

No Grounds For Action Decision
Competition Act 1998
Remicade

50236

Addressed to:
Merck Sharp & Dohme Limited
Merck & Co., Inc.

14 March 2019

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The Competition and Markets Authority has excluded from this published version of the decision information which the CMA considers should be excluded having regard to section 244 of the Enterprise Act 2002. Omissions are indicated by [✂]. Some numbers have been replaced by a range, which are shown in square brackets.

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1. INTRODUCTION AND SUMMARY

- 1.1. The Competition and Markets Authority (the '**CMA**') has decided to close its case in relation to Merck Sharp & Dohme Limited's ('**MSD**') discount scheme for Remicade¹ introduced in England in March and April 2015² ('**MSD's Discount Scheme**').
- 1.2. The CMA considers that MSD's Discount Scheme was designed to limit or delay the market entry or expansion of competing medicines, and that it had no pro-competitive rationale or efficiency justification. However, based on the factual circumstances at the time when MSD's Discount Scheme was introduced and on the basis of the information in its possession, the CMA considers that MSD's pricing scheme was not, in fact, likely to restrict competition. The CMA has therefore decided that there are no grounds for action on its part.
- 1.3. This document (the '**Decision**') is structured as follows:
 - a. first, it summarises the CMA's investigation and the reasons for the CMA's decision;³
 - b. it then sets out in more detail the relevant factual background,⁴ and the CMA's approach to market definition,⁵ dominant position⁶ and abuse in this case;⁷ and
 - c. finally, it outlines the CMA's overall conclusions.⁸
- 1.4. Where relevant, the Decision also summarises MSD's key submissions and the CMA's response. MSD's submissions are not, however, addressed exhaustively in the Decision.

A. Introduction

- 1.5. In December 2015, the CMA opened a formal investigation (the '**Investigation**') under section 25 of the Competition Act 1998 (the '**Act**'), on the basis that there were reasonable grounds for suspecting that MSD had infringed the prohibition imposed by section 18 of the Act (the '**Chapter II prohibition**') and Article 102 of the Treaty on the Functioning of the

¹ See section 2 below for more detail on Remicade.

² As explained at section 2.D below, MSD's Discount Scheme was introduced on different dates in different regions and sub-regions.

³ See sections 1.A and 1.B below.

⁴ See section 2 below.

⁵ See section 3.A below.

⁶ See section 3.B below.

⁷ See section 4 below.

⁸ See section 5 below.

European Union ('**Article 102**'). Specifically, the CMA considered that there were reasonable grounds for suspecting that MSD had abused a dominant position by offering loyalty-inducing discounts for the sale of Remicade in the UK.

- 1.6. Remicade is MSD's brand name for its infliximab product, which is a type of biological immunosuppressant medicine used to treat autoimmune inflammatory disorders such as Crohn's disease and Rheumatoid Arthritis.⁹ In March 2015, biosimilar infliximab products ('**Biosimilars**'), which are a competing type of infliximab that are similar to Remicade, were introduced in the UK.¹⁰
- 1.7. During the Investigation, the CMA exercised its formal powers under section 26 of the Act to request documents and information from MSD, as well as from a number of third parties, both within the NHS and suppliers of Biosimilars. The CMA also conducted interviews under section 26A of the Act with two MSD employees.
- 1.8. Subsequently, in May 2017, the CMA issued a Statement of Objections (the '**SO**') to MSD and its parent company, Merck & Co., Inc. In the SO, the CMA provisionally found that from 1 March 2015 to 29 February 2016 MSD had abused a dominant position in the market for the supply of infliximab in England by offering a discount scheme for Remicade which the CMA provisionally concluded was likely to produce an anti-competitive exclusionary effect, in breach of the Chapter II prohibition and of Article 102.
- 1.9. The CMA appointed a Case Decision Group (the '**CDG**') in June 2017. This originally consisted of Professor Philip Marsden (Senior Director of Case Decision Groups), Kate Collyer (Deputy Chief Economist) and Stephen Blake (at the time Senior Director, Cartels and Criminal, and subsequently Senior Legal Director, Cartels and Consumer Protection). Kate Collyer was later replaced by Dr Jenny Haydock (Economics Director) after leaving the CMA to take up another role. Philip Marsden has also since left the CMA but was not replaced on the CDG.
- 1.10. MSD submitted written representations on the SO in August 2017 and an oral hearing was held at the CMA's London office in November 2017.

⁹ See section 2.A below for more detail on infliximab and Remicade.

¹⁰ See section 2.A.IV below for more detail on Biosimilars.

- 1.11. Following MSD's written and oral representations, the CMA carried out voluntary interviews with a number of NHS employees between July and September 2018.
- 1.12. Having considered all of the information in the CMA's possession, including MSD's written and oral representations, the CDG concluded on the basis of that information that the conditions for prohibition were not met in relation to MSD's Discount Scheme and that there were no grounds for action on the CMA's part. Accordingly, the CMA has decided to close its case.

B. Summary

- 1.13. The CMA's concerns about MSD's Discount Scheme focused on the scheme's potential to induce the NHS to remain loyal to Remicade and to make it harder for suppliers of Biosimilars to compete with MSD, thereby producing an exclusionary effect.
- 1.14. Specifically, the CMA was concerned that MSD's Discount Scheme created a financial disincentive for the NHS to switch to Biosimilars, even though Biosimilars were significantly cheaper (per vial) than Remicade. Under MSD's Discount Scheme, switching from purchasing Remicade to purchasing Biosimilars risked the price of Remicade increasing for all future purchases of Remicade, which, in turn, risked the NHS having to pay more in total for purchases of infliximab products. The resultant cost pressure had the potential to affect decisions within the NHS, discouraging the use of Biosimilars and, thus, potentially making it harder for Biosimilar suppliers to win sales from MSD. Any such effect was likely to be felt for some time as clinical caution towards using Biosimilars needed to be overcome by the NHS starting to use and become confident in using Biosimilars.
- 1.15. The CMA considers that the way in which MSD's Discount Scheme was designed,¹¹ its criteria and rules,¹² and the way it was interpreted and understood by the NHS demonstrate the potential for MSD's Discount Scheme to induce the NHS to be loyal to Remicade and thereby to have an exclusionary effect on actual and potential competitors of Remicade. In particular,
 - MSD designed its Discount Scheme in such a way that Biosimilars would have to sell at very low prices in order to compensate the NHS for the discount it would lose on purchases of Remicade if it switched to

¹¹ See section 4.B.I below.

¹² See section 4.B.II below.

using Biosimilars for a relatively small proportion of total infliximab demand.¹³

- Under the criteria and rules of MSD's Discount Scheme as introduced, the NHS had to purchase Remicade for most of its infliximab requirements in order to benefit from the discount on purchases of Remicade. As the NHS started to switch from Remicade to Biosimilars, the level of this discount would reduce.¹⁴
- The NHS generally understood how MSD's Discount Scheme would work and had concerns about the implications for the price and cost of switching to using Biosimilars under MSD's Discount Scheme.¹⁵

1.16. However, in assessing whether or not MSD's conduct was abusive, it is necessary to consider all the relevant circumstances, including the market context at the time the conduct took place. The CMA ultimately concluded, on the basis of the information in its possession, that an exclusionary effect was not likely based on the particular factual circumstances at the time when MSD's Discount Scheme was introduced and that the conditions for prohibition are not therefore met.

1.17. The CMA's reasons are explained below.¹⁶ For MSD's Discount Scheme to be likely to have the effect that MSD intended, the market context at the time MSD's Discount Scheme was introduced needed to reflect certain broad assumptions by MSD. In fact, however, the factual circumstances at that time were such that MSD's assumptions were incorrect in a number of respects. In particular:

- The degree of clinical caution within the NHS and the likely attitude of the NHS towards using Biosimilars were different from what MSD had assumed when it designed its Discount Scheme, such that the financial incentive created by MSD's Discount Scheme was likely to be more quickly overcome than MSD had assumed.
- The relative strength of the financial incentive created by MSD's Discount Scheme at the time it was introduced was less strong than MSD had planned.¹⁷

¹³ See section 4.B.I below.

¹⁴ See section 4.B.II below.

¹⁵ See section 4.B.III below.

¹⁶ See section 4.B.IV below.

¹⁷ See section 4.B.IV below.

- 1.18. Accordingly, the CMA has decided that in the specific circumstances of this case there are no grounds for action on its part.

2. FACTUAL BACKGROUND

2.1. In this section, the CMA provides brief detail on:

- a. the relevant products;¹⁸
- b. how secondary healthcare is structured in England;¹⁹
- c. how decisions are made and can be influenced;²⁰
- d. the tendering process for infliximab;²¹
- e. what MSD's Discount Scheme was and how it worked;²²
- f. MSD's revised price offering;²³ and
- g. how prices and shares of supply for Remicade and Biosimilars changed over time.²⁴

2.2. Unless indicated otherwise, the factual description in this section relates to the period from early 2015 (when MSD's Discount Scheme was introduced)²⁵ until early 2016 (when MSD's Discount Scheme was replaced).²⁶

A. Infliximab, Remicade and Biosimilars

I. Infliximab

2.3. Infliximab is used to treat autoimmune inflammatory disorders and is one of a number of biological immunosuppressant medicines. At the relevant time, infliximab was licensed to treat gastroenterological (Crohn's disease and ulcerative colitis²⁷), rheumatological (rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis) and dermatological conditions (psoriasis). It is an artificial antibody, known as a tumour necrosis factor alpha inhibitor ('**TNF alpha inhibitor**'), which is produced by genetically engineered cell lines.

¹⁸ See section 2.A below.

¹⁹ See section 2.B below.

²⁰ See section 2.C below.

²¹ See section 2.D below.

²² See section 2.E below.

²³ See section 2.F below.

²⁴ See section 2.G below.

²⁵ Section 2.E below explains when MSD's Discount Scheme was introduced for each region and sub-region.

²⁶ Section 2.F below summarises when MSD's Discount Scheme was replaced and what pricing scheme replaced it.

²⁷ The NICE approval for infliximab (including both Remicade and Biosimilars) to treat ulcerative colitis was published in February 2015, just prior to the introduction of MSD's Discount Scheme (from March 2015).

- 2.4. There are a number of other TNF alpha inhibitors, which are used to treat similar disorders to those treated by infliximab, including, among others, adalimumab (branded as Humira, sold by AbbVie) and etanercept (branded as Enbrel, sold by Pfizer). There are also a wider set of biological immunosuppressant medicines (with TNF alpha inhibitors being a type of biological immunosuppressant medicine), some of which can be used to treat a subset of similar disorders (such as vedolizumab which can be used to treat Crohn's disease).
- 2.5. Infliximab is a prescription-only medicine mainly purchased by NHS Trusts for use in clinics and hospitals. It is administered intravenously under the supervision and monitoring of a specialised healthcare professional who has experience in the diagnosis and treatment of the diseases that infliximab can be used to treat.
- 2.6. As infliximab is administered by intravenous infusion, it is primarily administered in a hospital or clinic. By contrast, most other TNF alpha inhibitors are administered subcutaneously,²⁸ and are often delivered to a patient's home and self-injected directly by the patient.

II. Remicade

- 2.7. Remicade is the brand name of the patented version of infliximab. It was granted a European marketing authorisation on 13 August 1999 and is approved in the UK to treat six autoimmune conditions.²⁹
- 2.8. Remicade was originally developed by Centocor Inc and subsequently acquired by Johnson & Johnson. The Remicade patent expired in the UK on 24 February 2015.
- 2.9. Johnson & Johnson manufactures the active ingredient of Remicade and supplies it to Merck for distribution in Europe, Russia and Turkey. Merck group companies formulate and package the product and Merck's local subsidiaries then sell the finished Remicade product in the contract territory. As the relevant local subsidiary, MSD sells Remicade in the UK.

III. Biological and biosimilar medicines

- 2.10. Infliximab is a 'biological' medicine. Biological medicines are medicines which contain one or more active substances made by or derived from a

²⁸ A subcutaneous injection is a method of administering medication whereby a needle is used to inject a medicine just under the skin.

²⁹ Rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis.

living organism. Biological medicines are intrinsically different from small molecule medicines in a number of important respects:

- a. biological medicines have a much larger and more complex molecular structure than small molecule medicines;
- b. biological medicines have complex manufacturing processes that must be tightly controlled to provide a consistent product;
- c. due to their size and complexity, biological medicines have the potential to induce unwanted or unexpected immune reactions;
- d. most biological medicines must be administered by injection or infusion; and
- e. biological medicines tend to degrade quickly if subject to high temperatures.

2.11. Whereas small molecule medicines can be duplicated with relative ease to create generic alternatives, the complexity of a biological medicine is such that it cannot be precisely replicated as no two batches of any given biological product are identical.³⁰ These alternative versions are, therefore, only similar to an existing biological medicine (the '**originator medicine**'), not the same, and are known as **biosimilar medicines**.

2.12. Biosimilar medicines can offer a competitive alternative to biological originator medicines. As with biological originator medicines, the supply of biosimilar medicines is subject to the grant of a marketing authorisation, which within the European Union is granted by the European Medicines Agency.

2.13. Unlike for small molecule generic medicines, bioequivalence studies are insufficient for a biosimilar medicine to be granted a marketing authorisation. Instead, suppliers of biosimilar medicines need to go further and conduct clinical trials in order to demonstrate comparable clinical efficacy to the originator medicine. However, clinical trials only need to be carried out in respect of one of the major conditions that the originator medicine has been licensed to treat. Where the originator medicine has a number of indications (as was the case for Remicade) the results of clinical trials can be extrapolated to all other indications (the '**extrapolation principle**').

³⁰ In contrast to generic medicines, which are generally considered to be bioequivalent.

- 2.14. At the relevant time, biosimilar medicines were a relatively new phenomenon. Clinical experience of biosimilar medicines was, therefore, relatively limited and still developing.³¹
- 2.15. Given that bioequivalence cannot be assumed for biosimilar medicines, there is no practice of automatic substitution whereby biosimilar medicines are automatically dispensed instead of the originator medicine. For biological originator and biosimilar medicines, prescriptions are issued by brand name rather than by reference to the International Non-proprietary Name. Accordingly, a prescription will specify the precise brand that is to be dispensed by the pharmacist. In this case, a prescription would, therefore, have specified Remicade or the relevant brand of Biosimilar if a clinician had decided to prescribe an infliximab product.

IV. Biosimilar infliximab products

- 2.16. Since expiry of the Remicade patent, three Biosimilars have been granted European marketing authorisations: Remsima (sold by Napp), Inflectra (sold by Hospira) and Flixabi (sold by Samsung Biopis). Under their marketing authorisations, all three are licensed for all of the indications that Remicade is licensed for.
- 2.17. Inflectra and Remsima were introduced in the UK from March 2015. Inflectra and Remsima are both manufactured by Celltrion in South Korea and are identical.³² At the relevant time, the NHS was generally aware of this and tended to select Inflectra or Remsima (depending on which was cheaper) where it was decided that a Biosimilar would be used.
- 2.18. Flixabi was granted a marketing authorisation in May 2016 and was launched in the UK in September 2016. Given its later entry, Flixabi was not relevant to the Investigation.
- 2.19. To be granted a marketing authorisation, a supplier of a biosimilar medicine needs to demonstrate equivalence with the originator medicine through clinical trials in one of the originator medicine's major indications. In the case of Inflectra and Remsima, clinical trials to demonstrate biosimilarity with Remicade were carried out on patients with rheumatoid arthritis and ankylosing spondylitis. Through the extrapolation principle, Inflectra and Remsima were also approved for Remicade's other indications (Crohn's disease, ulcerative colitis, psoriatic arthritis and psoriasis). Further, the clinical trials conducted for Inflectra and Remsima considered only the

³¹ Experience in the UK of biosimilar medicines has subsequently increased, both as a result of biosimilar infliximab and through the introduction of biosimilar versions of other TNF alpha inhibitors (such as etanercept).

³² Inflectra and Remsima are different brand names for the same product manufactured by Celltrion.

comparability of Inflectra and Remsima with Remicade when used to treat newly diagnosed patients. Those trials did not consider the use of Inflectra or Remsima on patients already established on treatment with Remicade.

- 2.20. The results of clinical trials in Norway (NOR-SWITCH) were expected to provide further data, particularly on the comparability of Biosimilars with Remicade for existing patients (i.e. when switching a patient established on Remicade to a Biosimilar). However, the results of those trials were not expected for some time (at least until mid-2016). Accordingly, when Biosimilars first became available in the UK (from March 2015), very little clinical trial data was available.

B. The structure of secondary healthcare in the NHS

- 2.21. Secondary healthcare in England is multi-layered and complex, consisting of practitioners, managers, commissioners and advisory organisations and bodies. It is further complicated by the fact that the person who decides which medicine to prescribe (typically, a clinician) is different from the person who decides which medicine to purchase and dispense (typically, a pharmacist), who can, in turn, be different from the person who administers the medicine (typically, a specialist nurse). Those decisions tend to be taken within one body (a Trust, which may cover one or more hospitals) but, within each Trust, different approaches may be taken as between different hospitals, different areas of treatment or individual clinicians.
- 2.22. Additionally, for high-cost drugs,³³ the payer (a Clinical Commissioning Group) is different from the decision-maker.
- 2.23. Finally, advisory and oversight organisations and bodies are different from both the decision-maker and the payer.
- 2.24. This section summarises the various levels within secondary healthcare in England.

