

What's Wrong with the Therapeutic Goods Amendment Bill, 2005 ?

Term B : Adequately distinguish between natural medicines and synthetic drugs ?

Natural medicines (called complementary medicines by drug based medicine) are usually listed on the Australian Register of Therapeutic Goods (ARTG), and prescribed synthetic drugs are nearly always registered there.

This division reflects the fundamental division in modern western medicine, namely between natural and conventional medicine. Good regulation must reflect this fundamental difference. Does this Bill reflect this difference ??

Low Risk Nature. Natural medicines, like herbs, vitamin and mineral supplements and low potency homeopathics (<10X, <10C), usually have minimal toxicity in doses recommended by the supplier. They are like food, and indeed are regulated as food in many other countries. Moreover, they work by nurturing and supporting the bodies defences and vital organs, not by synthetically manipulating the physiology and related functions. So they are low risk with respect to toxicity and 'side effects,' compared to prescribed synthetic drugs.

So a supplier (or Sponsor) of natural medicines is far more likely to do good, not harm, when they supply the correct ingredients, without contamination, with appropriate dose recommendations.

So why should fines of \$3 million to \$5 million be imposed, when no real harm has happened, for offences like –

Sect 14A - Import or supply a natural medicine without TGA permission ?

Sect 20A - Supply a natural medicine without telling TGA who made it and where ?

Sect 21B (1) - Make a misleading statement with respect to certification ?

Sect 21B (2) - Breach a listing condition ?

Sect 21B (3) - Present a natural medicine as being listed on ARTG or approved when actually it's not ?

Sect 31 AAA - Provide false information when listing your natural medicine ?

Sect 35A (1,2) - Manufacture a natural medicine without a licence, nor exemption ?

Sect 35C - Breach a licence condition ?

An appropriate solution is already given by other parts of this Bill. These add an extra condition before an offence is committed, namely – will or might harm be caused to the consumer by the offence ?

What these offences might mean.

A listing condition might mean quoting therapeutic info from the British Pharmacopea (BP), and not quoting an eminent practitioner, researcher and pioneer of herbal medicine. (sect 21B (2))

A licence condition or standard might require expensive lab testing of each batch of herbs for microbial levels or 'active ingredient' (sect 35A (1,2) & 35C & 14A)

A wholesaler might not seek a licence because they believe their produce should be and will be regulated as food, not therapeutic goods. (sect 35A (1,2))

Therapeutic info quoted from sources other than the BP might be deemed misleading information. (sect 21B (1))

Assessing Risk of Harm A doctor has real expertise in drug based medicine, but this is not natural medicine. It is essential when assessing the risk of harm from natural medicines to consult experts in natural medicine, and not some other discipline.

Size of Company. Why should a small supplier of natural medicines, employing only five to ten people, be hit with the same fine as a trans national pharmaceutical corporation ?

Term D : The need for establishing appeals mechanisms.

Certainly, when the fine threatened is many times bigger than annual income or assets of the company, a wholesaler of natural medicines needs to have recourse to an appeals mechanism that actually works

Clearly, this Bill is geared towards prescribed synthetic drugs. It is not appropriate for listed therapeutic goods like natural medicines.

Mike Browning

The Therapeutic Goods Amendment Bill, 2005 (Sept) How It will Increase Penalties for Natural Medicines.

Section	Offence	Existing Penalty	New Penalty
14	Import or supply a non std NM	1,000pp 1 yr jail	
14	Import or supply a non std NM which will harm b/c it's non std	-	4,000 pp, 5 yr jail
14	Import or supply a non std NM which might harm b/c it's non std	-	1,000 pp, 1 yr jail
14A	Import or supply a non std NM without TGA permission	1,000 pp 1 yr jail	5,000 pp for indvd 50,000 pp for corp
20A	Supply a NM without telling TGA who made it or where	1000 pp 1 yr jail	5,000 pp for indvd 50,000 pp for corp
21A (4)	Make misleading statement wrt certification	-	1,000 pp, 1 yr jail
21B (1)	Make misleading statement wrt certification	-	5,000 pp for indvd 50,000 pp for corp
21A (8)	Breach a listing condition	60 pp	1,000 pp, 1 yr jail
21B (2)	Breach a listing condition	60 pp	5,000 pp for indvd 50,000 pp for corp
21B (3)	Present a NM as being listed on ARTG or approved when it's not	60 pp	5,000 pp for indvd 50,000 pp for corp
31 AAA	Provide false info when listing your NM	-	5,000 pp for indvd 50,000 pp for corp
35A (1,2)	Mfr a NM without a licence, nor an exemption	1,000 pp 1 yr jail	5,000 pp for indvd 50,000 pp for corp
35B (4)	Breach a licence condition	60 pp	1,000 pp. 1 yr jail
35C	Breach a licence condition	60 pp	5,000 pp for indvd 50,000 pp for corp

'Existing penalty' is the penalty in the Therapeutic Goods Act, 1989. 'New penalty' is the one in this Bill.

NM = natural medicine, pp = penalty point = \$110 fine, indvd = individual, corp = corporation, ARTG = Australian Register of Therapeutic Goods

Note. This Bill is 100 pages long, and the Act is 300 pages. The Bill increases the penalties to the 5,000/50,000 pp level (or 3,000/30,000) for many other offences, but in these sections a new condition is added to the Act before offence is committed, namely - Will or might harm be caused ?

This version of the Bill, which is before Parliament, has been on www.aph.gov.au under the Bills List for a month. It has some different penalties, and many differences in the numbering, to the version that has been on the activist website www.nzhealthtrust.co.nz for many months. Search www.comlaw.gov.au for Therapeutic Goods Act, 1989 using Google. Compare Act with Bill.

This Bill, if passed, is likely to become the basis for the new regulator of medicines; the JTA, planned to replace TGA before June 2006.

These massive penalty increases, to \$5 million fine, are appropriate to trans national pharmaceutical corporations (drug TNC's), but are quite unfair and impossible to the many small wholesalers of natural medicines that employ only 5 to 10 people.

A listing condition might require quoting therapeutic info from the British Pharmacopea, and not quoting from a leading practitioner, researcher and pioneer of herbal medicine. A licence condition or TGA standard might require lab testing all batches of herbs for microbial levels or 'active constituent'. Are the above penalties appropriate to such minor offences ???

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