

→ WHEN IS A MEDICINE NOT A MEDICINE?

OFF-LABEL USE OF MEDICINES

Medicines¹ are considered to be among the tightest regulated products in the world. →



They are licensed, for specific conditions, only after exhaustive trials. Manufactured to the highest standards and prescribed only after a consultation with a professional who has spent many years qualifying to practise, they are finally dispensed by another well-qualified professional, in strictly regulated conditions. That is the theory and in the vast majority of cases, the reality.

Physicians in Europe can prescribe medications 'off-label' (unlicensed). In the UK, according to the British General Medical Council, off-label prescriptions must better serve patient needs than alternatives and must be supported by evidence or experience to demonstrate safety and efficacy.²

However, it isn't always so. On occasion, decisions can and have been made that exploit loopholes and subjectivities in the above system. A doctor may decide to prescribe to a twelve year old, a product unlicensed for use in children, because there is no licensed alternative. A surgeon may decide that, as two medicines seem at first sight similar, an unlicensed one might do the same job as a licensed one (particularly if the former is much cheaper).

Tragically, people have died as adverse event reporting systems can fail to pick up critical side effects. This is because prescribing medicines not for the original licensed indication, in practice, for a number of reasons, fall out of the adverse event reporting system and may therefore not be recorded properly. The consequence of this is that proper analysis and action may not be deemed necessary or legally binding by those involved.

An example to highlight to risk of using unlicensed medicine occurred in France, where a medicine for treating obesity in diabetic patients was, until it was finally banned, routinely prescribed for general weight loss in non-diabetic patients. The French authorities estimate between 500 and 2,000 resultant deaths.³

This is not an isolated case. Neovascular (wet) age-related macular degeneration (AMD) is probably the leading cause of blindness in the elderly population in the developed world. It is a disease which slowly impairs the eyesight but it is not a deadly disease. Yet many doctors, instead of using the licensed product, are using a medicine called Avastin™ which is designed

for use in cancer patients. Avastin is not available in the right dosage for AMD and is not supposed to be injected in the eye – it is not licensed for this indication.

This practice is endangering patient safety: between 2007 and 2009, newspapers and studies reported clusters of adverse reactions including complete vision loss and higher risk of stroke,^{4,5} however the full extent remains unknown.

Ethical and best medical practice includes prescribing and dispensing only with the best interests of the patient in mind, and with the patient fully informed and involved in the decision-making process. When that best practice is compromised, those with the biggest vested interest, the patients, are left at serious risk.



Of course, it is entirely legitimate and acceptable to decide to modify a treatment regimen taking into account the financial implications, after discussion with the patient and considering the patient safety implications, but it is not acceptable when:

- ▶ The patient (or indeed the doctor) is ignorant of decisions affecting the patient's health
- ▶ The mutual bond of trust between patient and healthcare provider is broken through omission to fully inform
- ▶ That trust just becomes a one-way street

In any event it is wholly unacceptable when such an action compromised patient safety – with or without our consent.

- 1 → Throughout the report, the term 'medicines' is used in a non-technical manner and mean all products designed for healthcare usage, including medical devices and pharmaceuticals
- 2 → Good practice in prescribing medicines – guidance for doctors. General Medical Council; www.gmc-uk.org/guidance/current/library/prescriptions_faqs.asp#5d Last accessed: 30.03.11
- 3 → Mediator scandal rocks French medical community. *The Lancet*; [www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)60334-6/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60334-6/fulltext) Last accessed: 30.03.11
- 4 → <http://wissen.spiegel.de/wissen/image/show.html?did=60666870&aref=image038/2008/09/27/ROSP200804001400141.PDF&thumb=false>
- 5 → Carneiro AM, Barthelmes D et al in *Ophtalmologica* 2011, <http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowAbstract&ArtikelNr=323943&Ausgabe=254908&ProduktNr=224269>