EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Additional monitoring: public communication

PCWP/HCPWP, 5 June 2013

Reminder

- Black symbol: ▼
  - Selected in March following PRAC recommendation (after involving stakeholders)
- New text in product information:
  - *SPC: <{Black symbol}> This medicinal product is subject to additional monitoring. This is to allow any safety information to be identified rapidly. Healthcare professionals are encouraged to report any suspected adverse reactions. See section 4.8.>*
  - *PL : <{Black symbol} This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.*
- List of products:
  - Maintained by EMA/PRAC, kept updated

Communication strategy: key features

- Main objectives:
  - Publish clear information at relevant milestones, all EU languages
  - Enable 'information multipliers' to launch own campaigns, adapting EMA materials to specific audiences
  - Co-ordinate information across Member States
- Key target audiences: patients and healthcare professionals
- Limited resources – online based

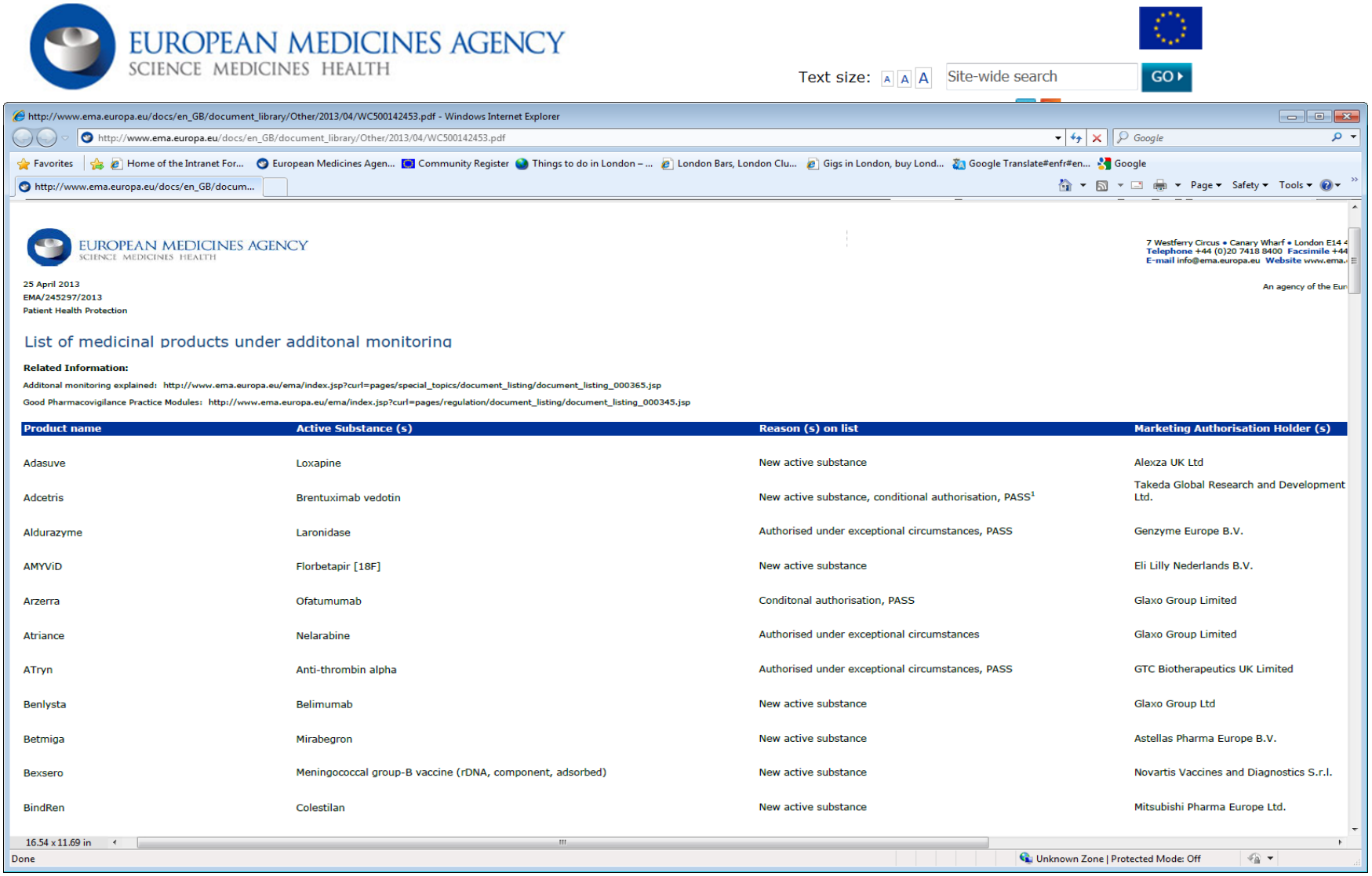
Main actions: completed

March 2013 - black symbol selected:

- Revised product information templates + implementation plan published (for industry)

April 2013 - initial list of medicines published:

- EMA web page on additional monitoring launched
- Public-friendly, all EU languages, links to related information
- Consulted stakeholders in advance
- Press release, on homepage
- Materials sent in advance to stakeholders (including translations)
- Also provided to Member States + Commission


An agency of the European Union
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
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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...
Google Translate#enfr#en...
Google
Page
Safety
Tools
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
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E-mail info@ema.europa.eu Website www.ema.
An agency of the Eur
25 April 2013
EMA/245297/2013
Patient Health Protection
List of medicinal products under additonal monitoring
Related Information:
Additonal monitoring explained: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000365.jsp
Good Pharmacovigilance Practice Modules: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp
Product name
Active Substance (s)
Reason (s) on list
Marketing Authorisation Holder (s)
Adasuve
Loxapine
New active substance
Alexza UK Ltd
Adcetris
Brentuximab vedotin
New active substance, conditional authorisation, PASS1
Takeda Global Research and Development Ltd.
Aldurazyme
Laronidase
Authorised under exceptional circumstances, PASS
Genzyme Europe B.V.
AMYViD
Florbetapir [18F]
New active substance
Eli Lilly Nederlands B.V.
Arzerra
Ofatumumab
Conditonal authorisation, PASS
Glaxo Group Limited
Atriance
Nelarabine
Authorised under exceptional circumstances
Glaxo Group Limited
ATryn
Anti-thrombin alpha
Authorised under exceptional circumstances, PASS
GTC Biotherapeutics UK Limited
Benlysta
Belimumab
New active substance
Glaxo Group Ltd
Betmiga
Mirabegron
New active substance
Astellas Pharma Europe B.V.
Bexsero
Meningococcal group-B vaccine (rDNA, component, adsorbed)
New active substance
Novartis Vaccines and Diagnostics S.r.l.
BindRen
Colestilan
New active substance
Mitsubishi Pharma Europe Ltd.
16.54 x 11.69 in
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Results: dissemination

1. Member States

Questionnaire + review of websites (>17 countries):

- Published information on national authority websites; timely; national language
- Newsletters; press releases; social media (Italy, Sweden, Norway)
- Dissemination to national associations of patients, healthcare professionals and industry
- Some national media coverage; interviews/quotes
- Future communication foreseen
- Issues:
  - Nationally authorised medicines: need to identify in which countries authorised


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...
Lipoplatin - ...
European M...
European M...
1st list publi...
Webtop
05 - May
Agencia Esp...
Zāļu vals...
Page
Safety
Tools
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!
LATVIJAS REPUBLIKAS ZĀĻU REĢISTRS
OFICIĀLS IZDEVUMS
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
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Results: dissemination

