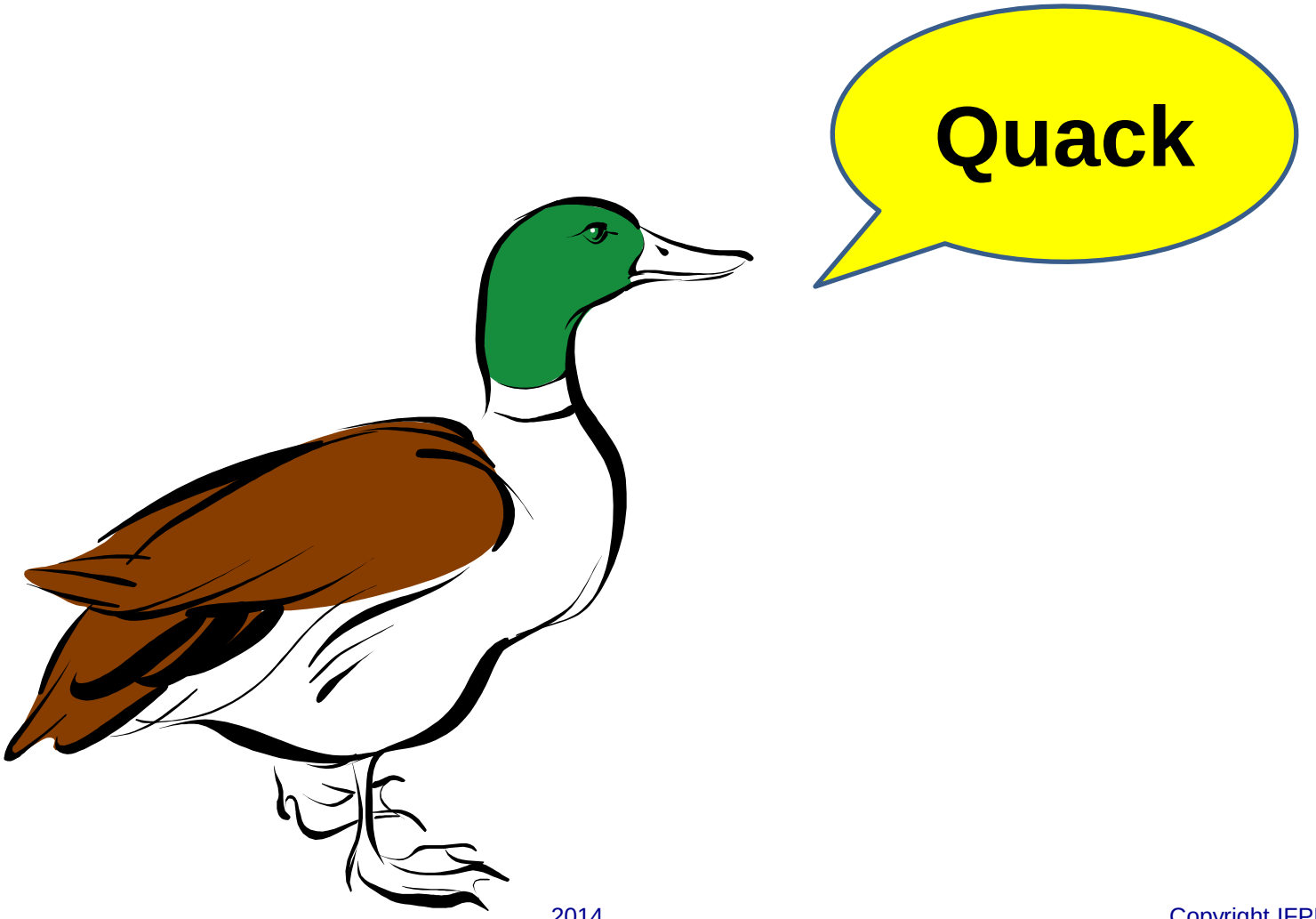
International Federation
of Pharmaceutical
Manufacturers & Associations

IFPMA

# *'Defining Promotion: Where to draw the line?'*

2014

IFPMA



# *Scope*

- The IFPMA Code covers interactions with healthcare professionals, medical institutions and patient organizations, and the promotion of pharmaceutical products

"Promotion" means any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet.

