Annex - e-Submission application

The tender should be submitted electronically using the e-Submission application, available on the e-Tendering website. Tenders should be submitted within the time limit for receipt of tenders indicated in the invitation to tender.

Make sure your tender is submitted on time. To avoid any complications with regard to late receipt/non receipt of tenders within the deadline, you are advised to submit your tender several hours before the deadline. A tender received after the deadline indicated in the procurement documents will be rejected.

1. STEP BY STEP E-SUBMISSION

The e-Submission application allows economic operators to respond to calls for tender by preparing their tenders electronically in a structured and secured way, and to submit their tenders electronically. The e-Tendering environment is the starting point for launching the e-Submission application.

The e-Submission platform can be accessed by consulting the corresponding call for tender in e-Tendering at the following link:
https://etendering.ted.europa.eu/cft/cft-display.html?cftId=2025

If you do not have account in the European Commission Authentication System (ECAS), you will be requested to create an account to access to e-Submission application. See 'How to create an ECAS account' for more details at: https://webgate.ec.europa.eu/cas/eim/external/register.cgi

1.1 Testing the e-Submission application

In order to familiarise yourself with the system and to test whether your workstation configuration is working correctly with the e-Submission environment, you may use the following test environments at:

Option 1 - Procurement procedures without lots
https://webgate.ec.europa.eu/supplier_portal_toolbox/spots/openSpots.do?CFTUUID=TEST_CFT_2016-NO_LOTS&VERSION=1&CAID=5790001791483&screenWidth=1000&screenHeight=850

Option 2 - Procurement procedures with lots
https://webgate.ec.europa.eu/supplier_portal_toolbox/spots/openSpots.do?CFTUUID=TEST_CFT_2016-3_LOTS&VERSION=1&CAID=5790001791483&screenWidth=1000&screenHeight=850

This will enable you to make a test submission well in advance of the time limit for receipt, as indicated in the invitation to tender letter.

Please note that data and documents uploaded through the test environment are not taken for consideration for a timely submission of the tender.

1.2 Step a: Access to the e-Submission application

After log-on in with your ECAS password, e-Tendering will display a button 'Submit a tender' and you will be able to access e-Submission. When accessing the application for the first time, you are requested to accept the terms & conditions and acknowledge the privacy statement of the e-Submission portal.

1.3 Step b: Welcome to the tender

The information and documents requested in the tender specifications should be provided using the e-Submission application. In the e-Submission application, please fill in all mandatory fields, marked with a *. Other fields should be completed as appropriate. Tenders must be clear, complete and consistent with the requirements laid down in the tender specifications, including the instructions in this annex.

1.4 Step c: Tendering data

You can either create a tender for the first time or load a draft tender created by you previously from your local disk.

Options 1 to 4 below describe the different ways to submit a tender. Please make sure the required documents and evidence are submitted with your tender.

Option 1: Submission by one tenderer: 'sole tender' in the e-Submission application.
Option 2: Submission by a group: 'joint tender' in the e-Submission application. In case of a group (joint tender) one member of the group must be designated as leader ('joint tender leader' in the e-Submission application).
Option 3: Submission by one tenderer with subcontractors: 'sole tender; involving subcontracting' in the e-Submission application**.**
Option 4: Submission by a group with subcontractors: 'joint tender; involving subcontracting' in the e-Submission application.

The administrative information concerning the tenderer should be provided for all the entities participating in the bid, in accordance with section 4.2.1 of the Tender Specifications.

1.5 Step d: Qualification – Exclusion criteria

For instructions, please refer to section 4.2.2 of the Tender Specifications.

1.6 Step e: Qualification – Selection criteria

For instructions, please refer to section 4.2.3 of the Tender Specifications.

1.7 Step f: Tender

a. Technical tender

For instructions please refer to section 4.2.4 of the Tender Specifications.

b. Financial tender

For instructions please refer to section 4.2.5 of the Tender Specifications.

1.8 Step g: Tender validation

To continue your submission, please click on 'validate'. A tender preview document will be generated on your local computer. This document is for your records only.

1.9 Step h: Consolidation of tender documents

Once all information and documents have been encoded and uploaded in the e-Submission application, and once you consider that the tender is complete, the application requires to create the consolidated tender package. A tender preparation report will be generated by the e-Submission application.

The application will instruct you to save both files (i.e. the consolidated tender package and the tender preparation report) on your local computer.

The tender preparation report must be signed, using one of the following possibilities:

a) Hand signature (preferably in blue ink): Print out the tender preparation report. The report should be hand signed by an authorised representative of the sole tender or the leading tenderer. The signed document should be scanned and uploaded in the e-Submission application.

In addition, the original of the hand signed tender preparation report must be sent by post, immediately after submission, to the following postal address:

European Commission
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Invitation to tender No: 590/PP/GRO/SME/16/F/121
Directorate F – Financial Team
Office address: N105 09/23
B-1049 Brussels, Belgium

b) Electronic signature: you may sign electronically with advanced electronic signature based on qualified certificates: the electronically signed tender preparation report must be uploaded in the e-Submission application.

For more details on the electronic Signature policy, please find below: https://webgate.ec.europa.eu/supplier_portal_toolbox/esubmissionFileProject/files/BT3/essiSignaturePolicy/essiSignaturePolicy_en.pdf

When you attach the tender preparation report, verify that it corresponds to the tender ID displayed on the screen. The contracting authority may reject your tender if you attach a tender preparation report with a different tender ID.

1.10 Step i: Submitting the tender

In order to submit the tender, both (i) the consolidated tender package; and (ii) the electronically signed or scanned hand signed tender preparation report need to be uploaded into the e-Submission application.

To start the submission of your tender, click on 'submit tender'. Please note that by clicking 'submit tender', no more changes can be made to the tender. The system will send a tender receipt confirmation to your e-Submission mailbox, indicating the timestamp put on your tender by the e-Submission system. This timestamp indicates the official time of receipt of the tender and will constitute proof of compliance with the deadline indicated in the invitation to tender.

2. RE-SUBMISSION OR ALTERNATIVE TENDER

After submitting a tender, but within the time limit for receipt of tenders, you may still resubmit the tender. To this end, generate a new consolidated tender package containing the corrected tender documents and resubmit.

In addition, a signed notification should be sent, stating that the previous tender is withdrawn. This notification should be sent by letter to the following postal address:

European Commission
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Invitation to tender No: 590/PP/GRO/SME/16/F/121
Directorate F – Financial Team
Office address: N105 09/23
B-1049 Brussels, Belgium

3. WITHDRAWAL OF TENDERS

If, after submission, you wish to withdraw your tender, you must send a scanned copy of a signed letter to this e-mail address: grow-dir-f-financial-team@ec.europa.eu identifying the name and reference of the tender (including Tender ID) you wish to withdraw. This notification must be signed by the same authorised legal representative(s) who previously signed the tender in question.

4. DEADLINE FOR RECEIPT OF TENDERS

The tender, including the electronically signed or hand signed scanned copy of the tender preparation report, must be fully uploaded, sent and received within the deadline for receipt of tenders indicated in the invitation to tender.

Please note that it is the responsibility of the tenderer to ensure that the complete tender reaches the destination in due time.

In case of problems with the submission of the electronic tender, we recommend to call the helpdesk, as identified in the e-Submission application, in reasonable time before the time limit for receipt. The time it takes to submit the tender and upload documents may vary considerably depending on the number of concurrent submissions by other economic operators, the size of your tender and the internet service used.

If the contracting authority detects technical defects in the functioning of the e-Submission application, due to which it is impossible to electronically submit and receive tenders, you will be informed of the extension of the time limit by the contracting authority at:

https://etendering.ted.europa.eu/cft/cft-display.html?cftId=2025

For more information on e-Submission, please find below the link to the user manual and frequently asked questions:
https://webgate.ec.europa.eu/supplier_portal_toolbox/esubmissionFileProject/files/BT3/spotsHelpPage_en.html

EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Directorate F: Innovation and Advanced Manufacturing

CALL FOR TENDER

590/PP/GRO/SME/16/F/121

STUDY ON THE ECONOMIC IMPACT OF SUPPLEMENTARY PROTECTION CERTIFICATES, PHARMACEUTICAL INCENTIVES AND REWARDS IN EUROPE

Open procedure

TENDER SPECIFICATIONS

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1. TECHNICAL SPECIFICATIONS

1.1. GENERAL BACKGROUND OF THE STUDY

The European Commission Single Market Strategy of October 2015 identifies the need to consolidate and modernise the intellectual property (IP) rights framework as a way to stimulate research, innovation and growth within the European Union and to engage in a reflection on ways to improve the patent system in Europe, in particular for pharmaceuticals and other industries whose products are subject to regulated market authorisations.

Recently, the Council Conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its Member States invited the Commission to prepare "an evidence based analysis of the impact of the incentives (…) on innovation, as well as on the availability, inter alia supply shortages and deferred or missed market launches, and accessibility of medicinal products, including high priced essential medicinal products for conditions that pose a high burden for patients and health systems as well as availability of generic medicinal products. Among those incentives, particular attention should be given to the purpose of supplementary protection certificates as defined in the relevant EU legislative instrument and the use of the “Bolar” patent exemption, the data exclusivity for medicinal products and the market protection for orphan medicinal products. Where relevant, the analysis of impacts should also address – inter alia – the development of medicinal products and the effects of the pricing strategies of industry in relation to these incentives".

The European Commission's Directorate General for Internal Market, Industry, Entrepreneurship and SMEs in the context of the evaluation of the EU legislation on supplementary protection certificates (SPCs) for the EU pharmaceutical and crop protection sectors, together with the Directorate General for Health and Food Safety regarding the evaluation of incentives related to pharmaceutical products, plan to contract an economic study to analyse the following issues:

Overview of existing IP related incentives and rewards supporting pharmaceutical innovation in the EU and analysis of their actual use by the pharmaceutical innovators throughout the entire product lifecycle management (from development to access), with particular focus on SPCs, data protection and market exclusivity related to medicinal products for human use. The study should in particular analyse instances where multiple incentives and rewards are available for the innovators. In this context it should assess (1) to what extent these multiple incentives and rewards are used in combination (where these incentives and rewards are cumulative), (2) whether choices are made by the innovators between the various available incentives and rewards (where these are non-cumulative), what are the preferred choices and what are the underlying reasons for these choices. There should be a clear focus on the economic implications.

Overall economic effects of SPC, data protection and market exclusivity on innovation, availability and accessibility. The economic incentives generated by SPC regulation, data protection and market exclusivity should be analysed separately and jointly, taking into account also the existing rules on patent protection in the EU, to assess their impact on innovation, availability and accessibility of medicinal products for patients in the European Union and the impact on the sustainability of health systems. The aim is to get economic evidence of the effects of the current incentives in the EU pharmaceutical system and the impact on availability and accessibility of pharmaceutical care for patients and the pressure on health systems across the European Union.

Economic impact of EU regulations on SPCs. The economic study will analyse the level of achievement of the objectives set out by regulations 1768/92 and 1610/96 on SPCs for pharmaceutical (human and veterinary) and plant protection products; and more particularly analyse whether the scope and term of protection of the EU SPC system are appropriate given the development of the first targeted markets and of other innovative product markets subject to lengthy market authorisation requirements. The analysis should provide evidence on whether the SPC framework is fit for purpose given the existing market authorisation requirements (and timing to obtain it) in the currently covered sectors and in light of the other available incentives and rewards seeking to ensure that in these sectors innovators / patent holders achieve sufficient returns on their research and development (R&D) investments taking into account other sectors with a high degree of innovation. Economic evidence and econometric models should be used to provide sound assessment of the regulations and their impact, including on the sustainability of health expenditure through delaying market access for generics and the competition and price reduction it brings. It should be also assessed whether it would be appropriate to potentially extend the scope of the SPC to other sectors. Economic evidence and econometric models should be used to provide sound assessment of the existing regulations and the potential changes thereof. In addition, the study should analyse the future impact of a possible European wide SPC following the Unitary patent reform in Europe.

Economic impact of rules on data protection and market exclusivity for medicinal products, including the impact on innovation, availability and accessibility of the medicinal products concerned and the impact on the health of the population (through the development and availability of innovative medicines or the lack of access to them) and the financial sustainability of health systems. The study should assess the economic impact of the current rules on data protection and market exclusivity in the EU pharmaceutical legislation, in particular whether, in light of the other available incentives and rewards, the current rules ensure that innovators achieve appropriate and proportionate returns on their R&D investments for innovative products, on investments of the pharmaceutical industry in research and development of innovative products, what is the impact on launches of new innovative products especially in the areas of unmet medical need, on market entry of generic products and on prices of the products concerned. The study should as requested in the Council conclusions address also the effect on supply shortages and deferred or missed market launches and assess the effect on the accessibility of medicinal products, including high priced essential medicinal products for conditions that pose a high burden for patients and as well as availability of generic medicinal products.

The economic analysis should also consider the specific rules on market protection for orphan medicinal products in Regulation (EC) 141/2000 and take into account the findings of the study on the economic impact of the Paediatric medicinal products Regulation, including its rewards and incentives. The study should assess in particular as requested in the Council conclusions whether the incentives are proportionate to the goal of encouraging innovation, improving patients' access to innovative medicines with therapeutic added value and budgetary impact; and analyse whether these rules contribute to create circumstances that might encourage unintended market behaviour of some manufacturers and/or hamper the emergence of new or generic medicinal products and in this way potentially limit patients' access to new medicines for unmet medical needs and that can affect the sustainability of health systems.

Overall, the evidence and analysis provided by this study should support the policy making in those areas. First, the context of the European Commission's Single Market Strategy of October 2015 mentioned above, the Commission will use this study as one of

the inputs into an evaluation report of the SPC system in the EU and to inform the decision on whether to come forward with a revision (notably with an option of establishing common SPC titles covering the entirety of the internal market)/scope and term/modification of the existing SPC acquis. Secondly, in view of the 17 June 2016 Council Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, this study will also contribute to analysing the impact of the incentives listed above on innovation, availability and accessibility of medicines in the EU as requested by the Council.

In relation to innovation, particular attention should be given to the impacts on innovative small and medium size companies (SMEs).