I. Healthcare professionals

- 2.25. At the heart of any decision to prescribe medicines in the secondary healthcare setting are the patient and their attendant clinician. Ultimately, the clinician will decide, in consultation with the patient, what medicine to prescribe.
- 2.26. Decision-making does not occur in isolation, however. In practice, decisions are taken against the backdrop of a complex funding and procurement

³³ Infliximab was classified as a high-cost drug.

landscape, which is intended to ensure that local decisions balance broader clinical and financial considerations appropriately.

- 2.27. Other healthcare professionals also play a role in decision-making, including various types of pharmacists (such as Chief Pharmacists, Lead Clinical Pharmacists and Lead Procurement Pharmacists) and specialist nurses (who typically administer the medicine).
- 2.28. Therapeutic autonomy³⁴ is an overriding principle. It does not, however, follow that clinicians act independently or in isolation from the rest of the NHS, be that other clinicians, pharmacist and nurse colleagues within the same or other hospitals or Trusts, Clinical Commissioning Groups or advisory or oversight bodies and organisations. Rather, various advice, guidance and recommendations feed into clinician's prescribing decisions, including from sources such as fellow clinicians (whether within the same or different Trusts) and pharmacists, as well as wider recommendations (from, for example, NICE) and funders.
- 2.29. Decisions can be informed by both clinical judgement and cost-effectiveness, which are not necessarily mutually exclusive.

II. Trusts

- 2.30. Various healthcare professionals, including clinicians, various categories of pharmacist and specialist nurses, are employed by individual Trusts. There are two types of Trust within the NHS in England: Acute Trusts and Foundation Trusts. A Trust may encompass one or more hospitals.

III. Clinical Commissioning Groups

- 2.31. Clinical Commissioning Groups ('**CCGs**') are clinically led bodies that are responsible for planning and commissioning most of the secondary care and community NHS services in the local areas for which they are responsible. CCGs are responsible for setting local policy in relation to healthcare services they commission. A CCG typically covers a number of Trusts within their relevant geographic area.
- 2.32. CCGs are legally obliged to provide funding for high-cost medicines and treatments that have been recommended by the appraisal board of NICE. As a high-cost medicine that had been recommended for use by NICE, CCGs

³⁴ Therapeutic autonomy generally refers to a clinician deciding, in consultation with a patient and subject to NICE recommendations and the general funding system, what the best or most appropriate treatment is for that patient. For example, the [NHS Constitution](#) sets out that patients '*have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you*'.

were legally obliged to provide funding for Remicade, Inflectra and Remsima.

IV. The Commercial Medicines Unit

2.33. At the time that MSD's Discount Scheme was introduced, the Commercial Medicines Unit (the '**CMU**') provided support to Trusts in managing the contracting process for the supply of medicines in England.³⁵ The CMU was responsible for co-ordinating the tendering process through which prices were established for Remicade and for Biosimilars.

V. NHS England and the four NHS commissioning regions

2.34. NHS England is an independent public organisation operating at 'arm's length' from the Government and authorises CCGs to improve health outcomes for people in England. NHS England oversees the operation of, and allocates resources to, CCGs. NHS England also commissions primary care and other directly commissioned services.

2.35. At the time that MSD's Discount Scheme was introduced, NHS England discharged its functions through four regional teams in the following areas:

- a. London;
- b. the Midlands and East of England;
- c. the North of England; and
- d. the South of England.

2.36. CCGs and NHS England worked alongside each other as co-commissioners in these four overarching regions.

2.37. Although NHS England has some commissioning functions in relation to infliximab, those are limited to speciality areas, such as paediatrics. The majority of infliximab commissioning in England is delegated to CCGs.

VI. NHS sub-regions

2.38. Until April 2013,³⁶ England was divided into 10 Strategic Health Authorities ('**SHAs**'). These SHAs have since been disbanded and their functions have

³⁵ The functions of the CMU have since been subsumed into the Medicine, Pharmacy and Industry group of the Department of Health and Social Care.

³⁶ When the Health and Social Care Act 2012 came into force.

been subsumed within the four new NHS commissioning regions described in section 2.B.V above.

- 2.39. Although SHAs no longer exist, their boundaries were still relevant at the time that MSD's Discount Scheme was introduced as the tendering process for infliximab (including both Remicade and Biosimilars) allowed pricing proposals to be defined either by reference to the four overarching NHS commissioning regions (the '**regions**', each a '**region**') or by reference to the sub-regions corresponding to the boundaries of the former SHAs (the '**sub-regions**', each a '**sub-region**'). Figure 2.1 below provides an overview of the four regions and ten sub-regions in England.

Figure 2.1: Regions and sub-regions of the NHS in England

Region	Sub-region
London	London
Midlands and East of England	East Midlands
	West Midlands
	East of England
North of England	North East of England
	North West of England
	Yorkshire and the Humber
South of England	South East Coast
	South West of England
	Thames Valley and Wessex

VII. Regional Pharmacy Procurement Specialists

- 2.40. At the time that MSD's Discount Scheme was introduced, Regional Pharmacy Procurement Specialists ('**Specialists**') played an important role within each sub-region in relation to medicines procurement. In particular, Specialists provided information, assessment, advice, guidance and/or recommendations in relation to the procurement of medicines to both policy makers (such as the CMU and commissioners) and to those responsible for implementing procurement decisions (such as Chief Pharmacists and Lead Procurement Pharmacists).

2.41. There was one Specialist appointed for each of the 10 sub-regions within England.

VIII. The Pharmaceutical Market Support Group

2.42. The Pharmaceutical Market Support Group (the '**PMSG**') brought together various healthcare professionals with a role in the procurement of medicines for secondary care. It included representatives of the CMU and the Specialist for each sub-region, along with other representatives of the Department of Health and Social Care, quality control pharmacists, and pharmacy procurement specialists from each of the Devolved Nations.

2.43. The PMSG's terms of reference indicate that its primary aim was to ensure that hospital patients had access to appropriate medicines at an economically sustainable price. It did this by:

*'Strategic advice to adjudicating groups to inform the decision-making process for contracts for pharmaceuticals, so that the long term interests of patients, providers of secondary care and pharmaceutical supply chain stakeholders are taken into account.'*³⁷

2.44. The PMSG was organised into a series of sub-groups. One such group was the Biosimilar Medicines Subgroup (the '**BMSG**'), whose role was primarily to devise strategies, so the NHS could make *'best use of biosimilar medicine which [had] patient safety as a priority whilst supporting a robust biosimilar market'*.³⁸

2.45. The BMSG was chaired by a member of the PMSG and comprised Specialists, representatives from the Department of Health and Social Care, a CCG pharmacist and a NICE representative.

C. Prescribing and purchasing decisions in secondary healthcare in the NHS

2.46. Cost-effective decision-making, both when prescribing and when purchasing medicines, is of importance to the NHS as a whole, as are initiatives to achieve cost savings.

2.47. At the time that MSD's Discount Scheme was introduced, there existed a number of mechanisms within and across the NHS to influence clinical decision-making (in terms of both prescribing and purchasing decisions) and encourage cost-effective decision-making, including actions by both

³⁷ Terms of reference for the Pharmaceutical Market Support Group.

³⁸ Terms of reference for the Biosimilar Medicines Subgroup of the Pharmaceutical Market Support Group.

Specialists and CCGs, as well as guidance provided through advisory bodies and committees.

- 2.48. Although decisions may ultimately have been taken by a clinician in consultation with his or her patient, those decisions would be informed by advice, guidance, recommendations and views from numerous other parts of the NHS. The provision of advice, guidance and recommendations on which medicine to prescribe and purchase was a common method within the NHS to share views and seek to guide and influence decisions.³⁹
- 2.49. It was through those mechanisms that various NHS bodies would seek to encourage cost-effective prescribing and purchasing decisions, including, for example, encouraging switching to a cheaper medicine (such as a generic or biosimilar version of an originator medicine) or sounding caution about the potential financial implications of switching to a different medicine in circumstances where the cost implications may not be immediately apparent.⁴⁰
- 2.50. The following bodies, organisations and individuals had a particular role in influencing what infliximab products were prescribed and purchased:
- a. Specialists, particularly through advice, guidance and recommendations;⁴¹
 - b. CCGs, particularly through the creation of financial incentives (typically through gain share agreements) and more general support to Trusts;⁴² and
 - c. advisory bodies and committees, particularly through advice, guidance and recommendations.⁴³
- 2.51. This section summarises how decisions were susceptible to influence at the time that MSD's Discount Scheme was introduced.

I. Specialists

- 2.52. The role of Specialists was important for the introduction of Biosimilars. Specialists for each sub-region were involved in considering MSD's Discount

³⁹ Even guidance and technical appraisals published by NICE provide guidance on prescribing and purchasing decisions but do not determine or dictate decisions. Such guidance informs decisions on what can be prescribed for particular conditions, not what must be prescribed.

⁴⁰ Such as, for example, when the price paid by a Trust within a particular region or sub-region changes based on the overall sales in a region or sub-region (such as was the case for MSD's Discount Scheme).

⁴¹ See section 2.C.I below.

⁴² Both gain share agreements and other support from CCGs to Trusts are explained in more detail in section 2.C.II below.

⁴³ See section 2.C.III below.

Scheme and the pricing offers from Biosimilar suppliers. Specialists then sought to gather information from those within their sub-region (including from Trusts and CCGs) that would allow them to assess likely uptake of Biosimilars in their sub-region and consider the implications of such an uptake for prices and costs within the sub-region.

- 2.53. Specialists also acted as a conduit of information to Trusts and CCGs, providing information about MSD's and Biosimilar suppliers' pricing proposals.
- 2.54. There were various ways in which Specialists could influence the choices of Trusts, including clinicians within those Trusts. This included through the provision of advice, guidance and recommendations on which medicine to use and the potential price and cost implications of choosing a particular medicine.
- 2.55. By way of example, a Specialist could have:
 - a. advised on the potential financial implications of particular purchasing decisions, such as whether the price of one product might have increased if another product was purchased or whether total expenditure might have increased depending on purchasing decisions;
 - b. chosen what information to communicate (or not communicate) with a view to influencing decision-makers;
 - c. encouraged a collective approach between Trusts within their sub-region; i.e. seeking to encourage those within their sub-region to try to co-ordinate decisions;
 - d. recommended caution towards using a particular product, where, for example, it risked price or total expenditure increasing;
 - e. requested that Trusts report back on planned actions before actually taking action, to enable the Specialist to consider the potential financial implications for all Trusts within their sub-region; or
 - f. actively monitored purchasing decisions and behaviour and reported changes and developments to Trusts and/or CCGs in their sub-regions.
- 2.56. Given their position as an interface between procurement and practice, Specialists also communicated with various groups of people within the NHS, all of whom had a role to play in decision-making, including:

- a. pharmacists, particularly Chief Pharmacists and Lead Procurement Pharmacists;
- b. CCGs;
- c. the CMU;
- d. representatives at the Department of Health and Social Care; and
- e. representatives at NHS England.

II. Gain share agreements and other CCG initiatives to encourage cost savings

- 2.57. Although NHS bodies have a shared collective interest in securing cost savings with a view to achieving the best possible outcomes for patients, there are particular mechanisms by which funders (i.e. those who ultimately pay for medicines purchased and dispensed) could seek to have direct influence over decisions at a Trust level.
- 2.58. One such mechanism was through a 'gain share agreement' which incentivised Trusts to achieve savings through changes in clinical practice⁴⁴ by giving them a share of such savings from the CCG. Such agreements could provide, for example, that half of any savings achieved from switching to a cheaper product would, for a period, be made available to the Trust for its own purposes or might be used to fund additional staff, services or equipment, for example, to assist in any switching programme.⁴⁵
- 2.59. A CCG could also seek to encourage or persuade clinicians to prescribe particular medicines that the CCG deemed most cost-effective through informal discussions and engagement.
- 2.60. A more direct mechanism available to CCGs was to stipulate that they would only reimburse the costs of the lowest-priced medicine within a particular group of substitutable treatments, with a view to incentivising uptake of such medicine.⁴⁶
- 2.61. Actions by CCGs, therefore, had the potential to affect decisions on which medicines to prescribe and purchase. The same was also true for inaction by

⁴⁴ Changes to clinical practice might have included reduction in dosages, avoiding wasteful practices or switching to cheaper alternative treatment options.

⁴⁵ The role and prevalence of gain share agreements in relation to Remicade and Biosimilars at the time that MSD's Discount Scheme was introduced is considered in section 4.B.V below.

⁴⁶ For example, a CCG could have decided to reimburse at the price of the cheapest available product for newly diagnosed patients. In that scenario, if a Trust decided to purchase a higher-priced product, it would have had to cover the shortfall from its own budget.

CCGs. For example, the absence of a gain share agreement had the potential to slow uptake of a newly introduced medicine (such as a generic or biosimilar medicine) as a Trust would not have benefitted financially from purchasing the lower priced medicine. Additionally, switching may not have been cost-free for the Trust and might have required the Trust to divert time and resource to managing switching programmes.⁴⁷ Absent a gain share agreement, all of the financial benefit accrued to the CCG (as the funder).

III. National, regional and sub-regional groups and committees

- 2.62. A number of national, regional and sub-regional group and committee meetings existed and were convened to consider and explore potential cost savings. The membership and coverage of such groups and committees varied. Some brought together key stakeholders at all relevant levels (for example, clinicians, nursing staff, pharmacists and commissioners) with the power to reach a collective position or decision. In other cases, groups and committees had more of an advisory role, or were influential in sharing best practice.
- 2.63. For Remicade and Biosimilars, the PMSG and the BMSG played important roles at a national level, with Specialists playing a role as members of those groups, as well as engaging with various NHS groups within their respective sub-regions.
- 2.64. Within sub-regions, there were also various bodies and networks that provided a forum for healthcare professionals from different Trusts and hospitals to discuss issues and share experiences. Examples included both common networks⁴⁸ and groups specific to particular sub-regions.⁴⁹

D. The tendering process within the NHS

- 2.65. At the time that MSD's Discount Scheme was introduced, the CMU coordinated the tendering process for the supply of branded medicines to secondary care providers. Following the tendering process, supply framework agreements ('**Framework Agreements**') were awarded, pursuant to which Trusts could make purchases directly from medicines suppliers.

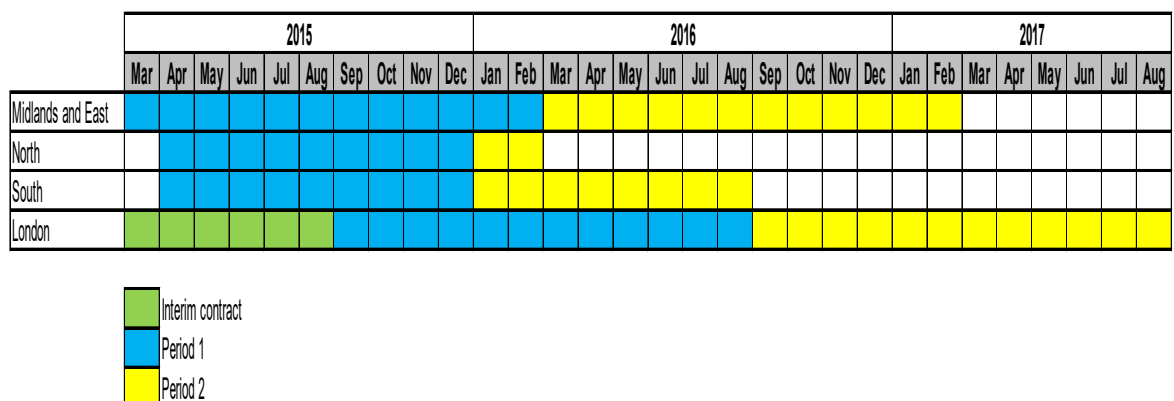
⁴⁷ Switching from an originator medicine to a newly introduced medicine was typically not cost-free. For example, a Trust may have had to engage with patients to agree to a switch and/or monitor patients who had been switched to ensure that there were no adverse reactions and that the new medicine remained effective at treating the patient's condition. All of those actions would have required additional staff time, which would have needed to be diverted from other activities.

⁴⁸ Such as for Chief Pharmacists and Area Prescribing Committees.

⁴⁹ Such as the clinical project group for biosimilars set up in Yorkshire and the Humber and the Northern Treatment Advisory Group in the North East of England.

- 2.66. In advance of the Remicade patent expiring and the expected market entry of Biosimilars, the CMU issued an invitation to tender in respect of each infliximab product anticipated to be available, seeking responses in respect of Remicade (from MSD), Inflectra (from Hospira) and Remsima (from Napp).
- 2.67. Tender offers were then reviewed and assessed against set criteria. In the first instance, that assessment was carried out by the CMU. The results were then shared with each Specialist before the contracts were awarded. Once award decisions were made, a Framework Agreement was concluded with the relevant supplier.
- 2.68. In relation to infliximab, Framework Agreements were concluded with MSD, Hospira and Napp across the regions and sub-regions. Figure 2.2 below summarises the contract awards, start dates and contract periods for MSD's Framework Agreements. Start dates differed between regions (and associated sub-regions), because pre-existing Framework Agreements were due to expire at different times for different regions and sub-regions.
- 2.69. MSD's Discount Scheme applied across two periods: Period 1 and Period 2. It was envisaged that the prices applying for Period 2 would be different (and lower) than for Period 1. Otherwise, MSD's Discount Scheme was the same across Periods 1 and 2. For the purposes of the Investigation, the CMA focused on Period 1 only. For the London region, an interim contract was agreed between MSD and the CMU as the existing London Framework Agreement was not due to expire for six months.

