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In the published version of this decision, some information has been omitted, pursuant to articles 24 and 25 of Council Regulation (EC) No 659/1999 of 22 March 1999 laying down detailed rules for the application of Article 93 of the EC Treaty, concerning non-disclosure of information covered by professional secrecy. The omissions are shown thus […].

PUBLIC VERSION

WORKING LANGUAGE

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Subject: State aid SA.33866 2011/N – Italy
Aiuto di Stato a favore di Ricerca, Sviluppo e Innovazione per il progetto FAIV (Faster Access to Innovative Vaccines) di Novartis Vaccines S.r.l.

Dear Sir,

1. PROCEDURE

(1) On 7 November 2011, the Italian authorities notified, according to Article 108(3) of the Treaty on the Functioning of the European Union[1] (hereafter "TFEU") the above-mentioned measure to be assessed on the basis of the Community Framework for State aid for research and development and innovation[2] (hereafter "the R&D&I Framework").

(2) The Commission asked for supplementary information by letter dated 21 December 2011 and e-mail of 22 February 2012, to which the Italian authorities replied on 24 January 2012 and 20 March 2012 respectively.

2. DESCRIPTION OF THE MEASURE

2.1. Objective and duration of the project

(3) The notified measure supports a research project called "Faster Access to Innovative Vaccines" (FAIV). The aim of the project is to contribute to the effective and rapid

[1] OJ L 115, 09.5.2008, p. 92
[2] OJ C 323, 30.12.2006, p. 1.

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development of innovative vaccines against infectious diseases and reduce disparity between developed and developing countries as to the accessibility of innovative vaccines.

(4) The project is in particular focused on ensuring that developing countries, especially the African market, gain quicker access to such innovative vaccines at affordable prices, thus responding to currently unmet medical needs.

(5) The objectives of the project are in line with the Millennium Development Goals[3] drawn up by the United Nations in 2000, in particular those which aim to eradicate extreme poverty and hunger (Goal 1), reduce infant mortality (Goal 4), improve maternal health (Goal 5), combat HIV/AIDS, malaria and tuberculosis (Goal 6), and develop a global partnership for development (Goal 8).

(6) The project covers a five-year period from 2012 to 2016.

2.2. The partners in the project

(7) The FAIV project is based on a partnership between Novartis Vaccines & Diagnostics s.r.l. (hereinafter, NV&D) and the Bill & Melinda Gates Foundation (hereinafter, BMGF), a charitable association which promotes initiatives aimed at improving the health of the world's poorest populations.

2.2.1. The aid beneficiary

(8) The beneficiary of the aid is NV&D, a pharmaceutical undertaking active also in the vaccines sector and located in the province of Siena. NV&D will carry out the R&D activities covered by the project. NV&D is part of the pharmaceutical multinational "Novartis International AG" (hereafter, Novartis) located in Basilea (Switzerland), composed of five international divisions. One of these divisions is Novartis Vaccines and Diagnostics Inc. (hereafter, NV&D Inc.), located in Cambridge, Massachusetts (USA), which finances NV&D as the centre of R&D activities for developing vaccines inside Novartis.

2.2.2. The collaboration with the Bill and Melinda Gates Foundation

(9) BMGF will financially support the FAIV project. Under the terms and conditions set out in the collaboration agreement with NV&D, BMGF will propose a set of candidate vaccines to be developed for developing countries' use at a new NV&D's research facility, thus taking advantage of the know-how and expertise of NV&D in the vaccines sector.

2.3. Description of the project

2.3.1. Innovative character and content of the project

(10) The rationale behind the FAIV project is that the vaccine market in developing countries is characterized by a sub-optimal supply both for the type of products available (innovative vaccines) and in terms of timing (i.e., innovative vaccines are introduced in developing countries 10 to 20 years after commercialisation in developed countries). The project will thus seek to reverse the standard process whereby an

3 See http://www.undp.org/content/undp/en/home/mdgoverview.html.

innovative vaccine is produced and introduced initially into developed countries and only several years later into developing countries.

(11) The project concerns only the development of innovative vaccines. Innovation will be present at all the development stages, including testing of novel delivery methods to improve suitability of vaccines for developing countries as well as novel methodologies and processes[4].

(12) Under the project, NV&D will carry out R&D activities on an estimated set of […]* antigens, which is, according to the Italian authorities, the minimum critical mass to launch the project given that the costs of developing new vaccines are linked to their volumes[5]. More specifically, NV&D will research:

a) […] antigens[6] to develop innovative vaccines capable of preventing sicknesses which affect specifically the population in developing countries, which will be distributed directly in those countries and at prices commensurate with local purchasing power (generally low). A swifter distribution of these vaccines will also be favoured by creating the conditions for in situ development through technology-transfer, assistance and training.

b) […] antigens to develop innovative vaccines targeted at both developing and developed countries.

(13) As regards vaccines described in point a) above, NV&D will in particular accept the selection of candidates vaccines proposed by BMGF and may only refuse to do so in specific circumstances, agreed by the parties beforehand (e.g. if the candidate vaccine does not meet certain criteria). In addition, once the required development is complete, NV&D will commit to transfer the relevant technologies to Product Development Partners (hereinafter, "PDPs)"[7] so as to ensure access to the intellectual property needed to produce the vaccine locally at low cost.

(14) As to the vaccines described in point b) above, NV&D will select the candidates in accordance with its own guidelines for prioritizing research and development projects, which are updated each year. For these candidate vaccines, NV&D will commit to determine the best strategy for faster commercialisation in developing countries. In particular, NV&D has committed to ensure that at least 30% of these candidate vaccines

[4] By way of example, NV&D is currently implementing a “Quality by Design” approach, a new concept to scientifically design product and process performance characteristics rather than empirically derive them from performance of test batches.

* Some parts of this text have been edited to ensure that no confidential information was disclosed. These parts are indicated by suspension points in square brackets.

[5] To determine the corresponding number of complete vaccine candidates, it is worth noting that each successful vaccine usually contains more than one antigen (in fact, up to four antigens is common). In the present case, the antigens identified by NV&D correspond to approximately […] new vaccines which would be developed during the period covered by the aid.

[6] These include […] antigens identified by Novartis Vaccines Institute for Global Health (NVGH), a non-profit organization of the Novartis group specialized in the research and development of vaccines for developing countries and […] antigens proposed by BMGF.