# *"Promotion means ..... any activities to promote ..."*

- Be honest with yourself!
  - Is the likely effect to encourage the prescription of a particular medicine?
    - By a prescriber
    - By a patient requesting a prescription
  - Why does your company wish to make the investment of money or resources?
- Scientific merit and whether an item or activity is promotional are separate decisions
  - Although not unrelated;
  - All promotion must be scientifically sound
- Content AND context are important
  - the way in which content is communicated may determine whether it is categorised as promotional

# *Non-promotional information*

- The IFPMA code doesn't set standards for non-promotional information such as Disease Awareness Campaigns, Information for Patients or Medical Information answers.
- But ...
  - Many national codes do cover such activities
  - Responsible companies will wish to set similar high information standards for both promotional and non-promotional information.

## IFPMA Code – Guiding Principles

1. The healthcare and well-being of patients are the first priority for pharmaceutical companies

4. Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.

# *Is it promotion?*

- If the activity IS promotion:
  - It cannot be undertaken before marketing authorisation for the product or use
  - It cannot be directed at the public (except USA & NZ)
  - It must include the statutory information (prescribing information, price, legal category etc.)
  - It must be approved by designated signatories
  - All requirements of the code apply
- Important to make the decision about which side of the line the activity lies

# *Make the decision*

- Is this promotion?
  - Make your decision on the information provided
- What are the consequences of your decision?

# *A scientific review inserted in a medical journal*

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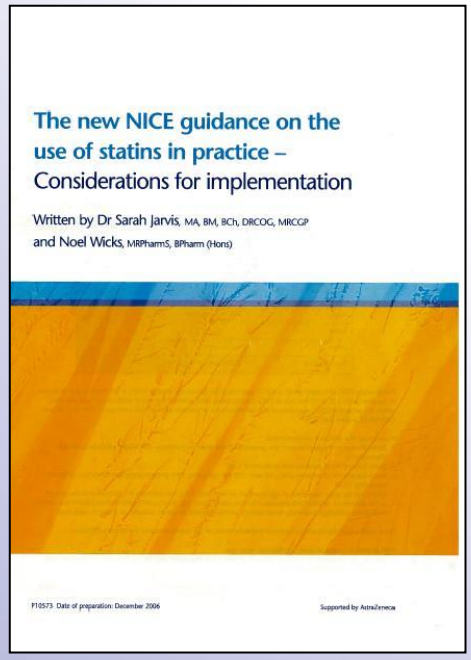
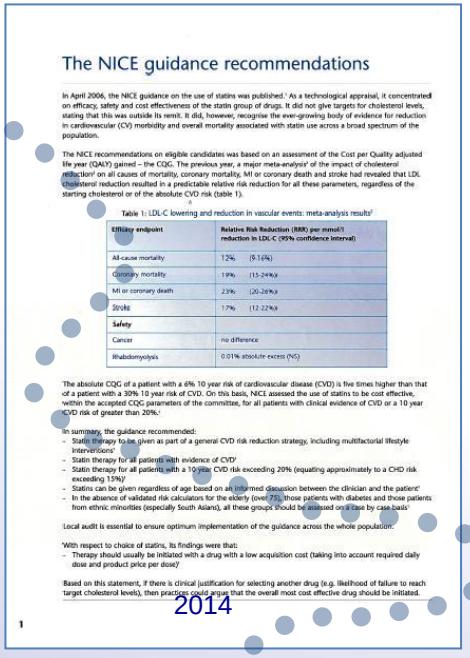

The new NICE guidance on the use of statins in practice – Considerations for implementation

