a draft instrument, requesting comment from stakeholders, getting feedback, making comments on feedback, and preparing the final instruments. The EMEA process also specifies time periods for each stage, how the stakeholder consultation is to be conducted, and the date on which new instruments will come into force. This type of approach would provide us with greater certainty in Australia.

Making PBAC processes fairer

We premise the decision to bring many expensive, specialised prescription medicines—such treatments for cancer, heart disease, schizophrenia—to Australia on our anticipation of achieving a PBS listing. PBS listing is also a factor in our decisions to conduct research and development in Australia. Consequently, certainty in the PBAC's decision-making process is essential to both our business objectives and our capacity to deliver medicines to Australian patients.

A major problem that Pfizer Australia has experienced in the past is the mismatch of early advice on our PBAC submissions and the PBAC's final recommendations.

Before Pfizer Australia lodges a major PBAC submission, like all manufacturers, we discuss it with representatives of the Pharmaceutical Benefits Branch of the Department if Health and Ageing. (The Branch provides secretariat and technical support to the PBAC). Submissions are complex and take many months to prepare, so these early meetings are an opportunity for both sides to:

- discuss issues with clinical evidence
- determine the comparator, and
- discuss approaches to the PBAC if there is a rejection.

There have been times when advice given to us by the Branch at this initial stage is not reflected *at all* in the independent evaluation (upon which the listing decision is based), or in the PBAC's final recommendations to the Minister. We have had submissions rejected or deferred, which we prepared in good faith using the advice provided by the Department. Our problem is that the advice provided by the Branch is non-binding, and the advice we have been given is not communicated to the external academic evaluation groups. (We face a similar, though less costly problem in the advice given to us by the TGA not being reflected in assessments of our manufacturing plants made by independent auditors.)

We want advice given by the Branch to be binding on the evaluators.

In the interim, Pfizer Australia will be recording all of the advice we are given by the Branch in our submissions—so that evaluators are aware of the reason we have taken some approaches. This, of course, will not bind the evaluators, but we hope that it will at least improve communication.

Improving the accountability of PBAC evaluations

When we make a submission to the PBAC, it is evaluated by external academic groups, and their commentary is then reviewed by the PBAC. Our submission and their commentary together form the basis of the PBAC's decision to recommend or not recommend the medicine for listing on the PBS.

In recent years, submissions have become steadily more complex. The main reasons for this are that medicines are generally becoming more specialised, and patient populations are generally becoming smaller. This means that greater sophistication is required to interpret the clinical trial data for re-imbursement, and the statistical methods required have become more technical. There have also been theoretical developments in the evaluation methods used by health economists to assess cost-effectiveness. Finally, the volume of data is also sometimes very large: some of Pfizer's submissions have involved data from up to 68 clinical trials. The net effect is that submissions are complex for companies to develop, and they are demanding for evaluators to assess—especially in the limited time that the evaluators have available.

We feel that an increasing number of elements in evaluations are either simply wrong or contain major omissions, and consequently the PBAC is being given guidance that may lead to them incorrectly reject our medicines.

Pharmaceutical manufacturers currently have only limited opportunities to address errors of fact or major omissions. While there is a review process, this can only assess the PBAC's own processes, not the evaluation itself. (We are aware of only one company that has requested a review. It is a measure of the complexity involved that no single evaluator could be found to conduct it and, in the end, the review had to be done by two separate people.)

We believe that, where we can demonstrate a substantial error of fact or a major omission, we should have a right of review—with formal acknowledgement of the incorrect assessment by the evaluator to the PBAC. (The reason we suggest that evaluators need to acknowledge problems is part of a performance improvement cycle and ownership of responsibility: if errors are detected, then they need to be recognised by those making them, and evaluators need to make changes to ensure that errors are not repeated—and the PBAC has to have confidence that change has been made.)

