EUROPEAN COMMISSION
DG Competition

Case M.8061 - IMS HEALTH / QUINTILES

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 12/08/2016

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In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE

To the notifying parties

Dear Sir/Madam,

Subject: **Case M.8061 - IMS HEALTH / QUINTILES**
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

1. On 7 July 2016, the European Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004[3] by which IMS Health Holdings ("IMS Health", the US) enters into a full merger with Quintiles Transnational Holdings Inc. ("Quintiles", the US) pursuant to Article 3(1)(a) of the Merger regulation. IMS Health and Quintiles are collectively referred to as the "Notifying Parties".

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1 OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation'). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ('TFEU') has introduced certain changes, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this decision.

2 OJ L 1, 3.1.1994, p. 3 (the 'EEA Agreement').

3 OJ L 24, 29.1.2004, p. 1 (the "Merger Regulation").

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I. THE PARTIES AND THE OPERATION

2. IMS Health is a global information and technology services company providing healthcare companies with solutions to measure and improve their performance, such as pricing and market access, data management, prescribing trends, etc.

3. Quintiles is a global provider of product development services and commercial outsourcing services to support healthcare companies develop and commercialize new therapies.

4. On the basis of an Agreement and Plan of Merger signed on 3 May 2016, IMS Health and Quintiles plan to enter into a full merger (the "Transaction"). Upon completion of the merger, IMS Health shareholders will own approximately 51.4% and Quintiles shareholders will own approximately 48.6% of the combined company. The Notifying Parties intend to use the trading name "Quintiles IMS, Inc.".

5. The Transaction therefore constitutes a concentration within the meaning of Article 3(1)(a) of the Merger Regulation.

II. EU DIMENSION

6. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million[4] (IMS Health: EUR 2 600 million, Quintiles: EUR 3 900 million). Each of them has an EU-wide turnover in excess of EUR 250 million (IMS Health EUR […] million, Quintiles EUR […] million), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State.

7. The Transaction therefore has an EU dimension pursuant to an Article 1(2) of the Merger Regulation.

III. MARKET DEFINITIONS

8. Pharmaceutical companies rely on several types of data that enable them to improve their sales, marketing and promotional activities. These data are also an important input for several related services (e.g. clinical trials) and software (e.g. client relationship management software), which can either be provided to the pharmaceutical companies by specialised third parties, or be developed by the pharmaceutical companies themselves.

9. On the upstream markets of intelligence provision, IMS Health is active in the provision of the following types of data / software: (i) healthcare professional databases; (ii) sales

4 Turnover calculated in accordance with Article 5 of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C 95, 16.4.2008, p. 1).

tracking data; (iii) data for the provision of real world evidence ("RWE")[5], (iv) and customer relationship management ("CRM") software.[6]

10. As regards the downstream markets, both parties are active in the provision of RWE services (data/studies), healthcare consulting services, and contract sales organisation ("CSO")[7] services, such as outsourced sales force services. In addition, Quintiles is also active in the area of contract research organisation ("CRO")[8] services.

III.1. Relevant markets

Healthcare marketing services (including CSO services)

11. Healthcare marketing services refer to services designed to support healthcare companies with various logistical marketing issues such as the provision of physical and electronic mailings, support for website publishers, optimizing marketing strategies for individual healthcare products, etc.

12. They can be performed directly by marketing companies for the healthcare companies (direct marketing services) or outsourced to third parties for specific projects or over a longer time period (CSO Services, such as outsourced sales force supporting healthcare companies in optimizing their marketing strategies for individual healthcare products, including through the use of sales representatives, nurse educators, and scientific/medical communication).

i. The Commission's previous practice

13. As regards direct marketing services, the Commission has identified an overall market for marketing communication services, which included direct marketing services (as well as advertising, information and consultancy, public relations, consumer relationship management, event management, identity design, and specialist communications services).[9]

14. As regards CSO services, the Commission has identified a separate market for CSO Services - temporary employment services relating to temporary workers posted to user firms for a temporary period of time.[10]

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5 Real World Evidence (RWE) refers to observational studies based on data on actual patient experiences and actual use of a product in "real life" clinical practice. Generally, Quintiles is active in primary RWE data and IMS Health in secondary RWE data. For a definition of primary and secondary data please refer to paragraph 30

6 CRM software helps businesses manage their customer interactions by organising, automating and synchronising data from sales, marketing, customer service and technical functions.

7 CSO refers to outsourced sales force supporting healthcare companies in optimizing their marketing strategies for individual healthcare products, including through the use of sales representatives, nurse educators, and scientific/medical communication.

8 CRO services refer to product development services used by healthcare companies to outsource the clinical development process and other processes from first-in-man clinical trials to post-launch monitoring.

