Brussels, 22 June 2017

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Procedure leading up to a decision on the relocation of the European Medicines Agency and the European Banking Authority in the context of the United Kingdom's withdrawal from the Union

In the margins of the European Council (Art. 50) held on 22 June 2017, the Heads of State or Government of 27 Member States endorsed the Procedure leading up to a decision on the relocation of the European Medicines Agency and the European Banking Authority in the context of the United Kingdom's withdrawal from the Union, as set out in Annex and on the basis of a proposal from the President of the European Council and the President of the European Commission.

ANNEX

Procedure leading up to a decision on the relocation of the European Medicines Agency and the European Banking Authority
in the context of the United Kingdom's withdrawal from the Union

1. Introduction

The United Kingdom is currently hosting the **European Medicines Agency** (EMA) and the **European Banking Authority** (EBA) which both have their seat in London, at Canary Wharf.

As the United Kingdom has notified the European Council under Article 50 of the Treaty on European Union of its intention to leave the Union, it is necessary to move the two United Kingdom-based Agencies to other locations within the Union's territory.

This note sets out the process that we recommend for reaching the decision of the remaining 27 Member States on where the two Agencies should have their seat after the United Kingdom's withdrawal from the Union.

This process is specific to the current situation and does not constitute a precedent for location of agencies in the future. [1]

2. The general principles for the process

The decision on where the two agencies should have their future seat should be taken on the basis of a fair and transparent decision-making process with an **organised call for offers**, based on specified objective criteria (cf. point 3). All interested Member States have the opportunity to submit their offer to host one or both of the Agencies by **31 July 2017** at the latest.

[1] This procedure neither affects applicable rules of primary law nor the decisions already taken regarding the seats of agencies and other bodies of the Union.

The Commission will examine the Member State offers that have been received within the deadline and will provide an **assessment** of these on the basis of the stipulated unweighted criteria. This assessment serves the purpose of informing the decision making process.
The decision will be taken by a **voting process** (cf. point 6) whose outcome the Member States agree in advance to respect.
In order to allow for a smooth and timely relocation of the two Agencies, the objective is to reach a decision on the new locations in the autumn of 2017. It is envisaged that the decision will be taken in the margins of the **General Affairs Council (Art. 50) in November 2017**.

3. Criteria

The criteria for the relocation of the two Agencies are based by analogy on criteria for the decision on the location of seat of an agency set out in point 6 of the Joint Statement and Common Approach on Decentralised Agencies, having special regard to the fact that the two Agencies already exist and that the business continuity of the two Agencies is vital and must be ensured.
Apart from the objective criteria, the Joint Statement also refers to the desirability of geographical spread and to the objective agreed by the leaders in 2003 and confirmed in 2008 to give priority to acceding States in the distribution of the seats of other agencies set up in the future. Although this procedure concerns relocation rather than setting up new agencies, the spirit of that leaders' agreement should be taken into account.

Therefore, the following criteria apply:

1) **The assurance that the agency can be set up on site and take up its functions at the date of the United Kingdom's withdrawal from the Union**

This criterion concerns in particular the availability of appropriate office premises in time for the Agency to be able to take up its functions at the new location at the withdrawal date. This should include the necessary logistics and sufficient space for offices, meeting rooms and off-site archiving, high-performing telecommunication and data storage networks as well as appropriate physical and IT security standards.

2) **The accessibility of the location**

This criterion concerns the availability, frequency and duration of flight connections from the capitals of all EU Member States to the airports close to the location, the availability, frequency and duration of public transportation connections from these airports to the location, as well as the quality and quantity of accommodation facilities. In particular, the criterion implies the capacity to allow for the continuation of the volume and intensity of current meeting activities of the Agency.

3) **The existence of adequate education facilities for the children of agency staff**

This criterion concerns the availability of multi-lingual, European-oriented schooling that can meet the needs for education facilities for the children of the current staff as well as the capacity to meet also the future education needs.

4) **Appropriate access to the labour market, social security and medical care for both children and spouses**

This criterion concerns the capacity to meet the needs of the children and spouses of the current as well as of future staff for social security and medical care as well as the availability to offer job opportunities for these.

