Prioritisation statement on combination therapies

17 November 2023

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1. Introduction and executive summary

1.1 This document sets out the Competition and Markets Authority's (the '**CMA**') statement that it will not prioritise investigations under the Competition Act 1998 (the **'CA98'**) into specific forms of engagement between medicine manufacturers which are carried out in good faith and aimed at making a combination therapy available to NHS patients in the UK, where certain market features are present and particular conditions are met.

1.2 A **'combination therapy'** is a treatment using two or more medicines in combination. The CMA has been told by the Association of the British Pharmaceutical Industry (the '**ABPI'**) and a number of its member companies that medicines often generate better health outcomes, including extended life expectancy, when used in combination because they can target different pathways or levels of the disease. In the future, more treatments are likely to be based on combination therapies – for cancer and in wider medicine.[1] So ensuring that combination therapies are available to NHS patients where possible is of fundamental importance.

1.3 The ABPI and a number of its member companies have told the CMA that many combination therapies are failing to get approval from the relevant UK healthcare technology assessment ('**HTA**') agencies and are therefore not being made available to NHS patients. This is because the price of the medicines, in combination, means that the treatment cannot be deemed sufficiently 'cost effective' under the current UK access systems (as described in paragraph 2.3 below).

1.4 The ABPI estimates,[2] and the National Institute for Health and Care Excellence ('**NICE**') and NHS England ('**NHSE**') have confirmed that, since the start of 2017, when the number of combination therapies being developed and submitted for appraisal significantly increased, 50 per cent of combination therapy appraisals for cancer treatment (with more than one branded component) have been terminated or not found to be 'cost effective'.[3] As a result, tens of thousands of NHS patients have been unable to access combination therapies developed to treat a range of devastating cancers, including advanced renal cell carcinoma, multiple myeloma, lymphocytic leukaemia, lung cancer, metastatic gastric cancer and breast cancer.

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[1] The clinical potential for combination therapies has also been recognised in non-cancer diseases, including treatment of HIV, hepatitis C, rheumatoid arthritis and COVID-19.

[2] Source: ABPI, based on ABPI analysis of NICE data and other data sources.

[3] Even in situations where combination therapies are recommended, this may not be for the total patient population but instead for only a subset of the patient population (an 'optimised' recommendation).

1.5 This challenge is likely to remain as an increasing number and range of treatments, including but not limited to cancer treatments, rely on combinations. ABPI's members report that up to half of their oncology pipelines are medicines used in combination, presenting a pressing need to find a solution.

1.6 The ABPI believes that it would be possible in a number of cases for the suppliers of the component medicines of a combination therapy to reach a commercial agreement that would allow the combination therapy to be supplied at a 'cost effective' price to the NHS, and therefore be made available to NHS patients. However, the ABPI and a number of its member companies have told the CMA that, at present, medicine manufacturers are reluctant to engage in the negotiations required to reach any such commercial agreement due to the perceived risk that doing so may be suspected and investigated by the CMA as breaching UK competition law.

1.7 Following engagement with the CMA, NICE and NHSE, the ABPI has proposed a negotiation framework (the '**negotiation framework**'). This is intended to permit companies to exchange information to seek to engage in a commercial agreement with a view to supplying combination therapies to the NHS at a 'cost effective' price within the existing access framework. The negotiation framework has been designed to minimise the risk of engagement between medicine suppliers and any potential resultant agreement raising competition law concerns.

1.8 Consistent with the CMA's 2023/4 Annual Plan priorities, the CMA is committed to taking action to ensure that innovating businesses can gain effective market access, particularly where this has a real impact on areas that are most important to people.[4] Making more combination therapies available to NHS patients – particularly given their increasing importance – will have a real, positive impact now and in the future, and will benefit patients, innovating businesses and the UK economy at large.