Figure 2.2: Contract periods for MSD's Framework Agreements



E. MSD's Discount Scheme

- 2.70. This section provides a brief description of MSD's Discount Scheme as it was introduced in March and April 2015 (depending on which region or sub-

region it applied to, as start dates were staggered, as explained in paragraph 2.68 above).

- 2.71. MSD's Discount Scheme comprised two key elements, each of which is summarised in the sections below:
- a. a matrix that set out a series of bands, with each band associated with a specified price and a specified volume for Remicade; and
 - b. a periodic review mechanism ('**Quarterly Reviews**') where purchases of Remicade would be reviewed against the volume specified in the matrix.

I. MSD's price-volume matrix

- 2.72. Under MSD's Discount Scheme, there was one matrix for each sub-region, as well as for each region.⁵⁰ In that regard, MSD's Discount Scheme set the price of Remicade on a regional or sub-regional basis and all Trusts within a region or sub-region paid the same price for Remicade.
- 2.73. Under MSD's Discount Scheme, the price that a Trust within a region or sub-region would pay for Remicade was determined by the relevant matrix and depended on the total volume of Remicade purchased by Trusts within that region or sub-region. An example of MSD's matrix (as set out in its tender offers) is set out in figure 2.3 below. As can be seen, MSD's matrix presented a series of bands, with a volume threshold and associated price for each band.

⁵⁰ MSD (as well as Hospira and Napp) was invited to tender on the basis of either the four regions or the 10 sub-regions. MSD decided to tender on both a regional and sub-regional basis, with its regional offers being the sum of its relevant sub-regional offers.

Figure 2.3: MSD's matrix for the North West of England region as submitted by MSD in response to the CMU's invitation to tender for Remicade

Remicade Discount Offer

- North West of England Region
 - Current Annual Remicade Usage (Sep 2014) [50,000 – 55,000] vials
 - Estimated total Infliximab market size (April 2015) [52,000 – 57,000] units
 - April 2015 – December 2015 Total ifx Market Size [40,000 – 45,000] units.*
- Target volume requirements may be attained from within the entire cytokine modulator
- Target volumes have been prorated from the annualized market usage
- Pricing bands apply to volumes purchased above corresponding volume threshold

Period 1: 1st April 2015 – 31st December 2015

Estimated <u>minimum</u> entry point to discount scheme for the North West of England region on 1 st April 2015	Period 1 Volume Thresholds		Price	
	[42,000 – 47,000]	£[320 – 340]		
	[41,000 – 46,000]	£[330 – 350]		
	[40,000 – 44,000]	£[330 – 350]		
	[38,000 – 43,000]	£[340 – 360]		
	[37,000 – 42,000]	£[350 – 370]		
	[36,000 – 41,000]	£[360 – 380]		
	[34,000 – 39,000]	£[390 – 410]		
	<[34,000 – 39,000]	£419.62		

2.74. MSD's tender offers described the operation of the matrix as follows:

1. *The discount matrix is available to all NHS Hospitals/outlets as stipulated as purchasing points within the tender specification.*
2. *Should there be a request to trigger any extension period (as per tender specification), the terms of the offer would be commensurate with the enhanced terms within period 2 of the current offer and there would be a requirement to review and refresh the target volume bands within the matrix from MSD.*
3. *This offer may be shared with the adjudication panel only. Any wider distribution will require authorization from an appointed MSD representative.*
4. *Should representatives from the tender adjudication panel disagree with MSD derived volume requirements, the relevant representatives for this tender from MSD and CMU North West Region reserves the right to engage with MSD during and/or after the process to discuss requisite volumes.*

5. *Actual performance to be measured at intervals of 3 months. In the event that actual performance deviates from that forecast, the existing price-band will be subject to review. Following discussions with CMU and Regional Procurement Specialists this could result in the selected volume-banding being moved to a more appropriate band consistent with current & projected volumes.*
6. *MSD reserves the right to withdraw from each framework subject to 3 months written notice.*
7. *MSD reserves the right to introduce additional pricing concessions during the lifetime of this framework.*
8. *Should a participating trust/outlet remove itself from the list of participating authorities during the term of this offer, MSD reserves the right to renegotiate the volumes for the region.*
9. *MSD reserve the right to provide services (non- specific) and where these incur no additional or separate charge they will be within the framework offer.'*

2.75. MSD's Discount Scheme provided for an initial price for Remicade (the '**starting price**'), which was the same for all regions and sub-regions: £[350 – 370] per vial of Remicade (representing a discount of [0 – 20]% from MSD's list price).⁵¹ The starting price was then charged for all Remicade purchases for an initial period (the '**initial period**') until the first Quarterly Review.⁵² The starting price assumed a particular volume of sales, which was determined for each region or sub-region according to MSD's expected sales of Remicade within that region or sub-region.

2.76. The various prices (and associated discounts) available under MSD's Discount Scheme were the same for every region and sub-region. In that respect, MSD's Discount Scheme was standardised across all regions and sub-regions. However, the volume associated with each price was different for each region and sub-region, as each region and sub-region was expected to purchase different volumes of Remicade. In that respect, MSD's Discount Scheme was individualised and tailored to the expected demands for each region and sub-region.

2.77. Although presented as volumes of Remicade, the volume thresholds in each matrix corresponded to a proportion (between 85% and 102%) of MSD's

⁵¹ This was lower than the previous price of £[360 – 380], prior to MSD's Discount Scheme, which represented a discount of [0 – 20]% from MSD's list price.

⁵² Quarterly Reviews are explained in section 2.E.II below.

estimate of total infliximab demand within the region or sub-region, with the volume associated with the starting price being set at 94% of that estimate.

- 2.78. Figure 2.4 below shows how the volume bands within MSD's Discount Scheme related to the proportion of total infliximab demand, as estimated by MSD.

Figure 2.4: Proportion of total infliximab demand associated with each band of MSD's matrix

Band	Period 1		
	Discount	Price	Proportion of anticipated demand
1	0%	£419.62	<85%
2	[0 – 10]%	£[390 – 410]	85%
3	[0 – 10]%	£[360 – 380]	91%
4	[0 – 10]%	£[350 – 370]	94%
5	[0 – 10]%	£[340 – 360]	96%
6	[0 – 10]%	£[340 – 360]	98%
7	[0 – 10]%	£[330 – 350]	100%
8	[20 – 30]%	£[320 – 340]	102%

Source: CMA analysis of Framework Agreements for Midlands and East of England, North of England, South of England, and London regions

- 2.79. The proportion of total infliximab demand that would need to be met through purchasing Remicade was the same for all regions and sub-regions. In particular:
- a. to benefit from the starting price, total purchases of Remicade in a region or sub-region needed to amount to at least 94% of MSD's estimate of total infliximab demand;
 - b. purchasing a larger proportion of total infliximab demand through Remicade (i.e. more than 94% of MSD's estimate of total infliximab demand) would result in a larger discount and lower price for Remicade;
 - c. purchasing a smaller proportion of total infliximab demand through Remicade (i.e. less than 94% of MSD's estimate of total infliximab demand) would result in a smaller discount and higher price for

Remicade. That higher price was at first the price that MSD had charged for Remicade prior to Biosimilar entry (band 3, i.e. the third band in figure 2.4 above), then higher than the price MSD had charged for Remicade before it faced competition from Biosimilars (band 2, i.e. the second band in figure 2.4 above); and

- d. purchasing less than 85% of total infliximab demand through Remicade would result in all discount being withdrawn and MSD's list price being charged. Indeed, that price (list price) was higher than the price that MSD had charged for Remicade prior to the expiry of the Remicade patent and competition from Biosimilars.

II. Quarterly Reviews

- 2.80. Under MSD's Discount Scheme, each region's and sub-region's performance against MSD's matrix would be reviewed periodically, every three months ('**Quarterly Reviews**'). MSD's Discount Scheme provided for discounts to change in accordance with changes in the volumes purchased.
- 2.81. Based on the start date for each Framework Agreement, the first Quarterly Reviews were expected to be held for each region and/or sub-region in June or July 2015,⁵³ with subsequent Quarterly Reviews expected every three months.
- 2.82. To the extent that the price of Remicade changed following a Quarterly Review, that price would then apply to all Remicade purchases up until the next Quarterly Review. In that regard, the price paid for all purchases following a Quarterly Review would be dependent on purchasing decisions prior to the Quarterly Review. Any price change would only apply to future purchases and was not retrospective, however.

F. MSD's revised pricing proposals for Remicade

- 2.83. MSD's Discount Scheme was expected to apply in the North of England region (and associated sub-regions) until February 2016, and in all other regions (and associated sub-regions) beyond that date.⁵⁴

⁵³ A Quarterly Review was generally expected to be held in the month following a three-month period, in order to collate the data for the relevant three months. For example, the Midlands and East of England Framework Agreements started in March 2015 and the first Quarterly Review was expected to cover purchases of Remicade in March, April and May 2015, with the review actually expected to be held in the following month, i.e. in June 2015.

⁵⁴ See figure 2.2 above for when each Framework Agreement commenced and was due to expire.

- 2.84. Prior to the expiry of the Framework Agreements for the sub-regions in the North of England region⁵⁵ MSD and Biosimilar suppliers were invited to tender for the new contracts in the North of England.
- 2.85. MSD submitted its tender offers for the sub-regions in the North of England region at the end of October 2015. MSD's offers involved a revised pricing scheme for Remicade that differed from MSD's Discount Scheme in two material respects:
- a. first, it set a maximum price that would be paid, by offering a flat-rate price for Remicade regardless of the volume of Remicade purchased; and
 - b. second, it offered a lower price at a Trust level if the volume of Remicade purchased exceeded a set volume threshold.
- 2.86. MSD's revised pricing scheme, therefore, did not penalise the NHS financially if the volume of Remicade purchased fell and offered a lower Remicade price at a local Trust level rather than at a regional or sub-regional level.
- 2.87. Following MSD's tender offers for the North of England sub-regions, the CMU requested price variations from MSD for all other regions and sub-regions. Under the Framework Agreements, the CMU was entitled to request a price variation where the price currently being paid *'does not in the reasonable opinion of the Authority reflect the market price'*. Although it was not required to do so,⁵⁶ MSD accepted the CMU's request for price variations.
- 2.88. As a result, MSD's Discount Scheme ceased to apply (and was replaced by new, flat rates prices) in the Midlands and East of England, North of England, and South of England regions (and associated sub-regions) from March 2016 and in London from September 2016.

G. Changes in prices and volumes of Remicade and Biosimilars

- 2.89. This section summarises how prices and volumes changed for both Remicade and Biosimilars in the period following the introduction of Biosimilars in England in March 2015 until July 2016. Overall, while prices of both Remicade and Biosimilars fell, Remicade continued to be priced at a significant premium to Biosimilars throughout this period. MSD's share of infliximab sales started to fall following the introduction of Biosimilars, but

⁵⁵ The North East of England, the North West of England, and Yorkshire and the Humber.

⁵⁶ MSD could, instead, have given notice of termination of the contract.

remained in excess of the share of Biosimilars for more than a year after Biosimilar entry.

- 2.90. Figure 2.5 below shows how the price of Remicade and Biosimilars changed over time. Prior to Biosimilar entry, the average selling price of Remicade remained constant for several years. In response to Biosimilar entry, the average selling price of Remicade was reduced with the introduction of MSD's Discount Scheme, and continued to fall over the next 15 months (as did the price of Biosimilars). However, Remicade was still priced at a significant premium to Biosimilars over this period.

Figure 2.5: Impact of Biosimilar market entry on Remicade pricing

[✂]

- 2.91. Figures 2.6 and 2.7 below show how the share of supply of infliximab sales changed as between Remicade and Biosimilars over time. Over time, Biosimilars won infliximab sales from Remicade. However, in spite of being priced at a premium to Biosimilars throughout the period, Remicade's share of infliximab sales by volume remained high for a significant period of time, falling from 100% in February 2015 to 70% in January 2016 and just under 50% in June 2016. Further, when considered by value, Remicade's share of infliximab sales was greater, reflecting the higher average price of Remicade when compared with the average selling price of Biosimilars, with Remicade having a 61% share of infliximab sales by value in July 2016.

Figure 2.6: Monthly infliximab sales by volume (units) for England

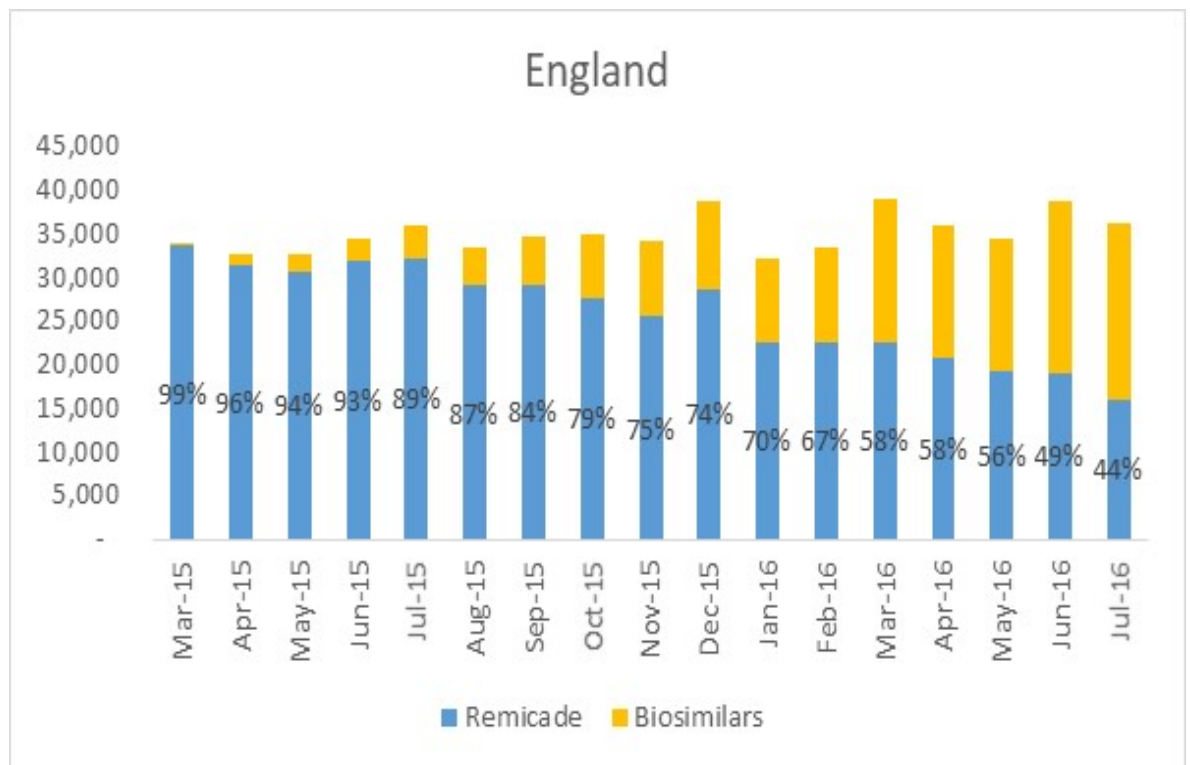
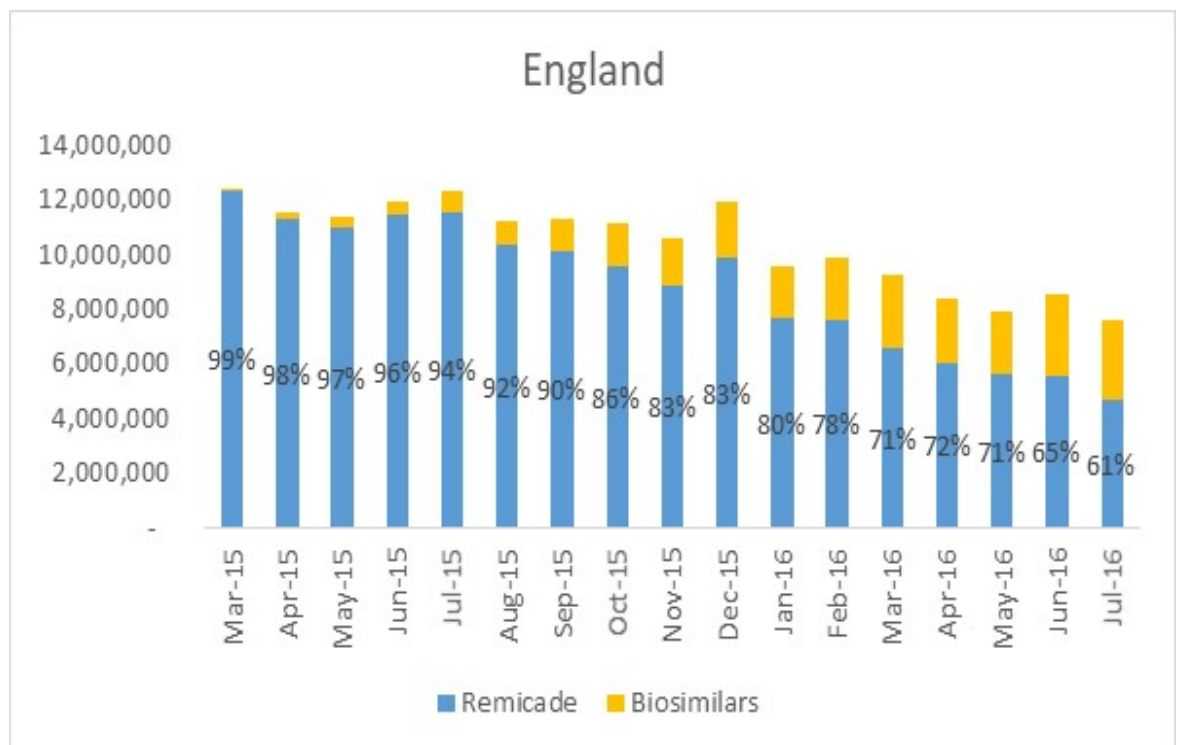


Figure 2.7: Monthly infliximab sales by value (£) for England



3. MARKET DEFINITION AND DOMINANT POSITION

3.1. This section summarises the CMA's approach to defining the relevant market for the purposes of this case and whether MSD held a dominant position in that market. Where relevant, the CMA also summarises MSD's submissions and the CMA's response.

