EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

TATFAR –Trans-Atlantic Task Force on Antimicrobial Resistance

EMA Workshop on development of new antibacterial medicines
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Establishment of TATFAR

In response to the mounting threat of antimicrobial resistance, the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) was established by Presidential declaration in 2009 at the annual summit between the EU and US presidencies. The purpose of the taskforce is to identify urgent antimicrobial resistance issues that could be better addressed by intensified cooperation between the US and the EU within the following key areas:

1. Appropriate therapeutic use of antimicrobial drugs in the medical and veterinary communities;

2. Prevention of both healthcare- and community-associated drug-resistant infections;

3. Strategies for improving the pipeline of new antimicrobial drugs.

TATFAR Report

Through regular meetings and several public consultations, the members of the TATFAR have identified a set of 17 recommendations in these key areas where future cooperation would prove fruitful.

Each recommendation is explained in detail in the report that was issued on 22nd September 2011 along with timelines for implementation and appropriate implementers in the Recommendations section. A summary of the recommendations can be found in the report:

http://ecdc.europa.eu/en/activities/diseaseprogrammes/tatfar/documents/210911_tatfar_report.pdf

Upon adoption of the recommendations, the TATFAR intended to begin the process of implementation.

Opportunities for collaboration of regulatory relevance–human medicine

Regulatory approaches for antibacterial products

Issue: Antibacterial drug development programmes that satisfy regulatory requirements in both the US and EU could facilitate antibacterial drug development

Recommendation 15: FDA and EMA plan to discuss ways to facilitate the use of the same clinical development programme to satisfy regulatory submissions to both Agencies

Implementers: FDA and EMA

Timeline: within one year of adoption of recommendation **ON TARGET**

Opportunities for collaboration of regulatory relevance–human medicine

Regulatory approaches for antibacterial products

Both EMA and FDA agree it is acceptable for a trial to have separate pre-specified statistical analysis plans that would evaluate different primary endpoints and/or would evaluate endpoints at different time points in accordance with the recommendations of both regulatory authorities. In certain instances, this should make it possible to utilise the same trial to meet the requirements of both regulatory authorities in those instances where the recommendations for the primary endpoint or the time of assessment are different.

Reflections on flexibility on acceptance of patients baseline characteristics, in case of different demands between EU-US, has also taken place

Opportunities for collaboration of regulatory relevance–human medicine

Regulatory approaches for antibacterial products

Issue: Enhanced communication between FDA and EMA on issues such as product review and emerging drug safety issues could be beneficial

Recommendation 16: Establish regular meetings between FDA and EMA to discuss common issues in the area of antibacterial drug development and regulation

Implementers: FDA and EMA

Timeline: within one year of adoption of recommendation **ON TARGET**

Opportunities for collaboration of regulatory relevance–human medicine

Regulatory approaches for antibacterial products

Issue: Antibacterial drug developers need clear guidance on the development of drugs with the potential to treat resistant bacterial infections

Recommendation 17: Exchange information on possible approaches to drug development for bacterial diseases where limited drugs are available (i.e. bacterial diseases where there is unmet need because there are insufficient antibacterial drug therapies available, often due to the development of antimicrobial resistance)

Implementers: FDA and EMA

Timeline: within one year of adoption of recommendation **ON TARGET**

e.g. TODAY!

Next Steps

In order to ensure that these recommendations are transformed into concrete actions, the TATFAR recommends extension of its mandate for two additional years following the endorsement of the proposed recommendations by the EU and US leaders.

During this time, the TATFAR intends to monitor the implementation of the recommendations via biannual audioconferences and, at the end of the two year extension, to hold a face-to-face meeting to review progress and consider potential next steps.

Conclusions

TATFAR has provided an excellent tool to foster discussion between EMA and FDA in the area of antibacterials drug development

There has been no commitment from FDA and EMA in the context of this exercise to align the potentially different regulatory requirements in the two Regions, but more realistically to promote an increase in dialogue in order to have mutual understanding and view sharing which could ultimately lead to a desirable level of convergence.

Activities as per recommendations 15, 16 and 17 have already taken place in the context of TCs between EMA IDWP and FDA, and via mutual participation in dedicated EU or US workshops.