[7] The Product Development Partners are research centres financed by BMGF for the development of safe and effective vaccines to prevent infections in developing countries.

will pursue, if successful, a 'FAIV strategy', that is prioritisation of commercialisation in developing countries[8].

2.3.2. Phases of the project

(15) The project will be carried out in two phases consisting of the following activities:

(i) Phase 1. Ramping up of industrial research on new antigens (2012 – 2013)

(16) Over the first two years, the project will focus on intensifying the research activities on the production and purification of protective antigens for infectious diseases and formulation of candidate vaccines. These activities will be carried out in the existing research facility owned by the aid beneficiary. A preliminary stage of the project will consist of identifying those pathogens which in particular affect developing country populations, including bacteria like […]. To this end, a detailed epidemiological survey is planned to identify vaccines which are most needed.

(ii) Phase 2. Experimental development of innovative vaccines (2014 – 2016)

(17) Development activities will be devoted to produce clinical batches of innovative vaccines and, more specifically:

- To develop vaccines containing the most appropriate formulations of protective antigens;
- To set up efficient processes for vaccine production which are suitable for transfer to vaccine manufacturers, in particular those in developing countries;
- To obtain batches suitable for clinical trials under *Good Manufacturing Practises* (hereinafter, "GMP conditions"[9]).

(18) These development activities will be carried out in a new research facility, to be built by NV&D in Rosia (in the province of Siena). At this facility, clinical batches will be produced according to GMP conditions for use in the phase I and phase II of clinical trials. Production of vaccines for commercial use will not be part of the aided project.

2.4. Granting authority and legal basis

(19) The aid will be granted by the Tuscany region from the budget of the "Regional Health Plan".

(20) The legal basis for the aid measure is the Tuscany Regional Council decision no. 848 of 10 October 2011 on State aid to research, development and innovation concerning the FAIV (Faster Access to Innovative Vaccines) project of Novartis Vaccines together with Bill & Melinda Gates Foundation (*Delibera Giunta Regionale Toscana n. 848 del 10 ottobre 2011 sull'aiuto di Stato a favore di Ricerca, Sviluppo e Innovazione per il*

[8] In doing so, NV&D will also seek partnership with other not-for-profit funding agencies to further accelerate access to these vaccines in developing countries.

[9] The manufacture of vaccines will be made in accordance with the Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practices in respect of medicinal products for human use and investigational medicinal products for human use. To develop the candidate vaccines, the production of batches under GMP conditions is an essential factor for clinical trials on human beings.

Progetto FAIV (Faster Access to Innovative Vaccines) con Bill & Melinda Gates Foundation).

2.5. R&D categories and eligible costs

(21) Under the project, NV&D will carry out the following specific research and development activities:

a) Industrial research

- Fermentation, recovery and purification development and scale up of drug substance;
- Execution of a non-GMP production/engineering run for bulk drug substance;
- GMP fermentation, recovery and purification;
- Cleaning validation for phases I and II clinical bulk drug substance;
- Formulation development and scale up for either a liquid or freeze dried final presentation;
- Cleaning validation for phases I and II clinical final drug product;
- Development, qualification and validation of standard analytical methods;
- Execution of a non-GMP production/engineering runs of final drug product.

b) Experimental development

- Supply of filled non-GMP material enabling toxicology studies (up to 2,000 final containers);
- GMP formulation and either fill-finish or fill-finish-lyophilization of up to 10,000 final containers.

(22) The eligible costs of the project, comprising 67% industrial research and 33% experimental development activities, amount to 76.9 million EUR, as specified in the table below.

Table 1. Eligible costs under the FAIV project (amounts in million EUR)

	Industrial research	**Experimental development**	**Total**
Personnel costs	[…]	[…]	[…]
Cost of instruments and equipment	[…]	[…]	[…]
Costs of buildings and land	[…]	[…]	[…]
Costs of contractual research, technical know-how and patents, acquired or obtained in the form of a license from external sources at market prices	[…]	[…]	[…]
Additional overheads	[…]	[…]	[…]

directly attributable to the research project			
Other operating costs	[…]	[…]	[…]
Total	**51.523**	**25.377**	**76.900**

(23) The costs of the project will be subject to accounting checks by Tuscany region or an entity especially designed to that purpose.

2.6. The aid instrument, amount and intensity

(24) The Tuscany region intends to provide a direct grant of 23 million EUR to NV&D to carry out the FAIV project, corresponding to an aid intensity of 30%. The grant will be paid in five instalments amounting to 4.6 million EUR each from 2012 to 2016 and cannot be cumulated with aid from other local, regional, national or EU schemes to cover the same eligible costs.

3. ASSESSMENT

3.1. Existence of aid

(25) According to Article 107(1) TFEU, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, insofar as it affects trade between Member States, be incompatible with the internal market.

(26) The notified grant will be provided by the Italian authorities (the Tuscany region) from the State budget, i.e. it is financed from State resources. It will be granted exclusively to one company, NV&D, which will be relieved from part of the R&D costs that it should otherwise have borne. It thus confers a selective advantage to the beneficiary which is active in a sector that is open to competition and trade between Member States. The aid could improve the financial situation and enhance the market position of the beneficiary, thereby distorting or threatening to distort competition and trade between the Member States. Consequently, the notified measure constitutes State aid within the meaning of Article 107(1) TFEU.

3.2. Legality of aid

(27) The Italian authorities have complied with Article 108(3) TFEU by notifying the aid measure to the Commission and by not putting it into effect until the Commission's authorisation thereof.

3.3. Basis for assessment of compatibility of the aid with the TFEU

(28) According to Article 107(3)(c) TFEU, aid may be compatible with the internal market if it facilitates the development of certain economic activities or of certain economic areas, where such aid does not adversely affect trading conditions to an extent contrary to the common interest.

(29) The R&D&I Framework sets forth criteria based on which the Commission will assess whether aid for certain R&D activities is compatible with the internal market under Article 107(3)(c) TFEU.

(30) The objective of the notified measure is to promote R&D activities (both industrial research and experimental development activities). Such aid falls within the scope of application of the R&D&I Framework, as defined in section 2.1 of that Framework.