1.1.1. *Background on supplementary protection certificates (SPCs), data and market exclusivity*

A wide range of sectors rely on the European industrial property (IP) framework. Some of those sectors develop products that for health and safety reasons are subject to lengthy and costly testing to comply with rigorous regulatory EU requirements related to safety, efficacy and quality before obtaining marketing authorisation. At the time of the adoption of the EU SPC rules, two decades ago, pharmaceutical and agrochemical industries were subject to the lengthiest product testing and market authorisation systems. Typically for these products, marketing authorisations were normally granted several years after the relevant patents were filed leading to a significant reduction of their effective patent protection (in Europe, patents are granted for 20 years as of the filing date).

To meet the innovative pharmaceutical concern that they were no longer given a fair opportunity to recover their Research and Development efforts and investments, the EU introduced the first SPC regime in 1992 with the Council regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products. Four years later, Regulation (EC) No 1610/96 of the European Parliament and of the Council was adopted concerning the creation of a supplementary protection certificate for plant protection products.

SPCs are sui generis intellectual property rights (IPRs) that should currently serve to compensate holders of patents for pharmaceutical and plant protection products for the loss of effective patent protection. The certificate does not extend the term of the patent itself, but the protection conferred by the patent and therefore confers the same rights and is subject to the same limitations as the patent.

For the pharmaceutical sector, where the time between filing a patent application and market launch can be significantly longer than in other sectors, SPCs can be issued in order to extend up to 5 years the standard term of patent protection. These extend the effective protection of products already on the market by a maximum of five years by excluding other companies to manufacturing and marketing their products.

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use provides for a six-month extension of the SPC duration under certain conditions in order to encourage research on paediatric applications of medicines.

In 1990, the proposal for a Council regulation (EEC) concerning the creation of a SPC for medical products presented by the Commission (COM(90)101 final) set out a number of objectives (and hypotheses) backing the proposal, inter alia: harmonisation of the SPC protection in the Internal Market, increase innovation productivity, limitation of patent erosion and therefore reinforced financial incentives for R&D, limited delocalization of

research, increased competition, reduction of the price of medicines by extending the investment's payback period under patent exclusivity and increased transparency.
The SPC regulations provide for substantive and some procedural requirements for the grant of SPCs at national level; they did not result in a European wide SPC protection but instead ensured that SPC protection could be applied for across all the Member States. It should be noted that at the time of these rules being adopted there was no prospect on a unitary patent title that is currently expected to soon come into force within the EU (The unitary patent was established by Regulations EU 1257/2012 and 1260/2012 and will be applicable from the date of the entry into force of the Agreement on a Unified Patent Court).

1.1.2. *Background on data protection and market exclusivity rules for medicinal products*

A medicinal product may be placed on the Single Market of the European Economic Area only when a marketing authorisation has been issued by the competent authority of a Member State for its own territory or when an authorisation has been granted in accordance with Regulation (EC) 726/2004 for the entire Union. In order to obtain a marketing authorisation pharmaceutical companies need to submit data relating to pre-clinical tests and clinical trials of the medicinal product concerned to the competent authority. That data is used to assess the quality, efficacy and safety of the medicines to be authorised.

The EU data and marketing protection regime is governed by Directive 2001/83/EC, as amended by Directive 2004/27/EC and by Regulation (EC) 726/2004. Data and marketing protection protect the economic interests of innovative companies in addition to the protection they enjoy from patents and SPCs.

Today, marketing authorisation applications for generic products cannot refer to the results of pre-clinical tests and clinical trials of the reference product until eight years have elapsed from the date of authorisation of the reference medicinal product. This period of data protection granted to innovative companies is complemented by an overlapping 10-year market protection which prevents a generic drug to be placed on the market before this ten year period from the date of authorisation of the reference medicinal product elapsed.

Medicinal products for human use benefit from an eight-year period of data protection and a ten-year period of market protection. The latter period shall can be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are considered to bring a significant clinical benefit in comparison with existing therapies.

1.1.3. *Background on orphan and paediatric rewards*

The main objective of Regulation (EC) 141/2000 on orphan medicinal products (OMPs) is to ensure that patients suffering from rare conditions have the same quality of treatment as any other patient in the EU. OMPs are intended for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affect no more than 5 in 10,000 people in the European Union.

The Orphan Regulation establishes a Union procedure for designating OMPs and proposes incentives for research in the field and the development and marketing of such products where the conditions that they address occur so infrequently that development

and marketing costs are unlikely to be recovered through sales. In addition, the Regulation encourages Member States to adopt similar and/or complementary measures at national level. OMPs can benefit from the incentives provided they are designated as such before the marketing authorisation is granted.

The cornerstone of the orphan rules is the principle of market exclusivity. When a marketing authorisation for an orphan medicinal products is granted, the Union and the Member States shall not for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation for the same therapeutic indication, in respect of a similar medicinal product.

Under the Regulation on medicinal products for paediatric use, market exclusivity may be extended to 12 years if a paediatric investigation plan is completed for an orphan medicinal product.

Regulation (EC) 1901/2006 on medicinal products for paediatrics uses was seen as a response to the absence of sufficient numbers of suitable, authorised medicinal products. To address the observed knowledge gap, the Regulation establishes a system of obligations, rewards and incentives, together with horizontal measures to ensure that medicines are regularly researched, developed and authorised to meet the therapeutic needs of children.

The main measures contained in the Paediatric Regulation are the following:

- requirement for companies to submit data on the use of a medicine in children in accordance with an agreed paediatric investigation plan (PIP) when applying for marketing authorisation and line-extensions for existing patent-protected medicines;
- system of waivers from the above requirement for medicines that are unlikely to benefit children and a system of deferrals in relation to the timing of the requirement;
- reward for complying with the requirement in the form of a six-month SPC extension;
- reward for compliance, in respect of orphan medicines, in the form of an extra two years of market protection added to the existing ten years awarded under the Orphan Regulation;
- new type of marketing authorisation, the paediatric use marketing authorisation (PUMA), to attract new paediatric indications for off-patent products.

1.1.4. *Background on SPC and data and marketing exclusivities in non-EU countries*

Major trade partners of the EU, such as the US, Japan and Korea provide for SPC protection and market exclusivity or data protection, as well as incentives related to orphan research and paediatric medicines. Other major economies such as China and India do not provide such incentives, for instance they do not have SPC protection or an equivalent mechanism, while Canada plans to introduce SPC protection as a result of its bilateral trade commitments with, for example, the EU.

1.2. THE PURPOSE OF THE CONTRACT

The contractor shall conduct an economic evaluation of the incentives and rewards for pharmaceutical innovation, in particular an economic evaluation of national SPC systems in Europe and provide an economic analysis of the functioning, use and effects of the incentives for pharmaceutical products, in particular, SPCs for pharmaceutical uses

(human and veterinary) and plant protection, data protection and market exclusivity for medicinal products for human use, in order to provide answers to the following issues:

1.2.1. *Overall economic effect of SPCs as well as data protection and market exclusivity on innovation, accessibility and availability of medicines in the EU*

1) **Overall economic effects**

The contractor shall analyse the overall impact of SPC and market and data protection on incentives to R&D and product availability and accessibility in the Internal Market. When analysing the global effect, the contractor should also consider elements such as: the timing of market authorisation, the new types of innovative products requiring market authorisations (such as in the field of medical devices, etc.), developments in research methods (that can shorten clinical trial processes for example).

The European Commission will provide the contractor with some preliminary economic analysis and statistical data in order to scope the study more precisely. The contractor is expected to build on those initial results to provide sound economic evidence based policy recommendations.

The results could serve as one of the inputs for an impact assessment for a potential proposal by the Commission to recalibrate the existing SPC system. They will also address the request of the Council Conclusions of June 2016 asking the Commission to analyse the impact of incentives on innovation, availability and accessibility of medicinal products.

1.2.2. *Specific challenges related to SPCs*

2) **The achievement of the objectives of Regulations 1768/92 and 1610/96.**

The attainment of objectives listed in the SPC regulations need to be evaluated following two decades of its application. Those objectives were identified in the Commission's proposal for a Council regulation (EEC) concerning the creation of a SPC for medicinal products (document COM(90)101 final) in 1990 and the recitals of the SPC regulations. They are detailed in section 1.3.1.2 below and cover incentives to innovation, investment, prevention of delocalization, competition, patients' driven innovation, etc.

The contractor is expected to provide sound economic analysis on the achievement of different objectives and the role played by the SPC regulation. Economic evidence should be provided on elements such as recovering of R&D investments due to extra protection, the economic benefits of SPC for different medicines types (blockbusters, antibiotics, personalised, etc.), economic evidence on the role of SPC to incentivise innovation in Europe, etc. It should also include the impact on the delayed entry of generics, price impact of SPCs as well as the issue of availability or accessibility of medicines and the economic/financial impact that the extended market exclusivity has on health expenditure/health insurance budgets.

3) **The need to restrict or widen the scope of innovative products or sectors covered by the SPC regulations**

The scope and sectors covered by the SPC regulation were decided over 20 years ago. However in these two decades many of the underlying aspects of the SPC regulation have changed, amongst others, changes in innovation patterns, big data, bio-medicines,

personalised medicines, increasing importance of medical devices as well as changes in marketing authorisation procedures.

Based on quantitative and qualitative evidence, the contractor shall identify new products not covered by SPC but suffering from reduced patent terms and disincentives to R&D because of lengthy premarket regulatory testing and authorisation procedures. On the other hand, the contractor shall identify products for which the current SPC protection did not lead to achieving the objective set by the SPC regulation. In so doing the contractor should give due consideration to the manner in which SPC protection provides incentivises (or disincentives) to innovation and market accessibility and availability (including prices) for the relevant products.

4) **The question of the "optimal" duration of the SPC protection**

The effective term of patent and SPC protection (i.e., the actual marketable period) in the EU shall be assessed in terms of its impact both on R&D stimulation and innovative product accessibility and availability within the Internal market.

The contractor should consider whether the extended EU SPC protection, as designed in 1990, might be less/more relevant for certain pharmaceutical products. Account should also be taken of how such developments will affect the availability and accessibility of the relevant products within the EU. In particular, certain pharmaceutical products may need this protection extended to recover R&D investments, while for others the current protection may result in overcompensation in comparison to the investment and therefore it may not be necessary. The contractor should analyse economically the specific situation of blockbusters, personalised medicines, bio-medicines. In addition, the combination with data protection should also be considered as well as the different medical uses for the same patent. Finally, a comparative analysis of differing SPC frameworks in other third country markets (e.g., US and Canada) as well as economies without SPC regulations (e.g. China and India) should be accounted for.

5) **Fragmentation of SPCs across the Internal Market**

The forthcoming unitary patent will allow innovative companies and notably innovative SMEs to have access to patent protection across multiple Member States with a single title rather, than as present, to have to validate a European patent in each and every Member State.

The unitary patent reform however does not include a European wide title for SPCs, despite the important economic benefits that could derive from its implementation.

The contractor shall analyse the need for a European wide SPC in Europe. The economic rationale should be explored together with a fully comprehensive cost benefit analysis. Elements such as legal certainty, cost savings for companies, SPC fees redistribution among member states, the need of a SPC grant authority should be analysed in terms of costs and possible benefits. Overall, it should be demonstrated whether European wide SPCs are considered to offer net economic benefit in terms of incentivising R&D and improved availability and accessibility of innovative pharmaceutical products.

1.2.3. *Specific challenges related to incentives and rewards under the EU pharmaceutical legislation including data and market exclusivity*

6) **Economic analysis of incentives and rewards**

The EU pharmaceutical system is regulated to ensure the continuous availability and the quality, the safety and the efficacy of medicinal products to patients. The IP incentives in the current legal framework are intended to encourage investment in innovation by pharmaceutical companies and to compensate for research, safety testing and other regulatory requirements that need to be fulfilled before placing a medicinal product on the EU market, but that prolong the time to market.

The system is important for patients and health care, as it determines to a large extent which products are allowed on the market. It also has a great impact on pharmaceutical companies, including through the incentives and protection it offers for innovative medicines. Member States rely on the centralized marketing authorization of many essential medicinal products at EU level, before they can decide on reimbursement of these through their national health insurance systems.

Therefore, it is important that the use and application of the data protection and market exclusivity are seen in the context of the whole pharmaceutical system. Most importantly, the contractor shall not only analyse from the economic point of view originator products that are on-patent, but also examine the possible economic effects of data and market exclusivity on availability and accessibility of medicinal products and the related budget impact on health systems when they do not benefit from IP incentives anymore.

The Council Conclusions request to evaluate whether the incentives in this specific legislation are proportionate to the goal of encouraging innovation, improving patients' access to innovative medicines with therapeutic added value and budgetary impact; and assess whether these rule would contribute to create circumstances that might encourage inappropriate market behaviour of some manufacturers and/or hamper the emergence of new or generic medicinal products and in this way potentially limit patients' access to new medicines for unmet medical needs and that can affect the sustainability of health systems.

Regarding orphan drugs specifically, there is an increasing interest from innovators to develop products in the field of rare diseases and more specifically in oncology. However, some Member States expressed concerns about the high prices of such medicines. Other Member States have serious problems of availability of those products which are not part of the reimbursement scheme and consequently not accessible for the patients. The contractor shall analyse from the economic point of view the importance of favourable incentives for orphan medicinal products.

There is a significant number of publications that describe how companies use the system by slicing indications to artificially design orphan drugs that in the end become blockbusters in terms of return for investment. The analysis shall review and analyse this evidence.

The specific situation of paediatric reward shall be also analysed from the economic point of view. For this purpose, the contractor should base its analysis on the findings of the study on the economic impact of the Paediatric Regulation, including its rewards and incentives.

1.3. CONTRACT SPECIFICATIONS

1.3.1. *Objectives and tasks*

1.3.1.1. Objectives

The study shall analyse from the economic point of view the current system of incentives and rewards for innovation in the pharmaceutical sector and assess their impact on innovation, availability and accessibility of medicinal products in the EU.

The study shall in particular analyse whether the existing EU framework for SPCs is fit for purpose according to the objectives of the regulations and the developments in the EU pharmaceutical and agrochemical sectors. The analysis shall provide solid evidence to inform the decision on whether to come forward with a revision of the SPC framework in Europe and therefore provide evidence-based recommendations in this respect.

The study will also analyse impact of the existing incentives and rewards under the EU pharmaceutical legislation including data protection and marketing exclusivity as discussed in the previous sections. The specific rules and incentives for OMPs and paediatric medicinal products should also be assessed and the result of the study on the economic impact of the Paediatric Regulation, including its rewards and incentives, should be taken into account.