1.9 The CMA is keen to ensure that the perceived risks of CMA enforcement action are not a barrier to companies seeking in good faith to negotiate agreements that would make new combination therapies available on the NHS. If properly implemented, the features of the negotiation framework should allow commercial negotiations to proceed in a manner that mitigates the competition concerns that normally arise from such negotiations. **This statement therefore explains that the CMA will not prioritise the investigation of commercial negotiations and any subsequent**

[4] See in this respect the CMA's 2023/2024 Annual Plan, available at CMA Annual Plan 2023 to 2024 - GOV.UK (www.gov.uk).

agreements that are carried out according to the negotiation framework, where particular market features are present (see paragraphs 2.7 and 2.9) and provided certain conditions are met (see paragraph 5.2).

1.10 By taking this step, the CMA aims to promote and facilitate the development and availability of combination therapies in the UK, thereby increasing the availability of innovative treatments to and for the benefit of NHS patients suffering from some of the most serious medical conditions, including multiple myeloma, lung and breast cancers. The CMA's approach to prioritisation outlined in this statement will stand unless and until this statement is revisited in the future.

1.11 The CMA sets out in this statement: (a) the market context and regulatory environment based on the CMA's understanding following engagement with the ABPI and its members as well as relevant HTA agencies and the NHS; (b) the competition law concerns expressed by the ABPI and its members as a barrier to making combination therapies available on the NHS; (c) the negotiation framework proposed by the ABPI, including the practical steps it involves; and (d) a statement on the CMA's approach to prioritisation.

2. Market context and regulatory environment

Overview of combination therapies

2.1 A combination therapy involves the use of two (or more) separate component medicines in combination to treat a disease. Combination therapies can be thought of as comprising (one or more) '**backbone**' treatments and one or more '**add-on'** treatments. In this context:

(a) the backbone treatment (or treatments) is a medicine that is already approved for use and reimbursement by the NHS and is thus available to NHS patients as a standalone medicine (monotherapy), prior to it being used in combination with another medicine. Such backbone treatments are often (although not always) the existing standard of care for a given disease; and

(b) an add-on treatment (or treatments) is a medicine that is added to an existing backbone treatment to create a combination therapy. This add-on 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. An add-on medicine is often developed by a different company from the backbone treatment.

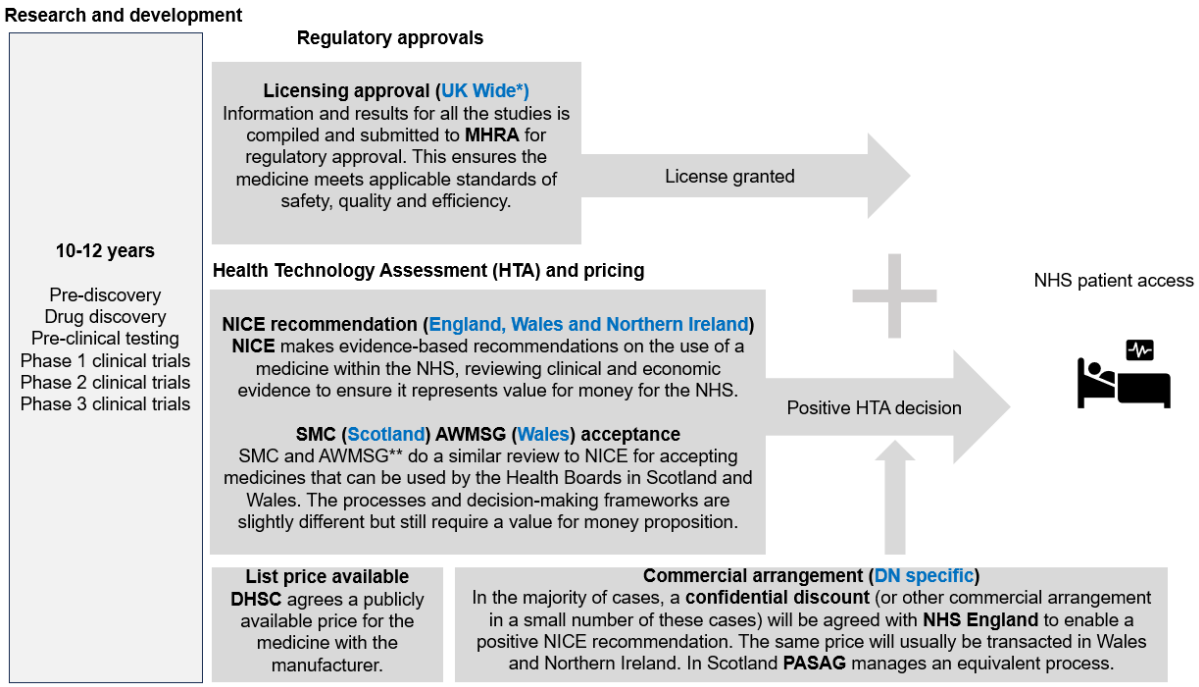
The access system for making medicines available on the NHS

