Belgian Competition Authority

Communication from the Belgian Competition Authority on information exchanges between pharmaceutical companies in the context of the reimbursement application procedure for combination therapies

I. Introduction

1. A combination therapy is a therapy using two or more distinct, patented and possibly unpatented medicines in the indication for which the combination therapy is intended, often from different companies, consisting of at least one of the following[1]:

(i) A "*backbone* medicine", whose use and reimbursement have already been approved in one or more specific therapeutic indications other than those pursued by the combination therapy. This medicine is therefore available and reimbursable for patients as monotherapy before being used in combination with another medicine. These basic treatments are sometimes (although not always) the existing standard of care for a given disease; and

(ii) An "*add-on* medicine", which is added to the *backbone* medicine to create a combination therapy. This complementary medicine may have been developed and introduced into the market as an independent monotherapy, or it may have been developed specifically to work in combination with the backbone treatment. The *add-on* medicine is often developed or brought to market by a different company (hereinafter *"add-on* company") from the *backbone* medicine (hereinafter *"backbone* company"). The (pre-)clinical trials relating to the combination therapy are carried out by the *add-on* company.

2. For certain medical conditions, combination therapies can achieve better clinical outcomes for some patients compared to monotherapy[2]. By combining several medicines with complementary mechanisms of action, combination therapies can target different biological signaling pathways responsible for the development of the disease or different levels of the disease, resulting in a stronger overall response and a reduced risk of treatment resistance.

3. Some combination therapies are already available on the Belgian market and are commonly used to treat patients affected, for example, by cancer or other serious diseases. These therapies are becoming increasingly important in the treatment of a number of conditions. In the future, health authorities and practitioners expect their use to continue to grow.

[1] See pharma.be, "*Réaliser la promesse des thérapies combinées : solutions pour combler l'écart entre l'innovation et l'accès*": https://pharma.be/fr/medias/actualites/realiser-la-promesse-des-therapies-combinees-solutions-pour-combler-lecart-entre-linnovation-et-lacces.

[2] Ibid.: According to Pharma.be, practical experience with complex diseases such as cancer, HIV, rheumatoid arthritis and hepatitis C has convincingly demonstrated that combination therapies can offer significant clinical benefits to patients.

4. The competent authorities and the pharmaceutical sector consider that there are obstacles to the availability of combination therapies on the Belgian market, in particular due to the current procedure for the reimbursement of medicines by the National Institute for Health and Disability Insurance (hereinafter "NIHDI"). This procedure currently stipulates that only the *add-on* company can submit a reimbursement application to the NIHDI[3]. The *backbone* company is not involved in this procedure. It is only after the *add-on* medicine has been approved for reimbursement by the NIHDI, that a specific procedure is initiated with regard to the *backbone* medicine, in order to adapt its reimbursement conditions to allow reimbursement in the context of combination therapy.

5. This procedure has shortcomings for both the NIHDI and the pharmaceutical companies involved. For the NIHDI, insofar as the combination therapy is assessed regarding its therapeutic efficacy as a single product by the Commission for Reimbursement of Medicines (hereinafter "CRM"), it is important that all the companies concerned are involved in the procedure and can reply directly to the questions from the regulatory authority[4]. For pharmaceutical companies, the procedure leads to a lack of predictability regarding the potential financial consequences of a possible adjustment to the reimbursement conditions for the *backbone* medicine. These potential financial consequences may be of various kind and may affect the income, the profitability and/or the long-term strategy of the involved pharmaceutical companies, depending on how the reimbursement conditions may be revised by the CRM[5].

6. In order to facilitate the bringing of combination therapies to market, the NIHDI is considering the adoption of a specific reimbursement application procedure, to be introduced individually and in parallel by the pharmaceutical companies involved in a combination therapy (hereinafter "Procedure"). As part of the implementation of this Procedure, the Belgian Competition Authority (hereinafter "BCA") has been asked to clarify the conditions under which pharmaceutical companies may exchange information to facilitate the development and the bringing to market of novel combination therapies for the benefit of patients suffering from serious diseases.

