



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

1 February 2018  
EMA/75627/2018  
Executive Director

## Decision of the Executive Director

### On rules governing the secondment of national experts to the EMA

THE EXECUTIVE DIRECTOR

Whereas:

- (1) Seconded National Experts (SNEs) should enable the Agency to benefit from the high level of their professional knowledge and experience, in particular in areas where such expertise is not readily available.
- (2) It is highly desirable to foster the exchange of professional experience in and knowledge of, European policies by temporarily assigning to the Agency experts from the administrations of the Member States of the European Union (EU). For the same reason, SNEs should also be available from the Member States of the European Free Trade Area (EFTA), candidate countries and public intergovernmental organisations (IGOs).
- (3) In order to ensure that the Agency's independence is not compromised by private interests, it should be stipulated that SNEs must come from a national, regional or local public administration or an IGO. The secondment of an SNE by an employer other than a national, regional or local administration or an IGO should be authorised only on a case-by-case basis, once it has been ascertained that the SNE's employer is part of the public sector or is an independent university or research organisation that does not seek to make profits for redistribution.
- (4) The rights and obligations of SNEs set out in this Decision should ensure that they carry out their duties solely in the interests of the Agency.
- (5) In view of the temporary nature of their work and their particular status, it should be provided that SNEs should not, acting on their own, take responsibility on behalf of the Agency for the exercise of its public law prerogatives.
- (6) It is desirable to simplify the rules on working conditions and allowances applicable to SNEs by bringing them as much as possible in line with the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Union, but without actually assimilating SNEs to these categories.



- (7) Steps should be taken to make it easier to review daily and monthly allowances, taking account of changes in the basic salaries of European Union officials in Brussels and Luxembourg.

HAS DECIDED AS FOLLOWS:

## Article 1 Scope

1. These Rules are applicable to national experts seconded to the Agency, hereinafter referred to as Seconded National Experts ("SNEs").

Seconded National Experts are staffs employed by a national, regional or local public administration or an IGO, who are seconded to the Agency so that it can use their expertise in a particular field.

For the purposes of this Decision, the public administration means all State administrative services, at central, federal and regional level, comprising ministries, government and parliament services, the courts, central banks, and the administrative services of local authorities, as well as the decentralised administrative services of the State and of such authorities.

2. The persons covered by these Rules must have worked for their employer on a permanent or contract basis before their secondment. The SNE's employer shall thus undertake to continue to pay his salary, to maintain his administrative status (permanent official or contract staff member) throughout the period of secondment and to inform the Agency of any change in this regard. The SNE's employer shall also continue to be responsible for all his social rights, particularly social security and pension.

The termination of or change in the SNE's administrative status (permanent official or contract staff member) may lead to the termination of his secondment by the Agency, without notice, in accordance with Article 10(2) (c).

3. Notwithstanding the second subparagraph of paragraph 1, the Executive Director may authorise the secondment of an SNE from an employer other than a State public administration or an IGO if the interests of the Agency warrant bringing in specific expertise as a temporary measure, provided that the SNE's employer:

- is an independent university or research organisation which does not set out to make profits for redistribution; or
- is in fact part of the public sector.

For the purposes of this Decision, to qualify as being part of the public sector the SNE's employer must meet all the following conditions:

- it must be attached to a public administration, as defined in paragraph 1, and specifically it must have been created by legislation or regulation;
- its resources must come primarily from public funding;
- any activities in which it competes against other private or public entities on the market must represent less than half of its activities.

Exceptionally and where justified by the interest of the service, the Executive Director may, on a case-by-case basis, authorise the secondment of an SNE by an employer that does not meet one or more of the above criteria.

4. Except where the Executive Director grants derogation, an SNE must be a national of an EU or EFTA Member State or a candidate country as decided by the Council. The Agency shall take account of geographical and gender balance and the principle of equal opportunities when accepting SNEs into its Divisions.
5. Secondment shall be effected by an exchange of letters between the Executive Director and the employer.

A copy of the rules applicable to national experts on secondment to the Agency shall be attached to the exchange of letters.

6. Any reference in these rules to a person of the male sex shall be deemed also to constitute a reference to a person of the female sex, and vice-versa, unless the context clearly indicates otherwise.