9 Case No COMP/M.7023 – *Publicis/Omnicom* and Case No COMP/M.7337 - *IMS Health/Cegedim Business.*

10 Case No COMP/M.5009 – *Randstad/Vedior*.

15. The Commission has previously defined national markets for marketing communications services[11] and CSO services.[12]

ii. Notifying Parties' view

16. The Notifying Parties agree with the previous decision practice of the Commission, and in particular, they do not consider it appropriate to subdivide the market by customer industry, as marketing businesses use the same resources and skill sets to advise customers in a variety of industries.

17. In any case, the Notifying Parties provided the market shares of both parties for marketing communications services and CSO services at national and EEA level.

iii. Conclusion

18. The Commission, on the basis of the results of the market investigation, does not find any reason to depart from the precedents, i.e. definition of the relevant markets.

19. In any event, for the purpose of this decision, the exact delineation of the relevant product and geographic market for the provision of marketing communications services and CSO services can be left open, since the Transaction does not give rise to competition concerns under any alternative market definition.

Healthcare consulting services

20. Healthcare consulting services refer to the provision of analytical and advisory services to healthcare companies that are intended to improve product development activities and technological capabilities, reduce operating costs, and strengthen companies' commercial strategies and business models.

i. The Commission's previous practice

21. Previously, the Commission has identified a market for management consultancy services, and considered a possible market sub segment of consulting services to healthcare companies.[13]

22. As regards the geographic market for consulting services, the Commission has left open the question of whether the market is national or multi-country – wide or even broader.

ii. Notifying Parties' view

23. The Notifying Parties do not consider it to be appropriate to subdivide the market by customer industry, as consultants use the same resources and skill sets to advise customers in a variety of industries. Consulting for healthcare companies does not require any specific knowledge, expertise, skills or tools that only certain consultancies can offer. A majority of consultancy firms provide services to several

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11 Case No COMP/M.7337 - *IMS Health/Cegedim Business.*

12 Case No COMP/M.5009 – *Randstad/Vedior.*

13 Case No COMP/M.1016 – *Price Waterhouse/Coopers & Lybrand* and Case No COMP/M.7337 - *IMS Health/Cegedim Business.*

industries, including the healthcare one, and increasingly more consultancies are extending their offerings to include services to the healthcare industry.

24. In any case, the Notifying Party has provided the market shares of both parties for healthcare consulting services at national and EEA level.

iii. Conclusion

25. The Commission, on the basis of the results of the market investigation, does not find any reason to depart from the precedents regarding the definition of the relevant markets.

26. In any event, for the purpose of this decision, the exact delineation of the relevant product and geographic market for the provision healthcare consulting services can be left open, since the Transaction does not give rise to competition concerns under any alternative market definition.

RWE services (RWE data and RWE studies)

27. Real World Evidence (RWE) refers to observational studies based on data on actual patient experiences and actual use of a product in "real life" clinical practice. Such studies help healthcare companies analyse many different aspects of their businesses, including the commercial aspects of treatments, the medical aspects of treatments, the scope for R&D and investment priorities.

28. RWE data is obtained from a variety of sources, such as Electronic Medical Records ("EMR") or pharmacy management software, insurers and national health reimbursement authorities and public health authorities.

29. RWE data can also be obtained on a standalone basis (that is to say without the accompanying study). Pharmaceutical companies can then carry out the study in-house or commission it to a third party consultant (different from the RWE data supplier). In the latter case, the pharmaceutical company and the RWE study provider are required to sign a third party access agreement ("TPAA") with the data supplier.

30. A distinction is customarily drawn between primary and secondary RWE data. The former[14] are generated/collected to answer specific questions from primary research, such as patient reported outcome studies, patient chart reviews or post-launch clinical research, while the latter[15] are generated as part of the day-to-day operations of a healthcare organization, institution or agency, e.g. EMR, disease registries, public health authority data, claims data, patient-level prescription (Rx) data, information from patient groups, social media information.

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14 This data is generally owned by the healthcare company (or other sponsor) that commissions a given study, and the RWE service provider is not free to license, or provide third parties with access to, these data.

