EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Communication campaign: medicines under additional monitoring

Patients' and Consumers' Working Party / Healthcare Professionals' Working Party joint meeting, 25 September 2013

Presented by: Christopher Gadd, Communication

Framework for campaign

- Developed by European Medicines Agency with close involvement of Member States and Commission
- Ultimate target audiences: patients and healthcare professionals
- Limited resources
- Close involvement of patient and healthcare-professional organisations:
  - Input on strategy and messages; support campaign (multipliers)
- Main aims:
  - Publish clear information at relevant milestones
  - Provide materials in all European Union (EU) and Economic Area (EEA) languages, for use at national level
  - Co-ordinate messages, expand outreach

Main actions - April 2013

First publication of list:

- Public-friendly web page launched, in all official EU languages
- Press release
- Materials shared in advance with Member States and European Commission (including translations)
- Also provided to patient and healthcare-professional organisations

Disease areas
Transparency
Releasing clinical-trial data
Antimicrobial resistance
Safety monitoring of medicines
2010 pharmacovigilance legislation
Medicines under additional monitoring
Medication errors
Medicines for children
Clinical trials
Medicines for rare diseases
Advanced therapies
Falsified medicines

Home ▸ Special Topics ▸ Safety monitoring of medicines ▸ Medicines under additional monitoring

Medicines under additional monitoring

Email Print Help Share

The European Union (EU) has introduced a new process to label medicines that are being monitored particularly closely by regulatory authorities. These medicines are described as being under 'additional monitoring'.

Medicines under additional monitoring have a black inverted triangle displayed in their package leaflet and in the information for healthcare professionals called the summary of product characteristics, together with a short sentence explaining what the triangle means:

▼ This medicinal product is subject to additional monitoring.

The black triangle will be used in all EU Member States to identify medicines under additional monitoring. It will start appearing in the package leaflets of the medicines concerned from the autumn of 2013. It will not appear on the outer packaging or labelling of medicines.

What does the black triangle mean?

All medicines are carefully monitored after they are placed on the EU market. If a medicine is labelled with the black triangle, this means that it is being **monitored even more intensively** than other medicines. This is generally because there is less information available on it than on other medicines, for example because it is new to the market or there is limited data on its long-term use. It does not mean that the medicine is unsafe.

Additional monitoring status is always applied to a medicine in the following cases:

- it contains a new active substance authorised in the EU after 1 January 2011;
- it is a biological medicine, such as a vaccine or a medicine derived from plasma (blood), for which there is limited post-marketing experience;
- it has been given a conditional approval (where the company that markets the medicine must provide more data about it) or approved under exceptional circumstances (where there are specific reasons why the company cannot provide a comprehensive set of data);

