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DE SANIDAD, SERVICIOS SOCIALES
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agencia española de
medicamentos y
productos sanitarios

La Actividad de los Comités Europeos relacionados con Riesgos Químicos
Madrid, 12 de abril de 2018

Comités de la Agencia Europea del Medicamento. EMA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Belen Gracia Moneva
Agencia Española de Medicamentos y Productos Sanitarios. AEMPS

Unión Europea

europa.eu

EUROPA > Información básica sobre la Unión Europea > Agencias y otros organismos de la UE

Inicio | Acerca de la UE | La UE por temas | Derecho de la UE | Vida y negocios | Contacto | Documentos y publicaciones

Agencia Europea de Medicamentos (EMA)

CONTENIDOS DE LA PÁGINA

Visión general

Función: La EMA garantiza la evaluación científica, la supervisión y el seguimiento de la seguridad de los medicamentos de uso humano y veterinario en la UE.

Director Ejecutivo: Guido Rasi

Año de creación: 1995

726/2004 (prev 2309/93)

Plantilla: 897

Sede: Londres (Reino Unido). Tras la retirada del Reino Unido de la UE no más tarde del 30 de marzo de 2019, la EMA se trasladará a Ámsterdam (Países Bajos).

Web: EMA EN

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

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Objetivo EMA

La Agencia Europea de Medicamentos es una agencia descentralizada de la Unión Europea (UE) responsable de la evaluación científica, supervisión y monitorización de la seguridad de los medicamentos en la UE.

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Base legal medicamentos:

-Directive 2001/82/EC, on the Community code relating to veterinary medicinal products, as amended.

-Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended.

-Regulation (EC) No 726/2004 (prev 2309/93) laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended.

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E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

¿Cómo funciona?

-La EMA coopera estrechamente con los ***reguladores nacionales*** *en los países de la UE y con la Dirección General de Salud de la* ***Comisión*** *en una asociación conocida como la* ***red europea de regulación de medicamentos***

-Interactúa con los ***pacientes, los profesionales sanitarios y las universidades.***

-Colabora con sus ***agencias homólogas y en especial con el Centro Europeo para la Prevención y el Control de las Enfermedades (ECDC) y la Autoridad Europea de Seguridad Alimentaria (EFSA)***

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medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

¿Cómo se organiza la EMA?

Management Board

Executive Director

Personal de la EMA

CHMP | **CVMP** | **COMP** | **HMPC** | **PDCO** | **CAT** | **PRAC**

+ 28 working parties

+ 8 scientific advisory groups

Agencias Nacionales
~4000 expertos Europeos

EU institutions

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agencia española de medicamentos y productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

¿Funciones EMA?

Coordinación

- solicitudes de **autorización de comercialización de la UE en el procedimiento** centralizado y supervisión de productos autorizados.
- solicitudes de designación de huérfano en la UE.
- planes de investigación pediátrica (o exenciones)
- sistema de farmacovigilancia de la UE
- inspecciones solicitadas por los comités

Apoyo a la innovación y la investigación en el sector farmacéutico (asesoramiento científico, directrices)

Aplicación del programa telemático de la UE (sistemas y bases de datos)

How the committees work
CHMP
CVMP
PRAC
COMP
HMPC
CAT
PDCO
Working parties and other groups

Home ▸ Committees

Committees, working parties and other groups

The European Medicines Agency has seven scientific committees and a number of working parties and related groups which conduct the scientific work of the Agency.

In this section

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

Comités y Expertos

Composición de los Comites

- **1 member + 1 alternate** nominado por cada uno de los 28 EMs EU
- 1 member + 1 alternate de NO e IS (**observers**)
- **Co-opted members** elegidos por su **expertise**
- **Patient representatives**
- **Chair** y **Vice-Chair** (mandato renovable a los 3 años)

Expertos

Working parties, equipo evaluador de cada agencia nacional, red grupo expertos.