2.2 To bring a treatment to market in the UK, for those medicines referred for assessment and not otherwise exempt, it is necessary to obtain both licensing approval from the Medicines and Healthcare products Regulatory Agency[5] ('**MHRA**') (i.e., confirming that the medicine or combination therapy of medicines meets efficacy, quality and safety standards) and a recommendation from the relevant UK HTA agency responsible for determining whether a medicine should be reimbursed by, and thus be available on, the NHS.[6] This process is set out below.

[5] In Northern Ireland, most new medicines are within the scope of the EC Centralised Authorisation Procedure (CAP) and so currently obtain approval for use through the European Medicines Agency. From January 2025, pursuant to the implementation of Windsor Framework, the MHRA will be responsible for the approval of all medicines introduced into the UK market, including in Northern Ireland.

[6] That is, NICE based on the applicability of its guidance in England, Wales (which may also consider medicines through the All Wales Medicines Strategy Group ('**AWMSG**')) and Northern Ireland, and the Scottish Medicines Consortium in Scotland ('**SMC**') (referred to as the '**relevant UK HTA agency**').

Figure 1



Notes:
*In Northern Ireland most new medicines are within the scope of the EC Centralised Authorisation Procedure and so currently obtain approval for use through the European Medicines Agency. From January 2025, pursuant to the implementation of the Windsor Framework, the MHRA will be responsible for the approval of all medicines introduced into the UK market, including in Northern Ireland.
** For some medicines that have not been recommended by NICE.

Source: ABPI

2.3 To optimise the allocation of finite healthcare budgets, the relevant UK HTA agency assesses whether, on the basis of the available clinical and economic evidence, the proposed therapy represents value for money for the NHS. In evaluating this, the relevant UK HTA agency determines whether it is 'cost-effective' as assessed against the prevailing standard of care at the time (that is, against existing treatment options currently available).[7]

2.4 Combination therapies are subject to economic evaluation through cost-effectiveness analysis in the same way as monotherapy treatments. The relevant UK HTA agency evaluates the health benefit of a new medicine compared with the standard of care and uses the same methods and cost effectiveness threshold for monotherapies and combination therapies.

[7] Even if a monotherapy or combination therapy has licensing approval from the MHRA, confirming that it is safe for patient use, it cannot be routinely prescribed for patient use on the NHS unless and until it receives approval for reimbursement by the relevant UK HTA agency on the basis it is 'cost effective'. Medicines can in some circumstances be prescribed on the NHS if approval is obtained via an Individual Funding Request (IFR), where a clinician applies for funding for a treatment that is not routinely available on the basis that it is the best treatment for an individual's clinical circumstances.

2.5 The supplier of the add-on medicine is usually solely responsible for applying to both the MHRA for a licence and to the relevant UK HTA agency for a reimbursement recommendation for the use of the combination therapy. It is only once such approval is granted that the combination therapy becomes routinely available to NHS patients.