(31) The R&D&I Framework provides conditions for two levels of compatibility analysis:

- *A general level of analysis*: Chapters 5 (for this case, particularly section 5.1 Aid for R&D projects), 6 (Incentive effect and necessity of the aid) and 8 (Cumulation) lay down general conditions for the compatibility of R&D aid.

- *A detailed level of analysis*: For aid in respect of which the risk for distortion of competition is higher (e.g. where the aid amount exceeds certain thresholds), a detailed analysis has to be carried out in addition to the general one. Chapter 7 of the R&D&I Framework provides assessment criteria for positive and negative effects of the aid and the balancing of such effects.

(32) The notified measure consists of an ad hoc aid of 23 million EUR for a project of predominantly industrial research. According to section 7.1 of the R&D&I Framework, aid which is covered by the Framework and supports projects in which the supported activities are predominantly industrial research, should be subject to a detailed assessment if the amount exceeds 10 million EUR per undertaking and per project. On that basis, a detailed assessment of the notified aid will be carried out.

(33) In order to carry out its assessment, the Commission first has to identify the aid beneficiary or beneficiaries. In this case, the entire state aid amount was requested by and granted exclusively to NV&D, who will undertake all the relevant R&D activities. The Commission however notes that NV&D does not define its own R&D policy autonomously nor fund it, but rather depends on NV&D Inc. NV&D Inc. is expected, as an independent division, to primarily fund its own growth and maintain a certain level of profitability. Novartis has no other vaccines business than NV&D. NV&D is in fact the centre of R&D activity for bacterial vaccines within NV&D Inc. Therefore, these entities of the Novartis group have aligned incentives in respect of any potential vaccine-related project, and any analysis of vaccine market dynamics and failure would be unchanged if considered from the perspective of either NV&D Inc. or NV&D. Therefore, in order to have a complete analysis of the impact of the aid on the market, the Commission will consider both NV&D and NV&D Inc. as beneficiaries.

(34) The analysis below follows the order of the criteria for detailed assessment, as presented in Chapter 7 of the R&D&I Framework. The assessment of the general conditions is therefore integrated in the appropriate parts of the detailed assessment. More precisely, the fulfilment of the conditions of Chapter 6 regarding the incentive effect and the necessity of the aid is assessed under point 3.4.3, while the compliance with the conditions set out in section 5.1. (Aid for R&D projects) and Chapter 8 (Cumulation) is assessed under point 3.4.4. regarding proportionality.

3.4. Positive effects

3.4.1. Existence of a market failure

(35) According to points 1.3.2 and 7.3.1 of the R&D&I Framework, market failures may prevent the market from achieving an optimal output, and State aid may be necessary to ensure a level of R&D that the market, on its own, would fail to deliver. The level of R&D activities and possible market failures should be analyzed at the EU level.

(36) Unlike many medical products, vaccines present a special challenge in terms of R&D. Because bacteria and viruses are biological organisms, they entail a heavier and more risky investment at the various stages of R&D than most drugs based on chemicals and molecules. They have to be tested on many people before they are licensed, and they are harder to manufacture on a commercial scale in a consistent way. The manufacturing process for each vaccine is different, resulting in a variety of systems for designing and testing efficiency and consistency.

(37) Under current commercial practices, new and innovative products are typically introduced onto the market first in developed countries. After they have been on sale for a period of time sufficiently long to enable manufacturers to recoup the funds invested in R&D and optimize their production process, the product will be introduced onto the market in developing countries, either by exporting the finished product or by transferring technology to local enterprises. This process generally extends over many years and depends on the ability and willingness of developing countries to pay for the vaccine concerned[10].

(38) To the extent that the present project aims at developing innovative vaccines targeting developing countries which entails sales at lower prices and higher risks due to the fact that R&D costs will not be amortized at the normal rate through the traditional system of prior commercialisation in high-yield developed countries, the Italian authorities argue that there is a specific market failure which makes private investors reluctant to finance the project in question due to imperfect and asymmetric information problems (3.4.1.2). In addition, private investors would be unable to appropriate all benefits generated by the project due to knowledge spill-overs and other positive externalities (3.4.1.3).

3.4.1.2. Imperfect and asymmetric information

(39) According to the Italian authorities, researching and developing vaccines targeted at developing countries is a lengthy[11] and costly process, involving huge investments and a high risk of failure. The level of risk connected with the development of a new vaccine is significant: the possibility of failure of any new antigen identified by research is roughly 85% set against huge initial investments (more than 1 billion EUR may be necessary for the whole process of development of each single vaccine) which are unlikely to be recovered if successful vaccines are targeted at developing countries.

(40) Given the level of risks and the extremely high upfront investment, companies usually seek to maximise the return and choose to develop those vaccines that target

[10] The Prevnar® vaccine, for example, was introduced in the US market in 2000 but was launched in developing countries only in 2010 with support of funding from GAVI (Global Alliance for Vaccines Initiative).

[11] Usually, it takes from 10 to 15 years to research, develop and commercialize a vaccine.

predominantly developed countries. In fact, vaccines targeting developing countries face the same technical risks as vaccines targeting developed countries[12], but they have a much higher commercial risk, essentially due to their low adoption percentage[13].

(41) The main barrier to adoption in developing countries is the lack of finance. Vaccines are biological products which require highly specialized machinery and operators to be produced. Another barrier is the lack of adequate infrastructure (the so-called "cold chain")[14] and key personnel, such as qualified health workers or vaccination campaign planners. A third significant barrier is the lack of information on the epidemiology of vaccine-preventable diseases. The lack of such information makes it difficult to justify the allocation of funds to combat these diseases.

(42) Moreover, vaccines targeted at developing countries will be sold at a price commensurate with local purchasing power (i.e. generally low), they are unlikely to provide an acceptable return on investment for a global pharmaceutical player. Even if there is a minimal market for such vaccines in developed countries (e.g. to meet the needs of travellers), this is generally not sufficient to justify the investment.

(43) Consequently, internal financing would not be available to finance the project as a whole because NV&D (and NV&D Inc.) cannot afford to prioritize the development of vaccines targeting specifically developing countries nor pursue a strategy focussing on an accelerated distribution in developing countries.

(44) Furthermore, external financing would not be available for such risky projects that not only face a high probability of technical failure but also follow a commercial strategy that goes against the traditional practices in the industry.