## **Article 2 Cost-free seconded national experts**

1. For the purposes of this Decision, "cost-free SNEs" means SNEs whose secondment does not entail any costs borne by the Agency.
2. Cost-free SNEs may be seconded from the public administration, as defined in Article 1(1), of an EU or EFTA Member State or a candidate country as decided by the Council, or from an IGO, as part of an agreement and/or exchange programme with the Agency.
3. In addition, the Executive Director may authorise the secondment of cost-free SNEs on a case-by-case basis, taking into consideration their place of origin, the Division in question, the geographical balance and the work to be carried out.
4. National civil servants may also be seconded as cost-free SNEs for up to a maximum term of four years in the context of bilateral agreements between the Agency and the Member State concerned. Such agreements require the prior approval of the Executive Director and must indicate the number of SNEs involved and the proposed duties to be performed. These conditions shall also apply to cost-free SNEs from countries belonging to the EFTA, and to candidate countries.
5. Cost-free SNEs shall be taken into account in the final allocation of human resources when establishing the Agency's budget.

## **Article 3 Selection procedure**

1. The selection procedures for SNEs are published in the Agency's website. Applications can be sent by interested candidates by submitting an application in the EMA Job Portal, Jobs@EMA. Interested candidates may submit an application for a specific position advertised on the Agency's website or send a generic expression of interest to be considered for any upcoming position.
2. A list of candidates interested in a short-term work opportunity as SNE is kept for three years. The applications are reviewed internally taking into account the suitability of the candidates and the required area of expertise.

## **Article 4 Period of secondment**

1. Periods of secondment may not be less than six months nor more than two years. They may be renewed once or more, up to a total period not exceeding four years. Exceptionally, at the request of the Division concerned and where the interests of the service warrant it, the Executive Director may authorise one or more extensions of the secondment for a maximum of two more years at the end of the four-year period.
2. The intended period of secondment shall be fixed at the outset in the exchange of letters provided for in Article 1(5). The same procedure shall apply in the case of a renewal of the period of secondment.
3. An SNE who has already been seconded to the Agency may be seconded to it a second time subject to any relevant internal rules laying down maximum periods during which such persons may be present in the Agency's Divisions, and subject further to the following conditions:
  - a) the SNE must continue to meet the conditions for secondment;
  - b) a period of at least six years must have elapsed between the end of the previous period of secondment and a new secondment; if at the end of the first secondment, the SNE has received a contract with the Agency, the six year period shall begin to run from the expiry of that contract.

The condition in point (b) shall not prevent the Agency from accepting the secondment of an SNE whose initial secondment has lasted for less than four years, but in that case the new secondment shall not exceed the unexpired part of the four year period, without prejudice to the possibility of extending it by up to two more years, as provided for in paragraph 1.

## **Article 5 Place of secondment**

The place of secondment shall be the place where the Agency has its office.

## **Article 6 Duties**

1. SNEs shall assist the Agency's temporary agents, performing the tasks assigned to them based on their professional knowledge and experience. They may not perform middle or senior management duties, even when deputising for their immediate superior.
2. An SNE shall take part in missions or external meetings only if accompanying a temporary agent, or acting alone as an observer or for information purposes.

However, the Executive Director may give a specific mandate for one or more missions to the SNE after having ensured that there is no potential conflict of interest. The Executive Director may delegate his power to derogate to the Head of Division of the SNE concerned. In such cases the SNE shall receive clear written instructions from the Head of Division on the position to be adopted during the missions or meetings in question. Under no circumstances may an SNE on his own represent the Agency with a view to entering into commitments, whether financial or otherwise, or negotiating on its behalf.

An SNE may however represent the Agency in legal proceedings as co-agent with a temporary agent and may as such act on its behalf.

3. The Agency shall remain solely responsible for approving the results of any tasks performed by an SNE and for signing any official documents arising from them.

4. The Divisions concerned in the Agency, the SNE's employer and the SNE must ensure that there is no conflict of interest or appearance of such conflict in relation to the SNE's duties while seconded to the Agency. For this purpose, the Division to which it is intended to assign the SNE shall provide the SNE and the employer with full information about the intended duties a reasonable time before the start of the secondment, and shall ask the SNE and the employer to confirm in writing that they do not know of any reason why the SNE should not be assigned to those duties. The SNE shall be asked in particular to declare any potential conflict between his family circumstances and the proposed duties while on secondment. In particular, he shall declare the professional activities of the household members or any important financial interests of his own, or of those persons.

The employer and the SNE shall be asked to undertake to declare any change of circumstances during the secondment which could give rise to any such conflict, or appearance of conflict, to the Administration Division of the Agency.

