COMMENT: THE MANAGEMENT OF ENL: CURRENT AND FUTURE OPTIONS

The above titled Editorial[1] makes reference to a 'Guideline for the clinical use and dispensing of thalidomide' by Powell & Gardner-Medwin, reprinted in this issue.[2]

Given the legitimate and justified concerns of many clinicians and the public generally, it is commendable that such guidelines for the use of thalidomide be drawn up and strictly adhered to. However, I would argue that these guidelines are only appropriate in their current form for use in the European clinical environment where the commitment to follow and closely monitor is likely to be more effective and reliable. In other parts of the world, particularly in Brazil, the evidence in recent years of misuse and abuse of thalidomide would lead me to caution against the unquestioning adoption of such consensual guidelines as a solution per se.

Thalidomide has been shown to be effective in over 90% of Type II leprosy reactions (ENL) and this accounts for most of its current use world-wide.[3] In Brazil in particular there remains widespread use of thalidomide in treating ENL and it appears that guidelines for its safe use have proven ineffective. In 1994 a survey by MORHAN (Movimento de Reintegração do Hanseniano) with the support of the Brazil National Leprosy Programme showed that of 31 cases of thalidomide syndrome, 55% resulted from the prescription of thalidomide to women of child-bearing age despite prohibition of its prescription to such women since the 1980s. The other 45% of cases I assume result from thalidomide either being purchased privately or unwittingly passed on to women from male patients. Either way, guidelines to ensure the patient has full access to information were clearly not enough. In July 1994 the Brazilian Ministry of Health passed a further decree prohibiting the prescription of thalidomide to women of child-bearing age and stating that there would be no exemption from legal sanctions for any medical professional flouting this decree. The effectiveness of this decree and sanctions needs to be continuously evaluated.

R.J. Powell argues that 'it is preferable that (thalidomide's) clinical use should be regulated by guidelines rather than law.' Clearly in the Brazilian context this is not enough. I accept that it is difficult to legislate for good practice when there will always be health professionals whose standards of patient care and provision of information to patients are poor. But by legislating for prescription on a named patient basis only with obligatory written consent, some of the problems of negligent medical practice may be overcome. In any event, such guidelines would need to be adapted for a cultural context in which patients are less likely to question a health professional; or indeed may be illiterate. Much more stringent controls would need to be built in to ensure that good practice becomes the norm.

On a separate but related point concerning thalidomide, Jakeman & Smith[4] refer to an earlier article by Hastings,[5] which states that 'the teratogenic and the anti-inflammatory effects of thalidomide are separable in derivatives of the drug'. To a lay person this would seem to provide the natural solution enabling the prevention of further tragedy. My assumption as to why this option has not been taken up is that such technical development is not profitable to the pharmaceutical companies. Perhaps since thalidomide is becoming increasingly used in the treatment of AIDS-related illness this constraint of nonprofitability might be removed to the eventual benefit of the leprosy world.

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References

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[3] Sheskin quoted in Powell RJ. New roles for thalidomide. *Brit Med J*, 1996; **313:** 17 Aug.
[4] Jakeman & Smith Thalidomide in leprosy reaction. *The Lancet*, 1994; **343:** Feb 19.
[5] Hastings R. *Ethiopian Med J*, 1980; **18**.