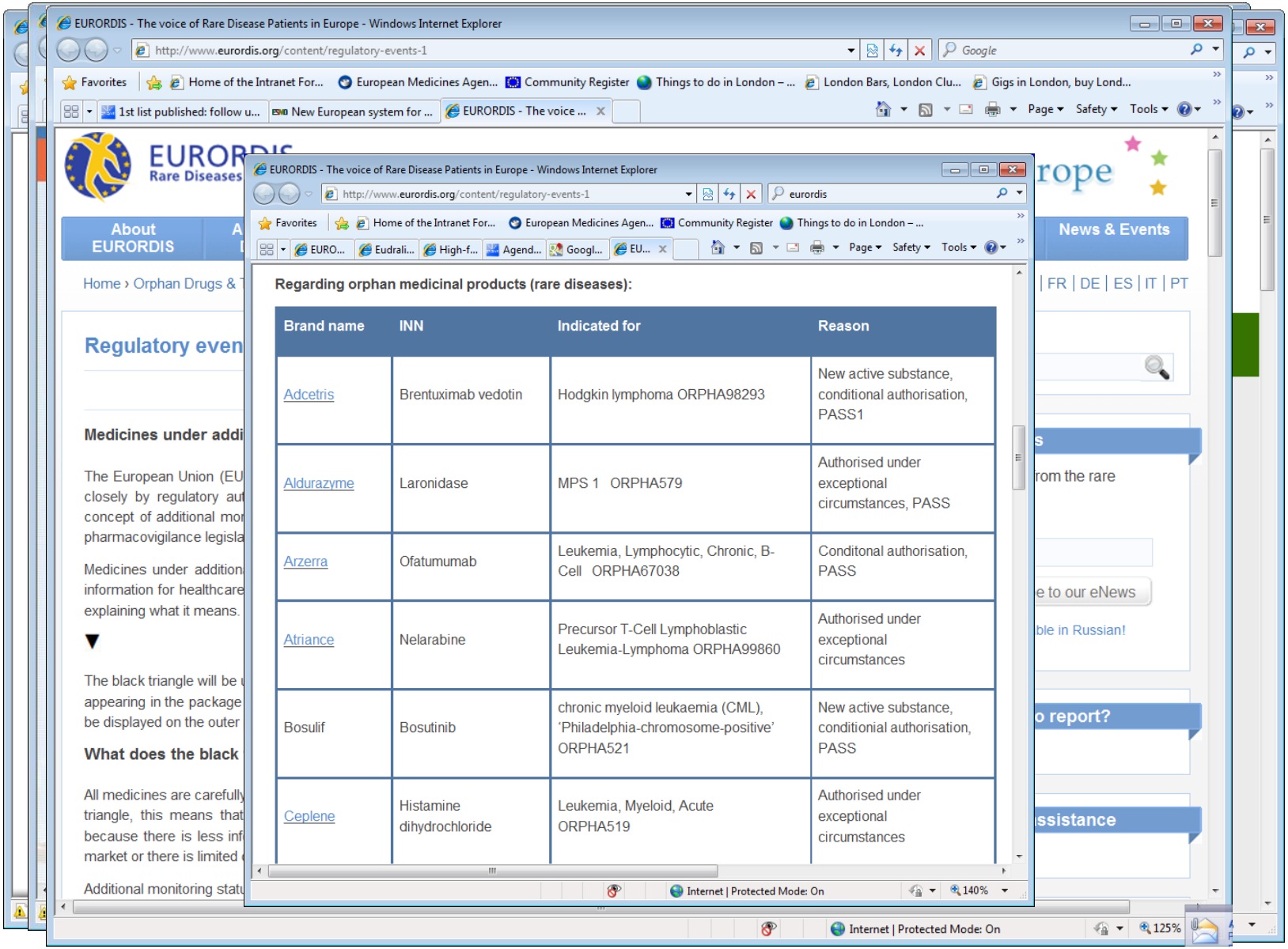
Coordination and dissemination: results

1. Patient, consumer and healthcare-professional organisations

Feedback from 11 organisations:

- Information shared with members; published on websites; included in newsletters
- Some tailoring of information to target audiences

Organisation	Info to members	Newsletter	Website	Social media
BEUC	x			
EACPT	x			
EATG			x	
EFA	x	x	x	x
EFNA	x	x	x	
EPF		x		
EPHA		x	x	
ESMO		x	x	
Eurordis	x		x	
PGEU	x			
IPOPI			x	



EURORDIS - The voice of Rare Disease Patients in Europe - Windows Internet Explorer

http://www.eurordis.org/content/regulatory-events-1

Regarding orphan medicinal products (rare diseases):

Brand name	INN	Indicated for	Reason
Adcetris	Brentuximab vedotin	Hodgkin lymphoma ORPHA98293	New active substance, conditional authorisation, PASS1
Aldurazyme	Laronidase	MPS 1 ORPHA579	Authorised under exceptional circumstances, PASS
Arzerra	Ofatumumab	Leukemia, Lymphocytic, Chronic, B-Cell ORPHA67038	Conditonal authorisation, PASS
Atriance	Nelarabine	Precursor T-Cell Lymphoblastic Leukemia-Lymphoma ORPHA99860	Authorised under exceptional circumstances
Bosulif	Bosutinib	chronic myeloid leukaemia (CML), 'Philadelphia-chromosome-positive' ORPHA521	New active substance, conditionial authorisation, PASS
Ceplene	Histamine dihydrochloride	Leukemia, Myeloid, Acute ORPHA519	Authorised under exceptional circumstances