The Administration Division shall keep all such exchanges of correspondence in its records and shall produce it to the Executive Director on request.

5. Where the Executive Director considers that the nature of the Agency's activities requires particular security precautions, security clearance shall be obtained prior to recruitment.
6. Failure on the part of the SNE to comply with his obligations arising under the provisions of paragraphs 2, 3 or 4 shall entitle the Agency, if it sees fit, to terminate the secondment of the SNE under the terms of Article 10.

## **Article 7 Rights and obligations**

1. During the period of secondment:
  - a) the SNE shall carry out his duties and shall conduct himself solely with the interests of the Agency in mind. He shall neither seek nor take instructions from any government, authority, organisation or person outside the Agency. He shall carry out the duties assigned to him objectively, impartially and in keeping with his duties of loyalty to the Agency.
  - b) an SNE wishing to engage in an outside activity, whether paid or unpaid, or to carry out any assignment outside the Agency shall be subject to the Agency's rules on prior authorisation for outside activities for temporary agents<sup>1</sup>. The Agency shall consult the SNE's employer before issuing an authorisation.
  - c) the SNE shall refrain from any action or behaviour which might reflect adversely upon his position and from any form of psychological or sexual harassment<sup>2</sup>.
  - d) the SNE shall not, in the performance of his duties, deal with a matter in which, directly or indirectly, he has any personal interests such as to impair his independence, and, in particular, family and financial interests. If it falls in the performance of his duties to deal with such a matter, he shall inform his Head of Division immediately who shall take any appropriate measure, and may, in particular, relieve the SNE from responsibility in this matter.

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<sup>1</sup> Article 12b of the Staff Regulations and the provisions implementing this Article shall apply mutatis mutandis.

<sup>2</sup> Article 12a of the Staff Regulations and the provisions implementing this Article shall apply mutatis mutandis.

- e) In line with the 'Management Board decision (EMA/259494/2016) concerning the handling of declared interests of employees of the European Medicines Agency', SNEs are not permitted to hold on starting the secondment or seek to acquire during their secondment at the Agency direct financial interests in a pharmaceutical company or own a current patent for a medicinal product. All such direct interests must be disposed of prior to the start of the secondment. SNEs will be required to make a public declaration of interests upon starting their secondment.

The SNE may neither keep nor acquire, either directly or indirectly, in undertakings which are subject to the authority of the Agency or which have dealings with the Agency, any interests of such kind or magnitude as might impair his independence in the performance of his duties.

- f) the SNE shall refrain from any unauthorised disclosure of information received in the line of duty, unless that information has already been made public or is accessible to the public.
  - g) the SNE has the right to freedom of expression, with due respect to the principles of loyalty and impartiality.
  - h) the SNE who intends to publish or causes to be published, whether alone, or with others, any matter dealing with the work of the Agency shall inform his Head of Division in advance. Where the Head of Division is able to demonstrate that the matter is liable seriously to prejudice the legitimate interests of the Agency, the Head of Division shall inform the SNE of its decision in writing within 30 working days of receipt of the information. If no such decision is notified within the specified period, the Head of Division shall be deemed to have had no objections.
  - i) all rights in any work done by the SNE in the performance of his duties shall be the property of the Agency;
  - j) the SNE shall reside at the place of secondment or at no greater distance therefrom as is compatible with the proper performance of his activities; and
  - k) based on his professional knowledge and experience, the SNE shall assist and tender advice to the superiors in the Agency to whom he is assigned and shall be responsible to his superiors for performance of the tasks entrusted to him.
2. Failure to comply with any of the provisions of paragraph 1 during the period of secondment shall entitle the Agency, if it sees fit, to terminate the secondment of an SNE pursuant to Article 10.
  3. After termination of the secondment, an SNE shall continue to be bound by the duty to behave with integrity and discretion as regards the exercise of new tasks assigned to him and the acceptance of certain appointments or benefits.

Upon leaving, during the time period equivalent to the length of the secondment or within two years whichever is the shorter period, SNEs are requested to inform EMA of any occupational activity, paid or unpaid, they engage in. Within 45 working days from the date of the SNE's request for engaging in an occupational activity, the Agency will communicate any objection or concerns to the SNE regarding his/her request. No reaction from the Agency after 45 working days implies tacit agreement to the occupational activity stated in the request.

