EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

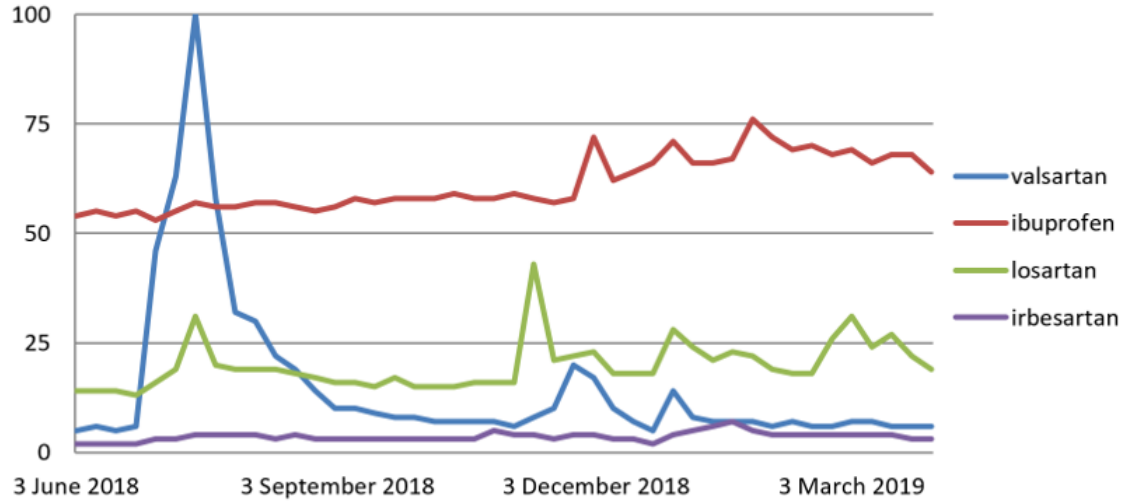
Information, coordination and public communication

Interested parties meeting on lessons learnt from presence of N-nitrosamine impurities in sartans

Amsterdam, 4 November 2019

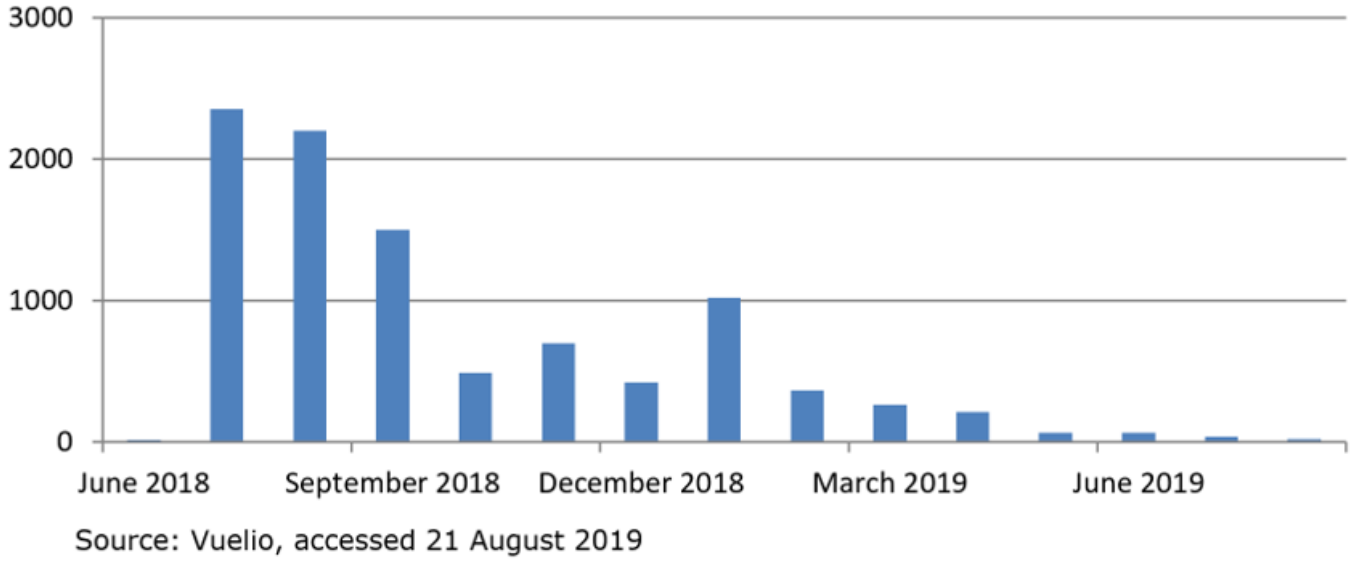
Presented by Nacho Mbaeliachi
Medical and Health Information Service

High public interest



Source: Google Trends, accessed 7 August 2019

Extensive coverage of valsartan



Source: Vuelio, accessed 21 August 2019

Interest in wider scientific community

- Regulators in spotlight
- What actions regulators should take future?
- BMJ editorial on regulators response
- Up to 11 publications identified in PubMed.

Queries received from concerned patients

- Will I get cancer as a result of *N*-nitrosamines?
- Is my medicine affected?
- Is my replacement medicine any safer?
- Why did regulators find out about the risk late?
- Where can I get more information?
- Can we trust the manufacturing outside the EU?

Concerns raised by healthcare professionals

- Where to find more information
- More guidance on switching patients' treatments
- More guidance on advice to patients

Questions from media

- Who knew what and when about nitrosamines in sartans?
- How was NDMA discovered?
- Who approved the change in manufacturing that led to formation of NDMA?
- Are changes in requirement in order to prevent nitrosamine impurities occurring medicines in EU?

Communication challenges faced by network

- Lack of complete information early on (particularly on risk estimation)
- A rapidly evolving (escalating) situation
- High public interest and concern
- Queries requiring translation highly technical information into public friendly language
- Explaining the complex regulatory system in the EU (e.g. relationship between EDQM and EMA/NCAs)
- Long-lasting nature of regulatory assessments

The network's communication response

- Regular updates published on regulators' websites
- Coordination of communication within the European network (lines-to-take)
- Strong cooperation with international partners (international working group)
- Explore measures for improving communication response (lessons learnt exercise and survey)

Survey of stakeholders on communication aspects

- Survey carried out in scope of lessons learnt exercise to:
  - assess how stakeholders rated communication from authorities
  - Explore ways to improve communication and interaction with stakeholders
- Stakeholders contacted:
  - Patients organisations
  - Healthcare professional organisations

Survey of stakeholders on communication aspects

- Separate survey sent to communication experts of authorities in Europe and international partners
- Feedback from this meeting and survey responses to help improve approach to communication in future

Further information

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