

Cell Therapy Limited

Ajan Reginald, CEO

EMA Roundtable
SME Office
27th November 2015



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Introduction to Cell Therapy Limited



- CTL is an SME based in Cardiff, Wales
- Founded by Ajan Reginald (CEO), and Sir Martin Evans (CSO)
- Lead product details:
 - Heartcel™ – Allogeneic immuno-modulatory progenitor cell
 - Tissue-engineered ATMP
 - Designed to regenerate heart tissue scarred by myocardial infarction
 - Adult indication in Congenital Coronary Artery Malformations (CCAM) targeted for Conditional MAA submission in 2016 – Letter of Intent to be submitted in January
 - Paediatric deferral to be requested – potential utility in rare paediatric diseases (Kawasaki Disease, ALCAPA)

Directors & Scientific Advisory Board



Ajan Reginald CEO

- Founder and Director
- Former Roche Global Head of Emerging Technologies
- Former BCG Consultant
- Fulbright Scholar



Digby, Lord Jones of Birmingham Chairman

- Former UK Minister for Trade & Investment
- Former Director-General of the Confederation of British Industry
- Chairman, Triumph Motorcycles
- Advisor to BP, JCB, Jaguar



Mr Rhodri Morgan Non-Executive Director, Head of Audit & Governance

- Ex-leader of Welsh Government
- First Minister of Wales (2000-2009)
- Chancellor, Swansea University



Dr. Francesco Granata Non-Executive Director

- Former cardiologist
- Executive-in-Residence at Warburg Pincus
- Chairman at Circassia
- Former senior executive at Pfizer, Schering-Plough, Biogen



Dr. Darrin Disley Non-Executive Director

- PhD in Biotechnology, Cambridge
- CEO, Horizon Discovery
- Business Leader of the Year, European Life Science Awards



Dr. Mubasher Sheikh Non-Executive Director

- Co-Founder
- Ex-Transplant Physician
- Head of Healthcare, Permira
- Ex-Partner and Head of Pharmaceuticals, McKinsey



Prof. Sir Martin Evans President & Chief Scientific Officer

- Founder and Director
- **Nobel Laureate, 2007**
- Copley Medal, Royal Society
- Knighted in 2004
- Albert Lasker Award, 2001



Prof. Steve Westaby Cardiac Surgery

- Distinguished Ralph Cicerone Professor, Oxford University
- Consultant Cardiac surgeon. John Radcliffe Hospital, Oxford



Prof. Armand Keating Chief Medical Advisor

- Director, Cell Therapy, Princess Margaret Hospital
- Past President, American Society of Hematology
- Professor of Medicine
- Director, Div'n of Haematology
- Epstein Chair in Cell Therapy



