



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Patient Health Protection

## List of Organisations which provided comments during the public consultation on the EU reference dates list

The list of Union reference dates and frequency of submission of periodic safety update reports (EU reference dates list) was released for public consultation between 4 April and 4 June 2012\*. Comments received were taken into account in the finalisation of the list adopted in September 2012 by the Committee for Medicinal Products for Human Use (CHMP) and the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) following consultation with the Pharmacovigilance and Risk Assessment Committee (PRAC).

**The European Medicines Agency thanks all the Organisations listed in the table below for their contribution in the development of the EU reference dates list.**

<b>Name of the Organisation hoch provided comments</b>
<b>Abbott Laboratories</b>
<b>Actelion Pharmaceuticals Ltd</b>
<b>Agencia Española de Medicamentos y Productos Sanitarios - AEMPS</b>
<b>Association of the European Self-Medication Industry - AESGP</b>
<b>Alcon laboratories</b>
<b>Alexion</b>
<b>Alfa Wassermann SpA</b>
<b>ALK-Abello A/S</b>
<b>Allergan Limited</b>
<b>Almirall</b>
<b>Amgen</b>

\* Feedback requested on the draft list of EU reference dates for periodic safety update reports in preparation for introduction of the new pharmacovigilance legislation – 4 April 2012  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2012/03/news\\_detail\\_001479.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/03/news_detail_001479.jsp&mid=WC0b01ac058004d5c1)



<b>Name of the Organisation hoch provided comments</b>
<b>APOGEPHA Arzneimittel GmbH</b>
<b>Astellas Pharma Europe B.V.</b>
<b>AstraZeneca AB, Sweden</b>
<b>Bausch + Lomb</b>
<b>Baxter</b>
<b>Bayer HealthCare</b>
<b>Besins Healthcare/Laboratoires Besins International/Besins Healthcare Benelux</b>
<b>Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM</b>
<b>Bial, Portela &amp; C<sup>a</sup> S.A</b>
<b>Biogen Idec</b>
<b>BioMarin Europe Limited</b>
<b>BioPhausia</b>
<b>Bristol-Myers Squibb - BMS</b>
<b>Boehringer Ingelheim</b>
<b>Bracco</b>
<b>Bristol-Myers Squibb</b>
<b>British Generic Manufacturers Association</b>
<b>C.B. Fleet Company Inc.</b>
<b>Cbfleet</b>
<b>Celgene Europe Ltd</b>
<b>Chiesi Farmaceutici S.p.A.</b>
<b>CIS BIO</b>
<b>Crucell</b>
<b>Crucell Sweden AB</b>
<b>Daiichi Sankyo Europe</b>
<b>Diomed Developments Limited, Dermal Laboratories Limited, Brome and Schimmer Limited</b>
<b>Dr.Falk Pharma GmbH</b>
<b>European Federation of Pharmaceutical Industries and Associations - Efpia</b>
<b>European Generic Medicines Association - EGA</b>

<b>Name of the Organisation hoch provided comments</b>
<b>Eisai</b>
<b>Elan Pharma International Ltd</b>
<b>Eli Lilly &amp; Company</b>
<b>European Medicines Agency - EMA</b>
<b>European Confederation of Pharmaceutical Entrepreneurs - EUCOPE</b>
<b>EvEpacks GmbH</b>
<b>F.Hoffmann - la Roche Ltd.</b>
<b>Ferring Pharmaceuticals A/S</b>
<b>Fresenius Biotech GmbH</b>
<b>GALDERMA INTERNATIONAL</b>
<b>Gebro Pharma GmbH</b>
<b>Genzyme Europe BV</b>
<b>Gilead Sciences International Limited</b>
<b>Grünenthal GmbH</b>
<b>Grupo Ferrer Internacional, S.A.</b>
<b>Grupo Uriach (ID: GRUPURIACH)</b>
<b>GSK</b>
<b>GSK Biologicals</b>
<b>Helsinn Birex Pharmaceuticals Ltd.</b>
<b>Committee on Herbal Medicinal Products - HMPC</b>
<b>ICHTHYOL-GESELLSCHAFT</b>
<b>Ipsen</b>
<b>Istituto Biochimico Italiano G. Lorenzini S.p.A.</b>
<b>Johnson &amp; Johnson</b>
<b>Kowa Pharmaceutical Europe Company Ltd</b>
<b>Lysoform</b>
<b>Marr Consultancy Ltd</b>
<b>Medac GmbH</b>
<b>MedImmune</b>
<b>Menarini Industrie Farmaceutiche Riunite</b>

<b>Name of the Organisation hoch provided comments</b>
<b>Merck KGaA</b>
<b>Merz Pharmaceuticals GmbH</b>
<b>Mibe GmbH Arzneimittel</b>
<b>MITHRA PHARMACEUTICALS</b>
<b>Mitsubishi Pharma Europe Ltd.</b>
<b>Mitsubishi Tanabe Pharma Corporation</b>
<b>Medical Products Agency - MPA</b>
<b>MSD</b>
<b>Mundipharma</b>
<b>Norgine Ltd</b>
<b>Novartis Consumer Health GmbH</b>
<b>Novartis Pharma AG</b>
<b>Novartis Switzerland</b>
<b>Novo Nordisk</b>
<b>Orion Corporation, ORION PHARMA</b>
<b>PAGB (Proprietary Association of Great Britain)</b>
<b>Peckforton Pharmaceuticals Ltd</b>
<b>Paul-Ehrlich-Institut - PEI</b>
<b>Pfizer</b>
<b>Pliva / Teva</b>
<b>Potter Clarkson</b>
<b>PregLem S.A.</b>
<b>Procter &amp; Gamble</b>
<b>Profile Pharma Ltd</b>
<b>Radaydrug Ltd.</b>
<b>Recordati</b>
<b>Sanofi Pasteur</b>
<b>Sanofi Pasteur MSD</b>
<b>Sanofi-Aventis</b>
<b>Sanquin</b>

<b>Name of the Organisation hoch provided comments</b>
<b>Servier</b>
<b>SFL Regulatory Affairs &amp; Scientific Communication Ltd.</b>
<b>Shire Pharmaceuticals</b>
<b>SpePharm</b>
<b>State Institute for Drug Control</b>
<b>Takeda</b>
<b>Tedec Meiji Farma, S.A.</b>
<b>Teva Pharmaceuticals Europe</b>
<b>THEA</b>
<b>UCB Pharma</b>
<b>URSAPHARM</b>
<b>Verla DE</b>
<b>Warner Chilcott UK Ltd</b>
<b>Weleda</b>
<b>ZAMBON S.p.A.</b>
<b>Zentiva Group, a.s.</b>