Prominence of important safety information for 2015-2017 branded consumer webpages

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Background
- Promotion of prescription drugs in the US is heavily regulated by the Food and Drug Administration (FDA) Office of Prescription Drug Promotion (OPDP).
- FDA regulations require that promotional pieces not be false or misleading and present all material facts in a balanced manner.6
- FDA research suggests that while direct-to-consumer (DTC) advertising increases patient awareness, DTC advertising may also send misleading messages to patients.4
- Both patients and providers believe DTC advertising overstates product efficacy and does not present a fair balance of benefit and risk information.3
- Recent OPDP findings indicate that location of important safety information (ISI) on consumer homepage can affect fair balance and consumer recall of safety information.4

Objective
- The purpose of this analysis is to evaluate the percentage of branded consumer webpages occupied by ISI for products approved during the years 2015-2017 in order to evaluate current marketing trends.

Methods
- All new molecular entities approved from 2015 until data collection conclusion on October 20, 2017 were included in the study.
- Products without branded consumer webpages were excluded.
- Percentages of the homepage occupied by ISI on Google Chrome were calculated (0 ISI = Area of ISI / Area of entire homepage x 100).
- Additional information captured from various FDA databases:
  - Therapeutic area
  - Sponsor company
  - Approval through accelerated approval, priority review, fast track, and/or breakthrough designation
  - Black Box Warning (BBW) requirement
  - Risk Evaluation and Mitigation Strategies (REMS) requirement

Results
- A total of 82 products were analyzed. A total of 18 products were excluded due to the lack of a branded consumer webpage.
- Four products contained no ISI in their branded consumer homepages.
- Percentages ranged from 2.51-52.38% with an average of 22.64%
- Year of approval, approval method, and therapeutic area did not appear to have a major correlation to the % ISI on the homepage (Figures 2-4.6).
- Products approved with a BBW for <25% and those without (n=56) had no or very few products in the addiction, analgesic, anesthetic, medical imaging, transplant, allergy, dental, and urology therapeutic areas were approved during the time of data collection.

Discussion
- As there are no FDA regulations or guidelines providing a quantitative measure of fair balance, there was a large range in the percent of homepage occupied by ISI for products approved from 2015-2017.
- Percent of consumer branded webpages occupied by ISI appears to have little correlation with the parameters assessed.
- The overall average ISI occupancy of 22.64% could serve as a reference point for future branded consumer webpages.
- Additional FDA guidance is needed to establish more uniform ISI occupancy on consumer webpages.

Limitations
- Products approved after October 20, 2017 and products without a branded consumer webpage were not included in analysis.
- Correlation between percent of homepage occupied by ISI and consumer understanding of risk was not assessed in this study.

Conclusions
- As there are no FDA regulations or guidelines providing a quantitative measure of fair balance, there was a large range in the percent of homepage occupied by ISI for products approved from 2015-2017.
- Percent of consumer branded webpages occupied by ISI appears to have little correlation with the parameters assessed.
- The overall average ISI occupancy of 22.64% could serve as a reference point for future branded consumer webpages.
- Additional FDA guidance is needed to establish more uniform ISI occupancy on consumer webpages.

References

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Figure 1 Number of Approved Products Per % ISI Range. The majority fell within the <20% range (n=64, 78%). Only three products had >40% of their homepages occupied by ISI.

Figure 2 Average % ISI Occupancy Stratified by Year of Approval.

Figure 3 Average % ISI Occupancy Per Approval Method. Four products had all five designations with an average of 23.23% occupied by ISI.

Figure 4 Average % ISI Occupancy Stratified by Therapeutic Area. Therapeutic area was stratified by OPDP task force. No ISI was evaluated. ISI (n=59), analgesic, anesthetic, medical imaging, transplant, allergy, dental, and urology were not approved for live data collection.