Co-ordination and dissemination: results

2. Member States

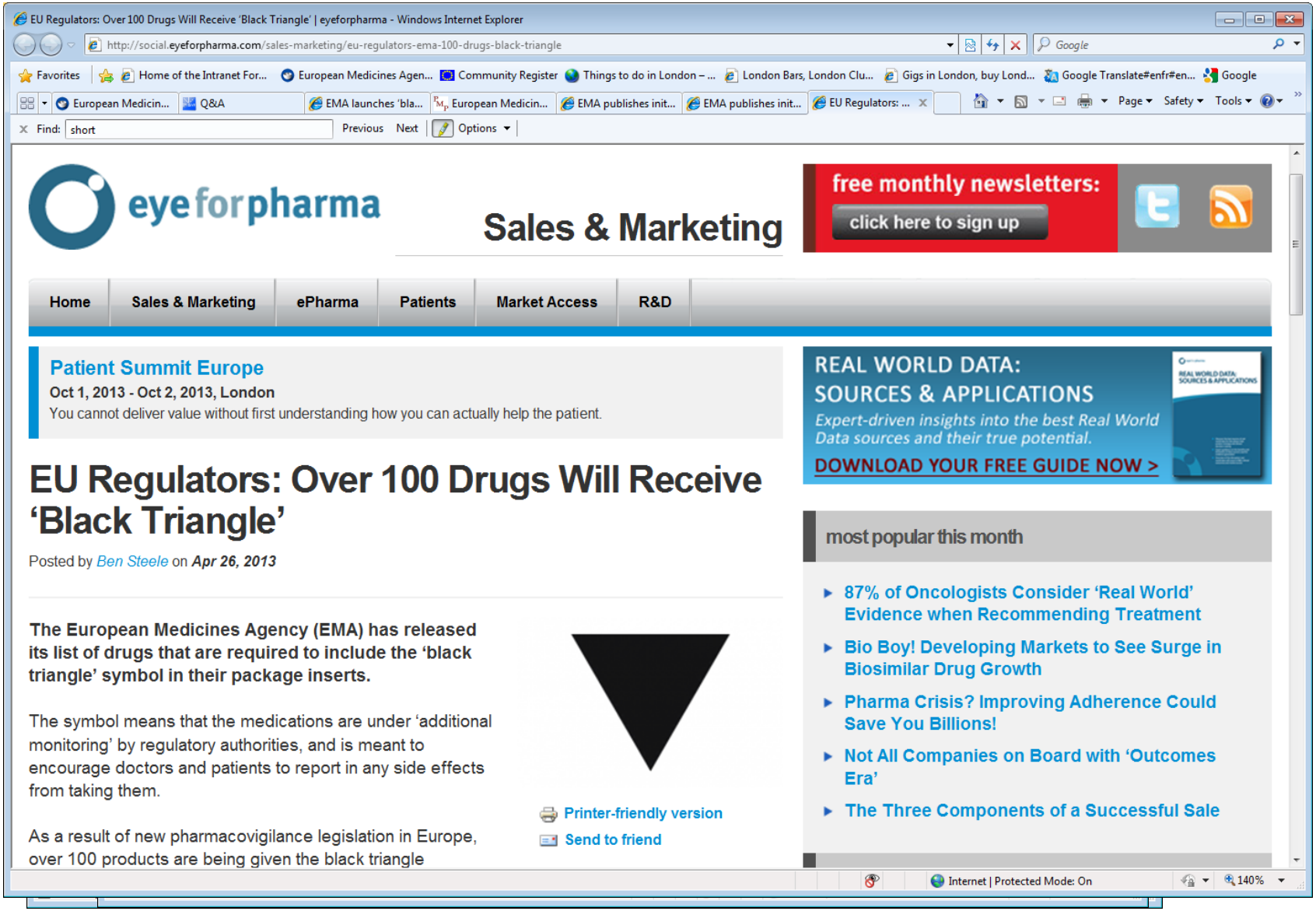
Questionnaire in May + review of websites (>17 countries):