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

Comité de Medicamentos de Uso Humano (CHMP)

- Emite dictamen en cualquier cuestión relacionada con la evaluación de medicamentos en **procedimientos centralizados** (autorización, modificación, suspensión o revocación de la autorización comercialización):
  - Solicitudes iniciales
  - Variaciones o modificaciones
- Emite dictamen en procedimiento de reconocimientos mutuos y descentralizados cuando hay desacuerdo entre los EMs .
- Asesora a las compañías en el desarrollo de nuevos medicamentos
- Prepara guías de contenido científico y regulatorio.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- work
- CHMP
- CVMP
- PRAC
- COMP
- HMPC
- CAT

CHMP: Working parties and other groups

The Committee for Medicinal Products for Human Use (CHMP) establishes a number of working parties at the beginning of each three-year mandate. These working parties have expertise in a particular scientific field, and are composed of members selected from the list of European experts maintained by the Agency.

The CHMP consults its working parties on scientific issues relating to their particular field of expertise, and delegates certain tasks to them associated with the scientific evaluation of marketing authorisation applications or drafting and revision of scientific guidance documents.

Standing working parties

Temporary working parties

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standing Working Parties

Son:

Safety Working Party

Scientific Advice Working Party

Healthcare Professionals' Working Party

Biologics Working Party

Patients' and Consumers' Working Party

Quality Working Party

Temporary working parties

- Biosimilar Medicinal Products Working Party
- Biostatistics Working Party
- Blood Products Working Party
- Cardiovascular Working Party
- Central Nervous System Working Party
- Infectious Diseases Working Party
- Oncology Working Party
- Pharmacogenomics Working Party
- Pharmacokinetics Working Party
- Rheumatology/Immunology Working Party
- Vaccines Working Party

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Drafting groups

- Excipients Drafting Group
- Gastroenterology Drafting Group
- Radiopharmaceuticals Drafting Group
- Respiratory Drafting Group

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Scientific advisory groups

The CHMP establishes scientific advisory groups to provide advice in connection with the evaluation of specific types of medicines or treatments. They consist of European experts selected according to the particular expertise required on the basis of nominations from the CHMP or the Agency.

The current CHMP scientific advisory groups are:

- Scientific Advisory Group on Cardiovascular Issues
- Scientific Advisory Group on Anti-infectives
- Scientific Advisory Group on Diabetes/Endocrinology
- Scientific Advisory Group on HIV / Viral Diseases
- Scientific Advisory Group on Neurology
- Inter-Committee Scientific Advisory Group on Oncology
- Scientific Advisory Group on Psychiatry
- Scientific Advisory Group on Vaccines

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Safety Working Party CHMP/EMA

Activities

- Providing support to dossier evaluation
- Preparation, review and update of guidelines
- Contribution to the Advices produced by the Scientific Advice Working Party of the CHMP
- Assessing non-clinical safety findings
- Providing advice, through the CHMP, on non-clinical safety-related matters to the European Commission , and the Committee on Herbal Medicinal Products (HMPC)
- Liaising with interested parties EFPIA, ECVAM (JRC)

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

DIR 2010/63/EU on the protection of animals used for scientific purposes (coming into operation 1 january 2013)

DIR 2001/82/EC and 2001/83/EC state:

-that Member States shall ensure that all tests on animals are conducted in accordance with Council Directive 86/609/EC (2010/63) on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.

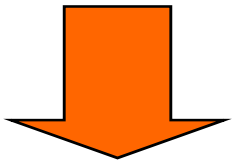
- Member States, shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used.

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

~~REACH~~



Medicines

(European Commission-specific legislation)

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DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Statement of the EMA position on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of human and veterinary medicinal products

-The European Medicines Agency (EMA) **commits** to the application of replacement, reduction and refinement (the 3Rs) of animal testing as detailed in Directive 2010/63/EU1.

-Joint ad hoc Expert Group (the JEG 3Rs) has been created in order to promote best practice in the implementation of the 3Rs in regulatory testing of medicinal products and to facilitate full and active cooperation with other European groups working in the 3Rs area.

