

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Single Technology Appraisal**

**Remibrutinib for treating chronic spontaneous urticaria inadequately  
controlled by H1-antihistamines ID6356**

**Final Stakeholder List**

<b>Provisional Consultees</b>	<b>Provisional Commentators (no right to submit or appeal)</b>
<p><u>Company</u></p> <ul style="list-style-type: none"> <li>Novartis Pharmaceuticals (remibrutinib)</li> </ul> <p><u>Patient/carer groups</u></p> <ul style="list-style-type: none"> <li>Allergy UK</li> <li>South Asian Health Foundation</li> <li>Specialised Healthcare Alliance</li> </ul> <p><u>Healthcare professional groups</u></p> <ul style="list-style-type: none"> <li>British Association of Dermatologists</li> <li>British Dermatological Nursing Group</li> <li>British Geriatrics Society</li> <li>British Skin Foundation</li> <li>British Society for Allergy &amp; Clinical Immunology</li> <li>British Society for Cutaneous Allergy</li> <li>British Society for Immunology</li> <li>Primary Care Dermatology Society</li> <li>Royal College of General Practitioners</li> <li>Royal College of Nursing</li> <li>Royal College of Pathologists</li> <li>Royal College of Physicians</li> <li>Royal Pharmaceutical Society</li> <li>Royal Society of Medicine</li> <li>UK Clinical Pharmacy Association</li> </ul> <p><u>Others</u></p> <ul style="list-style-type: none"> <li>Department of Health and Social Care</li> <li>NHS England</li> </ul>	<p><u>General</u></p> <ul style="list-style-type: none"> <li>All Wales Therapeutics and Toxicology Centre</li> <li>Allied Health Professionals Federation</li> <li>Board of Community Health Councils in Wales</li> <li>British National Formulary</li> <li>Care Quality Commission</li> <li>Department of Health - Northern Ireland</li> <li>Healthcare Improvement Scotland</li> <li>Medicines and Healthcare products Regulatory Agency</li> <li>National Association of Primary Care</li> <li>National Pharmacy Association</li> <li>NHS Confederation</li> <li>NHS Wales Joint Commissioning Group</li> <li>Scottish Medicines Consortium</li> <li>Welsh Government</li> </ul> <p><u>Possible comparator companies</u></p> <ul style="list-style-type: none"> <li>A Menarini Farmaceutica Internazionale SRL (bilastine)</li> <li>Advanz Pharma (methotrexate)</li> <li>Amarox (montelukast)</li> <li>Astellas Pharma (tacrolimus)</li> <li>Aurobindo Pharma – Milpharm (bilastine, cetirizine hydrochloride, montelukast)</li> <li>The Boots Company (cetirizine hydrochloride, fexofenadine hydrochloride, loratadine, ranitidine)</li> <li>Bristol laboratories (cetirizine hydrochloride)</li> <li>Brown and Burk (acrivastine, loratadine, levocetirizine dihydrochloride)</li> </ul>

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Provisional Consultees	Provisional Commentators (no right to submit or appeal)
	<ul style="list-style-type: none"> <li>• Celltrion Healthcare UK (omalizumab)</li> <li>• Cipla EU (cetirizine hydrochloride, fexofenadine hydrochloride, methotrexate)</li> <li>• Chiesi (tacrolimus)</li> <li>• Dexcel Pharma (ciclosporin)</li> <li>• Dr Reddy's Laboratories (cetirizine hydrochloride, fexofenadine hydrochloride, montelukast)</li> <li>• Flamingo Pharma UK (cetirizine hydrochloride, loratadine)</li> <li>• Haleon UK trading (cetirizine hydrochloride, fexofenadine hydrochloride)</li> <li>• Hospira (methotrexate)</li> <li>• Glenmark Pharmaceuticals (desloratadine, levocetirizine dihydrochloride, montelukast)</li> <li>• Krka (desloratadine, montelukast)</li> <li>• Leo Laboratories (tacrolimus)</li> <li>• McNeil products (acrivastine, cetirizine hydrochloride)</li> <li>• Medac Pharma (methotrexate)</li> <li>• Medley Pharma (cimetidine)</li> <li>• Morningside Healthcare (methotrexate)</li> <li>• Mylan (ciclosporin, desloratadine, nizatidine)</li> <li>• Nordic Pharma (methotrexate)</li> <li>• Novartis Pharmaceuticals (ciclosporin, omalizumab)</li> <li>• Novumgen (levocetirizine dihydrochloride)</li> <li>• Opella Healthcare (fexofenadine hydrochloride)</li> <li>• Organon Pharma (desloratadine, montelukast)</li> <li>• Orion Pharma (methotrexate)</li> <li>• Pinewood Healthcare (cetirizine hydrochloride, loratadine)</li> <li>• Ranbaxy (UK) a Sun Pharmaceutical Company (ciclosporin, loratadine, montelukast)</li> <li>• Reckitt Benckiser Healthcare (ranitidine)</li> <li>• Rivopharm (desloratadine, montelukast)</li> </ul>

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	<ul style="list-style-type: none"> <li>• Roche Products (mycophenolate mofetil)</li> <li>• Rosemont Pharmaceuticals (cimetidine, methotrexate, mycophenolate mofetil)</li> <li>• Sandoz (methotrexate, montelukast, tacrolimus)</li> <li>• Santen (ciclosporin)</li> <li>• Sigma Pharmaceuticals PLC (cetirizine hydrochloride)</li> <li>• Teva Pharma B.V. (mycophenolate mofetil)</li> <li>• Tillomed Laboratories (mycophenolate mofetil)</li> <li>• UCB pharma (cetirizine hydrochloride, levocetirizine dihydrochloride)</li> <li>• Wockhardt (cetirizine hydrochloride)</li> <li>• Zentiva (fexofenadine hydrochloride)</li> </ul> <p><u>Relevant research groups</u></p> <ul style="list-style-type: none"> <li>• British Skin Foundation</li> <li>• Cochrane Skin Group</li> <li>• Genomics England</li> <li>• MRC Clinical Trials Unit</li> <li>• National Institute for Health Research</li> </ul> <p><u>Associated Public Health groups</u></p> <ul style="list-style-type: none"> <li>• Public Health Wales</li> <li>• UK Health Security Agency</li> </ul>

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people who share a protected characteristic and those who do not. Please let us know if we have missed any important organisations from the stakeholder list, and which organisations we should include that have a particular focus on relevant equality issues.

### Definitions:

Consultee or commentator stakeholders are provisional until a signed Confidentiality Agreement & Undertaking form is submitted to NICE at the evaluation stage. Participating stakeholders will be listed on the project information page for the evaluation.

### Consultees

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Organisations that accept an invitation to participate in the evaluation; the company that markets the technology; national professional organisations; national patient organisations; the Department of Health and Social Care and relevant NHS organisations in England.

The company that markets the technology is invited to make an evidence submission, respond to consultations, nominate clinical experts and has the right to appeal against the Final Draft Guidance (FDG).

All non-company consultees are invited to submit a statement relevant to the group they are representing, respond to consultations, nominate clinical or patient experts and have the right to appeal against the Final Draft Guidance (FDG).

### Commentators

Organisations that engage in the evaluation process but that are not asked to prepare an evidence submission or statement, are able to respond to consultations and they receive the FDG for information only, without right of appeal. These organisations are: companies that market comparator technologies; Healthcare Improvement Scotland; related research groups where appropriate (for example, the Medical Research Council [MRC]); other groups (for example, the NHS Confederation and the British National Formulary).

All non-company commentators are invited to nominate clinical or patient experts.