EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Benefit-risk communication: Perspective from PRAC

June M Raine
Chair Pharmacovigilance Risk Assessment Committee
17 September, 2014

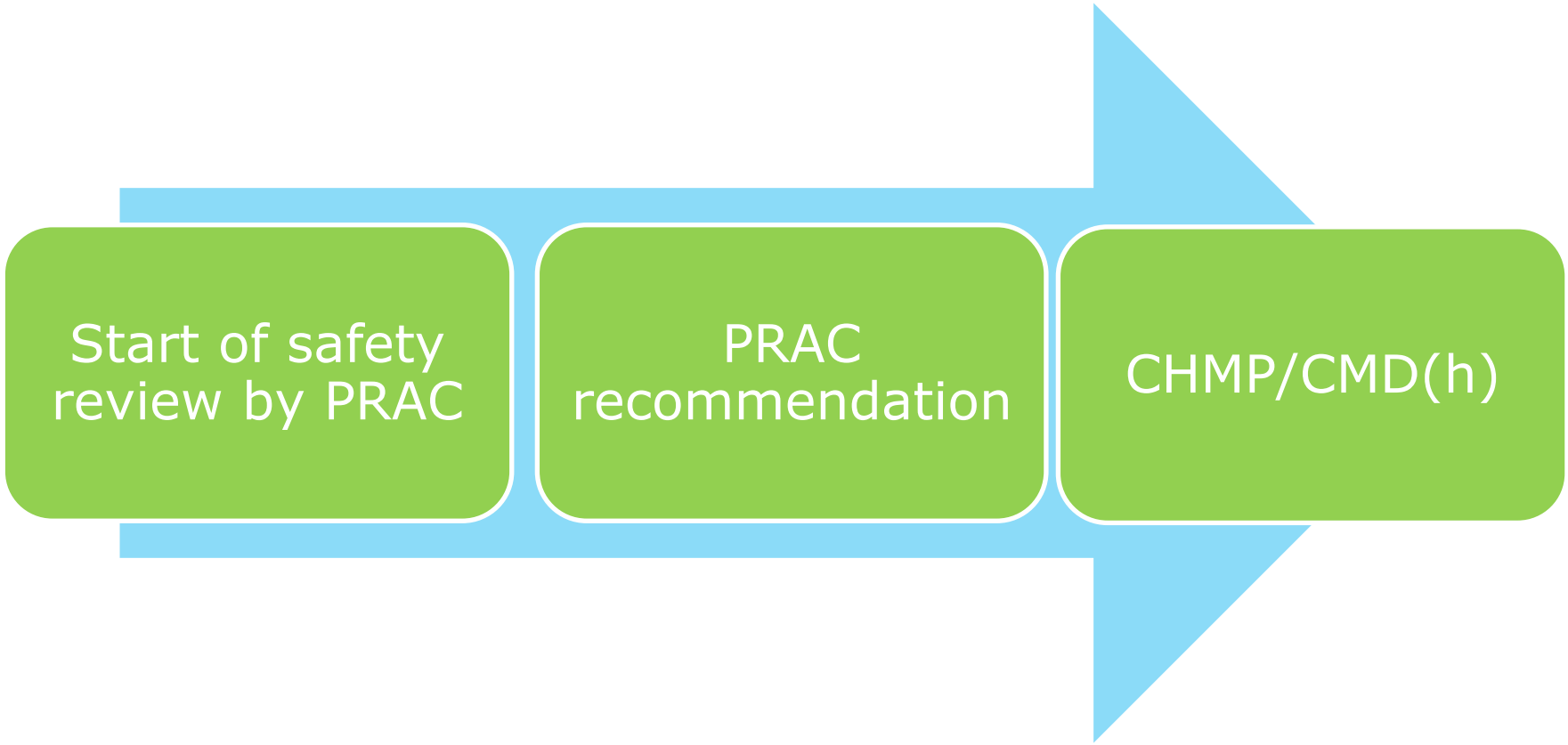
Outline

- PRAC's current approach to benefit risk communication
- PRAC's activities to strengthen its benefit risk communication
- A perspective on the challenges still to be tackled

Reminder - Mandate of Pharmacovigilance Risk Assessment Committee

All aspects of the risk management of the use of medicinal products including the detection, assessment, minimisation and communication relating to the risk of adverse reactions, having due regard to the therapeutic effect of the medicinal product, the design and evaluation of post-authorisation safety studies and pharmacovigilance audit

How safety communications evolve



PRAC's role in safety communication

port S10-11

The Daily

Thursday, May 30, 2013 ... telegraph

Painkiller taken for arthritis is heart risk

Health warning to millions of sufferers who regularly take high-dose ibuprofen

By Laura Donnelly
Health Correspondent

MILLIONS of arthritis sufferers could be increasing their risk of a heart attack or stroke by more than a third by taking large doses of drugs such as ibuprofen, according to one of the largest studies into painkillers.