15 Companies are generally able to license or provide access to the secondary RWE data that they have obtained on a non-exclusive basis from third-party sources.

i. The Commission's previous practice

31. In previous decisions the Commission has analysed potentially separate markets for the collection and provision of RWE data (upstream market) and the provision of RWE services (downstream market). However, it has ultimately left the market definition open.[16]

32. The Commission has not previously considered separate markets for primary and secondary RWE data.

33. As regards the geographic delineation of the market, the Commission has left open the question whether the market for RWE studies and data is national, covers several countries within the EEA, or is EEA-wide.[17]

ii. Notifying Parties' view

34. The Notifying Parties argue that it is appropriate to identify a single market for the provision of RWE services irrespective of the type of data used in any given service (e.g. electronic medical records, patient-level prescription data, healthcare professional surveys, patient chart reviews, etc.) or of the purpose for which the study is carried out (e.g. to answer commercial, medical or R&D questions). Furthermore, they submit that it is not appropriate to distinguish between an upstream market consisting of the collection and provision of RWE data and a downstream market for the provision of RWE services; the appropriate market definition is that of an overall market for the provision of RWE data and services.

35. The Notifying Parties submit that, on the one hand, there are indications that the market for RWE services may be national in scope, because, for instance, drugs are generally authorised and marketed at a national level and RWE services generally focus on real world practice at a national level. Therefore, RWE services often focus on particular countries or groups of countries. On the other hand, according to the Notifying Parties, there are also indications for a broader market, such as the fact that data from other countries may be used as a proxy for smaller countries (for which the information available for studies may be limited), that most healthcare companies are active across different countries, and that the majority of RWE service providers are able to provide services for more than one country.

iii. Conclusion

36. The Commission considers, on the basis of the results of the market investigation, that there is a difference between (i) primary and secondary RWE data as such[18] and (ii) the collection and provision of RWE data and (iii) the provision of RWE studies (services).

37. As regards the geographic definition, the Commission considers that with respect to RWE services / data, the market investigation provided mixed results. While some providers of RWE services seem to operate on a national basis and offer contracts

16 Case No COMP/M.7337 - *IMS Health/Cegedim Business.*

17 Case No COMP/M.7337 - *IMS Health/Cegedim Business.*

18 For a description of the differences between primary and secondary data, see paragraph 30.

limited to a single country, others deliver studies covering several countries within the EEA. Similarly, pharmaceutical companies seem to purchase RWE studies both at the national and EEA level.

38. In any event, for the purpose of this decision, the exact delineation of the relevant product and geographic market for the provision healthcare consulting services can be left open, since the Transaction does not give rise to competition concerns under any alternative market definition.

CRO services

39. CRO services refer to product development services used by healthcare companies to outsource the clinical development process and other processes from first-in-man clinical trials to post-launch monitoring. CRO services range from drug discovery tasks—including organic synthesis, analytical chemistry, biochemistry, molecular modelling, and medicinal chemistry—to clinical research trials.

i. The Commission's previous practice

40. The Commission has not previously dealt with CRO services.

ii. Notifying Parties' view

41. The Notifying Parties consider there is a single market for all CRO services, and that no distinction should be drawn between providers of CRO services based on the relative strength of their activities across the clinical development spectrum for purposes of market definition. Almost all CRO service providers offer services that span some combination of pre-clinical, clinical, and post-launch activities. Also, all CRO service providers benefit from the skills and facilities required to offer services across the entire pharmaceutical pipeline (e.g. a network of clinicians, lab facilities, expert scientists, clinical pharmacologists, project managers, etc.). In addition, the Notifying Parties claim that it would be unable to estimate revenue breakdowns for competitors according to the different CRO services they offer.

42. The Notifying Parties consider that the CRO services' market is at least EEA-wide. Although regulatory requirements vary between countries, in practice many healthcare companies instruct CRO service providers to conduct research on a global basis, and then submit the results to the European Medicines Agency ("EMA") for authorization at Member State level. There is, therefore, typically no need to seek regulatory approval in individual Member States. In addition, CRO service providers offer services across multiple countries, including because this allows healthcare companies to accelerate timelines, reach diverse patient populations, and access specialized expertise; healthcare companies therefore contract CRO service providers regardless of where they are located. Quintiles and all of its largest competitors offer services across the EEA (and elsewhere).

iii. Conclusion

43. In the light of the results of the market investigation which did not suggest a different market definition, for the purpose of this decision, the Commission considers the relevant market is the overall market for CRO services at the EEA level.

Healthcare professionals' database

44. Healthcare professionals' databases provide information about healthcare professionals to assist pharmaceutical companies' sales and marketing efforts. Two different sets of data can be distinguished in this context: (i) healthcare professionals contact details, which comprise the name, position, organisation to which a healthcare professional belongs, as well as address, telephone number, etc. and (ii) healthcare professionals profile information, which consists of qualitative information concerning, for instance, a healthcare professional's prescribing behaviour or his specialties or areas of expertise. IMS provides both types of databases in the EEA (IMS' *OneKey* database).