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Other CHMP-associated groups

Other groups are established by the CHMP to provide expertise in their respective areas. The CHMP consults these groups and delegates to them certain tasks associated with marketing authorisations, applications, and the drafting and revision of guidance documents.

- (Invented) Name Review Group
- Working Group on Quality Review of Documents
- Expert Group on the Application of the 3Rs in the Development of Medicinal Products
- Active Substance Master File Working Group
- Geriatric Expert Group
- Summary of Product Characteristics Advisory Group
- Modelling and Simulation Working Group

The CHMP is further supported by the work of the Good Manufacturing Practice (GMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) Inspection Services Groups. Information on their role is available under inspections.

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Expert Group on the Application of the 3Rs in the development of medicinal products (J3RsWG)

Composición

The J3RsWG consiste en un grupo de uno o dos expertos europeos de cada uno de los grupos de trabajo del CHMP/CVMP para los que las pruebas con animales son relevantes:

Joint CHMP/CVMP Quality Working Party;
CHMP Safety Working Party;
CVMP Safety Working Party;
CHMP Biologics Working Party;
CHMP Vaccines Working Party;
CVMP Immunologicals Working Party;
CVMP Efficacy Working Party.

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mandato y objetivos J3RsWG

El JEG 3Rs se establece para mejorar e impulsar la aplicación de 3Rs en las pruebas regulatorias de medicamentos a lo largo de su ciclo de vida. El grupo proporcionará **asesoramiento** y **recomendaciones** a los Comités en todas las materias relacionadas con el uso de los animales en pruebas de tipo regulatorio de medicamentos

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Tareas J3RsWG

-Identificar de oportunidades para la implementación de las 3Rs en las pruebas tipo regulatorio.

-Coordinar, facilitar y priorizar las actividades de EMA en el ámbito de las 3Rs.

-Establecer contactos trabajo con EDQM y ECVAM

-Formar en 3Rs a expertos implicados en regulación medicamentos

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Tareas J3RsWG (con´t)

-Contribuir al desarrollo de guías en los que los ppios 3Rs son aplicables, en colaboración con los *Working Parties*

-Proporcionar información y asesoramiento sobre 3Rs a partes implicadas

-Influenciar en el desarrollo de guías a nivel internacional (ICH/VICH, etc)

MINISTERIO
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E IGUALDAD

agencia española de
medicamentos y
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Working Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products

Email Print Help Share

The Joint Committee for Medicinal Products for Veterinary Use/Committee for Medicinal Products for Human Use Working Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products (J3RsWG) provides advice and recommendations to the Committee for Medicinal Products for Veterinary Use (CVMP) and Committee for Medicinal Products for Human Use (CHMP) on all matters relating to the use of animals and the application of the '3 R' principles (replacement, reduction and refinement) in the testing of medicines for regulatory purposes.

The Agency has also published its position on the application of the 3Rs in the testing of medicines, together with recommendations for marketing-authorisation holders on their need to comply with 3R methods in the European Pharmacopoeia:

- Statement of the Committee for Medicinal Products for Veterinary Use position on the ethical use of animals in the testing, development and manufacture of veterinary medicines
- Statement of the European Medicines Agency position on the application of the 3Rs in the regulatory testing of human and veterinary medicinal products
- Recommendation to marketing-authorisation holders, highlighting the need to ensure compliance with 3R methods described in the European Pharmacopoeia
- Recommendation to marketing-authorisation holders, highlighting recent updates for the 3Rs methods described in the European Pharmacopoeia applicable to human vaccines against hepatitis A
- Recommendation to marketing-authorisation holders for veterinary vaccines, highlighting the need to update marketing authorisations to remove the target animal batch safety test (TABST) following removal of the requirement from the European Pharmacopoeia monographs
- Recommendation to marketing authorisation holders, highlighting recent measures in the veterinary field to promote replacement, reduction, and refinement (3Rs) measures described in the European Pharmacopoeia - Applicable to human vaccines from 01/01/2018
- Recommendation to marketing authorisation holders, highlighting recent measures in the veterinary field to promote reduction, refinement and replacement (3Rs) measures described in the European Pharmacopoeia - Applicable to veterinary vaccines from 01/01/2017