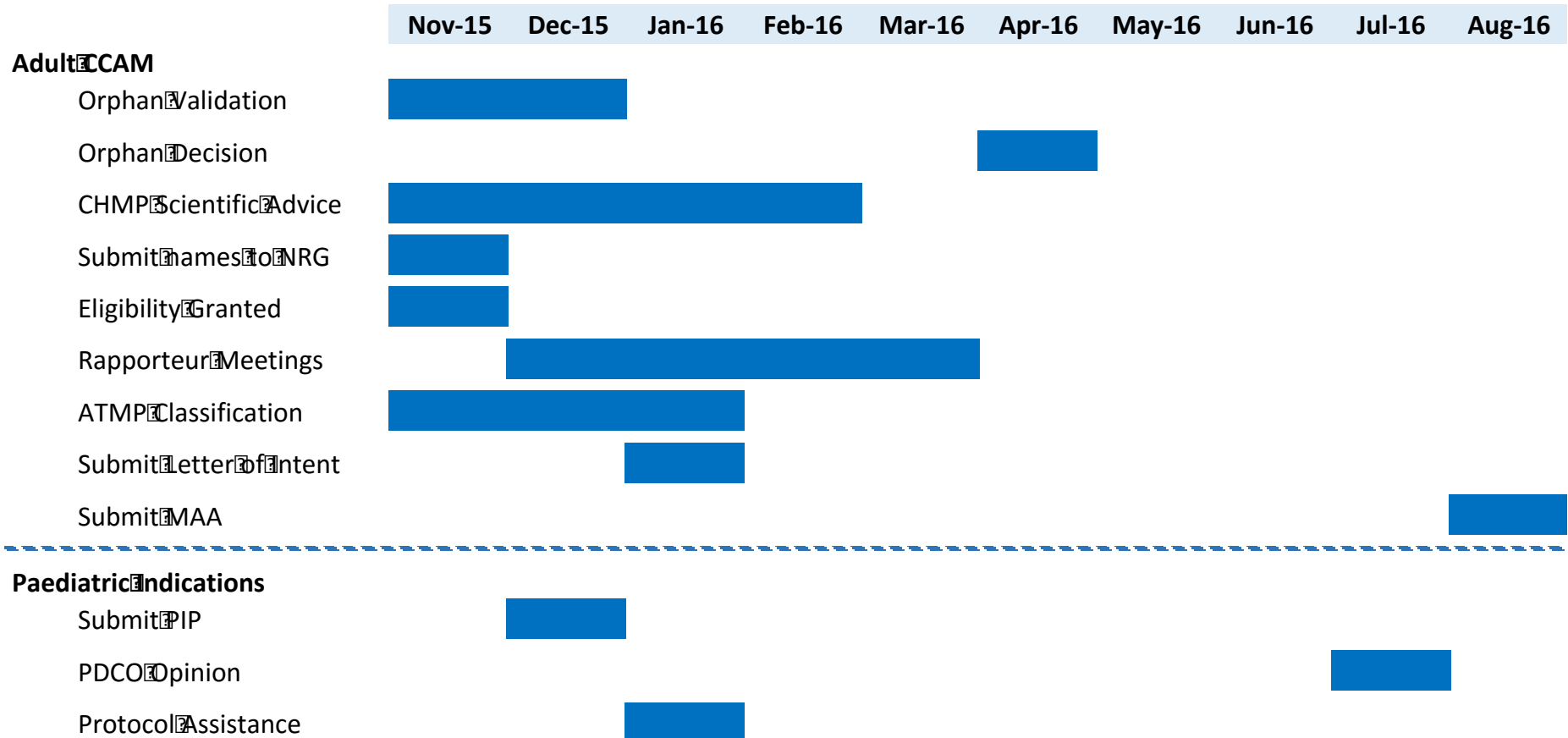
Prof. Sir Peter Bjerring Cosmetics & Dermatology

- Medical Director Mølholm Hospital, Denmark
- Professor, Faculty of Medicine
- President of European Society



