REPLY BY KCI MEDICAL TO THE SUBMISSIONS MADE TO THE PANEL OF INQUIRY INTO THE PRIVATE HEALTHCARE SECTOR

Introduction

These comments are made in response to references in various submissions to the Health Market enquiry by the Competitions Commissioner to Designated Service Provider (DSP) arrangements between medical schemes and providers (of services), as per the provisions set out in the Medical Schemes Act. It is curious that no medical scheme or administrator has raised the matter of DSPs being appointed in the field of suppliers of goods, in particular medical devices, where this has become fairly common practice, with unintended consequences.

Most stakeholders have referred to DSPs as being a successful mechanism for providers (healthcare professionals and health facilities), or have objected to it not being strict enough, or in same cases, not unilateral enough. We believe that it is important that the Commission is in possession of information as to how *medical device* DSP arrangements work in practice and the impact it has on patients, their choices, care and ultimately the cost of healthcare.

About KCI

KCI, a member of the Acelity Group of Companies, is a member of the SA Medical Device Association that has made a submission in October 2014. KCI offers a wide range of clinically proven and cost-effective, high technology medical therapies designed to deliver positive clinical outcomes for patients and healthcare professionals in the field of woundcare. What distinguishes KCI from its competitors, and the devices industry at large, is the level of evidence it possesses to show the efficacy and indeed superiority of its products.

DSPs – Designated Service Providers versus managed care regulations

While we acknowledge the intent of such arrangements with service providers, defined as medical practitioners and providers of clinical services, we do not believe that suppliers of product (medical devices and/or pharmaceuticals) fall into the definition of designated service providers. We see the role of formularies as the correct tool for such arrangements, subject to the provisions in the regulations, which require the use of evidence based medicine, amongst other requirements.

The DSP legal framework is inadequate and inappropriate as a maanged care tool for devices. It cannot ensure that patients are protected, and that suppliers compete in a fair manner and on sound clinical principles. The medical schemes regulations permit medical schemes to, unliterally, “select” a DSP (regulation 8(2)). How inappropriate regulation 8’s DSP provisions are, become clear when one analyses the “exceptions” to DSPs, i.e. where the DSP is not available, is too far from the patient’s home or work, or where immediate care was required (regulatuon 8(3)). It is clear that DSPs refer to service providers viz. doctors, hospitals, etc. Its application to devices allows schemes to place a barrier on entry to the market, or parts thereof, without substantive criteria.

No additional or further criteria have been set for the appointment of DSPs. For medicines the law ensures adequate protection through the operation of the principles set out in the chapter on managed care (regulations 15, and 15A to 15J). These include:

- Formularies, protocols and disease caps must be set on the basis of evidence-based medicine. This ensures that schemes do provide cover for products that are clinically appropriate, researched and consider treatment guidelines, as well as patients' clinical needs.
- Provision must be made for exceptions in cases where the patient experiences, or would experience harm, on the products preferred by the scheme (e.g. there is / could be infection), as well as where there has been treatment failure (e.g. the wound did not heal adequately) or an adverse event (e.g. an allergic reaction to a product).
- Selection of products can be made, within what would be "evidence-based medicine" on the basis of cost-effectiveness (not cheapness or expensiveness) and affordability (budget-impact).

By using regulation 8(2), schemes avoid the protections afforded by regulations 15 and 15H and 15I, as well as avoid competition law criteria to ensure fairness in competition between suppliers of goods.

We contend that such agreements with suppliers may have unintended consequences that may have both a clinical and financial impact to patients and schemes, and overall the quality of care. Furthermore, such arrangements interfere with the doctor patient relationship in that a specific treatment plan may be overturned/changed/compromised due to a change in prescription where alternative therapies are enforced, or are the only option? It could also be deemed to be a manifestation of scheme market power, being price-setters and excluding competitors from the market.

What follows is a sequence of events that has been experienced by a specific supplier of advanced wound care product.

