August 2016 – 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 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**

➔ **No studies were found that reported on the impact of direct to consumer advertising on health outcomes. We are therefore uncertain of the effects of direct to consumer advertising on health outcomes**

➔ **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 if 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-income countries

X 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 was an international project to support the use of policy relevant reviews and trials to inform decisions about maternal and child health in low- and middle-income countries, funded by the European Commission (FP6) and the Canadian Institutes of Health Research.

Glossary of terms used in this report: www.supportsummaries.org/glossary-of-terms

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.

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-income countries. The methods used to assess the reliability of the review and to make judgements about its relevance are described here: www.supportsummaries.org/how-support-summaries-are-prepared/

Knowing what's not known is important

A reliable review might not find any studies from low-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.

A lack of evidence does not mean a lack of effects. It means the effects are uncertain. When there is a lack of evidence, consideration should be given to monitoring and evaluating the effects of the intervention, if it is used.

About the systematic review underlying this summary

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

Types of	What the review authors searched for	What the review authors found
Study designs & Interventions	Randomized trials, controlled clinical trials, controlled before-after studies, interrupted time series studies, and cross-sectional studies with a control group	3 interrupted time series studies and 1 comparative cross sectional survey were found
Participants	Not pre-specified	Patients and physicians in primary care
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); patient-doctor communication and satisfaction with care (1)
Date of most recent search: October 2004		
Limitations: This is a well-conducted 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 included 4 studies that compared the impact of direct to consumer advertising. Of these, 2 were conducted in the USA, 1 in the USA and Canada and 1 in the Netherlands.

A synthesis of the four studies showed that:

➔ **Direct to consumer advertising increases patient requests and prescription volume for advertised drugs. The certainty of this evidence is high.**

➔ **No studies were found that evaluated the impact of direct to consumer advertising on health outcomes or the cost effectiveness of such advertising.**

About the certainty of the evidence (GRADE) *

⊕⊕⊕⊕
High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕◯
Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate.

⊕⊕◯◯
Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕◯◯◯
Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

* This is sometimes referred to as 'quality of evidence' or 'confidence in the estimate'.

† Substantially different = a large enough difference that it might affect a decision

See last page for more information.

Direct to consumer advertising

People 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**	Certainty of the evidence (GRADE)
Prescriptions	DTCA was consistently associated with increased numbers of patient requests and/or increased prescription volume for the advertised medicines*	⨁⨁⨁⨁ 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	-
Costs	No studies examined the cost effectiveness of DTCA by combining health outcomes, or the economic costs of altered prescribing	-

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-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 setting*
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 the effects of direct to consumer advertising on health outcomes and costs are needed* ▷ *In the absence of evidence of benefits, direct to consumer advertising in any setting should be closely monitored and evaluated, if it is implemented*

*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-income countries. For additional details about how these judgements were made see: www.supportsummaries.org/methods

Additional information

Related literature

Frosch DL, Grande D, Tarn DM, Kravitz RL. A decade of controversy: balancing policy with evidence in the regulation of prescription drug advertising. *Am J Public Health* 2010;100:24-32.

Mintzes B, Morgan S, Wright JM. Twelve years' experience with direct-to-consumer advertising of prescription drugs in Canada: a cautionary tale. *PLoS One* 2009;4(5):e5699.

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Law MR, Majumdar SR, Soumerai SB. Effect of illicit direct to consumer advertising on use of etanercept, mometasone, and tegaserod in Canada: controlled longitudinal study. *BMJ* 2008;337:a1055.

Hoffman JR, Wilkes M. Direct to consumer advertising of prescription drugs.*BMJ* 1999;318:1301–2

Mintzes B. Direct-to-consumer advertising of prescription drugs in Canada. What are the public health implications? Health Council of Canada. January 2006.

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Conflict of interest

None declared. For details, see: www.supportsummaries.org/coi

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This review should be cited as

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About certainty of the evidence (GRADE)

The "certainty of the evidence" is an assessment of how good an indication the research provides of the likely effect; i.e. the likelihood that the effect will be substantially different from what the research found. By "substantially different" we mean a large enough difference that it might affect a decision. These judgements are made using the GRADE system, and are provided for each outcome. The judgements are based on the study design (randomised trials versus observational studies), factors that reduce the certainty (risk of bias, inconsistency, indirectness, imprecision, and publication bias) and factors that increase the certainty (a large effect, a dose response relationship, and plausible confounding). For each outcome, the certainty of the evidence is rated as high, moderate, low or very low using the definitions on page 3.

For more information about GRADE: www.supportsummaries.org/grade

SUPPORT collaborators:

The Cochrane Effective Practice and Organisation of Care Group (EPOC) is part of the Cochrane Collaboration. The Norwegian EPOC satellite supports the production of Cochrane reviews relevant to health systems in low- and middle-income countries . www.epocoslo.cochrane.org

The Evidence-Informed Policy Network (EVIPNet) is an initiative to promote the use of health research in policymaking in low- and middle-income countries. www.evipnet.org

The Alliance for Health Policy and Systems Research (HPSR) is an international collaboration that promotes the generation and use of health policy and systems research in low- and middle-income countries. www.who.int/alliance-hpsr

Norad, the Norwegian Agency for Development Cooperation, supports the Norwegian EPOC satellite and the production of SUPPORT Summaries. www.norad.no

The Effective Health Care Research Consortium is an international partnership that prepares Cochrane reviews relevant to low-income countries. www.evidence4health.org

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