The analysis shall lead to detailed evidence based and clearly formulated conclusions on the impact of the existing system of the incentives and rewards on innovation, availability and accessibility of medicinal products in the EU.

In addition, the contractors shall provide an overall economic assessment to fully evaluate impacts of the regulations above on R&D, innovation performance and availability and accessibility across the Internal Market. When considering innovation, the study should also address the issue of therapeutic value. It should investigate whether innovation induced by exclusivity yields to therapeutic gains by new products.

Particular attention shall be also given to the needs of innovative small and medium size companies in all the relevant sectors.

1.3.1.2. Tasks to be performed by the contractor

In order to achieve the objectives of the study, the contractor will need to perform the tasks listed below. While the modalities are described in this term of reference, further clarifications may be provided during the kick off meeting. Moreover, the tenderer is invited to propose additional elements that in his opinion would merit examination in the light of the detailed objectives of the study.

Specific tasks of the contract are:

Task 1. Overview of economic incentives and rewards supporting pharmaceutical innovation and analysis of their actual use by pharmaceutical innovators

1. Provide an overview of the current EU legislative instruments and related economic incentives[1] that facilitate the investment in the development of medicinal products, with particular reference to SPC-type protection, data protection and market exclusivity, orphan market protection and paediatric reward frameworks.

   The tasks include:

   - Describing each incentive on the basis of a number of comparable characteristics. These may include: incentive type; original objective and purpose of the incentive; definition of product or substance targeted; conditions, eligibility and criteria; requirements and safeguards (e.g. registries); economic benefits or incentive for innovation.
   - Describing the safeguards that ensure proper use of thee incentives and examine if these safeguards are being used (e.g. review clause for orphan medicinal products; obligation to market products in all Member States).
   - Describing the legal possibilities for combining or stacking incentives for one single product and companies' strategy.
   - Provide a comparative overview of the IP legal framework and economic incentives in the US and Japan, Canada, China and India and explain the rationale behind the measures in place (other their absence) where relevant.

2. Provide economic and statistical evidence of the actual use of the above incentives and rewards by the pharmaceutical innovators. Particular attention should be paid to instances where multiple incentives and rewards are available for the innovators. In this context it shall provide evidence: (i) to what extent these multiple incentives and rewards are used in combination or separately; (ii) what are the preferred choices for sectors and types of medicines (e.g. blockbusters vs rare diseases medicines). The contractor should also provide explanations of the underlying reasons for these choices.

Task 2 – Analysis of the overall economic effects of the incentives and rewards and their impact on innovation, availability of medicinal products

3. The economic incentives generated by SPCs as well as data protection and market exclusivity shall be analysed: (i) jointly, providing a whole picture on innovation, availability, accessibility and related pricing strategies of companies; (ii) separately, for each specific instrument, with a detailed analysis on SPCs (see points 4 to 8). The contractor is requested to analyse the effects of each of the incentives and rewards on innovation, availability and accessibility and on the correlation with prices of medicinal products.

   The contractor shall also develop an econometric model aiming to test the combined effect, and interrelations, of the incentives above on innovation, availability and accessibility of medicines in the Single Market. Differentiated analysis should be done for different categories of products (e.g. blockbusters vs personalised medicines or medicines for rare diseases), market players by size and type as well as sectors. Economic incentives should be investigated together with their costs. In particular:

   a) Impact on innovation

[1] These include inter alia: Supplementary Protection Certificates; Market Protection and extension; Data Exclusivity; Bolar/ research exemption; Variations (major type II); Paediatrics SPC extension/ market exclusivity extension; Conditional Marketing Authorisation; Orphan Medicinal Product market exclusivity.

- Provide economic, statistical or econometric evidence to what extent the IP incentives and the revenues they generate lead to increased investment of the pharmaceutical industry (innovative and generic) into high skilled employment in the EU (R&D, production).
- Provide economic, statistical or econometric evidence to what extent the availability of certain IP incentives – e.g. market protection - has an impact of industries' focus in research, e.g. towards products for smaller patient groups (orphan medicinal products, oncolytic) addressing unmet medical needs. What can be said about the added value of these products in relation to their earning potential?
- Provide economic, statistical or econometric evidence to what extent the availability of certain IP incentives has had a positive effect on development of medicinal products for addressing unmet medical needs, the top priority diseases, biomedicines, antibiotics and combined medicinal products.
- Provide economic, statistical or econometric evidence whether strengthening or extending IP protection may can speed up and/ or delay innovation.
- Provide quantitative evidence on high revenue medicinal products to what extent these were the result of in-company research or of acquisitions.
- Analyse whether any other tools/mechanisms could proportionally achieve similar impact on innovation

b) Impact on availability

- Based on existing data, conduct an econometric or statistical analysis on whether medicinal products are not marketed, delayed, withdrawn in certain national markets. Provide explanations for such behaviour and of the role of IP protection.
- In several Member States, medicinal products that have run out-of-patent and no longer benefit from other IP incentives are no longer on the market. Examine, on the basis available statistics (e.g. IMS database), what types of products are mostly concerned, whether those products are replaced by second generation products and discuss what factors influence the discontinued availability.
- Conduct an econometric analysis of how the incentives/exclusivities above impact the market entry of generics, similar products and biosimilars in the different national markets of EU Member States. The analysis should consider elements such as countries' entry, timing, market penetration, prices, etc. The analyses can compare the availability of substances on the positive list of reimbursed products per Member State, both under exclusivity and after exclusivity.

c) Effect on accessibility

- Conduct a price analysis on authorised medicinal products across the EU, indicating the major differences in prices and related explanatory variables. Analyse whether not made available to patients in certain Member states because high prices.

- Examine with the econometric analysis what variables may have an impact on the extent to which EU patients have access to medicinal products.
- Provide statistical and econometric evidence in how many countries and after how many years a product enjoying a patent, SPC, data protection and market exclusivity becomes accessible to patients as patent protected and subsequently generic medicine.

d) Effect on generic medicines and health systems fiscal sustainability

- Conduct an econometric analysis of how the incentives/exclusivities above impact the market entry of generics and biosimilars in the different national markets of EU Member States. The analysis should consider elements such as countries' entry, timing, market penetration, prices, etc.
- Examine how the potential delayed entry affects health expenditure and social insurance budgets.

The contractor must provide clearly formulated conclusions on the functioning and the actual use of the incentives and rewards by the pharmaceutical innovators and their effects (jointly and individually) on innovation, availability and accessibility of pharmaceutical products for patients within the European Union, as well as on the pricing strategies. These conclusions must be based on quantitative and qualitative evidence and findings provided and summarised in the study.

Task 3 - Analysis of the SPC framework

4. Test from the economic point of view the level of achievement of the **objectives** of Regulations 1768/92 and 1610/96

In a first sub-section, provide economic evidence for the level of fulfilment of the following R&D stimulation/innovation objectives:

- Attraction of pharmaceutical and agrochemical innovation to the EU
- Prevention of delocalisation of pharmaceutical and agrochemical innovation and manufacturing.
- "Ensure that research based industry has a market protection of sufficient length to permit recovery of their investments"
- "Fall in prices" of medicines and agrochemicals following SPC expiry, or whether the setting of those prices have reflected the longer exclusivity "period for recuperation of investments" provided for by the rules.
- Promotion of "competition through innovation"
- Encourage innovation demanded/needed by consumers, patients and stakeholders.

The analysis shall provide economic and econometric evidence of the role played by the SPC regulations to support such objectives. The contractor should empirically test the achievements of all objectives set in the regulation. Desk research such as existing studies and reports, empirical literature etc. should be summarised and analysed. The

contractor should also use different commercial (and public) databases such as to build relevant statistics and econometric models to provide sound economic evidence on the importance of SPCs to support the above objectives. Amongst others, the report should analyse whether SPC helped the fall in prices of medicines compared to medicines without SPCs. The analysis should also consider whether the revenue and profits of certain medicines (e.g. blockbusters vs. medicines for rare diseases) justify the additional protection granted to certain pharmaceutical and agrochemical products.

The contractor should also consider how pharmaceutical and agrochemical innovation have evolved in major economies and in the benchmark countries identified in 1990 that had already introduced SPC-type protection (i.e., the US and Japan) in terms of investment and attraction of innovation, sales, etc.

In a second sub-section, the contractor should test the economic impact of the SPC, implemented, on pharmaceutical product amenability across the Internal market by identifying, inter alia supply shortages, deferred or missed market launches, accessibility and diffusion across the Internal market of the innovative medicinal products, including high priced essential medicinal products for conditions that pose a high burden for patients and health systems as well as availability of generic medicinal products. Also, where relevant and possible, the contractor should address how the pricing strategies of industry in relation to these products impacted on this amenability objective.

5. <u>SPC scope: economic analyse of the need to reduce/extend SPC-type protection</u>

The contractor shall provide economic evidence of the need to extend/reduce SPC protection in the pharmaceutical and agrochemical sectors as well as other potential sectors.

In particular, data analysis should provide a justification to the need of SPC protection in sectors currently covered and whether such protection should be modified, considering possible costs and benefits for various stakeholders (e.g. pharmaceutical companies, innovation patterns, patients/consumers, public health budget, etc.).

Economic evidence should also be provided for the need for SPC protection for additional potential products and sectors, that show the same features as pharmaceutical and plant protection products, and that may need extended patent protection to support innovation and amenability of products.

The contractor should also analyse economically the effects of SPC protection on certain pharmaceutical and agrochemical products where there is a strong public interest rationale for generic competition to enter as soon as terms of protection expire.

6. <u>Analyse the term of protection of the SPC</u>

Provide a solid economic and econometric analysis on whether the effective SPC term of protection in the EU is still appropriate given (i) innovation and changes in market authorisation and product testing methods, (ii) the nature of R&D and innovation models in the relevant markets (e.g., biologics), and (iii) the results of the analysis in point 3 above. The contractor should justify economically whether the five-year protection is the right incentive for innovative companies and whether its benefits for innovator outpace the costs for other stakeholders and society in general.

It shall also consider cost and benefits of potential alternative measures to the SPC protection (e.g. incentives related to prices, availability of interchangeability) according to different products (e.g. agrochemical, biotechnology products, improved products covered by follow-on patents).

Analyse cost and benefits of the temporary availability of a SPC-additional extension (i.e., like the 6-month paediatric extension) as the right instrument to encourage innovation and development of products that could be highly innovative, or that might be necessary to be developed to address emergency situations, etc.

7. Analyse the costs resulting from the fragmentation of the EU SPC system

Provide solid economic elements to test for the need for a European-wide SPC protection in Europe, underlining the advantages and possible costs. Analyse and discuss the potential costs in terms of reduced R&D incentives and lack of amenability of innovative products resulting from fragmentation of SPCs across the Internal Market vis-à-vis a unitary SPC title.

8. Provide conclusions and recommendations related to the evaluation of the SPC

It is expected that the study includes a specific section summarising the objectives of the SPC regulation identified above and its level of achievement in view of its interaction with data protection and market exclusivity rules, as well as a summary on how changes in the scope and term of protection possibly would impact in objectives of the SPC regulations previously discussed. These conclusions need to be supported by economic data and econometric analysis.

The study shall also include a specific section with a set of recommendations (based on sound evidence) to suggest possible improvements to the existing SPC in the EU.

Task 4 – Analysis of the specific incentives and rewards under the EU pharmaceutical law including data and market exclusivity

9. Economic analysis of incentives and rewards

The study shall analyse the specific impact of the existing specific incentives and rewards under the EU pharmaceutical law including data and market exclusivity on innovation, availability and accessibility. This analysis should be conducted with regards to the impact on innovative ("originator") products covered by the abovementioned protection/exclusivity, but also examine the possible economic effects of data and market exclusivity on availability and accessibility of medicinal products (including generic products) and the related budget impact on health systems.

The study shall further evaluate whether the incentives in this specific legislation are proportionate to the goal of encouraging innovation, improving patients' access to innovative medicines with therapeutic added value and budgetary impact; and assess whether these rule would contribute to create circumstances that might encourage inappropriate market behaviour of some manufacturers and/or hamper the emergence of new or generic medicinal products and in this way potentially limit patients' access to new medicines for unmet medical needs and that can affect the sustainability of health systems.

Regarding orphan drugs specifically, the study should analyse from the economic point of view the impact of the orphan incentives on development and availability of new orphan products, but also potential negative impacts on (high) prices of such products and on accessibility of those products to patients for example due to exclusion of these products from national reimbursement schemes.

There is a significant number of publications that describe how companies use the existing system by slicing indications to artificially design orphan drugs that in the end become blockbusters in terms of return for investment. The analysis should review and analyse also this evidence.

The contractor must provide clearly formulated conclusions on the impact of the specific incentives and rewards under the EU pharmaceutical legislation (in particular data protection and market exclusivity) on innovation, availability and accessibility of pharmaceutical products for patients within the European Union, as well as on the pricing strategies. These conclusions must be based on quantitative and qualitative evidence and findings provided and summarised in the study.

Task 5- Case studies

10. Identify and include a number of case studies

The aim of these case studies is to test the results of the previous sections and to undertake some sensitivity analysis of how the general results of the previous sections need to be adjusted according to differing product categories.

Case-studies shall be performed in order to get an understanding of the concrete use of SPC and pharmaceutical incentives throughout the entire product lifecycle management, and to identify the relative importance of the various incentives as perceived by companies and unintended effects. This requires identifying what is usually the effective period of protection/exclusivity of pharmaceutical innovation and to what extent the different types of instruments (SPC, regulatory data protection and market protection, orphan market protection etc.) contribute respectively to the overall effective period of protection/exclusivity.

The contractor is requested to explain the methodological basis used in his technical offer for selecting the specific case-studies, on the basis of the following elements:

- Select a minimum of 20 case-studies from different categories of products (e.g. vaccines, antibiotics, blockbusters, biologicals, "orphans blockbusters", paediatrics, oncology products for rare or common disease) and if possible, different therapeutic classes.
- Select cases allowing the analysis of SPC and pharma incentives in combination; need to identify the concrete use of SPC and pharmaceutical incentives and their impact across all steps of the product lifecycle management (i.e. from development to access).
- Need to have case-studies allowing the possibility to look at the impacts of SPC & the various incentives across the various Member States.
- Select cases with different timelines in terms of R&D and marketing authorisation (i.e. cases where the MA came early, e.g. through conditional marketing authorisation, others with standard or lengthy development times).