3.4.1.3. Knowledge spill-overs

(45) Apart from general potential benefits for public health, the project would create, if successful, significant knowledge spill-overs, particularly in favour of not-for-profit organisations.

(46) The technical development and production of vaccines under GMP conditions are highly complex processes, which require specific knowledge and skills, access to innovative technologies and appropriate infrastructures. The need to guarantee all these factors at the same time creates a significant barrier for companies not specialized in the sector. The FAIV project will allow not-for-profit organizations sponsored by BMFG to benefit from the advanced technology and the specific knowledge of NV&D. In particular, the project includes a long-term training program for talented young people from low-income countries aimed at enabling them to use innovative technologies to produce vaccines in their countries of origin.

(47) As to the intellectual property rights (IPRs), NV&D will in particular put its patents and innovative technologies at the disposal of the PDPs in their development activities of

[12] However, vaccines for the developing world use may involve additional hurdles when infectious pathogens vary from region to region. A vaccine that works well in a developed country may not be as effective in a developing country.

[13] Report on "Investing in Vaccines for the Developing Countries", PATH (International non-profit organisation for global health).

[14] Vaccines tend to be much more temperature-sensitive than other medical products and can spoil rapidly in the heat. Reliable refrigeration can be difficult in areas that have no electricity or developed transportation systems.

safe and effective vaccines against infectious diseases in developing countries. NV&D will also provide support for the production process to complete the transfer of the technology in question to the PDPs selected for the commercial manufacture of the new vaccine.

3.4.1.4. Conclusion

(48) The Commission concludes that the aid is aimed at correcting specific market failures resulting from imperfect and asymmetric information as well as from knowledge spill-overs and other positive externalities.

3.4.2. Appropriateness of the instrument

(49) An element in the balancing of positive and negative effects of the aid is whether, and to what extent, State aid can be considered as an appropriate instrument to increase R&D activities, given that other less distortive instruments may lead to the same result.

(50) The Italian authorities argue that the support measure will address the imperfect and asymmetric information problems by encouraging the aid beneficiary to pursue the innovative strategy of the FAIV project for the benefit of poor countries' populations.

(51) Moreover, they also claim that support measures like a repayable advance or a State loan would have not increased the profitability of the project at hand to a sufficient level. They affirm that, taking account of the peculiar nature of the FAIV project, only a direct grant can offset the market failures described above.

(52) On that basis, the Commission agrees that State aid in the form of a direct grant is an appropriate instrument in order to overcome the relevant market failures and to enable the implementation of the project.

3.4.3. Incentive effect and necessity of aid

(53) State aid must have an incentive effect, inducing the recipient to change its behaviour and to increase its level of R&D activity. In other words, the planned aid should induce the beneficiary to pursue R&D activities which it would not have pursued otherwise.

(54) As laid down in Chapter 6, second paragraph, of the R&D&I Framework, the aid does not present an incentive for the beneficiary where the R&D activity starts prior to the beneficiary applying for aid to the national authorities.

(55) In the case at hand, NV&D requested the aid on 7 November 2011 and the project has not started to date. There is thus no doubt that the formal condition relating to the presence of an incentive effect is fulfilled in the present case.

(56) However, when a measure is subject to a detailed assessment, the Commission requires that the incentive effect of the aid is substantiated more precisely in order to avoid undue distortion of competition. In its analysis, the Commission takes into consideration the following elements set out in point 7.3.3 of the R&D&I Framework: specification of intended change, counterfactual analysis, level of profitability, amount of investment and time path of cash flows, the level of risk involved in the research project and continuous evaluation. The Italian authorities have provided all elements required under point 7.3.3 of the R&D&I Framework enabling the Commission to assess the incentive effect of the aid.

3.4.3.1. Counterfactual analysis and specification of intended change

(57) According to the Italian authorities, without the aid, the project would not be carried out at all by the beneficiary due to its technological and financial risks. A project on a smaller scale would be of no interest for the aid beneficiary, since the FAIV project needs a minimal critical mass of R&D to achieve its objectives.

(58) As to the counterfactual, the Italian authorities analysed the change in the NV&D's behaviour by comparing how many and what types of vaccines the company would most likely develop as a result of the R&D activities covered by the project.

(59) As shown in the table 3 below, they underlined that, with the aid, NV&D would develop […] vaccines in total: […] vaccines developed from its own portfolio of […] antigens (namely, […] vaccines prioritized and targeted at developing countries only, […] vaccine targeted at both developing and developed countries and […] vaccines targeted at developed countries) and […] vaccines developed from BMGF's and NVGH's portfolios comprising […] antigens and specifically intended for developing countries.

Table 2. Portfolio of vaccines with aid

State aid scenario	**2012**	**2013**	**2014**	**2015**	**2016**	**Total**
BMGF and NVGH vaccines	[…]	[…]	[…]	[…]	[…]	[…]
NV&D vaccines:	[…]	[…]	[…]	[…]	[…]	[…]
- vaccines prioritized in developing countries	[…]	[…]	[…]	[…]	[…]	[…]
- vaccines targeted at both developed and Developing countries	[…]	[…]	[…]	[…]	[…]	[…]
- vaccines targeted at developed countries only	[…]	[…]	[…]	[…]	[…]	[…]
Total	[…]	[…]	[…]	[…]	[…]	[…]

(60) As shown in table 4 below, without the aid, NV&D would develop […] vaccines in total targeting only developed countries. Therefore, in such a scenario, NV&D would not develop […] additional vaccines that specifically target developing countries and […] additional vaccine with mixed potential on both markets. Moreover, with no FAIV project, the additional vaccines developed from antigens proposed by BMGF and NVGH would be dropped altogether.

Table 3. Portfolio of vaccines without aid

No State aid scenario	**2012**	**2013**	**2014**	**2015**	**2016**	**Total**
BMGF and NVGH vaccines	[…]	[…]	[…]	[…]	[…]	[…]

NV&D vaccines:	[…]	[…]	[…]	[…]	[…]	[…]
- vaccines prioritized in Developing countries (FAIV strategy)	[…]	[…]	[…]	[…]	[…]	[…]
- vaccines targeted at both Developed and Developing countries	[…]	[…]	[…]	[…]	[…]	[…]
- vaccines targeted at Developed countries only	[…]	[…]	[…]	[…]	[…]	[…]
Total	[…]	[…]	[…]	[…]	[…]	[…]

(61) In practice, under the current commercialization strategy, NV&D would research and develop a lesser number of vaccines […], targeted exclusively at developed countries. This would imply that an extension to developing countries would occur, if relevant in view of local medical needs, after 10 to 20 years from market launch (i.e. after recovery of NV&D's upfront investments).