The study of more than 350,000 patients taking prescription doses of such medications found the chance of a heart attack or stroke rose by almost 40 per cent.

The research found that the greater drugs, it would equate to an estimated 21,000 more heart attacks in sufferers, the study suggested.

Researchers said the study, funded by the Medical Research Council and the British Heart Foundation and led by the council's unit at Oxford, had looked at the risks from common painkillers in "unprecedented detail".

The lead author, Prof Colin Baigent from the University of Oxford, said: "The research shows that, when used in high doses, diclofenac and ibuprofen increase the risk of cardiovascular disease, on average causing about

Fears for missin

"Under the coordination of the Agency, ***the Member States shall make all reasonable efforts to agree on a common message***

The ***PRAC shall at the request of the Agency provide advice on those safety announcements"***

Information in member states National Web-Portals

National web-portal to contain:

- Public assessment Reports and Summaries
- SPCs and PILs
- Summary Risk Management Plans
- List of substances under additional monitoring
- Information on how to report and electronic reporting forms
- ***Important information for the public***

But there are questions…

- Does this wealth of information support benefit risk judgments?

- How can we know that risk has been minimised in practice and measure the impact of action?

PRAC's approach to BR communication

- Clarity on **scientific evidence** – absolute risk, exposure to medicine, background rates, age stratified etc
- Clarity on **uncertainties** where possible, and efforts to address these
- Taking account of the **therapeutic context** – place of medicine, alternatives
- Incorporating **views of medicines users**

PRAC 's links with the real world
- HCP and patient representatives

HAS ADOPTED THIS DECISION:

Sole Article

1. The following are hereby appointed members and alternates of the Pharmacovigilance Risk Assessment Committee to represent healthcare professionals for a term of three years from 1 March 2013:

— Member: Filip Babylon,

— Alternate: Kirsten Myhr.

2. The following are hereby appointed members and alternates of the Committee to represent patient organisations for a term of three years from 1 March 2013:

— Member: Albert van der Zeijden,

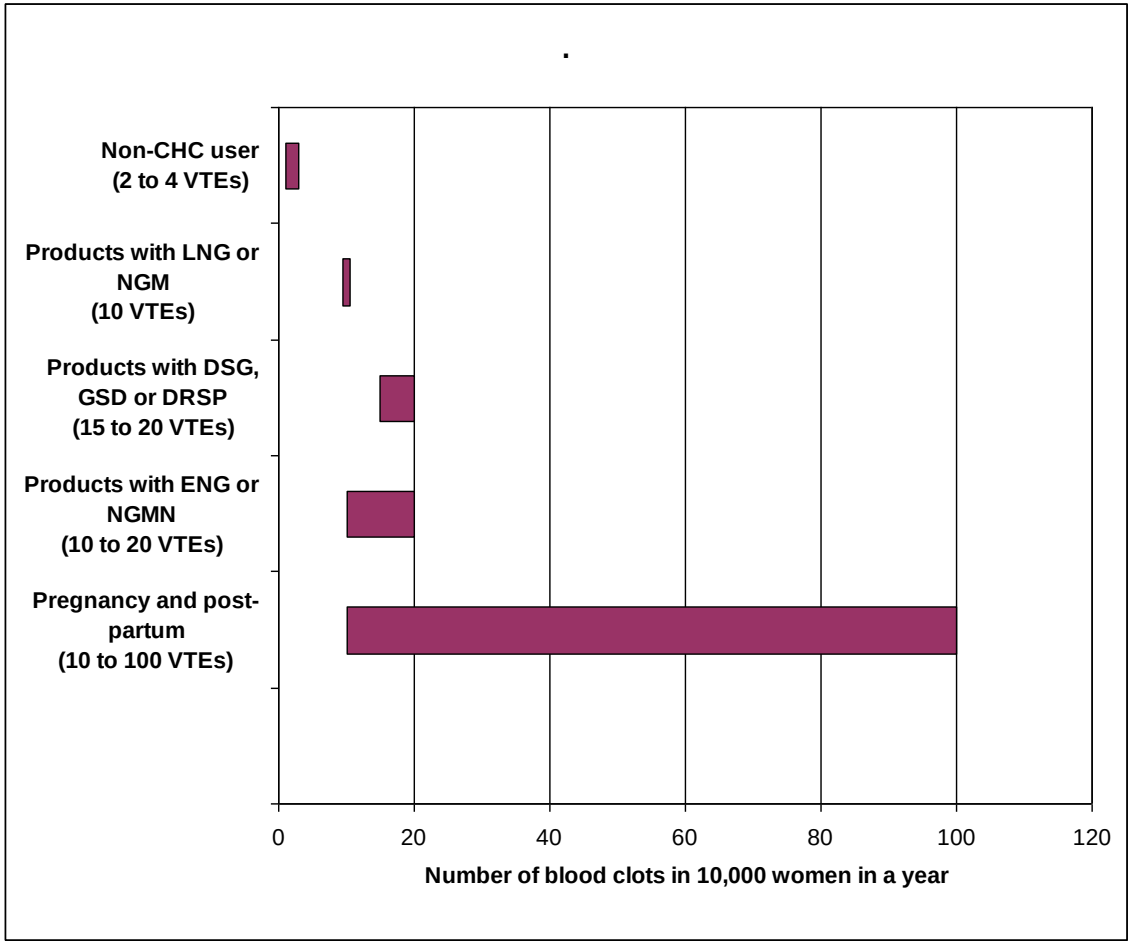
— Alternate: Marco Greco.