5) **Business continuity**

This criterion is relevant given the critical nature of the services provided by the Agencies and the need therefore to ensure continued functionality at the existing high level. The criterion relates to the timeframe required to fulfil the four criteria above. It concerns amongst other things the ability to allow the Agencies to maintain and attract highly qualified staff from the relevant sectors, notably in case not all current staff should choose to relocate. Furthermore, it concerns the capacity to ensure a smooth transition to the new locations and hence to guarantee the business continuity of the Agencies which should remain operational during the transition.

6) **Geographical spread**

This criterion relates to the agreed desirability of geographical spread of the agencies' seats, and to the objective set in December 2003 by the representatives of the Member States, meeting at Head of State or Government level and confirmed in 2008.

Factsheets for each of the two Agencies setting out the specific needs under each of the mentioned criteria are annexed to this note.

4. Offers to host

In order to ensure a fair and transparent process, the following rules and requirements apply to the offers:

General rules

1) Each Member State can offer to host **one or both of the Agencies**, but it can only offer **one single offer per Agency**. All offers should state which agency the Member State offers to host and at which location.

2) The Member State should in the offer **address the criteria** mentioned under point 3 and, for each of the criteria, specify the conditions that are offered. In particular, the offers should indicate how the Member State intends to ensure the business continuity of the Agency that it offers to host.

3) All offers should indicate the Member State's commitment to confirming these conditions in a **headquarters agreement**[2] with the Agency in question. That agreement should be signed before the Agency takes up its seat at the new location.

4) All offers to host one or both Agencies should be made in writing to the Secretary-General of the Council and copied to the Secretary-General of the Commission**. The deadline for submitting offers is 31 July 2017**.

5) Member States which have already submitted offers to host one of the two agencies or both are invited to **reconfirm** their expression(s) of interest within the above-mentioned deadline and, to the extent their initial offers would not address the above criteria, they are invited to complement or update them accordingly.

[2] Cf. the Commission guidelines with standard provisions for headquarters agreements of EU decentralised agencies: https://europa.eu/european-union/sites/europaeu/files/docs/body/2013-12-10_guidelines_hq_agreements_en.pdf

6) All offers from Member States received within the deadline will be **published** on the website of the European Council, with the exclusion of business secrets and other confidential information following consultation with the Member States concerned.

7) Member States may with their offer submit a **recorded short video presentation** in the form of a link to a Member State website. Such links will be published on the website of the European Council alongside the offers.

Specific issues to be addressed in the offer

The offers should indicate in detail how the six criteria are addressed and should specify the offered conditions.

In particular, the offer should indicate:

a) **The Member State's plan for when and how the relocation should take place** and how this plan would ensure that the Agency remains operational;

b) **The premises that would be offered to be rented or put at the disposal of the Agency and how these premises would meet the specific needs of the Agency** as indicated in the factsheet;[3]

c) **The financial terms for the Agency's use of these premises**, specifying in particular if the Member State would pay the rent for a given period of time or indefinitely;

d) **The terms concerning maintenance of the building including upgrading and future extensions if needed**;

[3] If the offered permanent premises will not be available in time for the Agency to take up its functions at the new location on the date of the United Kingdom's withdrawal, the offer should specify which temporary premises are offered and on which terms, when and how the further transition to the final premises would be ensured and who will pay the costs of the additional removal.

e) **Any special conditions offered with regard to all costs and dedicated infrastructures**; and

f) **Any benefits that would be granted to the Agency and/or its staff** in addition to those following from Protocol No 7 on the privileges and immunities of the European Union.

5. Commission examination of the offers

The Commission will carry out an examination of all the offers received within the deadline on the basis of the six objective criteria mentioned under point 3 as well as the specific issues set out under point 4. The Commission will consult the Agencies regarding technical requirements. For each Agency, the Commission will analyse the extent to which each offer meets the criteria and how it addresses the stipulated specific issues. By 30 September 2017 at the latest, the Commission will submit its assessment of the offers to the Secretary-General of the Council for distribution to the Member States and will also make it publicly available.