(62) The aid would effectively allow a radical change compared to the usual industrial strategy of the aid beneficiary. In fact, the aid will lead the company to undertake additional R&D activities and develop […] new vaccines specifically targeted at developing countries as well as […] new vaccines subject to the FAIV strategy.

3.4.3.2. Level of profitability

(63) According to point 7.3.3 of the R&D&I Framework, if a project would not in itself be profitable to undertake for a private undertaking, but would generate important benefits for society, it is more likely that the aid has an incentive effect.

(64) The FAIV project as a whole would not be profitable if NV&D were to embark on it without the financial support from the Tuscany region and the financial contribution from BMGF.

(65) To support this conclusion, the Italian authorities firstly analysed the different return on investments made by a single vaccine depending on its destination in: 1) developing countries only; 2) both developed and developing countries; and 3) developed countries only. This analysis was based on the experience gathered by NV&D and not on classic business plans. NV&D has declared that they do not make any business plans at this early stage of R&D, as this would be too theoretical in view of the estimated 85% failure rate of this type of R&D activities. Instead, they use qualitative criteria to rigorously assess the potential revenues of any new vaccine and determine the right development strategy.

(66) The data presented in Table 4 below show in particular that a typical vaccine commercialised only in developed countries with peak annual revenues of 300 million USD can achieve a reasonable return of about […] %. By contrast, a vaccine targeting only developing countries will not achieve a sufficient rate of return on investment due to its lower revenue potential (assuming peak sales of 100 million USD).

Table 4. Main financial data for vaccines commercialized in different markets

Vaccines market	Hurdle rate	IRR	Peak revenues
Vaccines for developing countries	[10%-20%]	[0%-10%]	100M$
Vaccines for both developed and developing countries	[10%-20%]	[10%-20%]	400M$
Vaccines for developed countries only	[5%-15%]	[10%-20%]	300M$

(67) The hurdle rate is also different between the two vaccines: […] % return is a typical hurdle rate used by NV&D for internal projects. The required hurdle rate would be significantly higher for projects focusing on developing countries, i.e. […] % or higher, due to the lower income from sales in developing countries. Moreover, the IRR is expected to be as low as […] % and NPV will therefore be […].

(68) Considering the content of the FAIV project and the lower economic attractiveness of vaccines targeted at developing countries, the Italian authorities argued that the aid will allow NV&D to reach the IRR of about […] %, which is the minimum required excess over the hurdle rate ([…] % under the ordinary industrial strategy) to proceed with the investment.

(69) Therefore, the Commission can conclude that the Italian authorities, by providing the grant, are raising the project's return on investment to the level that is necessary and sufficient to undertake the project, with due regard to the risk of failure and taking into account potential benefits to public health and other knowledge spill-overs connected with the project.

3.4.3.3. Investment amount and cash-flow

(70) High start-up investment, low level appropriable cash flows and a significant fraction of cash flows arising in the long-term are considered positive elements in assessing whether the aid has an incentive effect.

(71) The total costs of the project will be 76.9 million EUR spread over a five-year period, excluding the costs of construction of the research facility. Given the long-term horizon connected with researching, developing and, eventually, marketing a vaccine, and the low economic attractiveness of vaccines targeted at developing countries, it would take many years for any revenue to come in. It can therefore be excluded that the aid beneficiary could have financed the project in the absence of the aid.

3.4.3.4. Continuous evaluation

(72) Measures which define well specified milestones resulting in the project being terminated in the event of failure or where a publicly available ex-post monitoring is foreseen will, according to point 7.3.3 of the R&D&I Framework, be considered more positively as regards the assessment of the incentive effect.

(73) In accordance with Article 11 of the Tuscany regional law 20/2009[15], the Tuscany region will undertake a scientific assessment carried out by highly qualified and independent experts, selected outside the regional research network, to check the state of play and the achievement of the objectives of the project. The costs of the project will also be subject to accounting checks by the competent regional authorities or a body designed for that purpose. The project under examination is thus subject to continuous evaluation.

3.4.3.5. Conclusion

(74) In light of the above, given the project's high up-front investment costs, important risks and the low financial attractiveness of vaccines targeted at developing countries, the project would not be carried out without the aid. Consequently, the Commission can conclude that the aid has an incentive effect and enables the implementation of the project.

3.4.4. Proportionality of the aid

(75) Section 5.1 of the R&D&I Framework sets out general conditions for analysing the proportionality of State aid for R&D projects. Compliance with these rules is examined in section 3.4.4.1 below, as regards research categories and eligible costs and in section 3.4.4.2 for aid intensity.

(76) The R&D&I Framework states that additional information is necessary to demonstrate the proportionality of aid above certain thresholds in accordance with point 7.3.4 of the R&D&I Framework. Compliance with these rules is assessed under section 3.4.4.3.

(77) Finally, compliance with the cumulation rules set out in Chapter 8 of the R&D&I Framework is assessed in section 3.4.4.4.

3.4.4.1. Research categories and eligible costs

(78) In accordance with point 5.1.1 of the R&D&I Framework, the aided part of the research project must completely fall within one or more of the following research categories: fundamental research, industrial research, experimental development.

(79) According to point 5.1.1 of the R&D&I Framework, the Commission will refer to its own practice as well as to the Frascati Manual[16] in its classification of different R&D activities. According to point 130 of the Frascati Manual, phases 1 and 2 of clinical trials are usually treated as R&D for the purposes of international comparison.

(80) Under the FAIV project, the production and purification of protective antigens for infectious diseases and formulation of candidate vaccines were classified as industrial research, while the production of clinical batches of innovative vaccines for use in phases 1 and 2 of clinical trials were classified as experimental development.

[15] Article 11 of the Tuscany regional law 27 April 2009 concerning "Provisions on research and innovation" (O.J. no. 15, Part I, 6 May 2009).

[16] The Frascati Manual on "The Measurement of Scientific and Technological Activities, Proposed Standard Practice for Surveys on Research and Experimental Development" (Organisation for Economic Co-operation and Development, 2002).