Done at Brussels, 28 February 2013.

PRAC's activities to strengthen benefit risk communication

- **Learning from experience**, exploring new approaches and updating GVP guidance accordingly
- Participating in and **linking with research** –evaluating new methodologies
- **Fostering public understanding** of regulatory decision-making
- **Monitoring effectiveness of risk minimisation**

Graphical representation of incidence rate estimates for VTE associated with combined hormonal contraceptives



PROTECT

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Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

Welcome to the VISUALizE Study website and thank you for participating in this study. The data collected in this survey will help health authorities to improve the communciation of benefits and risks of medicines. We will collect data on your understanding of benefit-risk data for medicines and your preferences for possible treatment outcomes related to your disease. Please choose the correct questionnaire from the options below to enter the site and begin the survey.

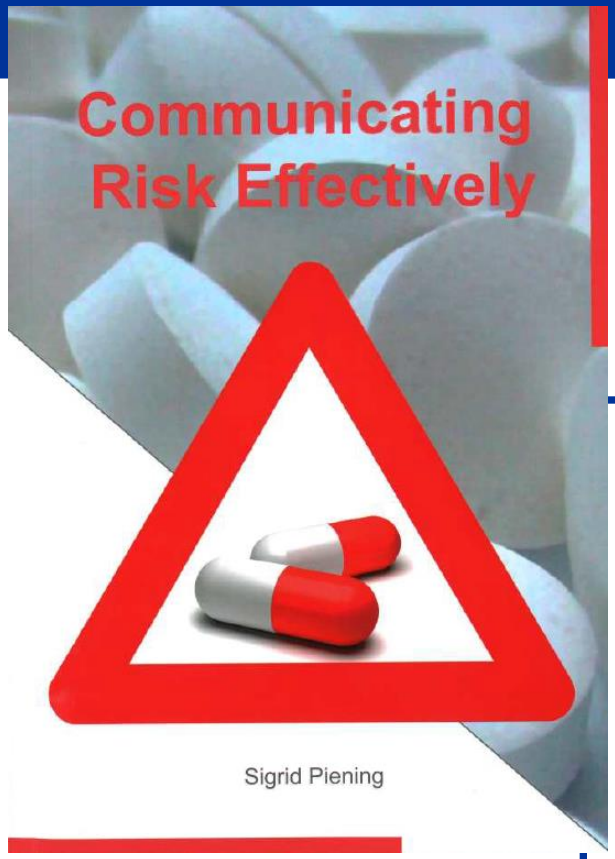
More information about the study »

Which of the statements below describes you?