Written by Dr Sarah Jarvis, MA, BM, BCh, DRCOG, MRCGP and Noel Wicks, MRPharmS, BPharm (Hons)

P10573 Date of preparation: December 2006

Supported by AstraZeneca


The NICE guidance recommendations

In April 2006, the NICE guidance on the use of statins was published.[1] As a technological appraisal, it concentrated on efficacy, safety and cost effectiveness of the statin group of drugs. It did not give targets for cholesterol levels, stating that this was outside its remit. It did, however, recognise the ever-growing body of evidence for reduction in cardiovascular (CV) morbidity and overall mortality associated with statin use across a broad spectrum of the population.

The NICE recommendations on eligible candidates was based on an assessment of the Cost per Quality adjusted life year (QALY) gained – the CQG. The previous year, a major meta-analysis[2] of the impact of cholesterol reduction[3] on all causes of mortality, coronary mortality, MI or coronary death and stroke had revealed that LDL cholesterol reduction resulted in a predictable relative risk reduction for all these parameters, regardless of the starting cholesterol or of the absolute CVD risk (table 1).

Table 1: LDL-C lowering and reduction in vascular events: meta-analysis results[2]

| Efficacy endpoint | Relative Risk Reduction (RRR) per mmol/l reduction in LDL-C (95% confidence interval) |
|---|---|
| All-cause mortality | 12% (9-16%) |
| Coronary mortality | 19% (15-24%) |
| MI or coronary death | 23% (20-26%) |
| Stroke | 17% (12-22%) |
| **Safety** | |
| Cancer | no difference |
| Rhabdomyolysis | 0.01% absolute excess (NS) |

The absolute CQG of a patient with a 6% 10 year risk of cardiovascular disease (CVD) is five times higher than that of a patient with a 30% 10 year risk of CVD. On this basis, NICE assessed the use of statins to be cost effective, within the accepted CQG parameters of the committee, for all patients with clinical evidence of CVD or a 10 year CVD risk of greater than 20%.[1]

In summary, the guidance recommended:
- Statin therapy to be given as part of a general CVD risk reduction strategy, including multifactorial lifestyle interventions[1]
- Statin therapy for all patients with evidence of CVD[1]
- Statin therapy for all patients with a 10-year CVD risk exceeding 20% (equating approximately to a CHD risk exceeding 15%)[1]
- Statins can be given regardless of age based on an informed discussion between the clinician and the patient[1]
- In the absence of validated risk calculators for the elderly (over 75), those patients with diabetes and those patients from ethnic minorities (especially South Asians), all these groups should be assessed on a case by case basis[1]

Local audit is essential to ensure optimum implementation of the guidance across the whole population.[1]

With respect to choice of statins, its findings were that:
- Therapy should usually be initiated with a drug with a low acquisition cost (taking into account required daily dose and product price per dose)[1]

Based on this statement, if there is clinical justification for selecting another drug (e.g. likelihood of failure to reach target cholesterol levels), then practices could argue that the overall most cost effective drug should be initiated.

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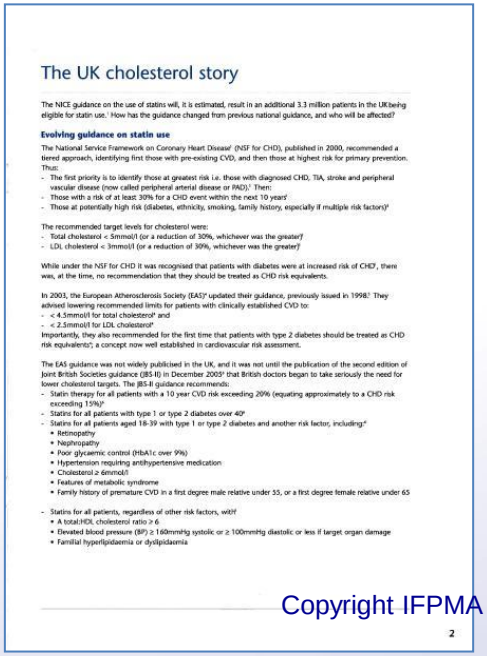
The UK cholesterol story

The NICE guidance on the use of statins will, it is estimated, result in an additional 3.3 million patients in the UK being eligible for statin use.[1] How has the guidance changed from previous national guidance, and who will be affected?