45. Healthcare professional data can be sold by providers on a stand-alone basis or together with other relevant software or services.

i. The Commission's previous practice

46. The Commission has previously left open the question whether healthcare professional contact details would belong to a different market from healthcare professional profile information. However, the Commission has concluded that the evidence suggests that as pharmaceutical companies appear to purchase healthcare professional databases as an overall product these two types of data should be considered as one market.[19]

47. The Commission has previously left open the question whether the market for healthcare professionals databases is national or EEA wide.[20]

ii. Notifying Parties' view

48. The Notifying Parties did not provide any views as regards the product and geographic market definition of the market regarding healthcare professionals databases.

iii. Conclusion

49. The Commission, on the basis of the results of the market investigation, does not find any reason to depart from the precedents regarding the definition of the relevant markets.

50. In any event, for the purpose of this decision, the exact delineation of the relevant product and geographic market for healthcare professionals databases can be left open, since the Transaction does not rise to competition concerns under any alternative market definition.

Sales tracking data

51. Sales tracking data enables a pharmaceutical company to monitor and analyse the sales performance of its products in order to improve its sales and marketing activities.

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19 Case No COMP/M.7337 - *IMS Health/Cegedim Business.*

20 Case No COMP/M.7337 - *IMS Health/Cegedim Business.*

i. The Commission's previous practice

52. The Commission has previously considered that the market for sales tracking data may be split between (i) national prescription data services, (ii) regional prescription data services, (iii) national distribution services, and (iv) regional distribution services. In addition, the Commission has considered that further sub-segmentations could be made depending among others on the type of pharmaceutical product assessed, thus distinguishing between health market research services supplied for prescription drugs as opposed to market research services supplied for OTC drugs. Lastly, the Commission has considered whether the provision of cross-country health market research services (for instance, data recognising the same product despite different trade names) may be distinct from the provision of such services at the single country level, in light of the need for uniformity and quality consistency across countries for such data. However, the Commission has ultimately left the market definition open.[21]

53. As regards the geographic scope of the market, the Commission has previously considered the provision of sales tracking data to be national.[22]

ii. Notifying Parties' view

54. The Notifying Parties did not provide any views as regards the product and geographic market definition of the market regarding sales tracking data.

iii. Conclusion

55. The Commission, on the basis of the results of the market investigation, does not find any reason to depart from the precedents regarding the definition of the relevant markets.

56. In any event, for the purpose of this decision, the exact delineation of the relevant product and geographic market for sales tracking data can be left open, since the Transaction does not give rise to competition concerns under any alternative market definition.

CRM software

57. CRM software helps businesses manage their customer interactions by organising, automating and synchronising data from sales, marketing, customer service and technical functions.

i. The Commission's previous practice

58. The Commission has previously defined a separate relevant product market for CRM software.[23] In addition, the Commission has ultimately left open the question whether CRM services should be further segmented according to specific functions,

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21 Case No COMP/M.7337 - *IMS Health/Cegedim Business*, Case No COMP/D3/38.044 – *NDC/IMS Health.*

22 Case No COMP/M.7337 - *IMS Health/Cegedim Business*, Case No COMP/D3/38.044 – *NDC/IMS Health.*

23 Case No COMP/M.3978 – *Oracle/Siebel*.

for example MDM (Master Data Management) software,[24] or to the industry sector.[25]

59. In previous decisions, the Commission has found that the geographic scope of the market for CRM software could be EEA-wide or worldwide, although the question was ultimately left open.[26]

ii. Notifying Parties' view

60. The Notifying Parties did not provide any views as regards the product and geographic market definition of the market regarding CRM software.

iii. Conclusion

61. The Commission, on the basis of the market investigation, does not find any reason to depart from the precedents regarding the definition of the relevant markets.

62. In any event, for the purpose of this decision, the exact delineation of the relevant product and geographic market for CRM software can be left open, since the Transaction does not give rise to competition concerns under any alternative market definition.

IV. COMPETITIVE ASSESSMENT

63. The Transaction gives rise to a number of horizontal overlaps and non-horizontal relationships between the Parties' activities, in particular:

- The provision of CSO healthcare services (a horizontally affected market)
- The provision of healthcare consulting services (a horizontal overlap);
- The provision of RWE services (a horizontally affected market);
- The upstream provision of RWE data and downstream provision of RWE studies (a vertical link) and;
- The upstream provision of various data/software (sales tracking data, healthcare professional database, CRM software) and downstream provision of various services (RWE services, healthcare consulting services, CSO services, CRO services) - (vertically affected markets).

IV.1. HORIZONTAL OVERLAPS

i. Healthcare marketing services (including CSO services)

64. As regards the provision of marketing communication services (including direct marketing services) to healthcare companies in the EEA, the Parties do not overlap in their activities, because Quintiles is not active in this area. The market share of

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24 Software used by a pharmaceutical company for the purpose of its promotional and sales activities.

