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## CRITICAL MEDICINES ALLIANCE (CMA)

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### GUIDELINES FOR COMPETITION LAW COMPLIANCE

#### WITHIN THE CRITICAL MEDICINES ALLIANCE

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Disclaimer: These guidelines offer general guidance and are without prejudice to the application of EU or national competition rules.

The Critical Medicines Alliance (“the Alliance”) is a voluntary collaboration of private and public stakeholders, open to participation by any company or organisation willing to sign the Alliance Declaration (“Declaration”).

#### GENERAL PRINCIPLES

The Alliance should strive for certain principles:

- **Open access:** as mentioned above, the Alliance is open to all companies or organisations willing to sign the Declaration, regardless of industry association.
- **Transparency:** meetings, discussions, information exchanged, and agreements reached will be well documented and minuted. Documents and minutes will be made available to the Commission, on request.
- **Necessity:** meetings, discussions, information exchanges will be strictly limited to what is indispensable to achieve the objectives set out below.

#### GENERAL OBJECTIVES

The Critical Medicines Alliance is a consultative mechanism which brings together all relevant stakeholders to identify the challenges, the priorities for action as well as the possible policy solutions to the shortages of critical medicines in the EU.

#### SPECIFIC OBJECTIVES AND EXPECTED RESULTS

The Alliance provides the Commission and other EU decision makers with advice on the most appropriate actions and instruments to tackle medicines shortages, drawing on a set of available tools:

- market incentives, such as the possibility to expand the use of capacity reservation contracts like EU Fab;

- joint procurement to enhance security of supply of critical medicines especially in the smaller markets;
- EU funding (including EU4Health, STEP, cohesion funding, RRF etc.), potentially coordinated with national funding to enable investment in manufacturing;
- partnerships with third countries to improve the security of supply.

The Alliances' recommendations are detailed in a multi-year set of actions ('Strategic Plan'), prepared by the Alliance Steering Board and endorsed by its Forum, containing milestones and corresponding deadlines. This document aims at guiding the Commission, the Member States and industry in the implementations of the recommendations, should they be chosen by respective parties.

## ENVISAGED ACTIONS

The Alliance Members join forces to reach the objectives stated above engaging in discussions and dialogue, data exchange and collaborations.<sup>1</sup>

In view of those activities and the risk of both intentional and inadvertent competition law infringements that they may pose, the Alliance Declaration provides that: "All members and persons involved in the activities of the Alliance shall fully respect all applicable laws and regulations, in particular national and EU competition rules. The Alliance members shall abide by the competition compliance programme."

The Alliance has adopted the following guidelines and instructions to ensure that its Members take particular care to ban any form of anti-competitive behaviour from their participation and activities in the Alliance, and comply with EU competition law and relevant national competition laws.<sup>2</sup>

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<sup>1</sup> In accordance with the below outlined guidelines to ensure full compliance with competition law.

<sup>2</sup> The Alliance Members are also encouraged to visit the dedicated webpage of the Commission's DG Competition, which provides information on compliance with EU competition law:

[https://ec.europa.eu/competition/antitrust/compliance/index\\_en.html](https://ec.europa.eu/competition/antitrust/compliance/index_en.html).

The Commission has issued several sets of guidelines that can help undertakings assess the compatibility of their business arrangements with EU competition law. See notably:

- Communication from the Commission — Notice — Guidelines on the application of Article 81(3) of the Treaty ([OJ C 101, 27.4.2004, p. 97](#)) ("Guidelines on Article 101(3)");
- Communication from the Commission — Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements ([OJ C 11, 14.1.2011, p. 1](#)) ("Horizontal Guidelines");
- Commission Notice – Guidelines on Vertical Restraints ([OJ C 130, 19.5.2010, p. 1](#)) ("Vertical Guidelines");
- Commission Regulation (EU) No 1217/2010 of 14 December 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements ([OJ L 335, 18.12.2010, p. 36](#)) ("R&D Block Exemption Regulation");

## 1. COMPETITION RISKS IN THE CRITICAL MEDICINES ALLIANCE

Alliance Members must always take into account that they may be exposed to certain anti-trust and competition law risks including – but not limited to – the following considerations:<sup>3</sup>

- one single verbal or non-verbal exchange of commercially sensitive information (*e.g.* related to price levels) can violate the competitions laws;
- conversations between Members at both formal and informal (including social) meetings may constitute illegal exchanges of commercially sensitive information;
- competitor meetings in the context of an association of undertakings can be used as evidence of a cartel or an anti-competitive agreement in the industry;
- rules of an association of undertakings or of its members on *e.g.* standard setting, if any, may be deemed to restrict competition;<sup>4</sup>
- EU competition law provides that fines imposed on an association of undertakings that is not solvent may be collected from any of its members whose representatives were members of the decision-making bodies of the association and, where necessary to ensure full payment of the fine, from any of the members of the association which were active on the market on which the infringement occurred. Payment of the fines shall not be required from undertakings which show that they have not implemented the infringing decision of the association, and either were not aware of its existence or have actively distanced themselves from it before the Commission started investigating the case.<sup>5</sup>
- The involvement of the Commission, notably in the context of Alliance meetings, does not exonerate participants from the application of competition law.

## 2. ILLEGAL INFORMATION EXCHANGES

Under EU competition law, exchanges of certain types of information can amount to a restriction of competition. In cases where the exchange of information is not a restriction of

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- Commission Regulation (EU) No 1218/2010 of 14 December 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of specialisation agreements, ([OJ L 335, 18.12.2010, p. 43](#)) (“Specialisation Block Exemption Regulation”);
  - Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements ([OJ L 93, 28.3.2014, p. 17](#)) (“Technology Transfer Block Exemption Regulation”);
  - Commission Regulation (EU) No 330/2010 of 20 April 2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of vertical agreements and concerted practices ([OJ L 102, 23.4.2010, p. 1](#)) (“Vertical Block Exemption Regulation”).