7. This communication aims to provide the necessary clarifications and is divided into three parts. The first part specifies the scope of the communication. The second part explains the regulatory framework relating to the bringing to market of medicinal products in Belgium. The third part describes the competition concerns that may arise from the exchange of commercially sensitive information between companies and the principles applicable to such exchanges within the framework of the procedure for the reimbursement of combination therapies in Belgium.

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[3] The *add-on* company is currently submitting the reimbursement claim, as it is the only company with clinical study results; furthermore, this pharmaceutical specialty is the only one with the combination indication registered in its label.

[4] See pharma.be, "*Réaliser la promesse des thérapies combinées : solutions pour combler l'écart entre l'innovation et l'accès*": https://pharma.be/fr/medias/actualites/realiser-la-promesse-des-therapies-combinees-solutions-pour-combler-lecart-entre-linnovation-et-lacces.

[5] Revisions to reimbursement conditions (Art. 59 of the Royal Decree of 1 February 2018 – Procedure for amending reimbursement conditions, here, by extending reimbursement to a new indication in combination) may include a reduction in the reimbursement value of the *backbone* medicine set by the NIHDI (the NIHDI's objective being to make the overall cost of combination therapy more accessible); in cost sharing with the *add-on* company; or in the possibility of negotiating with the *backbone* company within the framework of a contract (agreement under Articles 111/112/113 of the Royal Decree of 1 February 2018) providing for a mechanism for refunding (e.g. 90% or 100%) of the budget overrun (mechanism whereby medicine manufacturers reimburse budget overruns related to drug reimbursement when an absolute cap is set in the contract).

II. Scope of the communication

8. This communication has been drawn up by the BCA's Board of Directors on the basis of Article IV.25, 2° of the Code of Economic Law (hereinafter "CEL"). It aims to clarify the framework within which pharmaceutical companies can exchange information, while complying with competition law rules, in order to obtain reimbursement authorisations for combination therapies from the Belgian authorities.

9. This communication sets out the general principles applicable to the exchange of information within the described framework. It is the responsibility of each company to carry out, under its own responsibility, an independent and detailed assessment of the necessity and proportionality of any expected exchange of information, as well as its compliance with the applicable competition law. This communication does not prejudge the assessment that may be made in individual cases.

10. Agreements or cooperation between companies concerning research and development of new pharmaceutical treatments or products are expressly excluded from the scope of this communication.

11. The BCA may, as appropriate, revisit and/or update this communication as relevant circumstances evolve.

III. Regulatory background

12. In the European Union, a pharmaceutical product may only be brought to market after a scientific and administrative procedure consisting of several clinical studies and trials prior to obtaining a marketing authorisation[6].

13. The main steps that companies must follow in order to launch a medicine on the Belgian market are as follows[7]:

(i) Pre-clinical development and clinical trials: laboratory tests and clinical trials to assess the safety and efficacy of the medicine (phases I, II and III).

(ii) Application for marketing authorisation from the FAMHP, which evaluates the scientific data provided to determine whether the medicine is safe, effective and of high quality[8]. If the medicine is intended to be marketed in several EU countries, a centralised procedure via the EMA is required[9].

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[6] See note: European Medicines Agency (EMA), "*European Medicines Agency (EMA)*", European Union: https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-medicines-agency-ema_en; Federal Agency for Medicines and Health Products (hereinafter "FAMHP"), "*Marketing Authorisation Procedures (MA)*": https://www.famhp.be/en/human_use/medicines/medicines/MA_procedures

[7] Only the European Medicines Agency (hereinafter "EMA") is competent to issue a marketing authorisation (hereinafter "MA") valid throughout the European Union. Within this agency, the Committee for Medicinal Products for Human Use (hereinafter "CHMP") is responsible for issuing opinions on all matters relating to the admissibility of dossiers submitted under the centralised procedure, the granting and modification of marketing authorisations, and the monitoring of authorised medicinal products. CHMP) is responsible for issuing opinions on all matters relating to the admissibility of dossiers submitted under the centralised procedure, the granting, modification, suspension or withdrawal of marketing authorisations for medicinal products for human use, and pharmacovigilance.