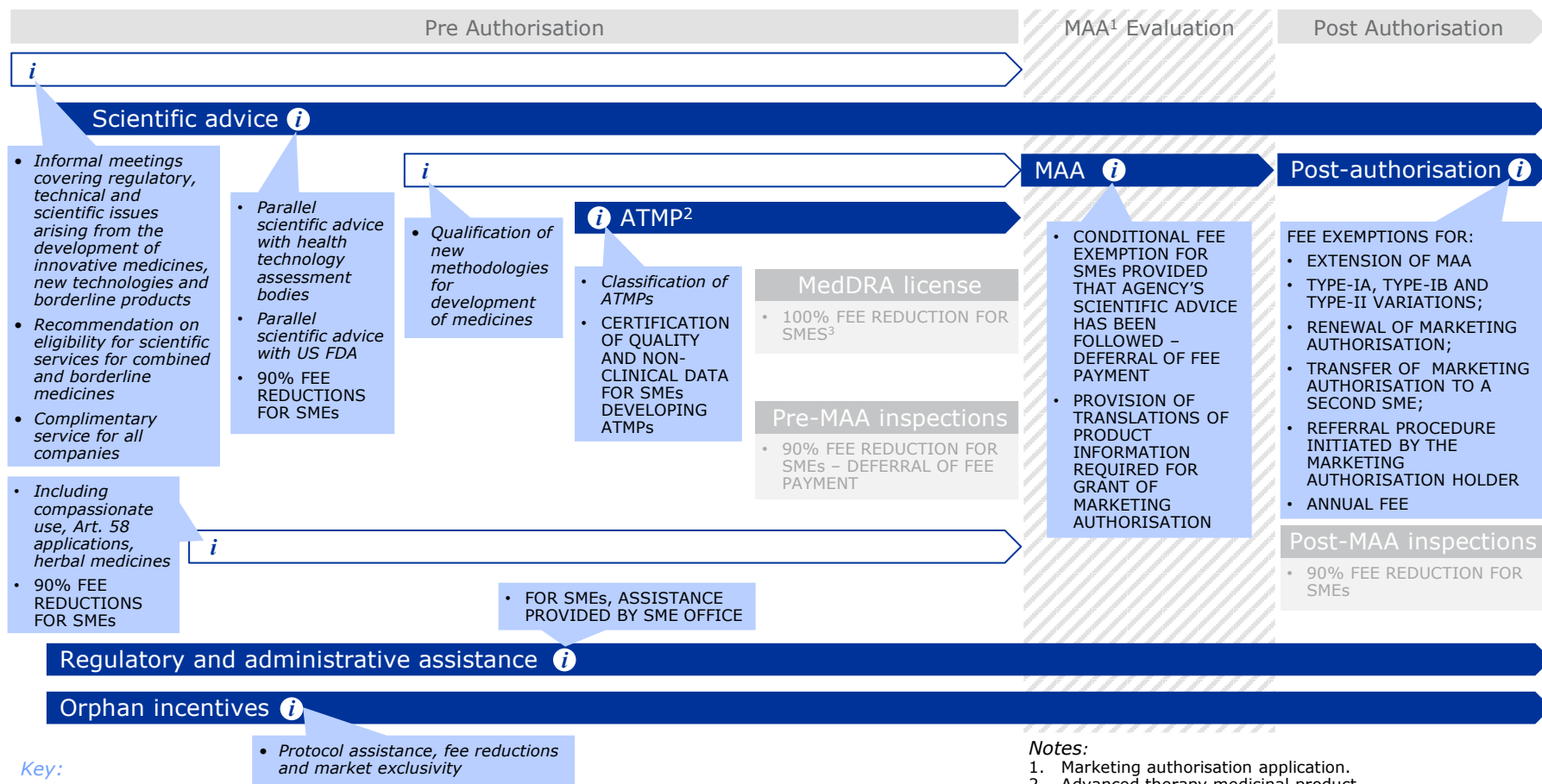
Mr Neil Roberts Cardio-vascular

- MB ChB MRCS MD FRCS
- Consultant Heart Surgeon
- St. Bartholemews Heart Hospital, London
- MD in progenitor cell therapy





Overview of support provided to medicines developers by the European Medicines Agency

