

MoCA: Points to consider for companies interested in approaching a potential pilot

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Note: This document is intended to be read in conjunction with the original MoCA documents as published since 2010, as well as the newest MoCA Terms of Reference from January 2016.¹

The objective of a pilot project within MoCA is to establish and facilitate tailored “early dialogue” between companies and participating competent authorities for pricing and reimbursement, focusing discussions on a company’s strategy, the targeted disease, the product and its development, the approach and identified challenges to access markets with a view to ultimately helping to speed up reimbursement and access for patients in EU Member States to the product in question.

All pilots shall start with a **first scoping meeting**, at which the company shall have the opportunity to introduce its potential asset to MoCA participants.

The main objective of such a first scoping meeting shall be (a) to ascertain whether there could be a shared interest in initiating and driving forward a pilot on this particular asset, and (b) to lay the foundations for a shared understanding on the asset in question, on the basis of which all parties can then take a decision on whether this dialogue can add value or not.

As a general reminder, the MoCA process and discussions are **non-binding. No formal recommendations shall be written and issued** beyond what a company shall consider relevant to capture and to write up for its own guidance and internal thinking, planning and approaches.

Companies that have participated are, however, encouraged to be open to share their overall learnings from the process – not about a specific product or dialogue, but in general – with the community, in order to build learnings at the end of the set of Pilots. This will not be compulsory.

The MoCA group meets under the umbrella of the Medicines Evaluation Committee (MEDEV)² about five times a year on average. It is left to the discretion of the company to identify and propose the

¹ Final report from 17 April 2013 on the outcomes of the Platform on Access to Medicines in Europe, within the Process of Corporate Social Responsibility in the Field of Pharmaceuticals, accessible [here](#).

The full documentation is available here:

<http://ec.europa.eu/DocsRoom/documents?locale=en&tags=Mechanism%20of%20coordinated%20access%20to%20orphan%20medicinal%20products>

² The Medicine Evaluation Committee (MEDEV) was established in 1998 and is hosted by the European Social Health Insurance Platform – a network of national liaison agencies, associations and institutions for social health insurance in the EU and Switzerland (WWW.ESIP.EU). Today, MEDEV represents the pharma experts of the national social health insurance organisations and other competent bodies in 14 EU Member States. The principal purpose of MEDEV is to provide the national health insurance organisations and other competent bodies with timely analyses about drug related trends and innovations at both national and European level.

Further, MEDEV aims to support the EU’s activities in formulating drug policies by giving input from the point of view of the statutory health insurers’ and other competent authorities, with the overall objective of providing a necessary counterweight to the pharmaceutical industry, especially at EU level. MEDEV can offer expert advice to all EU bodies from the earliest stage of the pharmaceutical decision-making process and help them analyse the possible impact of drug-related policies on national health schemes. For more information please visit the website www.medev-com.eu.

right timeline for its pilot, and to request to MoCA participants the possibility to participate in specific meetings at specific moments in time.

In order to support interested companies in preparing as effectively as possible for their first exchanges with MoCA, we propose below a “skeleton” view of what a company should in principle expect to feature on the agenda for discussions at a first scoping meeting and at the one next meeting right after it.

We believe this information shall be helpful not only to companies (in ensuring that they gather upfront the right information needed for such exploratory discussions to be meaningful and deliver a clear course of action and next steps) but also ultimately to MoCA as a whole (in ensuring that companies provide upfront key information most of interest to participating competent authorities to appreciate the specific nature of a given product and of the specific pricing, reimbursement and access challenges that may loom on the horizon for it).

***First Pilot Meeting:
Scoping + Shared consideration of the value of a pilot on this specific asset***

Tentative agenda items to cover should include:

- Short introduction [no marketing!] of the company, basic background
- Nature of the disease, condition or question to be put to the attention of MoCA
- Prevalence
- Specific focus on an individual country – genetic conditions can have “clusters”
- Or specific interest in a given country – lead scientists, centre of expertise, etc.
- Overview of the proposed molecule / treatment in question
- Mode of action
- Method of administration – e.g., if it is a gene-therapy, understanding the pathway of the treatment is critical
- What the intention / hope for the product or treatment is – what outcomes is the company seeking with the potential treatment
- Basic data about where it stands
- Timelines of the development programme
- Why there would be a shared interest / benefit in having the compound as a pilot – specific challenges that need to be addressed, particular acquisition costs, data requirements / endpoints, or contribution to building a robust outcome of the MoCA pilots evaluation and development phase

Please note that it is highly recommended to **provide MoCA participants with a concise “pre-read” document**, which would allow them (a) to gauge whether they should individually plan to attend this particular meeting, and (b) to make their travel arrangements accordingly. Since participation in any MoCA pilot for a given company and product is generally on a case-by-case, voluntary basis, MoCA members preferably need to know whether the proposed pilot could be an interesting/relevant one for them in good time for making travel plans. In turn, **the company may also express suggestions** to the MoCA leadership on which countries may have a particular interest in joining these discussions, e.g. based on a higher prevalence in their national population or for any other meaningful reason (such as the existence of a national centre of expertise, etc.).