25 Case No COMP/M.7337 - *IMS Health/Cegedim Business.*

26 Case No COMP/M.3978 – *Oracle/Siebel* and Case No. COMP/M.7337 - *IMS Health/Cegedim Business.*

IMS Health in this market does not exceed [5-10] % under any plausible market definition (such as national and EEA-wide).

65. As regards CSO services, the Parties' activities overlap at the EEA, as well as at national markets level. EEA-wide, the combined market share of the Parties amounts to [20-30]%; however, the increment, which comes from IMS Health, is less than [0-5]%. At national level, the combined market shares of the Parties in Italy reaches [20-30]%. In Spain, the combined market share of the Parties is [30-40]% and in Poland, the combined market share of the Parties is [10-20]%. For all these markets the increment is less than [0-5]%.

66. The Notifying Party submits that the merged entity will in any event compete with numerous other suppliers of CSO services, at EEA-level as well as at national level, such as Ashfield (EEA-wide: [10-20]%, Spain, [40-50]%), CSO Pharmitalia (EEA-wide [0-5]%-[5-10]%, Italy: [30-40]%) or APC Pharmaceuticals and Chemicals (Europe) (EEA-wide 0-5]%-[5-10]%, Poland: [30-40]%).

67. The Commission notes that the market investigation did not reveal any concerns, neither from competitors nor from customers, in relation to the EEA-wide and national markets for healthcare communication services (direct marketing healthcare services) and CSO healthcare services.

68. Based on the above considerations and on other availabe evidence, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to healthcare communication services (direct marketing healthcare services) and CSO healthcare services in the EEA and in Italy, Spain and Poland.

ii. Healthcare consulting services

69. Both Parties are active on the market for healthcare consulting services, however, the combined market share of the Parties is only [0-5]% at the EEA-level. As regards the national levels and any other plausible market definitions, the Parties' combined market shares never exceed more than [0-5]%. Moreover, the increment in all cases is either [0-5]% or less.

70. The Notifying Parties submits that the Parties are not each other's closest competitors as Quintiles' consulting services business focuses mainly on advices regarding product development advice strategies and transformation, market access and product commercialization and compliance, including clinical trial development support, while IMS Health's consulting offerings, on the other hand, focus primarily on market access and commercialization advice, including on the basis of sales tracking data and operational matters (focused on issues such as the use of technology and outsourcing).

71. Post – Transaction, as submitted by the Notifying Parties, the merged entity will face competition from such companies such as McKinsey with an EEA-wide market share ranging between [20- 30]%, Boston Consulting Group [10 – 20]%, Kantar Health [0-5]%-[5-10]% and IPSOS [0-5]%-[5-10]% .

72. The Commission also notes that the market investigation did not reveal any concerns, neither from competitors nor from customers, in relation to the EEA-wide and national markets for healthcare consulting services.

73. Based on the above considerations and on other availabe evidence, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to healthcare consulting services in the EEA.

iii. RWE Services (RWE studies and RWE data)

74. Both parties provide RWE services to pharmaceutical companies at the EEA level as well as at national level. France, Germany, Italy, Spain, and the United Kingdom together account for more than [80-90]% of the Parties' RWE revenues in the EEA.

75. The combined market shares of the Parties are as follows: EEA-wide [10-20]%; France [10-20]%, Germany [10-20]%, Italy [10-20]%, Spain [5-10]%, and United Kingdom [20-30]%.

76. The Notifying Parties submit that they provide RWE services based on different types of data. IMS Health collects and uses secondary RWE data for the supply of RWE services to pharmaceutical companies while Quintiles collects only primary data within the framework of RWE studies. Such primary data is usually not owned by Quintiles, but by the pharmaceutical companies (or any other sponsors) that commission a given study. Indeed, as regards RWE data used for the supply of RWE services, the respondents to the market investigation suggested that primary and secondary RWE data are rather complementary than substitutable.

77. As submitted by the Notifying Parties, post-Transaction, the merged entity will face competition from numerous competitors, such as ICON, MAPI, PAREXEL, PPD, RTI Health Solutions, and IPSOS all with the market shares ranging between [0-5]%-[5-10]% at the EEA level.

78. The Notifying Parties submit that they were not able to provide market shares of its competitors at national level due to the fact that there is no publicly available market share data available. While it is possible to estimate the Parties' own national market shares based on the Parties' detailed national sales data, such national sales data of their competitors is not available to the Parties. Nevertheless, the Notifying Parties submit that its competitors, such as ICON, MAPI, PAREXEL, PPD, RTI Health Solutions, IPSOS, are all active as suppliers of RWE services in the UK and in other EEA countries.

