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Shareable communications content

An overview of recent work

Patients and Consumers Working Party (PCWP) meeting with all EMA eligible patient/consumer organisations

Presented by Monika Benstetter on 22 November 2017
Head of Media and Public Relations

Talk to us!

EMA seeks views of women with bipolar disorder with experience of using valproate.

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#EMAPublicHearing #valproate #BipolarDisorder

World Hepatitis Day - 28 July 2017

4.7 million people live with chronic hepatitis B in EU

3.9 million people live with chronic hepatitis C

EMA authorised medicines in the EU:

5 vaccines for hepatitis A and B

8 medicines for hepatitis B

Baraclude, Lamivudine Teva, Sebivo, Tenofovir disoproxil Mylan, Tenofovir disoproxil Zentiva, Vemlidy, Viread, Zeffix

17 medicines for hepatitis C

Daklinza, Epclusa, Exviera, Harvoni, IntronA, Olysio, Pegasys, PegIntron, Rebetol, Ribavirin Mylan, Ribavirin Teva, Ribavirin Teva Pharma B.V., Sovaldi, Victrelis, Viekirax, ViraferonPeg, Zepatier

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#WorldHepatitisDay

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#YoungPatients

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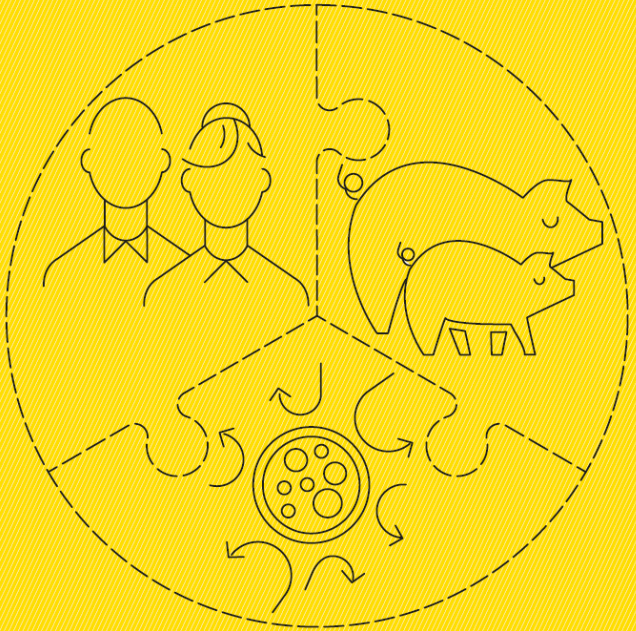
#SideEffects #patientsafety

THE GLOBAL THREAT OF ANTIMICROBIAL RESISTANCE

Awareness session

19 September 2017, 8.30am - 5.15pm

at EMA



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#AMR #AntibioticResistance

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#EMAPublicHearing #valproate

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PRIME

The first 12 months

The European Medicines Agency (EMA) developed its PRIority MEdicines (PRIME) scheme in line with the European Commission's priorities and the European medicines regulatory network's strategy to 2020.

Addressing patients' needs

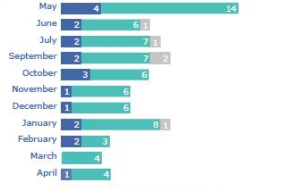
- PRIME aims to bring promising medicines that meet regulatory requirements to patients earlier by optimising and supporting their development.
- The scheme focuses on medicines that address an unmet medical need and that have the potential to bring a major therapeutic advantage to patients.
- With PRIME, EMA translates scientific advances into the development of medicines that can make a real difference to patients' lives.

20 requests granted (by type of medicine)

- 12 advanced therapies (of which 8 orphan medicines)
- 2 biological medicines (of which 1 orphan medicine)
- 5 chemical medicines (of which 3 orphan medicines)
- 1 vaccine

1 in 3 medicines targets a disease for which no treatment exists

96 requests processed (between April 2016 and April 2017)



22% success rate

71 requests denied (multiple reasons in some cases)

- ~70% Data not sufficiently robust
- ~40% Justification of therapeutic advantage insufficient
- ~20% Development too advanced

PRIME medicines (by therapeutic area)

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CMA

Conditional Marketing Authorisation

How early access to medicines has helped patients from 2006 to 2016

What it is

- an EU early access route for medicines
- for medicines that fulfil an unmet medical need
- only granted if the benefit of immediate availability for patients is greater than the risk of less comprehensive data than normally required
- valid for a year; can be renewed annually
- comprehensive data is generated post-authorisation, to agreed timelines

Scope includes

- medicines to target seriously debilitating or life-threatening diseases
- medicines to fight public health threats in emergency situations (e.g. a pandemic)
- medicines to treat rare diseases

30 CMAs

- 24 Target debilitating or life-threatening conditions
- 14 Are orphan medicines
- 3 Address emergency situations linked to a public health threat

By therapeutic area

- 17 Oncology
- 9 Infectious diseases
- 3 Neurology
- 1 Ophthalmology

107 post-authorisation obligations

(of these, 57 obligations were fulfilled before June 2016)

Categories of specific obligations imposed to companies

- 78 Final results from clinical studies or pool of studies
- 9 Interim results of a clinical trial
- 8 Additional analysis
- 3 Quality data
- 9 Other measures

How timely was the submission of specific obligation results?