**Evolving guidance on statin use**

The National Service Framework on Coronary Heart Disease[1] (NSF for CHD), published in 2000, recommended a tiered approach, identifying first those with pre-existing CVD, and then those at highest risk for primary prevention. Thus:
- The first priority is to identify those at greatest risk i.e. those with diagnosed CHD, TIA, stroke and peripheral vascular disease (now called peripheral arterial disease or PAD).[1] Then:
- Those with a risk of at least 30% for a CHD event within the next 10 years[1]
- Those at potentially high risk (diabetes, ethnicity, smoking, family history, especially if multiple risk factors)[1]

The recommended target levels for cholesterol were:
- Total cholesterol < 5mmol/l (or a reduction of 30%, whichever was the greater)[1]
- LDL cholesterol < 3mmol/l (or a reduction of 30%, whichever was the greater)[1]

While under the NSF for CHD it was recognised that patients with diabetes were at increased risk of CHD[1], there was, at the time, no recommendation that they should be treated as CHD risk equivalents.

In 2003, the European Atherosclerosis Society (EAS)[2] updated their guidance, previously issued in 1998.[3] They advised lowering recommended limits for patients with clinically established CVD to:
- < 4.5mmol/l for total cholesterol[2] and
- < 2.5mmol/l for LDL cholesterol[2]

Importantly, they also recommended for the first time that patients with type 2 diabetes should be treated as CHD risk equivalents[2], a concept now well established in cardiovascular risk assessment.

The EAS guidance was not widely publicised in the UK, and it was not until the publication of the second edition of Joint British Societies guidance (JBS-II) in December 2005[4] that British doctors began to take seriously the need for lower cholesterol targets. The JBS-II guidance recommends:
- Statin therapy for all patients with a 10 year CVD risk exceeding 20% (equating approximately to a CHD risk exceeding 15%)[4]
- Statins for all patients with type 1 or type 2 diabetes over 40[4]
- Statins for all patients aged 18-39 with type 1 or type 2 diabetes and another risk factor, including:[4]
  - Retinopathy
  - Nephropathy
  - Poor glycaemic control (HbA1c over 9%)
  - Hypertension requiring antihypertensive medication
  - Cholesterol ≥ 6mmol/l
  - Features of metabolic syndrome
  - Family history of premature CVD in a first degree male relative under 55, or a first degree female relative under 65
- Statins for all patients, regardless of other risk factors, with[4]
  - A total:HDL cholesterol ratio ≥ 6
  - Elevated blood pressure (BP) ≥ 160mmHg systolic or ≥ 100mmHg diastolic or less if target organ damage
  - Familial hyperlipidaemia or dyslipidaemia

