

**The Belgian Competition Authority publishes guidance on the exchange of information between pharmaceutical companies in the context of reimbursement applications for combination therapies**

Combination therapies bring together two or more distinct medicines, often developed by different pharmaceutical companies. These treatments can offer significant therapeutic advances in managing serious diseases, such as certain types of cancer. Compared to monotherapies, combination therapies may result in better clinical outcomes and reduce the risk of treatment resistance. Typically, such therapies involve a “backbone” medicine, which is already approved and reimbursed as a monotherapy for a specific therapeutic indication, and an “add-on” medicine, developed for a different indication.

In order for these medicines to be reimbursed by the National Institute for Health and Disability Insurance (hereinafter: “NIHDI”), pharmaceutical companies must follow a specific procedure after which the Federal Minister for Health and Social Affairs determines the reimbursement conditions.

To facilitate access to these innovative treatments for patients in Belgium while ensuring compliance with competition rules, the Belgian Competition Authority (hereinafter: “BCA”) closely collaborated with NIHDI, as well as with the pharmaceutical industry associations Pharma.be (representing the innovative pharmaceutical sector in Belgium) and Medaxes (the Belgian association of companies active in medical technologies and innovative healthcare products).

As part of this collaboration, the Authority has developed a guidance document outlining the framework within which companies may exchange specific and necessary information for the purpose of submitting a joint reimbursement application to NIHDI, while minimising the risk of infringing competition law.

The guidance emphasises that information exchanges between companies must be strictly limited to what is objectively necessary to obtain reimbursement for a combination therapy. It clarifies which types of data may, in principle, be shared—such as epidemiological data (e.g. number of patients affected, disease incidence) and patient-level data. Conversely, the exchange of commercially sensitive information is strictly prohibited, in particular cost data specific to pharmaceutical companies participating in combination therapy, net price data, and gross and net margin data for combination therapy components.

The BCA also stresses each company's individual responsibility to assess the necessity and proportionality of any sensitive information exchange. It also recommends precautionary measures, such as the designation of dedicated internal teams and the establishment of strict confidentiality protocols.

The full text of the guidance is available on the BCA's website: [official communication](#).

**For more information you may contact:**

Axel Desmedt

President

Tel: +32 (2) 277 92 80

E-mail: [axel.desmedt@bma-abc.be](mailto:axel.desmedt@bma-abc.be)

Website: [www.abc-bma.be](http://www.abc-bma.be)

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The Belgian Competition Authority (BCA) is an independent administrative authority that contributes to the definition and implementation of competition policy in Belgium. Concretely, the BCA pursues anti-competitive practices, such as cartels and abuses of a dominant position, and reviews the main merger operations. The BCA cooperates with the other competition authorities of the member states of the European Union and the European Commission within the European Competition Network (ECN)