[8] FAMHP, "*Marketing Authorisation Procedures (MA)*": https://www.famhp.be/en/human_use/medicines/medicines/MA_procedures.

[9] European Medicines Agency (EMA), "*European Medicines Agency (EMA), European Union*": https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-medicines-agency-ema_en.

(iii) Request for price fixing for the medicine (maximum ex-factory price) from the Minister of Economy after consultation with the Price Department of the Federal Public Service Economy (hereinafter "FPS Economy")[10]. The decision is made on the basis of specific and verifiable criteria, such as production, analysis, research and development costs, but also the company's general costs (wage costs, advertising and information costs, overhead costs), to which a margin is added. The price thus set is a public ex-factory price, excluding VAT. A decision is taken by the Minister within a statutory period of 90 days.

(iv) Reimbursement requests should be submitted to the CRM, a branch of the NIHDI[11]. The CRM analyses all requests for changes to the list of reimbursable specialities[12] and, by vote, draws up a proposal which is sent to the competent Minister. Within the NIHDI, the Pharmaceutical Policy Department acts as the secretariat for the CRM. The experts in this department draw up draft assessment reports and finalise them with the CRM. These reports form the basis for the CRM's reimbursement proposals. The criteria taken into account when making reimbursement decisions are as follows:

- The therapeutic value of the pharmaceutical specialty for the treatment of the indication;
- The price of the pharmaceutical specialty and the reimbursement basis proposed by the applicant;
- The value of the pharmaceutical specialty in medical practice in terms of therapeutic and social needs;
- The budgetary impact for the insurance scheme, taking into account budgetary objectives; and
- The relationship between the cost to the insurance system and the therapeutic value.

14. In Belgium, a reimbursement request must be submitted for each therapeutic indication of a medicine[13]. This means that even if a medicine is already reimbursed for one indication, a new request will be necessary if the company wishes to obtain the reimbursement of another or a new indication.

15. To submit its application, the pharmaceutical company must provide the CRM with a complete dossier containing a series of data and information, as follows:

(i) Clinical data, including:

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[10] Federal Public Service (FPS) Economy, "*Medicines for human use – Regulated prices*": https://economie.fgov.be/fr/themes/ventes/politique-des-prix/prix-reglementes/medicaments-usage-humain; Royal Decree of 10 April 2014 *amending the regulations on the sale of medicines*: https://www.ejustice.just.fgov.be/eli/arrete/2014/04/10/2014011283/justel.

[11] National Institute for Health and Disability Insurance (NIHDI), « *Procédure d'inscription et de modification de la liste des spécialités pharmaceutiques remboursables » :* https://www.inami.fgov.be/fr/themes/soins-de-sante-cout-et-remboursement/les-prestations-de-sante-que-vous-rembourse-votre-mutualite/medicaments/remboursement-d-un-medicament/specialites-pharmaceutiques-remboursables/procedure-d-inscription-et-de-modification-de-la-liste

[12] A pharmaceutical specialty is a medicine manufactured by a pharmaceutical company. See National Institute for Health and Disability Insurance (NIHDI): https://www.inami.fgov.be/fr/themes/soins-de-sante-cout-et-remboursement/les-prestations-de-sante-que-vous-rembourse-votre-mutualite/medicaments/remboursement-d-un-medicament/specialites-pharmaceutiques-remboursables

[13] Except when the medicine is reimbursable under Chapter I, which concerns reimbursable pharmaceutical specialities dispensed by a pharmacist on the basis of a prescription written by a doctor (or a dentist or midwife).

- The results of clinical trials demonstrating that the medicine is effective in the therapeutic indication for which reimbursement is requested;
- Data on side effects, risks and contraindications identified during clinical trials;
- A comparison with existing treatments on the market to prove that the drug provides a therapeutic improvement.

