Industry Perspective

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EMA Workshop: Ensuring safe and effective medicines for an ageing population

Overview

1. Background
2. EFPIA position on Safety evaluation in the elderly
3. EFPIA Survey on Legislation

Background

- Safe and effective use of medicines requires availability, accessibility and understanding of the benefits and risks of the medicine. Application of these by Healthcare providers in the geriatric population is of particular importance as they have specific issues which need to be managed.

General comments and EFPIA position

- The new pharmacovigilance legislation in Europe is in the process of implementation. Many of the features of the legislation will have an impact on the effectiveness of pharmacovigilance monitoring in the elderly population and we recommend that the legislation be implemented and evaluated before considering further initiatives specific for the geriatric population.
- Specific measures to identify and evaluate hepatic, renal and drug-drug interactions; which are all exacerbated in the elderly could be brought into drug development programs
- The risk of medication error and of compliance which is a particular problem in the geriatric population and for which there is often poor data is addressed in the New legislation.
- Under treatment in geriatrics also leads to safety and medication issues

EFPIA Survey results

- The EFPIA survey was conducted to investigate the impact of the new PV legislation on the collection and evaluation of geriatric safety data
- 15 member companies responded to the Survey
- Three questions were prepared to elicit insight and understanding from industry
- One critical question:
  - **Do you think that the new PV system will allow for the adequate collection and evaluation of geriatric safety data ?**

  With two further clarifying questions:
    - Do you think there is any room for further streamlining?
    - Is there any specific methodological issue in this domain that needs to be addressed by the Industry and/or the Regulators

EFPIA Survey results (cont)

1. **Do you think that the new PV system will allow for the adequate collection and evaluation of geriatric safety data ?**

- 66% felt the new Legislation did provide adequate guidance and requirements to collect and evaluate geriatric data
- 20% felt it was inadequate but that additional guidance should come in the CT directive to identify specific areas for geriatric population in drug development
- 14% felt further clarity in the implementation of the new PV legislation is required to determine whether the new legislation is adequate

EFPIA Survey results (cont)

2. Do you think there is any room for further streamlining?**?**

– 40% felt there was room for further streamlining
  - Legibility, better PIL, clear instructions, clear information on drug – drug interaction
  - Reduce LASA
  - Clarity in post authorisation measures in RMPs
  - user friendly collection tool
– 40% felt the legislation was adequate or that it was too early to respond until the legislation was implemented
– 20% did not respond to this question. Impossible to ascertain if this was concurrence or not

EFPIA Survey results (cont)

3. Are there any specific methodological issues in this domain that need to be addressed by the Industry and/or the Regulators**?**

– 26% felt that there was room for specific methodological improvement:
  - Education programs for patients and HCPs
  - Stricter guidance on the methodology for multi-therapy collection and evaluation
  - Specific measures on medication errors: education, drug-drug interaction evaluation, patient advocate groups greater involvement

– 66% felt the new legislation provides all the methodological aspects needed

– 8% did not respond to this question. Impossible to ascertain if this was concurrence or not

Conclusion

- Industry recognise that geriatric patients have specific needs and issues that need to be addressed with respect to ensuring the safe and effective use of medicines
- These specific issues are particular to physiological and pharmacodynamic changes that come on later in life and their diminishing understanding and legibility of information and ability to report these issues
- It is generally felt that the new legislation will be adequate to ensure appropriate collection and evaluation of medicines use in the elderly whilst ensuring that drug development measures to identify specific areas for concern are amended
- More collaboration between academia/industry/regulators needed to better understand and find solutions to these challenges