Confidential net prices for the NHS represent an upper limit after agreement with the NHS

2.6 The medicines that may be used in combination therapies will typically have two different prices: a list price, which is public and determined by the medicine manufacturer, and a confidential net price paid by the NHS, which reflects an agreed discount to the list price (that ensures the treatment is 'cost-effective') and the commercial agreement reached between the manufacturer and the NHS for purchase of that medicine. This confidential net price is the price that the NHS actually pays to the medicine manufacturer when a medicine is prescribed for use by a clinician.

2.7 Importantly, once a confidential net price for a given patented medicine has been agreed between the supplier and the NHS, it cannot be increased unilaterally by the supplier and is typically not increased over time. Any change to that agreed price, for example in the event that the supplier seeks approval from a relevant UK HTA agency for use of that medicine for a further treatment indication, could lead to the confidential net price staying the same, or being reduced, but would not generally be expected to lead to the price being increased. As such, the confidential net price represents the upper limit of the price the NHS pays for supply of that medicine after agreement with the NHS.[8]

2.8 The current pricing policy applicable to medicines in the UK normally requires that a medicine has a single net price across all its uses (or indications), regardless of differences in the value offered by the medicine in a particular use and irrespective of whether the medicine is used in each case as a monotherapy or in combination (the so called '**uniform pricing'** policy).

[8] There may be limited circumstances in which the relevant UK HTA agency or the NHS is willing to agree an increase to the confidential net price - for example, in certain circumstances where the medicine shows greater proven value than initially estimated - but this cannot be imposed unilaterally by the medicine supplier.

Prescribing for combination therapy medicines and components is driven by clinical and cost effectiveness guidance published by the relevant UK HTA agency

2.9 Following approval from the relevant UK HTA agency that a medicine is 'cost-effective', an individual clinician's decision about whether to prescribe a combination therapy would not be based on cost, but, as for any prescribing decision, would be based on guidance issued by the relevant UK HTA agency (which has established that the treatment is clinically and cost effective), the clinician's own evidence-based knowledge and experience and the treatment preferences of the patient. In the current candidate treatment areas for combination therapies (including cancer treatments), clinicians making prescribing decisions in relation to innovative combination therapies are likely to be following highly specific and tailored treatment plans, and would not in these specific situations be focused on considerations of cost above and beyond those already taken into account within the relevant UK HTA agency guidance.[9]

Challenges to getting a combination therapy approved as 'cost effective'

2.10 The CMA has been told by the ABPI and a number of its member companies that it is very challenging for combination therapies to reach the required 'cost-effectiveness' threshold to obtain a recommendation from the relevant UK HTA agency that the therapy should be reimbursed by, and thus be available on, the NHS. The reasons provided to the CMA for this are:

(a) First, the component treatments are often patented / branded medicines, both with a higher price than an off-patent / generic option.

(b) Second, the confidential net price of the existing backbone medicine may already be close to the cost effectiveness threshold when it was previously approved as a monotherapy treatment. So there is little, if any, scope to accommodate the additional cost of the add-on treatment.

(c) Third, the backbone medicine supplier will usually have a reduced incentive to cut the price to the NHS of its component medicine to the extent uniform pricing regulations apply (see paragraph 2.8 above) because it would then have to lower prices elsewhere.

[9] Guidance and advice is provided by healthcare bodies (see NICE website, AWTTC website, and the SMC website). Further information is available at: https://www.gmc-uk.org/-/media/documents/prescribing-guidance-updated-english-20210405_pdf-85260533.pdf.

(d) Fourth, the use of the combination therapy often means that the patient will stay healthier and potentially live longer so they remain on therapy for longer. In real terms, the cost effectiveness for the incremental benefits generated by the combination therapy is often already absorbed solely by a corresponding increase in the cost of the extended use of the backbone treatment, thereby leaving no room for the additional cost of the add-on treatment.

