PATIENT INFORMATION ON DRUGS

Just another form of advertising?

Having followed the heated debate on proposed changes to European drug advertising legislation, I cannot help but notice a familiar ring to Shaw’s endorsement of the European Union’s patient information initiative, including her many uses of the words information, factual, and regulated, but infrequent mention of advertising.1

The initiative’s provisions to make approved patient leaflets, monographs, and European public assessment reports more accessible are uncontroversial; easier access is a boon. It is the increased leeway for industry to produce overtly or covertly promotional websites that raises a red flag, whether or not these are pre-vetted.

Shaw castigates opponents to this proposal as “uncomfortable with the idea of empowered patients,” without noting the universal opposition among non-industry funded European consumer and patient groups, the very sector that champions consumer health rights. Shaw chairs DataPharm, funded by “about 190 pharmaceutical companies.”4 Her main argument seems to be that the EU proposal is too timid because of “its anxiety to restrict the drug industry.”5

Why be anxious? It is worth looking at other countries’ experiences. Canada has partially subverted its ban on prescription drug advertising, to restrict the drug industry.”6

The German situation shows that they are right about the difficulty of the control of information by well intentioned health professionals is unhelpful to patients.

Research by academics, such as Theo Raynor at Leeds, shows that health professionals’ (doctors, nurses, and pharmacists) assumptions about the information that patients want about drugs is consistently wrong.

British patients and the public prefer to be able to get such information from a range of providers than from one single approved source—in the ratio of about 80:20 (Medicines Partnership research).

The German situation shows that they are right to be suspicious of a single authorised version. The German consumer drug bulletin mentioned by Dr Mintzes is a great publication, but it is a magazine, not a reference source. German patients are still hugely frustrated at their inability to access basic information about drugs.

Inevitably, failure to allow companies to provide regulated, objective information in European languages drives more confident patients to US sites—24% of German web users and 22% of Italian users, according to Datamonitor—while leaving less confident ones in an information black hole.

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Competing interests: JS is chairman of Datapharm Communications, which publishes Medicine Guides.

Legislation is no masterpiece

The draft European legislation on patient information on prescribed drugs enthusiastically received by Shaw is far from being a masterpiece.1 It does little to meet the real needs of patients and consumers but goes a long way to soothe the requests of “reputable information providers” such as the pharmaceutical industry. No wonder that so many have been critical of the use of the term patient information to disguise proposals that include substantial amendments to pharmaceutical advertising regulations.

The main criticism is that the proposals do not provide patients and consumers with unbiased, comparative information on health and medicines, or address inequities in information access.

Shaw also seems to have overlooked the legislative co-decision procedure. This legislation has not been adopted into law: it has been endorsed by the EU parliament and is being revisited by the European Commission but it will need to be discussed by the European Council. The council has already expressed concerns: “The distinction between ‘information’ and ‘advertising’ is not sufficiently clear. . . . the proposals will not provide sufficient guarantees that the prohibition of advertising of prescription-only medicinal products to the general public will not be circumvented.”5 It is likely to hear the public’s concerns and just say no.

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Competing interests: None declared.

Author’s reply

I support Mintzes’ concern about protecting the public from covert drugs promotion. But her fear and dislike of the drug industry has blinded her to the realisation that the control of information by well intentioned health professionals is unhelpful to patients.

Research by academics, such as Theo Raynor at Leeds, shows that health professionals’ (doctors, nurses, and pharmacists) assumptions about the information that patients want about drugs is consistently wrong.

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Inevitably, failure to allow companies to provide regulated, objective information in European languages drives more confident patients to US sites—24% of German web users and 22% of Italian users, according to Datamonitor—while leaving less confident ones in an information black hole.
US. Why are US drug companies lobbying against Pharmac when the New Zealand drug market is insignificant in global terms? Pharmac’s success has probably made it a target.

