

# ENFORCEMENT GUIDELINES

Rules of Procedure

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## 1. Medicines for Europe Code of Conduct: Enforcement Mechanism

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- In accordance with chapter 5 of the Medicines for Europe Code, Medicines for Europe member companies should follow the complaint and enforcement procedures set out by the relevant Medicines for Europe national association or the national accepted procedure/guidelines as adopted by the relevant national association. A complaint and enforcement process should preferably be handled through this self-regulatory procedure. This self-regulatory procedure does not cause prejudice to any judicial or administrative process.
- The outcome of a national self-regulatory procedure has to be considered as final within Medicines for Europe and its national associations and will be accepted by Medicines for Europe. No appeal using Medicines for Europe procedure will be possible.
- In the exceptional case where no Medicines for Europe national association or accepted national complaint and enforcement procedure exists in an EU member state, the following procedure set out in this document will apply to lodge a complaint to Medicines for Europe directly.

## 2. What circumstances can give rise to a complaint?

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- Those Medicines for Europe member companies with serious concerns, concrete allegations and supported by evidence about another Medicines for Europe company's violations in relation to the Code may complain to the Medicines for Europe if the intercompany dialogue as set out in chapter 5 of the Medicines for Europe Code has failed.

## 3. The admissibility process

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- Written complaints signed by a legal representative of the Medicines for Europe member company should be sent by email in English to Medicines for Europe [complaints@medicinesforeurope.com](mailto:complaints@medicinesforeurope.com) or addressed to the Director General:

Director General - Medicines for Europe  
50 Rue d'Arlon - Brussels, 1000 – Belgium

### Complaint dossier:

- For a complaint to be admissible, it should clearly refer to the paragraph of the Medicines for Europe Code which has allegedly been breached
- It should name the respective Medicines for Europe member company and the specific subsidiary and provide detailed facts including locations and dates of the alleged breach.
- Any evidence to substantiate the complaint should be included. No complaint will be considered without concrete evidence in order to avoid misinformation.
- All complaints and related documents will be treated confidentially throughout the self-regulatory process and shall be marked as such.
- The complaint shall include evidence that the inter-company dialogue has failed, it should provide the name and contact details of the person in the alleged breaching company with whom the complainant engaged in the failed inter-company dialogue.

### Administrative route:

- The Medicines for Europe Director General will acknowledge receipt of the complaint within five working days and enact the Medicines for Europe Executive process to jointly assess the admissibility of the complaint within 30 working days.
- If admissible, the Secretariat shall send the complaint by registered letter to Medicines for Europe member companies concerned by the breach. The letter shall include the request to the alleged breaching company to provide a response within the timetable outlined in this procedure.
- Confidentiality of the admissibility and handling of the complaint will be respected at all stages.
- Following receipt of the registered letter, the alleged breaching company shall respond within 30 days to the complaint by registered letter to the Medicines for Europe Secretariat. The Medicines for Europe Secretariat will then communicate the response to The Medicines for Europe Executive and to the claimant by registered letter.

## 4. Review of the complaint

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- All cases will be considered by a 3 person Review Committee appointed by the Medicines for Europe Executive on a case by case basis: one external independent (legal) expert (Chairman), one Medicines for Europe Secretariat Member and one national association member who will declare that they have no conflicting interests with the parties involved in the matter to be adjudicated. The Review Committee is entitled to contract with external experts as required.
- The Medicines for Europe Executive Committee can also consider appointing a standing Review Committee for a fixed time period to review complaints.