Even if the current system cannot be changed significantly, there are a number of things that would help make it somewhat fairer. For example:

1. Currently, when we make a submission, we may address the PBAC for a maximum of 10 minutes following receipt of the commentaries and at the PBAC hearing. This is disproportionate to the amount of time invested in developing a submission, and the complexity that submissions often involve.
2. According to PBAC Guidelines, manufacturers have five days to respond to the evaluator's comments (which often run over 50 pages and are highly technical). Five days is quite disproportionate to the months that are spent preparing and evaluating submissions.
3. Even if the time to respond or the number of pages in the response cannot be changed, we would ask that commentary be sent by email or fax. Currently, the PBAC posts commentaries by mail, reducing the already-limited time we have to respond. (Commentaries are posted on Wednesday, and we receive them by at best mid-morning on Thursday—and must be returned to the PBAC by the midday on the following Wednesday.)
4. As manufacturers making submissions are required to make submissions in a useable electronic format, we believe that it would be helpful for the commentaries to be delivered in a like format—not a printed document which creates more work for us.
5. We want commentaries to be binding. An evaluator's commentary on a medicine should have force if we make a subsequent submission for a comparable use of the same medicine (This assumes that there is no change to the evidence—no extra clinical trials or any problems reported in post-marketing surveillance).
6. The evaluators should receive the feedback that we provide the PBAC, as we believe this will help improve their understanding of why we—and manufacturers generally—prepare submissions in the way we do, and problems we have with evaluations. Feedback is crucial to performance improvement.

Finally, we do not know how much time the PBAC allocates to assessing commentary and submissions, but we are concerned that it is increasingly insufficient. The number of submissions has grown in recent years and, as we noted above, they are becoming

increasingly complex. In 2000, each PBAC meeting made around 15-25 recommendations to list medicines on the PBS; in November 2007, they recommended 53 medicines for listing. Despite this increase, the PBAC has not advertised any increase in the time devoted to evaluations, or in specialist subcommittees or in PBAC meetings.

A Altering government subsidies which close markets and reduce competition

The Fourth Community Pharmacy Agreement (or 'Guild Government Agreement') imposes obligations and offers incentives which disadvantage manufacturersthat wish to distribute products directly to pharmacies.

Prescription medicines are generally distributed to pharmacy in the following way:

1. the manufacturer sells the product to wholesale customers at ex-factory price
2. the wholesaler then adds a percentage
3. the wholesaler then sells to pharmacies, which in turn add their own mark-up and dispensing fees.

The margins that wholesalers may charge for PBS products are set by the Australian Government. In the Fourth Guild-Government Agreement, the previous margins were reduced, and a Community Services Obligation (CSO) introduced. This included the requirement to supply all medicines on the PBS within 24 hours of a pharmacy placing an order in most areas of Australia. Another key criteria is being able to supply the full range of PBS products, with set criteria on lower volume products. In return for these restrictions, the Australian Government provided funds to eligible suppliers to ensure universal patient access. There is an annual pool of $150m for the life of the current agreement, and eligible wholesalers can claim funds on a monthly basis, depending on sale volume. Only wholesalers are currently eligible to compete for the funds.

While Pfizer can and is supplying direct to pharmacies, the current CSO incentive scheme creates disincentives for doing so and prevents Pfizer from competing on an equal footing with wholesalers. We cannot—by definition—meet the CSO obligations, because we do not sell the full range of PBS-listed medicines. This creates an inequity, as eligible wholesalers receive funding (which can be passed on to pharmacies) for our products. Wholesalers immediately have a price advantage which they can use to gain sales and market share.

There are several consequences for both Pfizer and the Australian Government. First, Pfizer is locked out of a market where it could deliver cost savings through supply chain efficiencies. It is the Australian Government that would benefit directly from lower savings (as prices for pharmacy and patients are fixed). Second, the subsidies prevent competition in this market, and have contributed to the departure of some players. For example, Pfizer's logistics service provider, DHL were initially eligible for CSO funding, but the CSO criteria and competition from wholesalers for the fixed subsidy pool contributed to their decision to cease claiming the CSO funding. The wholesalers now have a government-subsidised stranglehold on the supply of product to market.