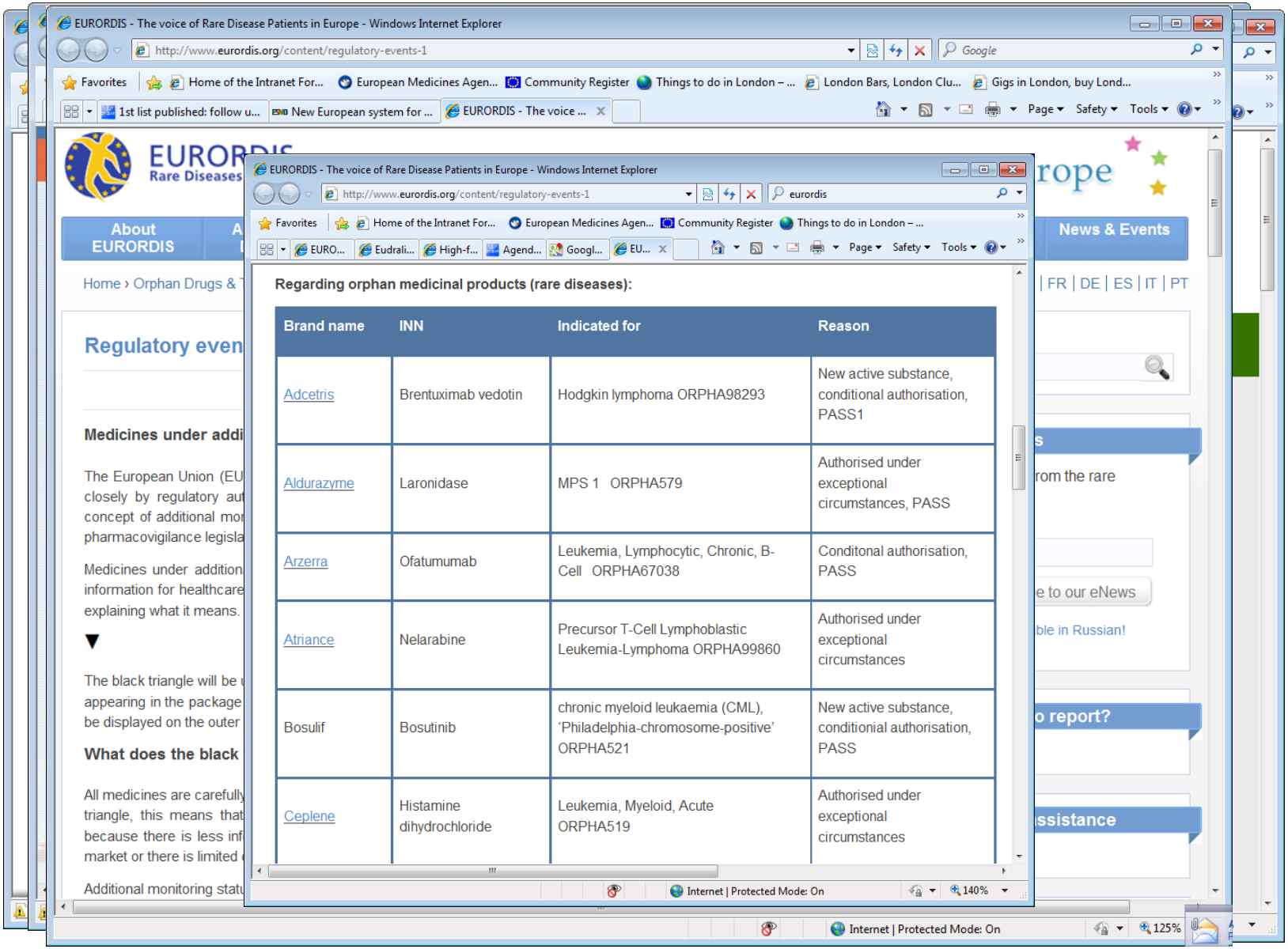
1. Member States
2. Stakeholders

Stakeholders

- 11 respondents so far
- Information shared with members; newsletters; websites

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	

- Issues:
  - How to target information for specific audiences (e.g. role of community/hospital pharmacists in different MS)


