



7th February 2019

Regulatory Pricing and Review Section
Regulatory Support and Drug Control Branch
Therapeutic Goods Administration
PO Box 100
WOODEN ACT 2606

RE: TGA Consultation - Fees and Charges Proposal 2019-20

Dear Sir/Madam,

The Country Care Group (CCG) is Australia's leading provider of assistive technology (AT), AT contract management services and home modifications. Company owned stores include 11 retail sites with warehousing and distribution, servicing and hire product decontamination services, 3 manufacturing facilities and a centralised warehousing operation located in Melbourne. The trading names we operate under are "Country Care Group" and "K Care Healthcare Solutions". CCG/K Care manufactures AT locally and is an importer of an extensive AT portfolio. We are members of Assistive Technology Suppliers Australia (ATSA).

Through our various business entities, we have more than 150 Class 1 medical devices listed on the ARTG. We also regularly introduce new products to the Australian marketplace both through our internal R&D team and by international sourcing.

IMPACT OF THE NEW TGA FEES AND CHARGES REGIME

We are yet to fully model the impact of the significant increase in fees and charges on our businesses to register and maintain our range of Class 1 devices on the ARTG. However, the dramatic increase in the registration fees for new devices from \$0 to \$530 is beyond any reasonable person's expectation.

Whilst CCG/K Care may be able to absorb charges of this magnitude, many niche AT businesses focussing on specialist products will not. This will inevitably lead to businesses opting not to supply new and innovative devices into smaller, specialist markets and thereby reduce consumer choice. Although demand for such devices may be small in number, they often fulfil a critical need for those Australian who rely on them.

Continued increases in the renewal fee for new devices will only compound the problem and we cannot envisage any compelling argument for raising the annual fee. This simply adds to the costs of doing business, all costs which will inevitably be passed on to the consumer and government AT funders.

CCG/K Care is also disappointed with the lack of consultation from the TGA on such significant changes to the costs of listing Class 1 devices. This consultation is at best overdue and businesses large and small should have had more opportunity to comment much earlier.

URGENT NEED FOR AN UPGRADE TO TGA BUSINESS PORTAL FUNCTIONALITY

Following advice from ATSA, we are keen to see how CCG/K Care can legitimately rationalise our ARTG entries with a view to reducing the annual cost of renewals. For a business of our size and complexity this is no small task and we are cognisant of the need to ensure we comply with all relevant TGA regulations.

As a starting point, we need to export all ARTG data for CCG/K Care's various entries to allow for detailed analysis. However, the TGA business portal only enables a basic export of a very limited data subset (see below).

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Date	ARTG	Product	Product Name	Category	Sponsor
2018-09-27	309803	636322	R & R Healthcare Equipment Pty Ltd - Vibrator, genital	Class Iia	R & R Healthcare Equipment Pty Ltd
2016-08-28	279676	556561	R & R Healthcare Equipment Pty Ltd - Mattress,	Class 1	R & R Healthcare Equipment Pty Ltd
2016-08-26	279624	556475	R & R Healthcare Equipment Pty Ltd - Chair, bath/shower	Class 1	R & R Healthcare Equipment Pty Ltd
2016-08-26	279623	556474	R & R Healthcare Equipment Pty Ltd - Chair, bath/shower	Class 1	R & R Healthcare Equipment Pty Ltd
2016-08-26	279626	556476	R & R Healthcare Equipment Pty Ltd - Chair, bath/shower	Class 1	R & R Healthcare Equipment Pty Ltd
2015-09-30	260451	511930	R & R Healthcare Equipment Pty Ltd - Walking aid, one arm, crutch, axillary	Class 1	R & R Healthcare Equipment Pty Ltd
2015-04-02	235753	452138	R & R Healthcare Equipment Pty Ltd - Bed, general-purpose, electrical	Class 1	R & R Healthcare Equipment Pty Ltd

Additional data is essential to easily review CCG/K Care's ARTG entries including (as a minimum) manufacturer, GMDN Code and intended purpose. To obtain this information through the portal, it is necessary to individually open and print the certificate for each entry. The fact that the portal does not have a 'print all certificates' option only compounds the difficulties involved.

For a business the size of CCG/K Care, this means a significant cost in terms of staff time and there is the added risk of data transposition errors which could result in accidental noncompliance.

CCG/K Care urges the TGA to address these deficiencies in the portal as a matter of urgency so that businesses can sensibly rationalise their listings in an efficient and accurate manner.

If required, I would be happy to discuss these issues further on behalf of CCG/K Care.

Your sincerely,



Rob Hogan
Chief Executive Officer