3.2. Given the CMA's decision that there are no grounds for action in relation to MSD's Discount Scheme,⁵⁷ it has not been necessary for the CMA to reach a final view on the definition of the relevant market or whether MSD held a dominant position. For the purposes of this Decision, however, and based on the information in its possession, the CMA has proceeded on the basis that the relevant market was no wider than the supply of infliximab products in England and that MSD held a dominant position in that market during the period in which MSD's Discount Scheme applied, namely from March 2015 until February 2016 (the '**relevant period**').⁵⁸ The analysis in this section is focused on that period.

A. Market definition

3.3. This section summarises the legal framework and the CMA's assessment, based on the information in its possession, of the relevant market (both the product and geographic elements of the relevant market) for the purposes of this case.

I. Legal framework

3.4. To determine whether an undertaking holds a dominant position, it is first necessary to define the relevant market⁵⁹ in both its product and geographic dimension,⁶⁰ by identifying and defining the boundaries of competition between undertakings.⁶¹

⁵⁷ See section 4.B below.

⁵⁸ This was the relevant period used in the SO. Given the CMA's conclusion that there are no grounds for action, it is not necessary for the CMA to reach a final conclusion on the duration of the alleged abusive conduct.

⁵⁹ Judgment in *Europemballage Corporation and Continental Can v Commission*, C-6/72 EU:C:1973:22, paragraph 32. See also, for example, the judgments in *United Brands v Commission*, C-27/76, EU:C:1978:22 ('*United Brands*') paragraph 10; *Hoffman-La Roche v Commission*, C-85/76, EU:C:1976:36 ('*Hoffman-La Roche*'), paragraph 21; and *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4 ('*Aberdeen Journals I*'), [88] and [101].

⁶⁰ Commission Notice on Market Definition, paragraphs 2 and 9.

⁶¹ See, for example, *Albion Water and Another v Water Services Regulation Authority and Others* [2006] CAT 36 ('*Albion Water I*'), [90]; and *Commission Notice on the definition of the relevant market for the purposes of Community competition law*, OJ C 372, 9.12.1997, p.5 to 13 (the '*Commission Notice on Market Definition*'), paragraph 2.

a. Relevant product market

- 3.5. The relevant market implies the existence of effective competition between products with a sufficient degree of interchangeability,⁶² i.e. products which are '*close enough*' substitutes.⁶³ According to the Competition Appeal Tribunal (the '**CAT**'),⁶⁴ the definition of the relevant product market is fact-specific and takes into account the whole economic context: it is necessary to examine the particular circumstances of the case to find whether the products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm, and, therefore, sufficiently compete with each other to be sensibly regarded as being in the same market.⁶⁵
- 3.6. The definition of the relevant product market typically starts by identifying the closest substitutes to the product that is the focus of the investigation (the '**Focal Product**') through the application of the hypothetical monopolist test.⁶⁶ The application of this test in dominance cases must take into account a problem usually referred to as the 'cellophane fallacy',⁶⁷ which might result in false positive outcomes, particularly in markets where products are protected by patents.⁶⁸
- 3.7. Functional interchangeability or similarity of characteristics will not, in themselves, provide sufficient criteria to determine whether two products are demand substitutes.⁶⁹ In this respect, the European Commission has repeatedly rejected the proposition that pharmaceutical products that are used to treat the same medical condition can necessarily be regarded as demand substitutes.⁷⁰ The key consideration is the extent to which different product types can be expected significantly to constrain the conduct of a given undertaking.⁷¹ Where available, evidence of actual substitution arising

⁶² *Hoffmann-La Roche*, paragraph 28.

⁶³ OFT403 Market definition, paragraph 2.5.

⁶⁴ References to the CAT should be read as including reference to the Competition Commission Appeal Tribunal where appropriate. See section 12 of the Enterprise Act 2002.

⁶⁵ *Aberdeen Journals I*, [96] to [97].

⁶⁶ OFT403 *Market Definition*, paragraphs 2.5 to 2.13. The hypothetical monopolist test seeks to establish whether a hypothetical monopolist of the Focal Product, which is Remicade in this case, in a focal area (the geographic area in which the product is sold, the '**Focal Area**'), which is England in this case, could profitably sustain a small but significant non-transitory increase in price (a '**SSNIP**') above the competitive level.

⁶⁷ Named after a US case involving cellophane products, see *US v E.I. du Pont de Nemours & Co*, 351 US 377 (1956).

⁶⁸ Where the 'cellophane fallacy' occurs, the current price of the Focal Product may be substantially higher than the competitive level and a further increase in price might induce customers to purchase other products. In these circumstances, however, it would be wrong to conclude that these other products in the same relevant market as the Focal Product.

⁶⁹ Commission Notice on Market Definition, paragraph 36.

⁷⁰ See, for example, Case COMP/A. 37.507/F3, *AstraZeneca*, 15 June 2005, paragraph 381.

⁷¹ See European Commission decision, Case COMP/A. 37.507/F3, *AstraZeneca*, 15 June 2005, paragraph 370. See also European Commission decision, Case AT.39612, *Perindopril* (Servier), 9 July 2014, footnote 3215;

from past events or shocks will normally be fundamental for market definition, including reactions to changes in relative prices and to the launch of new products.⁷²

b. Relevant geographic market

3.8. The relevant geographic market comprises the area in which the conditions of competition are sufficiently homogeneous, and which can be distinguished from neighbouring areas where these conditions are appreciably different.⁷³

3.9. In previous decisions in the pharmaceutical sector, it has been found appropriate to define the relevant geographic market as national in scope.⁷⁴

II. Summary of the CMA's analysis of the relevant market

3.10. For the purposes of this Decision and based on the information in its possession, the CMA has proceeded on the basis that the relevant market was the supply of infliximab, including both Remicade and Biosimilars, in England (the '**Relevant Market**').

a. Summary of the CMA's analysis of the relevant product market

3.11. For the purposes of this Decision, the CMA has proceeded on the basis that the relevant product market was the supply of infliximab, including both Remicade and Biosimilars (the '**Relevant Product Market**').

3.12. In particular, the CMA considers that Biosimilars exerted a sufficient competitive constraint on Remicade such that Biosimilars should be included in the Relevant Market for the following reasons.

3.13. First, although Biosimilars were not exact equivalents of Remicade, they could have been used to treat all of the same conditions as Remicade and, unlike most other major biological immunosuppressant medicines,⁷⁵ were administered in the same way as Remicade.⁷⁶

CMA decision case CE-9531/11, *Paroxetine*, 12 February 2016 ('*Paroxetine*'), paragraph 4.24; and OFT decision CA98/02/2011, *Reckitt Benckiser*, 12 April 2011 ('*Reckitt Benckiser*').

⁷² Commission Notice on Market Definition, paragraph 38.

⁷³ Commission Notice on Market Definition, paragraph 8.

⁷⁴ See, for example, European Commission decision, Case COMP/A.37.507/F3, *AstraZeneca*, 15 June 2005, paragraph 503. This was not discussed before the EU General Court or by the EU Court of Justice, on appeal.

⁷⁵ As explained in section 2.A.I above, infliximab (including both Remicade and Biosimilars) is a TNF alpha inhibitor and TNF alpha inhibitors are a category of biological immunosuppressant medicines. For its assessment of market definition, the CMA has generally considered TNF alpha inhibitors and some other biological immunosuppressant medicines because some other biological immunosuppressant medicines can be used to treat a subset of similar disorders to infliximab.

⁷⁶ As explained in section 2.A.I above, Remicade is administered through an intravenous infusion. In contrast, most other TNF alpha inhibitors are administered through subcutaneous injection.

- 3.14. Second, the competitive constraint imposed by Biosimilars on Remicade caused MSD significantly to change its pricing strategy after several years of stable prices, by introducing its Discount Scheme, specifically in anticipation of the entry of Biosimilars. As figures 2.5 and 2.6 above show, the introduction of Biosimilars led to a decrease in the Remicade price and in the share of infliximab sales accounted for by Remicade.
- 3.15. MSD submitted that the relevant market was wider than infliximab and included other TNF alpha inhibitors.⁷⁷ According to MSD, Remicade competed against a range of other biological medicines, in addition to Biosimilars, that addressed the same therapeutic needs.⁷⁸ Of these, Humira (adalimumab) and Enbrel (etanercept) generated especially large sales.
- 3.16. Whilst the CMA accepts that there was a degree of therapeutic substitutability between infliximab and a number of other biological immunosuppressant medicines, the CMA considers it appropriate also to take into account other factors, not just therapeutic substitutability, for the purpose of defining the boundary of the relevant product market in this case.
- 3.17. In particular, there was an important difference between Remicade and most other biological immunosuppressant medicines, which limited the extent to which they were substitutable, namely how Remicade and Biosimilars were administered (the '**mode of administration**'). As a result of this difference, Remicade and Biosimilars would generally only be prescribed when other biological immunosuppressant medicines were not suitable. This was because medicines delivered by intravenous infusion had inherent disadvantages for patients and clinicians compared to medicines delivered by subcutaneous injection. Biological immunosuppressant medicines delivered by subcutaneous injection were generally preferred by clinicians and patients because:
- a. they suited patient lifestyles better (i.e. delivery through subcutaneous injection was more convenient as it did not require a hospital visit);
 - b. there were limitations on capacity in hospital infusion units, leading clinicians to prefer to prescribe subcutaneous injection medicines when they could; and

⁷⁷ MSD's written representations, Section 3, Part I.

⁷⁸ MSD's written representations, Section 3, Part II.

c. administration of subcutaneous injection was generally cheaper for the hospital.⁷⁹

3.18. In that respect, the CMA considers that Remicade or a Biosimilar would have been chosen where intravenous infusion was the preferred mode of administration.⁸⁰ This would have limited the competitive constraint imposed by other biosimilar immunosuppressant medicines on infliximab.

b. Summary of the CMA's analysis of the relevant geographic market

3.19. For the purposes of this Decision and based on the information in its possession, the CMA has proceeded on the basis that the relevant geographic market was England (the '**Relevant Geographic Market**').

3.20. In considering the boundaries of the relevant geographic market in this case, it is appropriate to have regard to the way that infliximab (including both Remicade and Biosimilars) was procured – through tender processes⁸¹ – and the different tendering procedures (and tender outcomes) in different parts of the UK.

3.21. There were different bodies and procedures for procuring infliximab in the different home nations of the UK. In particular, the tenders for infliximab (including both Remicade and Biosimilars) for each region and sub-region of England were run centrally by the CMU, whereas in Scotland and Wales, tenders were undertaken by the respective procurement bodies for those nations.⁸²

3.22. Those different arrangements had some implications for the conditions of competition in each home nation.⁸³ Moreover, the tender outcomes were not the same in each of the home nations of the UK. For example, not all Biosimilars were accepted onto framework agreements in each of the home nations.

⁷⁹ This is because intravenous infusion generally requires hospital resources and medicines administered in a hospital attract VAT charges whereas home administered medicines do not.

⁸⁰ Where, for example, a patient may not correctly follow the prescribed course or treatment or where a patient had a needle phobia.

⁸¹ See section 2.D above.

⁸² For Scotland and Wales, the relevant entities were National Procurement Scotland and the Shared Services Partnership, respectively. The CMA understands that the Northern Ireland Procurement and Logistics Service did not run a tender for Biosimilars during the relevant period.

⁸³ For example, in terms of the timing of Biosimilar entry, and the type of pricing structures allowed.

B. Dominant position

3.23. This section summarises the legal framework and the CMA's assessment, based on the information in its possession, as to whether MSD held a dominant position in the Relevant Market.

I. Legal framework

3.24. An undertaking holds a dominant position where it enjoys a position of economic strength which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of consumers.⁸⁴ The existence of some degree of competition on the market is a relevant, but not decisive factor.⁸⁵

3.25. The CMA will only find that an undertaking is in a dominant position if it has substantial market power.⁸⁶ In its assessment, the CMA will consider any competitive constraints – including existing and potential competitors as well as buyer power – that may prevent an undertaking from profitably sustaining prices above competitive levels.⁸⁷

a. Market shares

3.26. Maintaining higher prices than those of its competitors, while retaining a much higher market share, can indicate that an undertaking holds a dominant position.⁸⁸

3.27. Market shares of other undertakings operating in the same market and their evolution over time can also be relevant.⁸⁹ Where there is a substantial gap between the market shares of the undertaking concerned and of its competitors and this is maintained over time, this may support a finding of

⁸⁴ *United Brands*, paragraph 65.

⁸⁵ Judgment in *France Télécom SA v Commission* T-340/03, EU:T:2007:22, paragraph 101. See also *Hoffmann-La Roche*, paragraph 70; *United Brands*, paragraphs 108 to 129.

⁸⁶ OFT402 *Abuse of a dominant position* (December 2004), paragraph 4.11, adopted by the CMA.

⁸⁷ OFT415 *Assessment of market power* (December 2004), adopted by the CMA, paragraphs 3.2 to 3.3.

⁸⁸ Judgment in *AstraZeneca AB and AstraZeneca plc v Commission* T-321/05, EU:T:2010:266, ('T-321/05 *AstraZeneca*'), paragraph 266. See also *Hoffman-La Roche*, paragraph 41; *Napp Pharmaceutical Holdings Limited and Subsidiaries v Director General of Fair Trading* [2002] CAT 1 ('*Napp*'), [157] to [158]; and *Aberdeen Journals II*, [310]. Undertakings holding persistently a market share of 50% are deemed to be dominant. See Judgment in *AKZO Chemie BV v Commission* C-62/86, EU:C:1991:286 ('*AKZO*'), paragraph 60; judgment in *AstraZeneca AB and AstraZeneca plc v Commission* C-457/10 P, ECLI:EU:C:2012:770 ('C-457/10 P *AstraZeneca*'), paragraph 176.

⁸⁹ OFT415 *Assessment of market power* (December 2004), paragraph 3.3. See also *Aberdeen Journals II*, [310]; *Communication from the Commission — Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, OJ C 45, 24.2.2009, p. 7–20; paragraph 13.

dominance.⁹⁰ This position of economic strength makes the concerned undertaking an unavoidable trading partner and, at least for relatively long periods, secures that freedom of action which is the special feature of a dominant position.⁹¹

- 3.28. A decline in market shares does not, in itself, constitute proof of the absence of a dominant position,⁹² particularly where those market shares are still very large.⁹³ Nonetheless, it may be appropriate to treat market shares with a degree of caution where an undertaking has previously held a monopoly, and this comes to an end.⁹⁴

b. Barriers to entry and expansion

- 3.29. The existence and the extent of barriers to entry and expansion can impact on the competitive constraint from potential competition, either from new entry or expansion by existing competitors. Both the credibility and the timeliness of any potential entry, as well as the new entrant's ability to attain a sufficiently large scale, are likely to be relevant to a finding of dominance.⁹⁵ Barriers to expansion can be closely related to barriers to entry and can be analysed in a similar way.⁹⁶

- 3.30. An undertaking's first-mover status can give that undertaking an appreciable competitive advantage.⁹⁷ This is particularly the case in pharmaceutical markets where there can typically be a degree of caution from prescribing doctors,⁹⁸ although this may be less pronounced in secondary care than it is in primary care.⁹⁹

c. Countervailing buyer power

- 3.31. The strength and structure of the buyers' side of the market may constrain the market power of a seller¹⁰⁰ if the degree of such countervailing buyer

⁹⁰ Judgment in *British Airways plc v Commission* T-219/99, EU:T:2003:343, ('T-219/99 *British Airways*'), paragraph 224; T-321/05 *AstraZeneca*, paragraph 289.

⁹¹ *Hoffmann-La Roche*, paragraph 41; judgment in *Telefónica, SA and Telefónica de España, SA v Commission* T-336/07, EU:T:2012:172, paragraph 149.

⁹² T-219/99 *British Airways*, paragraph 224; T-321/05 *AstraZeneca*, paragraph 288.

⁹³ Judgment in *Compagnie maritime belge transports SA and Compagnie maritime belge SA, et al. v Commission* T-24/93, T-25/93, T-26/93 and T-28/93, EU:T:1996:139, paragraph 77; judgment in *France Télécom SA v Commission* T-340/03, EU:T:2007:22, paragraph 104.

⁹⁴ *National Grid PLC v The Gas and Electricity Markets Authority* [2009] CAT 14 ('*National Grid*'), [51].