A **confidentiality agreement** between the company and individual MoCA participants (incl. patient representatives) may be in order, but that aspect is left to the discretion and appreciation of the company on the basis of the information it intends to share. Most of the MoCA participants are bound by their employment contracts as Civil Servants, to respect confidentiality of all information that they receive, as part of their normal activities. No additional agreements in this case are, therefore, necessary. The company shall determine which participants are covered; and which – if any – might need specific agreements to be created and will be responsible for securing that these are in place. EURORDIS, on its side, shall also ensure confidentiality agreements are in place as necessary and appropriate with individual expert patients that may be called on to join and participate in MoCA discussions on specific pilots.

After the meeting, the company should be prepared to **write up minutes from the conversation**, which will then be shared with MoCA. These minutes shall be meant to ensure that all participants, including the company, are fully aligned on a shared understanding of what was discussed and of the potential next steps that have been laid out or could be explored in the immediate future. Given the timescales for pharmaceutical development, it may be several months between MoCA conversations, and it is useful for the company to not have to spend parts of the meeting reminding participants of the context, but be able to refer to earlier minutes and records in order to bring participants back up to speed, thus maximising the time spent together in the meetings.

If the participation of specific patient representatives with expertise on the medical condition affected by the proposed product could be of interest at this stage, **the company is encouraged to make advanced contacts with EURORDIS-Rare Diseases Europe so that they may make contact with one or more national patient organisations competent on the said medical condition.** EURORDIS shall handle any subsequent contacts with such national experts to arrange their active participation, or advance contribution, to the MoCA meetings and also to brief them ahead of such meetings. As a repository of patient experience in the MoCA process and previous pilots, EURORDIS can serve as a neutral enabler and interface.

As a last note, the company should ensure to work closely at all times with the lead for all MoCA activities within the secretariat of ESIP, the European Social Insurance Platform, Chris Dawson (christine.dawson[at]esip.eu, tel: +32 2 282 05 60) and the MoCA Project Advisor³). The company should in particular support them in the delivery of all necessary materials to MoCA participants sufficiently ahead of time prior to each meeting, and liaise with them for all necessary follow-up steps (incl. selecting an appropriate date and time for a next presentation).

Second Pilot Meeting:

Alignment on areas of shared work + Building the work programme

It is assumed that, after the first pilot meeting, **MoCA participants and the company shall be in a position to decide clearly whether a pilot should be continued or not.**

If the decision is positive, this second pilot meeting could, and should, be dedicated to laying out a **“roadmap” for subsequent meetings** with a view to ensuring that, by the time the pilot reaches completion, major questions for the company and participating competent authorities have been fully answered, and all areas where divergent interpretations may arise between the company and competent authorities have been fully addressed so that different points of view can be “bridged”.

³ Dr. Anna Bucsics, moca.omp[at]gmail.com

For this second meeting, EURORDIS will liaise with relevant patient organisations on the medical condition of interest to facilitate the participation of patient experts during the discussion and brief them ahead of time.

- Following on from the first introductory meeting, the companies should be ready to develop a proposed working plan to address all relevant aspects of the product that need to be discussed with participating competent authorities. The company and MoCA participants should jointly establish a list of issues where they believe a shared dialogue will deliver a mutual benefit for all parties.
- The company should make all due efforts to identify early on, and proactively work with, specific countries which can have an even more specific interest in the medical condition at hand and in the product to be offered by the company.
- The company should be ready to start working on the data development, study design and other elements, depending on which stage the project or product programme is at.
- Confidentiality agreements will likely need to be in place by this point, but again if and as the company deems necessary.

Where next?

Steering a pilot to completion

While the first two meetings of a given pilot shall be critical to determine its viability, more meetings shall inevitably be necessary for the company and MoCA participants to have sufficient time and opportunity to explore all issues and aspects requiring discussion.

This being noted, the chances for the pilot to reach successful completion shall only increase if these intermediate meetings are all approached not as an end in themselves, but as stepping stones to a greater end – i.e. **building some form of common understanding amongst all participants** on how the specific challenges raised by a given product with regard to its pricing, reimbursement and access may be overcome. If, at the end of the pilot project, participants so desire, this common understanding can be the basis of a formal agreement. However unless and until this is the case, all exchanges are non-binding, as explained above.

From a principle standpoint, it should be clearly noted upfront that, to be considered as successful, **a pilot does not necessarily have to deliver absolute consensus amongst participants** on every single aspect discussed through the meetings. It is hereby accepted that a pilot may be considered successful and complete if common agreement can be found on a substantial number of issues, even if divergent points of view may still manifest themselves on a few other aspects.