79. In addition to the existing competitors, the Notifying Parties state that the merged entity will also be constrained by its customers. The customers have either the possibility to use internal resources to collect and analyse RWE data themselves or to sponsor the entry of new RWE service suppliers, as they deem necessary. Indeed, customers who responded to the market investigation indicated the existence of in-house RWE research teams.

80. The Commission also notes that the market investigation did not reveal any concerns, neither from competitors nor from customers, in relation to the EEA-wide and national markets, in particular UK market, for RWE services.

81. Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to RWE services, neither at the EEA, nor at national market level.

IV.2. VERTICAL LINKS

82. The Transaction leads to various vertical links between the provision of RWE data and access to various data bases (sales tracking data, healthcare professional database, CRM Software) where IMS Health is primarily active and the provision of various services (RWE services, Health consulting services, Health marketing services, CRO services) where Quintiles is primarily active.

i. Vertical link between the provision of RWE data and provision of RWE services

83. Access to RWE data is essential to supply RWE studies. While some of the Notifying Parties' competitors have established relationships with upstream data suppliers, others maintain their own internal RWE databases.

84. The question arises as to whether the Transaction would increase IMS Health's ability and incentives to limit third party access to RWE data and, if so, whether this possible conduct is likely to have anti-competitive foreclosure effects.

85. The Notifying Parties claim that there is no risk of input foreclosure as Quintiles is not free to license, or provide third parties with access to primary data it collects; Quintiles does not license secondary data in the EEA; secondary RWE data is available from many sources and IMS Health does not have access to any unique (or exclusive) data sources; many of its competitors also maintain and license RWE databases; and the merged entity has a low market share in downstream RWE services.

86. Similarly, the Notifying Parties state that there is no risk of customer foreclosure, as Quintiles is not a significant customer of secondary RWE data; in situations where Quintiles has sought access to secondary RWE data, it has typically obtained those data directly and not through IMS Health or any of its competitors; and the merged entity will represent only a small share of RWE data demand.

87. In the course of the market investigation, some market participants expressed concerns regarding access to secondary RWE data for the provision of RWE studies, which could be perceived as a critical input.[27] A competitor mentioned that *"IMS Health has the broadest access to country specific RWE assets, some proprietary with others available through collaboration partners within various countries in EEA."*[28] However a majority of respondents to the market investigation stated that the information is also available from other sources than IMS Health.[29] Therefore, it is unlikely that the merged entity will have the ability to foreclose access to RWE data for the provision of RWE studies.

88. The market investigation did not reveal any concerns as regards potential customer foreclosure.

89. Based on the results of the market investigation and the evidence provided by the Notifying Parties, the Transaction does not raise serious doubts as to its

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27 See replies to question 27 of Questionnaire Q 1 Competitors.

28 See replies to question 22 of Questionnaire Q 1 Competitors.

29 Conference calls with market participants held on 2 and 3 August 2016.

compatibility with the internal market regarding access to RWE data and the provision of RWE services in the EEA.

ii. Vertical link between the provision of data/software and the provision of CRO services

90. As described above, IMS Health is active in the provision of various data / CRM software, which may be considered (depending on the project) as input for various downstream activities of Quintiles, such as CRO services, CSO services, healthcare consulting services and RWE services.

91. In addition to the services already discussed above, Quintiles' main business is the provision of CRO services. Its market share amounts to [10-20]% at EEA level. There are various alternative competitors to Quintiles in the EEA, such as Covance with a market share amounting to [5-10]%, PAREXEL [5-10]%, PPD [5-10]%, and ICON [0-5]%.

92. The Notifying Parties state that none of the data or services provided by IMS Health are essential inputs required to enable third parties to compete downstream and that all of the relevant data and services can be obtained from sources other than IMS Health. Besides, IMS Health routinely gives other providers of the services access to data such as sales tracking data, healthcare professional databases, RWE data, and licenses out CRM Software.

93. As regards sales tracking data[30], where IMS Health has a market share amounting to [70-80]% at EEA level[31], the Notifying Parties claim that as such data is also available from sources such as Celtipharm, Datamonitor, GfK, Insight Health, Ipsos, IRI, Kantar Health, Nielsen, Symphony, and TNS, as well as national data providers, such as Accuracy Market Research (Ireland), CAN (Bulgaria), etc., IMS Health does not have access to any unique (or exclusive) data sources. In any event, competitors have access to IMS' sales tracking data through its third party access agreements ("TPAA").[32]

94. The TPAA process worked as follows: the healthcare customer would first submit a TPAA request to IMS Health. IMS Health would then review the request to ensure that the assets were appropriate for their intended use, that the project complied with IMS Health's contractual obligations to its own data providers, and that its intellectual property would be maintained securely. Finally, IMS Health and the third-party would execute a TPAA, which would enable IMS Health's client licensee (i.e., the relevant healthcare company) lawfully to provide the third-party with access to the relevant data.