- I have been diagnosed with atrial fibrillation
- I have been diagnosed with breast cancer
- I have been diagnosed with diabetes
- I am being treated for obesity

VISUALizE

Better communication of medicines for better health



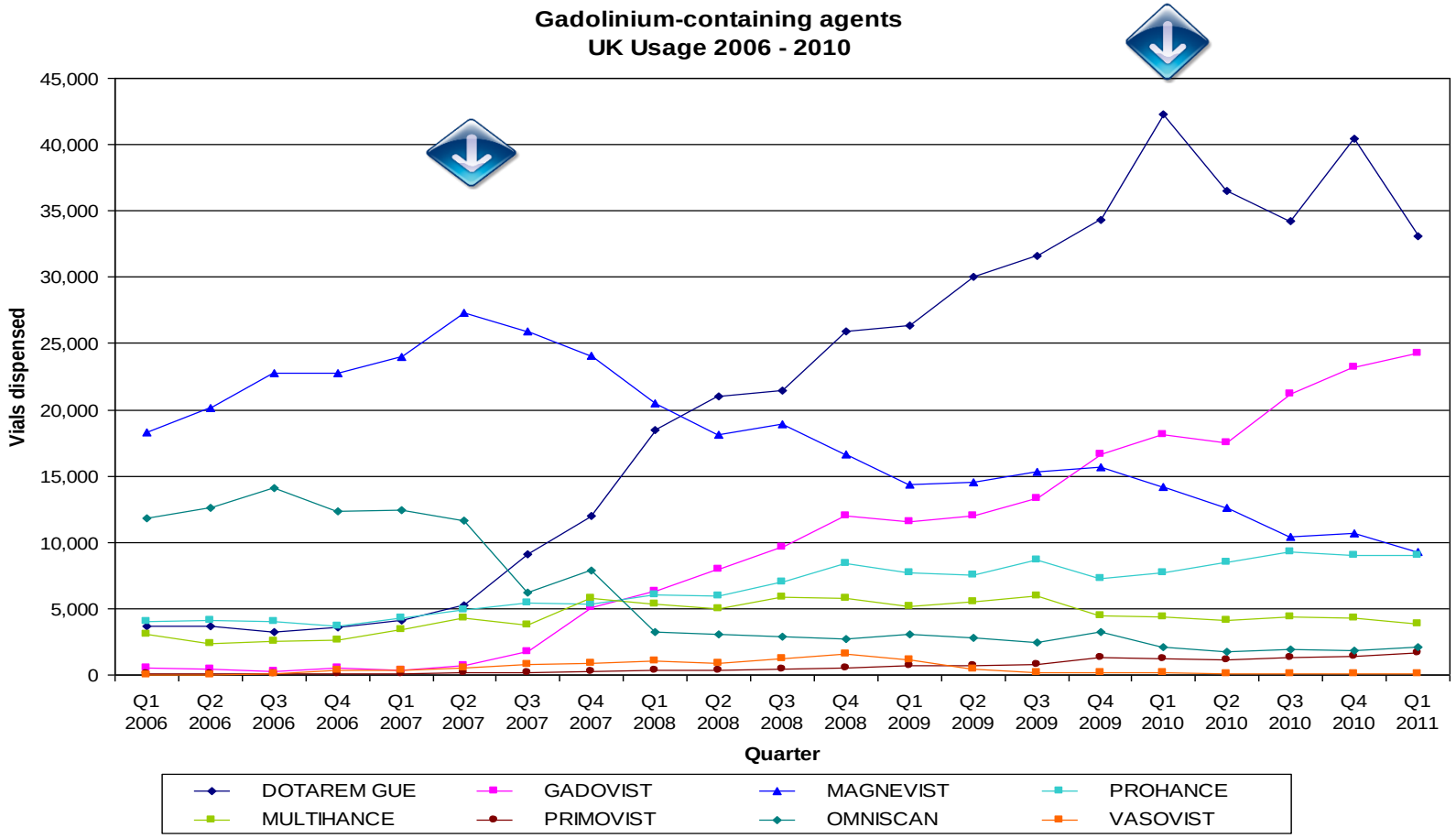
When Direct Health-Care Professional Communications Have an Impact on Inappropriate and Unsafe Use of Medicines

KC Reber[1], S Piening[2], JE Wieringa[1], SMJM Straus[3,4], JM Raine[5], PA de Graeff[2,3], FM Haaijer-Ruskamp[2] and PGM Mol[2,3]