2.11 The add-on medicine supplier is the company applying for reimbursement approval for a combination therapy. The only pricing lever at its disposal to try to reach the 'cost-effectiveness' threshold for the combination therapy is to reduce the price of its own component medicine (the add-on medicine) until the combined price of the combination therapy medicines is below the relevant 'cost effectiveness' threshold. However, in many cases the extent of the price reduction of the add-on medicine that would be required to achieve this would not be regarded as commercially viable.

2.12 The CMA understands from the ABPI and a number of its member companies that many medicine manufacturers developing combination therapies have therefore concluded that, without some form of commercial agreement between the component medicine suppliers in the combination, it is extremely challenging to supply the combination therapy in the UK at a price that will meet the relevant 'cost effectiveness' threshold for reimbursement by the NHS. As a result, many companies have aborted efforts and NHS patients are not able to access these potentially innovative treatments. The overall result is therefore reduced patient access to innovative treatments for serious diseases, and potentially a discouraging of investment in research and development in this area in the UK.

2.13 The CMA has been informed by NICE and NHSE that there is not a regulatory solution to the challenge posed to bringing combination therapies to market that would be administratively feasible, due to a range of factors including resource implications and inequity for other patients waiting for treatments. NHSE and NICE have informed the CMA that full consideration has been given to alternative solutions and none is viable without detriment to NICE and NHSE's statutory duties to NHS patients.[10]

[10] Under current rules, there is some 'commercial flexibility' of rules on indication-based pricing and combination pricing, but NHSE has confirmed that this is only available on an exceptional basis.

3. Competition law concerns in relation to combination therapies

3.1 Perceived concerns about infringing competition law and enforcement action by the CMA acts as a barrier to the suppliers of the components of a combination therapy being willing to exchange information and seek to negotiate a commercial agreement between them, in circumstances where they may be actual or potential competitors. The exchange of information that is not public and / or the terms of any commercial agreement between the component medicine suppliers could, in some circumstances, breach UK competition law. In particular:

(a) the exchange of competitively sensitive information between actual or potential competitors is well established as coordination that may breach Chapter I of the CA98; and

(b) to the extent that any commercial agreement involved coordination on the price of a component medicine, this raises the concern, in particular given the application of uniform pricing rules, that actual or potential competitors would have agreed prices in potential breach of Chapter I of the CA98.

3.2 To minimise these risks, the ABPI has developed the negotiation framework, as outlined in the next section.

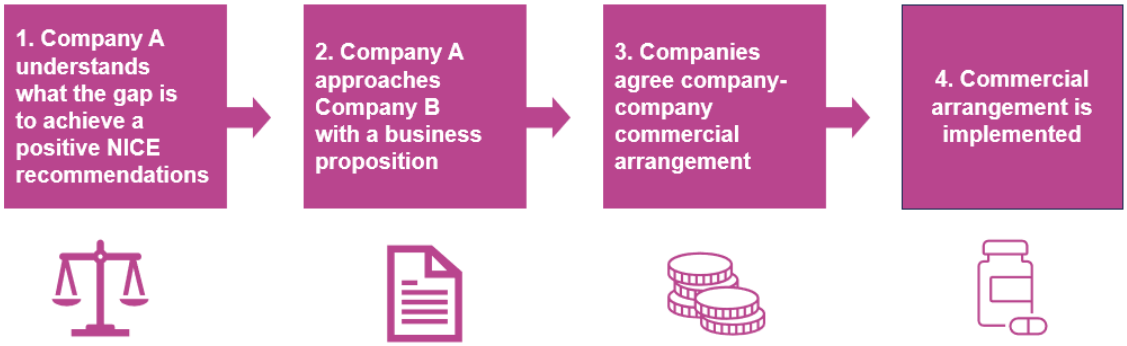
4. The Negotiation Framework

Overview of the negotiation framework

4.1 Following discussions between the CMA, the ABPI and its member companies, NICE and NHSE regarding possible means of reducing the competition law risks described above, the ABPI has designed a specific negotiation framework for use in relation to combination therapies. This framework is intended to allow the suppliers of the component medicines to seek to negotiate a commercial agreement that would result in a combination therapy being supplied to the NHS at a 'cost effective' price, while minimising the risk that the negotiations and / or the resultant agreement would raise competition concerns.