- The case studies should not look only at the various protection periods but also on the situation once the overall effective protection/exclusivity period expired, i.e. entry of competing products on the market, price development, availability of the product etc. This means that the case studies should preferably cover products for which the protection already expired.
- Mitigation measures should be foreseen to avoid conclusions from cases that would not reflect the general practice.

The contractor is requested to provide a methodology in his technical offer for selecting the specific case-studies.

The contractor should liaise with the Commission to decide the how to organise the work in a timely manner. In line with the Commission's announcement in the Single Market Strategy 2015, and to the extent it is possible, tasks 4 to 8 related to SPCs must be analysed as a matter of priority. Solid results on SPC should be already provided in the interim report.

The contractor will be obliged to fulfil the following cross cutting activities in order to fulfil the tasks outlined above:

1. Provide sound economic and econometric analysis, based on sound methodologies to be clearly outlined in the offer responding to the invitation to tender.

2. Conduct desk research on economic literature (e.g. studies, publications, relevant Commission preparatory documentation, Commission sector inquiry[2] or specialised blogs) to gather the knowledge necessary to analyse the subject matter being the object of this study, indicated in 1.3.1 above.

3. Collect, process and analyse pharmaceutical sector analysis reports, UN and WHO reports (e.g. on access, essential medicines), reports and databases on medicinal products (EMA).

4. Collect, process and analyse quantitative and qualitative data relevant for an economic and econometric analysis of the specific objectives set out above.

   In particular, the contractor should indicate in the offer what databases he/she intends to use for the analysis as well as mention possible data limitations and how to overcome them. Use of other available specialised commercial databases can also be discussed with the Commission's services. The Commission's services may provide statistical data related to SPCs and SPCs applications, as well as on paediatric rewards.

   To address the specific issues in the tender, amongst others, the contractor shall create a database relevant for the econometric analysis with relevant information such as:

   - Patents: application date, granted date, renewal fees, country, name of applicant, expiry date, etc.);
   - SPC: filings, name of applicants, product patent number, medicine-plant, grant/refusal date of SPC, granted term, application fee, renewal fees, paediatric extension, human/veterinary, plant protection, etc.);

[2] DG COMP Sector Enquiry report 2009 – Pharmaceutical sector.

- Marketing authorisation: name of market authorisation (MA) holder, application date, grant date, etc.
- Product information: active substance, ATC code, human/veterinary, dosages, pharmaceutical or biological product, second generation product, etc.
- Generic companies: first generic entry, Member States of entry, market shares over time, etc.
- Originator companies: first entry into the market, headquarters, large or small entities, production sites, etc.
- Commercial data: Ex-factory prices before and after generic entry; retail prices (if possible); discounts; annual revenue in Member States (and abroad, if possible)
- Data on pharmaceutical and agrochemical innovation investments obtained from different sources such as commercial databases, companies' annual reports, existing studies etc. The Commission's services may give access to Orbis database.
- Data on manufacturing and delocalisation of pharmaceutical and agro-chemical production facilities. While certain data can be obtained by MA authorities, the contractor should investigate other sources.
- Other data necessary for the analysis.

Based on the data collected, the contractor shall provide descriptive statistics and econometric models. The econometric models should consider all main relevant dependent variables, fixed effects etc. The offer should provide an initial description of the econometric analysis to be used.

On the specific analysis on pricing of medicinal products, information on national final prices tends to be confidential or difficult to access. The contractor should suggest possible datasets to be used for this purpose is therefore advised to use stock exchange filing in order to get information on main medicinal products, earnings, investments and profits (annual reports), as well as the list prices of general medicinal products and orphan drugs . General information on discounts regarding product groups can be obtained through qualitative interviews and by reviews of studies on European Reference Product and other price systems. The contractor should suggest possible datasets to be used for this purpose. In addition, the Commission's services may give access to further databases (e.g. EURIPID, IMSHealth database, Orbis) and facilitate data collections with the help of Member States[3] and industry associations. The contractor shall propose a methodology to collect this information, including surveys with Member States and relevant stakeholders[4], and agreed by the Commission Services.

5. Face-to-face interviews with 20 well-known academic and professional experts in the pharmaceutical and public health sectors to obtain qualitative information on the pharmaceutical developments concerning the issues to be investigated. Experts from international organisations active in this area such as OECD, WHO, WIPO should be interviewed. The contractor shall provide the Commission's services with the list of such experts and questions for approval prior to the start of the structured interviews.

[3] Member States' authorities must be understood as those responsible for authorizing and controlling the use of the medicinal products, but also those responsible for pricing and reimbursement.

[4] The stakeholders consulted should represent all relevant and interested parties (including in particular, industry, patients, health care professionals, consumer and public health organisation, payers, academia…..) in a balanced way and at a European level.

6. Establish an Expert Board, made up of three renowned experts in the area, to review critically the economic and econometric analyses as well as the policy analyses and recommendations related to the economic impact of SPCs.

7. Write the study following a clear and logical structure, and provide precise and concise presentation of the facts, analyses and assessments in professional and proof-read English.

1.3.2. *Geographic coverage, input by the contracting authority and references*

1.3.3.1 Geographical coverage

The study has a specific EU geographic coverage. However comparison with main non-EU economies should be also provided for as indicated above.

1.3.3.2 Input by the contracting authority

The complexity of the subject implies a close cooperation between the contractor and the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, and the Directorate General for Health and Food Safety of the European Commission. The contractor is therefore expected to maintain direct contact with the Commission officials responsible for the study, in order to deliver information on the work progress at regular intervals. These contacts should lead to a frequent exchange of information between the Commission's services and the contractor beyond formal deliverables, including, if necessary, the participation to supplementary meetings at the Commission's premises.

The following list of sources of information is to provide the tenderers with references of some of the existing documents on the topics dealt under the current tender, and it is far from exhaustive. The tenderers are encouraged to look for more detailed and up-to-date data and literature for the preparation of the offer.

- The EU legislation cited in the background above, and the Commission preparatory working documents corresponding to that legislation.

- Previous studies on the pharmaceutical sectors carried out by the Commission services.

- The SPC-specialised blog: http://thespcblog.blogspot.be

- Supplementary protection certificates (SPC), Marco Stief, Dirk Bühler (eds.). München: C.H. Beck, 2015.

- Data exclusivity, Bolar exemption and generic drugs in the EU, Paul Garland and H. Kristjan Larusson, in European Intellectual Property Review 2007,v. 29, n.4, April, p. 128-133.

- Articles 3 (a) and 3 (b) of the SPC Regulation: an analysis, Paramjeet Singh Berwal. In: European Intellectual Property Review 2014, v.35, n.1, o. 29-38.

- The legal scope and content of the right to SPC extension under the Paediatric Regulation 1901/2006, Ulrich Reese, Claudia Milbradt, Christian Stallberg. In: European Intellectual Property Review 2010, v. 32, n.4, p. 146-154.

- Relations between SPC and data exclusivity, Katarzyna Zbierska, Pharmaceuticals Policy and Law 16 (2014) 73–87 73.

- Comparison of Stakeholder Metrics for Traditional and Adaptive Development and Licensing Approaches to Drug Development, Lynn G. Baird et. Al., Therapeutic Innovation & Regulatory Science 00(0) 1-10.

- EvaluatePharma® Orphan Drug Report 2015, Evaluate, 3rd Edition – October 2015.

- The Orphan Drug Act Restoring the Mission to Rare Diseases, Michael G. Daniel et. al. Am J Clin Onco/ 2016;39:2W-213.

- The economic returns of paediatric clinical trials of antihypertensive drugs, Am Heart J 2008;156:682-8.

- Other relevant studies, reports, etc.

1.3.3. *Indicative methodology*

The contract shall result in a study based mainly on economic models of research, industrial organisation and pricing models for the relevant sectors that will be tested both quantitatively and qualitatively.

The tenderer can decide on the optimal combination of methodologies to achieve the objectives specified above. The methodological approach shall be described in detail in the tender with due account being taken of the specifications made above and with a reasoned explanation of how the proposed methodology meets the required criteria. The tenderer shall provide information on the dataset to be used to overcome data limitations. The final methodology may be fine-tuned as the study progresses, after obtaining the Commission's services consent.

The tenderer will have to carry out desk research and economic literature reviews, interviews as well as make use of different databases.

Regarding the case-studies, they should be examples from different categories of products (e.g. blockbusters, biologicals, orphans blockbusters, paediatrics) and if possible, different therapeutic classes. They should allow for the possibility to look at the impacts of SPC & the various incentives across the various Member States. The contractor shall provide the Commission's services with the list of case studies for comments and approval.

1.4. DELIVERABLES, MEETINGS AND COMMUNICATION

The contractor must provide the required reports and documents in accordance with the conditions of the draft service contract.

The deliverables of this contract are:

1) The Roadmap

A detailed Roadmap taking into account the conclusions of the kick-off meeting. It will present a clear economic methodology and datasets to be used to perform tasks in section 1.3.2 above. A draft overview of the experts to be consulted and possible questions will also be made available. It should be delivered no later than one month after the signature of the contract.

2) The Interim Report

The **interim report** will be delivered to the Commission **no later than 4 months from the start of the contract**.

The **interim report** shall include at least the following:

- The first draft of the study, based on the information and data gathered during the first 4 months;
- Solid analysis on the economic evaluation of SPC regulations.
- Information on the progress of the work: the Contractor will inform in detail which data have been collected, what qualitative information has been collected by interviewing experts and what are the results and conclusions of the preliminary analysis. Moreover, the contractor will inform on any difficulties encountered and propose solutions to solve at the next stages of his/her work;
- Any other information the contractor considers relevant at this stage of the study.

3) The draft Final Report, for Commission's comments and last review

The draft final report must include:

- All elements requested in sections 1.2 and 1.3
- an abstract of no more than 200 words and an executive summary of maximum 6 pages, both in English and French;
- specific identifiers which must be incorporated on the cover page provided by the Contracting Authority;
- the following disclaimer:

  "*The information and views set out in this [report] [study] [article] [publication…] are those of the author(s) and do not necessarily reflect the official opinion of the European Commission or of the Commission. The Commission cannot guarantee the accuracy of the data included in this study. The Commission or any person acting on their behalf may not be held responsible for the use which may be made of the information contained therein.*"

4) The Final Report

5) Data Annex – detailed data on SPC applications collected under task 6 of specific objectives.

) A Power point presentation (20 slides maximum) with the main results of the study.

Each deliverable will be submitted in 3 copies in paper version and in electronic format compatible with Word in English.

1.4.1. *The form*

All studies produced for the European Commission and Executive Agencies must conform to the corporate visual identity of the European Commission by applying the graphic rules set out in the European Commission's Visual Identity Manual, including its logo[5].

The Commission is committed to making online information as accessible as possible to the largest possible number of users including those with visual, auditory, cognitive or physical disabilities, and those not having the latest technologies. The Commission supports the Web Content Accessibility Guidelines 2.0 of the W3C.

For full details on Commission policy on accessibility for information providers, see: http://ec.europa.eu/ipg/standards/accessibility/index_en.htm

Pdf versions of studies destined for online publication should respect W3C guidelines for accessible pdf documents. See: http://www.w3.org/WAI/

1.4.2. *The language*

All the deliverables, both in their interim and final versions, will be made available in English of publishable quality. The contractor will need to put into place a system to check the linguistic quality of the deliverables.

1.4.3. *The deadlines*

The draft interim report will be delivered 4 months from the start of the actions. It will include a detailed analysis on SPCs (Task 3: point 1.3.1.2) as well as an analysis on the other tasks. The **draft final report,** taking into account the Commission's feedback on the interim report, will be delivered to the Commission **7 months** from the start of the action. Its contents will include an analysis of feedback received from the Commission on the interim report. The Commission will provide its comments on the draft final report within 30 days from its receipt. The draft final study shall include at least all the elements specified in the section 1.4 "Deliverables, meeting and communications".

The **final version**, taking into account the Commission's feedback on the draft final report will be delivered no later than **9 months** from the start of the action.

[5] http://ec.europa.eu/dgs/communication/services/visual_identity/index_en.htm

Timetable (months/weeks/days)	**Meetings**	**Actions/Deliverables**
Reference date (T0)		Start date of the contract
+ 1 month	kick-off meeting	*Submission Roadmap one week before the kick-off meeting*
+2 months		*Comments, revision (if needed) and acceptance of revised Roadmap*
+4 months	Meeting (15-30 days after receiving the interim report)	*Submission Interim report, discussion, comments and revision*
+5 months		*Submission revised interim report (if needed) and approval*
+ 7 months	Meeting (15-30 days after receiving the draft final report)	*Submission Draft final report*
+ 8 month		*Comments on final report*
+ 9 months		*Submission final report and approval*

1.4.4. *The procedure for approval of the reports*

The final report will be assessed on the basis of the following quality criteria:

1) Relevance: Does the study deal adequately with requests for information from the European Commission and is it in line with the specifications?
2) Appropriate methodology: Is the design of the study adequate and suitable for providing the results required (within time limits) to answer the objectives of the study?
3) Reliable information: Is the information and material collected or selected relevant and valid?
4) **Sound analysis**: Is the analysis of the information and material complete and appropriate? Are proposed datasets relevant for the analysis?
5) **Credible results**: Are the results logical and justified by the analysis of the data and literature?
6) **Valuable results**: Are the results valuable and representative?
7) **Clarity**: Does the report describe the context and goal of the work and are the results presented in such a way that they can be validated and transferred by stakeholders?
8) **Language**: Is the English language used in the report understandable, of high quality and publishable?
9) **Overall assessment of the study**

1.4.5. *Meetings*

For the execution of the study and its communication, the tenderer shall budget in its offer all own relevant travel expenses, as indicated in Section 4.2.5. More specifically the following meetings in Brussels shall be foreseen and budgeted for:

- 3 meetings (kick off and assessment of interim and final reports)

Meetings will be complemented with telephone calls when needed.

