December 2010 – SUPPORT Summary of a systematic review

What are the benefits and harms of direct to consumer advertising?

Direct to consumer advertising is increasingly used by the pharmaceutical industry and its merits have been extensively debated. Regulations related to such advertising vary: in New Zealand and the United States of America (USA), for example, regulations do not explicitly prohibit such advertising and its use has grown. In other countries, however, the practice has been banned and heavy lobbying by the pharmaceutical industry has been resisted.

Key messages

- **Direct to consumer advertising increases patient demand for advertised medicines and the number of related prescriptions by doctors**
- **The effects of direct to consumer advertising on health outcomes are uncertain**
- **In light of the lack of evidence of the benefits, potential harms, and costs of direct to consumer advertising**
  - The value of policies that allow for the increased use of direct to consumer advertising is uncertain at best; and
  - Rigorous monitoring and evaluation are warranted when such policies are implemented

Who is this summary for?

People making decisions concerning the regulation of direct to consumer advertising.

This summary includes:

- **Key findings** from research based on a systematic review
- **Considerations about the relevance of this research** for low- and middle-income countries

Not included:

- Recommendations
- Additional evidence not included in the systematic review
- Detailed descriptions of interventions or their implementation

This summary is based on the following systematic review:

Gilbody S, Wilson P, Watt I. Benefits and harms of direct to consumer advertising: a systematic review. *Qual Saf Health Care* 2005;14:246–50.

What is a systematic review?

A summary of studies addressing a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise the relevant research, and to collect and analyse data from the included studies.

SUPPORT – an international collaboration funded by the EU 6th Framework Programme to support the use of policy relevant reviews and trials to inform decisions about maternal and child health in low- and middle-income countries.
www.support-collaboration.org

Glossary of terms used in this report:
www.support-collaboration.org/summaries/explanations.htm

Background references on this topic:
See back page.

Background

The promotion of prescription-only medicines using direct to consumer advertising is used increasingly by the pharmaceutical industry. Proponents of direct to consumer advertising argue that it increases the use of effective treatments for under-treated conditions. Opponents, however, suggest that it drives up demand for newer, higher-cost drugs that may have marginal benefits and unknown safety profiles.

This summary is based on a review published in 2005 by Gilbody and colleagues, on the effects of direct to consumer advertising.

How this summary was prepared

After searching widely for systematic reviews that can help inform decisions about health systems, we have selected ones that provide information that is relevant to low- and middle-income countries. The methods used to assess the quality of the review and to make judgements about its relevance are described here: www.support-collaboration.org/summaries/methods.htm

Knowing what's not known is important

A good quality review might not find any studies from low- and middle-income countries or might not find any well-designed studies. Although that is disappointing, it is important to know what is not known as well as what is known.

About the systematic review underlying this summary

Review objective: To examine the benefits and harms of direct to consumer advertising of prescription-only medicines

	What the review authors searched for	What the review authors found
Interventions	Randomised controlled trials, controlled clinical trials, controlled before-and-after studies, interrupted time series analyses, and cross-sectional studies with a control group	3 interrupted time series analyses, 1 comparative cross sectional survey
Participants	Not pre-specified	Patients and physicians in primary care (4 studies)
Settings	Not pre-specified	USA (2 studies), USA and Canada (1), Netherlands (1)
Outcomes	Health seeking behaviours of patients at the point of access to care; requests for prescription only medicines; patient-doctor communication and satisfaction with care; prescribing patterns; costs	Requests for prescription only medicines (4 studies); prescription volume (4 studies); patient-doctor communication and satisfaction with care (1 study)
Date of most recent search: October 2004		
Limitations: A good quality systematic review with only minor limitations		

Gilbody S, Wilson P, Watt I. Benefits and harms of direct to consumer advertising: a systematic review. *Qual Saf Health Care* 2005;14:246-50

Summary of findings

The review identified 2,853 publications from which 6 publications (of 4 studies) met the inclusion criteria. Three studies were interrupted time series: of these, 2 were conducted in the USA and 1 in the Netherlands. The fourth study was a cross-sectional survey comparing the impact of direct to consumer advertising in the USA and Canada.

1) Health outcomes

A synthesis of the four studies showed that:

- ➔ **Direct to consumer advertising increases patient requests for advertised drugs and related prescription volume**
- ➔ **No studies reported the effects of direct to consumer advertising on health outcomes or the cost effectiveness of such advertising**

About the quality of evidence (GRADE)

⊕⊕⊕⊕
High: Further research is very unlikely to change our confidence in the estimate of effect.

⊕⊕⊕◯
Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

⊕⊕◯◯
Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

⊕◯◯◯
Very low: We are very uncertain about the estimate.