Pharmac operates within a set budget, which by law it cannot exceed, while striving to fund the most appropriate range of community drugs possible. Strategies include preferentially funding generic drugs, forcing drug companies to tender for the right to have their brand subsidised, and reference pricing. Importantly, Pharmac has to subsidise only (at least) one drug within each therapeutic subgroup, so it does not have to list higher priced drugs that have no significant benefit over others in the class. Patients still have access to drugs that are not listed, but at their own expense.

With a community drugs budget of around $NZ2700m (£1367m; €1313m; $613m) a year, tough price negotiating and other strategies by Pharmac save the health system more than $NZ2300m a year. It is clearly why drug companies are keen to shake Pharmac and obstruct the spread of this successful model to other countries. According to Organisation for Economic Cooperation and Development data, per capita spending on drugs in New Zealand is less than a third of that in the US, and half of that in Australia. This does not seem to have been at the cost of health outcomes (life expectancy is two years greater in New Zealand than in the US).

Ironically, the US health system could become more efficient by adopting the Pharmac model.

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Competing interests: None declared.

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3. Organisation for Economic Cooperation and Development. OECD health data 2011—frequently requested data. www.oecd.org/document/16/0,3343, en_2669_34631_2085200_1_1_1_1,00.html.

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WARNINGS ON TOBACCO PACKETS

Is your MP concerned about public health?

WHO has pledged to urge more countries to adopt large graphic health warnings on tobacco products because countries vary greatly in the use of such warnings.

Canada was the first country to implement health warnings on cigarette packages in 2001, long before the Framework Convention on Tobacco Control, which came into force in 2005. The convention called for health warnings on tobacco packaging to cover at least 30% (ideally 50% or more) of display areas.

France was only the 39th country to enforce the recommendation about pictures on packages (in 2011) because the government allowed the industry an unbelievable two years for discussions plus one year delay for the sale of stock. In addition, the required size of the picture is only 30% of the front and 40% of the back.

In March 2010 Uruguay became the first country to require 80% of the package to be given up to health warnings. The effectiveness of such warnings in stopping the deadly tobacco pandemic is demonstrated by the fact that the giant Philip Morris International (market capital of $107bn; £65.5bn; €75bn) has filed a complaint with the World Bank’s International Centre for Settlement of Investment Disputes against the small but courageous Uruguay (gross domestic product of $44bn).

Health warnings on cigarette packs are a powerful tool for tobacco control. But their size may turn out to be the result of a complex balance between MPs’ concerns about public health and the influence of the tobacco lobby.

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Competing interests: AL is a senior tenured consultant in public health, was sacked by the French Department of Health against the advice of the National Statutory Committee. GD is being sued for libel by the French Tobacconists Union (Tobacco Control Blog 8 November 2010 http://blogs.bmj.com/hc/2010/11/06/). Jo Zarocostas L. WHO urges more countries to adopt large graphic health warnings on tobacco products. BMJ 2011;343:d4237. (7 July.)


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DENIAL IN ASSISTED DYING

So, farewell then, doctrine of double effect

Spence offers the cases for and against assisted suicide in a balanced way that is often lacking in such debates. He then raises the issue of double effect as a result of strong opioids. This is important because, if this effect exists, many doctors stand accused of the hypocrisy of not supporting assisted suicide while regularly hastening death.

Opioid overdose (whether deliberate or unintentional) can have serious adverse effects, including agitation. However, when opioids are correctly prescribed they do not hasten death and there is no need to invoke the doctrine of double effect to justify their use. Opioid dose requirements cannot be predicted so, to avoid adverse effects, doses should always be titrated to the individual. As for where the dividing line exists, this was finally resolved in a General Medical Council decision last year that clearly distinguished between safe and dangerous prescribing of strong opioids. There are no circumstances in which the prescription of a lethal dose of opioid is necessary to control suffering, and therefore there is no need to invoke the doctrine of double effect.

Double effect with opioids is a perennial myth that has been used to defend unsafe prescribing.

