Concept Note on Joint Assessments Some key aspects

28 June 2018

(Good Review Practice – Communications)

Good Registration Management Conference

Background

- Results of survey on country specific requirements and gaps in the implementation of ACTD & ACTR by individual AMS
- Decision of HoD meeting, Makati, 28 October 2015, to develop “further cooperation among NRAs, such as joint assessment of applications for marketing authorization”.

Joint assessments - conceptual framework document for discussion

What is a Joint Assessment?

- Formal procedure in which the <u>same</u> application is <u>simultaneously</u> submitted to a number of participating NRAs.
- Assessment work is carried out together by staff of participating NRAs and a joint assessment report is produced.
- The final decision on the application is taken by <u>each individual NRA</u> through their normal decision-making process.
- Same application refers to the technical content of the application; national administrative parts remain different.
- Simultaneously refers to the fact that JA process <u>will not start</u> until applications are received in all participating NRAs.

What is the purpose of Joint Assessments?

- **Primary purpose**: strengthen NRAs technical capacity and foster mutual trust and reliance among AMS.

- **A second purpose**: facilitate the review of priority medicines throughout ASEAN while respecting existing national decision-making processes.

What is the scope?

- Implemented in a gradual manner …..

<u>In the first phase</u>:

a) medicines for treatment of malaria, TB, HIV/AIDS or other locally meaningful priority disease;

b) already approved for marketing by a reference NRA or prequalified by WHO;

c) manufactured in a PIC/S-GMP compliant site (documentary verification only, no inspections foreseen);

d) medicines offering an advantage over existing treatments (to be decided case by case on the basis of documentation submitted and opinion of national disease control programmes).

Scope revised as appropriate at a later stage.

Participation

- Open to all AMS but not compulsory.
- Participation related to each product. Each AMS decides for which product(s) to participate.
- Minimum of two AMS.
- After JA, the final approval of the product will be a national decision.

An AMS who has not participated may request another AMS to share the assessment report of the JA and rely on such report for its own national decision.

Role of WHO

WHO can:

- Provide direct advice and support for the finalization of procedures and implementation of JA
- Facilitate contacts with reference NRAs and manufacturers to enable exchange of information
- Facilitate participation of experts from reference NRAs to assist in the assessment
- Provide direct support until an operational platform is established by AMS - Broker donor’s support

Expected benefits for participating NRAs

- Stronger and broader basis for technical decisions
- Improved management of work load and assessment duration
- Harmonious interpretation of harmonized requirements
- Stronger mutual understanding and trust
- Strengthened overall capacity of all AMS to ensure that medicines of assured quality, safety and efficacy, become accessible to ASEAN citizens within the best possible assessment timeline