



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 August 2016
EMA/302717/2015
Administration and Corporate Governance Division

Annual reports for the period from 2012 to 2015 on staff engaging in an occupational activity within two years of leaving the service (article 16 of the staff regulations)

Annual report for 2015

On leaving the Agency, staff members are required to seek permission to engage in an occupation within a period of two years of leaving the Agency, in accordance with Article 16 of the Staff Regulations. National experts are also required to seek permission, although the period is restricted to the equivalent duration of the secondment or two years, whichever is the shorter period. In all cases, applications are reviewed to establish any potential conflict of interests to the Agency, and if so required, on the basis of an opinion of the Agency's Joint Committee, the Executive Director will issue a decision, which may impose restrictions on the staff member to mitigate against any potential conflict of interests.

For the period from 1 January 2015 to 31 December 2015, a total of 28 applications were made, resulting in 23 authorisations without restrictions and 5 applications with restrictions. Examples of restrictions imposed include: a distance clause, whereby the former staff member may not contact individual Agency staff or attend meetings at the EMA for a period of time, e.g. 6-12 months; explicit prohibition of handling medicinal-product dossiers on which they have worked during their employment at the Agency; a reminder of the binding obligation of confidentiality after leaving; and a requirement that opinions given in public presentations must be stated to be the former staff member's own and not linked to their former employment at the Agency. Other individual restrictions will be applied on a case-by-case basis. Information on restrictions applied to applications in 2015 is given below.

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5565
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union



Engaging in an occupational activity within two years of leaving the service-restrictions applied to applications in 2015:

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|---------|--|--------------------------------|---------------------|---------------------------------|--------------------|--|---------------------|
| 1 | Trainee + Contract Agent / Procedure Management Department | 9 months + 2 years 5 months | 19/06/2015 | Authorisation with restrictions | 24/06/2015 | <p>To refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his /her last three years of service.</p> <p>To refrain from individually liaising with any member of staff of the European Medicines Agency with respect to interactions on any specific products s/he may have worked on in the performance of his /her responsibilities at the Agency during his /her last three years of service for a period of 12 months to be counted as of the date of leaving service.</p> | 16/07/2015 |
| 2 | Contract Agent / Product Development Scientific Support Department | 18 months | 28/08/2015 | Authorisation with restrictions | 23/09/2015 | <p>To refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her last three years of service.</p> <p>To refrain from individually liaising with any member of staff of the European Medicines Agency with respect to interactions on any [REDACTED] product s/he worked on in the</p> | 05/10/2015 |

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|---------|--|-------------------|---------------------|---------------------------------|--------------------|---|---------------------|
| | | | | | | performance of his/her responsibilities at the Agency during his/her last three years of service. This provision includes a restriction on assisting any third party in any legal case concerning any ██████ product. | |
| 3 | Temporary Agent / IT Division | 3 years | 13/07/2015 | Authorisation with restrictions | 22/07/2015 | <p>To refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her last three years of service.</p> <p>S/he and ██████ is prohibited from taking part in/bidding for or contributing to a service provider or contractor offering services to, or proposing to offer services to the EMA in matters for which s/he was responsible.</p> <p>Rrefrain from holding managerial or executive roles in companies that provide IT services to the Agency.</p> | 29/07/2015 |
| 4 | Contract Agent / Regulatory, Science and Innovation Support Department | 18 months | 16/10/2015 | Authorisation with restrictions | 04/11/2015 | <p>To refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her one year and six months of service.</p> <p>To refrain from individually liaising with any member of staff of the European Medicines Agency with respect to interactions on the specific products s/he worked on in the performance of his/her responsibilities at the Agency during his/her one year and six</p> | 16/11/2015 |

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|---------|---|--------------------|---------------------|---------------------------------|--------------------|--|---------------------|
| | | | | | | months of service. | |
| 5 | Trainee + Contract Agent / Legal Department | 10 months + 1 year | 19/11/2015 | Authorisation with restrictions | 04/12/2015 | <p>Should refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her one year and then months at the Agency.</p> <p>In line with professional ethics applied at the level of bar associations throughout Europe, s/he should not, on a permanent basis, represent/assist a third party in any case lodged with the European Court of Justice, national or international courts which s/he dealt with while in service at the Agency.</p> | 16/12/2015 |