(ii) Pharmacoeconomic data, including:

- An assessment of the relationship between the treatment cost and the clinical benefits it provides. This analysis must demonstrate that the medicine is economically affordable for the public finances in order to be included in the reimbursement system;
- Financial projections of the impact of the medicine's introduction on the social security budget, including an estimate of the number of patients likely to receive the treatment.

(iii) Justifications for the reimbursement category requested by the pharmaceutical company:

- A proposed category: the company must propose a reimbursement category. In Belgium, there are several main categories (A, B, C, Cs, Cx, Fa and Fb) corresponding to different levels of reimbursement (from 100% to partial reimbursement). The chosen category must be justified on the basis of the severity of the condition and the needs of patients.

(iv) Medical justifications: an explanation of the therapeutic value of the medicine, particularly if it concerns a serious or chronic disease, or if it is a first-line or last-resort treatment.

(v) Data concerning the ex-factory price: information on the ex-factory price of the medicine. Once set by the Minister of Economy, this data is made public. The request may also include comparisons with the prices of the same medicine in other European countries.

(vi) Other administrative information, including:

- Documents relating to the marketing authorisation (hereinafter "MA"), the regulatory status of the medicine, and information about the company that manufactures and markets the medicine.
- A Summary of Product Characteristics (hereinafter "SmPC"): transmission of the SmPC, including therapeutic indications, doses, methods of administration and other relevant information on the medicine.

16. After evaluation, the CRM issues an opinion on the reimbursement of the medicine. If this opinion is positive, it proposes either a partial or total reimbursement level (depending on the category in which the medicine should be classified), as well as reimbursement conditions (specific indications, restrictions, etc.), or a framework that will then be used for confidential negotiations between the NIHDI and the pharmaceutical company[14]. These negotiations aim to establish a cost of treatment that is acceptable to the NIHDI, while respecting the budgetary constraints of the medicine reimbursement system.

[14] The term "medicine budget" refers to the overall budget allocated by the NIHDI to reimburse medicines under the compulsory health insurance scheme. The aim is to manage this budget in such a way as to guarantee access to treatment while keeping public expenditure under control.
See National Institute for Health and Disability Insurance (NIHDI), *MORSE Report*: https://www.inami.fgov.be/fr/publications/rapport-morse.

17. This opinion is forwarded to the Minister for Social Affairs and Public Health, who makes the final decision. If agreed, the medicine is then added to the list of reimbursable medicines in Belgium, in accordance with the terms and conditions defined.

18. In view of the above, the pharmaceutical companies concerned may be required to share commercially sensitive information and/or data with each other in the context of the proposed procedure for the reimbursement of combination therapies, which will need to be analysed in the light of competition rules.

IV. Rules applicable to the exchange of information in the context of the procedure for the reimbursement of combination therapies

IV.1 General framework

19. Article 101(1) of the Treaty on the Functioning of the European Union (TFEU) and Article IV.1(1) of the CEL prohibit agreements between undertakings, decisions by associations of undertakings or concerted practices which have as their object or effect the prevention, restriction or distortion of competition. The concepts of "agreements" and "concerted practices" also include the exchange of information under certain conditions.

20. The general principle is that exchanges of information fall within the scope of Article 101(1) TFEU and Article IV.1(1) CEL if they are concluded between existing or potential competitors. The information in question may be exchanged directly between competitors (in the form of unilateral communication or as part of a bilateral or multilateral exchange) or indirectly through a third party, such as a common supplier, customer or partner[15].

21. Information exchanges may take place in the context of regulatory initiatives. Whether companies are encouraged by legislative provisions or by public authorities to share information with other companies, or whether they decide on their own initiative to share such information with other companies, Article IV.1(1) CEL and Article 101(1) TFEU continue to apply. In practice, this means that companies subject to regulatory requirements cannot use these requirements to contravene Article IV.1(1) CEL and Article 101(1) TFEU. The parties must therefore limit the scope of information exchanges to what is required by the applicable regulation or rules and may need to take precautionary measures if commercially sensitive information is exchanged[16].