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2012 EMA/CHMP/CVMP/JEG-3Rs/252137/2012
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Recommendation to marketing authorisation holders, highlighting the need to ensure compliance with 3Rs methods described in the European Pharmacopoeia

Applicable to all medicinal products regardless of type

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 10 November 2016
2 EMA/CHMP/CVMP/JEG-3Rs/742466/2015
3 Committee for Medicinal Products for Human Use (CHMP)

4 Reflection paper providing an overview of the current 5 regulatory testing requirements for medicinal products for 6 human use and opportunities for implementation of the 7 3Rs

8 **Draft**

9

Draft agreed by JEG 3Rs following review by respective WPs (SWP, QWP, BWP, CAT and BMWP)	October 2016
Adopted by Committee for medicinal products for human use for release for consultation	10 November 2016
Start of Public consultation	18 November 2016
End of Public consultation (deadline for comments)	31 May 2017

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Reflection paper on providing an overview of the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs

Table of contents

2.2. CHMP Safety Working Party

Overview of animal testing requirements for non-clinical studies for human pharmaceuticals (SWP Working Party - CHMP)

Topic	Regulatory provision	Animal testing requirements	Implemented 3Rs opportunities	Newly identified opportunities for 3Rs implementation
Repeated dose toxicity	Note for Guidance on Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorisation for Pharmaceuticals (CPMP/ICH/286/95; ICH M3(R2)) Guideline on repeated dose toxicity (CPMP/SWP/1042/99 Rev 1 Corr)	The recommended duration of repeated-dose toxicity studies to support clinical trials and/or marketing depends on the duration of the indicated treatment and ranges from 2 weeks up to 9 months.	One species could be acceptable on a case by case approach, and if clearly justified.	Inclusion e.g. of safety pharmacology or genotoxicity endpoints: need for retrospective data analysis to expand concept beyond ICH S9 Exposure-based setting of the maximum tolerated dose (MTD): is a 25-fold exposure sufficient?
Repeated dose toxicity: reversibility	Q&A to the Note for Guidance on Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorisation for Pharmaceuticals (CPMP/ICH/286/95; ICH M3(R2))	ICH M3(R2) states the following in Section 1.4, General Principles: "The goals of the non-clinical safety evaluation generally include a characterisation of toxic effects with respect to target organs, dose dependence, relationship to exposure, and, when appropriate, potential reversibility."	Recommendations to avoid unnecessary studies: A toxicity study that includes a terminal non-dosing period is generally not warranted when the toxicity: - can be readily monitored in humans at an early stage before the toxicity becomes severe; or - is known to be irrelevant to humans (e.g., rodent Harderian gland toxicity); or - is only observed at high exposures not considered clinically relevant; or	