- 33 Due date +/- 1 month
- 15 Early (1-6 months)
- 4 Early (6-12 months)
- 1 >1 year early
- 2 Late (1-6 months)
- 2 Late (6-12 months)

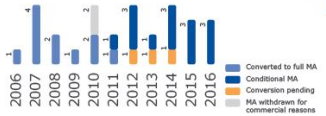
>90% of completed specific obligations did not have major changes to their scope

≈70% of specific obligations were completed within specified timelines

By year

EMA's Committee for Medicinal Products for Human Use (CHMP) reviews all data collected annually to decide about a further renewal of the CMA or its conversion into a standard marketing authorisation.

On average, a CMA is converted into a standard marketing authorisation **within 4 years.**



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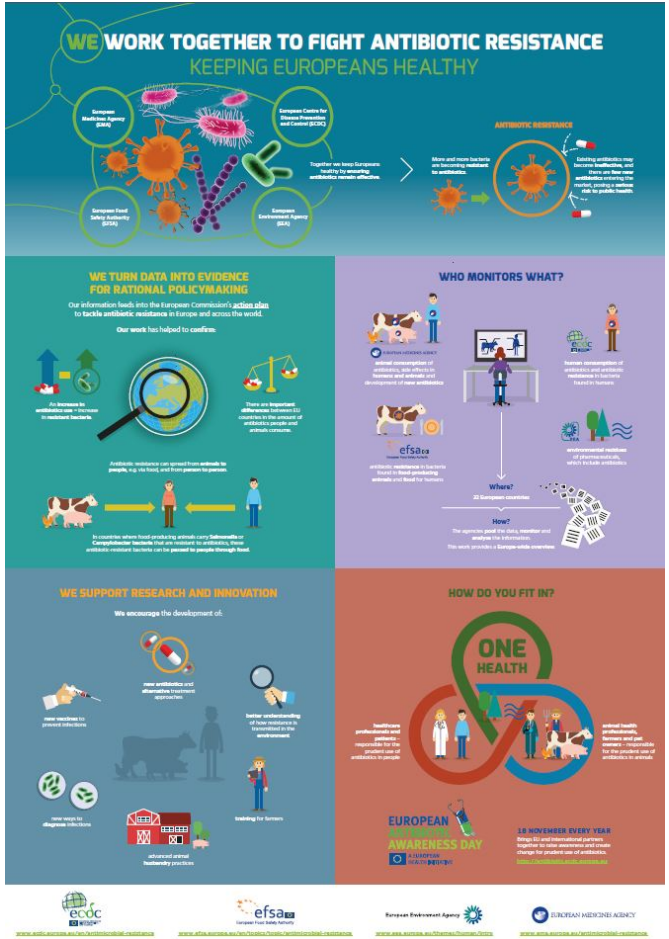
» The cut-off date for data collection is June 2016



EMA 1 year anniversary of clinical data publication

Clinical data publication - background

- In October 2016, EMA started to publish clinical reports underpinning the market authorisation of new medicines for human use
- Hundreds of clinical reports submitted by pharmaceutical companies have already been published
- Clinical data publication is a groundbreaking transparency initiative and, worldwide, EMA is the first regulatory authority to provide such broad access to clinical data

Data published so far

50 medicines relating to 54 regulatory procedures

36 marketing authorisation applications including 2 withdrawn applications

18 variations to extend the clinical use of a marketed medicine

3,279 documents

1.3 million pages

What is published and when?

- Clinical reports are published on a dedicated website (clinicaldata.ema.europa.eu) for:
  - all marketing-authorisation applications submitted to the Agency as of 1 January 2015
  - all applications submitted to extend the existing clinical indication of a medicine as of 1 July 2015
- the reports are published once authorisation is granted by the European Commission
- reports supporting applications that are withdrawn

Users

3,641 registered

Usage

22,164 views

80,537 downloads

Who benefits?

- Patients
  Better medicines, protection from unnecessary trials
- Academia and researchers
  Enhanced scientific knowledge
- Pharma industry, including small and medium-sized enterprises
  Quality research & development and innovation
- Healthcare professionals
  Better practice of medicines

Responders of a recent survey say that ...

- Data are:
  - useful **62%**
  - not useful 6%
  - in an understandable format **87%**
  - *32% remaining responders are unsure
- Publishing clinical data helps:
  - EMA to build **trust and confidence** in its scientific and decision-making processes - 3/4 responders
  - researchers to **re-assess the clinical data** - 2/3 responders

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For more information on clinical data publication visit our website.

www.clinicaldata.ema.europa.eu

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For discussion

Have you shared or used any of these materials?

What is the biggest obstacle for you/your organisation to share/use this?

Your feedback matters to us – how can we best collect it?

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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