Consequences of using regulation 8 instead of managed care

Example 1: Flaws in the RFP process for device suppliers as DSP's

a. KCI was requested (only after an explicit request to participate was made) to submit a proposal to the specific scheme, afer hearing that the scheme was considering a DSP agreement with suppliers. The only explicit criteria required, apart from product and pricing information, were details on the national footprint of the supplier.
b. The supplier offered further information on clinical evidence; relative adoption of the technology; efficacy; differences in performance and intended purposes of various technologies; etc, although this was not requested by the scheme and did not appear to be important criteria to the scheme.
c. In the interim (i.e. before conclusion of this process), a 3 quote system is/was being used for price comparisons. No cost-effectiveness analyses were undertaken. Irrespective of differences in performance of the technologies, mention was made

by the scheme that as they wish to ensure members receive clinically appropriate services, are therefore not prescriptive regarding specific products/services a doctor may prescribe, but that they ultimately make funding decisions. If this funding is limited to the cheapest quote, members may elect to self fund alternative treatments.

d. The scheme revealed that all suppliers had been sent a request for proposal (RFP) in August of the previous year on products and services; but KCI responded never having received this RFP, but requested to meet as soon as possible to be given a fair opportunity to participate in this RFP.
e. Clarity was subsequently sought on whether a DSP had already been appointed prior to the RFP process being completed, as motivations for the product according to a specific treatment plan were being referred to an alternative supplier for substitution. At time of meeting this was refuted.
f. The RFP was submitted by the supplier, without any further opportunity to engage with appropriate clinical advisors within the scheme, where there was a clear need for this.
g. In the end, KCI was not apponted, nor dit it appeared to have been considered, as a supplier to the members of the scheme, and criteria relating to the clinical appropriateness, evidence and cost-effectiveness appear to not have been considered.

Exaample 2: Flaws and unintended consequences of appointing device suppliers as DSP's:

a. Motivations for this supplier's product are submitted via the schemes' pre-authorisation email portal. The scheme refers these motivations to their appointed DSP and state that if any product other than that from the DSP is preferred the patient is responsible for payment of the full(??) account.
b. The scheme expects the suppliers to communicate this to the doctors and do not seem to proactively engage with the treating doctors.
c. As PMB's, where the DSP cannot provide the service, it is pointed out that the treatment should be covered in full and without co-payment. Information is provided to the scheme regarding this being the only treatment available without comparators.
d. It is always recommended that any change in treatment plans and prescription should be verified by speaking with the treating doctor, and the schemes who want to change the treatment plans are required to do so.
e. The supplier also offers meetings with the medical advisors to discuss differences in therapies, as presented by qualified representatives and clinical opinion leaders, where the DSP could not provide the product.
f. These motivations are referred to a clinical advisor used by the scheme, but who in this instance is also an employee of the DSP and competitor supplier.
g. Requests by the treating doctors to discuss the case receive no response, nor does the scheme inform the doctors of the switch and/or change in treatment.

h. Approvals are in some cases eventually made, but with significant delay in treatment.
i. Where the supplier continued to engage with the scheme in the interests of the patients receiving the most appropriate care from their doctors, the supplier was warned to desist from this practice.
j. The unintended consequences from delays in approvals means extended hospital stays, delays in recovery and discharge, with potential catastrophic results if the DSP product is used, with an increase in health care costs. The scheme insists on referring all requests to their DSP, they will continue to make funding decisions and an appeals process exists should the members and/or doctors wish to use it.
k. Furthermore, there is a clear conflict of interest where the medical advisor being used by the scheme is also an employee of the DSP, who supplies a competitive product, and is paid for nursing services. This raises concerns about objectivity of the advisor whose recommendations, as a nurse, would override the treating doctor.

Conclusion

The informtion above is provided to show how the appointment of suppliers as DSPs lead to outcomes that are not in the interests of patients, are not based on clinical appropriateness and outcomes, and excludes players from the market.

For further information, please contact:

Charl Louw
Vice President and Managing Director
Acelity
24 Thornhill Office Park
94 Bekker Road
Midrand, 1685
Office: 011-3150445
Cell: 082-3788802
Email: clouw@Acelity.com