## **Article 8 Professional experience and knowledge of languages**

1. To qualify for secondment to the Agency a national expert must have at least three years experience of administrative, scientific, legal, technical, advisory or supervisory functions which can be regarded as equivalent to those of function groups AD or AST - this latter function group being taken into consideration only for highly specialised job profiles - as defined in the Staff Regulations of Officials of the European Union and in the Conditions of Employment of Other Servants of the European Union.
2. An SNE must have a thorough knowledge of English (the Agency's official language), and a satisfactory knowledge of a second language, for the performance of his duties. An SNE from a non-member country must have a thorough knowledge of English.

## **Article 9 Suspension of secondment**

1. At the written request of the SNE or his employer, and with the latter's agreement, the Agency may authorise suspensions of periods of secondment and specify the terms applicable. During such suspensions:
  - a) the subsistence allowances referred to in Article 17 shall not be payable;
  - b) the expenses referred to in Article 20 shall be payable only if the suspension is at the Agency's request;
2. The period of suspension shall not be counted in the period of secondment as defined in Article 4.

## **Article 10 Termination of periods of secondment**

1. Subject to paragraph 2, the secondment may be terminated at the request of the Agency or of the SNE's employer, on the party concerned giving three months' notice to the other party. It may also be terminated on giving the same notice at the SNE's request, subject to the agreement of the Agency and the SNE's employer.
2. In exceptional circumstances the secondment may be terminated without notice:
  - a) by the SNE's employer, if the employer's essential interests so require;
  - b) by the Agency and the employer acting jointly, on request by the SNE to both parties, if the SNE's personal or professional interests so require;
  - c) by the Agency in the event of a failure by the SNE to respect his obligations under this Decision.

In the event of termination under point (c), the Agency shall immediately inform the SNE and his employer accordingly.

## **Article 11 Social security**

1. Before the period of secondment begins, the national public administration or IGO from which the SNE is to be seconded, shall certify to the Agency that he will remain, throughout the period of secondment, subject to the social security legislation applicable to the public administration that employs him and will assume responsibility for expenses incurred abroad.

2. Before the period of secondment begins, the SNE's employer shall provide the Agency with the certificate referred to in Article 11(1) of Council Regulation (EEC) No 574/723.
3. From the day on which their secondment begins, SNEs shall be covered by the Agency against the risk of accident. The Agency shall provide them with a copy of the insurance summary and procedure to follow in case of accident.

## **Article 12 Working hours**

1. The working hours for SNEs shall be the same as those determined in the rules on hours of work in force at the Agency<sup>4</sup>.
2. The SNE shall serve on a full time basis throughout the period of secondment. Following a duly justified request originating from the Division to which the SNE is assigned and subject to compatibility with the interests of the Agency, the Executive Director may authorise the use of part-time working by an SNE after agreement by her or his employer. In this case the SNE shall be entitled, during the period of secondment, to a percentage of the daily subsistence allowance corresponding to the percentage of the time worked, as laid out in Article 17. The amount of annual leave shall also be reduced accordingly.
3. Where part-time working is authorised, the SNE must work every month at least half of the normal working time.
4. An SNE serving on a full time or a part-time basis may work flexible hours in accordance with the rules on Flexitime in force at the Agency. An SNE may work flexible hours but flexi leave may only be taken in exceptional circumstances to be decided by the Head of Division.

## **Article 13 Sick leave**

1. The rules in force at the Agency on absence due to sickness or accident shall apply to SNEs<sup>5</sup>.
2. If such absence due to sickness or accident of not more than three days exceeds a total of twelve days over a period of twelve months, the SNE shall produce a medical certificate for any further absence due to sickness.
3. Where the period of sick leave exceeds three months, or the period of service performed by SNE, whichever is longer, the allowances referred to in Article 17 shall be automatically suspended. This provision shall not apply in the event of illness linked to pregnancy.

Sick leave may not extend beyond the duration of the secondment of the person concerned.

4. SNEs who are the victim of a work related injury which occurs during the secondment shall continue to receive the allowance in full throughout the period during which they are unfit for work up to the end of the secondment.

## **Article 14 Annual and special leave**

1. With exception of the provisions relating to grade, the rules in force at the Agency on annual and special leave, applicable to temporary agents, shall apply to SNEs<sup>6</sup>.

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<sup>3</sup> OJ L 74, 27.3.1972, 1. 1.