22. Article IV.1(3) CEL and Article 101(3) TFEU recognise that certain restrictive agreements, including exchanges of information, may, under certain conditions[17], generate objective economic benefits that offset the negative effects of the restriction of competition. These justifications may apply to individual cases or categories of agreements and concerted practices.

[15] See paragraphs 368 and 401 of the Horizontal Guidelines.
[16] See paragraph 401 (note 269) of the Horizontal Guidelines.
[17] The applicable conditions are as follows: (i) the agreements or practices in question must contribute to improving the production or distribution of products or promoting technical or economic progress; (ii) the restrictions must be indispensable to the attainment of the objectives pursued; (iii) consumers must receive a fair share of the resulting benefit; and (iv) the agreement must not afford the parties the possibility of eliminating competition in respect of a substantial part of the products concerned.

IV.2 Specific framework for the exchange of commercially sensitive information

23. The European Commission's Guidelines on the applicability of Article 101 TFEU to horizontal cooperation agreements[18] (hereinafter "Horizontal Guidelines") provide guidance on the application of competition law to exchanges of information[19]. According to these guidelines, exchanges of information are compatible with Article 101 TFEU insofar as they comply with the principle that each undertaking determines independently its economic conduct on the relevant market[20]. Conversely, competition law precludes the exchange of commercially sensitive information that is likely to influence the commercial strategy of competitors, thereby creating or potentially creating conditions of competition that do not correspond to the normal conditions of the market in question, taking into account the nature of the products or services provided, the size and number of the undertakings concerned and the volume of that market. This is particularly the case where the exchange of information reduces uncertainty about the functioning of the market in question. In such cases, the exchange concerns sensitive information which it is normally important for an undertaking to protect in order to maintain or improve its competitive position on the market(s)[21].

24. Information on pricing is generally considered commercially sensitive and competition law applies even if the exchange does not have a direct effect on the prices paid by end users. Other categories of potentially commercially sensitive information include information on costs, capacity, production, quantities, market shares, customers, plans to enter or exit markets, or concerning strategic information of a firm's strategy that undertakings active in a genuinely competitive market would not have an incentive to reveal to each other. The fact that the exchanged information may be incorrect or misleading does not in itself eliminate the risk that it may influence the conduct of competitors on the market[22].

25. Exchanges of commercially sensitive information may, depending on the objectives that the exchange seeks to attain, and the legal and economic context thereof, constitute restrictions of competition by object[23]. An exchange of commercially sensitive information which, in itself, does not appear to be sufficiently harmful to competition in view of its content, its objectives and the economic and legal context in which it takes place, may nevertheless have restrictive effects on competition and constitute a restriction of competition by effect[24]. In such cases, the actual or potential effects of the exchange of information on the market must be compared with the situation that would prevail in the absence of that specific exchange of information[25].

26. In general, for an exchange of information to have restrictive effects on competition, it must be likely to have an appreciable adverse impact on the operation of the market in question by impacting one or more of the parameters of competition in that market, such as price, output, quality or innovation[26]. In

[18] Commission Communication of 21 July 2023, C(2023) 4752 final, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements, Chapter 6.

[19] See Chapter 6, paragraphs 366 et seq. of the Horizontal Guidelines.

[20] See paragraph 374 of the Horizontal Guidelines; See C-298/22, *Banco BPN/BIC Português and Others,* paragraph 54: " *in order for a market to operate under normal conditions, each operator must, first, be obliged to determine independently the policy which it intends to adopt on the single market […] and, second, be uncertain at least as to the timing, extent and details of any future changes in the conduct of its competitors on the market* " (also paragraph 61).

[21] See paragraph 384 of the Horizontal Guidelines.

[22] See paragraph 385 of the Horizontal Guidelines.

[23] See paragraph 414 of the Horizontal Guidelines. C-298/22, *Banco BPN/BIC Português and others.*

[24] See paragraph 420 of the Horizontal Guidelines.