For more information, see last page

Direct to consumer advertising

Patients or population: Patients and clinicians
Settings: Primary care in USA (2), USA and Canada (1), and Netherlands (1)
Intervention: Direct to consumer advertising
Comparison: No intervention

Outcomes	Impact	Number of participants (studies)	Quality of the evidence (GRADE)
Prescriptions	DTCA was consistently associated with increased numbers of patient requests and/or increased prescription volume for the advertised medicines	(4 studies)	⊕⊕⊕⊕ High
Health outcomes	No studies examined the impact of DTCA on patient satisfaction with care, or the impact of DTCA and altered prescribing on actual health outcomes	[0] (No study)	⊕◯◯◯ Very low
Costs	No studies examined the cost effectiveness of DTCA by combining health outcomes, or the economic costs of altered prescribing	[0] (No study)	⊕◯◯◯ Very low

p: p-value GRADE: GRADE Working Group grades of evidence (see above and last page)
DTCA: Direct to consumer advertising
[?]: The study in the Netherlands had a total 470,775 patients and 1.5 million patient years, the first study in the USA analysed 195,577 clinician encounters and the second one studied four representative geographical areas but did not give the total number of participants of physician encounters, and the study that compared the USA to Canada recruited 1431 patients and 78 physicians.

Relevance of the review for low- and middle-income countries

➔ Findings	▷ Interpretation*
APPLICABILITY	
➔ **The studies, all conducted in high-income countries, show that direct to consumer advertising alters prescribing behaviour and volume; but no studies examined the impact of such advertising on health outcomes**	▷ *Given the absence of any evidence of improvement in health outcomes from direct to consumer advertising, its benefits are uncertain in any settting*
EQUITY	
➔ **None of the studies provided data on the differential effects of direct to consumer advertising**	▷ *The forms of mass media used by pharmaceutical companies may not be available or appropriate for reaching low-income households* ▷ *However, disadvantaged persons who have access to such mass media may easily be misinformed (due to their relatively lower educational attainment). This may lead to high demand for newer, expensive drugs with unknown safety profiles, and exacerbate existing inequalities*
ECONOMIC CONSIDERATIONS	
➔ **None of the studies examined the cost effectiveness of direct to consumer advertising, or the economic costs of altered prescribing**	▷ Any further studies of direct to consumer advertising should evaluate its costs and health and social consequences
MONITORING & EVALUATION	
➔ **Direct to consumer advertising has not been subject to extensive and rigorous evaluation, even in high-income countries**	▷ *Rigorous studies of direct to consumer advertising (with an appropriate control) are needed* ▷ *In the absence of such new evidence, the implementation of direct to consumer advertising in any setting should be closely monitored and evaluated*

*Judgements made by the authors of this summary, not necessarily those of the review authors, based on the findings of the review and consultation with researchers and policymakers in low- and middle-income countries. For additional details about how these judgements were made see: http://www.support-collaboration.org/summaries/methods.htm

Additional information

Related literature

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Conflict of interest

None. For details, see: www.support-collaboration.org/summaries/coi.htm

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All Summaries: evidence-informed health policy, evidence-based, systematic review, health systems research, health care, low- and middle-income countries, developing countries, primary health care, direct to consumer advertising

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About quality of evidence (GRADE)

The quality of the evidence is a judgement about the extent to which we can be confident that the estimates of effect are correct. These judgements are made using the GRADE system, and are provided for each outcome. The judgements are based on the type of study design (randomised trials versus observational studies), the risk of bias, the consistency of the results across studies, and the precision of the overall estimate across studies. For each outcome, the quality of the evidence is rated as high, moderate, low or very low using the definitions on page 3.

For more information about GRADE:
www.support-collaboration.org/summaries/grade.htm

SUPPORT collaborators:

The Alliance for Health Policy and Systems Research (HPSR) is an international collaboration aiming to promote the generation and use of health policy and systems research as a means to improve the health systems of developing countries. www.who.int/alliance-hpsr

The Cochrane Effective Practice and Organisation of Care Group (EPOC) is a Collaborative Review Group of the Cochrane Collaboration: an international organisation that aims to help people make well informed decisions about health care by preparing, maintaining and ensuring the accessibility of systematic reviews of the effects of health care interventions.
www.epocoslo.cochrane.org

The Evidence-Informed Policy Network (EVIPNet) is an initiative to promote the use of health research in policymaking. Focusing on low- and middle-income countries, EVIP-Net promotes partnerships at the country level between policy-makers, researchers and civil society in order to facilitate both policy development and policy implementation through the use of the best scientific evidence available. www.evipnet.org

For more information:
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