4.2 Under the negotiation framework, the suppliers of the component medicines would negotiate with the objective of agreeing an amount per patient (the '**contribution payment**') to be paid from the backbone medicine supplier to the add-on medicine supplier(s) when the backbone medicine is supplied as part of the combination therapy. This contribution payment would compensate the add-on medicine supplier(s) for offering their component medicine(s) to the NHS at a price low enough that the combination therapy can meet the relevant 'cost effectiveness' threshold and thus be approved for reimbursement by the NHS. The broad structure of this framework is set out in the diagram below.

Figure 2



Source: ABPI

4.3 The ABPI has explained that the negotiation framework will involve the following steps for medicines that will be considered by NICE:

Table 1

NICE evaluation process stage[11]	Process
Invitation to Participate	The add-on company has a view of the value proposition for the combination therapy and considers it to meet the scenario described in this framework. The add-on company writes to the backbone company with a business proposition. The appraisal timelines are clearly set out in the document to clarify when the backbone company will need to respond by.
Company submission	The add-on company submits a dossier to NICE for the appraisal of the combination therapy. The backbone company responds in writing to the add-on company's business proposition either: - agreeing to meet with the add-on company to discuss the terms; or - declining to enter into discussions about a potential commercial agreement. If the backbone company agrees to engage, a confidentiality agreement is put in place allowing additional clinical data / model assumptions pertaining only to the NICE assessment of the indication being evaluated to be shared if required and agreed to by both parties. All correspondence between the two companies is fully documented and retained on file by both companies.
Evidence Assessment Group report through to Evaluation Committee Meeting	The add-on company and the backbone company meet to negotiate a commercial agreement. Potential outcomes: - Commercial agreement agreed and written up for company sign off. The add-on company adjusts the net price of the add-on medicine for the combination therapy evaluation. - Commercial agreement not agreed, and the combination therapy is not positively recommended by NICE. - Commercial agreement not agreed but a counteroffer is proposed by the backbone company for the add-on company to consider. Additional meeting may need to be convened to further negotiate this.
Publication of Final Draft Guidance	Commercial agreement signed by both parties and implemented according to its terms: Duration of agreement is set out so as the companies do not need to reconvene to amend the terms unless a break-clause is triggered. Payment schedule and data requirements set out.
Post NICE evaluation	Implementation of commercial agreement. Payments made from the backbone company to the add-on company as per the terms of the agreement.

Source: ABPI

4.4 A key aspect of the negotiation framework is that the information exchanged between the suppliers as part of the above negotiations or in any subsequent agreement will be limited to what is strictly necessary to reach the commercial agreement and to implement the mechanism for the contribution payment. The ABPI has stated that the following information will need to be exchanged between the component medicine suppliers to agree a commercial agreement (which will not include, or allow to be calculated through reverse-engineering, confidential net prices for any of the component medicines):

[11] The CMA understands that other UK HTA agencies follow a similar process.

(a) Combination therapy and expected indication.

(b) HTA agency evaluation timelines and requirement for a response, for example confirming the backbone company is willing to engage during the evaluation process.

(c) Treatment pathway / line of therapy, including comparators / standard of care.

(d) Expected patient population numbers for the indication and assumed duration of treatment (including extrapolation analyses if applicable).

(e) The sum (£) the add-on company requires per patient to make their own (confidential) discount sufficient for a positive HTA agency evaluation and commercially viable.[12]

(f) Proposed implementation of the agreement: data to be shared, source and analysis of data; frequency of payments.

(g) Proposed scoping meeting date, venue, agenda, terms of engagement if a discussion about the commercial agreement is required.

(h) Proposed duration of agreement and any conditions for termination.