Serious safety issues relating to drugs are communicated to health-care professionals via Direct Health-Care Professional Communications (DHPCs). We explored which characteristics determined the impact of DHPCs issued in the Netherlands for ambulatory-care drugs (2001–2008). With multiple linear regression, we examined the impact on the relative change in new drug use post-DHPC of the following: time to DHPC, trend in use, degree of innovation, specialist drug, first/repeated DHPC, DHPC template, and type of safety issue. DHPCs have less impact on use of specialist drugs than nonspecialist drugs ($P < 0.05$). The DHPCs' impact increased after availability of a template emphasizing the main problem ($P < 0.05$), and for safety issues with a risk of death and/or disability (both $P < 0.05$) (adjusted $R^2 = 0.392$). Risk communication can be effective, specifically in case of well-structured information, and very serious safety issues. Effectiveness may improve by tailoring DHPCs and adding other communication channels, for example for drugs that are increasingly being used.

Effectiveness of Risk Minimisation

Use of Gadolinium contrast agents after nephrogenic systemic fibrosis



Did you know?

You can report side effects yourself

As a patient, you have the right to report unwanted side effects of medicines directly to the authorities. You can also report a side effect on behalf of someone in your care, such as a child or relative.

Remember to speak to your doctor or pharmacist if you are worried about any suspected side effects.

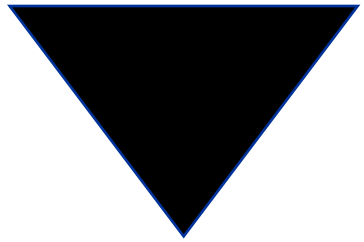
Why report a side effect?

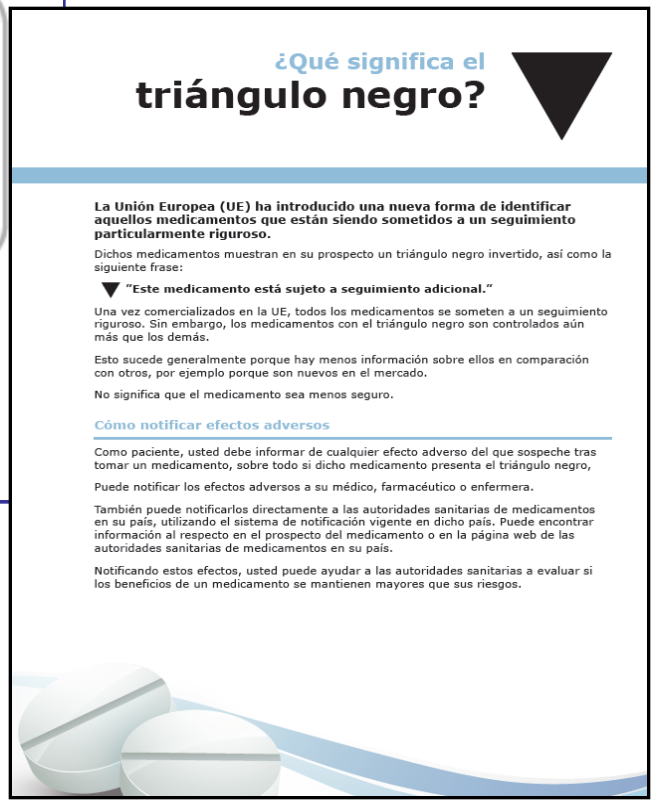
We are always learning more about medicines.

Although they are tested extensively in clinical trials before they are authorised, not everything can be known about their side

How do I report a side effect?

If you think a medicine has caused a side effect, please check the package leaflet that comes with the medicine for information on how to report it.





¿Qué significa el

triángulo negro?

La Unión Europea (UE) ha introducido una nueva forma de identificar aquellos medicamentos que están siendo sometidos a un seguimiento particularmente riguroso.

Dichos medicamentos muestran en su prospecto un triángulo negro invertido, así como la siguiente frase:

▼ **"Este medicamento está sujeto a seguimiento adicional."**

Una vez comercializados en la UE, todos los medicamentos se someten a un seguimiento riguroso. Sin embargo, los medicamentos con el triángulo negro son controlados aún más que los demás.

Esto sucede generalmente porque hay menos información sobre ellos en comparación con otros, por ejemplo porque son nuevos en el mercado.

No significa que el medicamento sea menos seguro.