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
About EURORDIS
News & Events
Home › Orphan Drugs &
FR | DE | ES | IT | PT
Regulatory even
Medicines under addi
The European Union (EU
closely by regulatory aut
concept of additional mor
pharmacovigilance legisla
Medicines under addition
information for healthcare
explaining what it means.
The black triangle will be
appearing in the package
be displayed on the outer
What does the black
All medicines are carefully
triangle, this means that
because there is less inf
market or there is limited
Additional monitoring statu
rom the rare
e to our eNews
ble in Russian!
o report?
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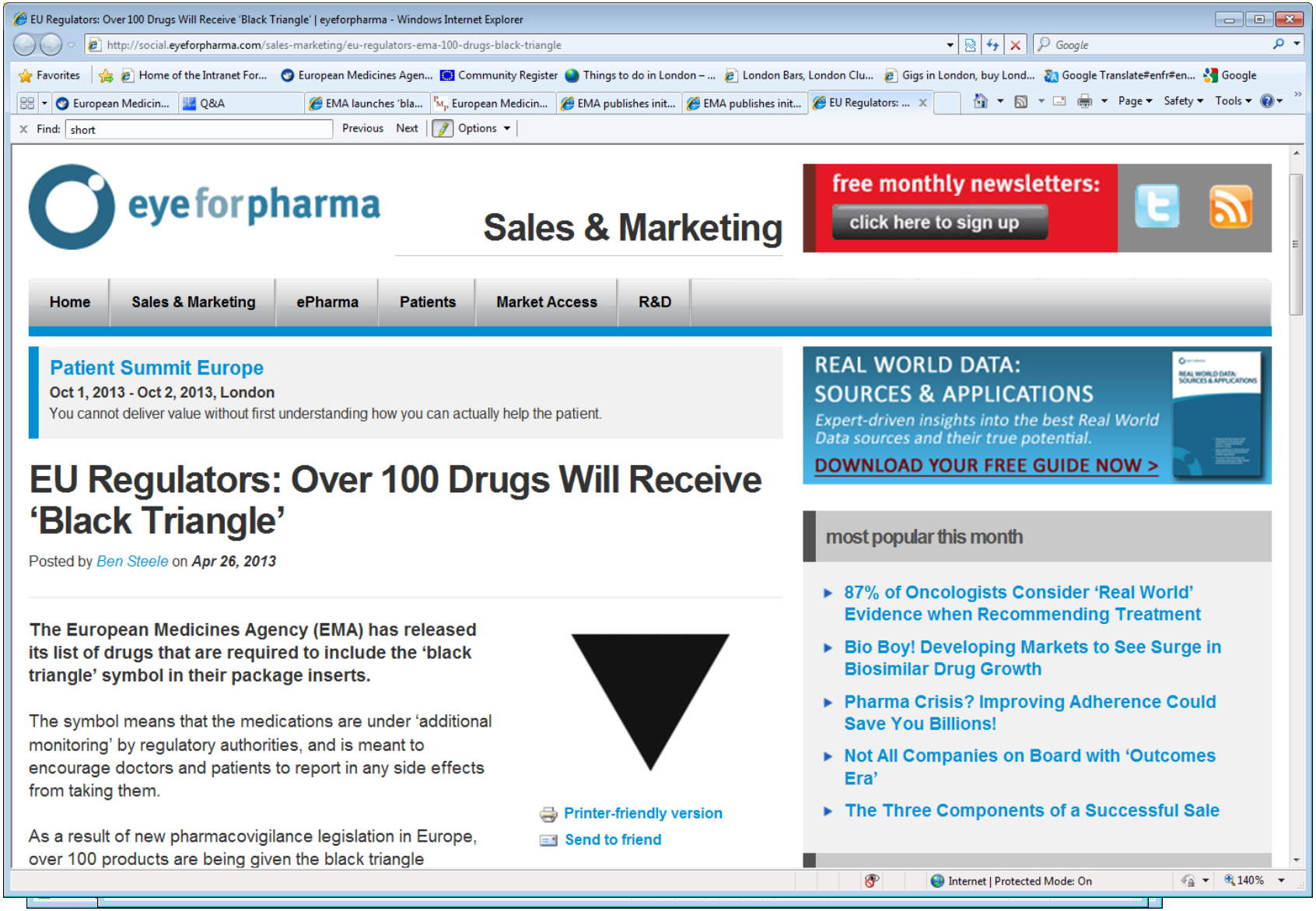
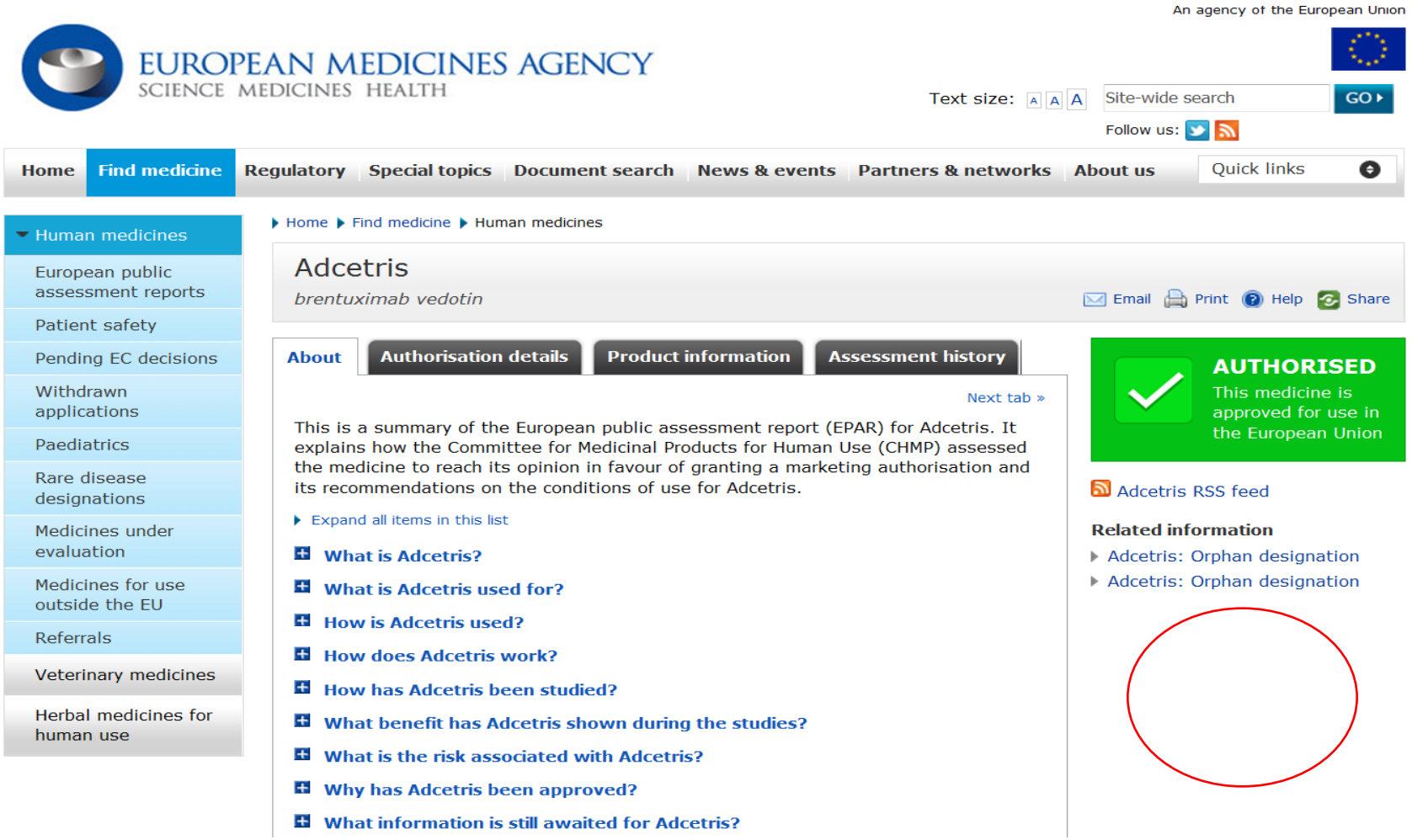
Results: EMA initial statistics