6. Decision-making and voting process

The decision-making process is informed by the assessment referred to in section 5. It will be preceded by a political discussion organised among the representatives of the Member States on the basis of the Commission's assessment. This discussion will be thoroughly prepared at Coreper level (art. 50) and take place in the margins of the General Affairs Council (art. 50) in October. During the preparation at Coreper level the Commission will make an oral presentation of its assessment of the offers. Member States which have submitted one or more offers to host will be given the occasion to make a short presentation of their offer (maximum 3 minutes). In the margins of the European Council (art.50) in October, the Prime Minister of the Member State holding the Presidency will inform the 27 Heads of State or Government about the discussion among ministers.

The decision will be taken by vote in the margins of the General Affairs Council (art.50) in November. All offers, except for any withdrawn by the Member States concerned, will be submitted to the vote. The voting process should be similar to the process used for the decision on the relocation of the European Union Agency for Law Enforcement Training (CEPOL), namely the outcome of a vote consisting of successive voting rounds, with the votes cast by secret ballot and all 27 Member States having the same number of votes. However, the specific rules for the voting rounds have been adjusted in light of the expected high number of offers and the need to ensure a decision at the end of the procedure.

The first voting session will be on the European Medicines Agency. The Member State selected for the European Medicines Agency cannot be candidate to host the European Banking Authority. As a consequence, if that Member State has also submitted an offer to host the European Banking Authority, its offer will be discarded in the voting process on the latter. The Member State selected for hosting the European Medicines Agency can take part in the vote on the European Banking Authority.

1st voting round

In the first voting round, each Member State has **one vote consisting of six voting points** which should be allocated with three points to the preferred offer, two points to the offer which the Member State ranks second and one point to the offer which the Member State ranks third. All six voting points must be allocated in this manner for a vote to be valid.

If an offer receives 3 voting points from at least 14 member States, hence being the preferred offer for 14 Member States (14 Member States awarding three points to the same offer), that offer is considered to be the selected offer.

If no offer receives 3 voting points from at least 14 Member States, **the three offers which receive the highest number of points will proceed to the second voting round**. In case of more than three offers receiving the highest number of points, all offers that have received the same highest score will go on to the second voting round.

2nd voting round

In the second voting round, **each Member State has one vote (consisting of one voting point)** that it can give to one of the three (or more) offers which have been chosen for the second voting round.

If an offer receives 14 votes or more, hence representing the majority, it is considered to be the selected offer.

If no offer receives 14 votes or more, the two offers which receive the highest number of votes will proceed to the third round.

In case of a tie between three (or more) offers, these will all go on to a third voting round.

3rd voting round

In the third voting round, **each Member State has one vote (consisting of one voting point)** that it can give to one of the offers which have been chosen for the third voting round.

An offer that receives the highest number of votes, will be considered the selected offer.

In case of a tie, the decision will be taken by the Presidency drawing lots between the tied offers. The offer drawn will be considered the selected one.

Decisions

The decisions on the new locations on the seats of the Agency outcome of the voting process will be confirmed in the margins of the General Affairs Council (Art. 50).

On this basis, and considering the particular nature and context of these decisions, the Commission will, without delay, prepare legislative proposals to modify Article 7 of Regulation (EU) No 1093/2010 establishing a European Supervisory Authority (European Banking Authority) and to confirm the new location of the seat in Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. The Council and the Commission commit to give priority to the handling of the legislative proposals in view of the urgency.

Annexes: 1. Factsheet on the European Medicines Agencies
2. Factsheet on the European Banking Authority

Factsheet on the European Medicines Agency

1. EMA'S MISSION [4]

The European Medicines Agency (EMA), a decentralised Agency of the EU, took up its function in 1995.

EMA's mission is to evaluate and supervise human and veterinary medicinal products, on grounds of safety, efficacy and quality, in order to protect human and animal health in the EU.

EMA does not conduct itself research (no laboratory work, animal tests, or clinical trials), nor does it produce medicines.

EMA receives application files and information from various sources e.g. industry, Member States, health professionals, patients. Its mission is to coordinate the scientific expertise and resources of Member States, who assess this scientific information in the setting of "committees", and provide scientific opinions. EMA relies on its internal expertise provided by its staff as well as on the external scientific expertise provided by the Member States.

EMA's key activities consist in:

– Providing a single route for the evaluation of innovative medicines in the EU, hereby avoiding the duplication of the evaluation in Member States (centralised procedure).