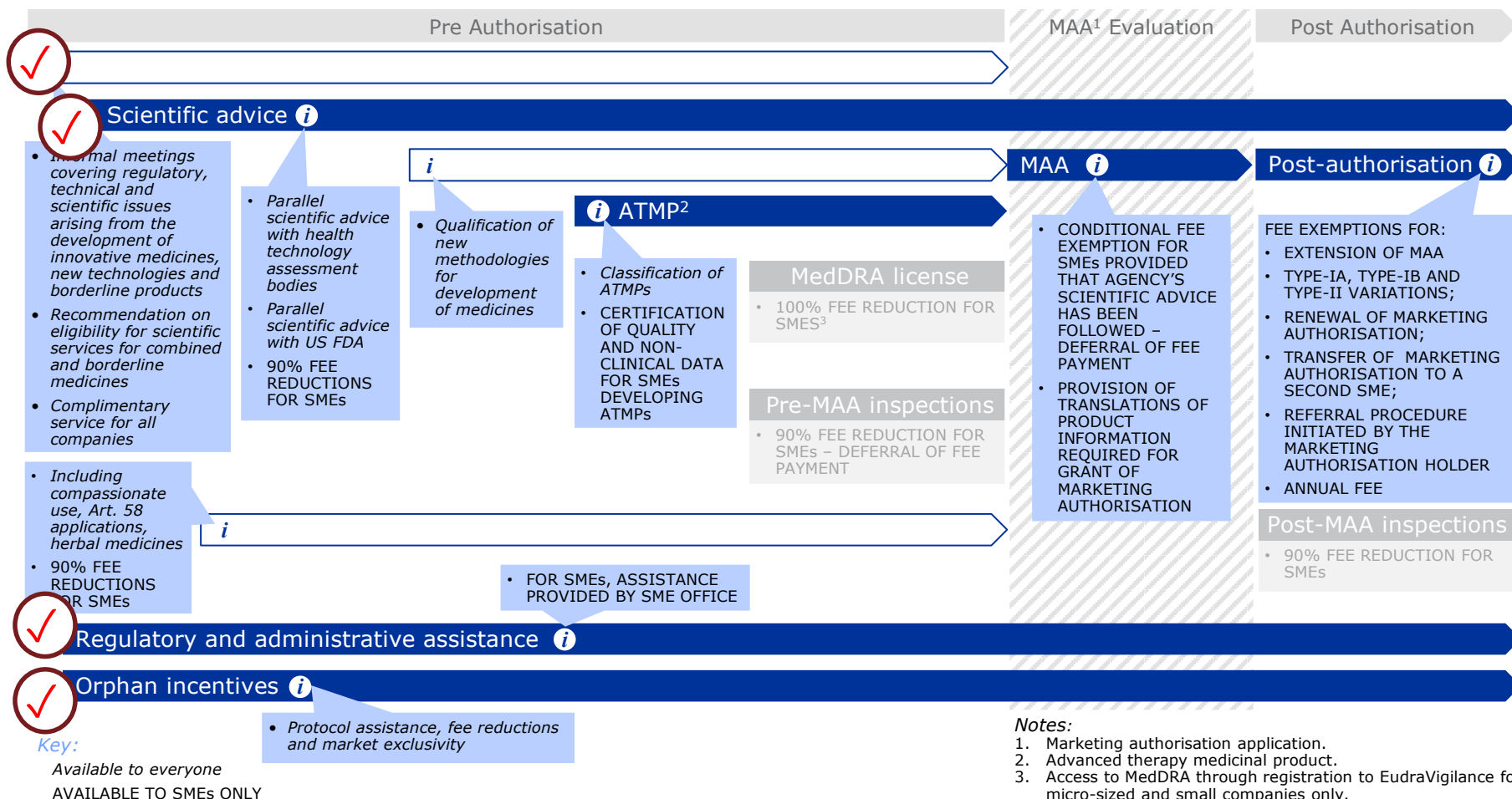


Key:

Available to everyone
AVAILABLE TO SMEs ONLY



Overview of support provided to medicines developers by the European Medicines Agency