Annual report for 2014

On leaving the Agency, staff members are required to seek permission to engage in an occupation within a period of two years of leaving the Agency, in accordance with Article 16 of the Staff Regulations. Trainees and national experts are also required to seek permission, although the period is restricted to the equivalent duration of the traineeship or, in the case of national experts, the period of secondment or two years, whichever is the shorter period. In all cases, applications are reviewed to establish any potential conflict of interests to the Agency, and if so required, on the basis of an opinion of the Agency's Joint Committee, the Executive Director will issue a decision, which may impose restrictions on the staff member to mitigate against any potential conflict of interests.

For the period from 1 January 2014 to 31 December 2014, a total of 55 applications were made, resulting in 49 authorisations without restrictions and 6 applications with restrictions. Examples of restrictions imposed include: a distance clause, whereby the former staff member may not contact individual Agency staff or attend meetings at the EMA for a period of time, e.g. 6-12 months; explicit prohibition of handling medicinal-product dossiers on which they have worked during their employment at the Agency; a reminder of the binding obligation of confidentiality after leaving; and a requirement that opinions given in public presentations must be stated to be the former staff member's own and not linked to their former employment at the Agency. Other individual restrictions will be applied on a case-by-case basis. Information on restrictions applied to applications in 2014 is given below.

Engaging in an occupational activity within two years of leaving the service-restrictions applied to applications in 2014:

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|---------|---|-------------------|---------------------|---------------------------------|--------------------|---|---------------------|
| 1 | Temporary Agent / Paediatrics Medicines | 4 years 10 months | 27/01/2014 | Authorisation with restrictions | 30-Jan-14 | To refrain from individually liaising with any member of staff of the EMA with regards to any professional activity the staff member may have dealt with in the performance of his/her responsibilities at the EMA for a period of 6 months to be counted as of the date of leaving service. This is without prejudice to the possibility of liaison, attendance at meetings through the standard channels available to all members | 12-Feb-14 |

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|---------|---|--------------------|---------------------|---------------------------------|--------------------|--|---------------------|
| | | | | | | of the public. | |
| 2 | Contract Agent / Manufacturing and Quality Compliance | 2 years 3.5 months | 5-Feb-14 | Authorisation with restrictions | 27-Feb-14 | To refrain from individually liaising with any member of staff of the EMA with regards to any professional activity the staff member may have dealt with in the performance of his/her responsibilities at the EMA for a period of 6 months to be counted as of the date of leaving service. This is without prejudice to the possibility of liaison, attendance at meetings through the standard channels available to all members of the public. | 17-Mar-14 |

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|---------|--|--------------------|---------------------|---------------------------------|--------------------|---|---------------------|
| 3 | Temporary Agent / Pharmacovigilance department | 16 years 10 months | 14-Feb-14 | Authorisation with restrictions | 27-Feb-14 | <p>1) To refrain from individually liaising with any member of staff of the EMA with regards to any professional activity the staff member may have dealt with in the performance of his/her responsibilities at the EMA for a period of 6 months to be counted as of the date of leaving service. This is without prejudice to the possibility of liaison, attendance at meetings through the standard channels available to all members of the public.</p> <p>2) To refrain from individually liaising with any member of staff of the European Medicines Agency with respect to interactions on specific products s/he may have worked on in the performance of his/her responsibilities at the Agency during his/her last three years of service for a period of 12 months to be counted as of the date of leaving service.</p> <p>In addition, the former staff member can no longer participate as a co-leader on behalf of EMA [REDACTED] project and any activity or lecture that former staff member was requested to undertake as an EMA staff member should be taken over by another EMA staff member.</p> | 17-Mar-14 |