2

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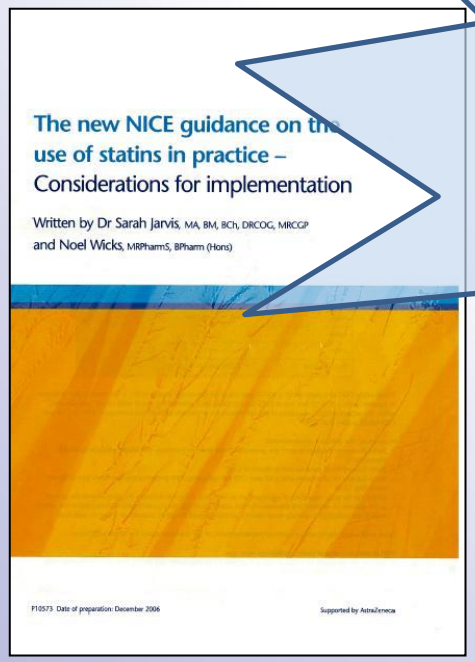
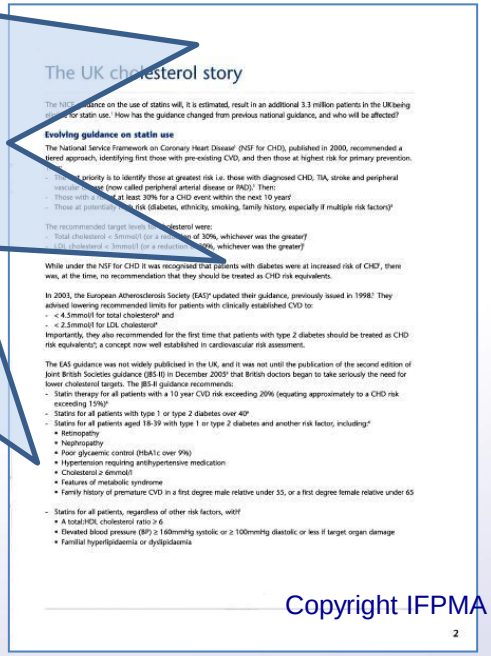


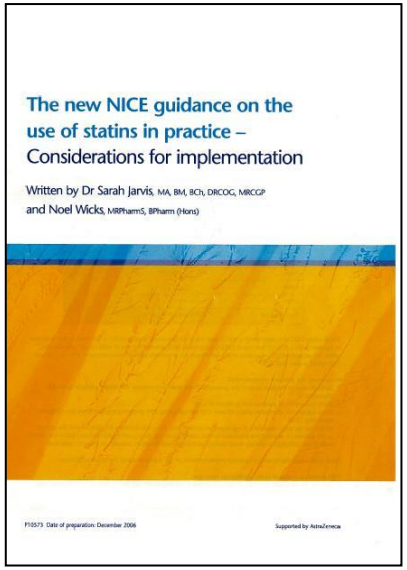


**Is it Promotion?**



# *A scientific review inserted in a medical journal*

- The article was a one-off publication and not an official supplement to the journal
- It included a favourable comparison of the sponsor company's drug with a competitor
- Although company sponsorship was acknowledged on the front page this was not prominent
- An agency working on behalf of the company had initiated the publication
- The company had provided relevant factual information to the authors to help their writing
- The company considered it an independent scientific publication so it had not been approved by the nominated signatories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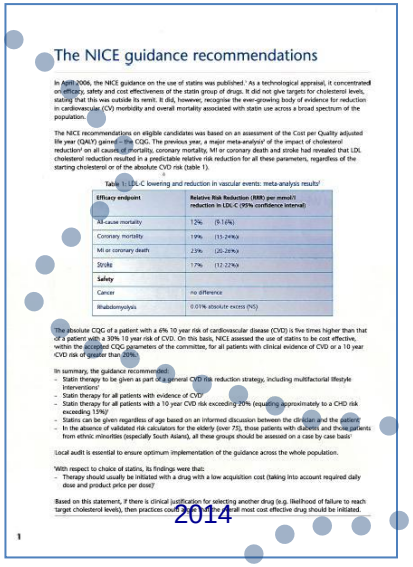
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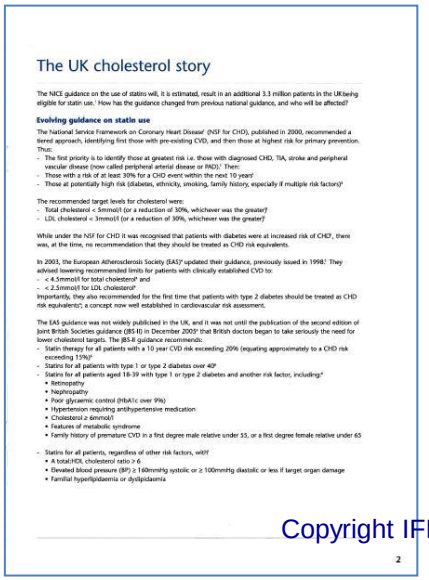
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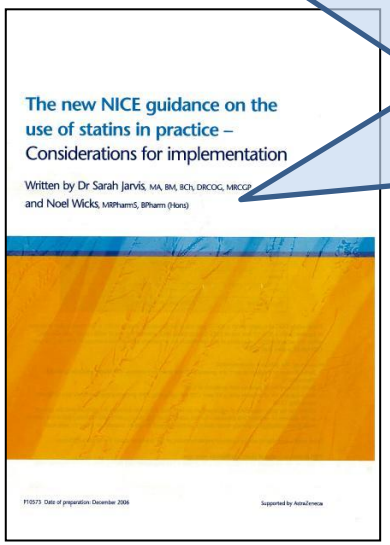