(81) An examination of the activities to be undertaken during the project allows the Commission to conclude that they comply with the definition of industrial research and experimental development given respectively in point 2.2 (f) and (g) of the R&D&I Framework.

(82) The Commission has also verified that the eligible costs specified in the notification are in line with the eligible costs listed in point 5.1.4 of the R&D&I Framework:

- personnel costs are included to the extent that researchers, technicians and other supporting staff are employed on the research project;
- the only costs included for instruments, equipment, buildings and land are the costs corresponding to the life of the research project, as calculated on the basis of good accounting practice;
- costs of contractual research, technical knowledge and patents are bought or licensed from external sources at market prices; and
- other operating expenses include e.g. the costs of materials and consumable supplies for the experimental development phase.

(83) The Commission can, therefore, conclude that the proposed aid is in compliance with points 5.1.1 and 5.1.4 of the R&D&I Framework.

3.4.4.2. Aid intensity

(84) According to point 5.1.2 of the R&D&I Framework, the maximum allowed aid intensity for industrial research and experimental development activities is respectively 50% and 25 %. In this particular case, about two thirds of all eligible R&D costs fall within the definition of industrial research. The beneficiary of the aid is, in accordance with the definition provided in Commission Recommendation concerning the definition of micro, small and medium-sized enterprises[17], a large enterprise. The maximum allowed weighted aid intensity would thus be 41 %. As shown in section 2.6. above, the support for the project will amount to around 30% of NV&D's eligible costs. The aid intensity in this case is therefore below the one allowed by the R&D&I Framework.

3.4.4.3. Aid limited to the minimum necessary

(85) In addition to the general provisions regarding proportionality, in cases requiring a detailed assessment the Commission assesses whether the aid is limited to the minimum amount necessary to implement the project in accordance with point 7.3.4 of the R&D&I Framework.

(86) Although there was not an open selection process in the case at hand, the aid amount is the minimum required by the beneficiary to carry out the project according to the Italian authorities. In their view, the aid is not only limited to, but significantly below, the maximum allowed under the R&D&I Framework. Furthermore, the grant does not render the project as much as profitable for the beneficiary as it would be the alternative consisting in focussing R&D activities on products designed primarily for developed markets.

[17] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, OJ L 124, 20.5.2003, p. 36

(87) In the light of the above, the Commission considers the aid to be proportional and limited to the minimum necessary to induce NV&D to change its industrial strategy and engage in the implementation of the FAIV project

3.4.4.4. Cumulation of aid

(88) According to Chapter 8 of the R&D&I Framework, the aid ceilings fixed in that Framework apply regardless of whether the aid is financed entirely from State resources or is partly financed by the EU. The Italian authorities have confirmed that the aid measure at hand cannot be cumulated with aid received from other local, regional, national or EU schemes to cover the same eligible costs. The conditions set out in Chapter 8 of the R&D&I Framework are thus met.

3.4.4.5. Conclusion

(89) The aid intensity is below the maximum allowed by the R&D&I Framework, the aid amount is limited to the minimum necessary and cannot be cumulated with other aids for the same eligible costs. The Commission thus finds that the aid is proportionate.

3.5. The distortion of competition and trade

(90) As set out in section 7.4 of the R&D&I Framework, the Commission focuses its analysis of the distortions of competition on the foreseeable impact the R&D aid has on competition between undertakings in the product markets concerned. The relevant market for the case at hand is identified in section 3.5.1 below.

(91) In the following sections, the potential effects of the aid on this market will be analysed. As set out in point 7.4, fifth paragraph, of the R&D&I Framework there are three distinct ways in which R&D aid can distort competition in product markets: it can distort the dynamic incentives of market players to invest (section 3.5.2), it can create or maintain positions of market power (section 3.5.3) and it can maintain an inefficient market structure (section 3.5.4).

3.5.1. Identification of the relevant market

(92) As regards vaccines or medication in general, the Commission practise is that the analysis of market share is carried out at the level of Anatomical Therapeutic Chemical classification (ATC) 3[18], based on the intended use of medication. This implies that evaluating the market share of the aid beneficiary for future vaccines is not possible because the research is currently not sufficiently advanced to know what vaccines will eventually be developed. The relevant market considered is therefore that of production of vaccines for preventable diseases.

(93) The market of vaccines is a world market. In 2010, the total vaccines market was worth 22.8 billion $, excluding one-off sales of the influenza pandemic vaccine. The vaccines market is currently dominated by five multinational companies, sharing roughly 85% of the total market. NV&D Inc. ranks as the fifth in terms of market share, behind

[18] Anatomical Therapeutic Chemical classification (ATC), devised by European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and Intercontinental Medical Statistics (IMS). The ATC is hierarchical and has 16 categories (A, B, C, D, etc.) each with up to four levels. The first level (ATC 1) is the most general and the fourth level (ATC 4) the most detailed. The third ATC level allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use.

GlaxoSmithkline, Sanofi Pasteur, Merck and Pfizer, in that order. In the first quarter of 2011, NV&D had a global market share of […] % ([…] % in Europe).

3.5.2. Distorting dynamic incentives

(94) According to the R&D&I Framework, the main concern related to R&D aid is that competitors' dynamic incentives to invest may be undermined by such aid. When an undertaking receives aid, this generally increases the likelihood of successful R&D of that undertaking leading to a future increased presence on the product market. This may lead competitors to reduce the scope of their original investment plans (crowding out).

(95) In its analysis of the potential distortion of dynamic incentives, the Commission considers the following elements: aid amount, closeness to the market, exit barriers, incentives to compete for a future market, product differentiation and intensity of competition.

3.5.2.1. Aid amount

(96) In nominal terms, the maximum aid amount is EUR 23 million, which will be disbursed over five years (from 2012 to 2016). Although the aid amount is significant in itself, the Italian authorities claimed, as described in paragraph 86, that the aid is strictly limited to the minimum necessary. This should limit any distortive effects that the aid may have.

(97) Moreover, the amount of state aid proposed is not significant when compared to the total amount invested in research and development by bigger companies in the vaccines sector. Compared to its four main competitors, the R&D amount spent by Novartis is relatively small. In 2010, for example, Novartis spent a total of around […] million USD (about […] million EUR) on research and development as opposed to Sanofi Pasteur[19] which invested approximately […] million USD (about […] million EUR) or Glaxo SmithKline[20], the market leader in the vaccines field, which invested roughly […] million USD (about […] million EUR). Therefore, the envisaged state aid is not likely to upset the balance between the relevant market actors in any significant way, by undermining rival companies' incentives to invest.