⁹⁵ *Genzyme Limited v Office of Fair Trading* [2004] CAT 4 ('*Genzyme*'), [231] to [239]; and *Albion Water Limited & Albion Water Group Limited v Water Services Regulation Authority and Others* [2006] CAT 23, Annex A, [43].

⁹⁶ OFT415 *Assessment of market power*, paragraph 5.37.

⁹⁷ T-321/05 *AstraZeneca*, paragraph 278.

⁹⁸ T-321/05 *AstraZeneca*, paragraph 278.

⁹⁹ OFT decision CA98/2/2001, *Napp Pharmaceuticals Holdings Limited and subsidiaries* ('*Napp*'), 30 March 2001, paragraphs 114 to 118, as upheld by the CAT in *Napp*, [267] to [288].

¹⁰⁰ OFT415 *Assessment of market power*, paragraph 6.1.

power operates as a constraint on the undertaking's ability to exert market power.¹⁰¹ Buyer power does not come from size alone: the buyer must have alternative sources of supply.¹⁰² The existence of commercial negotiations between supplier and customer or of concessions to the benefit of a customer does not necessarily mean that the customer held sufficient buyer power to offset the supplier's dominance position.¹⁰³

II. Summary of the CMA's analysis of dominant position

3.32. For the purposes of this Decision and based on the information in its possession, the CMA has proceeded on the basis that MSD held a dominant position in the Relevant Market during the relevant period.

a. Barriers to entry and expansion

3.33. The key barrier to entry and expansion in this case was clinical caution. As explained in section 2.A.III above, the nature of Biosimilars (being only similar to the originator medicine, not equivalent or identical) meant that clinical confidence in Biosimilars needed to be developed through either clinical trial data (to provide evidence on the safety and efficacy of Biosimilars) or through practical use. The limited clinical trial data available at the time¹⁰⁴ suggested that practical experience of using Biosimilars would be needed to overcome clinical caution.

3.34. In contrast to Biosimilars, MSD benefitted from Remicade having been used in the NHS for many years, which meant that MSD had a significant first mover advantage.¹⁰⁵ Around the time of Biosimilar entry in the UK, clinical concerns about the limitations of the available evidence on the safety and efficacy of Biosimilars were high. This was encapsulated in a position statement from the British Society of Rheumatology published in February 2015:

'the equivalence clinical trials for each biosimilar are conducted within a small trial population and no clinical trial is undertaken for each licensed indication of the reference products, weakening the evidence used to support extrapolation of indications from reference treatments. Furthermore, there appears to be little evidence of the safety and

¹⁰¹ *National Grid*, [60], referring to *Hutchinson 3G UK Limited v Office of Communications* [2005] CAT 39.

¹⁰² *Genzyme*, [242]; and *National Grid*, [69].

¹⁰³ *National Grid*, [66] to [67]

¹⁰⁴ Particularly on the safety and efficacy of using Biosimilars for patients who were currently being treated with Remicade, see section 2.A.IV above.

¹⁰⁵ Although Biosimilars were capable of exercising a material competitive constraint on Remicade particularly for new patients they faced a significant barrier to expansion when they first entered the market due to clinical caution.

*effectiveness of switching to biosimilars in patients who are stable on a reference agent and a lack of knowledge of the long term safety of biosimilar drugs which may have subtly different immunogenic profiles.*¹⁰⁶

3.35. For the purposes of this Decision, the CMA has proceeded on the basis that clinical caution – as a result of the nature of biosimilar medicines (being only similar, not identical, to the originator medicine), the lack of previous experience of using Biosimilars, and the paucity of relevant clinical trial data – was a key barrier to entry and expansion, and that the NHS would therefore have continued to meet a significant proportion of its total infliximab demand through Remicade throughout the relevant period.¹⁰⁷

b. Market shares

3.36. The CMA considers that the evolution of market shares, by both volume and value, also suggests that MSD held a dominant position in the Relevant Market. Prior to the introduction of Biosimilars, MSD was the monopoly supplier of infliximab with a 100% share of the Relevant Market. As might be expected, MSD's share of the Relevant Market declined month on month (see figures 2.6 and 2.7 above) after the expiry of the Remicade patent. The CMA nevertheless considers that the high market shares MSD continued to enjoy were indicative of market dominance.

3.37. MSD submitted that the deterioration of Remicade's prices and the loss of market shares following Biosimilar entry was incompatible with a finding of dominance and that it lost market power as soon as Biosimilars entered the market.¹⁰⁸

3.38. The CMA does not accept MSD's submission. Sales data showed that MSD was able to sustain a high share of the Relevant Market for a significant period following the entry of Biosimilars. As can be seen from figures 2.6 and 2.7 above, MSD's share of the Relevant Market remained at 79% by volume and 86% by value in October 2015,¹⁰⁹ and at 67% by volume and 78% by value in February 2016.¹¹⁰ Such high shares were maintained despite Remicade selling at a substantial premium to Biosimilars, as shown by figure

¹⁰⁶ February 2015 British Society for Rheumatology Position statement on biosimilar medicines: www.rheumatology.org.uk/includes/documents/cm_docs/2015/b/bsr_biosimilars_position_statement_feb_2015.pdf.

¹⁰⁷ MSD made submissions about the scale of clinical caution and the existence/size of the non-contestable share. These are relevant to whether MSD's Discount Scheme was likely to produce an exclusionary effect and are considered in section 4.B.IV below.

¹⁰⁸ MSD's written representations, paragraphs 287 to 301.

¹⁰⁹ As explained in section 2.F above, MSD offered a different pricing scheme in October 2015, in response to the invitation to tender for the North of England region and associated sub-regions.

¹¹⁰ As explained in section 2.F above, MSD's Discount Scheme was replaced from March 2016.

2.5 above) and are consistent with clinical caution being a barrier to entry and expansion (as explained in section 3.B.II.a above).

c. Countervailing buyer power

3.39. The CMA also considers that MSD's conduct was not likely to be constrained by any countervailing buyer power.

3.40. MSD submitted that the CMU, operating on behalf of the NHS in England, had the ability to require MSD to alter Remicade prices, and that it actually did so.¹¹¹

3.41. As explained in section 2.F above, the CMU requested price reviews and MSD agreed to reduce Remicade prices. However:

- a. after the new prices came into effect, the price of Remicade was still substantially in excess of the price of Biosimilars;¹¹²
- b. there was a minimum period of at least five months during which the CMU was unable to invoke the price review clauses;¹¹³ and
- c. the key factor which influenced the CMU's decision to request price reviews was the Remicade prices submitted by MSD itself in its response to the CMU's second invitation to tender for infliximab in the North of England region; i.e. it was only MSD's decision to tender a lower Remicade price for a particular region (and associated sub-regions) that enabled the CMU to request price reviews for other regions and sub-regions.

3.42. In the light of the above, the CMA has proceeded for the purposes of this Decision on the basis that MSD enjoyed a dominant position in the Relevant Market during the relevant period.

¹¹¹ Page 13 of Response by MSD UK to Part B of Section 26 Notice of December 1, 2015.

¹¹² Hospira and Napp also submitted substantially lower prices for the new North of England tender. CMA analysis of pricing information provided by MSD, Hospira and Napp shows that the average selling price of Remicade was at least [50 – 70]% greater than the average selling price of the next most expensive infliximab product (Inflectra).

¹¹³ Paragraph 1.6 of document 00056.11, Appendix 3 of the Framework Agreements, states the clause can be invoked at *'the end of 5/11 months'*. The CMA understands that this means that where a framework agreement is for one year then the clauses cannot be invoked before 5 months have elapsed and if the agreement is longer than this then this minimum period increases to 11 months.

4. ABUSE

- 4.1. This section summarises the legal framework applied by the CMA¹¹⁴ and the CMA's assessment, based on the information in its possession, as to whether MSD's conduct constituted an abuse of a dominant position.¹¹⁵ Where relevant, the CMA also summarises MSD's submissions and the CMA's response.
- 4.2. In assessing whether MSD's conduct was abusive, the CMA has considered whether MSD's Discount Scheme was likely to produce an exclusionary effect;¹¹⁶ in particular, whether it was likely to induce the NHS to remain loyal to Remicade and make it harder for suppliers of Biosimilars to compete with MSD. This is an objective assessment based on the relevant circumstances when the conduct took place.
- 4.3. As explained in more detail below,¹¹⁷ the CMA considers that MSD designed its Discount Scheme to have an exclusionary effect¹¹⁸ and the criteria and rules¹¹⁹ and the NHS's understanding¹²⁰ of MSD's Discount Scheme demonstrate its potential to produce an exclusionary effect. However, for MSD's Discount Scheme to be likely to have the effect that MSD intended, the market context at the time MSD's Discount Scheme was introduced needed to reflect certain broad assumptions by MSD.¹²¹ As it is, the factual circumstances at the time meant that MSD's assumptions were incorrect in a number of respects. In particular, the NHS's attitude towards using Biosimilars (and the prevailing level of clinical caution) was more positive than MSD had expected when it designed its Discount Scheme, and the financial incentive created by MSD's Discount Scheme was less strong than MSD had planned.¹²² As a result, the CMA has concluded that, given the factual circumstances at the time it was introduced, and on the basis of the information in its possession, MSD's Discount Scheme was not likely to produce an exclusionary effect and that there are, therefore, no grounds for action on the CMA's part.

A. Legal framework

- 4.4. Section 18(1) of the Act prohibits any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position if it may

¹¹⁴ See section 4.A below.

¹¹⁵ See section 4.B below.

¹¹⁶ See paragraphs 4.11 to 4.12 below.

¹¹⁷ See paragraphs 4.19 to 4.27 below.

¹¹⁸ See section 4.B.I below.

¹¹⁹ See section 4.B.II below.

¹²⁰ See section 4.B.III below.

¹²¹ See section 4.B.IV.a below.

¹²² See section 4.B.IV.b below.

affect trade within the UK. Article 102 provides that any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited in so far as it may affect trade between EU Member States.

- 4.5. An abuse of a dominant position is an objective concept.¹²³ A dominant undertaking has a special responsibility not to allow its conduct to impair genuine undistorted competition on the market.¹²⁴ The scope of that responsibility must be considered in the light of the specific circumstances of each case.¹²⁵
- 4.6. Although anti-competitive intent is neither a prerequisite nor sufficient in itself to establish an abuse, it is one of the factors that may be taken into account when determining whether a dominant position has been abused.¹²⁶
- 4.7. The anti-competitive nature of the dominant undertaking's acts must be evaluated at the time when those acts were committed.¹²⁷

I. Abusive discounts

- 4.8. Not all discounts¹²⁸ granted by undertakings in a dominant position are contrary to Article 102 or the Chapter II prohibition. Discounts linked solely to the volume of the purchases from the manufacturer concerned are not, in principle, liable to infringe Article 102.¹²⁹
- 4.9. In contrast, an undertaking which is in a dominant position on a market and ties purchasers – even if it does so at their request – by an obligation or promise on their part to obtain all or most of their requirements exclusively from that undertaking abuses its dominant position within the meaning of Article 102, whether that obligation is stipulated without further qualification or whether it is undertaken in consideration of the grant of a discount or payment. The same applies if the undertaking in question, without tying the

¹²³ *Hoffman-La Roche*, paragraph 91; judgment in *Tomra Systems and Others v Commission* C-549/10 P, EU:C:2012:221 ('C-549/10P *Tomra*'), paragraph 17.

¹²⁴ Judgment in *NV Nederlandsche Banden Industrie Michelin v Commission* C-322/81, EU:C:1983:313 ('*Michelin I*'), paragraph 57.

¹²⁵ Judgment in *Tetra Pak v Commission* C-333/94 P, EU:C:1996:436, paragraph 24; *Napp*, [219].

¹²⁶ T-321/05 *AstraZeneca*, paragraph 359, upheld in C-457/10 P *AstraZeneca*. See also C-549/10P *Tomra*, paragraphs 20, 23 and *United Brands*, paragraph 189.

¹²⁷ Case C-457/10P *AstraZeneca*, paragraph 110.

¹²⁸ For the purposes of this Decision, the CMA uses the terms 'discount' and 'rebate' interchangeably.

¹²⁹ Judgment in *Post Danmark v Konkurrenceradet* C-23/14, EU:C:2015:651 ('*Post Danmark II*'), paragraph 27 citing *Michelin I*, paragraph 71. See also Judgment in *Tomra Systems and Others v Commission* T-155/06, EU:T:2010:370 ('T-155/06 *Tomra*'), paragraphs 212-213. A rebate which is not granted in respect of each individual order, thus corresponding to the cost savings made by the supplier, but on the basis of the aggregate orders placed over a given period, cannot be regarded as a simple quantity rebate linked solely to the volume of purchases. See *Post Danmark II*, paragraph 28.

purchasers by a formal obligation, applies, either under the terms of agreements concluded with those purchasers or unilaterally, a system of loyalty discounts, that is to say, discounts conditional on the customer obtaining all or most of its requirements – whether the quantity of its purchases be large or small – from the undertaking in a dominant position.¹³⁰

- 4.10. Even if the grant of the discount is not conditional on customers obtaining all or most of their requirements from the dominant undertaking, a discount which, by offering customers financial advantages, tends to prevent them from obtaining all or most of their requirements from competing manufacturers, may be abusive. In order to determine whether such a discount is abusive, it is necessary to consider all the relevant circumstances, particularly the criteria and rules governing the grant of the discount, and investigate whether, in providing an advantage not based on any economic service justifying it, the discount tends to remove or restrict the buyer's freedom to choose their sources of supply; to bar competitors from access to the market; to apply dissimilar conditions to equivalent transactions with other trading parties; or to strengthen the dominant position by distorting competition.¹³¹
- 4.11. In that regard, it has to be determined whether the discounts can produce an exclusionary effect, that is to say whether they are capable, first, of making market entry very difficult or impossible for competitors of the undertaking in a dominant position and, secondly, of making it more difficult or impossible for customers of that undertaking to choose between various sources of supply or commercial partners.¹³²
- 4.12. In order to constitute an abuse of a dominant position within the meaning of the Chapter II prohibition or Article 102, it is not necessary that the discount has had an actual, concrete anti-competitive effect.¹³³ However, the anti-competitive effect must not be purely hypothetical; rather, it must be likely.¹³⁴

¹³⁰ Judgment *Intel Corp. v European Commission* C-413/14 P, EU:C:2017:632 ('C-413/14 P *Intel*'), paragraph 137, citing *Hoffmann-La Roche*, paragraph 89. See also judgment in *Irish Sugar plc v Commission* T-228/97, EU:T:1999:246 ('*Irish Sugar*'), paragraph 213.

¹³¹ *Post Danmark II*, paragraphs 28-29, citing judgments in *British Airways v Commission* C-95/04 P, EU:C:2007:166 ('C-95/04 P *British Airways*'), paragraphs 67-68, and C-549/10 P *Tomra Systems and Others v Commission*, paragraph 71.

¹³² *Post Danmark II*, paragraph 31. See also C-95/04 P *British Airways*, paragraphs 68-69.

¹³³ *Post Danmark II*, paragraph 66. See also C-457/10 P *AstraZeneca*, paragraph 112.

¹³⁴ *Post Danmark II*, paragraphs 65, 67, 69 and 74. In previous cases, the expressions '*tends to*' and '*capable of*' have also been used variously in place of the word '*likely*'. For the purposes of assessing the anti-competitive foreclosure effect of MSD's Discount Scheme in this case, the CMA has treated these terms as synonymous with '*likely*'.

- 4.13. The EU Courts have identified some positive indicators of likely anti-competitive effects:
- a. where the discount applies to all purchases in the reference period not just those exceeding the volume threshold (i.e. it is not a purely 'incremental' discount);¹³⁵
 - b. where the granting of a discount is linked to the attainment of individually defined sales objectives, in particular where the volume thresholds for granting a discount are established on the basis of a customer's estimated requirements and/or past purchasing volumes;^{136, 137}
 - c. where the volume thresholds correspond either to the customer's total requirements or a large proportion of those requirements;¹³⁸
 - d. where the discount applies without distinction to every unit purchased by a customer from the dominant undertaking, including both (i) the portion of demand for which the customer may switch away from the dominant undertaking (the contestable share); as well as (ii) the portion of demand that would be purchased by the customer from the dominant undertaking in any event (the non-contestable share);¹³⁹ and
 - e. where a discount covers the majority of customers on the market, that may constitute a useful indication as to the extent of that practice and its impact on the market, which may bear out the likelihood of an anti-competitive exclusionary effect.¹⁴⁰

¹³⁵ *Post Danmark II*, paragraphs 25 and 32. See also *Michelin I*, paragraph 81; C-95/04P *British Airways*, paragraphs 73-74.

¹³⁶ See, in particular, C-95/04 P *British Airways*, paragraph 71 and C-549/10 P *Tomra*, paragraph 75. Individualised rebates have been held to be more likely to be loyalty-inducing because of the closer connection with a particular customer's requirements. However, in certain circumstances, discounts offered to all customers on the same terms ('standardised' discounts) may also be found to be abusive in certain circumstances, see *Post Danmark II*.

¹³⁷ Judgment in *Tomra Systems and Others v Commission* T-155/06, EU:T:2010:370 ('T-155/06 *Tomra*'), paragraph 261.

