Safety communications across the pond

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Background

- Regulatory agencies, in addition to approving medications for use, are responsible for protecting the public health by assuring the safety of medications.
- Safety communications are part of the flow of information to manage the risks associated with medications between all of the stakeholders.
- Once a drug has been marketed, the safety concerns continue building on mandatory and voluntary reporting, data analysis, postmarketing surveillance, and other initiatives which allow regulatory agencies to communicate with healthcare professionals and the public.
- However, as many drugs are approved based on multinational clinical trials, much of the safety communication appears to be based on the postmarketing surveillance in one country.
- This is a continuation of a previous poster that evaluated 2016 data.

Objective

The objective of this study is to compare the timing of communications from the U.S. Food and Drug Administration (FDA) and the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) from 2016 and 2017.

Methods

- All safety communications published on the website for the FDA and MHRA in calendar years 2016-2017 were identified.
- Inclusion criteria:
  - Medications must be available in both the US and UK
  - The communications clearly identified the medication.
- Exclusion criteria:
  - Medications only available in one country.
  - Communications that only dealt with specific lots or compounded medications
- Outcome measurements:
  - Total number of safety communications evaluated
  - Total number of communications concerning drugs common to both countries
  - Timing of safety communication in relationship to each country
- Information in safety communication and inclusion in the product labeling (US package insert (PI) or UK the Summary of Product Characteristics (SPC)) from the other country.

Results

Safety communications in calendar years 2016-2017

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<th>FDA Safety Communications</th>
<th>MHRA Safety Communications</th>
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<tr>
<td></td>
<td>Total Number of Safety Communications</td>
<td>MHRA Safety Communications</td>
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<td>Safety Communications for drugs available in both countries</td>
<td>12</td>
<td>6</td>
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<tr>
<td>Excluded: 104</td>
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<td>Excluded: 22</td>
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(FDA) released a communication after 26 days; (MHRA) released a communication after 28 days.

Results (continued)

- FDA released more overall safety communications than MHRA. However, MHRA released more communications that were relevant from an international perspective.
- Of the relevant 2016-2017 FDA communications, 35% were not included in the SPC or other MHRA communications (as of September 2018).
- Of the relevant 2016-2017 MHRA communications, 23% were not included in the US PI or other FDA communications (as of September 2018).
- Some concerns in the unaddressed communications include acute kidney injury, CNS depression and death, heart problems with high dose, impulse control, laboratory interaction, osteonecrosis, vascular occlusive events, cholestatic hepatopathy, and progressive multifocal leukoencephalopathy.

Conclusions

- While the information available from the FDA and MHRA is reliable and based on both reports to the specific agency as well as available literature, there are large differences in the information provided by both agencies.
- In the area of safety communication, while there is significant overlap of available products in both the United Kingdom and the United States, there was very little (6%) overlap in the agencies safety communications.
- While the information may take some time to be incorporated in the two countries, eventually 49 of the 71 total communications (69%) were incorporated into the product labeling of the other country.
- As globalization with healthcare continues and information sharing is critically important, it is crucial for medical information specialists, both industry-based and clinically-based as well as other healthcare providers to be aware of looking for information from all sources including regulatory agencies and product labeling in other countries.

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