4.5 The CMA has based its approach to prioritisation on the ABPI's description of the negotiation framework and the information to be disclosed, both as set out above.

[12] Details of what the 'per patient' amount is based on (i.e., per patient initiated on therapy, per cycle, patient weight, vial size, vial sharing, wastage etc.).

5. Circumstances where the CMA will not prioritise investigations under the CA98

The CMA's approach to prioritisation – including necessary market features and conditions

5.1 Before committing resource to a formal investigation, the CMA considers whether investigation would represent the most effective possible use of its resource. The CMA does so by applying its Prioritisation Principles,[13] assessing whether the CMA is best placed to act, a potential investigation's impact, strategic significance and risks, as well as the resources that would be required to complete it.

5.2 Having considered the issues involved in making combination therapies accessible to NHS patients against its Prioritisation Principles, for the reasons set out in the following section, **the CMA will not prioritise investigation of (i) the exchanges of information in the commercial negotiations or (ii) any subsequent agreements related to the payment of contribution payments entered into by component medicine manufacturers, in circumstances where:[14]**

(a) the specific **market features** set out in paragraph 2.7 (agreed pricing limiting the price paid by the NHS) and paragraph 2.9 (basis for prescribing decisions) are present;[15]

(b) the negotiations between the component medicine suppliers and associated exchanges of information are carried out according to the **negotiation framework** (as set out in paragraphs 4.2 to 4.4 above) in a good faith attempt[16] to reach an agreement with a view to making a combination therapy available to NHS patients;

(c) the **information exchanged** between the component medicine manufacturers must be limited to public information, the information set out in the ABPI list in paragraph 4.4 above, and any additional information that is reasonably necessary for the component suppliers to agree the contribution payments, but should not include (or allow to be calculated

[13] See CMA Prioritisation Principles: https://www.gov.uk/government/publications/cma-prioritisation-principles.

[14] This statement is not intended to (and indeed, cannot) itself create any additional obligations on either the backbone medicine supplier or the add-on medicine supplier beyond those arising under existing competition law rules. For example, this statement does not imply any obligation to negotiate or reach an agreement between component medicine suppliers. However, it also does not negate any such obligation should one arise under law.

[15] To the extent that these market features were to change in the future, the comfort provided in this statement would no longer be applicable.

[16] The CMA's approach to prioritisation is not dependent on an actual agreement being reached.

through reverse-engineering) the confidential net price of a component medicine;

(d) the **terms of any agreement** reached between the component suppliers are directly related and necessary for the calculation or operation of the contribution payments that have been agreed according to the negotiation framework, and do not:

(i) involve an agreement to fix the prices of either of the component medicines (which should remain individually determined by each supplier); or

(ii) extend to provisions that agree or discuss any collective action outside of the narrow scope of seeking to obtain reimbursement approval for a combination therapy; and

(e) the manufacturers involved implement measures to ensure that information exchanged between them as part of the commercial negotiations or as part of any subsequent agreement **are not disseminated more widely than necessary and are not used for any other purposes.**

Basis for the CMA's prioritisation statement

5.3 The CMA reached its conclusion on the approach to prioritisation set out at paragraph 5.2 based on the Prioritisation Principles (see note 13). This was a holistic assessment, taking into account all the relevant factors, including the CMA's understanding of the market context and regulatory framework (summarised at Chapter 2 above) and the impact of compliance with each of the conditions set out in paragraph 5.2 above. In this section, the CMA sets out the key factors and how they informed its prioritisation assessment[17].