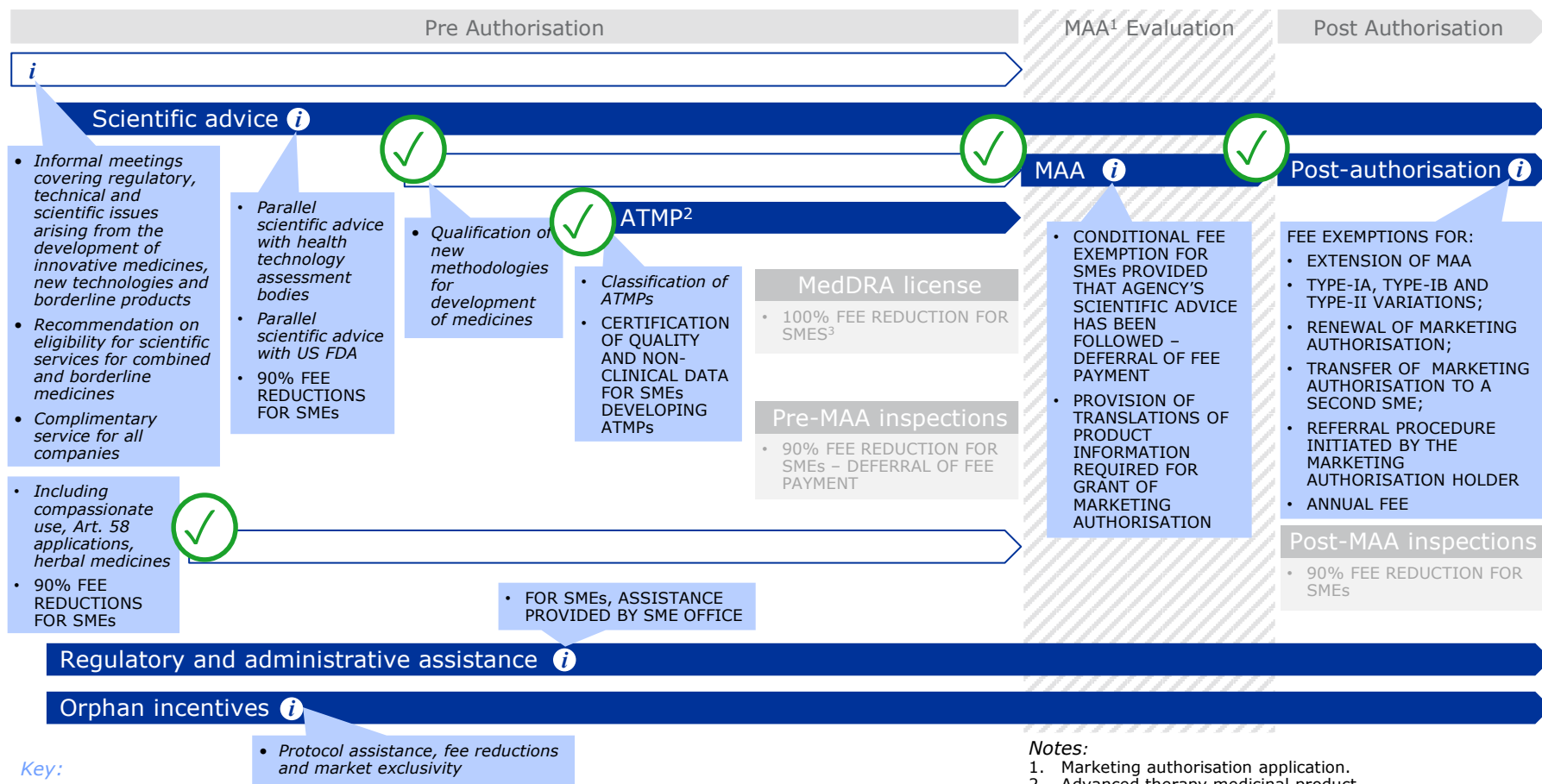


CTL has received significant support

- SME incentives and support received to date include:
 - Advice from SME office on administrative and procedural issues around:
 - ATMP classification
 - Orphan designation
 - Paediatric investigation plans
 - Protocol assistance from CHMP, including potential paediatric indications to consider, opportunity to submit for Conditional Approval
 - Fee reductions for scientific advice



Overview of support provided to medicines developers by the European Medicines Agency



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CTL intends to ask for additional support

- SME incentives and support to be requested:
 - Certification of Quality and Non-Clinical Data for ATMP
 - Advice from SME office on administrative and procedural issues around Conditional MAA
 - Scientific advice on Conditional MAA in adults
 - Scientific advice on Paediatric plans
 - Scientific Services on Compassionate Use Programmes
 - Fee reductions for procedures in the pre- and post-marketing-authorisation phases, including scientific advice, inspections, line extensions and variations
 - Assistance in translating product information submitted within the Conditional MAA
 - Deferral of the fee payable for an application for marketing authorisation or related inspection