– Monitoring the safety of all medicines authorised in the EU throughout their life cycle.

– Stimulating research and innovation by giving scientific advice and guidance to developers of medicines.

[4] It is recalled that the EMA has been established by Regulation (EU) No 726/2004, where its scope of action, tasks and powers are set out.

– Coordinating inspections to verify the compliance with good manufacturing, clinical and laboratory practices.

– Hosting IT services to implement the EU pharmaceutical policy and legislation.

2. OBJECTIVE CRITERIA

Criterion 1: The assurance that the agency can be set up on site and take up its functions at the date of the United Kingdom's withdrawal from the Union (adequate office logistics)

Key figures (2015):

– The EMA staff amounts to 890 members.

– EMA held 564 meetings with around 36000 visitors and held 4273 teleconferences.

– EMA has 27,000 m² of offices space including:

  - 250 m2 reception area with disability access as well as with adequate security structure in the vicinity;
  - Access control system and closed circuit television (CCTV);
  - Conference facilities consisting of:
    - 6,000m² of meeting rooms of different sizes (5 rooms with 70-120 seats, 2 rooms with 35 seats and 10 rooms with 4-24 seats) with internet 4G connection, audio and video conference facilities, broadcasting and recording equipment and voting system per seat,
    - one enclosed lounge of 500 m2 and another lounge for 50 persons, both lounges with desk/work stations and storage facilities,
    - an auditorium for around 300 people;

- 18.500 m2 in offices and open-plan with capacity for 1300 office work stations;
- Adequate internal meeting rooms;
- High quality IT facilities, such as centralised Uninterruptible Power Supply, WiFi throughout the premises, technical rooms, main and secondary equipment rooms, IT build and IT store rooms.

– EMA requires a telecommunications network with high capacity digital network and with high-speed connectivity.

– EMA requires a main and a backup data centre for disaster recovery, both to be accessible from EMA premises via a fast high volume internet or fibre connection. Security and operational IT standards apply.

– EMA's on-site and off-site archiving facilities: EMA's current off-site archive is 600m² and 9m high. On site, EMA has an archive room of approx. 30m² as well as on-floor filing rooms on floors 1 and 5-10 of 5m² each.

Criterion 2: The accessibility of the location

Key figures (2015):

– EMA builds on the scientific expertise from 3,700 experts across the EU.

– EMA coordinates the work of 7 scientific committees, supported by 34 working parties and advisory groups who meet regularly, in many cases monthly. Almost all these meetings are attended by delegates from all Member States of the Union as well as, in some cases, by delegates from contracting states of the European Economic Area and other third countries.

– 36,000 visitors (staff of national competent authorities, scientists, patients, health professionals, industry), including 4000 non-EU visitors requiring intercontinental flights (US, Japan, Korea etc.), came to the Agency for meetings which last up to 4 days.

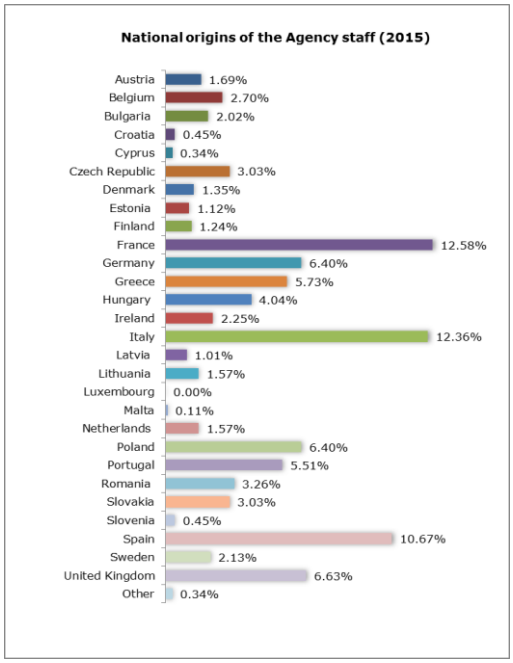
– 30,000 hotel nights were booked, with a daily peak hotel capacity needed of 350 rooms.