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|---------|---|-------------------|---------------------|---------------------------------|--------------------|---|---------------------|
| 4 | Contract Agent / Signal Management | 6 years 9 months | 25/03/2014 | Authorisation with restrictions | 10-Apr-14 | <p>1) To refrain from individually liaising with any member of staff of the EMA with regards to any professional activity the staff member may have dealt with in the performance of her responsibilities at the EMA for a period of 6 months to be counted as of the date of leaving service. This is without prejudice to the possibility of liaison, attendance at meetings through the standard channels available to all members of the public.</p> <p>2) To refrain from individually liaising with any member of staff of the European Medicines Agency with respect to interactions on specific products s/he may have worked on in the performance of his/her responsibilities at the Agency during his/her last three years of service for a period of 12 months to be counted as of the date of leaving service.</p> | 06-May-14 |
| 5 | Contract Agent / Development and Evaluation of Veterinary Medicines | 2 years | 28/03/2014 | Authorisation with restrictions | 10-Apr-14 | To refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity he may have dealt with in the performance of his responsibilities at the Agency during his period of service. Since the period of six months has already elapsed, no further distance clause restrictions need to be applied. | 06-May-14 |

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|---------|--|-------------------|---------------------|---------------------------------|--------------------|--|---------------------|
| 6 | National Expert on secondment / Legal department | 1 year 4.5 months | 14/04/2014 | Authorisation with restrictions | 29-Apr-14 | <p>1) To refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity s/he may have dealt with in the performance of his/her responsibilities at the Agency during his/her last three years of service. The distance clause is without prejudice to the possibility of the former SNE to liaise or attend meetings through the standards channels available to all members of the public.</p> <p>2) The former SNE should not, on a permanent basis, represent/assist a third party in any case lodged with the European Court of Justice, national or international courts which s/he dealt with while in the service of the Agency.</p> | 11-Jun-14 |

Annual report for 2013

In accordance with Article 16 of the Staff Regulations, staff members are required to seek permission to engage in an occupation within a period of two years of leaving the Agency. Trainees and national experts are also required to seek permission, although the period is restricted to the shorter of the two: the equivalent duration of the traineeship or the period of secondment for national experts, or two years. In all cases, applications are reviewed to establish any potential conflict of interests to the Agency, and if so required, the Executive Director will issue a decision on the basis of an opinion of the Agency's Joint Committee, which may impose restrictions on the staff member to mitigate against any potential conflict of interests.

During the period from 1 January 2013 to 31 December 2013, a total of 42 applications were made, resulting in 36 authorisations without restrictions and 6 applications with restrictions. Information on the restrictions applied to former staff members in 2013 is given below.

Engaging in an occupational activity within two years of leaving the service

Restrictions applied to applications in 2013

| Case no | Job title / function at the EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|----------------|--|--------------------------|--|-------------------------------------|---------------------------|---|----------------------------|
| 1 & 2 | Temporary Agent / Safety and Efficacy | 6 years 3.5 months | 2/1/2013 & 1/3/2013 (2 applications) | Authorisation with restrictions | 4/2/2013 | Confirms that the former staff member may not have contact with the staff of the Agency other than through official written communication and may not appear at nor attend any administrative or product-related hearings or meetings involving the Agency for a period of 2 years from 16 March 2012. This is without prejudice to the possibility of requesting information from the Agency through the standard channels available to all members of the public. | 19/2/2013 |

| Case no | Job title / function at the EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|---------|---------------------------------------|-------------------|---------------------|---------------------------------|--------------------|---|---------------------|
| | | | | | | Through its opinion no 8 of 16 July 2012, the former staff member should for a period of two years from 16 March 2012 refrain from holding any kind of managerial or executive role in pharmaceutical companies, whether gainful or not, and also from providing guidance or advice with regard to any procedure concerning product development, assessment, supervision or evaluation on any specific product with which the former staff member was previously involved directly or indirectly and which falls within the remit and the area of responsibilities assigned to the European Medicines Agency. | |
| 3 | Contract Agent / Scientific Committee | 2 years | 3/6/2013 | Authorisation with restrictions | 20/6/2013 | To refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity the staff member may have dealt with in the performance of responsibilities at the European Medicines Agency for a period of six months, to be counted as of the date of leaving the service. This is without prejudice to the possibility of liaison or attendance at meetings through the standard channels available to all members of the public. | 10/7/2013 |