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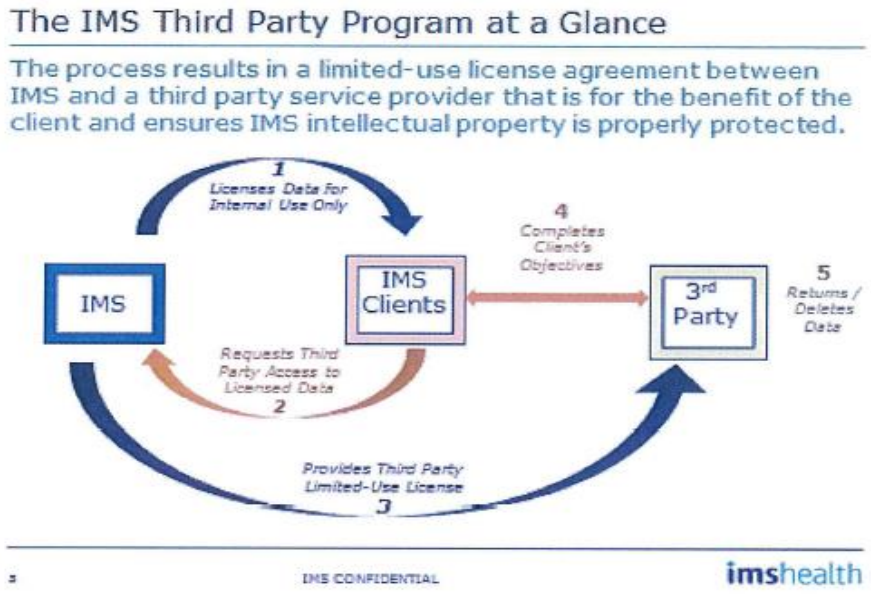
30 IMS provides its sales tracking data to pharmaceutical companies on the basis of a predefined geographical segmentation known as "brick structure".

31 IMS Health has in France [50-60] % market share, in Germany [60-70]%, in Italy [70-80]%, in Spain [80-90]%, and in the United Kingdom [80-90]%.

32 Post-Transaction, the merged entity will have every incentive to continue providing access to sales tracking data, because its customers (healthcare companies) license IMS Health's data in the expectation that they will be free to make it available to their selected third-party service providers.



95. As regards CRM software, where IMS Health has a market share amounting to [30-40]% at EEA level, the Notifying Parties state that such software is available from numerous other providers, such as Veeva, Oracle, Media-Soft, Synergistx, StayinFront, Update, Sage, etc., and that healthcare companies have increasingly sophisticated in-house capabilities that combine off-the-shelf software with their own solutions, therefore IMS Health's CRM software is not essential for downstream competition, and in any event, IMS Health licenses and makes available CRM software to its and Quintiles' competitors, including through TPAAs.

96. As regards healthcare professionals databases, where IMS Health has a market share amounting to [40-50]% at the EEA level, the Notifying Parties state that such data is available from numerous rival suppliers, such as aPureBase and Veeva, and many pharmaceutical companies also maintain their own databases of healthcare professionals, and IMS Health makes its database *OneKey* available to its and Quintiles' downstream competitors through TPAAs.

97. In the course of the market investigation, several CRO service providers expressed concerns regarding access to the above mentioned data sources as well as to secondary RWE data such as prescription data, EMR and other patients' level data. A majority of respondents to the market investigation confirmed that they need access to a large variety of different data sources in order to be able to supply CRO services in the EEA.[33] These databases are used, among others, for the elaboration of the design of the clinical trials and the protocols.

[33] See replies to question 52 of Questionnaire Q 1 Competitors.

98. Indeed, regarding availability of the data, the respondents to the market investigation confirmed IMS Health's argument that the data necessary for CRO service providers in the EEA is either publically available, albeit in a less efficient way, or accessible from other data providers than IMS Health, or CRO service providers have their own databases.[34] A market participant mentioned that "*Each Company has direct access to the set of information associated to their expertise and positioning. All other information is generally acquired from the market*".[35]

99. The Notifying Parties provided evidence illustrating that IMS Health generates only limited revenues from licensing data to CRO service providers in the EEA (less than EUR […] per year during the last three years). This information was confirmed by CRO service providers, including those that expressed concerns regarding the availability of such data.