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

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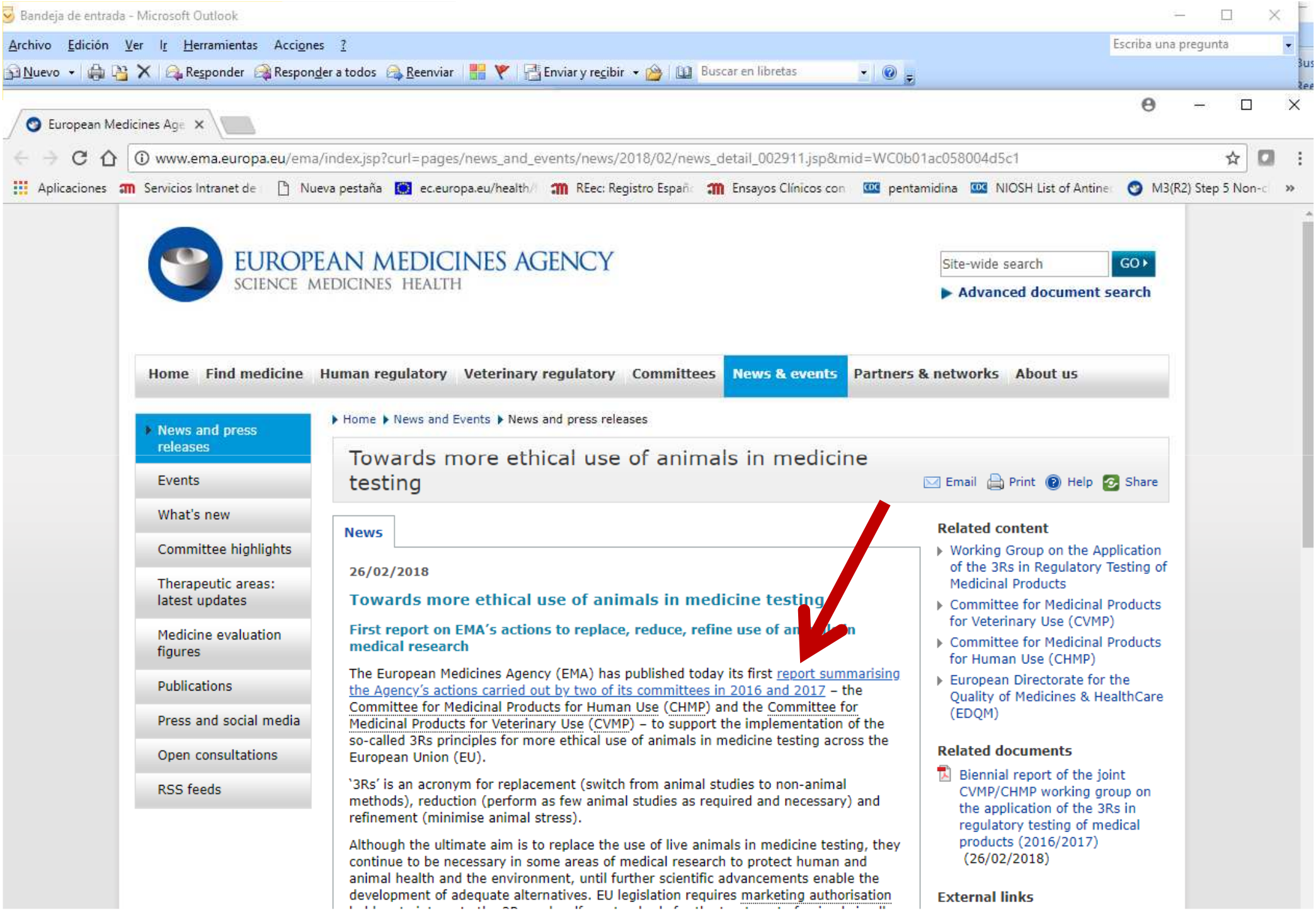
SCIENCE MEDICINES HEALTH

PARERE (Preliminary Assessment of Regulatory Relevance network)

Directive 2010/63/EU on the protection of animals used for scientific purposes requires increased involvement of regulators in the process of prioritising alternative methods for entry into the formal ECVAM validation procedure.

The PARERE network has been created to put this into practice.