¹³⁸ Judgment in *Tomra Systems and Others v Commission* T-155/06, EU:T:2010:370 ('T-155/06 *Tomra*'), paragraphs 260-262. In that case, the discounts were conditional on the customer purchasing at least 75% to 80% of its total requirements (see paragraph 85). In *Hoffmann-La Roche*, 75% or more of a customer's requirements was also deemed to represent most of a customer's requirements (*Hoffmann-La Roche*, paragraph 83).

¹³⁹ *Post Danmark II*, paragraph 35.

¹⁴⁰ *Post Danmark II*, paragraph 46. See also C-413/14 P *Intel*, paragraph 139.

- 4.14. In assessing the legality of a discount, what matters are the expectations of the customer at the time when it placed the orders in conformity with the terms and conditions of the offer.¹⁴¹
- 4.15. A discount may be found to be abusive where the financial incentive is likely to influence purchasing behaviour, even though the discount is not directed at the ultimate purchaser of the product or service in question.¹⁴² Moreover, a discount may be abusive where it is negotiated on behalf of a number of different individual purchasers and the discount is calculated based on those purchasers' aggregate purchases.¹⁴³
- 4.16. It is not a prerequisite for finding a discount to be abusive for the prices offered to be below cost.¹⁴⁴ Nor is there a legal obligation requiring a finding to the effect that a discount offered by a dominant undertaking is abusive to be based on the as-efficient competitor test.¹⁴⁵ Nonetheless, where a dominant undertaking concerned submits, during the administrative procedure, on the basis of supporting evidence, that its conduct was not capable of restricting competition and, in particular, of producing the alleged foreclosure effect, it is also necessary to analyse – in addition to the extent of the undertaking's dominant position on the relevant market, the share of the market covered by the challenged practice and the conditions and arrangements for granting the discounts as well as their duration and their amount – the possible existence of a strategy aiming to exclude a competitor that is at least as efficient as the dominant undertaking from the market.¹⁴⁶

II. Objective justification

- 4.17. A dominant undertaking may justify behaviour that would otherwise be abusive by showing either that it is objectively necessary or that the exclusionary effect produced by that behaviour is counterbalanced, or

¹⁴¹ T-155/06 *Tomra*, paragraph 300. See also judgment in *Intel Corp v Commission* T-286/09, EU:T:2014:547 ('T-286/09 *Intel*'), paragraph 527.

¹⁴² For example, in *Michelin I* the discounts applied to tyre dealers and in *British Airways* applied to travel agents. Neither the tyre dealers, nor the travel agents exercised absolute control over how many purchases were made – the ultimate consumer did. However, the tyre dealers and travel agents were in a position to influence purchasing decisions. In T-219/99 *British Airways*, the General Court rejected an argument by BA that its performance reward schemes did not have a fidelity-building effects as travel agents have only a slight influence on travellers' choice of airlines. The General Court noted that "*BA has itself argued that those agents provide a useful service filtering information communicated to passengers who are faced with the proliferation of different air transport fare structures*" (paragraph 274).

¹⁴³ T-155/06 *Tomra*, paragraphs 61 to 66, the General Court held that "*it is inherent in the negotiation of that type of agreement [where a discount scheme is negotiated by a central purchasing organisation on behalf of individual purchasers] that the agreement will encourage members of the organisation to make purchases with a view to achieving the target set*" and that "*the central purchasing organisation had the power to influence the behaviour of independent retailers*".

¹⁴⁴ C-549/10 P *Tomra*, paragraph 73. See also *Post Danmark II*, paragraph 56.

¹⁴⁵ *Post Danmark II*, paragraphs 56, 57 and 62. See also C-549/10 P *Tomra*, paragraphs 73 and 80.

¹⁴⁶ C-413/14 P *Intel*, paragraphs 138 to 139.

outweighed, by advantages in terms of efficiency gains that also benefit consumers.¹⁴⁷

- 4.18. It is for a dominant undertaking to raise any plea of objective justification or efficiency defence and to support it with arguments and all the evidence necessary. It then falls to the CMA to make an assessment.¹⁴⁸

B. The CMA's analysis of MSD's Discount Scheme

- 4.19. The advent of Biosimilars was an important and generally unprecedented event. As a high-cost drug, the NHS's total expenditure on infliximab was large and expected to increase as demand had been growing and was expected to continue to grow. In the year preceding the introduction of MSD's Discount Scheme, overall demand for infliximab had increased by around 8%. The overall value of infliximab expenditure within the NHS at the time was around £140 million per year.
- 4.20. Containing and reducing such costs was of particular importance given the context in which the NHS found itself – being both budget-constrained (having to make difficult decisions about which treatments to fund and which patients to treat with particular treatments) and under increasing pressure to reduce costs.
- 4.21. Biosimilars promised significant cost savings for the NHS. It was generally expected that Biosimilars would be priced much lower per vial than Remicade – around 30% cheaper. However, biosimilar medicines were a new phenomenon, broadly untried and untested, particularly for complex medicines such as infliximab, and with no meaningful comparison from past experiences with generic medicines.
- 4.22. Unlike for generic medicines, the nature of biosimilar medicines¹⁴⁹ meant that clinical caution towards using biosimilar medicines was expected to be high. That was particularly the case for biosimilar infliximab given the paucity of data on safe use, especially when switching patients already being treated with Remicade to a Biosimilar.¹⁵⁰ As a consequence, it was expected that competition from Biosimilars would be limited at first to only a small part of the total market (the '**contestable share**').

¹⁴⁷ C-95/04 P *British Airways*, paragraphs 85 and 86; See also judgements in *Post Danmark A/S v Konkurrenceradet* C-209/10, EU:C:2012:172 ('*Post Danmark I*'), paragraphs 40 and 41; *Post Danmark II*, paragraphs 47 and 48.

¹⁴⁸ Judgment in *Microsoft Corp. v Commission* T-201/04, EU:T:2007:289, paragraph 688; *Post Danmark I*, paragraph 42; *Post Danmark II*, paragraphs 47-49.

¹⁴⁹ Being only similar, not equivalent or identical, as was the case for simple molecule generic medicines – see section 2.A.III above.

¹⁵⁰ See section 2.A.IV above.

- 4.23. Confidence needed to be increased through practical and successful use of Biosimilars, both for new patients and those patients already using Remicade. The more Biosimilars were used successfully to treat patients, the more clinical confidence was expected to increase, and the less clinical caution was expected to endure.
- 4.24. Over time, it was expected that practical experience of using Biosimilars would enable more effective competition from Biosimilars. The longer it took the NHS to trial Biosimilars, the longer clinical caution was expected to remain. Further, the longer clinical caution remained, the longer it was expected to take for effective competition to emerge, and for the NHS fully to realise the cost savings that Biosimilars promised.
- 4.25. Given the importance of being able successfully to trial Biosimilars with patients, discouraging the use of Biosimilars (such as through a financial disincentive) had the potential to prolong clinical caution towards Biosimilars, thereby maintaining barriers to entry and expansion and delaying the NHS from realising fully the cost savings promised from competition.
- 4.26. It was in that context that MSD designed and introduced its Discount Scheme, and against that backdrop that the CMA considered MSD's Discount Scheme.
- 4.27. The following sections set out the CMA's analysis of MSD's Discount Scheme and whether it was likely to produce an exclusionary effect. The CMA's assessment considers:
- a. the aims and design of MSD's Discount Scheme;¹⁵¹
 - b. the rules and criteria of MSD's Discount Scheme as introduced;¹⁵²
 - c. the NHS's understanding of MSD's Discount Scheme;¹⁵³
 - d. the relevant circumstances in which MSD's Discount Scheme was introduced;¹⁵⁴
 - e. MSD's representations;¹⁵⁵ and

¹⁵¹ See section 4.B.I below.

¹⁵² See section 4.B.II below.

¹⁵³ See section 4.B.III below.

¹⁵⁴ See Section 4.B.IV below.

¹⁵⁵ See section 4.B.V below.

- f. whether there was any objective justification for MSD's Discount Scheme.¹⁵⁶

I. The aims and design of MSD's Discount Scheme

- 4.28. This section considers the evidence on the design of MSD's Discount Scheme and explains why the CMA considers that this evidence demonstrates that MSD had an anti-competitive strategy.
- 4.29. The CMA's assessment in this section is based on MSD's internal analysis at the time of designing its Discount Scheme. This analysis assumed that there would be a single price that would apply to all units purchased during the contract period and that the price would depend on the total purchases made during the contract period as a whole. In fact, under MSD's Discount Scheme as introduced, any price change made at a Quarterly Review would be prospective only. The significance of this difference between MSD's internal modelling at the design stage and MSD's Discount Scheme as introduced is explained at paragraph 4.44 below.
- 4.30. MSD considered the design of its Discount Scheme for over nine months before submitting its Discount Scheme in response to the CMU's invitations to tender. During the design phase, MSD analysed the impact its pricing strategy would have both on MSD's revenue (from the sale of Remicade) and on the NHS's total infliximab expenditure (i.e. the cost to the NHS of purchasing Remicade, Biosimilars or some combination of Remicade and Biosimilars). It was a significant change from MSD's pricing strategy prior to patent expiry, where MSD had sold Remicade at a set discount off its list price, regardless of the volume of Remicade purchased.
- 4.31. As explained below, MSD's internal analysis demonstrates that MSD designed its Discount Scheme to result in:
 - a. Biosimilar suppliers having to charge very low prices in order to match the effective price charged by MSD over the contestable share of demand; and
 - b. the NHS having to pay more in total for infliximab products if it chose to switch from purchasing Remicade to purchasing Biosimilars.
- 4.32. The CMA infers from this evidence that MSD had an anti-competitive strategy in designing its Discount Scheme. MSD structured its Discount Scheme so that, over the portion of the market where MSD was likely to face

¹⁵⁶ See section 4.B.VI below.

competition, the NHS would be disincentivised to switch to Biosimilars and Biosimilar suppliers would struggle to compete against MSD.

a. MSD designed its Discount Scheme so that Biosimilar suppliers would have to charge very low prices in order to match the effective price charged by MSD

- 4.33. Under MSD's Discount Scheme, as MSD's share of total expected infliximab demand increased from 85% to 100%, the price of Remicade would fall.
- 4.34. MSD's internal analysis showed that, within this 85% to 100% range, MSD would achieve similar levels of revenue irrespective of Remicade's share of total expected infliximab demand obtained over the duration of the contract.¹⁵⁷ By way of illustration, MSD's internal analysis showed that, if MSD achieved a market share of 100%, (i.e. if the NHS purchased all of its expected infliximab demand from MSD) MSD would generate sales of £31.1 million.¹⁵⁸ If it lost a proportion of total expected infliximab demand and its market share fell to 85%, MSD forecast that it would still generate revenue of £30.9 million.
- 4.35. Accordingly, the structure of MSD's Discount Scheme would mean that the difference in revenue between 85% and 100% market share was £[0 – 1] million. The effective price over this range was therefore only approximately £[0 – 20] per unit of Remicade.¹⁵⁹ In contrast, MSD expected that Biosimilars would be priced at around £230 per unit and, as it turned out, the price of the cheapest available Biosimilar on entry in March 2015 was £210 per unit.
- 4.36. MSD therefore designed its Discount Scheme so that the effective price for each unit of Remicade was very low over a portion of expected demand, and significantly below the level that MSD expected Biosimilars to be priced at (at around £230). This portion of demand corresponded closely to the share of the Relevant Market which MSD expected that Biosimilars would compete for, i.e. the contestable share. As explained in section 3.B.II above, it was expected that Biosimilars were likely to be able to compete for only a small proportion of the Relevant Market, corresponding mainly to new patients

¹⁵⁷ MSD's revenue would only begin to fall when its share of a region's or sub-region's total expected infliximab demand fell below 85%. As explained in section 2.E.I above, below 85%, MSD would have reverted to its list price for Remicade and removed all discounts.

¹⁵⁸ Volume of [87,000 – 92,000] units multiplied by a price of £[330 – 350].

¹⁵⁹ Effective price of Remicade for purchasing between 85% and 100% is the difference in cost/difference in the number of units, which in this case is £[0 – 1] million/[10,000 – 15,000] units, which is £[0 – 20] per unit. In other words, it would cost the NHS £[0 – 20]/unit of Remicade if the NHS increased its Remicade purchases from 85% to 100%.

(which MSD estimated to account for around 18% of expected infliximab demand) and a small number of existing patients.

4.37. In order to compete for sales of infliximab within this range of demand, Biosimilar suppliers would have had to sell at very low prices, commensurate with the low effective prices created by MSD's Discount Scheme, to offset the increased expenditure that the NHS would have incurred as a result of the loss of Remicade discount.¹⁶⁰ If effective prices were below the cost of production (which may be the case where effective prices are very low), Biosimilar suppliers would have had to make a financial loss to win sales from Remicade. It is unlikely that this would have been a commercially viable strategy, in which case it would have been impossible for a Biosimilar supplier to compete with MSD unless the NHS was willing to switch a larger proportion of sales from Remicade to Biosimilars.

b. MSD designed its Discount Scheme so that switching to Biosimilars would result in the NHS having to pay more in total for infliximab

4.38. MSD also analysed the effect of its Discount Scheme on the NHS's total expenditure for infliximab products. Based on the price that MSD expected Biosimilars to enter at, that analysis showed that as the NHS started to use Biosimilars, the effect of MSD's Discount Scheme would be to increase the NHS's total infliximab expenditure.¹⁶¹ It was only if the NHS met 30% or more of its total infliximab demand through Biosimilars (significantly above MSD's estimate of the contestable share) that the NHS would start to make any savings by switching to Biosimilars. Unless the NHS switched a significant portion of total demand to Biosimilars – which based on MSD's estimates would need to have included not only new patients but also a portion of existing Remicade patients – switching to Biosimilars would be expected to have cost the NHS more under MSD's Discount Scheme and prevented it from realising cost-savings. This was despite the fact that MSD expected the unit price of Biosimilars to be significantly below the unit price of Remicade.

II. The criteria and rules of MSD's Discount Scheme as introduced

4.39. This section assesses the criteria and rules of MSD's Discount Scheme as it was introduced. The CMA has identified a number of features of MSD's

¹⁶⁰ Essentially, in order to be able to compete and win sales, a Biosimilar supplier would have needed to compensate the NHS for the Remicade discount it lost from purchasing less Remicade.

¹⁶¹ Because over a range of total demand the NHS would pay the same in total for Remicade under MSD's Discount Scheme regardless of whether the NHS purchased 100% of its total demand from Remicade.

Discount Scheme, as it was introduced, that had the potential to produce an exclusionary effect.

- 4.40. First, the discount granted under MSD's Discount Scheme was conditional on a region or sub-region purchasing a minimum volume of Remicade. Although those thresholds were presented as volumes (i.e. the thresholds were not explicitly linked to market shares), they were, in fact, determined by the proportion of each sub-region's total expected infliximab demand.¹⁶² In that respect, MSD's Discount Scheme was akin to a market share-based discount scheme, with the discount granted being conditional on the proportion of total infliximab demand met through Remicade. The volume thresholds under MSD's Discount Scheme were tailored for each region or sub-region, based on each region or sub-region's total expected infliximab demand.¹⁶³ As a market-share based scheme, the discount granted under MSD's Discount Scheme was also a function of how much Biosimilar was purchased, given that the more Biosimilar that was purchased, the less Remicade would be purchased.
- 4.41. Second, the proportion of total expected infliximab demand that a region or sub-region needed to purchase under MSD's Discount Scheme to avoid having to pay a higher Remicade price amounted to a very large proportion of the region or sub-region's total expected infliximab demand. As explained in section 2.E above, if Remicade purchases fell below 94% of total expected infliximab demand, the price of Remicade would increase. Below 85% of total expected infliximab demand, all discount would be withdrawn, and the region or sub-region would be charged the list price for Remicade.¹⁶⁴ In that respect, MSD's Discount Scheme was akin to an exclusivity discount, with the thresholds accounting for most or all of a region's or sub-region's total demand.¹⁶⁵
- 4.42. Third, if the volume of Remicade purchased fell sufficiently far, a region or sub-region would end up paying more for Remicade than it had done previously, before Biosimilar entry. In that respect, under MSD's Discount Scheme, the emergence of new competition risked the NHS having to pay a higher price for Remicade than it had had to pay prior to competition. This

¹⁶² See section 2.E above.

¹⁶³ The relevant volume thresholds for each region and sub-region were specific and tailored as each region and sub-region had a different total expected infliximab demand. In contrast, the share of total expected infliximab demand for each threshold (i.e. the proportion of total infliximab demand that a sub-region needed to meet through purchasing Remicade) was the same for all regions and sub-regions.

¹⁶⁴ Prior to the introduction of its Discount Scheme, MSD had never charged list price in the UK for Remicade.

¹⁶⁵ As explained in paragraph 4.12.c above, in previous cases, 75% of total demand has been considered to a large proportion of a customer's total requirements.

was the case despite the fact that Biosimilars were priced at a level significantly below the price of Remicade.