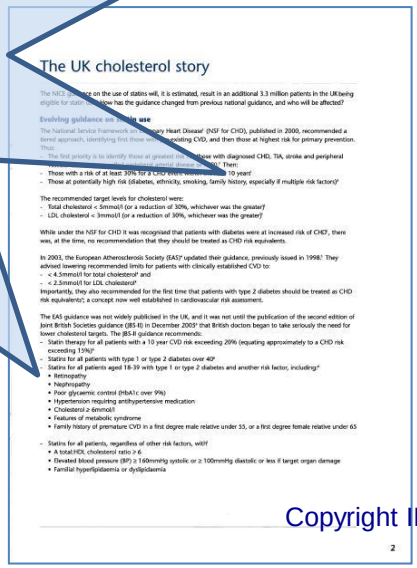


2014

# *A scientific review inserted in a medical journal Important learning*

- An item can be highly scientific, the editorial control may rest with independent HCPs but it may still be promotion.
- There must be a truly ‘arms length’ relationship if the communication is not to be considered as the responsibility of the sponsoring company.
- The role of the sponsoring company must be clear in all items. It must not be disguised promotion.
- If an item is classified as promotion it must comply with all aspects of the code including:
  - Inclusion of prescribing information, cost etc
  - All information must be ‘on-label’
  - Requirements on balance, fairness, accuracy etc apply
  - It must be approved by the nominated signatories, submitted externally for approval (if applicable) - according to local requirements

# *Imported medicine, unlicensed locally*

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- An important new medicine for a rare disease has been granted a marketing authorisation in Europe and USA, but registration is delayed in your country while formalities are completed
- The medicine is however available through a government-approved early access scheme if a hospital doctor makes a written application for a named patient.
- A 'notice of availability' has been produced by company headquarters to draw attention to the medicine's availability among hospital neurologists (who are most likely to treat patients with this rare disease) in countries such as yours.
- You are asked to approve placing this notice in a neurology newsletter that is distributed to local specialists. A small cost for insertion of the notice will apply.

**Notice to Neurologists**

Fapima (raredisabab) is now available for the treatment of patients with Kluver-Bucy Syndrome. This agent has received regulatory approval by the European and US regulatory authorities and has demonstrated efficacy in this rare disease for which no other treatments are available.

'Fapima' is available from PharmaDistn distributors for named patients.

Email Info@PharmaDistn.com for further information

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# *Imported medicine, unlicensed locally*

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- It is suggested that the information should be made available by sending the notice to the newsletter editor rather than buying advertising space. The notice will be sent by the local distributor rather than the pharmaceutical company.
- Also the regional regulatory director asks that 'This product has not been granted a marketing authorisation in *Country X'* be added to the text.
- You also say that the trade name should be removed and only the non-proprietary name be included.

**Notice to editors**

Raredisabab is now available for the treatment of patients with Kluver-Bucy Syndrome. This agent has received regulatory approval by the European and US regulatory authorities but has not yet received approval in Country X. It has demonstrated efficacy in this rare disease for which no other treatments are available.