Cómo notificar efectos adversos

Como paciente, usted debe informar de cualquier efecto adverso del que sospeche tras tomar un medicamento, sobre todo si dicho medicamento presenta el triángulo negro,

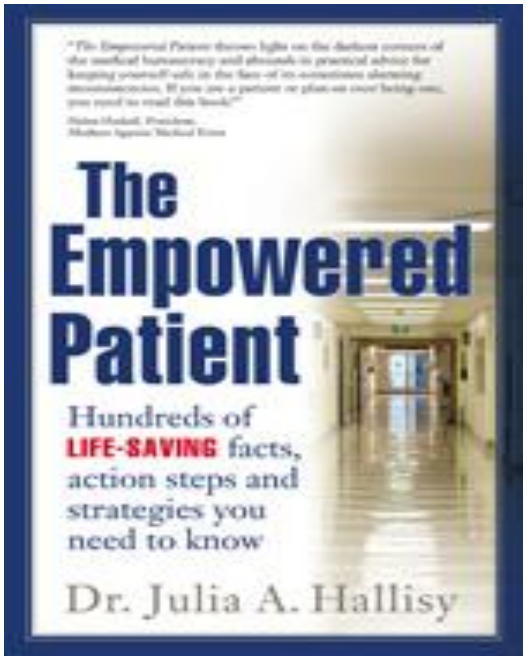
Puede notificar los efectos adversos a su médico, farmacéutico o enfermera.

También puede notificarlos directamente a las autoridades sanitarias de medicamentos en su país, utilizando el sistema de notificación vigente en dicho país. Puede encontrar información al respecto en el prospecto del medicamento o en la página web de las autoridades sanitarias de medicamentos en su país.

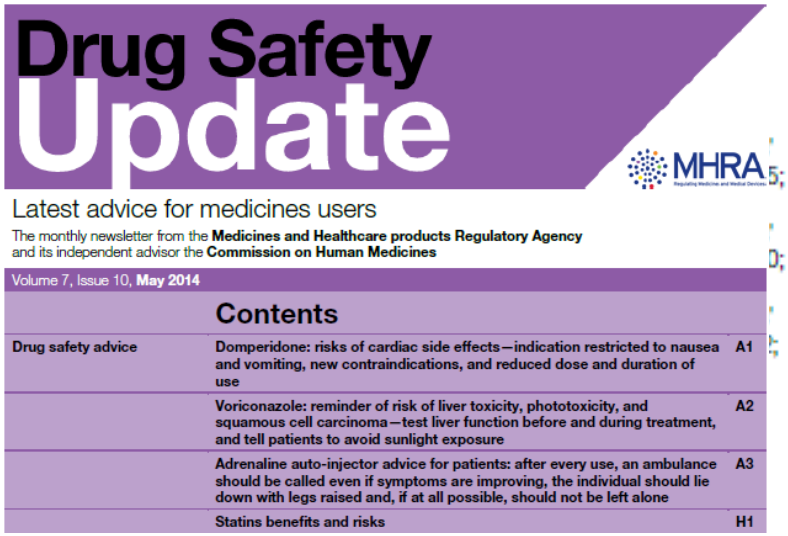
Notificando estos efectos, usted puede ayudar a las autoridades sanitarias a evaluar si los beneficios de un medicamento se mantienen mayores que sus riesgos.

Challenges still to be tackled?

- Are we getting the balance right or is there too much on risk and not enough on benefit?
- Are we reaching the right audiences and tailoring the messages to audience needs?
- Do PRAC's communications have an impact on benefit risk judgements?



Statins - a UK learning experience…



Drug Safety Update

MHRA

Latest advice for medicines users

The monthly newsletter from the **Medicines and Healthcare products Regulatory Agency** and its independent advisor the **Commission on Human Medicines**

Volume 7, Issue 10, **May 2014**

Contents

Hot topic

H1 **Statins benefits and risks**

Statins (HMG-CoA reductase inhibitors) are widely used medicines for patients with lipid disorders and in the primary and secondary prevention of heart attack and stroke. The statins currently available in the UK are simvastatin, atorvastatin, pravastatin, fluvastatin, and rosuvastatin.

Evidence from large clinical trials[1-4] shows that statins can reduce heart attacks and the need for bypass surgery, and can save lives in certain patient groups. Meta-analysis of randomised trial data shows that if patients with a 10-year cardiovascular risk of at least 20% take statins for 5 years, it would prevent at least 450 heart attacks, strokes, or vascular deaths per 10,000 treated patients.[3]