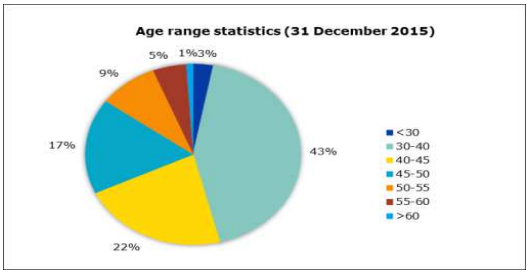
Criterion 3: The existence of adequate education facilities for the children of agency staff

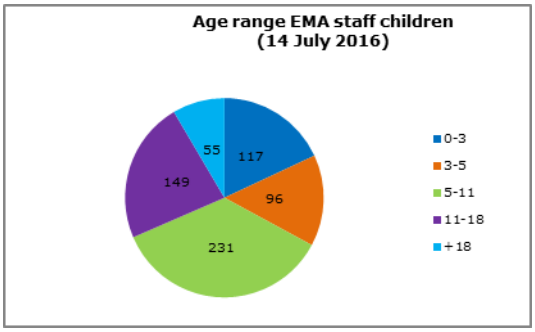
Key figures:

– The EMA staff amounts to 890 members (2015).

– 648 children of EMA staff aged 0 to 18 were schooled in September 2016 (117 in nursery/day care, 96 in pre-school, 231 in primary school, 149 in second level and 55 third level/university).







Criterion 4: Appropriate access to the labour market, social security and medical care for both children and spouses

– Some 55% of EMA staff has a partner (married or registered partnership).

– Medical care needed for 890 EMA staff and extended family members.

Criterion 5: Business continuity

Activities:

Key figures (2016):

– EMA recommended 81 medicines for marketing authorisation, including 27 new active substances (i.e. substances that have previously never been authorised in a medicine in the EU) as well as 11 new veterinary medicines for marketing authorisation; six of these medicines contain a new active substance.

– EMA received 84 PRIME (Priority Medicines) applications, a new scheme providing early and enhance support to medicines that have the potential to address patients' unmet needs.

– The total number of applications for initial evaluation received was 114.

– EMA received 118 notifications of withdrawn products from pharmaceutical companies.

– EMA received 672 inspection requests for Good Manufacturing Practices and 121 for Good Clinical Practices.

– EMA received 1843 requests for information.

Budget: (2017)

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017B0317(07)&from=EN

Staff:

Key figures (budget 2017)

Temporary agents:	
Administrators (ADs):	340
Assistants (ASTs):	256
	596

Contract agents and seconded national experts:	
Contract agents (groups II-IV):	158
Seconded national experts:	45
	203

Staff are specialised and experienced doctors, pharmacists and veterinarians as well as experts in law and finance.

Factsheet on the European Banking authority

1. EBA'S MISSION [5]

The European Banking Authority (EBA) was established on 1 January 2011 as part of the European System of Financial Supervision and took over all existing responsibilities and tasks of the Committee of European Banking Supervisors.

EBA is a decentralised EU Agency which works to ensure effective and consistent prudential regulation and supervision across the European banking sector. Its overall objectives are to maintain financial stability in the EU and to safeguard the integrity, efficiency and orderly functioning of the banking sector.

The main task of the EBA is to contribute to the creation of the European Single Rulebook in banking whose objective is to provide a single set of harmonised prudential rules for financial institutions throughout the EU. The Authority also plays an important role in promoting convergence of supervisory practices and is mandated to assess risks and vulnerabilities in the EU banking sector.

The Authority also plays an important role in promoting convergence of supervisory practices to ensure a harmonised application of prudential rules. Finally, the EBA is mandated to assess risks and vulnerabilities in the EU banking sector through, in particular, regular risk assessment reports and pan-European stress tests.

Other tasks set out in the EBA's mandate include:

– investigating alleged incorrect or insufficient application of EU law by national authorities;

[5] It is recalled that the EBA has been established by Regulation (EU) No 1093/2010, where its scope of action, tasks and powers are set out.

– taking decisions directed at individual competent authorities or financial institutions in emergency situations;

– mediating to resolve disagreements between competent authorities in cross-border situations;

– acting as an independent advisory body to the European Parliament, the Council or the Commission;

– taking a leading role in promoting transparency, simplicity and fairness in the market for consumer financial products or services across the internal market.

