



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Maintenance of Rapid Alert/Non-Urgent Information (RA/NUI) contact points list and fax machine for RA/NUI use		
Applies to: Assistants in PhVWP Secretariat, Coordination and Networking Section, Pharmacovigilance and Risk Management Sector, Patient Health Protection Unit		
Status: PUBLIC		Document no.: WIN/H/3150
Lead Author	Approver	Effective Date: 29-JUL-11
Name: Anya Stang	Name: Peter Arlett	Review Date: 29-JUL-14
Signature: ON FILE	Signature: ON FILE	Supersedes: WIN/H/3150 (05-DEC-08)
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1. Changes since last revision

Updated to reflect the new organisational names in the Agency.

2. Records

All electronic correspondence is saved in DREAM folder "RA-NUI contact points DO NOT DELETE!!!" [DREAM link:] <https://docs.eudra.org/webtop/drl/objectId/0b0142b280014979> ('breadcrumb trail': Cabinets/Old EDMS Structure/Operational Units/Human/Post/PHVSE/Drug Monitoring (RA-NUI)/RA-NUI contact points DO NOT DELETE!!!) in the folder of the current year. Hardcopies of the correspondence and the updated Contact Points List is filed in the folder labelled "Contact Points / Crisis Management 2006- / RA-NUI" by desk 1-737a.

3. Instructions

Document needed for this WIN:

- RA-NUI Contact Points List, Doc.Ref. EMEA/40852/2004, located in DREAM folder "RA-NUI contact points DO NOT DELETE!!!" [DREAM link:] <https://docs.eudra.org/webtop/drl/objectId/0b0142b280014979> ('breadcrumb trail': Cabinets/Old EDMS Structure/Operational Units/Human/Post/PHVSE/Drug Monitoring (RA-NUI)/RA-NUI contact points DO NOT DELETE!!!).



Related documents:

- Volume 9A of The Rules Governing Medicinal Products in the European Union, Part II, Chapters 4.3.1 "Sending a Rapid Alert or a Non-Urgent Information" and 4.3.2 "Responses to a Rapid Alert or Non-Urgent Information" [direct weblink:] http://ec.europa.eu/health/documents/eudralex/vol-9/index_en.htm (http://europa.eu/index_en.htm 'breadcrumb trail': [European Commission](#) - [DG Health & Consumers](#) - [Public health](#) - [Reference documents](#) - [Eudralex](#) - [Vol9: Pharmacovigilance Human & Veterinary](#));
- PhVWP Mandate (latest version as published on the Agency's website [direct link:] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/02/WC500073703.pdf (<http://www.ema.europa.eu/> 'breadcrumb trail': [Home](#) - [About Us](#) - [Working parties and other groups](#) - [CHMP](#) - [Pharmacovigilance Working Party](#)).

Update of RA-NUI Contact Points List and related fax numbers stored in fax machine

The RA/NUI Contact Points List serves as back-up for the electronic distribution of RAs/NUI via EudraNet (address list "All Human RA" – see Chapter II.4, Section 3.1 in Volume 9A of The Rules Governing Medicinal Products in the European Union). In case EudraNet is unavailable, RAs/NUI are exchanged via fax. Therefore it must be ensured that the list is always up-to-date and the fax numbers of the latest list version stored in the P-PV Sector's fax machine located in print area 1-736.

Quarterly Action – responsible: Assistants in PhVWP Secretariat

Step	Action
1	Circulate (email) current document "RA-NUI Contact Points List" via EudraNet to "All Human RA", requesting checking of details and notification of changes with a deadline of today plus 10 days.
2	Save this email incl attachment in msg or rtf format in DREAM (see above under 2. Records) and name it e.g. "email to AllHumanRA for update 19-06-2008"
3	Print and file this email incl attachment (see above under 2. Records).
4	Save responses (emails) incl any attachments in msg or rtf format in DREAM (see above under 2. Records), indicating in the file name the country, changes or no changes, and the date, e.g. "IS changes 23-06-2008" or "PT no changes 11-11-2011".
5	Print responses incl any attachments and file (see above under 2. Records).
6	1 day (2 days at the most) after expiry of deadline, update the RA-NUI Contact Points List on the basis of the responses and mark all changes in bold. NB: Only names, telephone and fax numbers should be amended this way. The email addresses stay the same unless notification of a new, or a change in a, EudraNet address. This should come from EMA Information and Communications Technology (ICT) Unit and should be processed via the Ad Hoc action steps, see below.
7	Amend previous "Updated" dates in document a) on first page top right underneath "London, 4 August 2004" (this is the create date of the document and not to be changed) and b) in the footer of the second page with "Updated: <today's date>" and save document.
8	Circulate (email) updated (=new current) document "RA-NUI Contact Points List" via EudraNet to "All Human RA", indicating that all changes are highlighted in bold and

	that any changes should be notified at any time to keep the list up-to-date.
9	Save this email incl attachment in msg or rtf format in DREAM (see above under 2. Records) and name it e.g. "email to AllHumanRA update 01-07-2008".
10	Print and file this email incl attachment (see above under 2. Records).
11	Re-open document "RA-NUI Contact Points List" in DREAM, unbold all changes and save.
12	Update information stored in fax machine (name and/or number), and change name label if necessary, according to the change of the RA-NUI Contact Points list.
13	Print fax machine's Touch Speed Dial List and Group Dial List and affix to the wall above the fax machine (replacing previous lists).
14	Stick a label on the fax machine indicating the date of the last change/last review for RA/NUI.

Ad Hoc Action – responsible: Assistants in PhVWP Secretariat

Step	Action
1	Receipt of email(s) requesting a change of RA-NUI Contact Point(s).
2	Save email(s) incl any attachments in msg or rtf format in DREAM (see above under 2. Records), indicating in the file name the country, "changes" and the date, e.g. "IS changes 23-06-2008" or "IT EudraNet changes 21-05-2008".
3	Print email(s) incl any attachments and file (see above under 2. Records).
4	Update the RA-NUI Contact Points List on the basis of the email(s) and mark all changes in bold.
5	Amend previous "Updated" dates in document a) on first page top right underneath "London, 4 August 2004" (this is the create date of the document and not to be changed) and b) in the footer of the second page with "Updated: <today's date>" and save document.
6	Circulate (email) updated (=new current) document "RA-NUI Contact Points List" via EudraNet to "All Human RA", indicating that all changes are highlighted in bold.
7	Save this email incl attachment in msg or rtf format in DREAM (see above under 2. Records) and name it e.g. "email to AllHumanRA update 01-07-2008".
8	Print and file this email incl attachment (see above under 2. Records).
9	Re-open document "RA-NUI Contact Points List" in DREAM, unbold all changes and save.
10	Update information stored in fax machine (name and/or number), and change name label if necessary, according to the change of the RA-NUI Contact Points list.
11	Print fax machine's Touch Speed Dial List and Group Dial List and affix to the wall above the fax machine (replacing previous lists).