1.4.6. *Indicative Timetable:*

Months									
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Contract Signature ↓ **Prefinancing** **30%** ↓ Kick-off meeting	Detailed Roadmap			Interim report (including solid evidence on the economic analysis of SPCs) (month **4)** ↓ +/- 20 days comments ↓ Discussion on Interim report ↓ Submission revised interim report (if needed) ↓ Approval of interim report (month 5) ↓ 30% Interim Payment (month 5)		DRAFT Final report (month 7) ↓ +/- 30 days comments ↓ Discussion Final Report ↓ Approval of draft final report (month 9)			Submission Final invoice, Final Report, Executive summary and Abstract ↓ 60 days for payment ↓ 40% Final Payment

2. CONTRACTUAL CONDITIONS

2.1. NATURE OF THE CONTRACT

An open call for tenders is launched by the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs for a "**Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe**". The contract will be awarded in accordance with the criteria laid down in section 5 hereafter.

2.2. STARTING DATE OF THE CONTRACT AND DURATION OF THE TASKS

The contract shall enter into force on the date on which it is signed by the last contracting party.

It is expected to be signed in March **2017** (tentative date)

The duration of the tasks shall not exceed **9 months**.

The execution of the tasks may not start before the contract has been signed. The period of execution of the tasks may be extended, only with the written agreement of the contracting parties, before the end of the period originally stated in the contract.

2.3. TERMS OF PAYMENT

Payments shall be made in accordance with Articles I.4, I.5 & II.21 of the draft service contract (Annex 6.2).

The payment scheme will consist of:

- A pre-financing of 30 %
- one interim payment of 30 %
- and the balance of 40 %.

The schedule and the procedure for the approval of payments and the documents to be submitted are described in Articles I.5, II.21, II.22 and II.23 and in Annex I to the draft contract referred to above.

2.4. GUARANTEES

The Contractor may be required to provide a guarantee for pre-financing of 30% of the amount specified under I.4.1 of the contract, in compliance with article II.21.5 of the draft contract. The Commission reserves the right to cancel the pre-financing foreseen, according to its management risk analysis or in the case the awarded tenderer refuses such pre-financing guarantee, and to modify the final version of the contract accordingly.

A model guarantee is provided in annex 6.3 of these tendering specifications.

2.5. PLACE OF PERFORMANCE

The place of performance of the tasks shall be the Contractor's premises or any other place indicated in the tender, with the exception of the Commission's premises.

2.6. SUBCONTRACTING

Subcontracting is defined as the situation where a contract has been or is to be established between the Commission and a contractor and where the contractor, in order to carry out that contract, enters into legal commitments with other legal entities for performing part of the service. However, the **Commission has no direct legal commitment with the subcontractor(s)**.

At the level of the liability towards the Commission, tasks provided for in the contract may be entrusted to subcontractors, but **the contractor retains full liability towards the Commission for performance of the contract as a whole**.

Accordingly:

- The Commission will treat all contractual matters (e.g. payments) exclusively with the contractor, whether or not the tasks are performed by a subcontractor;

- The Commission will privilege direct contacts with the contractor, who is responsible for executing the contract;

- Under no circumstances can the contractor avoid liability towards the Commission on the grounds that the subcontractor is at fault. The contractor remains notably fully responsible for timely execution.

A contract which includes subcontracting is subject to certain general conditions in particular the provisions on subcontracting, checks and audits, and confidentiality. Where justified by the subject matter of the contract, a statement of confidentiality may be required to be submitted to the Commission. **The subcontracting arrangement between the contractor and his subcontractor is supposed to render directly applicable all those contractual obligations with regard to the Commission to the subcontractor**.

Consequently, the bid must clearly identify the subcontractor(s) and document their willingness to accept the tasks and their acceptance of the terms and conditions set out in paragraph 3.3, in particular article II.24 of the standard service contract by returning the form in annex 6.5, filled in and signed (insert in e-Submission under: “Qualification" -> "Identification of the tenderer" under "Documents").

Tenderers must inform the subcontractor(s) and include in their sub-contracting documents that Article II.24 of the standard service contract (Annex 6.2) may be applied to sub-contractors.

<u>Once the contract has been signed</u>, Article II.10 of the above-mentioned service contract shall govern the subcontracting.

Special attention of tenderers is brought to Article II.10.4, according to which the contracting authority may request the contractor to replace a subcontractor found to be in a situation provided for in points (d) and (e) of Article II.18.1.

2.7. JOINT OFFERS

A joint offer is a situation where an offer is submitted by a group of tenderers. If awarded the contract, the tenderers of the group will have an equal standing towards the Commission in executing a supply, service or works contract.

The Commission will not request consortia to have a given legal form in order to be allowed to submit a tender, but reserves the right to require a grouping to adopt a given legal form **before the contract is signed** if this change is necessary for proper performance of the contract. This can take the form of an entity with or without legal personality but offering sufficient protection of the Commission's contractual interests (depending on the Member State concerned, this may be, for example, a consortium or a temporary association).

The documents required and listed in the present specifications must be supplied by every member of the grouping; the checklist in annex 6.7 will help verifying the level of information to be provided according to the role of each entity in the tender.

Each member of the grouping assumes a joint and several liability towards the Commission.

To this end all members of the grouping should sign a **power of attorney** (see models in annex 6.6). This document must be scanned and included in the offer (Qualification" -> "Identification of the tenderer" under "Documents"). For groupings not having formed a common legal entity, model 1 should be used, and for groupings with a legal entity in place model 2.

The expression "joint tender leader" in the e-Submission application is equivalent to "Group Leader" or "Group Manager" in the document of power of attorney.

The offer (Tender Preparation Report) has to be signed by the joint tender leader (hand or electronic signature, as explained in point 1.9 of the Annex to Invitation to Tender: e-Submission application).

Partners in a joint offer assume joint and several liability towards the Commission for the performance of the contract as a whole.

Statements, saying for instance: "that one of the partners of the joint offer will be responsible for part of the contract and another one for the rest", or "that more than one contract should be signed if the joint offer is successful", are thus incompatible with the principle of joint and several liability. The Commission will disregard any such statement contained in a joint offer, and reserves the right to reject such offers without further evaluation, on the grounds that they do not comply with the tendering specifications.

An economic operator can only participate once as a tenderer, whether as sole tenderer, leader in a joint tender or partner in a joint tender. **The economic operator may however agree to act as a subcontractor in a distinct bid** from which it is participating as either of the aforementioned options. However, such a situation is not advisable for the high potential of conflicts of interest it may generate.

3. ADMINISTRATIVE INFORMATION CONCERNING THE INVITATION TO TENDER

These specifications follow the publication of a contract notice in OJ S.

3.1. DATE AND PLACE OF OPENING OF THE TENDERS

The received electronic tenders will be opened at **14.00 on 10/02/2017.**

at the following location:

Office address:

Av. des Nerviens 105
1040 Brussels

An **authorised representative** of each tenderer may attend the opening of the bids. Companies wishing to attend are requested to notify their intention by sending an e-mail to grow-dir-f-financial-team@ec.europa.eu.at least 48 hours in advance. This notification must be signed by an authorised officer of the tenderer and specify the name of the person who will attend the opening of the bids on the tenderer's behalf. **On the day of opening the representatives of tenderers should present the tender receipt confirmation sent by e-Submission application in order to be allowed to the opening meeting.**

The economic operators who submitted an offer and whose representative was not present at the opening meeting may send an information request to grow-dir-f-financial-team@ec.europa.eu. They will be informed per e-mail if their offer was admissible as well as of the identity of the other tenderers

3.2. CONTACT BETWEEN THE TENDERER AND THE COMMISSION

Contacts between the Commission and the tenderers may take place only in **exceptional circumstances** and under the following conditions only:

Before the final date for submission of tenders:

- Upon request, the contracting authority may provide additional information solely for the purpose of clarifying the procurement documents.
- Any request for additional information must be made in writing only through the e-Tendering website at https://etendering.ted.europa.eu/cft/cft-display.html?cftId=2025 in the "questions and answers" tab, by clicking "create a question".
- The contracting authority is not bound to reply to requests for additional information received less than six working days before the final date for submission of tenders.

- The contracting authority may, on its own initiative, inform interested parties of any error, inaccuracy, omission or any other type of clerical error in the text of the procurement documents.

- Any additional information including that referred to above will be posted on the e-Tendering website indicated above. The website will be updated regularly. It is the responsibility of the tenderer to check regularly for updates and modifications during the submission period.

After the opening of tenders :

The Commission shall contact the tenderer in order to correct obvious clerical errors or to require confirmation of a specific or technical element, except in duly justified cases. This shall not lead to changes in the procurement documents or substantial changes to the terms of the submitted tender.

3.3. GENERAL TERMS AND CONDITIONS FOR THE SUBMISSION OF TENDERS

The present procurement documents are drawn up in respect of the Financial Regulation applicable to the general budget of the European Union (Regulation (EU, Euratom) No 966/2012 of the European Parliament and the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union, as amended by Regulation (EU, Euratom) No 2015/1929 of the European Parliament and the Council of 28 October 2015., as well as its Rules of Application (Commission Delegated Regulation (EU, Euratom) No 1268/2012 of 29 October 2012, amended by Commission Delegated Regulation (EU) C(2015)7555 of 30 October 2015.

Participation in procurement procedures is open on equal terms to all natural and legal persons from one of the EU Member States and to all natural and legal persons in a third country which has a special agreement with the European Union in the field of public procurement on the conditions laid down in that agreement. It is also open to international organisations.

Where the Plurilateral Agreement on Government Procurement (GPA) concluded within the WTO applies, the contracts are also open to nationals of the countries that have ratified this Agreement, on the conditions laid down therein.

The parties to the GPA can be consulted on the following web page:

https://www.wto.org/english/tratop_e/gproc_e/gp_gpa_e.htm.

Operators in third countries which have signed a bilateral or multilateral agreement with the European Union in the field of public procurement must be allowed to take part in the tendering procedure on the conditions laid down in this agreement. The Commission refuses tenders submitted by operators in third countries which have not signed such agreements for the present call for tender.

Submission of a tender implies acceptance of the terms and conditions set out in the procurement documents and, where appropriate, waiver of the tenderer's own general or

specific terms and conditions. It is binding on the tenderer to whom the contract is awarded for the duration of the contract.

Once the Commission has accepted the tender, it shall become the property of the Commission and the Commission shall treat it confidentially.

The Commission shall not reimburse expenses incurred in preparing and submitting tenders.

The Protocol on the Privileges and Immunities or, where appropriate, the Vienna Convention of 24 April 1963 on Consular Relations shall apply to this invitation to tender.

Variants are NOT allowed.

3.4. NO OBLIGATION TO AWARD THE CONTRACT

This invitation to tender is in no way binding on the Commission. The Commission's contractual obligation commences only upon signature of the contract with the successful tenderer.

Up to the point of signature, the contracting authority may cancel the award procedure. This decision must be substantiated and the tenderers notified.

No compensation may be claimed by tenderers whose tender has not been accepted, including when the Commission decides not to award the contract.

3.5. DATA PROTECTION

If processing your reply to the invitation to tender involves the recording and processing of personal data (such as your name, address and CV), such data will be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Unless indicated otherwise, your replies to the questions and any personal data requested are required to evaluate your tender in accordance with the specifications of the invitation to tender and will be processed solely for that purpose by DG GROW, Unit F5 - Intellectual property and Fight against Counterfeiting. Details concerning processing of your personal data are available on the privacy statement at the page

http://ec.europa.eu/dataprotectionofficer/privacystatement_publicprocurement_en.pdf.

You are informed that for the purposes of safeguarding the financial interest of the Union, your personal data may be transferred to internal audit services, to the Court of Auditors, to the Financial Irregularities Panel and/or to the European Anti-Fraud Office (OLAF).

Your personal data may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 106 of the Financial Regulation. For more information, see the Privacy Statement on http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm)

3.6. OPPORTUNITIES FOR SMALL AN D MEDIUM SIZED ENTERPRISES

The Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs has the task to promote opportunities for Small and Medium sized Enterprises (SMEs) and is aiming in its activities to facilitate the activities of SMEs. In this context, **SMEs are particularly encouraged to submit tenders** either on its own if feasible or by constituting a bid using either of the options mentioned in paragraphs 2.6 and 2.7.

The **Enterprise Europe Network** provides advice on tender opportunities and training in relation to procurement, which may be of assistance to newly initiated tenderers. Please refer to the following web-site for further details:

http://een.ec.europa.eu/content/advice-eu-law-and-standards

The Commission has further published a brochure on "Doing business with the European Commission – Tips for potential contractors":
http://ec.europa.eu/budget/library/biblio/publications/business/doing_business_en.pdf

4. FORM AND CONTENT OF THE TENDER

4.1. HOW TO SUBMIT A TENDER

Tenderers shall observe precisely the indications in point 1 and 2 of the invitation to tender, as well as in the Annex to Invitation to tender: "e-Submission application" in order to ensure their tenders are admissible. **Only electronic submission through e-Submission application is allowed for this call.**

Offers sent on paper, by e-mail or by fax will be non-admissible.

Evidence of timely receipt will be constituted by the timestamp in the tender receipt confirmation which will be sent to your e-Submission mailbox.

Receipt after the deadline will lead to the non-admissibility of the tender and its rejection from the award procedure for this contract.

4.2. STRUCTURE OF THE TENDER

- Tenders shall be perfectly legible so there can be no doubt as to words and figures.
- Tenders shall be clear and concise.
- Tenders shall be written in one of the official languages of the European Union.
- Tenders shall include the information and documents requested by the Commission in order to assess the tender. In order to help tenderers presenting a complete tender, a checklist of the documents to be submitted is provided in annex 6.7. This checklist does not need to be included in the tender, but it is encouraged to use it in order to ease the assessment of the tenders;
- Prices shall be established in euros.

All tenders must be presented in five sections:

Section	**Where to insert in e-Submission**
Section one: Administrative information	"**Qualification**" → "Identification of the Tenderer" → "[Party Name]"
Section two: Exclusion and selection criteria form	**Qualification**" → "Identification of the Tenderer" → "[Party Name]"
Section three: Evidence relating to the selection criteria	"**Qualification**" -> "Selection Criteria" -> "Financial and Economic Capacity" -> "[Party name]" "**Qualification**" -> "Selection Criteria" -> "Technical and Professional Capacity" -> "[Party name]"
Section four: Technical Offer – Addressing technical specifications and award criteria	"**Tender**" → "[name of Call for Tender/ Lot name]"
Section five: Financial Offer	"**Tender**" → "[name of Call for Tender/ Lot name]"

4.2.1. *Section One: Administrative information*

Tenderers may choose between presenting a **joint bid** (see 0) and introducing a bid as a **sole economic operator,** in both cases with the possibility of having one or several subcontractors (see 2.6).

