

Conflict of interest and regulatory authorities

To the Editor: Parrish and Blockman^[1] make excellent points about conflict of interest (COI), particularly in the context of 'medical leadership'. As key opinion leaders themselves (both are members of the National Essential Medicines List Committee (2013 - 2015), as is the second signatory to this letter – the term does not imply membership of an advisory panel to any for-profit vendor of health-related goods or services), the authors are well placed to make comments. An aspect of COI not considered in their article relates to regulatory authorities.

Managing COI effectively is a regulatory concern internationally.^[2,3] The most explicit legislation about COI, of all the Acts controlling statutory health councils, is the Medicines and Related Substances Act.^[4] Section 6 of this Act has the heading 'Disqualifications, vacation of office, filling of vacancies and declaration of interest'. Subsection 1(d) unequivocally states that 'No person shall be appointed as a member of the council – who is employed in the pharmaceutical industry.' Parrish and Blockman point out the shortcomings of 'disclosure' as an intervention for dealing with COI. The Medicines Act goes further than disclosure, and demands, in sub-section 6(4), that a Council or Committee member '*shall* recuse' themselves 'from any discussion or decision-making to which the said interests relate or may relate'^[4] (our emphasis).

Unfortunately these clear directives do not appear in the Medicines and Related Substances Amendment Act, 2008 (Act 72 of 2008), or in the Medicines and Related Substances Amendment Bill (Bill 6 of 2014). Once brought into effect, these legislative instruments will replace the Medicines Control Council with a South African Health Products Regulatory Authority (SAHPRA). Section 34, the 'preservation of secrecy' clause, remains, as do deficiencies in the description of the roles of advisory committees; and whether their advice to the authority will routinely be made public (with the necessary redaction of commercially sensitive information).

It is vital that the employees of this new authority should not have any commercial interests related to the pharmaceutical, foods, cosmetics, medical devices or *in vitro* diagnostics industries. The members of 'expert committees' envisaged for the new authority should not be employed by these industries. Apart from declaring their interests, members of such committees should recuse themselves from 'any discussion or decision-making to which the said interests relate or may relate'. Whether or not such members actually leave the room for the duration of such discussion should be a policy decision of SAHPRA. How transparently declarations of COI are shared publicly also requires careful consideration.

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1. Parrish A, Blockman M. Who will guard the guards? Medical leadership and conflict of interest in South African healthcare. *S Afr Med J* 2014;104(11):757-758. [<http://dx.doi.org/10.7196/SAMJ.8546>]
2. Watson R. European Medicines Agency is accused of weakening its conflict of interest policy. *BMJ* 2014;349:g7431. [<http://dx.doi.org/10.1136/bmj.g7431>]
3. EMA. European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts. EMA/626261/2014. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/11/WC50017253.pdf (accessed 17 December 2014).
4. Medicines and Related Substances Act, 1965 (Act No. 101 of 1965). http://www.mccza.com/genericDocuments/Act_101_of_1965_published_2003.pdf (accessed 17 December 2014).

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