## 5. Hearings

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- The Chair of the Review Committee shall fix the date and time of the hearing in consultation with the Parties and the other external independent experts. This will be confirmed by email to the Parties.
- The hearing shall be held in Brussels, unless the Parties agree otherwise.
- The Review Committee may convene additional hearings if requested by either Party. However, the Review Committee may also refuse to do so if it feels it has sufficient evidence after the first hearing to make a decision.
- The duration of the complaint procedure should be limited. The timeline will start following receipt of the reaction of the alleged breaching company by the Medicines for Europe Secretariat. In principle the review procedure should be completed within 90 days. The Review Committee can decide, after consultation with the parties involved, to extend this period by a maximum of 30 days.
- The complainant and the alleged breaching company will need to submit all evidence within the procedural timelines set by the Review Committee. Their inability to meet those timelines will not be cause for appeal.
- The Chairman and the two members of the Review Committee shall be present during the entirety of all hearings. The following persons may also attend the hearings:
  - a) representatives of the Parties;
  - b) advisers to the Parties;
  - c) Arbitrators' assistants.
- No later than five working days before the date of a hearing, each Party shall deliver to the Review Committee, and simultaneously to the other party, a list of the names of persons who will make oral arguments or presentations at the hearing on behalf of that Party and of other representatives or advisers who will be attending the hearing. Any important additional documentation shall also be made available to the Review Committee and the alleged party, no later than 5 working days before the date of the hearing.
- The Review Committee shall conduct the hearing in a manner ensuring that the complaining Party and the Party complained against are afforded equal time:

- The hearings of the Review Committee are to take place as closed sessions, unless the Parties decide differently.
  - The Review Committee shall not meet, hear or otherwise contact a Party in the absence of the other Party.
  - Each of the Review Committee Members (three) has an equal voting weight. In principle the Review Committee decides unanimously.
  - Confidentiality obligations for all members of the committee involved in the hearing
    - a) Names of the companies / identity of members involved in the complaint procedure
    - b) Discussion during the sessions of the Review Committee
    - c) Each member and participant of the Review Committee to sign a confidentiality commitment, which shall contain adequate penalties for violations and which shall be made enforceable to the parties under review.
- The final decision of the Review Committee will be communicated to the parties involved, to the Medicines for Europe Executive and to the Medicines for Europe Board. It will be publicly available on the Medicines for Europe Website. If an appeal procedure is initiated by one of the party, the communication will be suspended until the final decision of the appeal procedure has been reached.
- If one of the parties would like to start an appeal procedure, they have to notify the Medicines for Europe Director General within 7 working days. The appeal procedure will then be started.

## 6. Appeal procedure

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- The appeal procedure will not review the facts of the case. It will only evaluate the fairness of the procedure and the correct/incorrect interpretation of the Medicines for Europe Code by the Review Committee.
- The appeal procedure will be conducted by the Medicines for Europe Executive which may designate a group of Executive members with no conflict of interest in relation to the parties to conduct the appeal procedure. The Executive also has the possibility to consult experts on the interpretation of the code. The appeal procedure should be completed within 60 working days.

## 7. Report of the outcome of the hearing and appeal procedure

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- Complaint decisions will be made public. A summary of completed cases including the essential details will be published immediately on the Medicines for Europe website and in printed form in the Medicines for Europe annual Code of Conduct Review which will be freely available on request.

## 8. Fees and costs related to the use of the Medicines for Europe complaint procedure

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- The succumbing party will bear all costs related to the procedure before the committee or the appeal procedure, including the costs of the experts contracted by the committee or the appeal procedure, if any;
- The cost of filing a complaint will be 2,500 Euro.
- However, each party will bear the costs of its own experts, counsel (...).

## 9. Summary of the timelines

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Acknowledgement of the complaint	5 working days
Admissibility of the complaint	30 working days
Responses from alleged parties	30 working days
Hearing	90 + 30 days
Appeal Procedure	5 + 30 days
TOTAL	220 days

## 10. Temporary suspension of the procedure

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- The procedure before the Review Committee will be suspended if a party to the procedure is pursuing or subject to a legal complaint before a court or an administrative authority directly related to the case pending before the Review Committee until the final court decision.
- Following the court decision, the parties will promptly inform Medicines for Europe of the decision, in English. Medicines for Europe Director General will then promptly evaluate the merits of resuming the procedure and will inform the parties of its decision. If the procedure resumes, the above mentioned timelines will apply.