Whichever type of bid is chosen, the tender shall stipulate the legal status and role of each legal entity in the tender proposed and the monitoring arrangements that exist between them and, failing this, the arrangement they foresee to establish if they are awarded the contract (see 2.6 and 2.7).

A. In the e-Submission application, tab "Qualification" -> "Identification of the Tenderer", the tenderers should fill out the required information (Identification info, Registration info, Fiscal info, Contact info, Power of representation), according to the type of bid. The information has to be completed for all entities participating in the bid, including subcontractor.

In addition, to identify himself the tenderer must fill in a Legal Entity Form and a Financial Identification Form:

B. **The Legal Entity Form** shall be duly filled in and signed by a representative of the tenderer authorised to sign contracts with third parties. It should be uploaded under "Documents" in the section "Qualification" -> "Identification of the Tenderer".

A standard template in each EU language is available at http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm

The Legal Entity Form **shall be accompanied** with **the information** indicated in the form. When neither this form nor the evidence to be attached to them includes the following information, the tender must include:

For private and public entities:

- A legible copy of the notice of appointment of the persons authorised to represent the tenderer in dealings with third parties and in legal proceedings, or a copy of the publication of such appointment, where the legislation which applies to the legal entity concerned requires such publication. Any delegation of this authorisation to another representative not indicated in the official appointment must be evidenced.

For Individuals:

- Where applicable, a proof of registration, as prescribed in the country of residence, on one of the professional or trade registers or any other official document showing the registration number.

In case of a joint bid, all tenderers part of a joint tender must provide their legal entity files as well as the necessary evidence. For subcontractors a legal entity file shall be submitted, without evidence.

C. The **Financial identification form** shall be duly filled in and signed by an authorised representative of the tenderer and his or her banking institution, where the references account is held.

The form needs to be printed, filled in, signed and then scanned and uploaded in the section "Qualification" -> "Identification of the tenderer" -> "Documents".

The form is available on:

http://ec.europa.eu/budget/contracts_grants/info_contracts/financial_id/financial_id_en.cfm

In case of a joint bid or a bid presenting subcontracting, only the leader is obliged to return the financial identification form (i.e. for a joint tender only one financial identification from the leading tenderer is required).

Economic operators already registered as a legal entity in the Commission (i.e. they are or have been contractors of the Commission) may refer to evidence provided for other procedures. In that end, the tender should indicate the references of the procedure concerned and the Commission department to which this evidence was provided.

4.2.2. *Section Two: The Exclusion and Selection Criteria Form*

Tenderers or their representatives shall provide a declaration on their honour, duly signed and dated in which they:

1. state whether or not they are in one or more of the situations referred to in Articles 106 and 107 of the Financial Regulation and detailed in the form;

2. state whether they fulfil the selection criteria

3. undertake to submit to the Commission any additional document relating to the exclusion/selection criteria, that the Commission considers necessary to perform its checks, within fifteen calendar days following the receipt of the Commission's request.

To this end, tenderers must fill in and sign the form in Annex 6.1 to these specifications.

The declaration(s) shall be signed by an authorised representative either with advanced electronic signature based on qualified certificates or by scanning and uploading a hand signed copy. The declaration(s) must be uploaded under "Qualification" → "Identification of the Tenderer" → "<'Member Name'>" → Tab "Documents"

If the declaration on honour is signed by hand, the original declaration must also be sent by post immediately after electronic submission of the tender.

Where the bid involves more than one legal entity (including subcontractors), each entity must provide the form.

4.2.3. ***Section Three: Evidence relating to the selection criteria***

Tenderers shall provide proof of their economic and financial capacity by submitting the documents stated under paragraph 5.2.2 below. In case of a joint tender/tender with subcontractors, the documents concerning each economic operator shall be submitted under the respective party name.

Documents certifying financial and economic capacity must be included in section "Qualification" -> "Selection Criteria" -> "Financial and Economic Capacity" -> "[Party name]" in the e-Submission application.

Tenderers shall equally provide the proof of their professional and technical capacity by submitting the documents required under paragraph 5.2.3 below.

Proof of technical and professional capacity must be included in section "Qualification" -> "Selection Criteria" -> "Technical and Professional Capacity" -> "[Party name]" in the e-Submission application.

If evidence has already been provided for another procurement procedure and if the documents are up to date, reference can be made to the earlier procedure. The declaration on honour stating the reference of the procedure and the confirmation that there has been no change in the situation must be uploaded under "Qualification" -> "Selection Criteria".

4.2.4. *Section Four: Technical proposal*

The technical proposal needs to be uploaded in the section "Tender → <'name of Call for Tender' / 'Lot name'>" in the e-Submission application.

The tenderer must select the "Technical Tender" from the dropdown box ("Financial Tender or Technical Tender"). The e-Submission application allows attachment of as many documents as necessary.

Tenderers shall include in their bids a **technical proposal addressing the aspects detailed in the technical specifications** in sections 1.2 and 1.3.

The technical proposal shall comply with the technical specifications and provide, as a minimum, the information specifically requested.

The following aspects should in particular be taken into consideration when drafting the tender:

(a) methodology for implementation;

(b) reasons for the proposed methodology;

(c) where applicable, the link with previous activities and how they relate to the present tender;

(d) project management and procedures for internal evaluation;

(e) level of involvement and activity of other stakeholders;

(f) role of each partner in case of a joint bid and/or use of subcontractors, the role of each partner and subcontractor in the implementation of the contract;

(g) team proposed for implementation of the contract. The composition of the team, which will be implementing the project must be properly described. Team staff should be singled out by function (E.g. project managers, administrator, secretary, expert, technical assistant);

(h) a plan of action with description of activities and their timing.

Due consideration should be given to the award criteria and method as stipulated under section 5.3 in this document.

Please note that, to grant equal treatment of all tenders**, it is not possible to modify offers after their submission in relation to the technical and financial proposals**.

Please note that incomplete financial or technical proposals may have a considerable negative impact the evaluation on award criteria. Proposals deviating from the technical specifications risk to be considered as non-conform to the specifications.

The technical specifications and the tenderer's bid shall be integral parts of the contract and will constitute annexes to the contract.

4.2.5. *Section Five: Financial proposal*

A complete financial proposal, including the breakdown of the price, to be provided per category, as indicated in the tender specifications needs to be uploaded in section "Tender → <'name of Call for Tender' / 'Lot name'>" in the e-Submission application. The tenderer will need to select the "Financial Tender" from the dropdown box ("Financial Tender or Technical Tender").

The total price (including any options and renewals) needs also to be encoded directly in the e-Submission application (section "Tender → <'name of Call for Tender' / 'Lot name'>")

Tenderers must use the following format to formulate their financial proposal.

Price component	*Unit price*	*Quantity*	*Total*
Human resources			
Person X (role)			
Person Y (role)			
…..			
Subtotal (1)			
Other			
Item X			
Item Y			
…..			
Subtotal (2)			
TOTAL (1+2)			

The tenderer's attention is drawn to the following points:

1. prices must be expressed in euros;

2. **prices should be quoted free of all duties, taxes and other charges, i.e. also free of VAT**. The European Union Institutions are exempt from such charges in the EU under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union of 8 April 1965 (OJ 152 of 13 July 1967). Exemption is granted to the Commission by the governments of the Member States, either through refunds upon presentation of documentary evidence or by direct exemption.

For those countries where national legislation provides an exemption by means of a reimbursement, the amount of VAT is to be shown separately. In case of doubt about the applicable VAT system, it is the tenderer's responsibility to contact his or her national authorities to clarify the way in which the European Union is exempt from VAT;

3. Prices shall not be conditional and be directly applicable by following the technical specifications.

4. **Prices shall be** fixed and not subject to revision

5. The reference price for the award of the contract shall consist of **the amount in payment of the tasks executed**, as stated in Article I.4.1 of the contract.

   For each category of staff to be involved in the project, the tenderer must specify:

   - the total labour costs;
   - the **daily rates** and **total number of days** (man-days) each member of staff will contribute to the project;
   - other categories of costs, indicating the nature of the cost, the total amount, the unit price and the quantity. Flat-rate amounts should be avoided. If, exceptionally, they are used, specimen quotations for the flat-rate amounts must be provided;
   - travel expenses which will be incurred by the contractor or its representatives in the context of the work to be done or to attend the project meetings as indicated, should be included in the budget estimate included in the Financial Proposal. **In the budgeting the contractor should foresee travel expenses for 3 meetings in Brussels (kick off meeting, and preparatory meetings for the interim and the final report).** No specific reimbursement foreseen.

   Bids involving more than one legal entity must specify the amounts for each legal entity.

The Commission will reject tenders where no technical offers or financial offers are proposed.
Non-compliance with the minimum requirements in section 1.1 will also result in rejection from award.
The Commission reserves the right, however, to request clarification of the tender after the opening. It may furthermore require (additional) evidence in relation to the administrative information, exclusion and selection criteria. The information required shall be provided within a time-limit stipulated in its request and under the conditions explained in section 3.3.

5. ASSESSMENT AND AWARD OF CONTRACT

The assessment will be based on the information provided in the tender. The Commission reserves the right to use any other information from public or specialist sources. This assessment will be performed by applying the criteria set out in these specifications. To award the contract, the assessment of admissible bids (see paragraph 1 of the Invitation to tender) will be carried out under exclusion, selection and award criteria in no particular order.

The aim of this assessment is:

1) to verify compliance with the exclusion criteria as defined in article 106 and 107 of the Financial Regulation, in order to determine whether the tenderer can take part in the procedure and, where applicable, be awarded the contract;
2) to verify compliance with the selection criteria, technical and professional capacity and economic and financial capacity required by these specifications;
3) to verify compliance with the minimum requirements specified in the tender documents and to assess the technical and financial offer in relation to the award criteria, including compliance with the quality thresholds set in these specifications.

5.1. APPLICATION OF EXCLUSION CRITERIA AND EXCLUSION OF TENDERERS

5.1.1. *Declaration*

As mentioned above under paragraph 4.2.2, tenderers or their representatives shall provide the form in Annex 6.1 duly signed and dated in which they declare:

1. not to be in one or more of the situations referred to in Articles 106 and 107 of the Financial Regulation and detailed in the form;

2. to undertake to submit to the Commission any additional document relating to the exclusion criteria, that the Commission considers necessary to perform its checks, within 15 days following the receipt of the Commission's request.

5.1.2. *Grounds for disqualification*

In accordance with Article 107 of the Financial Regulation, a contract for a given procedure may not be awarded to an economic operator who:

- is in an exclusion situation established in accordance with Article 106;
- has misrepresented the information required as a condition for participating in the procedure or has failed to supply that information;
- was previously involved in the preparation of procurement documents where this entails a distortion of competition that cannot be remedied otherwise.

5.1.3. *Evidence*

The tenderer to whom the contract is to be awarded shall provide, within the 15 days following the receipt of the letter informing him of the proposed award of the contract

and preceding the signature of the contract, the evidence confirming the declaration referred to in paragraph 5.1.1 (for the details of requested documents please see directly the text of the declaration).

The Commission may waive the obligation of a tenderer to submit the documentary evidence referred to above if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that the issuing date of the documents does not exceed one year and that they are still valid. In such a case, the tenderer shall declare on his honour that the documentary evidence has already been provided to the Commission in a previous procurement procedure and confirm that no changes in his situation have occurred. He shall indicate in its tender all the references necessary to allow the Commission services to check this evidence.

You may refer to the e-Certis web-site listing the certificates available in EU Member States:

http://ec.europa.eu/markt/ecertis/login.do

5.2. APPLICATION OF SELECTION CRITERIA (SELECTION OF TENDERERS)

This part of the tender concerns the criteria and evidence relating to the technical and professional capacity and economic and financial capacity of the service provider(s) involved in the bid. It should also contain any other document that the tenderer(s) wish(es) to include by way of clarification.

An economic operator may rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. In that case, evidence must be provided that it will have at its disposal the resources necessary for performance of the contract, for example by producing a clear undertaking on the part of those entities to place those resources at its disposal.

If the economic and financial selection criteria are fulfilled by relying on a third party, the contracting authority may demand, if that tender wins the contract, that this third party signs the contract (becomes a contractor) or, alternatively, provides a joint and several first-call guarantee.

If the third party chooses to sign the contract, the contracting authority should ensure that it is not in exclusion situation and it has access to the market.

If several service providers are involved in the bid, each of them must have the professional and technical capacity to perform the tasks assigned to them in the tender and have the necessary economic and financial capacity.

This rule applies to all legal entities once they have chosen to be tenderers. If the tender includes subcontractors, the Commission reserves the right to request evidence of their economic and financial capacity, where the tasks subcontracted represent a substantial part of the contract.

5.2.1. *Selection criteria*

SELECTION CRITERIA
1. FINANCIAL AND ECONOMIC CAPACITY
1.1 Sufficient economic and financial capacity to guarantee continuous and satisfactory performance throughout the envisaged lifetime of the contract. 1.2 Sufficient financial capacity in relation to the pre-financing foreseen under the contract.
2. TECHNICAL AND PROFESSIONAL CAPACITY
2.1 Tenderers (in case of a joint tender the combined capacity of all tenderers and identified subcontractors) must comply with the following criteria: - The tenderer must prove experience in the field of pharmaceutical sectors, data collection, statistical and econometric analyses as well as in drafting reports and recommendations. - Strong record of independent and high-quality research in the field of health economics and patents, including the "unitary patent", pharmaceutical/agrochemical patents and SPC-type protection, as demonstrated by publications, previous research or other activities carried out. - Resource capacities necessary to ensure the coverage of all EU Member States. - Management ability to carry out projects of this scale and scope, proven by previous projects of similar nature carried out on related topics. - Capacity to draft reports in English. - Experience in comparative analysis of regulations as well as survey techniques, data collection and analysis and drafting reports and providing recommendations. All the criteria must be verifiable with a proven level of experience and track record.
2.2 The team delivering the service should include, as a minimum, the following profiles: - Project Manager: At least 5 years' experience in project management, including overseeing project delivery, quality control of delivered service, client orientation and conflict resolution experience in project of a similar size (at least € EUR 100.000) and coverage (at least 10 EU countries covered), with experience in management of team of at least 4 people. - Expert in pharmaceutical sector and health economics: At least 10 years of professional experience. Relevant higher education degree or equivalent professional experience and at least 3 years' professional experience in the field. - Health economist with relevant higher education degree and at least 3 year experience in the field. - Language quality check - at least one member of the team should have English proficiency speaker language skills or equivalent, as guaranteed by a certificate or relevant experience. - Expert in data collection and econometric models: the expert(s) should have knowledge of English language and proven experience of 5 years in data collection and econometric techniques.

