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To: The Medicines Australia Oncology Industry Task Force

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Re: Submission to *Access to Cancer Medicines* Report

Fresenius Kabi Australia Pty Limited (FKA) is responding to the Report facilitated by the Medicines Australia Oncology Industry Taskforce (MA OIT) and launched on 31 July.

FKA's submission responds to the part of the Report that outlines "Issues relating to inadequate remuneration for the supply of chemotherapies". This issue states that inadequate funding for cancer drugs following the 2010 PBS reforms introducing price disclosure and expanded and accelerated price disclosure have substantially decreased the prices of some cytotoxic chemotherapies and, while meeting the intended purpose of these reforms (to generate savings to re-invest in the funding of new medicines), such significant reductions in price have resulted in a decrease in remuneration for service providers. "Since these 'extra' remunerations have previously been used to cross-subsidise inadequate remunerations for the provision of chemotherapy services in general, the reform may reduce the capacity of some providers to supply certain medicines, particularly for patients in regional areas"[1].

FKA is the Australian market unit of Fresenius Kabi AG, a global organisation with offices in Europe, North America, Asia, South America and Australia. We are a leading supplier of compounded cancer medicines.

FKA owns and operates medicines compounding facilities across Australia and as such is part of the sector of compounders that is licensed by the Therapeutic Goods Administration (TGA) and defined as compounding manufacturers. This sector provides approximately 63% of the sterile compounded chemotherapy drugs in Australia. As third party providers we supply patient-specific doses on a daily basis to pharmacies and public and private hospitals across Australia for administration to patients. "The vast majority of medicines supplied in Australia by community pharmacy are manufactured by pharmaceutical manufacturers regulated by the TGA"[2].

The role FKA plays in providing sterile compounded chemotherapy drugs is typically as follows: a patient is diagnosed with cancer by a physician and is prescribed a chemotherapy medication to be administered, usually at a hospital. In most cases the chemotherapy medication will require preparation (typically an infusion) for that patient into a specific dosage form. In many cases the hospital or clinic where the patient will receive the infusion will work with a third party provider,

[1] Medicines Australia Oncology Industry Taskforce and Deloitte Access Economics, July 2013, ibid, Px and 67.
[2] Therapeutic Goods Administration, Options for reform of the regulatory framework for pharmacy compounding, V1.0, June 2013, P8.

such as FKA, to compound and sometimes dispense the required dose for the patient according to the physician's prescription. FKA's role in this process is to provide the chemotherapy product to the hospital or clinic for the patient, either by compounding the infusion or by both compounding and dispensing it.

Oncology medicines are 'high risk' and as such their preparation involves the use of potent pharmaceutical agents and hazardous compounding techniques. As highly toxic substances each chemotherapy infusion needs to be prepared for each patient and be tailored to that patient's disease state and body type including age, weight, sex, blood type and stage of medication cycle.

Undertaking such activities in a TGA-licensed manufacturing facility using aseptic techniques in a sterile environment with quality and sterility assurances is significantly more complex and costly than doing so in a non-licensed facility.

TGA licensing mandates that toxic substances are prepared according to world's best practice quality and sterility standards and assurances to ensure products remain safe and efficacious over their shelf life. This includes complying with the requirements of the *Therapeutic Goods Act 1989*; Therapeutic Goods Regulations 1990; Therapeutic Goods Orders (which detail technical requirements for specific groups of products); Therapeutic Goods of Australia's Good Manufacturing Practice Code (cGMP); Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 2013 (which adopts the International Pharmaceutical Inspection Co-operation Scheme (PICS) Guide to Good Manufacturing Practice for Medicinal Products, PE 009-8); and PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments PICs (PE010-3).

These requirements mandate adherence on a daily basis to complex and rigorous treatment protocols regarding dose changes, storage, specialized labour handling, air-handling, cytotoxic drug disposal, constant microbial monitoring, environmental systems, delivery, facility maintenance, sterile protective clothing, quality assurance and special operator training and re-training. All manufacturing is precisely defined and controlled. There is extensive validation to ensure consistency and compliance with specifications. Any changes to processes must be evaluated and changes impacting on drug quality validated. Instructions and procedures are comprehensive. Records must be made during manufacture demonstrating that all steps required by a defined procedure were in fact taken and that the quantity and quality of the drug was as expected. Deviations are investigated and documented. Records of manufacture enabling a complete history of a drug batch to be traced must be retained. A system must be available for recalling any batch of drug from sale or supply. Any complaints about distributed drugs must be comprehensively examined, the causes of quality defects investigated, and appropriate measures taken regarding defects to prevent recurrence.