With no two pilots being absolutely identical, it may not be straightforward how a pilot should be handled over time from the moment of its first and second meetings to its theoretical completion. In addition, given the timescales and nature of the drug development process, precise timelines are difficult to predict from programme to programme. However, in general:

- As captured in the revised MoCA Terms of Reference dated January 2016, the vision of MoCA participants is that **a timeline of 18 months** should be seen as realistic minimum. However, the actual duration of a pilot project will depend on the stage of development of the product at which the MoCA process is initiated.
- As for the preparation of the very first meetings, **it is ultimately the responsibility of the company** to map out to the fullest extent possible and as early in the process as possible the

list of issues, aspects or anticipative ideas it wishes to submit to the consideration and feedback of MoCA. **Fundamentally, the duration and course of a given pilot is intrinsically linked to this one point** – a pilot focusing on a very narrow and specific set of issues shall typically have greater chances of reaching completion faster than a pilot exploring a much larger array of questions.

In line with the MoCA Terms of Reference, it is nevertheless possible to outline some useful advice for companies willing to optimise the conduct of their pilot within MoCA:

- **Think clearly and as early as possible about the open-ended question marks** on which you wish MoCA to give you input, or on which you wish to arrive at a shared understanding with MoCA participants. This will give you sufficient time to build meaningful exchanges of views and to obtain the feedback you need. **You will usually have one hour altogether per meeting for your presentation and discussion.**
- **Work incrementally by elimination.** Once a company has a clear view of issues to be submitted to the consideration of MoCA, it should proceed to addressing them in a logical order over a suitable number of meetings. The company should also **keep track of the ultimate objective**, i.e.: to capture and consolidate MoCA’s feedback in a document (a) that can be endorsed by all participants as an accurate reflection of previous discussions; (b) from which, as per the Terms of Reference, a report narrating the experience of the pilot can be extracted in order to draw all useful lessons about the process and shape recommendations for the future. We strongly recommend that the writing of such a consolidated document be started from the very first meetings onwards. (For absolute clarity, the first document referred to under (a) would remain confidential while the second one referred to under (b) could be disseminated more widely to support public awareness about MoCA and could serve as a basis for a public workshop or event.)
- Advice in preparing for the meetings and planning of the timeline can be provided by MoCA’s Project Advisor. Furthermore, if needed, a company should proactively avail itself of the possibility foreseen in the Terms of Reference to **request that one participating national competent authority within MoCA should be appointed as main contact point** and coordinator, and could serve as a reference point or “rapporteur” for the company in the run-up to, and in between meetings. Both opportunities are advisory in nature and the company will still retain the responsibility for the capturing, coordination and “driving” the process, because the MoCA is on a voluntary basis also from the competent authorities, who do not have resources to dedicate for secretariat or project support work.
- **Plan one or even two steps ahead.** The best way in which a company can maximise the efficiency of a meeting with MoCA will be not only to carefully prepare for that one meeting, but also to keep an accurate vision of points that will remain to be explored and discussed after that meeting. **Try to proactively come to each meeting with a structured proposal on how the n+1, n+2... meetings should be handled** – topics and the order in which you wish to tackle them, timeframe, etc. While this may represent a more significant investment of work at the outset, it will pay off as the pilot proceeds by giving you and other MoCA participants a much better visibility as to where the pilot stands and how much ground remains to be covered.
- **Monitor whether the timeframe that you initially proposed is still realistic**, and give sufficient visibility to MoCA participants on progress made at all steps.

Concluding Thoughts:

What companies should be prepared to play their part in ensuring a successful MoCA process

- **Take responsibility** – in collaboration with the MoCA / MEDEV leadership – to “own” and drive the process forward, to secure that it is a jointly developed and delivered road-map.
- **Proactively prepare the meetings** and identify at which points during their development programme a meeting with the MoCA / MEDEV group will be useful. Make sure that they flag this sufficient time ahead to secure that the MoCA / MEDEV group can prepare the agenda in time. If you think you need a 2-hour conversation about subject X – because... -- the company needs to flag it sufficiently ahead to allow for planning in the agenda and travel and logistics for the participants.
- **Prepare the pre-reads and secure the follow up notes and actions.** Track and support the progress.
- **Have participants** that are sufficiently senior and expert; and who are fully mandated to have open conversations and to take decisions on behalf of their organisation.
- **Devote sufficient time and resources** to coordinating and driving the process forward, securing the logistical elements in conjunction with the MEDEV secretariat and taking responsibility for managing the content and progress of the dialogue.
- **Secure that any confidentiality agreements are in place.**
- **Provide any background documents sufficiently ahead of time** in order to allow preparation and – if needed – internal consultation about the matters to be discussed.
- **Be willing to participate in collaborative efforts** to keep the wider community informed.