More generally, the current subsidy scheme does not create efficiencies in the supply chain and prevents competition. It is interesting to note that during the time DHL were a competitor for the funding, the wholesalers were forced to reduce over-servicing (which was effectively being subsidised by the Australian Government).For instance, before our entry, three major wholesalers allowed community pharmacies to order and receive medicines twice a day. After the entry of DHL and Pfizer, all three decided to reduce their service to one order per day.

What Pfizer Australia would like to see is a system that:

- achieves the intent of the CSO—universal patient access and prompt supply, and
- allows more players into the supply channel on equal terms.

What we suggest is not one but two subsidy schemes, operating in parallel:

- Wholesalers supplying under the current CSO with a greater weighted incentive for low volume products
- Manufacturers supplying direct to pharmacy under the same CSO, with the single distinction that they are only obliged to stock all of their own medicines (not the full PBS list).

One point that we want to stress is that, in order to be eligible for government funds, any supplier must include the full range of medicines which they may legally access (for wholesalers, the full PBS list; for manufacturers, their full medicines list). No supplier—whether manufacturer or warehouse—should be able to 'cherry-pick' profitable products. This would not be in the interests of patient health nor the principle of universal access to medicines.

Removing or amending unworkable requirements in the US Free Trade Agreement

During the negotiation of the Australia-US Free Trade Agreement in 2004, the then-Opposition Labor Party introduced a number of amendments (the so-called "Latham Amendments") which imposed a number of perverse requirements our industry and its relationship with manufacturers of generic medicines.

The Latham Amendments require applicants who are seeking to register a generic medicine to certify to the TGA that either:

(a) they do not propose to market the therapeutic good in a manner that would infringe a patent or

(b) that a product is patented and the applicant has notified the patent holder that it will be applying to register the medicine.

The problem for companies like Pfizer Australia is that, while the TGA may receive such certificates from a generic company, the TGA does not notify the patent holder (such as innovative medicine manufacturers). Consequently, the patent holder has no way of knowing whether a generic company is about to register a product that infringes its patent. The patent holder may only find out if an infringing medicine is to be marketed *after* the TGA has registered it. At that point, the innovative company is forced to commence

expensive legal proceedings to restrain the generic manufacturer from marketing and selling the infringing medicine.

At the very least, the TGA needs to notify innovative companies that they have received a patent certificate from a company *before* beginning to register a generic product. This is particularly important in the case of the Latham Amendments because they also require a patent holder that wishes to bring proceedings against an infringer to first certify that the legal proceedings:

- are to be commenced in good faith
- have reasonable prospects of success, and
- will be conducted without delay.

If this certificate is found to be false or misleading—even if no legal proceedings are commenced—then the patent holder may be fined up to $10 million and, under some circumstances, may also be ordered to pay compensation to the infringing company.

The Latham Amendments were introduced into the FTA to target the alleged practice of 'evergreening' (perpetually renewing medicine patents to prevent the introduction of generic medicines). At the time the FTA was being negotiated, 'evergreening' was said to rife in the United States and would be a significant threat in Australia once the FTA passed into law. However, evergreening is a non-existent threat in Australia—we are not aware of any evidence of it in this country. Indeed, we doubt that it is even a reality in the United States. In any case, the Australian legal system is very different from the United States, and consequently the certification requirements:

- do not work in a practical sense
- are administratively burdensome, and
- are legally risky to the innovative company for no good reason.

We would like to see the certification requirements either (a) abolished or (b) significantly amended to provide a link between the certificates provided to the TGA and the innovative company. An innovative company should be notified of an application to register a generic version of its medicine *before* the TGA registers the medicine, so that it can object that its patent is being infringed.