3.5.2.2. Closeness to the market

(98) The more the aid measure is aimed at R&D activities close to the market, the more it is liable to develop significant crowding out effects.

(99) In the case at hand, given that the project covers predominantly industrial research activities, the R&D activities concerned cannot be considered as being close to the market. Moreover, it will take several years before the future products will be ready for market launch, the success of which is still very uncertain at the present stage of R&D, due to very high rate of failure characterizing this type of products.

(100) In particular, the process of identification and production of new antigens usually takes from two to four years and costs between […] million USD. At this stage, the success rate of R&D is […] %. Moreover, the initial development (Phase I) comprises trials on

[19] See http://en.sanofi.com/Images/29618_20120208_2011_Results_EN.pdf.

20 See http://www.gsk.com/investors/reports/q42010/q42010.pdf

animals and clinical trials with human volunteers, and takes a further two to three years. The cost of taking a vaccine to this stage is around […] million USD, and the likelihood of success is still less than […] %. The next stages of development (Phases II-III) take a further two to five years. The total cost at this point is somewhere between 500 and 1,000 million USD. A vaccine which overcomes these obstacles will have a success rate of around […] %. Finally, the regulatory procedures to obtain a sales license typically take a further one to three years, and only at that point, the clinical development of the vaccine is completed. It should be noted that, once the sale license has been obtained, the authorizing bodies normally issue specific recommendations before a vaccine can be effectively adopted by the market, which can further delay the actual commercialization of the product[21].

(101) As to vaccines targeted at developing countries additional costs and risks need to be taken into account, given in particular that target countries may find it difficult to afford them. In addition, the clinical development of a vaccine may be even riskier and take longer if the pathogen concerned is widespread only in countries or regions with deficient health systems, as is often the case in such countries.

3.5.2.3 Exit barriers

(102) Point 7.4.1 of the R&D&I Framework indicates that the existence of exit barriers may reduce distortions of competitors' dynamic incentives. The reason is that competitors are more likely to maintain (or even increase) their investment plans when exit barriers to the innovation process are high. This may be the case when many of the competitors' past investments are locked in to a particular R&D trajectory.

(103) As described in paragraph 97, other actors have already undertaken high R&D investments, which create relatively high exit barriers in the vaccine markets. Due to the long term commitment that these companies have made to their projects, it is unlikely that they would abandon them as a result of the success of the project under assessment.

(104) Moreover, in the vaccines sector, high risk connected with R&D projects favors a situation in which, for every pathogen, many different approaches to developing a vaccine are being tried at the same time, both within a certain company and between competing companies. It is therefore unlikely that an increase in NV&D's development capacity and activity would result in competitors abandoning their plans to develop competing vaccines.

3.5.2.4. Incentives to compete for a future market

(105) R&D aid may lead to a situation where competitors of the aid beneficiary renounce competing for a future market, because the advantage provided by the aid reduces the possibility for them to profitably enter this future market.

(106) In the case at hand, it is unlikely that the aid under consideration will discourage competitors to invest in the vaccines market in the future.

[21] See e.g. the report "Investing in Vaccines for the Developing world" edited by the non-profit organisation PATH, which confirms estimated costs of $500-$1 billion to develop a new vaccine (http://www.path.org/publications/files/VAC_vacc_invst_fs.pdf).

(107) The vaccine market is growing. It will be worth […] billion USD by 2016 with an expected increase in turnover of […]% per year[22] and it will continue to grow rapidly thereafter. Recently, strong multinationals entered the vaccines market through companies' acquisition (Johnson&Johnson acquired Crucell and Pfizer acquired Wyeth). These acquisitions give a clear indication of the strong competition for the future vaccines markets, where sales of existing vaccines are increasing and there are credible prospects for new market launches of innovative vaccines in the years to come.

(108) On that basis, the Commission concludes that there is no significant risk that the aid will discourage competitors to compete on the relevant markets in the future.

3.5.2.5. Product differentiation and intensity of competition

(109) According to point 7.4.1 of the R&D&I Framework, where product innovation concerns developing differentiated products (related e.g. to distinct standards, technologies and consumer groups) and when there are many effective competitors on the market, competitors are less likely to be affected by the aid.

(110) With very few exceptions, all the vaccines already on the market or under development have two or more competitors. Vaccines developed to combat the same pathogen by different companies are deemed to be completely interchangeable, both by the doctors responsible for prescribing them and the bodies which reimburse the costs of purchase. This has clear benefits for buyers, who typically enjoy a strong bargaining position as described in point. 3.5.3.3 below, and can adopt competitive tendering mechanisms to drive prices down. This situation leads in turn to fierce competition between vaccines manufacturers to promote and differentiate their products, thus resulting in a strong incentive to innovate[23].

(111) Therefore, it is unlikely that the aid will stifle the intensity of competition.

3.5.2.6. Conclusion

(112) Although R&D aid may have potential crowding out effects, this is counter-balanced in the case at hand by several factors, namely the relatively limited aid amount, the relatively high exit barriers and the level of competition on the relevant market, which is also expected to considerably grow at a rapid pace. It can thus be concluded that the aid will not have the effect of distorting the dynamic incentives of competitors.

3.5.3. Creating market power

(113) As mentioned in point 7.4.2 of the R&D&I Framework, aid in support of R&D may have distortive effects in terms of increasing or maintaining the incumbent's market power, i.e. the power to influence prices, output, the variety or quality of goods and

[22] These figures are based on Novartis analysis of sales and forecasts from external sources, mainly, Evaluatepharma (http://www.evaluatepharma.com/default.aspx), an independent third party data provider. The link to the database cannot be disclosed since Novartis can access it under a license agreement with the company.

[23] By way of example, Pfizer managed to win significant market share with its Prevnar® vaccine, the class of vaccines developed to combat the Pneumococcus bacterium, which was originally developed to protect against seven different strains of Pneumococcus. GlaxoSmithKline subsequently launched a vaccine which protects against ten different strains of Pneumococcus, and Pfizer has recently responded with a product that protects against thirteen.

services, or other parameters of competition on the market for a significant period of time, to the detriment of consumers.