- 4.43. As explained above,¹⁶⁶ performance against MSD's Discount Scheme was expected to be monitored on a regular basis through Quarterly Reviews. At Quarterly Reviews,¹⁶⁷ Remicade purchases were expected to be assessed against expectations under MSD's Discount Scheme. Where a threshold was exceeded, the Remicade discount was expected to increase (i.e. the Remicade price would decrease if expectations were exceeded). Where purchases fell below a threshold, it was expected that the Remicade discount would decrease (i.e. the Remicade price would increase if expectations were not met). Any change in the price of Remicade (either up or down) would have applied to every vial of Remicade purchased in the region or sub-region from the point at which the price changed.¹⁶⁸
- 4.44. As noted above,¹⁶⁹ the inclusion of Quarterly Reviews was the key difference between the way MSD modelled the Discount Scheme when it was originally conceived by MSD and the Discount Scheme that MSD introduced.¹⁷⁰ MSD modelled its Discount Scheme as an all-unit scheme (i.e. it assumed that any change to the Remicade price would apply to all purchases of Remicade).¹⁷¹ The addition of Quarterly Reviews meant that MSD's Discount Scheme was not retroactive.¹⁷² Instead, any change to the Remicade price would apply prospectively only to all future Remicade purchases.
- 4.45. The CMA considers that the fact that MSD's Discount Scheme was not retroactive reduced the strength of the financial incentives which the Scheme created compared to a retroactive discount scheme. However, the CMA considers that this did not prevent MSD's Discount Scheme from having the potential to induce the NHS to remain loyal to Remicade. The expectation that the volume of Remicade purchases would be periodically reviewed was well understood within the NHS. It was also understood that the price of Remicade could change following a Quarterly Review and that under the

¹⁶⁶ See section 2.E.II above.

¹⁶⁷ It was expected that Quarterly Reviews would be attended by representatives from MSD, the CMU and the relevant Specialist. The format for Quarterly Reviews was not prescribed and may have been held as a meeting or by telephone. The format was, however, inconsequential.

¹⁶⁸ See section 2.E above.

¹⁶⁹ See section 4.B.I above.

¹⁷⁰ At the point of introduction, there was also a lack of clarity over how MSD's Discount Scheme would be implemented in practice, in particular, how a region's or sub-region's purchases of Remicade may be measured for the purposes of Quarterly Reviews. This became clearer over time as MSD implemented its Discount Scheme, although customer understanding remained mixed. It was not necessary for the CMA to conclude on this point, however, given its decision that there are no grounds for action.

¹⁷¹ See section 4.B.I above.

¹⁷² In that any price change would not also apply to volumes of Remicade purchased prior to the price changing following a Quarterly Review.

Discount Scheme the price for Remicade following a Quarterly Review would be determined by purchasing decisions prior to the Quarterly Review. In that regard, the risk of having to pay a higher price for all future Remicade purchases had the potential to impact on immediate purchasing decisions.

- 4.46. As explained above, the CMA considers that MSD's strategy was anti-competitive¹⁷³ and there were a number of features of its Discount Scheme that had the potential to produce an exclusionary effect.¹⁷⁴ However, in order to determine the likelihood of MSD's Discount Scheme producing an exclusionary effect, the CMA considers it necessary to examine both the NHS's likely response to MSD's Discount Scheme and the relevant circumstances in which MSD's Discount Scheme was introduced. Those factors are assessed in the following sections.

III. The NHS's understanding of MSD's Discount Scheme

- 4.47. In determining whether MSD's Discount Scheme was likely to induce the NHS to be loyal to Remicade and, thus, likely to produce an exclusionary effect, the CMA has also had regard to the way in which the Discount Scheme was understood within the NHS.
- 4.48. For the reasons set out below the CMA considers that the NHS's understanding of MSD's Discount Scheme at the time at which it was introduced was consistent with MSD's Discount Scheme being likely to produce an exclusionary effect.
- 4.49. MSD submitted that the matrix included in its tender offers was not incorporated into the Framework Agreements but rather that a single price applied under the Framework Agreements. Moreover, MSD argued that, under the terms of the Framework Agreements, it could not unilaterally increase the price of Remicade and there was no volume commitment. The implication, according to MSD, was that if volumes of Remicade purchased fell, MSD could not increase the price of Remicade.¹⁷⁵
- 4.50. In applying competition law, the CMA considers that the likely effect of MSD's Discount Scheme needs to be assessed in the light of how it was understood within the NHS at the relevant time and how MSD and the NHS behaved, rather than by reference solely to what the strict contractual position may or may not have been under the Framework Agreements. In particular, what factors the NHS was likely to take into account, what decisions were likely to be taken, and whether those decisions were likely to

¹⁷³ See section 4.B.I above.

¹⁷⁴ See section 4.B.II above.

¹⁷⁵ MSD's written representations, section Introduction and summary, paragraph 20

be influenced by MSD's Discount Scheme will all have been informed by the NHS's understanding of the Scheme at the point at which orders were placed.¹⁷⁶

- 4.51. In this case, NHS views were of particular relevance given that the NHS was the end customer and selling direct to the NHS was the only route to market for infliximab suppliers.¹⁷⁷ If MSD's Discount Scheme was likely to affect whether the NHS chose Remicade or a Biosimilar, it was, in turn, likely to affect the ability of Biosimilar suppliers to compete by potentially foreclosing the only route to market.
- 4.52. In considering the NHS's understanding of MSD's Discount Scheme, the CMA focused on the views and understanding of Specialists given the role they played and the mechanisms available to them to seek to influence decisions.¹⁷⁸
- 4.53. Evidence gathered from Specialists during the Investigation identified that they had a common understanding of the following two key features of MSD's Discount Scheme, consistent both with how MSD had designed its Discount Scheme¹⁷⁹ and with the criteria and rules of MSD's Discount Scheme outlined above:¹⁸⁰
- a. the price of Remicade was expected to increase if the volume of Remicade purchased fell (which would have been the case if the NHS purchased Biosimilars in place of Remicade); and
 - b. total expenditure on infliximab products was expected to increase as the NHS moved from purchasing Remicade to purchasing Biosimilars, thus creating a cost pressure. That cost pressure would persist until sufficient demand was switched to Biosimilars to offset the higher price of Remicade.
- 4.54. The CMA considers that both of those features had the potential to disincentivise the NHS from using Biosimilars and, accordingly, remain loyal to Remicade. In particular, the key driver for using Biosimilars was to achieve cost savings,¹⁸¹ with cost savings being of particular importance to

¹⁷⁶ See paragraph 4.14 above.

¹⁷⁷ In contrast, where the customer group in question is an intermediary customer (such as a wholesaler or retailer), competitors may have alternative routes to sell direct to end customers such that they may be able to overcome any loyalty-inducing effect from a discount scheme.

¹⁷⁸ See section 2.C.I above.

¹⁷⁹ As explained in section 4.B.I above.

¹⁸⁰ As explained in section 4.B.II above.

¹⁸¹ Biosimilars were similar to Remicade but did not offer any functional or clinical advantage over Remicade. By their nature (being, at most, similar, but not identical to Remicade), Biosimilars could not offer better quality than

the NHS.¹⁸² In that context, the risk of price and cost increases had the potential to discourage the NHS from using Biosimilars. Moreover, the risk under MSD's Discount Scheme of price and cost increases as a result of switching to Biosimilars was well understood within the NHS.

- 4.55. The potential of MSD's Discount Scheme to increase prices and costs was also a cause of concern within the NHS, particularly among certain Specialists. Given their role and the mechanisms available to them to seek to influence decisions in the NHS,¹⁸³ those concerns about MSD's Discount Scheme had the potential to encourage Specialists to seek to influence those within their respective regions and sub-regions not to switch to Biosimilars so as to avoid the risk of a price increase under MSD's Discount Scheme and the resulting cost pressure.
- 4.56. Concerns were expressed by the NHS to MSD on a number of occasions about the potential implications of switching to using Biosimilars, both on the potential for the price of Remicade to increase under MSD's Discount Scheme and for total expenditure on infliximab to increase. MSD did not seek to suggest at the time that the concerns raised were mistaken, nor did MSD seek to alter the NHS's view. Indeed, in a number of instances, MSD sought to reinforce the concerns and reminded the NHS about the potential financial implications under MSD's Discount Scheme if it started to switch to using Biosimilars.

IV. The relevant circumstances in which MSD's Discount Scheme was introduced

- 4.57. In order to assess whether MSD's Discount Scheme was likely to produce an exclusionary effect it is necessary to consider all the relevant circumstances, including the context in which it was introduced.¹⁸⁴ This is an objective assessment¹⁸⁵ of the likely effect¹⁸⁶ of MSD's Discount Scheme based on the facts and relevant circumstances at the point at which MSD's Discount Scheme was introduced in March and April 2015.

Remicade. Accordingly, price was the key competitive factor on which Biosimilars could seek to compete with Remicade.

¹⁸² As explained in section 4.B above, the NHS was under pressure to achieve cost savings. Further, reducing the total cost of infliximab treatment would have allowed the NHS to, for example, provide infliximab treatment to a larger number of patients or redeploy those resources to other treatment areas. As such, cost savings from Biosimilars could have allowed the NHS to increase the number of patients it could treat.

¹⁸³ See section 2.C above.

¹⁸⁴ See paragraph 4.10 above.

¹⁸⁵ See paragraph 4.5 above.

¹⁸⁶ See paragraph 4.12 above.

- 4.58. This section sets out the CMA's assessment of the relevant circumstances at the point at which MSD's Discount Scheme was introduced and explains why the CMA has concluded, based on the information in its possession, that MSD's Discount Scheme was not likely at that time to produce an exclusionary effect and accordingly that there are no grounds for action on the CMA's part.
- 4.59. In summary, although MSD designed its Discount Scheme to have an exclusionary effect by making entry more difficult¹⁸⁷ and the criteria and rules¹⁸⁸ and the NHS's understanding of MSD's Discount Scheme¹⁸⁹ demonstrated the potential for it to produce an exclusionary effect, the actual likelihood of such an effect depended on the accuracy of the various assumptions made by MSD at the time that MSD's Discount Scheme was introduced.¹⁹⁰
- 4.60. Some of MSD's assumptions were incorrect in a number of material respects, notably the degree of clinical caution, and the NHS's likely reaction and attitude to using Biosimilars.¹⁹¹ The relative strength of the financial incentive created by MSD's Discount Scheme was also less than when MSD designed its Discount Scheme.¹⁹² As a result, at the time it was introduced, the CMA considers that MSD's Discount Scheme was not likely to produce an exclusionary effect.¹⁹³
- 4.61. In the following paragraphs, the CMA:
- a. explains the factors on which the likelihood of MSD's Discount Scheme producing an exclusionary effect depended and why these factors were uncertain;¹⁹⁴
 - b. explains the relevant circumstances in which MSD's Discount Scheme was introduced and how these differed from the assumptions underlying MSD's Discount Scheme, focusing on the degree of clinical caution and the likely attitude of the NHS to using Biosimilars, and the relative strength of the financial incentive that MSD's Discount Scheme was likely to create;¹⁹⁵ and

¹⁸⁷ See section 4.B.I above.

¹⁸⁸ See section 4.B.II above.

¹⁸⁹ See section 4.B.III above.

¹⁹⁰ See section 4.B.IV.a below.

¹⁹¹ See section 4.B.IV.b below.

¹⁹² See section 4.B.IV.b below.

¹⁹³ See section 4.B.IV.c below.

¹⁹⁴ See section 4.B.IV.a below.

¹⁹⁵ See section 4.B.IV.b below.

c. concludes on the likelihood of MSD's Discount Scheme to produce an exclusionary effect in the relevant circumstances in which it was introduced.¹⁹⁶

a. Key factors on which the likelihood of MSD's Discount Scheme producing an exclusionary effect depended

4.62. As explained above,¹⁹⁷ MSD designed its Discount Scheme to produce an exclusionary effect by making entry more difficult. The likelihood of MSD's Discount Scheme producing an exclusionary effect, by inducing the NHS to remain loyal to Remicade, was dependent both on the strength of the financial incentive created by MSD's Discount Scheme and on how long the cost pressure¹⁹⁸ was likely to persist. Whether MSD's Discount Scheme was likely to produce an exclusionary effect depended on various factors about which there was uncertainty at the time at which MSD's Discount Scheme was introduced, including the following:

- the NHS's reaction to and appetite for using Biosimilars;
- the strategies of Biosimilar suppliers, including the price at which Biosimilars would enter; and
- the rate of growth of overall demand for infliximab.

4.63. There was uncertainty about how the NHS would react to Biosimilars and the appetite within the NHS to use Biosimilars. Although it was generally expected that Biosimilar use would focus on new patients (where clinical caution was least acute),¹⁹⁹ the willingness and speed at which the NHS would trial and adopt Biosimilars for existing patients were unclear. The point at which MSD's Discount Scheme was introduced was also the first time that biosimilar medicines had been introduced in the UK for this kind of particularly complex biological medicine. Although a few biosimilar medicines had been previously introduced for other biological medicines, biosimilar infliximab was somewhat of a test case for biosimilar medicines and the NHS's approach to and appetite for using them. As MSD explained, *there*

¹⁹⁶ See section 4.B.IV.c below.

¹⁹⁷ See section 4.B.I above.

¹⁹⁸ As explained in section 4.B.I above, the potential cost pressure created by MSD's Discount Scheme arose from the price of Remicade increasing as a region or sub-region purchased more Biosimilars and less Remicade, which, in turn, meant that the total that a region or sub-region spent on infliximab (both Remicade and Biosimilars) would increase. The extent to which total infliximab expenditure increased for a region or sub-region was dependent on both the price of Remicade and the price of Biosimilars, with the lower Biosimilar price partially offsetting the higher Remicade price.

¹⁹⁹ Clinical caution towards using Biosimilars for new patients was expected to be less both because some clinical trial data existed (see section 2.A.IV above) and because concerns over therapeutic failure did not arise where a patient was not already using Remicade.

was little previous experience of biosimilar entry (for any originator product), and the uptake of generic versions of chemical products was not an accurate comparator'.²⁰⁰

- 4.64. Further, Biosimilars were not yet available at the point at which MSD designed and tendered its Discount Scheme. There was, therefore, uncertainty about the strategies of Biosimilar suppliers, including the price at which they would enter the market, and how Biosimilars would affect Remicade sales. Further, the tender processes were sealed bids and contract awards were commercially confidential.
- 4.65. Finally, overall demand for infliximab had been growing and was expected to increase but the rate of growth was uncertain and unpredictable, meaning that the total size of the infliximab market was uncertain.

b. The relevant circumstances in which MSD's Discount Scheme was introduced

- 4.66. In an attempt to address the uncertainty at the time, MSD carried out detailed research, including surveying a number of NHS staff, including clinicians. The results of that research fed into how MSD calibrated the thresholds within its Discount Scheme,²⁰¹ which were based on assumptions about:
- a. the total infliximab demand that MSD expected within each region and sub-region;
 - b. the willingness with which and the speed at which the NHS was expected to use Biosimilars;
 - c. all regions and sub-regions acting in a similar way; and
 - d. the price at which Biosimilars would enter.
- 4.67. The market reality at the time that MSD's Discount Scheme was introduced did not reflect the assumptions underlying MSD's Discount Scheme in several material respects. Those differences are explained below, focusing on:
- the likely attitude of the NHS to using Biosimilars; and

²⁰⁰ MSD's written representations, introduction and summary, paragraph 5.

²⁰¹ The thresholds under MSD's Discount Scheme were a function of total infliximab demand, being set by proportions of total expected infliximab demand – see section 2.E.I above.

- the relative strength of the financial incentive that MSD's Discount Scheme was likely to create.

The likely attitude of the NHS to using Biosimilars

- 4.68. The likelihood that MSD's Discount Scheme would induce the NHS to remain loyal to Remicade was dependent on attitudes within a region or sub-region towards using Biosimilars, including both the degree of clinical caution and whether regions and sub-regions took a short or longer-term view of the costs and benefits of Biosimilars.
- 4.69. When MSD's Discount Scheme was introduced, clinical caution varied both within and between different regions and sub-regions and was less than MSD expected in a number of regions and sub-regions. In particular, there were a number of Trusts which decided to adopt Biosimilars soon after they became available, not just for new patients (which MSD had expected to be the case generally), but also for existing patients (which MSD had not expected to be the case). A notable example is University Hospital Southampton NHS Foundation Trust, which decided to purchase Biosimilars for all its gastrointestinal patients (both new and existing).
- 4.70. The speed with which certain Trusts adopted Biosimilars – effectively acting as 'pioneers' – meant, in turn, that other Trusts were more likely to follow suit more quickly, once such trials had proved successful and demonstrated that Biosimilars could be used safely, particularly for existing patients. The benefits of such learning were particularly relevant for other Trusts within the same sub-region, making it more likely that clinical caution within a whole sub-region would be lower than MSD had assumed.
- 4.71. MSD's Discount Scheme determined prices based on regional and sub-regional volumes.²⁰² Accordingly, the attitudes of particular Trusts towards using Biosimilars were likely to have a wider effect both on whether the price of Remicade would increase and on the ability and speed at which a region or sub-region might be able to overcome the cost pressure arising from MSD's Discount Scheme.
- 4.72. MSD's Discount Scheme was also not likely to affect prescribing and purchasing decisions in those regions or sub-regions which took a longer-term view of the costs and benefits of Biosimilars. In particular, Trusts within a region or sub-region could decide to risk facing a short-term increase in total expenditure on infliximab, in recognition of the fact that the more

²⁰² See section 2.E above.

Biosimilars were used, the more confident the NHS was expected to become in using Biosimilars and the less clinical caution was likely to endure.²⁰³ As explained above,²⁰⁴ the cost pressure created by MSD's Discount Scheme would reduce once sufficient demand had been switched from Remicade to Biosimilars. The quicker a region or sub-region could switch to using Biosimilars, the shorter the period that any cost pressure would remain.

