Human Medicines Division
EMA/115804/2025

Mandate, objectives and rules of procedure for the CHMP-Companion diagnostics expert group

These mandate, objectives and rules of procedures will be incorporated in and adapted as required to the general rules of procedures governing all Working Parties, Operational Expert Groups and Drafting Groups.

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To best address the needs of the Committees and the European Medicines Agency (EMA) regulatory network while making the best use of the available expertise, the CHMP thereby formalise the following:

- Companion Diagnostics Expert Group

1. General considerations

The Companion Diagnostics (CDx) Expert group is a community of experts part of the European Regulatory Network in charge on medicinal products with knowledge in the area of the *in vitro* diagnostics and companion diagnostics.

The CDx expert group has been established initially by the EMA with the aim to support the implementation of the EMA responsibilities following the introduction of the In Vitro Diagnostic Devices Regulation (EU) 2017/746 (IVDR), in particular, to oversee the consultation procedure on companion diagnostics by Notified Bodies (NBs) with CHMP and support the CHMP on referred matters related to in-vitro diagnostics and companion diagnostics used in combination with medicinal products.

The IVDR introduced a new classification system of in-vitro diagnostics for companion diagnostics and the obligation to undergo a conformity assessment by a notified body requiring a consultation by the Notified Body with a medicinal product competent authority on the suitability of the companion diagnostic with the concerned medicinal product. For products within the scope of Annex to Regulation (EC) No 726/2004 of the European Parliament and of the Council (1) that are centrally authorised, the EMA should be consulted on the *suitability of the device in relation to the medicinal product concerned.*

The CDx expert group was previously called 'EMA/CHMP/CAT experts group on CDx' and was part of the CDx Working Group (CDx WG, including representatives of the Notified Bodies initially) established in 2021 to develop the procedural guidance for the implementation of the CDx consultation procedure. The CDx WG included representatives from the EMA, experts from the European Regulatory Network, device NCA, EC and notified bodies (NB). Meetings held by the CDx WG were used as a forum to initially develop the consultation procedure with the Notified Bodies. Once the procedural guidance was drawn up, the EMA/CHMP/CAT expert group on CDx have continued to discuss outstanding issues in relation to operating the actual consultation procedures whilst the involvement of Notified Bodies just took place on an *ad-hoc* basis.

2. Mandate and objectives

Mandate:

The CDx Expert group is mandated by CHMP to facilitate the CHMP activities related to the consultation procedure on companion diagnostics and marketing authorisation / extension of indication applications related to medicinal products used with companion diagnostics.

The CDx expert group will report to the Clinical Domain Governance and inform the EMA Committees as needed.

This is to be achieved by:

- Providing scientific and regulatory support to the CHMP/CAT/PRAC on IVDs (in vitro diagnostics) on referred matters by CHMP or working parties in the context of CDx consultation

procedures, the evaluation of initial Marketing Authorisation Application (iMAAs) and, post-authorisation applications such as extension of indications.

- Updating guidance and/or assessment templates on topic related to consultation procedures.

- Developing guidance for CHMP on the Summary of Product Characteristics as regards to information related to In vitro diagnostics intended to select the patient population to be treated with the medicinal product, required for use with the medicinal product as provided in the iMAA and post-authorisation lifecycle changes.

- Monitoring biomarker related data assessments at iMAAs level and post-authorisation lifecycle changes in order to build knowledge.

- The group may be act as a forum for sharing knowledge on the evolution of the landscape on aspects related to clinical trials for medicinal products including used in combination with in-vitro diagnostics, and contribute to improving consistency within the European system.

- Providing *ad-hoc* input to the undertakings of SAG or other EMA meetings if IVD/CDx expertise is needed depending on the questions raised.

Strategic Objectives:

The main tasks and topics of interest of the CDx expert group comprise the following:

- Support the CHMP in identifying general principles and establishing learnings from the CDx consultation procedures reviewed.

- Ensure that the EU regulatory network keeps pace with innovation, identifies and addresses gaps to ensure that the EU regulatory framework is reliable and predictable for developers. Support the progress of these technologies into: CDx consultation procedures, actual medicinal product regulatory submissions, such as scientific advice, marketing authorisation applications, and related post-authorisation lifecycle changes.

- Identify and prepare topics for interaction with external stakeholders (e.g. industry, notified bodies) to discuss issues related to data requirements and process improvements of the CDx consultation procedures.

- Support pre-submission interactions between EMA and the NB, device manufacturer and/or MAH/applicant of the medicinal product.

- Taking into account the global approach to development, the CDx expert group will engage with international partners (US and Japan, etc.) on matters related to medicinal products to facilitate regulatory convergence by using established channels of communication.

3. Composition and rules of participation

3.1. Membership

Core membership

The CDx expert group is composed by 12 NCA expert members, plus the EMA secretariat, endorsed by CHMP. The experts are selected from the European experts database according to their specific expertise and are appointed by the CHMP.

A chairperson is elected to manage the work of the group for three years. The appointed chair will become a member of the Domain Governance.

Virtual platform

The CDx expert group is supported by an IT platform (e.g. Microsoft Teams) with collaborative tools and access will be given to all its members.

4. Meeting frequency

- The CDx Expert group will convene at least twice a year through virtual platform. Frequency can be adjusted depending on the topics to be discussed.
- Meeting duration will be determined based on the topics in the agenda.

5. Rules of procedures

5.1. Responsibilities of chairperson

The chairperson and in his/her absence the vice-chairperson appointed, is responsible for the efficient conduct of the activities of the CDx Expert group and, together with the EMA Secretariat shall in particular:

• Plan the work of the CDx Expert group.

• Monitor that the rules of procedures are respected.

• Ensure that, at the beginning of each meeting, any potential conflict of interest is declared regarding any particular item to be discussed by the CDx Expert group.

• Aim to achieve consensus on issues discussed by the CDx Expert group.

• Ensure, together with the CDx Expert group, the regulatory and scientific consistency of the recommendations given.

• Co-ordinate the work of the CDx Expert group with that of other relevant Committees of the Agency.

• Report on the activities of the CDx Expert group to the CHMP, CAT or other working party as appropriate.

5.2. Code of conduct

Members of the CDx expert group meeting and experts participating in the EMA's activities shall abide by the principles set out in the Policy/044.

6. Agency secretariat

Under the authority of the Executive Director, the EMA secretariat shall provide technical, scientific and administrative support to the CHMP CDx expert group. This includes the following:

- Prepare and co-ordinate the work in consultation with the Chairperson.
- Organise the TC ensuring timely circulation of meeting documents.
- Facilitate the necessary contacts between the CHMP CDx expert group and the Committees and Working parties.
- Prepare the agenda and minutes of the TC in consultation with the Chairperson.

The Executive Director of the Agency, (Vice)Chair of the CHMP and members of the EMA secretariat may attend the TC of the CHMP CDx expert group.

7. General provisions

The Members of the CDx expert group shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by individual professional secrecy. When participating in international or other fora on behalf of the EMA/CHMP, members shall ensure that the views expressed are those of the EMA/CHMP.

When participating in international or other fora not specifically on behalf of the EMA/CHMP, members shall make clear that the views expressed are their own views and not those of the EMA/CHMP.

8. Queries and answer process

Queries, within the scope of the mandate and on an ad-hoc basis, should be triggered by CHMP, CAT, SAWP and PRAC members. Requests for advice or for participation to a meeting can also be triggered on behalf of a committee or a working party by its Chair or secretariat. The expert group may ask for clarifications prior to providing advice.