Abbott's experience
PV in Africa

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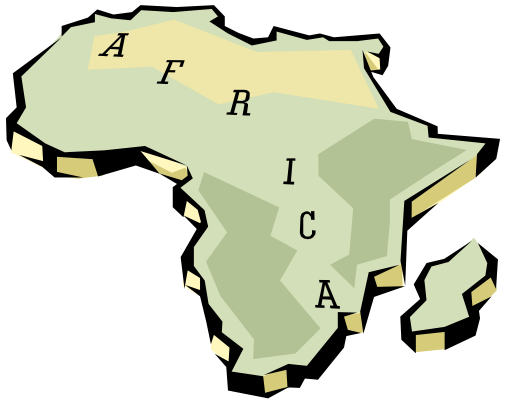
Main issue driving our evaluation of spontaneous reporting

– Differences in patient populations make it important to continue to monitor a drug even years after it has been on the market

– AE profile may manifest differently depending on different concomitant medications and/or diet, different co-morbid conditions, etc.:

- Genetics, diet, traditions etc
- Use of other medicines (ie. Herbal remedies, other concomitant medicines)
- Presence of other conditions such as TB, malaria, etc. which may be different compared to other regions



Abbott Virology

Basic question

Known safety profile for compound

Safety profile with caveats given different population

Are there differences in safety for a compound when used in a different setting?

Assembly of small group and objective

A small group was assembled and included pharmacovigilance, clinical team, Regulatory, and commercial

Objective for the group was:

- Identify ways to optimize PV reporting in Africa given the large volume of Aluvia distribution which is currently taking place.

For Abbott our South African Affiliate is center for reporting

- There are 23 countries which report their adverse events to Abbott Park through the South African affiliate
- Many of these countries have distinct regulatory requirements and timelines which must be met by the South African affiliate
- This puts the South African affiliate in a unique position

Recommendations based on group discussion

Key methods of improving PV reporting for the countries which report to the South African affiliate should involve:

- Easily accessible method for health care workers to communicate adverse events to the affiliate
- Education of health care workers on adverse event reporting and the importance of this
- Further education for distributors of lopinavir/ritonavir (this will impact all Abbott products) to ensure they are knowledgeable about PV reporting

Recommendations for an easily accessible method of communication to the SA affiliate

- **Centralized phone number and email to the SA Affiliate to help PV reporting**
  - A toll-free number can be obtained for individuals within South Africa
  - A reverse charges number can be obtained for countries outside South Africa
  - A central email address to the safety group within the South African affiliate is also possible

- **These phone numbers and email addresses can be added to distributed commercial materials such as dosing cards, brochures etc.**

Supply agreements - pharmacovigilance

- We've started to include clauses related to pharmacovigilance in our supply agreements with implementers in Africa.

Pharmaco-vigilance

– Without limiting the generality of the foregoing, XXXX and/or the Procurement Agent shall notify Supplier of reports of adverse events associated with the Product by telephone or if in writing (by facsimile) within twenty-four (24) hours after XXXX and/or its Procurement Agent receives such information. The report to Supplier shall contain (i) the date the report was received by XXXX and/or the Procurement Agent; (ii) the name of the reporter; (iii) the address and telephone number of the reporter; (iv) the patient details; (v) a description of the event; and (vi) any additional relevant information. All such information should be sent to the following contact person:

- Name: XXXX
- Abbott Laboratories South Africa (Pty) Ltd.
- Telephone: +27 11 XX
- Facsimile: +27 11 XX
- Email: XX

Recommendations for PV education and its importance

- Identified that use of a training slide deck at seminars, HIV-treater speaker series may improve adverse event reporting (targeting health care workers).
  - A training deck was developed and presented at seminars and HIV-treater series

- The South African affiliate currently trains distributors and Abbott employees. Additional training of distributors will improve PV.

Additional Issues which were considered

Differentiation of Aluvia from generics

- Differentiation occurs at our affiliate level, so standard questions were generated which helped to identify whether Aluvia or generic LPV/r was being used
  - If generic was being used and the company was known, the report would be forwarded to the other company

Follow-up post initiation of these simple measures

- Additional reports have been received, however, the number of reports are still below those received outside Africa, despite the increase in prescriptions for Aluvia over time.

Summary

- We are continuing to see increasing distribution of Aluvia within Africa
- Many clinical studies involve Africa and include Aluvia
- Spontaneous reporting noted to be low and simple measures put into place to try and improve this
- Continued education on importance of reporting is likely needed with goal being that a safety profile for Aluvia can be defined within the population receiving it
- Other options may be required

Known safety profile for compound

Safety profile with caveats given different population

Key questions

- What are other experiences?
- Is a goal of defining AE profile for a compound within Africa feasible? What are the hurdles that need to be dealt with?
- Is a more active form of pharmacovigilance better? What are the issues with this?
- How should reports from generic compounds be handled?

BACK up slides

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