<sup>4</sup> Articles 55 to 56c of the Staff Regulations and the provisions implementing these Articles, as appropriate, *mutatis mutandis*.

<sup>5</sup> Articles 59 and 60 of the Staff Regulations and the provisions implementing these Articles shall apply *mutatis mutandis*.

2. Leave is subject to prior authorisation by the service to which the SNE is assigned. In case of unauthorised leave, the relevant daily allowance shall not be paid.
3. Upon a duly justified request from the SNE's employer, the SNE may be granted up to two days of paid special leave in a 12-month period to visit his employer. This additional special leave may be granted by the SNE's Head of Division in agreement with the Head of Administration on a case-by-case basis and if this paid special leave is in the interest of the Agency.
4. In the case of part-time work, the annual leave shall be reduced accordingly.
5. Days of annual leave not taken by the end of the secondment shall be forfeited.

## **Article 15 Maternity leave**

1. The rules in force at the Agency on maternity leave shall apply to SNEs<sup>7</sup>. While on maternity leave the SNE shall receive the subsistence allowances as set out in Article 17.
2. Where the relevant rules binding the employer of the SNE provide for a period of maternity leave longer than that granted by the Agency, the secondment may, at the SNE's request, be interrupted and the provisions of Article 9 shall be applied for the period exceeding that granted by the Agency.

A period equivalent to the break shall be added to the end of the secondment if the interests of the Agency warrant it.

3. An SNE may, as an alternative, apply for a break in the secondment to cover the sum of the periods allowed for maternity leave. In that case, the second subparagraph of paragraph 2 shall apply.

## **Article 16 Management and control**

Management and control of leave, working time and absences shall be the responsibility of the Division, Department and Service/Office to which the national expert is assigned.

## **Article 17 Subsistence allowances**

1. An SNE shall be entitled, throughout the period of secondment, to a SNE daily subsistence allowance (DSA) and a monthly subsistence allowance.

In the date of entry into force of this decision, on 1 February 2018:

- the daily subsistence allowance shall be GBP 138.22. Where the SNE is serving on a part-time basis the DSA shall be paid at the rate of the part-time work.
- the monthly subsistence allowance shall be paid in accordance with the following table:

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<sup>6</sup> Articles 57 and 59a of and the Annex V to the Staff Regulations and the provisions implementing these Articles shall apply *mutatis mutandis*.

<sup>7</sup> Article 58 of the Staff Regulations and the provisions implementing this Article shall apply *mutatis mutandis*.

Distance between the place of origin and the place of secondment (km)	Amount	
0 – 150	GBP	0.00
> 150	GBP	75.86
> 300	GBP	136.63
> 500	GBP	222.06
> 800	GBP	358.72
> 1300	GBP	563.70
> 2000	GBP	674.76

For the purpose of the payments under Article 17 the distance within the meaning of these rules shall be calculated using the same method applied to temporary agents when establishing the kilometric distance between the place of origin and employment<sup>8</sup>.

2. These subsistence allowances shall be granted where the place of origin, as determined by Article 19 of these rules, is located more than 70km from the place of secondment.
3. In the case of cost-free SNEs, the exchange of letters referred to in Article 1(5), shall stipulate that the allowances and expenses referred to in this articles and articles 18 and 20, shall not be paid.
4. Subsistence allowances shall be payable for every day of the week, including during periods of mission, annual leave, special leave and holidays granted by the Agency, unless otherwise indicated.
5. When the SNE starts the secondment, the first 75 days of the subsistence allowances to which he is entitled shall be advanced in the form of a lump sum and the allowances shall not be paid during the corresponding period. This lump sum shall be paid by the last day of the month for SNEs starting on the first day of the same month. For SNEs starting on the 16th day of the month, this lump sum will be paid by the 15th day of the following month. If the secondment is ended during the first 75 days, the SNE shall return the amount corresponding to the remainder of that period.
6. The SNE shall inform the Administration Division of the Agency of any similar payments received from other sources. Any such amounts shall be deducted from the corresponding allowance paid by the Agency pursuant to paragraph 1.
7. The subsistence allowances shall be reviewed each year, with effect from 1 February, taking into account the adjustments to remuneration pursuant to Article 64 and 65 of the Staff Regulations.
8. The daily and monthly allowances are intended to cover on a flat rate basis the living expenses of SNEs in the place of secondment, and shall in no circumstances be construed as remuneration paid by the Agency.
9. The daily and monthly allowances shall be paid by the 15th day of each month.