A balanced debate on assisted suicide that continues without this confusion is long overdue.

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Competing interests: All the co-signatories are senior clinicians in palliative care.


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My experience with euthanasia

As a Dutch GP I would like to share my personal experience. In the Netherlands euthanasia and terminal sedation are allowed under very strict rules.

I am experienced in delivering palliative care. I have been asked dozens of times whether I would...
be prepared to perform euthanasia if there was no other option. I only had to do it twice.

Terminal sedation feels more “natural” because it is performed only if all other options to relieve symptoms fail and life expectancy is less than two weeks. High doses of a sedative (usually midazolam) are given to ensure that the patient is free of pain until nature takes its course.

Although as a doctor I favour euthanasia, as a person I find it hard to perform. It is a great burden on my personal life and causes me extreme stress. The days before I performed my second (and so far last) euthanasia were very emotional. I shifted between enjoying life and extreme sadness that life had nothing to offer my patient that could make up for the suffering she experienced.

There is also the stress of doing it right and waiting to see whether the committee decides you abided by the rules and will not prosecute.

Euthanasia law grants a patient the right to determine what is and is not psychologically and physically bearable. As a doctor I sometimes feel caught between my desire to do well and the fact that I have to be the means to a patient’s self-determination.

I wanted to be a doctor to help patients, not to kill them.

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Competing interests: None declared.

I hold no brief for the drug industry but must point out that no single organisation determines the NCD Alliance’s policy. No commercial organisations participated in the recent Moscow global ministerial meeting, which formulated the Moscow Declaration for presentation to the September UN summit on prevention and control of NCDs.3

Cheap generic drugs must be widely available to combat NCDs; this requires support from the drug industry. Similarly, achieving dietary change requires the food industry’s support.

The sheer size of the global NCD problem makes it of prime importance. Of course, extending lifespan increases the likelihood of developing NCDs, but reducing overall mortality and morbidity from chronic diseases at any age must be valuable.

The aim is to reduce the incidence of NCDs in high, medium, and low income countries. This must entail a financial cost. Savings in reduced cost of prolonged morbidity and reduced sickness absence will far outweigh these costs.4

Without political will, global availability of improved healthcare facilities, involvement of civil society and the corporate sector, and international collaboration, primary care will be unable to translate these aims into practical measures.

Global measures require global application of universal standards and methods, with local modifications when necessary. To achieve reduced levels of illness and death requires general acceptance of common criteria, based on WHO protocols.5

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Competing interests: HML is a member of the Non-Communicable Diseases Alliance.


3. First Global Ministerial Conference on Healthy Lifestyles and NCD Control, April 2011.


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Why we should emphasise prevention over treatment

I sympathise with Heath’s anxiety about turning people into “patients” by identifying those at risk of developing non-communicable diseases (NCDs), but is she really advocating that we wait until people are “sick” and then have them looked after by doctors? She seems to argue for treatment rather than prevention.

Her thinking perhaps flows from an attachment to the medical model. She is surely not against...
policy interventions like raising taxes on alcohol and reducing salt intake, the “best buys” recommended by WHO. Most of the interventions advocated by WHO are nothing to do with doctors and health systems. Most of what needs to be done to counter NCDs lies outside the health system. We have strong evidence that we can prevent prediabetes and prehypertension progressing to the full blown conditions by helping people change their lifestyles and lose weight. Again, this is nothing to do with doctors and drugs. The programmes are unaffordable if they use doctors rather than community health workers. Surely Heath is not suggesting that these people should be simply watched as they develop full blown disease?

There are difficult questions about how much countries should invest in policy changes, prevention, and treatment programmes. Heath’s thinking is the opposite of many in low and middle income countries. Our network of researchers from some of these countries thinks that the emphasis must be on prevention—because the Western model of emphasising treatment is unaffordable and unachievable when health workers are in such short supply.