| Case no | Job title / function at the EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|---------|--|--------------------|---------------------|---------------------------------|--------------------|--|---------------------|
| 4 | Temporary Agent / Risk Management | 9 years 4.5 months | 25/6/2013 | Authorisation with restrictions | 17/7/2013 | To refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity the staff member may have dealt with in the performance of responsibilities at the European Medicines Agency for a period of six months, to be counted as of the date of leaving the service. This is without prejudice to the possibility of liaison or attendance at meetings through the standard channels available to all members of the public. Since the period of six months has already elapsed, no restrictions need to be applied. | 2/8/2013 |
| 5 | National expert on secondment /Scientific support & Projects | 1 year | 17/5/2013 | Authorisation with restrictions | 20/6/2013 | To refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity the national expert may have dealt with in the performance of responsibilities at the Agency for a period of six months, to be counted as of the date the staff member left the service. This is without prejudice to the possibility of liaison or attendance at meetings through the standard channels available to all members of the public. Since the period of 6 months has already elapsed, no restrictions need to be applied. | 12/7/2013 |

| Case no | Job title / function at the EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Decision of Executive Director (ED) | Date of ED decision |
|---------|---|-------------------|---------------------|---------------------------------------|--------------------|--|---------------------|
| 6 | Contract Agent / Anti-infectives & Vaccines | 1 year 1 month | 15/10/2013 | Authorisation with restrictions | 24/10/2013 | To refrain from individually liaising with any member of staff of the European Medicines Agency with regard to any professional activity the staff member may have dealt with in the performance of responsibilities at the European Medicines Agency for a period of six months, to be counted as of the date of leaving the service. This is without prejudice to the possibility of liaison or attendance at meetings through the standard channels available to all members of the public. | 18/11/2013 |

Annual report for 2012

On leaving the Agency, staff members are required to seek permission to engage in an occupation within a period of two years of leaving the Agency, in accordance with Article 16 of the Staff Regulations. Trainees and national experts are also required to seek permission, although the period is restricted to the equivalent duration of the traineeship or, in the case of national experts, the period of secondment or two years, whichever is the shorter period. In all cases, applications are reviewed to establish any potential conflict of interests to the Agency, and if so required, on the basis of an opinion of the Agency's Joint Committee, the Executive Director will issue a decision, which may impose restrictions on the staff member to mitigate against any potential conflict of interests.

For the two-year period from 1 January 2011 to 31 December 2012, a total of 60 applications were made, resulting in 48 authorisations without restrictions and 12 applications with restrictions. Examples of restrictions imposed include: a distance clause, whereby the former staff member may not contact individual Agency staff or attend meetings at the EMA for a period of time, e.g. one year; explicit prohibition of handling medicinal-product dossiers on which they have worked during their employment at the Agency; a reminder of the binding obligation of confidentiality after leaving; and a requirement that opinions given in public presentations must be stated to be the former staff member's own and not linked to their former employment at the Agency. Other individual restrictions will be applied on a case-by-case basis. Information on restrictions applied to applications in 2012 is given below.

Engaging in an occupational activity within two years of leaving the service-restrictions applied to applications in 2012:

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Executive Director (ED) decision | Date of ED decision |
|---------|---------------------------------------|--------------------|---------------------|---------------------------------|--------------------|---|---------------------|
| 1 | Contract Agent / Quality of Medicines | 2 years 2.5 months | 20/01/2012 | Authorisation with restrictions | 27-Feb-12 | Authorisation with restrictions to refrain from individual contact with staff members with regard to any medicinal products falling under the remit of EMA | 02-Mar-12 |
| 2 | Temporary Agent / Safety and Efficacy | 6 years 3.5 months | 02/04/2012 | Authorisation with restrictions | 15-May-12 | Authorisation with restrictions to refrain from holding managerial or executive role in pharmaceutical companies/giving guidance or advice on any product issue that falls under the remit of the Agency/ individual contact with staff members for 2 years | 15-May-12 |

