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ISPOR South Africa Newsletter 1

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ISPOR conference 2009 and PCMA short courses

The second annual congress of the South African chapter of the International Society for Pharmacoeconomic and Outcomes Research (ISPOR SA) was held from the 22nd to 24th of September, in conjunction with the short course health economics workshops, organized by the Pharmaceutical Care Management Association (PCMA).

Pharmacoeconomic evaluation and outcomes research have their own particular challenges in the South African setting, and the congress aimed at addressing some of these, as well as some practical approaches in the context of access to new medical technology.

This year, we were delighted by the presence of representatives of the medical devices industry amongst the 50 delegates. Also represented were the pharmaceutical and private funding industries.

The congress kicked off with a plenary lecture by our guest speaker from Milan, Dr Renato Dellamano, entitled "The Value of a Value Dossier". Dr Dellamano brought with him his vast experience in pricing and value arguments for pharmaceutical products, gleaned from his position of many years, as Head of Strategic Pricing at the global headquarters of Hoffmann-La Roche in Basel, as well as his subsequent work as a consultant to the global pharmaceutical industry as President of Value Vector, a consultancy based in Milan, Italy. Dr Dellamano offered his audience some important insights into the structure of a value argument and the processes to follow to best develop a value argument and documentation for presentation to reimbursement decision-makers.

Following up on this, Dr Anban Pillay (DoH), discussed the Department of Health's eagerly anticipated proposed guidelines for economic

analysis. Dr Pillay addressed the key areas for inclusion, in an economic submission, and outlined the proposed content in detail. Dr Pillay suggested that the publication of guidelines had been delayed as a result of the significant influence of the pursuit of legislation for the proposed National Health Insurance scheme, but that the basic structure for economic analyses would remain, even in this instance going forward.

Dr Trevor Terblanche (South African Medical Association – SAMA) followed, with the views of the South African Medical Association on the proposed national health insurance scheme. SAMA recognizes the intentions behind the government's proposal and emphasizes the necessity of stakeholder involvement in order to ensure the retention of the best skills in both the private and public sectors. Dr Terblanche discussed the example of the Eastern

Cape Independent Practitioners Association (ECIPA) as a model of a provider-driven, aligned-rewards, value-based decision-making medical care system.

Kirti Narsai (PIASA) presented the results of the Health Economics Survey, conducted by PIASA and the PCMA, during 2009, which had aimed to establish the level of skills in the areas of pharmaco- and health economics, and contribute to the understanding of training needs going forward.

Respondents to the survey had been largely from the pharmaceutical and devices sectors, and most respondents had no formal qualifications in health- or pharmaco-economics. The survey suggested that major concerns amongst the respondents was the lack of national standards for PE and HE evaluations, as well as the absence of guidance from the Department of Health. There seems to be a generally good understanding of technical issues, but still a need for ongoing training programmes.

Panel Discussion – Does South Africa need a NICE? (National Institute of Clinical Excellence)

The United Kingdom's National Institute of Clinical Excellence has created much provocative debate in the UK regarding their decisions and guidance and the processes followed in their recommendations. Several other countries have similar bodies, which perform clinical and health economic review and make recommendations for the nation. The issue of whether or not such a structure is necessary and feasible in the South African context was addressed. The panel for the discussion comprised Professor Marc Blockman (University of Cape Town), Jacques Snyman (ISPOR Chair), Gavin Steele (Management Sciences for Health) and Hasina Cassim (Discovery Health).

Ms. Cassim discussed the experiences of HEAL - Healthcare Evaluation and Leadership Institute, which was conceptualized within the private sector in 2006, in response to the increasing numbers of new and expensive technologies entering the South African market. The intention behind HEAL was to represent an independent decision-making body, although it

unfortunately lacked government support and guidance, which differentiated HEAL from the NICE structure in the UK. This resulted in challenges to find common ground, as well as to giving the Institute credibility for such decisions.

Professor Blockman was upbeat at the idea of a SA NICE. Taking a very pragmatic approach, in the context of South Africa's skills availability as well as funds available for such an institute, Prof. Blockman discussed the successes and limitations in the experience of international models, similar to NICE, and addressed some of the challenges that SA would also be facing under the recommendations of such an institute. In conclusion, Prof Blockman suggested that a practical team approach is required, involving a transparent process, but not always involving a formal cost-effectiveness review. ISPOR would provide the perfect platform to drive such an initiative – one of the major challenges to such a process is the lack of capacity and skills.

PCMA Short courses

The PCMA organised the short course workshops to run alongside the ISPOR congress, and three very topical issues were addressed:

Risk sharing agreements, Biotech and pharmaceutical pricing, and patient registries.



**Pharmaceutical Care
Management Association of
South Africa**

Workshop 1: Risk Sharing

Dr. Jacqui Miot kicked off the risk sharing workshop with a thorough review of the reasons behind why risk sharing agreements are coming to the fore both internationally and locally, and gave some insights into examples of risk sharing models the world over, including successes and challenges experienced along the way.

Shelley McGee (Discovery health) presented on a local model for risk sharing agreements – which are particularly problematic in the South African setting because of regulations around pharmaceuticals. Discovery Health has been approached by several companies to consider risk sharing agreements for submission to the Department of Health, and Shelley elaborated on the structure and principles behind the proposals so far, as well as where these seemed to promise success in terms of both improved access and capturing of outcomes data, as well as where the challenges had been experienced.