TGA licensing also requires significant initial and ongoing annual investments by providers in establishing and operating the required sterile manufacturing infrastructure and operating and maintaining the sterile infrastructure and systems, including equipment maintenance, provision of clean rooms, staff and facility validation, stringent OH&S requirements, specialist staff training and retraining, quality assurance processes and TGA auditing costs.

As the demand for compounded drugs has grown worldwide in recent years, so has the number of adverse safety events. In the US there have been serious cases of error resulting from compromised compounding facilities and practices which have led to death and disability. Adverse events have also occurred in Australia. Whilst complex and costly to establish and run, TGA-licensed compounding facilities provide a level of safety and quality otherwise not assured[3].

Over the last two years FKA has experienced a significant impact across our business resulting from the PBS price disclosure reforms on relevant chemotherapy drugs first implemented in 2010. FKA is also absorbing increasing costs in our licensed manufacturing business from losses incurred in the preparation of some new innovative targeted cancer treatments, and in the areas of freight and ongoing compliance and reporting requirements.

In May 2013 the Federal Government announced a review of the funding arrangements for chemotherapy services to examine how much it should be paying to support the ongoing viability of the provision of chemotherapy medicines. The review is due to report to the Health Minister by October 2013 with the aim of introducing a new funding arrangement for chemotherapy services in 2014. This review followed the Government's implementation on 1 December 2011 of the Efficient Funding of Chemotherapy Drugs (EFC) program, concerns raised in 2012 about the impact of the price reduction of Docetaxel on the provision of chemotherapy medicines under the EFC as a result of price disclosure, and a recommendation from the resulting 2013 Senate Community Affairs Committee Inquiry into the Supply of chemotherapy drugs including Docetaxel.

While FKA supports the policy of price disclosure, the funding arrangements under the EFC program implemented in December 2011 do not reflect contemporary chemotherapy drug preparation practice and do not support future practice in the supply of chemotherapy drug services. Similar views have been put by other cancer medicine stakeholders[4]. As outlined in FKA's submission to the Senate Community Affairs Committee's Inquiry into the Supply of chemotherapy drugs such as Docetaxel:

- The "rolled up" single price does not recognise that the majority of chemotherapy suppliers are TGA licensed manufacturers and that one price does not fit all components of supplying drug services.
- The funding shortfall occasioned by the December 2012 price reduction of Docetaxel highlights the non-viability of the EFC model, for all stakeholders in the chemotherapy drug supply chain. Future price disclosure-related reductions on other drugs and cost increases in other areas will further highlight the model's non-viability and the ongoing knock-on impact this would have on third party licensed compounding manufacturers.
- The costs associated with TGA licensing and GMP compliance, the premium that is added in quality and safety assurance provided by licensed manufacturers and the threats to the sustainability of licensed manufacturers are not recognised in the EFC funding arrangements.

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[3] K Ridel and Y Alcindor, 6.3.13, "US compounding deaths" USA Today. National Coordinating Committee on Therapeutic Goods, April 2008.

[4] Submissions to the Senate Community Affairs Committee's Inquiry into the Supply of chemotherapy drugs such as Docetaxel, April 2013.

In FKA's view, future remuneration for the supply of chemotherapy drugs needs to:

1. Recognize that the functions involved in providing chemotherapy medicines to patients - 'dispensing'; 'clinical services'; 'compounding'; 'manufacturing' and 'licensed manufacture' - are in many cases different functions with different processes and degrees of complexity, risk, cost, compliance burden and safety and quality premium.
2. Accurately and transparently reflect the costs of each of these essential components of the chemotherapy drug preparation and delivery supply chain.
3. Pay an appropriate differential rate for each of these essential components, recognising the differences in risk, complexity and cost in each component.
4. Acknowledge the complexity and added safety and quality premium involved in preparing chemotherapy drug treatments in TGA licensed manufacturing facilities.
5. Structured in a way to incentivise ongoing value, rather than lowest price.
6. Consider the outcomes of the TGA's Review into the Regulation of Compounding to ensure compatibility in the future regulation and funding arrangements for the preparation and supply of chemotherapy drugs.

Licensed manufacturers are a key part of the cancer medicines supply chain. An understanding by decision-makers and stakeholders of the role of licensed manufacturers, and establishing appropriate remuneration for the future supply of cancer medicines, will assist the long-term sustainability of this sector and correspondingly support consumer access to cancer medicines.

Sincerely

Zita Peach
Managing Director

References

Department of Health and Ageing, Submission to the Senate Community Affairs Committee's Inquiry into the Supply of chemotherapy drugs such as Docetaxel, April 2013.

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