100. Furthermore, regarding access to sales tracking data, the Notifying Parties submitted evidence that under the TPAA program, access has been systematically granted to any company upon request. In any event, in the EEA, the Notifying Parties also demonstrated that CRO service providers have only occasionally requested access to sales tracking data for their activities in the EEA. This was confirmed by respondents to the market investigation.

101. The Commission therefore considers, on the basis of the results of the market investigation, that IMS Health is currently a negligible supplier of data to CRO service providers in the EEA.

102. Furthermore, the Notifying Parties submit that IMS Health will not have the incentive to limit access to its sales tracking database to competing CRO service providers. This is because pharmaceuticals companies are both the main customer and the most important category of providers for the information contained in the database. Pharmaceutical companies have any interest in being able to freely use the data, including by granting access to CRO service providers. A refusal by IMS Health to provide access to this data downstream would jeopardize IMS Health's relationship with the pharmaceutical companies both as a client and as a raw data provider.

103. Based on the results of the market investigation and the evidence provided by the Notifying Parties, it is unlikely that the merged entity will have the ability or the incentive to foreclose access to essential input for the provision of CRO services. Accordingly, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market regarding access to IMS Health data and the provision of CRO services in the EEA.

iii. Vertical link between the provision of data and the provision of Healthcare consulting services and Healthcare marketing services

104. Sales tracking data, healthcare professionals' database and CRM Software are inputs used for the supply of healthcare consulting services and healthcare marketing services.

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34 See replies to question 53 of Questionnaire Q 1 Competitors.

35 See replies to question 54 of Questionnaire Q 1 Competitors.

105. The Commission considers, on the basis of the results of the market investigation that providers of this type of services have alternative sources to IMS Health data for their activities. Among the alternatives sources, companies have identified IMS Health competitors, namely IPSOS and Symphony, local suppliers, healthcare providers and other public institutions, and in-house databases.[36] As regards the software solutions, competitors' identified alternative providers, among which Oracle, Salesforce, Quickbase were named.[37]

106. Based on the results of the market investigation, it is unlikely that the merged entity will have the ability to foreclose access to essential input for the provision of Healthcare consulting services and Healthcare marketing services. Accordingly, the Transaction does not raise serious doubts as to its compatibility with the internal market regarding access to IMS Health data and the provision of Healthcare consulting services and Healthcare marketing services in the EEA.

IV.3. CONGLOMERATE EFFECTS

107. As mentioned above, IMS Health and Quintiles have an important offering in, respectively and particularly, various types of data/databases/software and CRO services, while both are active in RWE services.

108. The Notifying Parties claim that there is no risk of possible conglomerate effects as (i) the merged entity will face strong competition from alternative providers in every area in which it competes, (ii) the Parties serve different groups within healthcare companies: Quintiles sells mainly to the R&D groups of healthcare companies, while IMS Health sells mainly to their commercial groups, (iii) neither IMS Health nor Quintiles engages in tying or bundling today nor have they done so in the past, (iv) the Parties' customers are large and sophisticated companies that would resist any attempt by the merged entity to bundle services.

109. Respondents to the market investigation suggested that in the next three to ten years, a new format for regulatory product approval, namely "adaptive licensing" could become important. Adaptive licencing was launched by the European Medical Agency ("EMA") as a pilot project in 2014. It aims to improve timely access for patients to new medicines and takes the form of a prospectively planned process, starting with the early authorisation of a medicine in a restricted patient population, followed by iterative phases of evidence gathering (based on RWE data) and subsequent adaptations of the marketing authorisation to expand access to the medicine to broader patient populations.

110. For CRO service providers, this means that the collection of RWE data will become more important in the next years so that eventually RWE data might be as important for product approval as clinical research data. Companies, such as the merged entity, could then have a competitive advantage in the future due to the combination of the two business models of CRO service provider and RWE services and data supplier enabling them to offer such bundled services.

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36 See replies to question 55.2 of Questionnaire Q 1 Competitors.

37 See replies to question 55.5 of Questionnaire Q 1 Competitors.

111. However, as stated by respondents to the market investigation, the process of adaptive licencing is still in pilot phase and affects less than 1% of the current product approval procedures. There is no indication that the importance of adaptive licencing will increase significantly in the foreseeable future, or will become the standard procedure for regulatory approvals. Therefore, the Commission considers that the market investigation did not reveal any concerns in relation to adaptive licensing and the supply of bundled CRO/RWE services.

112. Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to conglomerate effects.

V. CONCLUSION

113. For the above reasons, the European Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission

(Signed)

Violeta BULC
Member of the Commission