Raredisabab is available from PharmaDistn distributors for named patients.

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# *Imported medicine, unlicensed locally Important learning*

- Information on a medicine presented in a factual and sober fashion may still constitute advertising. Although use of the trade name does not automatically make a communication promotional it is one factor amongst many that an adjudication panel might consider
- Drawing attention to product availability is designed to encourage the prescribing of that product and is likely to be judged as promotion. Statements about product efficacy reinforce the promotional impact.
- It is helpful to make the registration status of a product clear.
- Payment for advertising space is factor that may contribute to information being considered as promotional.
- Press releases and other material sent to publications may be judged promotional. However important medical news might be considered as a non-promotional exchange of scientific information.
- A pharmaceutical company will be held responsible under the code for activities undertaken by agencies and distributors on their behalf.

# *Patient Support Programme*

**The situation:**

- A major concern in your country is that patients fail to recognise the symptoms of type 2 diabetes and can go undiagnosed for years, leading to serious complications.
- An additional problem is that, after diagnosis, many patients fail to continue their medication for more than a few months. Cost, lack of disease understanding, no established health communication programme for doctors and pharmacists and an absence of patient support organisations may all be contributory factors
- You have recently launched a prescription medicine for type 2 diabetes. Your global product strategy has identified patient education about type 2 diabetes as a key objective and supports using up to 25% of your promotion budget in years 1-2 on patient education.
- An expert agency has been engaged to propose non-promotional patient support activities. Their proposals follow:

# *Proposals for a Patient support programme.*

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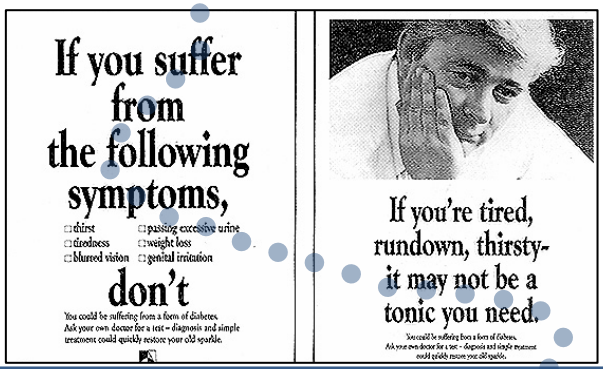
**1. Disease Awareness Advertisements**

- A series of advertisements will be placed in national newspapers and magazines describing diabetes symptoms. Readers will be urged to consult their doctor or pharmacist if they experience these problems.
- They will also be referred to a) the ‘Diabetes Awareness Foundation’ website b) a ‘Diabetes Foundation’ helpline which will be manned by nurses funded by the company.
- Cost: $10,000 per annum; Projected increased sales: $75,000 in year 1, $125,000 in year 2



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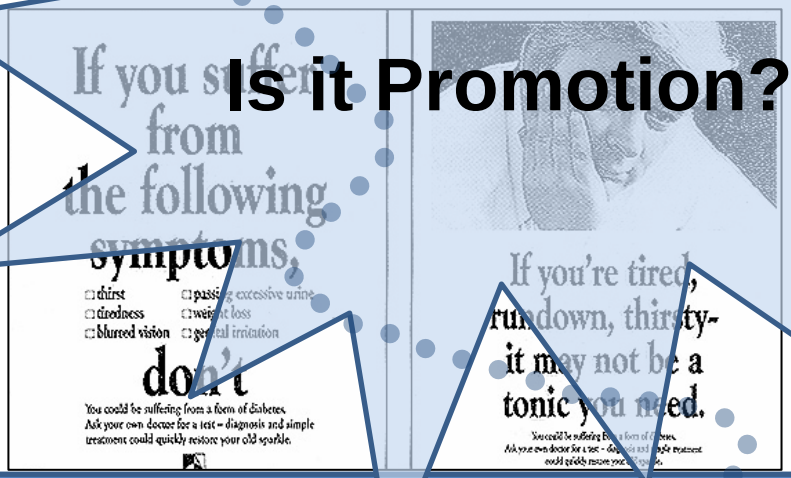