Bandeja de entrada - Microsoft Outlook
Archivo Edición Ver Ir Herramientas Acciones ?
Escriba una pregunta
Nuevo Responder Responder a todos Reenviar Enviar y recibir Buscar en libretas
European Medicines Age
www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/02/news_detail_002911.jsp&mid=WC0b01ac058004d5c1
Aplicaciones Servicios Intranet de Nueva pestaña ec.europa.eu/health/ REec: Registro Espa Ensayos Clínicos con pentamidina NIOSH List of Antine M3(R2) Step 5 Non-c
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Advanced document search
Home
Find medicine
Human regulatory
Veterinary regulatory
Committees
News & events
Partners & networks
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Events
What's new
Committee highlights
Therapeutic areas: latest updates
Medicine evaluation figures
Publications
Press and social media
Open consultations
RSS feeds
Home News and Events News and press releases
Towards more ethical use of animals in medicine testing
Email
Print
Help
Share
News
26/02/2018
Towards more ethical use of animals in medicine testing
First report on EMA's actions to replace, reduce, refine use of an
medical research
The European Medicines Agency (EMA) has published today its first report summarising the Agency's actions carried out by two of its committees in 2016 and 2017 – the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Medicinal Products for Veterinary Use (CVMP) – to support the implementation of the so-called 3Rs principles for more ethical use of animals in medicine testing across the European Union (EU).
'3Rs' is an acronym for replacement (switch from animal studies to non-animal methods), reduction (perform as few animal studies as required and necessary) and refinement (minimise animal stress).
Although the ultimate aim is to replace the use of live animals in medicine testing, they continue to be necessary in some areas of medical research to protect human and animal health and the environment, until further scientific advancements enable the development of adequate alternatives. EU legislation requires marketing authorisation
Related content
Working Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products
Committee for Medicinal Products for Veterinary Use (CVMP)
Committee for Medicinal Products for Human Use (CHMP)
European Directorate for the Quality of Medicines & HealthCare (EDQM)
Related documents
Biennial report of the joint CVMP/CHMP working group on the application of the 3Rs in regulatory testing of medical products (2016/2017) (26/02/2018)
External links

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SCIENCE MEDICINES HEALTH

Joint CVMP/CHMP Working group on the Application of the 3Rs in Regulatory Testing of Medical Products

Biennial report 2016/2017

Executive summary

This report is aimed at informing pharmaceutical companies and the public of the EMA activities in relation to "3Rs" (replacement, reduction, refinement) during 2016 and 2017. The report summarises the recommendations developed and the organisational structure enabling the development of such guidance. It also looks into the future with details about a new mandate to continue providing advice and recommendations to the Committee for Medicinal Products for Veterinary Use (CVMP) and Committee for Medicinal Products for Human Use (CHMP) on all matters relating to the use of animals and the application of the '3Rs' principles in the testing of medicines for regulatory purposes.

The period 2018 – 2019 poses some specific challenges resulting from Brexit and the associated move of the Agency to Amsterdam. Inevitably the focus will be on core-business activities during the period of transition. However, the 3Rs will continue to be addressed, not least through the continued endeavour of the working parties and committees to implement the 3Rs principles without putting public health and animal welfare at risk.

3Rs guidance documents

Regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012)

This guideline describes the process for submission and evaluation of a proposal for regulatory acceptance of 3Rs testing approaches for use in the development and quality control during production of human and veterinary medicinal products. It also presents the scientific and technical criteria for validation of 3Rs testing approaches and explains the pathways for regulatory acceptance of 3Rs testing approaches.

The guideline was adopted in 2016 and has been in force since 1 January 2017.

Reflection paper providing an overview of the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs (EMA/CHMP/CVMP/JEG-3Rs/742466/2015)