These criteria will be assessed on the basis of the documents referred to in 5.2.2 and 5.2.3.

5.2.2. *Evidence of the economic and financial capacity of the service provider(s)*

All tenderers must provide proof of their economic and financial capacity by submitting the following documents:

a) Annex 6.4, consisting of an extract of the concerned legal entities' annual accounts (balance sheet, profit and loss account, notes on the accounts and auditors' remarks when applicable) of the last two years, as approved by the general assembly of the company and, where applicable, audited and/or published. These documents must be signed by the authorised representative of the tenderer.

b) a statement of overall turnover and turnover concerning the tasks, supplies or services covered by this contract for the last three financial years;

If, for some exceptional reason which the Commission considers justified, a tenderer is unable to provide one or other of the above documents, he or she may prove his or her economic and financial capacity by any other document which the Commission considers appropriate. In any case, the Commission must at least be notified of the exceptional reason and its justification in the tender. The Commission reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

The Commission may waive the obligation of a tenderer to submit the documentary evidence referred to in paragraph 1 if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that it complies with the requirements of the present call for tenders. In such a case, the tenderer shall indicate in the tender reference to the contract and Commission service for which the evidence has been provided, in order to allow the Commission services to check this evidence.

5.2.3. *Evidence of the technical and professional capacity of the service provider(s)*

The ability of service providers to perform services will be assessed in particular with regard to their know-how, efficiency, experience and reliability as specified in paragraph 5.2.1.

Evidence of the technical and professional capacity of the providers involved in the tender may be furnished on the basis of the following documents:

- The educational and professional qualifications of the service provider or contractor and/or those of the firm's managerial staff and, in particular, those of the person or persons responsible for providing the services or carrying out the tasks; the Europass curriculum vitae format (http://europass.cedefop.europa.eu/europass/preview.action?locale_id=1) shall be filled in and signed, by each person involved in the execution of the tasks foreseen in the tender. The precise contractual link with the tenderer will also be described.

The CVs must specify:

- The different diplomas obtained (copies of which may be requested by the contracting authority where appropriate);
- Languages spoken;
- Expertise and experience relevant to the subject matter of the present invitation to tender gathered within the last three years;
- For the project leader, proof of experience in project management, or coordination of similar projects, gathered within the last two years.

This evidence refers to selection criteria 2.1 to 2.2

- List of relevant services provided in the past five years, with sums, dates and recipients, public or private. The most important services shall be accompanied by certificates of satisfactory execution.

This evidence refers to selection criteria 2.1 to 2.2

A summary table indicating the members of the team and describing their roles and involvement in each project phase. It should also include the number of hours / days each team member will spend on each project phase.

By submitting a tender, each legal entity involved therein accepts the possibility of a check being carried out by the Commission on its technical capacities and, if necessary, on its research facilities and quality control measures.

In addition, all tenderers are informed that they may be asked to prove that they are authorised to perform the contract under national law, as evidenced by inclusion in a professional or trade register or a sworn declaration or certificate, membership of a specific organisation, express authorisation, or entry in the VAT register.

5.3. APPLICATION OF AWARD CRITERIA (ASSESSMENT OF TENDERS)

The contract will be awarded to the **tender offering the best price-quality ratio**. The following award criteria will be applied:

No	Qualitative award criteria	Weighting (maximum points)
1.	**Clear identification of objectives and tasks** The degree to which the tender shows that the objectives and tasks involved as well as issues have been clearly assessed, understood and potential solutions discussed.	20
2.	**Quality and relevance of the proposed methodology** - Relevance, completeness and viability of the proposed methodology and manner in which the tasks study will be conducted. - Overall presentation and analysis of the economic implication of the different regulations. - Overall presentation and analysis of the current economic and policy debate surrounding the European pharmaceutical sector. - Assessment of the proposed economic and econometric analysis, including databases and econometric models used. - Overall presentation and analysis of SPC in Europe, main objectives and possible analysis to evaluate their achievement. - Overall presentation and analysis of data protection and market exclusivity in Europe, main objectives and possible analysis to evaluate their achievement. - Overall presentation and analysis of the issues concerning accessibility and availability of medicines in Europe. - Relevance of the case studies in the context of the overall study. Justification for selection. - Relevance of selected experts for the structured interviews and potential questions.	50
3.	**Organisation of the work** - Team's roles and responsibilities proposed to carry out the requested services, and their respective degrees of participation in the project. - Risk assessment and mitigation measures for all tasks - Assessment of how the tenderer intends to ensure the coverage of all EU Member States. - Soundness of the work plan and timeliness	15
4.	**Quality control measures** This criterion will assess the quality control system applied to the service foreseen in the tender specifications concerning the quality of the deliverables (e.g. experts' board), the language quality check, and continuity of the service in case of absence of the member of the team. The quality system should be detailed in the tender and specific to the tasks at hand; a generic quality system will result in a low score.	15
	Total number of points	100

The selected tender is assessed according to the above qualitative award criteria and the weighting applicable to each criterion.

Tenders scoring

* less than 65 % in the overall points total or

* less than 50% in the points awarded for a single criterion

will be excluded from the rest of the assessment procedure.

Price award criterion
Total price

! **Tenders presenting a total price superior to the maximum amount of €280.000.00) will be excluded from the rest of the assessment procedure.**

The contract will be awarded to the tender offering the best price-quality ratio on the basis of below calculation.

Final Evaluation
Score for Tender X = (Technical Score X 0.7) + [(Lowest price/Price of Tender X) x 100] x 0.3.

Tenders should elaborate on all points addressed by these specifications in order to score as many points as possible. The mere repetition of mandatory requirements set out in these specifications, without going into details or without giving any added value, may result in a significantly lower score. Where essential elements of these specifications are not expressively covered by the tender, the Commission may decide to give a zero mark for the relevant qualitative award criteria.

The tender may be rejected as non-compliant, when the minimum requirements set in the specifications are not met.

5.4. INFORMATION FOR TENDERERS

The Commission will notify all tenderers of decisions reached concerning the outcome of the procedure, indicating the grounds on which the decision was taken. This also applies to a decision not to award a contract or to cancel the procedure.

The Commission will inform the rejected tenderers of the reasons for their rejection. Each tenderer who is not in an exclusion situation and whose tender is compliant with the procurement documents and who makes a request in writing, shall be informed of the characteristics and relative advantages of the selected tender, of the name of the successful tenderer and of the price or contract value.

However, certain information may be withheld where its release would impede law enforcement or otherwise be contrary to the public interest, or would prejudice the legitimate commercial interests of economic operators, public or private, or might prejudice fair competition between them.

5.5. AWARD OF THE CONTRACT

The procurement procedure is concluded by a contract signed by the parties. In this case, the General Terms and Conditions applicable to service contracts referred to above shall apply.

After the period of validity of the tender has expired, conclusion of the contract shall be subject to the tenderer's agreement in writing.

The Commission shall not sign the contract with the successful tenderer until a standstill period of 10 calendar days has elapsed, counting from the day after simultaneous dispatch of the notification by electronic means to all tenderers (successful and unsuccessful).

After the award, during standstill period, the Commission will request to the tenderer proposed for award the evidence on exclusion criteria defined in section 5.1.3. If this evidence was not provided or proved to be unsatisfactory the Commission reserves the right to cancel the award procedure or to change the award decision to the benefit of the next best ranked tenderer on condition that he satisfies with the provision of the evidence on exclusion.

6. ANNEXES

ANNEXES

6.1. EXCLUSION AND SELECTION CRITERIA FORM

INVITATION TO TENDER 590/PP/GRO/SME/16/F/121

STUDY ON THE ECONOMIC IMPACT OF SUPPLEMENTARY PROTECTION CERTIFICATES, PHARMACEUTICAL INCENTIVES AND REWARDS IN EUROPE

Declaration on honour on exclusion criteria and selection criteria

The undersigned [*insert name of the signatory of this form*], representing:

(*only for natural persons*) himself or herself	(*only for legal persons*) the following legal person:
ID or passport number: ('the person')	Full official name: Official legal form: Statutory registration number**:** Full official address: VAT registration number: ('the person')

I – Situation of exclusion concerning the person

(1) declares that the above-mentioned person is in one of the following situations:	YES	NO
a) it is bankrupt, subject to insolvency or winding up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under national legislation or regulations;	☐	☐
b) it has been established by a final judgement or a final administrative decision that the person is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the contracting authority is located or those of the country of the performance of the contract;	☐	☐
c) it has been established by a final judgement or a final administrative decision that the person is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibity where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:		
(i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract;	☐	☐
(ii) entering into agreement with other persons with the aim of distorting competition;	☐	☐

(iii) violating intellectual property rights;	☐	☐
(iv) attempting to influence the decision-making process of the contracting authority during the award procedure;	☐	☐
(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure**;**	☐	☐
d) it has been established by a final judgement that the person is guilty of the following:		
(i) fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;	☐	☐
(ii) corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of EU Member States, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the legal provisions of the country where the contracting authority is located, the country in which the person is established or the country of the performance of the contract;	☐	☐
(iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;	☐	☐
(iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;	☐	☐
(v) terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;	☐	☐
(vi) child labour or other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;	☐	☐
e) the person has shown significant deficiencies in complying with the main obligations in the performance of a contract financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an Authorising Officer, OLAF or the Court of Auditors;	☐	☐
f) it has been established by a final judgment or final administrative decision that the person has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;	☐	☐
g) for the situations of grave professional misconduct, fraud, corruption, other criminal offences, significant deficiencies in the performance of the contract or irregularity, the applicant is subject to: i. facts established in the context of audits or investigations carried out by the Court of Auditors, OLAF or internal audit, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body; ii. non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the	☐	☐

verification of the application of standards of professional ethics; iii. decisions of the ECB, the EIB, the European Investment Fund or international organisations; iv. decisions of the Commission relating to the infringement of the Union's competition rules or of a national competent authority relating to the infringement of Union or national competition law; or v. decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.		

II – Situations of exclusion concerning natural persons with power of representation, decision-making or control over the legal person

Not applicable to natural persons, Member States and local authorities

(2) declares that a natural person who is a member of the administrative, management or supervisory body of the above-mentioned legal person, or who has powers of representation, decision or control with regard to the above-mentioned legal person (this covers company directors, members of management or supervisory bodies, and cases where one natural person holds a majority of shares) is in one of the following situations:	YES	NO	N/A
Situation (c) above (grave professional misconduct)	☐	☐	☐
Situation (d) above (fraud, corruption or other criminal offence)	☐	☐	☐
Situation (e) above (significant deficiencies in performance of a contract)	☐	☐	☐
Situation (f) above (irregularity)	☐	☐	☐

III – Situations of exclusion concerning natural or legal persons assuming unlimited liability for the debts of the legal person

(3) declares that a natural or legal person that assumes unlimited liability for the debts of the above-mentioned legal person is in one of the following situations:	YES	NO	N/A
Situation (a) above (bankruptcy)	☐	☐	☐
Situation (b) above (breach in payment of taxes or social security contributions)	☐	☐	☐

IV – Grounds for rejection from this procedure

(4) declares that the above-mentioned person:	YES	NO
h) has distorted competition by being previously involved in the preparation of procurement documents for this procurement procedure.	☐	☐

V – Remedial measures

If the person declares one of the situations of exclusion listed above, it must indicate measures it has taken to remedy the exclusion situation, thus demonstrating its reliability. This may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines. The relevant documentary evidence which illustrates the remedial measures taken must be provided in annex to this declaration. This does not apply for situations referred in point (d) of this declaration.

VI – Evidence upon request

Upon request and within the time limit set by the contracting authority the person must provide information on the persons that are members of the administrative, management or supervisory body. It must also provide the following evidence concerning the person itself and concerning the natural or legal persons which assume unlimited liability for the debt of the person:

For situations described in (a), (c), (d) or (f), production of a recent extract from the judicial record is required or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of establishment of the person showing that those requirements are satisfied.

For the situation described in point (a) or (b), production of recent certificates issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the person is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions. Where any document described above is not issued in the country concerned, it may be replaced by a sworn statement made before a judicial authority or notary or, failing that, a solemn statement made before an administrative authority or a qualified professional body in its country of establishment.

The person is not required to submit the evidence if it has already been submitted for another procurement procedure. The documents must have been issued no more than one year before the date of their request by the contracting authority and must still be valid at that date.

The signatory declares that the person has already provided the documentary evidence for a previous procedure and confirms that there has been no change in its situation:

Document	**Full reference to previous procedure**
Insert as many lines as necessary.	

VII – Selection criteria

(5) declares that the above-mentioned person complies with the selection criteria applicable to it individually as provided in the tender specifications:	YES	NO	N/A
(a) It fulfills the applicable economic and financial criteria indicated in section 5.2.1 of the tender specifications;	☐	☐	☐
(b) It fulfills the applicable technical and professional criteria indicated in section 5.2.1 of the tender specifications.	☐	☐	☐

(6) if the above-mentioned person is the **sole tenderer** or the **leader in case of joint tender**, declares that:	YES	NO	N/A
(c) the tenderer, including all members of the group in case of joint tender and including subcontractors if applicable, complies with all the selection criteria for which a consolidated asseessment will be made as provided in the tender specifications.	☐	☐	☐

VII – Evidence for selection

The signatory declares that the above-mentioned person is able to provide the necessary supporting documents listed in the relevant sections of the tender specifications and which are not available electronically upon request and without delay.

The person is not required to submit the evidence if it has already been submitted for another procurement procedure. The documents must have been issued no more than one year before the date of their request by the contracting authority and must still be valid at that date.