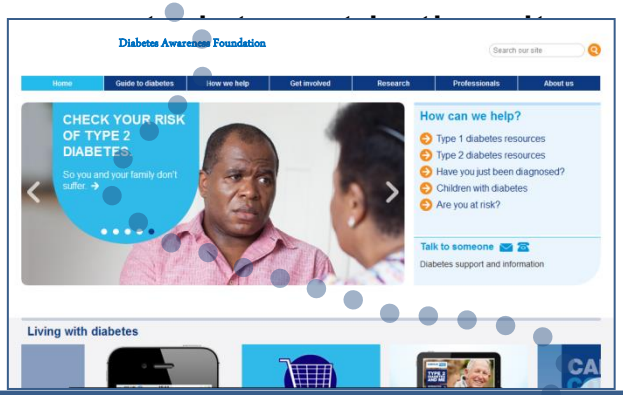
# *Proposals for a Patient support programme.*

**2. Creation of Diabetes Awareness Foundation and associated website**

• A national ‘Diabetes Awareness Foundation’ should be established. A national personality with diabetes will be recruited to act as president and an advisory board of people with diabetes will be sought to advise on activities.

• The initial main activity will be through a website

- •The website will contain information on diabetes – how to recognise it and treatment options. All medical treatment options will be included including the sponsoring company’s medicine.
- • An ‘Ask the expert’ facility will be included. The company medical information service will be required to provide answers to queries submitted.
- • Regular ‘tweets will



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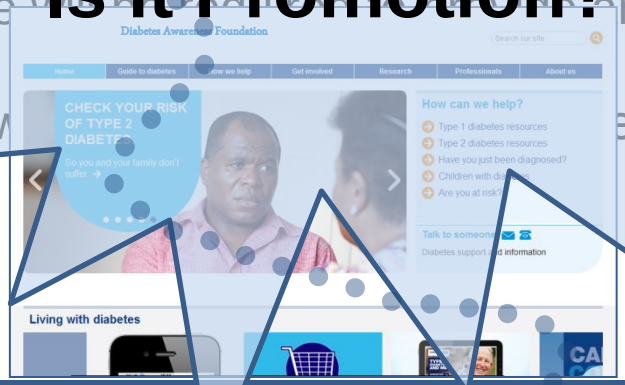

# *Proposals for a patient support program: Important Learning*

- Disease awareness advertisements are likely to be considered as non promotional providing they don't lead readers towards requesting a particular medicine.
- Return on Investment calculations should not form part of the justification for patient support activities. They indicate a primarily promotional rather than a patient welfare intent.
- Establishing a separate organisation as a facade for company activities does not absolve the company of responsibility under the code
- Disease information resources that include treatment options should be comprehensive (i.e. include medical and non-medical options) and should not favour the sponsors treatment.
- Take care with interactive elements. These should not include personal medical advice and any product content could easily become promotional.
- Twitter is unlikely to be a suitable medium for any product related content

# *Finally - Some quick decisions*

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- The BMJ has published a paper on an unapproved use of your medicine
  - Can a reprint be provided by your medical department in response to medical information requests?
  - Can a reprint be made available from a company promotional booth at an international congress?
  - Can a reprint be made available from a medical information area in a company booth at an international congress?
  - Can a link to the paper be provided on your password protected product website for HCPs?
  - Can you send a copy to investigators currently working on clinical trials on the medicine?

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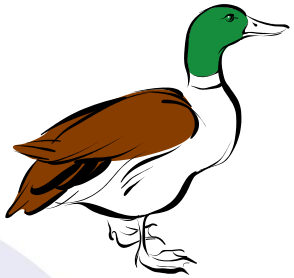
***'Defining Promotion: Where to draw the line?'***



Thank You