

Roles of NMRA executing a function of rotating ZaZiBoNa secretariat

In line with the agreement among the heads of ZaZiBoNa NMRAs, individual NMRAs share on a rotating basis the role of the secretariat supporting ZaZiBoNa operations and functions. The normal period for acting as a secretariat is 3 months and secretariats rotate quarterly in a sequence agreed by HoA.

During the period of its acting capacity, the secretariat and the respective HoA execute the following:

- Represents ZaZiBoNa to external partners, if official representation or opinion is requested. If necessary and following discussion and agreement of ZaZiBoNa HoA, communicates the respective matter and coordinates the adoption of the agreed common position.
- Leads in management of issues important for ZaZiBoNa's functionality and, if not otherwise agreed, presides ZaZiBoNa meetings..
- Leads in organization of professional and managerial meetings according to an agreed schedule, including logistical support and proposals for the agenda.
- Leads or monitors work of ZaZiBoNa task forces established on specific subjects.
- In case that a person co-ordinating then registration procedures (co-ordinator) is appointed to support ZaZiBoNa operations, co-operates with the person, assigns the tasks on behalf of ZaZiBoNa and supervises the respective deliverables.
- Transfers functions and pending agenda to the next acting ZaZiBoNa secretariat.

Assumed roles of ZaZiBoNa coordinator of registration procedures

Expected professional profile - junior professional with a degree in general science or scientific discipline relevant to medicine regulatory functions. At least 2 years experience in a regulatory function and familiar with procedures and requirements for registration of medicines.

The position of a co-ordinator is proposed to be established to maintain continuity of ZaZiBoNa registration processes and other routine agenda and to provide support to ZaZiBoNa rotating secretariats in execution of its functions. Optimally, the co-ordinator should be closely associated with one of ZaZiBoNa NMRAs, which will be hosting this function. Coordinator is responsible for performance of his/her duties to ZaZiBoNa HoA, which are represented by the HoA from the rotating secretariat. Funding of the co-ordinator position during the extended pilot is assumed to be provided by an external donor.

The main tasks of the co-ordinator are:

- Monitors smooth conduct of ZaZiBoNa registration procedures, focusing on compliance with procedural steps, deadlines, ZaZiBoNa agreements and other agreed actions. Reminds participants in case of deviation from regular conduct of individual procedures and proposes remedial actions, if necessary, to be executed by responsible professionals or HoA.
- Coordinates with the secretariat in preparation for ZaZiBoNa meetings with regards to distribution of, invitations, identification of venues, travel arrangements and preparation of the agenda.
- Coordinates communication among ZaZiBoNa assessors and inspectors and facilitation of availability of external expertise in support of ZaZiBoNa registration processes.

- Keeps records of ZaZiBoNa meetings, including agenda, agreed outcomes, recommendations, training materials, and other relevant documents.
- Establishes and/or maintains a robust tracking process of registration of medicines via Zazibona process, maintains the database of dossiers, assessments, lists of questions to applicants and registration outcomes. Monitors agreed timelines.
- Is responsible for distribution of documents to relevant parties and posting of relevant information on Mednet or other ZaZiBoNa communication media.
- Keeps and maintains an electronic archive of ZaZiBoNa agreed documents and training materials. Maintains ZaZiBoNa agreed technical interpretations and position to ensure consistency of decisions (regulatory memory).
- Keeps updated list of relevant ZaZiBoNa contacts, including focal persons, NMRA and WHO addresses, websites etc.
- Facilitates communication between ZaZiBoNa professionals and task forces and supports smooth transfer of ZaZiBoNa agenda among rotating secretariats.
- Prepares drafts and coordinates updates of Zazibona documents, including proposals to donors and communication to external partners (e.g. SADC). Prepares ZaZiBoNa budgetary plan and monitors expenditures.
- If required, facilitates communication with applicants and their headquarters on behalf of Zazibona

Rapporteur

Leads in assessment of assigned medicinal product, including determination of status of compliance with GMP and/or other relevant good practices (GXP). For this purpose

- develops a primary draft assessment report and list of questions (LOQ) to the applicant,
- provides opinion as regards GXP compliance and/or need of GMP or other inspections,
- submits the draft for comments to ZaZiBoNa assessors and invited external experts (e.g. WHO) and presents the product for the discussion among Zazibona assessors and inspectors,
- incorporates comments and prepares consolidated AR (CAR) and LOQ.
- leads in communication with applicant with regards responses to the questions, in assessment of responses from the applicant and in resolution of pending issues,
- proposes a Zazibona position on registration,
- . In the post registration phase leads in management of variations to the respective medicinal product.

Rapporteur's functions are performed in line with the time schedule of the ZaZiBoNa collaborative registration process.

Participating and concerned NMRAs

Participating NMRA (application for respective registration has been submitted to NMRA) submit comments and contribute by providing the relevant qualified expertise to the ongoing registration procedures and other ZaZiBoNa activities. The concerned NMRA (application for respective registration has not been submitted to NMRA) can comment and contribute by the expertise if being

interested. The functions of the participating and concerned NMRAs are performed in line with the time schedule of the ZaZiBoNa collaborative registration process.