- Information published on national competent authority websites; timely; national language
- Inclusion in newsletters, press releases, some social media
- Dissemination to national associations of patients, healthcare professionals and industry
- Future communication foreseen


Zāļu valsts aģentūra - Windows Internet Explorer
http://www.zva.gov.lv/?rel=1453
Lipoplatin
Favorites
Home of the Intranet For...
European Medicines Agen...
Community Register
Things to do in London – ...
London Bars, London Clu...
Gigs in London, buy Lond...
Zāļu valsts aģentūra
Jersikas iela 15, Rīga, LV-1003, Latvija
Tālr.: 67078424
Mob. tālrunis: 29447659
Fakss: 67078428
e-pasts: info@zva.gov.lv
Visi kontakti
Meklēt
Jaunumi
Par mums
Normatīvie akti
Pakalpojumi
Publikācijas
Pacientiem
Atsauksmes un jautājumi
Reģistrs
2013. gada 31. maijs
Sākums
Lapas karte
RSS
Iznācis otrais 2013. gada bezmaksas izdevums "Cito!"
"Cito!" var saņemt Zāļu valsts aģentūras (Jersikas ielā 15, Rīgā) 11. kabinetā
ZVA izdevusi Zāļu reģistru 2013!
Lasīt vairāk par Zāļu reģistru
Aptieku karte
Pārbaudi zāļu cenu šeit!
Jaunumi
drukāt
2013. gada 3. maijs
Lai veicinātu cilvēkiem paredzēto zāļu drošuma uzraudzību visā Eiropā, ievieš jaunu simbolu - melnu, apgrieztu trīsstūri
Zāļu valsts aģentūra (turpmāk ZVA) informē, lai uzlabotu cilvēkiem paredzēto zāļu drošuma uzraudzību visā Eiropā, spēkā ir stājies Eiropas Komisijas lēmums un grozījumi normatīvajos aktos, kas paredz ieviest jaunu simbolu zāļu aprakstos un lietošanas instrukcijās. Jaunais simbols – melns apgriezts trīsstūris – no 2013.gada rudens tiks iekļauts to zāļu dokumentācijā, kurām tiek piemērota papildu uzraudzība.
ZVA direktore I.Adoviča norāda, ka „Eiropas Savienības, tajā skaitā Latvijas, iedzīvotājiem pieejamās reģistrētās zāles tiek pastāvīgi uzraudzītas. Tiek vērtēts to drošums ne tikai pirms reģistrācijas, bet arī pēc reģistrācijas, kad tās nonāk nacionālā zāļu tirgū. Ja zāles tiek atzīmētas ar melnu apgrieztu trīsstūri, tas nenozīmē, ka tās ir nedrošas un tās lietot nav ieteicams. Simbols liecina, ka ir paredzēta papildus uzraudzība, proti, vajadzīga papildus informācija no lietošanas gadījumiem, kuru farmācijas uzņēmumiem jāanalizē un jāsniedz izvērtēšanai".
Lai nodrošinātu veselības aprūpes speciālistu un pacientu informētību par zālēm, kurām ir noteikta papildu uzraudzība, Eiropas Zāļu aģentūra (turpmāk EMA) ir izveidojusi zāļu sarakstu, kurā minētajām zālēm lietošanas instrukcijā un zāļu aprakstā ir iekļauts melns apgriezts trīsstūris un uzraksts „Šīm zālēm tiek piemērota papildu uzraudzība".
Zāles sarakstā var tik iekļautas pirms to reģistrēšanas vai arī citā laikā, ja tiek saņemti signāli par šo zāļu pastiprinātas uzraudzības nepieciešamību. Lēmumu par papildu uzraudzību pieņem EMA Farmakovigilances riska vērtēšanas komiteja (PRAC). Papildu uzraudzība zālēm vienmēr tiek piemērota šādos gadījumos:
1. zāles satur jaunu aktīvo vielu, kas Eiropas Savienībā reģistrēta pēc 2011. gada 1.janvāra;
2. bioloģiskas izcelsmes zāles, kas reģistrētas pēc 2011. gada 1. janvāra un kuru lietošanas pieredze pēc pieejamības nodrošināšanas pacientiem ir ierobežota;
3. zāles reģistrētas ar nosacījumiem (zāļu izmantošanas laikā zāļu reģistrācijas apliecības īpašniekam ir jāiesniedz papildu dati par zālēm) vai arī zāles ir reģistrētas izņēmuma kārtā (ir objektīvi iemesli, kādēļ nav iespējams iesniegt visus nepieciešamos datus);
4. zāļu reģistrācijas apliecības īpašniekam ir jāveic papildu pētījumi, piemēram, lai sniegtu papildu datus par zāļu ilgstošu lietošanu vai par retām zāļu blaknēm, kas novērotas klīnisko
ATKLĀJ ZĀĻU OTRU PUSI
Ziņo par blaknēm
Publiskais novērtējuma ziņojums (PNZ)
Ziņot par zāļu blakusparādību
Baltijas marķējuma procedūra
E-dokumenti
Aktīvo vielu nosaukumi latviski, latīniski, angliski
Farmācijas termini
Viegli lasīt
Pasākumu kalendārs
Jaunumi e-pastā
Aptauja
Vai esat pamanījis ZVA uzsāktās kampaņas "Atklāj zāļu otru pusi!" informatīvos materiālus?
Jā, esmu pamanījis aptiekā
Done
Internet | Protected Mode: On
100%