The signatory declares that the person has already provided the documentary evidence for a previous procedure and confirms that there has been no change in its situation:

Document	Full reference to previous procedure
Insert as many lines as necessary.	

The above-mentioned person may be subject to rejection from this procedure and to administrative sanctions (exclusion or financial penalty) if any of the declarations or information provided as a condition for participating in this procedure prove to be false.

Full name Date Signature

6.2. DRAFT SERVICE CONTRACT

See separate document

6.3. MODEL GUARANTEE

[MODEL] LETTER FOR PRE-FINANCING FIRST DEMAND GUARANTEE[6]

Financial institution/Bank (Letterhead)
[Place/Date]

European Union
Represented by the European Commission
Directorate-General for Internal Market, Industry,
Entrepreneurship and SMEs – [Unit]
B – 1049 Belgium

Reference: Contract N° and exact title: […]

ARTICLE 1 – DECLARATION ON GUARANTEE, AMOUNT AND PURPOSE

We, the undersigned [name and address of the financial institution or bank] (hereinafter referred to as "the Guarantor") hereby confirm that we give the European Union, represented by the European Commission (hereinafter referred to as "the Commission"), an unconditional, irrevocable and independent first-demand guarantee consisting in the undertaking to pay to the Commission a sum equivalent to the amount of:

EUR [in figures: …] (in words: … EUR)

upon simple demand, for guarantee of the pre-financing(s) stipulated in the contract (N°/exact title, hereinafter referred to as the "contract") concluded between the Commission and [name and address], (hereinafter referred to as "the Contractor").

ARTICLE 2 – EXECUTION OF GUARANTEE

If the Commission gives notice that the Contractor has for any reason failed to reimburse pre-financings paid by the Commission, we, acting by order and for account of the Contractor, shall undertake to immediately pay up to the above amount, in EUR, without exception or objection, into [Option 1: *a bank account designated by the Commission*] [Option 2: *the following bank account: (…)*], on receipt of the first written request from the Commission sent by registered letter or by courier with acknowledgement of receipt. We shall inform the Commission in writing as soon as the payment has been made.

ARTICLE 3 – OBLIGATIONS OF THE GUARANTOR

1. We waive the right to require exhaustion of remedies against the Contractor, any right to withhold performance, any right of retention, any right of avoidance, any right to offset, and the right to assert any other claims which the Contractor may have against the Commission under the contract or in connection with it or on any other grounds.

2. Our obligations under this guarantee shall not be affected by any arrangements or agreements made by the Commission with the Contractor which may concern his obligations under the contract.

3. We shall undertake to immediately inform the Commission in writing, by registered letter or by courier with acknowledgement of receipt, in the event of a change of our legal status, ownership or address.

[6] The footnotes are internal instructions for the authorising officers only and must be deleted before the guarantee is signed. [Plain text]: items to be filled in. [*Text in italics*]: these items are optional and may be deleted depending on the context of the guarantee.

ARTICLE 4 – DATE OF ENTRY INTO FORCE

This guarantee shall come into force upon its signature. If, on the date of its signature, the [*first*] pre-financing has not been paid to the Contractor, this guarantee shall enter into force on the date on which the Contractor receives the [*first*] pre-financing.

ARTICLE 5 – END DATE AND CONDITIONS OF RELEASE

1. We may be released from this guarantee only with the Commission's written consent.

2. This guarantee shall expire on return of this original document by the Commission to our offices by registered letter or by courier with acknowledgement of receipt.

3. [Option 1: *This must occur at the latest one month after the payment of the balance under the contract has been made or three months after the issuance of the corresponding recovery order.*[7]]

   [Option 2: *This must occur at the latest during the month after the pre-financing under the contract has been cleared through interim payment[s].*]

   [Option 3: *This must occur in any case, at the latest, on* (indicate a precise date[8]).]

4. After expiry, this guarantee shall become automatically null and void and no claim relating thereto shall be receivable for any reason whatsoever.

ARTICLE 6 – APPLICABLE LAW AND COMPETENT JURISDICTION

Option 1

1. *This guarantee shall be governed by and construed in accordance with the law applicable to the contract.*

2. *The courts having jurisdiction for matters relating to the contract shall have sole jurisdiction in respect of matters relating to this guarantee.*

Option 2

Any dispute concerning this guarantee shall be governed by and construed in accordance with the Law [of the country of establishment of the [Contractor][Bank]] and fall within the sole competence of the [corresponding national] Courts.

ARTICLE 7 - ASSIGNMENT

The rights arising from this guarantee may not be assigned [*without our written consent*].

Done at [insert place], on [insert date]

_____	[_____]
[Signature/ Function at the Financial Institution/Bank]	[Signature/ Function at the Financial Institution/Bank]

[7] In any case, this period should never be reduced.

[8] This mention has to be inserted where the law applicable to the guarantee imposes a precise expiry date.

6.4. FINANCIAL AND ECONOMIC CAPACITY OVERVIEW FORM

Invitation to tender 590/PP/GRO/SME/16/F/121
Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe

Financial and Economic Capacity Overview			
Currency : *EURO*			**Figures** ***(000)***
	N*(* most recent figures available)	**N-1**	**N-2**
Total Balance Sheet			
TRADE DEBTORS *Amounts due by commercial customers*			
CAPITAL and RESERVES (Equity) *Amounts owned by the company*			
TRADE CREDITORS *Amounts due to commercial suppliers*			
SHORT TERM DEBT			
LONG TERM DEBT			
LIQUIDITY *Bank accounts, cash at hand*			
About PROFIT & LOSS			
TURNOVER			
ORDINARY RESULT			
EXTRAORDINARY RESULT			
INCOME TAX			
NET RESULT			

You may add any data that you would consider of vital relevance for your organisation and for the understanding of the above figures.

Comments: Please explain BRIEFLY important variations from one year to another if appropriate. In case of negative equity or repeated losses, please explain how the future of the organisation will be ensured.

6.5. SUBCONTRACTOR / LETTER OF INTENT

INVITATION TO TENDER 590/PP/GRO/SME/16/F/121

STUDY ON THE ECONOMIC IMPACT OF SUPPLEMENTARY PROTECTION CERTIFICATES, PHARMACEUTICAL INCENTIVES AND REWARDS IN EUROPE

The undersigned**:** …….

Name of the company/organisation**:** ……

Address: ……

Declares hereby the intention to collaborate in the execution of the tasks subject to the above call for tender, in accordance with the terms of the offer to which the present form is annexed, if the contract is awarded to … …. *(name of the tenderer).*

Declares hereby accepting the general conditions attached to the tendering specifications for this call for tender, and in particular art. II.18 in relation with checks and audits.

Full name **Date** **Signature**

.....

6.6. POWER OF ATTORNEY

POWER OF ATTORNEY – MODEL 1

Agreement / Power of Attorney

(DESIGNATING ONE OF THE COMPANIES OF THE GROUP AS LEADER AND GIVING A MANDATE TO IT)

We the undersigned:

– Signatory 1 (Name, Function, Company, Registered address, VAT Number)
– Signatory 2 (Name, Function, Company, Registered address, VAT Number)
– …..
– Signatory N (Name, Function, Company, Registered address, VAT Number),

Each of them having the legal capacity required to act on behalf of his/her company, HEREBY AGREE AS FOLLOWS:

In case the European Commission awards Contract …. (« **the Contract** ») to Company 1, Company 2, …, Company N (« **the Group Members** »), based on the joint offer submitted by them on … ….. for the supply of ….. and/or the provision of services for … (« **the Supplies and/or the Services** »).

(1) As co-signatories of the Contract, all the Group Members:

(a) Shall be jointly and severally liable towards the European Commission for the performance of the Contract.
(b) Shall comply with the terms and conditions of the Contract and ensure the proper execution of their respective share of the Supplies and/or the Services.

(2) To this effect, the Group Members designate Company X as **Group Leader**. *[N.B.: The Group Leader has to be one of the Group Members*]

(3) Payments by the European Commission related to the Supplies or the Services shall be made through the Group Leader's bank account .[*Provide details on bank, address, account number, etc.*].

(4) The Group Members grant to the Group Leader all the necessary powers to act on their behalf in connection with the Supplies and/or the Services. This mandate involves in particular the following tasks:

(a) The Group Leader shall sign any contractual documents —including the Contract and Amendments thereto— and issue any invoices related to the Supplies or the Services on behalf of the Group Members.

(b) The Group Leader shall act as single point of contact for the European Commission in connection with the Supplies and/or the Services to be provided under the Contract. It shall co-ordinate the provision of the Supplies and/or the Services by the Group Members to the European Commission, and shall see to a proper administration of the Contract.

Any modification to the present agreement / power of attorney shall be subject to the European Commission's express approval.

This agreement / power of attorney shall expire when all the contractual obligations of the Group Members towards the European Commission in connection with the Supplies and/or the Services to be provided under the Contract have ceased to exist. The parties cannot terminate it before that date without the Commission's consent.

Signed in …… on …….. ……
Name
Function
Company

Name
Function
Company

Name
Function
Company

Name
Function
Company

POWER OF ATTORNEY – MODEL 2

Agreement / Power of Attorney

(CREATING THE GROUP AS SEPARATE ENTITY, APPOINTING A GROUP MANAGER AND GIVING A MANDATE TO HIM/HER)

We the undersigned:

– Signatory 1 (Name, Function, Company, Registered address, VAT Number)
– Signatory 2 (Name, Function, Company, Registered address, VAT Number)
– …..
– Signatory N (Name, Function, Company, Registered address, VAT Number),

Each of them having the legal capacity required to act on behalf of his/her company, HEREBY AGREE AS FOLLOWS:

In case the European Commission awards Contract …. (« **the Contract** ») to Company 1, Company 2, …, Company N (« **the Group Members** »), based on the joint offer submitted by them on … ….. for the supply of ….. and/or the provision of services for … (« **the Supplies and/or the Services** »).

(1) As co-signatories of the Contract, all the Group Members:

(a) Shall be jointly and severally liable towards the European Commission for the performance of the Contract.

(b) Shall comply with the terms and conditions of the Contract and ensure the proper execution of their respective share of the Supplies and/or the Services.

(2) To this effect, the Group Members have set up under the laws of ……. the Group ….. (« **the Group** »). The Group has the legal form of a …... [*Provide details on registration of the Group: VAT Number, Trade Register, etc.*].

(3) Payments by the European Commission related to the Supplies or the Services shall be made through the Group's bank account . [*Provide details on bank, address, account number, etc.*].

(4) The Group Members appoint Mr/Ms ……. as **Group Manager**.

(5) The Group Members grant to the Group Manager all the necessary powers to act alone on their behalf in connection with the Supplies and/or the Services. This mandate involves in particular the following tasks :

(a) The Group Manager shall sign any contractual documents —including the Contract and Amendments thereto— and issue any invoices related to the Supplies or the Services on behalf of the Group Members.

(b) The Group Manager shall act as single point of contact for the European Commission in connection with the Supplies and/or the Services to be provided under the Contract. He/she shall co-ordinate the provision of the Supplies and/or the Services by the Group Members to the European Commission, and shall see to a proper administration of the Contract.

Any modification to the present agreement / power of attorney shall be subject to the European Commission's express approval.

This agreement / power of attorney shall expire when all the contractual obligations of the Group Members towards the European Commission in connection with the Supplies and/or the Services to be provided under the Contract have ceased to exist. The parties cannot terminate it before that date without the Commission's consent.

Signed in …….. on …….. ……
Name
Function
Company

Name
Function
Company

Name
Function
Company

Name
Function
Company

6.7. CHECKLIST OF DOCUMENTS TO BE SUBMITTED

The purpose of the table below is to facilitate the preparation of the tender by providing an overview of the documents that must be included (marked by ■) depending on the role of each economic operator in the tender (coordinator/group leader in joint bid, partner in joint bid, sole tenderer, subcontractor).

Some of the documents are only relevant in cases of joint bids or when subcontractors are involved. Additional documents might be necessary depending on the specific characteristics of each tender.

Description	Section	Joint tender leader in joint bid	Partners in joint bid	Sole tenderer	Sub-contractor(s)	Where to fill in / upload a document in e-Submission
Power of attorney of partners in joint bid indicating the group leader (see annex 6.6)	1		■			"Qualification" -> "Identification of the tenderer" under "Documents"
Letter of intent of subcontractor (see annex 6.5)	1				■	"Qualification" -> "Identification of the tenderer" under "Documents"
Legal Entity Form (see section 4.2.1)	1	■	■	■	■	"Qualification" -> "Identification of the tenderer" under "Documents"/
Supporting documents for the Legal Entity File Form	1	■	■	■		"Qualification" -> "Identification of the tenderer" under "Documents"/
Financial Identification form (see section 4.2.1)	1	■		■		"Qualification" -> "Identification of the tenderer" under "Documents"
Exclusion and selection Criteria form (see section 5.1.1 and annex 6.1)	2	■	■	■	■	""Qualification" -> "Identification of the tenderer" under "Documents"
Evidence of Economic and financial capacity (see section 5.2.2 and annex 6.4)	3	■	■	■		"Qualification" ->"Selection Criteria" -> "Financial and Economic Capacity"

Evidence of Technical and professional capacity (see section 5.2.3) Go to the following page to fill in the CV: http://europass.cedefop.europa.eu/en/documents/curriculum-vitae	3	■	■	■	■	"Qualification" ->"Selection Criteria" -> "Technical and Professional Capacity"

The following sections must be provided in the bid, their absence would mean rejection of the bid for incompleteness:

Description	Section	Joint tender leader or sole tenderer	Where to upload a document in e-Submission
Technical Offer (see section 4.2.4 and 1.)	4	■	"Tender" → <'name of Call for Tender' / 'Lot name'>"
Financial Offer (see section 4.2.5)	5	■	"Tender" → <'name of Call for Tender' / 'Lot name'>"

Once all information and documents have been encoded and uploaded in the e-Submission application and you consider that the tender is complete, the application will require you to consolidate the tender into one consolidated tender package. A Tender Preparation Report will be generated by the e-Submission application. It will have to be signed (hand signature or electronic signature), as explained in point 1.9 of the Annex: e-Submission application.

Description	Section	Joint tender leader in joint bid	Partners in joint bid	Sole tenderer	Sub-contractor	Where to upload a document in e-Submission
Tender Preparation Report	N/A	■		■		In Step 4 of the e-Submission wizard

6.8. Model for cover page for studies