(114) The Commission is concerned mainly about those R&D measures allowing the aid beneficiary to transfer or strengthen market power held on existing product markets to future product markets. The Commission is therefore unlikely to identify competition concerns related to market power in markets where each aid beneficiary has a market share below 25% and in markets with a market concentration with Herfindahl-Hirschman Index (HHI) of below 2000.

(115) In its analysis of creation of market power, where relevant the Commission takes into account the following elements: market power of aid beneficiary and market structure, level of entry barriers, buyer power and the selection process.

3.5.3.1. Market power of the beneficiary and market structure

(116) Where the recipient is already dominant on a product market, the aid measure may reinforce this dominance by further weakening the competitive constraint that competitors can exert on the recipient undertaking. Similarly, state aid measures may have significant impact in oligopolistic markets where only a few players are active.

(117) In the first quarter of 2011, NV&D's share in the overall vaccine market was […] % worldwide and […] % in Europe. For the sake of comparison, the European market share of GlaxoSmithkline, the world leader in vaccines production, was […] %. Taking also into account the dynamics of the vaccines market as described in points 3.5.1 and 3.5.2.4 above, it is unlikely that the aid would significantly strengthen the company's position in the relevant market to the detriment of rival companies.

3.5.3.2. Level of entry barriers

(118) In the field of R&D, significant entry barriers may exist for new entrants. These barriers include legal entry barriers (in particular intellectual property rights), economies of scale and scope, access barriers to networks and infrastructure, and other strategic barriers to entry or expansion.

(119) Whilst the vaccines market has always been characterized by significant barriers to entry (such as intellectual property, specific knowledge and intensity of investment), the main players in the market are increasingly threatened by companies located in emerging markets (e.g., China and India), which are able to produce vaccines at lower costs and are especially competitive in their home markets. Furthermore, companies in emerging economies are becoming more proactive in R&D activities and more and more capable of developing innovative vaccines locally[24].

3.5.3.3. Buyer power

(120) A salient feature of the vaccines market is that the major buyers are generally institutional customers which adopt refined purchasing systems. Very often, these

[24] In 2010, for example, the Serum Institute of India launched MenAfrivac, a vaccine to combat the type-A meningococcus bacterium in African countries, developed with support from the Meningitis Vaccines Partnership.

buyers are public authorities, which purchase vaccines through tender procedures, thus ensuring fierce competition among suppliers (especially as regards prices) and incentivizing product differentiation. The Italian authorities have reported in this respect that […] % of NV&D's sales in 2010 were made to governments or government agencies.

(121) In case of distribution to developing countries, the major purchasers are again institutions (GAVI, UNICEF and PAHO, for instance), which buy most of their vaccines, in volume terms, from companies producing them at low cost in those countries. As explained above, the strong position of these institutional buyers puts further competitive pressure onto undertakings.

3.5.3.4. Conclusion

(122) Taking into consideration in particular the position currently held by the beneficiary on the relevant market, the fact that the vaccines market is expected to considerably grow in the near future, and that the buyers on the vaccines market have significant market power, the Commission finds that the aid is not likely to reinforce, maintain or create significant market power in favour of the beneficiary.

3.5.4. Maintaining inefficient market structures

(123) R&D aid must not support inefficient undertakings and thus lead to market structures where many market players operate significantly below efficient scale. In its assessment of the market structure, the Commission will consider whether the aid is granted in markets featuring overcapacity, in declining industries or in sensitive sectors. Concerns are less likely in situations where R&D aid aims at changing the growth dynamics of the sector, notably by introducing new technologies.

(124) Based on its Annual Report of 2011, NV&D and NV&D Inc. are not companies in difficulties nor inefficiently run. The net sales of the independent division NV&D Inc. amounted to 1996 million USD with a growth rate of 22% compared to 2010[25] and its own core operating income[26] was of 135 Million USD. The number of employees also increased from 5394 FTE in 2010 to 6122 FTE in 2011.

(125) Moreover, the vaccines market is not in decline, but, on the contrary, is expected to continue to grow considerably during the coming years. The Commission hence finds that there are no indications that the aid would contribute to maintaining inefficient market structures. On the contrary, the FAIV project might contribute, if successful, to the introduction of innovative new vaccines onto a market in rapid expansion.

3.6. Balancing test

(126) Pursuant to section 7.5 of the R&D&I Framework, the Commission balances the effects of the measure in light of the positive and negative elements assessed above and determines whether the resulting distortions adversely affect competition and trading conditions to an extent contrary to common interest.

[25] The comparison does not take account of the impact of A (H1N1) pandemic flu vaccines sales in 2010.

[26] The core operating income excludes the impact of acquisition-related factors and other significant exceptional items or events.

(127) Following a detailed assessment, the Commission considers that the project suffers from market failure since the market would not deliver the product without aid because of imperfect and asymmetric information, linked to the level of technological and commercial risks of the project, and to the inability to appropriate knowledge spill-overs and other positive externalities. Being necessary for the project to be carried out, the notified aid has a clear incentive effect and is moreover limited to the minimum necessary and proportionate. Due to the peculiar features of the vaccines market and its expected growth in the next future, on one side, and the limited market shares of the beneficiary, on the other, the negative effects of the aid are limited. Thus, the aid measure does not support the creation of a position of market power nor maintain inefficient market structures.

(128) Since the positive effects of the measure significantly outweigh its negative effects, the Commission finds that the balancing test for the aid under assessment is positive.

4. DECISION

(129) The Commission considers the notified aid compatible with Article 107(3)(c) TFEU and has accordingly decided not to raise objections to its implementation.

(130) The Commission reminds the Italian authorities of their obligations to submit an annual report on the implementation of the aid measure.

(131) The Commission further reminds the Italian authorities that, in accordance with Article 108(3) TFEU, all plans to alter the project must be notified to the Commission.

If this letter contains confidential information, which should not be disclosed to third parties, please inform the Commission within fifteen working days of the date of receipt. If the Commission does not receive a reasoned request by that deadline, you will be deemed to agree to the disclosure to third parties and to the publication of the full text of the letter in the authentic language on the Internet site:

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Your request should be sent by registered letter or fax to:

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Yours faithfully,
For the Commission

Joaquin ALMUNIA
Vice-President of the Commission