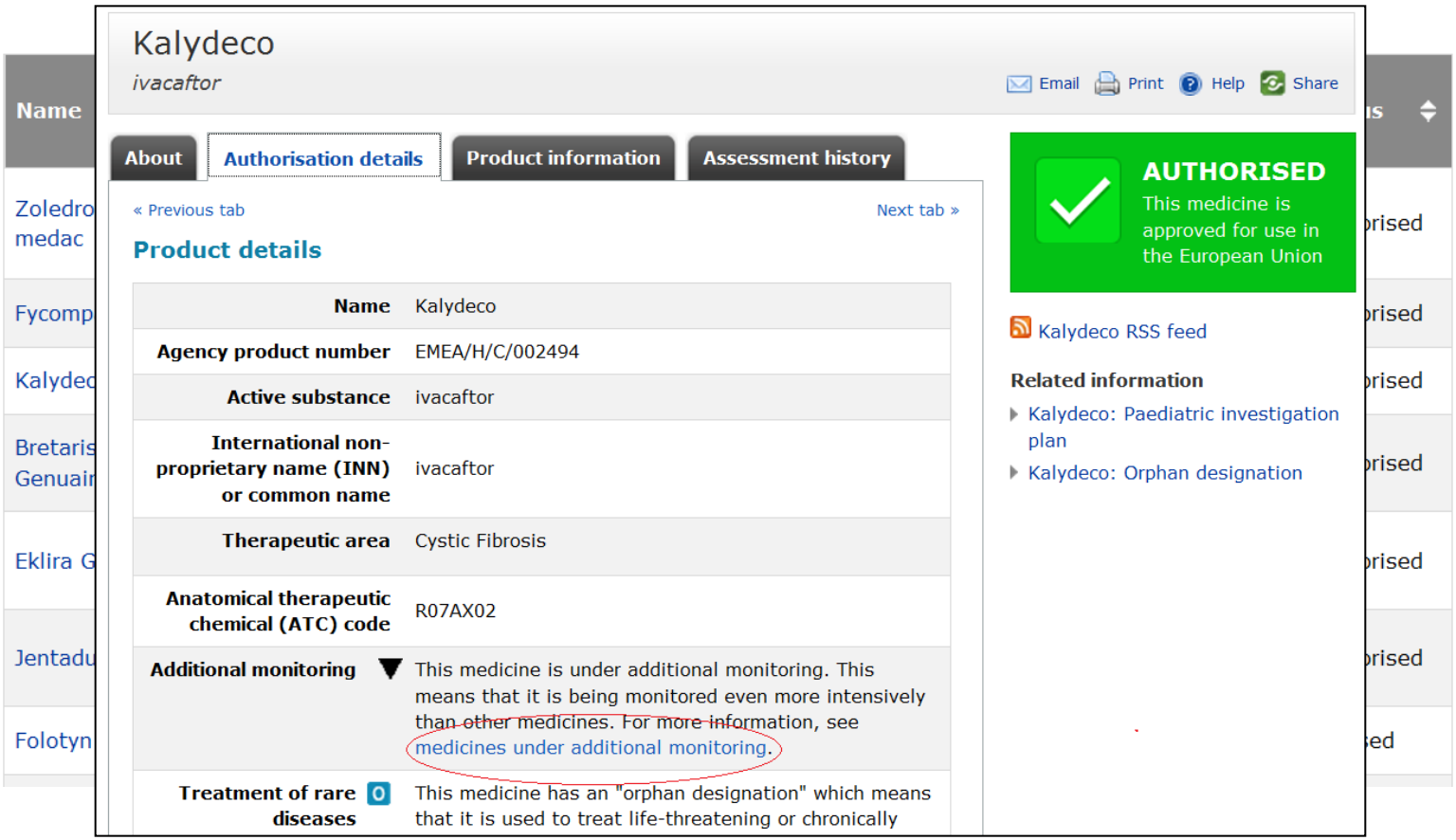
Our initial statistics in April

- Low media and stakeholder response:
  - 3 minor enquiries
  - Some online articles, all in industry-facing media
  - Stakeholder organisations did not report a high level of attention from members
- But web traffic high:
  - List: among top 1% documents viewed in April/May
  - Public-friendly page: among top 3% pages viewed in April/May


EU Regulators: Over 100 Drugs Will Receive 'Black Triangle' | eyeforpharma - Windows Internet Explorer
http://social.eyeforpharma.com/sales-marketing/eu-regulators-ema-100-drugs-black-triangle
eye for pharma
Sales & Marketing
free monthly newsletters:
click here to sign up
Home
Sales & Marketing
ePharma
Patients
Market Access
R&D
Patient Summit Europe
Oct 1, 2013 - Oct 2, 2013, London
You cannot deliver value without first understanding how you can actually help the patient.
REAL WORLD DATA: SOURCES & APPLICATIONS
Expert-driven insights into the best Real World Data sources and their true potential.
DOWNLOAD YOUR FREE GUIDE NOW >
EU Regulators: Over 100 Drugs Will Receive 'Black Triangle'