2. OBJECTIVE CRITERIA

Criterion 1: The assurance that the agency can be set up on site and take up its functions at the date of the United Kingdom's withdrawal from the Union (adequate office logistics)

Key figures (2016):

– The EBA staff amounts to 189 members. 30-35 external staff are working on the premises.

– EBA has 2,345m² of offices space, 841m² of meeting rooms, 774m² of space for storage, print room and other service promises and 190m² reception and lobby, in total 4,150 m².

– The staff office areas are open space.

– EBA has a total of 24 meeting rooms, including 3 large meeting rooms (up to 68 persons), 17 medium meeting rooms (up to 28 persons) and 4 small meeting rooms (for 2 persons).

– EBA has 2 externally hosted data centres, currently located in the UK, with all infrastructure components (servers, network, storage, etc.) and equipment owned and managed by external provider.

Criterion 2: The accessibility of the location

The criterion "appropriate transport connections" is explicitly mentioned in the second paragraph of Article 74 of the EBA Regulation[6] with regards to the Headquarters Agreement with the host Member State.

Key figures (2016):

– EBA has organised 340 events (meetings, workshops, seminars, public hearings etc.), which is approximately 44 meetings more than last year. The overall number of meeting participants has seen an increase of 588 participants making a total of 9,215.

– On average, these visitors generate 1 night's stay in a hotel, so there are almost 9,000 nights/year booked in hotels.

– The EBA organised about 700 missions for its staff, the vast majority of which are within Europe and require air transport.

[6] Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority) (OJ L 331, 15.12.2010, p.12).

Criterion 3: The existence of adequate education facilities for children of staff members

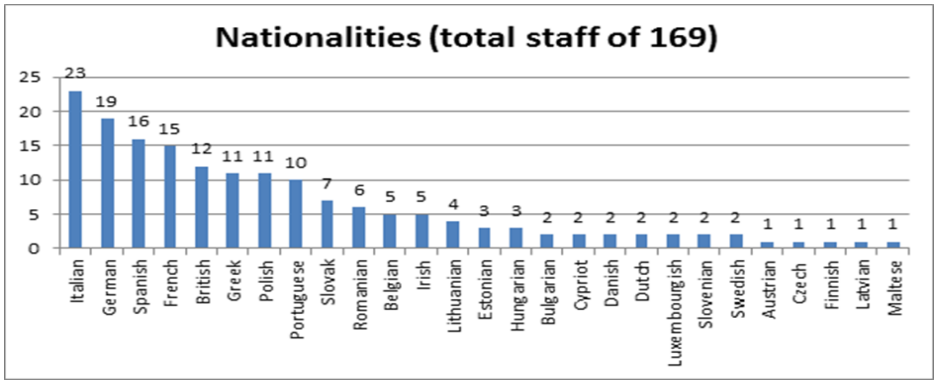
The criterion "multilingual European-oriented schooling" is explicitly mentioned in the second paragraph of Article 74 of the EBA Regulation with regards to the Headquarters Agreement with the host Member State.

Key figures (2016):

– The EBA staff amounts to 189 members.

– The total of 130 children, of which 39 attend nursery and 77 attend primary/secondary schools, and 14 attend universities.

– In terms of geographical balance, the nationalities of the EBA staff are present in the graph below (relevant data for 2015).



Criterion 4: Appropriate access to the labour market, social security and medical care for both children and spouses

Key figures (2016):

– Ca. 50% of EBA staff is married.

– Medical care needed for 189 EBA staff and extended family members.

Criterion 5: Business continuity

Activities:

Key figures: (2016)

EBA issued:

- 19 Guidelines
- 11 Implementing Technical Standards
- 15 Regulatory Technical Standards
- 23 opinions/advice
- 34 published reports
- 2 recommendations
- 1 peer review
- 1 transparency exercise
- 42 consultation papers
- 2 discussion papers

EBA organised 24 trainings for competent authorities.

Budget: (2017)

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017B0317(38)&from=EN

Staff:

Key figures (budget 2017)

Temporary agents:	
Administrators (ADs):	123
Assistants (ASTs):	11
	134
Contract agents and seconded national experts:	
Contract agents (groups III-IV):	33
Seconded national experts:	17
	50

Staff has expertise in economics, law, statistics, business administration etc.