Gavin Steele, speaking on behalf of the Department of Health, gave a thorough review of what sort of risk sharing proposals would be deemed acceptable to the DoH. Access remains one of the most important

elements of the DoH drug policy – Gavin elaborated exactly what the DoH understands access to pharmaceuticals to mean, and whether the proposals which have been put to the department address their requirements in this respect. He then gave some insight into the processes around risk sharing agreements, which are complex, and involve multiple stakeholders. He finished off with some alternative strategies for access. Currently the regulatory environment would serve to block many models based on international risk sharing structures – consultation on amending the current legal structure would have to be broad and extensive and exemptions from the pricing provision of Act 101 would have to be made.

Depending on one's definition of risk sharing, there are seemingly few models which have yet been successful in South Africa, both because of lack of agreement between parties involved, as well as regulatory constraints and lack of guidance. Several examples of access models other than pure risk sharing have been successful, however, and may pave the way for these types of reimbursement agreements.

Workshop 2: Biotech pricing

The second day of the PCMA workshops began with a workshop and discussion of the pricing and value arguments for pharmaceuticals and biotechnology.

Dr Renato Dellamano (Value Vector and Medical Marketing Europe) presented the address he is to

deliver at the ISPOR Europe conference in October 2009, adapted for the South African group. Dr Dellamano provided valuable insight into pricing approaches and the art that is pricing, worldwide. He emphasized the importance of consideration of the different prices quoted in overseas contexts,

particularly pertinent when it comes to comparing prices to those internationally. Dr Dellamano discussed how drugs are a major focus of cost containment policies, and how international reference pricing has influenced the markets in the developed countries. At the request of the delegates, he went into the specific example of Canada's pricing and pharmaceutical reimbursement, and the role of CADTH and health technology assessment in the country.

Tanya Davies (Nycomed and Innovative Medicines South Africa - IMSA) elaborated on the value of medicine in the South African context. Tanya presented statistics to put medicine costs into perspective in the overall health care spend in South Africa, and show that Single Exit price medication is not the cost-driver behind health care expenditure. IMSA's view is that medicines are cost-effective

Workshop 3 - Patient Registries

Possibly the most interesting of the congress, this workshop received input from numerous stakeholders, as well as the input and wisdom from local experience with registries and their utilisation

The basics of registries and essential components for registries were covered by Dr. Jacqui Miot, who elaborated on the types of real world data, and types of registries available internationally. Dr. Miot then further explored some of the uses of the data from registries as well as the challenges that have been experienced worldwide, where registries are in operation.

E2 Solutions is seen as the market leader in the healthcare space for developing innovative e-business solutions and supporting services. Director, Eric Stokes spoke about E2's involvement in facilitating and housing some of the patient registries which are already up and running in South Africa, providing some valuable and practical insights into how these ideas can be operationalized into user friendly and indispensable data-capturing tools.

One of the most well-known registries in South Africa is that of the South African Rheumatism Arthritis Association, for biologics for patients with rheumatological conditions. Dr. Elsa van Duuren,

interventions, helping to control hospital and ambulatory costs, and that costs of medicines can not be considered without considering the outcomes achieved from these interventions.

Gavin Steele emphasised the challenges in pricing biotechnology, as well as the many issues around value-based pricing in South Africa. Currently, there are no specific provisions for value-based arguments in SA, but as implementation of policy develops, Gavin stated that these will most certainly have to be investigated.

SARAA president, spoke about SARAA's registry, as well as the plans for the data collected and the registry going forward, and provided some valuable insights into registry planning and the value of appropriate parameters in setting up a registry framework.

The registry of the South African Oncology Consortium has only been running since 2006, but registry entry is essential for reimbursement on the oncology benefit of medical aids in South Africa. Dr Miot presented an analysis, on behalf of Dr. Samuel Fourie, on the budget impact of new treatments for renal cell carcinoma, for which the SAOC had used their database of registered patients, and extrapolated the potential impact using monte carlo simulations. The results of the analysis suggested a significant budget impact to funders, were all eligible patients to be treated with the new agents, although additional analysis would be required to assess such factors as opportunity costs and costs over and above current standards of care.

Francois Wessels provided some fascinating insights into the use patient records, extracted from a hospital database, used to perform a cost-benefit analysis of antibiotics in an ICU setting. Francois explored in detail the methodology, data and results of the study,

demonstrating a practical and meaningful application of in-hospital patient outcomes to a health economics study.

Thanks again to all our sponsors, guest speakers and delegates for your contribution to the success of the Congress!

ISPOR SA into the future

The content of this year's congress brought to the fore that understanding the theory behind health economic evaluations is not sufficient on its own in the South African context. We are still in need of practical guidance and solutions to the dilemmas around pricing, access, reimbursement and value arguments.

The AGM held at the congress helped the board in getting input from members as to where we need to place the focus of the society, and what the priorities are for the coming year.

Addressing these issues becomes the mission of ISPOR SA going forward. Look out for upcoming projects and working groups for 2009/2010 – we are excited about the challenges ahead and welcome new members and input from all stakeholders.

The current ISPOR board consists of:

- Jacques Snyman (Agility Health Solutions)
- Kirti Narsai (Pharmaceutical Industry Association of South Africa – PIASA)
- Jacqui Miot (University of Pretoria)
- Fuad Salie (Pfizer Pharmaceuticals)
- Mark Brand (BrandTech Healthcare Technology Consulting)
- Huib Schejbel (Wyeth Pharmaceuticals)
- Shelley McGee (Discovery Health)
- Joubert Krugel (Medtronic SA)

ISPOR SA Congress 2010

The 2010 Congress has been planned to take place during the week of 13th to 20th of September 2010. Official notification will be going out soon – please make a note of the dates in the interim.

Future events will include:

- Working groups suggested at AGM as well as way forward
 - Thresholds and QALY working group
 - Interaction with Government and Private funder stake holders
 - Closer association with Academic Institutions
 - Value guarantee for members