<sup>3</sup> See footnote 4.

<sup>4</sup> See [Guidelines](#) on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements (OJ 2011 C 11/1).

<sup>5</sup> Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (Text with EEA relevance); OJ L 1, 4.1.2003, p. 1–25; in particular Article 23(4).

competition by object, the likely effects of an information exchange must be analysed on a case-by-case basis, as the results of the assessment depend on a combination of various case specific factors. Whether or not an exchange of information will have restrictive effects on competition depends on both the economic conditions on the relevant markets and the characteristics of information exchanged.<sup>6</sup>

Alliance Members must not have formal or informal discussions, in particular with other Members who are or may become competitors, relating – but not limited to – the following types of information capable of amounting, according to the principles of EU competition law, to commercially sensitive information.<sup>7</sup>

A non-exhaustive list of examples of what could constitute commercially sensitive information include:

- current or future individual company or industry pricing or any matters likely to have an impact on current or future prices such as competitive strengths and weaknesses, price changes, profit margins, discounts, rebates, surcharges, credit lines offered or other terms of sale;
- individual company cost information including any cost components such as production or distribution costs, cost accounting formulas and cost computing methods;
- individual company sales or production information including sales volumes, sales revenues, market share, production volumes, production capacity, capacity utilisation, stock levels and supplies, bid amounts and terms, and any limits on sales;
- current and future company plans and business strategy relating – but not limited – to bidding, investment, marketing and advertising, production, purchasing, sales or technology;
- any matters relating to individual customers, distributors or suppliers such as, for example, boycotting or blacklisting;
- salaries and wages, or limitations on hiring a competitor's employees;
- investment plans, plans to enter the market, individual measures or planned adjustments of commercial policy for supply of the products or services;
- information on capacities, future use or plans to expand capacities.

### **3. ALLOWED INFORMATION EXCHANGES**

To the extent that they do not amount, in the sense of competition law, to commercially sensitive information. Alliance Members may have formal or informal discussions, and exchange of information, on the following subjects:

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<sup>6</sup> See Chapter 6 of the Horizontal Guidelines, in particular Section 6.2.6. on restriction of competitions by object and Section 6.2.7. on restriction of competition by effect.

<sup>7</sup> See in particular Chapter 6 of the Horizontal Guidelines.

- public policy and regulatory matters of general interest;
- non-confidential current or historical information that is in the public domain;
- non-confidential technical issues relevant to the industry in general such as standards or health and safety matters;
- general, non-proprietary technology and related issues such as the characteristics and suitability of particular equipment (but not a particular company's proposals regarding the adoption of specific equipment or technology);
- general promotional opportunities such as possible new markets for, or new uses of, a product (but not a particular company's promotional plans);
- non-strategic educational, technical, or scientific data that results in consumer benefits;
- industry public relations or lobbying initiatives.

#### **4. APPROPRIATE CONDUCT AT ALLIANCE MEETINGS**

As a general matter, it should be highlighted that just being present when illegal discussions are taking place may be sufficient to consider a company liable for a competition law infringement, even if that company and/or its representative(s) did not proactively engage in those discussions.

Transparency, notably through the documentation of all exchanges in the context of the Alliance meetings is essential. Alliance Members should therefore, when attending meetings, always:

- be fully familiar with the contents of the current guidelines for competition law compliance within the Alliance;
- carefully review the agenda and purpose of meeting in advance for possible problems under the competition law and seek advice from the Member's legal department if necessary;
- insist on legal counsel being present at meetings in order to ensure that no commercially sensitive information is discussed;
- be vigilant to ensure that discussions at meetings stick to the agenda items, object if they do not, and make sure such an objection is reflected in the meeting minutes;
- ensure that they make or promptly receive detailed, accurate minutes of meetings and immediately voice any objections to the minutes.

#### **5. HOW TO ADDRESS COMPETITION LAW RELATED PROBLEMS?**

If while present at a formal or informal meeting of the Alliance -or with representatives of competitors- the conversation turns to prohibited anti-competitive subjects, Alliance Members should:

- immediately and expressly state that they cannot be party to discussions on the subject at issue due to competition law concerns and ask that the subject be changed immediately;
- if their objection and request is ignored, immediately leave the meeting in a manner that makes the reason for their departure apparent to all present;
- ensure that their departure be recorded in any formal minutes or, if there are no such minutes, record that departure in their own notes of the meeting;
- promptly report the matter to Members' legal department and ensure that a note is made thereof for the file.

The presence of a Commission representative does not release participants from liability should the exchange of sensitive information occur.

In addition, Alliance Members should, if they become aware of a competition law infringement or are uncertain whether particular conduct within the Alliance is allowed under the competition law:

1. Immediately inform their company legal counsel and/or compliance officer;
2. If their concerns are confirmed, report the anti-competitive conduct to the Alliance Secretariat. The Alliance Secretariat reserves its right to inform the competent competition authorities about conduct reported to it.

In addition, Alliance Members and/or their representatives can make use of the Anonymous Whistleblower Tool, available here:

<http://ec.europa.eu/competition/cartels/whistleblower/index.html>.

Alliance Members should always keep in mind that any failure to take the above actions promptly will make it difficult to later convince a court or competition authority of their opposition to an infringement.