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Competing interests: UnitedHealth together with the National Heart, Lung and Blood Institute funds and works with 11 centres in low and middle income countries that are doing research, training people, and developing policy to counter NCDs. Together with the Centers for Disease Control, UnitedHealth has developed a programme for preventing people with prediabetes developing diabetes.

1 Heath I. Seeming virtuous on chronic diseases. BMJ 2011;343:d4239. (8 July.)

Cite this as: BMJ 2011;343:d4888

RESPONSE

NCD Alliance responds to Iona Heath

Congratulations for including perspectives on the prevention and control of non-communicable diseases (NCDs) in a recent issue of the BMJ, in preparation for September’s high level summit at the United Nations. This summit is a rare opportunity to bring together heads of state and governments to shape a global response to one of the most pressing health and development issues of the 21st century.

The NCD Alliance (NCDA) was one of the earliest voices calling for such a summit, and has been central to preparations for this unprecedented event. The alliance comprises four international federations (International Diabetes Federation, International Union Against Tuberculosis and Lung Disease, Union for International Cancer Control, and the World Heart Federation), world leaders in the fight against cancer, cardiovascular disease, chronic respiratory disease, and diabetes, as well as 900 member associations and 350 common interest group members, in mainly low and middle income countries (LMICs). Together we have raised NCDs out of the shadows, and with the summit we expect to change the global health landscape forever.

A vital element of the official preparations for the summit has been the World Health Organization’s development of the Global Status Report on Non-Communicable Diseases. Heath questioned the alliance’s statistics, taken from the WHO report, regarding the international morbidity and mortality caused by NCDs. But it is true that NCDs make the largest contribution to mortality globally, and four in every five deaths from NCDs occur in LMICs. Eliminating the four main risk factors of NCDs (unhealthy diet, physical inactivity, tobacco use, and harmful consumption of alcohol) would prevent up to 80% of heart disease, stroke, and diabetes and more than a third of cancer.

Heath compares the proportion of deaths caused by NCDs in Africa with those in Europe; she argues that when people live into old age most will die from NCDs, and that the focus should be on premature avoidable mortality. She fails to acknowledge that in LMICs people die from NCDs at a much younger age than in Europe; age standardised stroke mortality rates in people under 65 years are up to 10 times higher in Tanzania than in England and Wales. NCDs also account for half of all global disability, and their impact is being shouldered by families, healthcare systems, business, and national economies alike. Their costs are staggering, and the World Economic Forum has consistently ranked NCDs as one of the top global threats to economic development.

The case for investment in NCDs is strengthened by the existence of cost effective and cost saving interventions. As the recent joint article by the Lancet NCD Action Group and the alliance outlined, many effective interventions have a net economic benefit, costing far less than treating the illness.

Heath notes that in Norway three quarters of adults have high blood pressure, yet they live long and healthy lives, but this is not representative of most people living with poorly functioning health systems in developing countries. In sub-Saharan Africa, about 80% of people with diabetes are undiagnosed, although the disease can be managed with cheap generic drugs. Like Heath, we support expanding the role of primary care in combating NCDs and population wide prevention approaches. Both feature prominently in our proposed outcomes document for the UN summit. The question for debate must no longer be “is this a problem?” but “how do we solve this problem together?” NCDs are more than just a health issue and are too large a problem for governments to solve alone. Turning this around will require a “health in all policies” approach, which engages government, the private sector, non-governmental organisations, researchers, the UN, media, and the public.

With political leadership and cooperation at both international and national level, a comprehensive balance of prevention and treatment commitments, and a cross-sector accountability mechanism to drive implementation of measurable commitments after September, the summit could be the turning point for which we have all been working. We look forward to joining world leaders in September, continuing to build global commitments for NCDs, and working together to fight against NCD morbidity and mortality.

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Competing interests: None declared.

1 Heath I. Seeming virtuous on chronic diseases. BMJ 2011;343:d4239. (8 July.)

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