Posted by Ben Steele on Apr 26, 2013
The European Medicines Agency (EMA) has released its list of drugs that are required to include the 'black triangle' symbol in their package inserts.
The symbol means that the medications are under 'additional monitoring' by regulatory authorities, and is meant to encourage doctors and patients to report in any side effects from taking them.
As a result of new pharmacovigilance legislation in Europe, over 100 products are being given the black triangle
Printer-friendly version
Send to friend
most popular this month
87% of Oncologists Consider 'Real World' Evidence when Recommending Treatment
Bio Boy! Developing Markets to See Surge in Biosimilar Drug Growth
Pharma Crisis? Improving Adherence Could Save You Billions!
Not All Companies on Board with 'Outcomes Era'
The Three Components of a Successful Sale

Main actions - August 2013

Medicines now labelled on our website



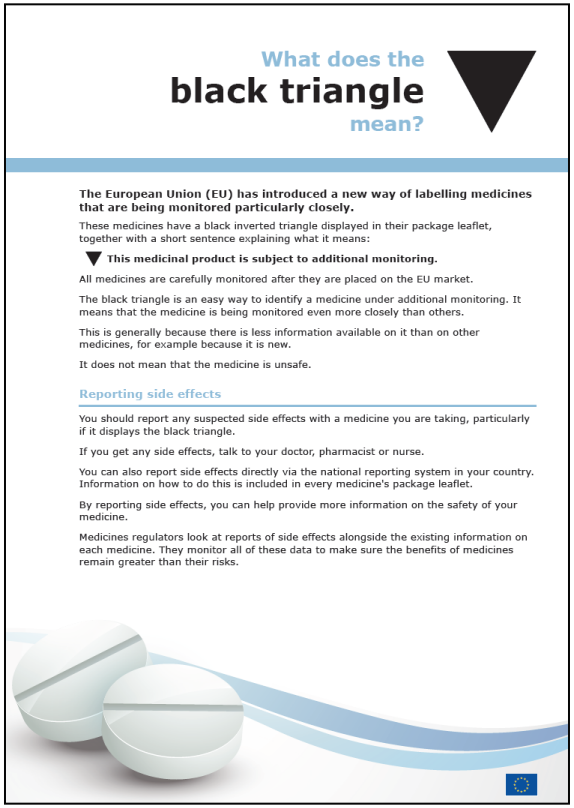
Main actions – coming on 1 October 2013

Black triangle entering into circulation, increasingly visible:

- Further information material to be published, can be used by all partners:
  - 'Fact sheet' with 3 logos (European Commission, Heads of Medicines Agencies and European Medicines Agency)
  - Video
  - Website banner
  - Press release
- European Medicines Agency and European Commission will go public on 1 October.
  - You are encouraged to do so as well

Factsheet

- Consultation: European Commission, Heads of Medicines Agencies involved in preparation
- All EU languages, Icelandic and Norwegian
- Easily printable
- Based on already published information



What does the
black triangle
mean?

The European Union (EU) has introduced a new way of labelling medicines that are being monitored particularly closely.

These medicines have a black inverted triangle displayed in their package leaflet, together with a short sentence explaining what it means:

▼ **This medicinal product is subject to additional monitoring.**

All medicines are carefully monitored after they are placed on the EU market.

The black triangle is an easy way to identify a medicine under additional monitoring. It means that the medicine is being monitored even more closely than others.

This is generally because there is less information available on it than on other medicines, for example because it is new.

It does not mean that the medicine is unsafe.

Reporting side effects

You should report any suspected side effects with a medicine you are taking, particularly if it displays the black triangle.

If you get any side effects, talk to your doctor, pharmacist or nurse.

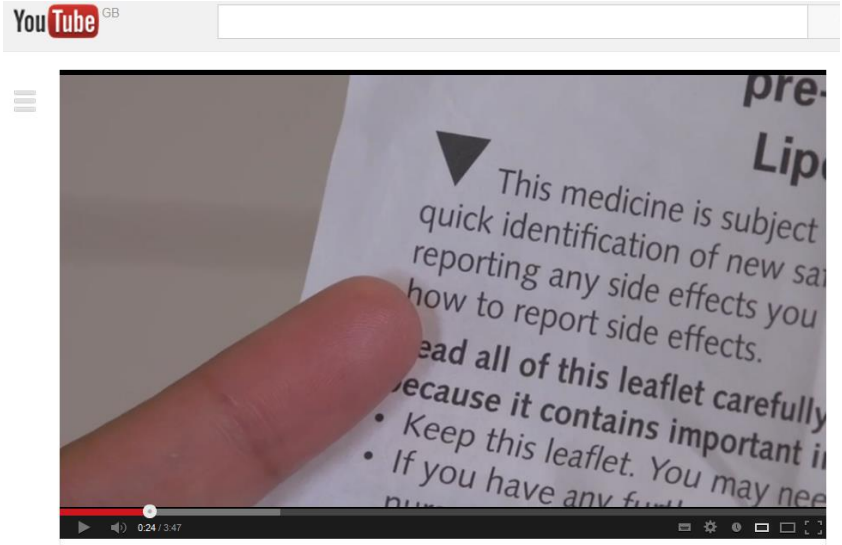
You can also report side effects directly via the national reporting system in your country. Information on how to do this is included in every medicine's package leaflet.

By reporting side effects, you can help provide more information on the safety of your medicine.

Medicines regulators look at reports of side effects alongside the existing information on each medicine. They monitor all of these data to make sure the benefits of medicines remain greater than their risks.

Video

- Under 3 minutes
- Stock shots with narration + interviews
- Audio in 5 languages
- Subtitles in all EU languages, Icelandic and Norwegian
- Focused on black symbol, real-life situations, what to do
- Limited content on Agency and committees



Dissemination

- You will receive all materials in advance with a link to a 'hidden' webpage on our website
- We aim to provide final materials on 27 September
- Further dissemination planned through Member States

Thank you