[25] See paragraph 421 of the Horizontal Guidelines.

[26] See paragraph 421 of the Horizontal Guidelines.

principle, the undertakings involved in the exchange of information must cover a sufficiently large share of the relevant market[27].

27. Information which is generally not commercially sensitive includes, for instance, information relating to the general functioning or state of an industry; public policy or regulatory matters (which could be used, for example in industry-wide public relations or lobbying initiatives), 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, and general promotional opportunities relevant to the industry in general. It also includes non-strategic educational, technical or scientific data that results in consumer benefits and non-strategic information needed to build new business partnerships between undertakings[28].

IV.3 Application of the principles to combination therapies

28. In light of the principles outlined above, this section clarifies the conditions under which the exchange of certain information between actual or potential competitors, within the context of the combined therapy reimbursement application procedure, could be considered compatible with competition law.

29. With regard to combined therapy reimbursement application procedures, the exchange of non-price data has been characterised by several national competition authorities, including the UK Competition Authority (CMA)[29], as being less problematic *a priori*. This data relates in particular to product characteristics, the efficacy and safety of the therapy, epidemiological data and data on patient dosage and treatment duration[30].

30. Nevertheless, prior exchanges of information between companies, within the framework of the Procedure and even beyond it, must be limited to what is objectively necessary to obtain a reimbursement for a combination therapy. Any communication beyond this scope could raise competition law issues. Therefore, any exchange of information on the net price of a pharmaceutical component or on information that would allow the net price to be calculated by reverse engineering must be excluded. By extension, it is advisable to limit the level of sharing and communication to the minimum necessary, in particular with regard to cost and pricing structures.

31. In view of the principles summarised above, the following data and information should in principle be exchangeable between pharmaceutical companies involved in the marketing of combination therapy in the context of a procedure before the NIHDI:

- The purpose of the application;
- Administrative data concerning the timelines for the Procedure;
- The identification of the comparator(s)/standard of care used to demonstrate the therapeutic efficacy of the combination therapy;
- Epidemiological data (number of patients concerned, incidence of the disease);

[27] See paragraph 423 of the Horizontal Guidelines.

[28] See paragraph 386 of the Horizontal Guidelines.

[29] See, in particular, "Prioritisation statement on combination therapies", available at https://www.gov.uk/government/publications/combination-therapies-prioritisation-statement (accessed on 8 April 2025).

[30] This data is required by the NIHDI when assessing applications for reimbursement of the various components of combination therapy.

- Patient-level data (assumed duration of treatment, dose intensity in the clinical trial);
- Summary of therapeutic value (based on data from clinical studies);
- An analysis of the budgetary impact of the proposal from the perspective of the NIHDI and the patient, based on the data provided (volume, incidence) and the ex-factory price (if publicly available) set by the FPS Economy for each component of the combination therapy (level 1 budget impact)[31]. This analysis includes an assessment of the expenditure related to the pharmaceutical specialty per year for the first three years.

32. *Con*vers*ely*, the following data are in principle considered commercially sensitive and their exchange is considered neither strictly necessary nor proportionate to the objective of a request for reimbursement of a combination therapy. Consequently, this data should not be shared before, during or after the Procedure, without the list below being considered exhaustive:

- Information relating to the cost structure specific to the pharmaceutical companies participating in the combination therapy;
- Data concerning the net price, as well as the gross and net margins of the components of the combination therapy;
- Information concerning the marketing strategies, investment strategies and future plans of the companies participating in the combination therapy (expansion plans, market entry/exit, planned acquisitions, etc.);
- Specific market data (e.g. data concerning suppliers or customers);
- Information on the distribution of therapeutic value among the different products comprising the combination;
- Analysis of the budgetary impact on the medicine budget (level 2 budget impact) and on the healthcare budget (level 3 budget impact): financial details and cost projections, information on changes in volumes/turnover of one of the components of the combination therapy that have an impact on the negotiation with NIHDI about the net price of the components of the combination therapy.