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<sup>8</sup> Article 8 (2) of Annex VII to the Staff Regulations and the provisions implementing this Article shall apply mutatis mutandis

## **Article 18 Possible reimbursement of remuneration**

1. If its interests so require, the Agency may reimburse all or part of the gross remuneration of an SNE during the period of secondment to his employer under an agreement to be concluded in advance and recorded in the exchange of letters provided for in Article 1(5).
2. The reimbursement of remuneration shall be authorised on a case-by-case basis by the Executive Director, taking into account the specific needs of the Service and, in particular, the need to use SNEs from all Member States.
3. Expenses resulting from the reimbursement shall be charged against the SNE allocation of the Agency's general budget.
4. The employer shall submit an invoice for reimbursement every four months covering the gross remuneration paid to the SNE in the preceding quarter. Failure to provide an invoice within nine months of the end of the relevant quarter fully discharges the Agency of its obligation and no reimbursement will be made for the relevant quarter.

## **Article 19 Place of origin**

1. For the purposes of this Decision, the place of origin shall be the place where the SNE performed his duties for his employer at the time of his secondment. The place of secondment shall be the place where the Agency is located. Both places shall be identified in the exchange of letters mentioned in Article 1(5).
2. If, on a date six months before his secondment to the Agency as an SNE, a national expert already has his main residence in a place other than that in which the employer's headquarters is located, the place of origin shall be deemed to be whichever of the places is closer to the place of secondment.

## **Article 20 Travel expenses**

1. SNEs other than those seconded cost-free, shall be entitled to a flat-rate payment towards the cost of their travel between their place of origin and the place of secondment, as defined in Article 19, at the beginning and end of their secondment.
2. The flat-rate payment shall be based on the kilometric distance in accordance with the relevant rules and conditions in force at the Agency<sup>9</sup>.
3. By way of derogation from paragraph 1, SNEs who prove that they have changed the place at which they will be primarily employed after the end of the secondment shall be entitled to reimbursement of the travel expenses to that place under the conditions laid down in paragraph 2. However, the reimbursement may not involve the payment of a sum higher than that to which he is entitled in case of return to the place of origin.
4. The Agency shall not reimburse any expenses referred to in the preceding paragraphs where they have actually been met or reimbursed by the employer or any other body. For this purpose the SNE shall declare any such payments or reimbursements to the Agency.

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<sup>9</sup> Article 7(1) and (2) of Annex VII to the Staff Regulations and the provisions implementing these Articles shall apply *mutatis mutandis*.

## **Article 21 Missions and mission expenses**

1. An SNE may be sent on mission subject to Article 6.
2. Mission expenses shall be reimbursed in accordance with the rules and conditions relating to the payment of mission expenses in force at the Agency<sup>10</sup>.

## **Article 22 Training**

SNEs shall be entitled to attend training courses organised by the Agency, if the interests of the Agency warrant it. The reasonable interests of the SNE in attending, in particular in the light of his reintegration into his original administration following secondment, shall be considered when a decision is taken on whether to permit attendance.

## **Article 23 Administrative provisions**

The SNE shall report to the Agency's Administration Division on the first day of the secondment to complete the relevant administrative formalities. He shall take up duty on either the first or the sixteenth day of the month.

## **Article 24 Complaints**

Any SNE may submit to the Executive Director of the Agency a complaint against an act under this Decision by the Agency, adversely affecting him except decisions, which are direct consequences of decisions taken by his employer. The complaint must be lodged within two months. The period shall start to run on the date of notification of the decision to the person concerned, but in no case later than the date on which the latter received such notification.

The Agency shall notify the person concerned of its reasoned decision within four months from the date on which the complaint was lodged. If at the end of that period no reply to the complaint has been received, this shall be deemed to constitute an implied decision rejecting it<sup>11</sup>.

## **Article 25 Entry into force**

This decision enters into force on 1 February 2018 and supersedes previous decision of the Executive Director dated 1 February 2017 (EMA/27614/2017).

London, 1 February 2018

*[Signature on file]*

Guido Rasi

Executive Director

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<sup>10</sup> Articles 11 and 12 of Annex VII to the Staff Regulations and the provisions implementing these Articles shall apply *mutatis mutandis*.

<sup>11</sup> However, this Article does not prevent a SNE from bringing an action against the initial decision, under the conditions laid down in Article 230 of EC Treaty.