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Executive Director (ED) decision | Date of ED decision |
|---------|--|--------------------|----------------------------------|---------------------------------|------------------------|---|------------------------|
| 3 | Temporary Agent / Quality of Medicines | 6 years 3.5 months | 04/04/2012 | Authorisation with restrictions | 15-May-12 | Authorisation with restrictions to refrain from holding managerial or executive role in pharmaceutical companies/giving guidance or advice on any product issue that falls under the remit of the Agency/ individual contact with staff members for 2 years | 23-May-12 |
| 4 | Temporary Agent / Safety and Efficacy | 6 years 3.5 months | 17/05/2012-26/06/2012-06/07/2012 | Authorisation with restrictions | 15-May-12 16-Jul-12 | Authorisation with restrictions to refrain from holding managerial or executive role in pharmaceutical companies/giving guidance or advice on any product issue that falls under the remit of the Agency/ individual contact with staff members for 2 years | 07-Jun-12 26-Jul-12 |
| 5 | Temporary Agent / Legal Sector | 7 years 7 months | 16/06/2012 | Authorisation with restrictions | 16-Jul-12 | Authorisation with restrictions: may not engage in any activity which concerns any legal case involving the EMA or any case that is connected to the EMA, with which he was previously involved with, directly or indirectly as [REDACTED]. This applies indefinitely. Shall refrain from holding any kind of managerial or executive role in pharmaceutical companies, whether gainful or not, and also from providing legal guidance or advice with regard to any procedure concerning product development, assessment, supervision and evaluation, or otherwise falling within the remit and the area of responsibilities assigned to EMA. In relation to these activities, refrain from individually liaising with any member of staff of the EMA or attending any administrative or product related hearings or meetings involving the Agency for a period of 2 years from leaving service | 27-Jul-12 |

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Executive Director (ED) decision | Date of ED decision |
|---------|---------------------------------------|--------------------|---------------------|---------------------------------|--------------------|--|---------------------|
| 6 | Temporary Agent / Safety and Efficacy | 4 years 9.5 months | 05/07/2012 | Authorisation with restrictions | 02-Aug-12 | Authorisation with restrictions to refrain from individually liaising with any member of staff on regulatory issue relating to products dealt with at EMA for a period of two years or attending any administrative or product related hearings or meetings involving EMA for a period of 1 year from leaving service. | 03-Aug-12 |
| 7 | Contract Agent / Medical Information | 1 year 1 month | 27/08/2012 | Authorisation with restrictions | 02-Oct-12 | Authorisation with restrictions to refrain from individually liaising with any member of staff at EMA or attending any administrative or product related hearings or meetings involving EMA for a period of 6 months from leaving service. | 16-Oct-12 |
| 8 | Temporary Agent / Safety and Efficacy | 3 years 3 months | 17/09/2012 | Authorisation with restrictions | 02-Oct-12 | Authorisation with restrictions to refrain from individually liaising with any member of staff on regulatory issue relating to products dealt with at EMA for a period of two years or attending any administrative or product related hearings or meetings involving EMA for a period of 1 year from leaving service. | 19-Oct-12 |
| 9 | Temporary Agent / Safety and Efficacy | 3 years 3 months | 22/10/2012 | Authorisation with restrictions | 02-Oct-12 | Authorisation with restrictions to refrain from individually liaising with any member of staff on regulatory issue relating to products dealt with at EMA for a period of two years or attending any administrative or product related hearings or meetings involving EMA for a period of 1 year from leaving service. | 19-Oct-12 |

| Case No | Job Title / Function at EMA | Length of service | Date of application | Joint Committee (JC) opinion | Date of JC opinion | Executive Director (ED) decision | Date of ED decision |
|---------|-----------------------------------|-------------------|---------------------|---------------------------------|--------------------|--|---------------------|
| 10 | Temporary Agent / Human Medicines | 3 years 4 months | 19/10/2012 | Authorisation with restrictions | 22-Nov-12 | Authorisation with restrictions to refrain from individually liaising with any member of staff on any product related query or attending any administrative or product related hearings or meetings involving EMA for a period of 1 year from leaving service. | 03-Dec-12 |