- Media
  - Low coverage: articles in online specialised media (industry)
  - 3 minor enquiries
- Stakeholder enquiries
  - Zero
- Web traffic
  - High
  - List: top 1% documents viewed in April/May (~45,000)
  - Public-friendly page: top 3% pages viewed in April/May (~5,000)


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
eyeforpharma
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: future



Main actions: future

By September 2013:

- Publish short video on EMA website:
  - 3-4 minutes
  - Stock shots with narration, interviews (sound bytes), animations (?)
  - All EU languages: audio for narration, subtitles for interviews
  - Focus on black symbol, real-life situations, use a mock-up
  - Limit any content on the EMA and committees etc.

Main actions: future

Also planned:

- Print-out leaflet
- Information packs for stakeholders
- Promotion via social media, news/media activities
- Taking stock of impact: web statistics, surveys, etc. – ongoing feedback helpful
- Repeat or enhance in 2014 as appropriate

Considerations

- Early stages in a gradual process
- Expect low awareness for patients and healthcare professionals at this stage, industry more focussed
- Awareness will grow, updated leaflets will enter circulation
- Clear information published; consistency across Member States
- Good basis for future communication
- Impact measurable in–depth at later stage

Your co-operation + input highly valued

- Feedback
- Suggestions
- Experience
- Issues

Thank you!