33. In any event, the factors to be taken into account in determining on a case-by-case basis whether exchanges of information are potentially restrictive of competition are the following: (i) the nature of the information exchanged (e.g. whether it is non-public or not readily accessible to all competitors and the granularity of the information exchanged), (ii) the ability to reduce uncertainty about the commercial strategy of the companies concerned, and (iii) the ability to maintain or strengthen the competitive position of the companies concerned on the market(s) concerned. Consequently, an exchange of information between the companies involved in the Procedure is likely to restrict competition within the meaning of Article 101(1) TFEU and/or Article IV.1(1) CEL if it concerns commercially sensitive non-public and/or particularly detailed information that would give access to information from which the commercial strategy of the companies concerned or their competitors could be inferred.

[31] Since the epidemiological data (number of patients concerned and expected prescription volume) are exchanged between the companies involved in the combination therapy for the purposes of the Procedure and the ex-works prices are public data (once they have been set by the Minister for the Economy), the companies are able to provide a Level 1 budget impact assessment within the framework of the Procedure.

34. In order to limit the risk of undue exchange of commercially sensitive information, the BCA recommends that each company adopt certain precautionary measures, including:

- The appointment of an internal team responsible for implementing and monitoring the Procedure. This team will ensure strict compliance with confidentiality policies by implementing procedures to control and trace communications between pharmaceutical companies;
- Traceability of access to information, which must be limited to those persons who are essential to the process, with appropriate security and data storage systems to prevent unauthorised disclosure or use;
- Clear internal compliance protocols must be put in place to strengthen legal certainty and minimise the risk of competition law infringements.

35. These measures should enable companies to keep a record of the nature and scope of the information exchanged and to demonstrate, if necessary, that they have indeed exchanged such information in good faith, i.e. with the aim of obtaining a favourable decision on the reimbursement of the products involved in the combination therapy by the NIHDI.

36. Each company must also ensure that the data is stored securely and, if the Procedure fails, that it is destroyed in accordance with internal confidentiality policies and applicable legal requirements. Rigorous traceability of the secure archiving or destruction of data must be maintained to ensure the confidentiality of the information exchanged. It is also essential that companies review their internal processes to ensure that this information is not integrated and/or used, even unintentionally, in other projects or files.

37. Finally, pharmaceutical companies retain the right to freely engage in the Procedure established by the NIHDI for determining reimbursement conditions, to terminate it at any time if they so wish, or, conversely, to continue it until its completion. Depending on the strategy of the companies involved in combination therapy (and in particular that of the *Backbone* medicine*)*, the stage of the life cycle of the products concerned at the time the combination therapy is placed on the market, and the level of reimbursement acceptable to the NIHDI, the company may decide not to commit to and/or not to continue the reimbursement application procedure for its medicine in the context of combination therapy until its completion.

38. By way of illustration, an *add-on* medicine may be the subject of a reimbursement application under the Procedure and, in this case, the NIHDI may propose a reduction in the reimbursement value of the *backbone* medicine to offset the additional cost associated with the reimbursement of the combination therapy. If the reduction in the reimbursement value proposed by the NIHDI is deemed unacceptable by the company*,* the latter has the right to refuse, to make a counterproposal to the NIHDI, or even to withdraw from the Procedure. It is therefore recommended that the companies concerned ensure that internal procedures are in place to guarantee that the information exchanged in the context of the Procedure remains confidential and is not disclosed beyond what is strictly necessary. Furthermore, this information must not be used for any purpose other than those provided for in the Procedure.

V. Entry into force

39. This notice shall enter into force on the day of its publication on the BCA's website. By its nature, it cannot cover all situations that may arise for companies involved in the development of a combination therapy. Each situation must therefore be assessed on its own merits and may require a flexible application of the principles set out in this Communication. This Communication should also be read in conjunction with the Horizontal Guidelines and is without prejudice to the interpretation of Article 101 TFEU and/or Article IV.1 CEL by the competent courts and tribunals.

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