- 4.73. As a result of lower clinical caution towards Biosimilars and a greater desire to use Biosimilars for both new and existing patients than MSD had originally assumed, it followed that certain regions or sub-regions were likely to overcome the cost pressure created by MSD's Discount Scheme relatively quickly. This is because a region or sub-region would have been able to purchase a sufficiently large volume of Biosimilars such that, despite facing a higher price for Remicade, this would be offset by the lower price of Biosimilars, meaning that the total amount paid for infliximab would still be lower overall.
- 4.74. Moreover, at least some sub-regions took a longer-term view at the time that MSD's Discount Scheme was introduced, recognising that greater use of Biosimilars was likely to make it quicker to overcome the cost pressure created by MSD's Discount Scheme and to achieve total cost savings for infliximab. As a result of the NHS's attitude to Biosimilars when introduced in the UK, the contestable share of demand was larger than MSD had expected when it designed its Discount Scheme.

The relative strength of the financial incentive that MSD's Discount Scheme was likely to create

- 4.75. The likelihood that MSD's Discount Scheme would produce an exclusionary effect, by inducing the NHS to remain loyal to Remicade for some time, was also dependent on the strength of the financial incentive created by MSD's Discount Scheme. The greater the financial impact for a region or sub-region from switching to using Biosimilars,²⁰⁵ the more likely it was that Trusts within a region or sub-region would choose to remain with Remicade rather than start to use Biosimilars. The financial incentive created by MSD's Discount Scheme when it was introduced was less strong than MSD's initial

²⁰³ See section 4.B above.

²⁰⁴ See section 4.B.I above.

²⁰⁵ The financial implication for the NHS from MSD's Discount Scheme was dependent on whether and by how much the price of Remicade would increase, the price of Biosimilars, and the amount by which total infliximab expenditure would increase.

internal modelling had assumed.²⁰⁶ In particular, as explained above,²⁰⁷ the inclusion of Quarterly Reviews and the consequent lack of retroactivity reduced the strength of the financial incentive created by MSD's Discount Scheme.

c. The CMA's conclusion on the circumstances in which MSD's Discount Scheme was introduced

4.76. In the light of the above points, the CMA considers, based on the information in its possession, that, at the point when MSD's Discount Scheme was introduced, the factual circumstances were such that MSD's Discount Scheme was not likely to produce an exclusionary effect. Considered in the relevant context at the time it was introduced, the financial incentive created by MSD's Discount Scheme was likely to be overcome in those regions or sub-regions where clinical caution was lower than MSD had expected and/or where a longer-term view of the costs and benefits of Biosimilars was taken, and was less strong than MSD had originally assumed.

V. MSD's representations

4.77. MSD made various submissions to the CMA as to why its conduct did not constitute an abuse, including in response to the SO. The CMA addresses the following submissions from MSD below and explains why it did not accept these submissions:

- a. observed actual effects undermined the CMA's proposed finding that MSD's Discount Scheme was likely to produce an exclusionary effect;
- b. the CMA should have applied the as-efficient competitor test (the '**AEC test**') and that the application of that test showed that MSD's Discount Scheme was not likely to exclude an as-efficient competitor;
- c. there was no non-contestable share of demand or, even if there was, the CMA underestimated its size; and
- d. the CMA wrongly equated Specialists as customers for the purposes of MSD's Discount Scheme.

²⁰⁶ Albeit, the CMA considers that the lack of retroactivity was not such to prevent MSD's Discount Scheme from having the potential to induce the NHS to remain loyal to Remicade, see section 4.B.II above. See also section 4.B.I above on MSD's internal modelling of its Discount Scheme.

²⁰⁷ See section 4.B.II above.

a. Actual effects

4.78. MSD submitted that actual market developments undermined the CMA's proposed finding in the SO, that MSD's Discount Scheme was likely to produce an exclusionary effect. MSD argued that where actual effects can be readily observed, those should be taken into account, indeed that an assessment of likely effects must take account of what actually happened.²⁰⁸ In support of that point, MSD submitted that:

- a. the evidence showed that Biosimilar sales developed contrary to the CMA's theory of harm. First, because sales data indicate that, both at regional and local level and for a significant period of the alleged abuse, Biosimilars market shares lay in the range (6% to 30%) where Biosimilars purchases were allegedly disincentivised by the Discount Scheme. Second, because individual Trusts and clinicians adopted a policy of treating new patients with Biosimilars;²⁰⁹
- b. overall, the evidence suggested there was no delay in Biosimilar uptake as a result of MSD's Discount Scheme. In particular, Biosimilar uptake increased throughout the period that MSD's Discount Scheme was in force and the NHS purchased more Biosimilars than initially expected. In some instances, MSD's Discount Scheme accelerated rather than delayed Biosimilar uptake;²¹⁰
- c. the evidence showed that the speed of Biosimilar uptake was driven by factors other than MSD's Discount Scheme;²¹¹ and
- d. when compared to Scotland (where MSD's Discount Scheme did not apply), purchases across the NHS in England did not show that Biosimilar uptake had been delayed, demonstrating that MSD's Discount Scheme had no effect in England.²¹²

4.79. The CMA considers that for the purposes of applying the Chapter II prohibition and Article 102, the likely effect of a dominant undertaking's conduct should be assessed by reference to the point at which the allegedly abusive conduct was implemented rather than at some point after the allegedly abusive conduct had been in place.²¹³ That is the approach that

²⁰⁸ MSD's written representations, Introduction and summary, paragraph 10.

²⁰⁹ MSD's written representations, Introduction and summary, paragraph 20.

²¹⁰ MSD's written representations, section Introduction and summary, paragraph 29

²¹¹ MSD's written representations, section Introduction and summary, paragraph 38

²¹² MSD's written representations, section introduction and summary, paragraph 28

²¹³ See paragraph 4.7 above.

the CMA took when assessing the relevant circumstances in which MSD's Discount Scheme was introduced.²¹⁴

b. The as-efficient competitor test

- 4.80. MSD submitted that the CMA should apply the AEC test and that, if it did, it would show that MSD's Discount Scheme was not likely to exclude an as-efficient competitor from competing with Remicade.²¹⁵
- 4.81. The CMA did not apply an AEC test in the SO and did not consider it necessary to do so in order to determine whether MSD's Discount Scheme was likely to produce an exclusionary effect. The CMA comments below on the reasons that were particularly relevant to its consideration of an AEC test to appraise MSD's Discount Scheme.
- 4.82. First, the AEC test is not the only way in which a discount can be assessed under competition law. Although the AEC test can be informative and useful when assessing a discount offered by a dominant undertaking,²¹⁶ it is not required.²¹⁷ Neither is it a 'safe harbour'. It is necessary to consider all the relevant circumstances. This includes the possible existence of a strategy aiming to exclude competitors that are at least as efficient as the dominant undertaking.²¹⁸ Other circumstances will be relevant too, including:
- a. the extent of the undertaking's dominant position on the relevant market;
 - b. the share of the market covered by the discount;
 - c. the conditions and arrangements for granting the discount(s) in question;
 - d. the duration of the discount(s) granted; and
 - e. the amount of the discount(s) granted.²¹⁹

²¹⁴ See section 4.B.IV above.

²¹⁵ MSD's written representations, Part 2, section 5.

²¹⁶ As the CJEU observed in *Post Danmark II*, 'that conclusion [that there is no 'legal obligation requiring a finding to the effect that a rebate scheme operated by a dominant undertaking is abusive to be based always on the as-efficient-competitor test'] ought not to have the effect of excluding, on principle, recourse to the as-efficient competitor test in cases involving a rebate scheme for the purposes of examining its compatibility with Article [102] EC' (paragraph 58). See also paragraph 61: 'The as-efficient-competitor test must thus be regarded as one tool amongst others for the purposes of assessing whether there is an abuse of a dominant position in the context of a rebate scheme'.

²¹⁷ See paragraph 4.16 above. See also *Post Danmark II*, paragraphs 56, 57 and 62; CJEU's judgment in *Tomra*, paragraphs 73 and 80.

²¹⁸ See paragraph 4.16 above.

²¹⁹ C-413/14 P *Intel*, paragraph 139.

- 4.83. Second, the AEC test may set too high a threshold for finding a discount to be an abuse, which, in turn, may risk under enforcement. In particular, the following points were relevant to the CMA's assessment of MSD's Discount Scheme:
- a. The AEC test indicates whether it is impossible for an as-efficient competitor to compete profitably.²²⁰ However, as a matter of law, to establish an abuse it is sufficient to show that a discount was likely to make it very difficult for a competitor to compete.²²¹
 - b. It is also sufficient to show that the conduct in question was likely to produce an exclusionary effect. It is not necessary to show that the conduct in question was likely to lead to total exclusion (i.e. that existing competitors were likely to exit the market or that potential entrants were likely not to enter the market).²²² In this case, the CMA considered that MSD's Discount Scheme would have been abusive had its likely effect been to delay the introduction of Biosimilars rather than to prevent entry altogether.
 - c. Placing a significant burden on entry may make it very difficult for a competitor to compete, particularly in the context of newly emerging and nascent entry and where the prior situation was one of a monopoly supplier.
 - d. More generally, a predation-type test, such as the AEC test, may not be appropriate where a dominant undertaking can use a discount profitably to exclude actual or potential competitors. In that scenario, the dominant undertaking can implement its discount over a prolonged period without making losses but nevertheless excluding or delaying competitive entry. The AEC test implicitly assumes the entrant can survive on variable costs during the period of predation or low prices. However, since the discount can be profitable for the incumbent in perpetuity, the AEC test at least needs to be assessed on the basis of long-run variable costs (or total costs).
- 4.84. Third, the results of an AEC assessment need to be interpreted with caution, particularly where there is uncertainty over how a discount is interpreted by customers. In order for the assessment to be considered in the relevant context in which the discount is deployed, it needs to be grounded in the

²²⁰ Where a discount scheme passes the test (i.e. where it supports that an abuse has occurred), that shows that an as-efficient competitor cannot compete profitably. In that scenario, it would be economically rational for the as-efficient competitor to either exit the market or not enter the market in the first instance.

²²¹ See paragraph 4.11 above.

²²² See paragraph 4.12 above.

reality in which customers (who will be the entities who decide whether and how they will react to changes in price) view and react to the different price offerings and how quickly and easily competitors are able to respond.

c. The existence and size of the non-contestable share of demand

- 4.85. MSD submitted that the CMA had failed to show to the requisite legal standard that there was a non-contestable share of demand for Remicade.²²³ In particular, according to MSD:
- a. The CMA had not attempted to identify a non-contestable share, nor had the CMA claimed that there was a non-contestable share or explained what the non-contestable share could be. Further, the CMA had not claimed that Remicade was a must-have product.²²⁴
 - b. Actual market developments showed that existing Remicade patients did not constitute a non-contestable share of demand. Any expectation as to what market share Biosimilars could compete for was incorrect.²²⁵
 - c. Whatever barriers to switching might have existed, those could be overcome – and frequently were.²²⁶
 - d. The existence of clinical caution did not mean that existing patients were non-contestable.²²⁷
- 4.86. MSD also submitted that the contestable share that the CMA posited in the SO was implausibly low and that in the SO the CMA overestimated the minimum share required for profitably switching to Biosimilars.²²⁸
- 4.87. The CMA does not accept that there was no non-contestable share of demand, particularly in the light of the existence of clinical caution.²²⁹
- 4.88. As explained above, the CMA has taken into account the degree of clinical caution when deciding whether on the basis of the information in its possession MSD's Discount Scheme was likely to produce an exclusionary effect.²³⁰ However, the CMA did not consider it necessary to conclude on the size of the non-contestable share of demand, particularly in the light of its overall conclusion that there are no grounds for action in this case.

²²³ MSD's written representations, paragraph 196.

²²⁴ MSD's written representations, paragraph 199.

²²⁵ MSD's written representations, paragraph 198.

²²⁶ MSD's written representations, paragraph 198.

²²⁷ MSD's written representations, paragraph 201.

²²⁸ MSD's written representations, paragraph 204.

²²⁹ See section 3.B.II.a above.

²³⁰ See section 4.B.IV above.

d. The role of Specialists

- 4.89. MSD challenged the CMA's focus on Specialists, arguing that the SO wrongly equated the Specialists with MSD customers. MSD argued that Specialists were not purchasers and had no decision-making powers: they did not make purchasing decisions and were not able to dictate such decisions. In addition, MSD argued that Specialists could not co-ordinate views or decisions within regions or sub-regions. MSD argued that prescribing decisions were made at the local level by clinicians, based solely on therapeutic autonomy. According to MSD, those decisions could not have been influenced by Specialists and even Trusts had little scope to influence clinical decision-making. Accordingly, Trusts took purchasing decisions based on clinicians' prescriptions, not the preferences of Specialists. MSD also suggested that, even if the Specialists may have espoused views on the theoretical regional or sub-regional strategies, they had no ability to implement such strategies.²³¹
- 4.90. MSD further submitted that:
- a. the structure of secondary healthcare in England meant that a regional price would not have been capable of influencing decisions at a local Trust level, as no individual Trust's actions would have been sufficient to impact on regional or sub-regional volumes in total;²³² and
 - a. absent an ability to co-ordinate local decisions at a regional or sub-regional level, MSD's Discount Scheme would not have been able to impact on local Trust decisions.²³³
- 4.91. The CMA considers that, whilst Specialists were not 'customers' in the sense that they made purchases or determined prescribing, purchasing or funding decisions, they had an important role to play in seeking to encourage cost-effective decisions within the NHS.
- 4.92. The CMA does not accept that for MSD's Discount Scheme to have had an exclusionary effect it was necessary for decision-makers within a sub-region to be able to co-ordinate purchases. Nor does the CMA accept that for such an exclusionary effect to occur it was necessary for Specialists to have the ability and/or means available to them to co-ordinate purchases within their respective sub-regions.

²³¹ MSD's written representations, Introduction and summary, paragraph 36.

²³² MSD's written representations, Part 2, section 2, paragraph 101.

²³³ MSD's written representations, Part 2, section 2, paragraph 101.

4.93. Rather, as explained above,²³⁴ the CMA considers that there existed a number of mechanisms across the NHS to seek to influence clinical decision-making and encourage cost effective decision-making. It was through the exercise of those mechanisms of influence that the CMA considers that MSD's Discount Scheme had the potential to influence decision-making within the NHS, thus having the potential to produce an exclusionary effect.

VI. Objective justification

4.94. MSD submitted that its matrix was pro-competitive and benefitted the NHS. Specifically, according to MSD the volume bands provided CCGs with a hedge against the budgetary risk they faced due to the prevailing uncertainty around how infliximab demand would change.²³⁵

4.95. The CMA does not accept that there was a pro-competitive rationale for MSD's Discount Scheme and has not been able to identify anything that would objectively justify MSD's Discount Scheme. In particular, the changing price of Remicade under MSD's Discount Scheme was not associated with any cost or efficiency savings that MSD would have achieved from selling larger volumes – that can be seen from different sub-regions being charged the same Remicade price despite purchasing very different volumes of Remicade. Alternative pricing structures were also available to MSD, including those used by MSD both prior to²³⁶ and subsequent to its Discount Scheme.²³⁷

4.96. The only argument MSD put forward was that its Discount Scheme acted as a *'hedge'* for the NHS in the context of uncertain levels of demand. MSD noted that the NHS demand for infliximab was uncertain because it had recently been recommended by NICE for use with patients with severe ulcerative colitis. MSD submitted that its Discount Scheme provided the NHS with a *'hedge against unexpected spending on Remicade'* if volumes were *'unexpectedly high'*, *'providing CCGs with a hedge against the budgetary risk that they faced'*. MSD submitted that its Discount Scheme was, in effect, insurance for the NHS against purchasing higher than expected volumes of Remicade, whereby if the NHS did purchase more Remicade than expected

²³⁴ Section 2.C above.

²³⁵ MSD's written representations, paragraph 222.

²³⁶ Prior to its Discount Scheme, MSD offered a flat-rate discount from its list price. That discount was the same regardless of volumes purchased.

²³⁷ See section 2.F above for a summary of MSD's revised pricing scheme for Remicade.

its overall expenditure would not increase because, under MSD's Discount Scheme, the price of Remicade would fall.²³⁸

- 4.97. The CMA does not accept that argument. MSD's Discount Scheme provided for the total cost of Remicade to remain at a fairly constant level if the NHS purchased between 85% and 100% of its total infliximab requirements from MSD. This meant that if the NHS purchased less Remicade than expected (approximately 94% of MSD's estimate of total infliximab demand, corresponding to the starting price on MSD's matrix) because it switched to Biosimilars, the overall costs of its Remicade purchases would remain constant but its overall infliximab cost would either remain constant or increase. The '*hedge*' therefore did not provide any value to the NHS if it was seeking to purchase volumes of Biosimilars.

²³⁸ MSD's written representations, paragraph 225.

5. THE CMA'S CONCLUSION

- 5.1. In the light of the above, the CMA has decided that there are no grounds for action on its part in relation to MSD's Discount Scheme.
- 5.2. Although MSD designed its Discount Scheme to have an exclusionary effect by making entry more difficult and the criteria and rules, together with the NHS's understanding of MSD's Discount Scheme, demonstrate its potential to have an exclusionary effect, the CMA has concluded on the basis of the available information that the factual circumstances at the time MSD's Discount Scheme was introduced meant that it was not likely to have such an effect. Accordingly, the CMA has decided to close its case.

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For and on behalf of the Competition and Markets Authority

14 March 2019