5.4 The starting point for the CMA's prioritisation assessment is to consider the extent to which the envisaged conduct, taken as a whole, is likely to harm competition and ultimately UK consumers, or in this context the NHS and patients. The limitations imposed by the conditions set out at paragraph 5.2 mean that, taken overall, there is limited scope for the **exchange of information** under the negotiation framework to lead to higher prices to the NHS or poorer patient outcomes, for example:

(a) As outlined at paragraph 2.7 above, because the reimbursement approval process acts in effect to limit the price that can be charged for each

[17] This reasoning should not be taken as expressing a view on whether or not the envisaged conduct actually breaches Chapter I of the CA98.

treatment, there is limited scope for firms that receive such information to use it to inflate their own price. For example, insofar as a backbone medicine supplier received information concerning the target population of the proposed combination therapy that gave it reassurance regarding the extent to which it would face competition in the supply of another patient population, it would not normally be open to the backbone supplier to increase its price beyond the level that had already been agreed between that supplier and the NHS.

(b) The negotiation framework restricts the component suppliers from sharing their confidential net pricing and generally seeks to limit the information shared between suppliers. So information exchanged under the negotiation framework would not be expected to have a material negative effect on medicine suppliers' independent pricing incentives.

(c) Clinician decision-making about the range of treatments for which combination therapies are currently anticipated[18] is not driven by price competition between medicine suppliers but instead by non-price factors, primarily clinical effectiveness which is based on public guidance issued by the relevant UK HTA agency. So exchange of the information at paragraph 4.4 is unlikely to have a significant negative impact on market outcomes, as the participating companies' incentives to alter their pricing or marketing strategies based on the information they receive are unlikely to be materially affected.

5.5 In addition, the overall negative impact on competition of any **agreements** made according to the negotiation framework can be expected to be limited:

(a) The goal of the contribution payment is to facilitate a commercially viable offer of a lower price for the combination therapy to the NHS. If implemented as suggested by the ABPI, the contribution payment is not made on condition of any other conduct on the part of the add-on medicine supplier and the agreement between the parties does not include amendment to the confidential net price paid by the NHS to the backbone medicine supplier and should not itself therefore result in terms that negatively impact the NHS or patients.

(b) It is possible that an agreement could be followed by the emergence of a combination therapy and the withdrawal of one or more of the relevant monotherapies previously used for treatment in that area. This would result in fewer competitors present overall on the market. However, such an impact would be the consequence of the clinical preference for the

[18] The CMA has been informed that this is the case in respect of oncology and the other current candidate treatment areas for combination therapies (namely the treatment of HIV, hepatitis C, rheumatoid arthritis, and COVID-19).

new and improved combination therapy treatment, and not itself the consequence of the terms of the agreement. Indeed, in other circumstances where the clinical guidance provided for the use of the pre-existing monotherapy agreements alongside the newly approved combination, the same form of agreement would enable a market outcome characterised by a greater number of available treatments.

5.6 The CMA has taken account of the expected overall impact of such information exchange and agreements made under the negotiation framework, and the absence of any particular strategic significance that would be derived from the investigation of such information exchange or agreements.

5.7 The CMA is also mindful that the conduct envisaged by the negotiation framework has the potential to generate significant improvements in patient outcomes by allowing more combination therapies to become available to NHS patients. As noted above, combination therapies are becoming increasingly important to the effective treatment of a number of conditions, including very serious ones like cancer. Intervening to try and increase the availability of such important treatments to NHS patients was a significant factor in the CMA's prioritisation assessment.

5.8 On the basis of these considerations, the CMA considers it appropriate to publish this statement confirming that it would not investigate this conduct in the circumstances described at paragraph 5.2. There may be other approaches to make combination therapies available to NHS patients and parties will need to self-assess whether they are compliant with competition law.

5.9 The CMA would like to thank ABPI and its member companies, the NHS and relevant UK HTA agencies, for their extensive engagement to date on these complex matters, to seek to find a workable solution within the current regulatory frameworks to help ensure the NHS and its patients can get access to these critical treatments. The CMA appreciates that the negotiation framework is unlikely to be the 'last word' on the matter of bringing combination therapies to market. The challenges of bringing combination therapies to market are long-standing - new and different approaches and solutions have emerged and are likely to continue emerging. Given the importance of the issues relating to patient access to critical and novel therapies, the CMA may, as appropriate, revisit and / or update this statement as circumstances evolve.