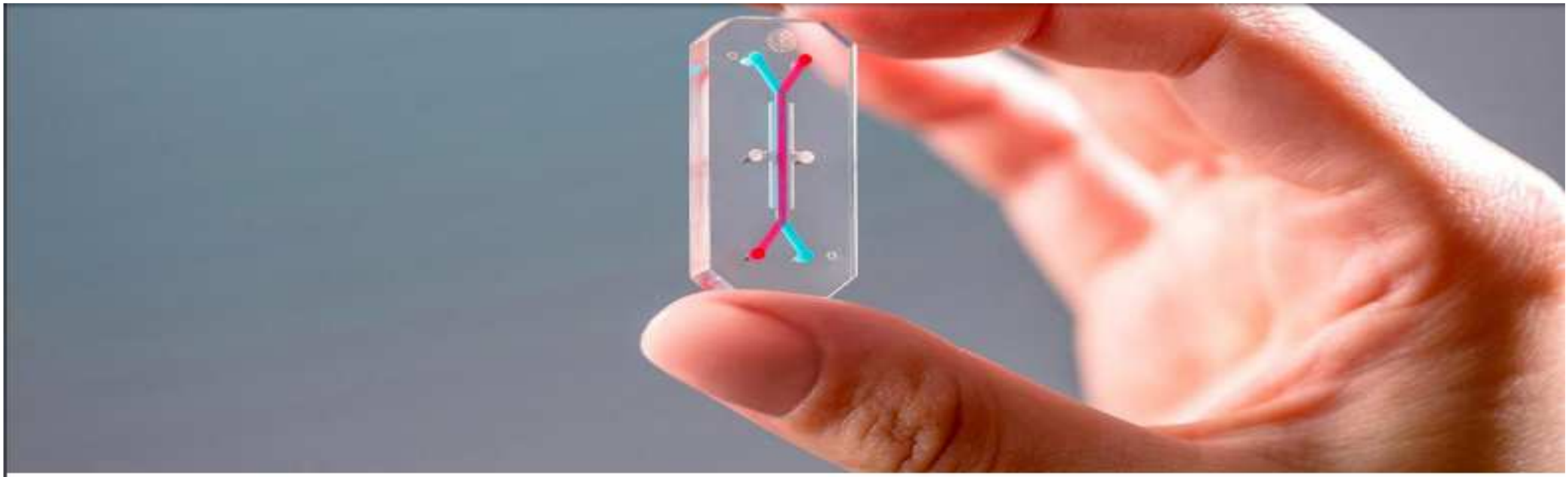
This reflection paper was developed as a complement to the guideline on Regulatory acceptance of 3Rs testing approaches (see above) and provides an overview of the main animal tests required for the regulatory testing of medicinal products for human use. It includes information on opportunities

Reflection paper providing an overview of the current regulatory testing requirements for medicinal products for veterinary use and opportunities for implementation of the 3Rs (EMA/CHMP/CVMP/JEG-3Rs/164002/2016)

This reflection paper was developed as a complement to the guideline on Regulatory acceptance of 3Rs testing approaches (see above) and provides an overview of the main animal tests required for the regulatory testing of medicinal products for veterinary use. It includes information on opportunities for limiting animal testing that can already be implemented, where appropriate, as well as information on opportunities that may become available in the future. It is expected that the document stimulates further requests for CVMP advice on the regulatory acceptance of new 3Rs approaches.

The public consultation ended on 31 October 2016 and the final reflection paper is scheduled for publication in Q1 2018.

Guidance for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs (EMA/CHMP/CVMP/JEG-3Rs/94436/2014)



Objectives for 2018 and beyond

The tasks of the new J3RsWG remain relatively unchanged with a focus in the following areas:

(1) Finalisation and adoption of reflection papers and guidelines under development on 3Rs

(2) Evaluation of 3Rs issues related to batch release testing for veterinary immunologicals and human vaccines & biologicals

(3) Support and promotion of the implementation of Directive 2010/63/EU for the use of 3Rs principles (best practices), including 3Rs training for regulators

(4) Agency platform for 3Rs-related issues

In 2018/2019, 3Rs activities may be impacted by Agency business continuity considerations in light of Brexit and the relocation of the Agency.

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

Biannual report JEWG-Rs:

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/02/WC500244422.pdf

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de medicamentos y productos sanitarios

CEPAFIC

Comité español para la protección de animales utilizados con fines científicos

Vocales

Vocales: MSSSI, AEMPS (Medicamentos, Cosméticos)

Real Decreto 53/2013, de 1 de febrero, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia.

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E IGUALDAD

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¡Muchas gracias!

bgracia@aemps.es