Procter & Gamble Technical Centres Ltd
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10th June 2022

Dear Colleague,

Re: EudraCT final reminder to P&G detected contact point (SafetyGlobalPHC, Ion <safetyglobalphc.im@pg.com>) 6th May 2022.

Further to your final reminder from 6th May 2022, we would like to clarify the current ownerships and responsibilities for your requested clinical studies.

Procter and Gamble Pharmaceuticals divested its entire pharmaceutical business in 2009 to Warner Chilcott. The only exception was Pexelizumab where P&G were in a joint venture with Alexion which was also terminated at the same time.

Please note that as a condition of the divestitures, we were obligated to hand over all data to the receiving companies. Per EudraCT version 10, 2014, question 17, we understand that "in the case of liquidation, insolvency, merger or divestiture, the obligation to post results resides with the new sponsor".

It may be that the receiving companies have not updated all study details to reflect this change of ownership.

To assist EMA to the best of our ability, we have provided the current owner of the licenses or our understanding of data ownership in the table attached.

Where the data remain the responsibility of P&G, we have uploaded the studies into the database to comply with EMA request.

These is one exception. This is 2011-002443-10, a study to evaluate the effectiveness of a diagnostic tool in measuring nasal decongestant efficacy of Vicks Sinex Micromist relative to a sham control. We believe this has been submitted in error to EudraCT. Please let us know if you concur.

In the event of further questions, please contact Anne Moclair, Senior Director, Regulatory Affairs, P&G, moclair.a@pg.com, 07741 605666,

Yours faithfully,

Karen Foster

Digitally signed by Karen Foster
Date: 2022.06.10 14:00:20 +01'00'

P.P Dr. Anne Moclair

Senior Director, Global Product Stewardship

Procter & Gamble Personal Healthcare

Responses to study requests from EMA to P&G May 2022.

EudraCT number	Sponsor code	Title	Sponsor at trial initiation	Current license holder/data owner
2013-005006-66	2013118	A 2-arm, randomised, single - (Investigator) blind, controlled, parallel design study in common cold sufferers experiencing nasal congestion to assess the speed of action of Vicks® VapoRub® (VVR)	Procter And Gamble	POSTED
2004-004077-29	2004112	A Double-blind, Randomized, Multicenter, Active-control, 56-day Study with a 28-day Follow-up to Assess the Efficacy and Safety of RDP58 200 mg/day plus Mesalazine 2.4 g/day and RDP58 600 mg/day plus Mesalazine 2.4 g/day Each Compared to Mesalazine 4.8 g/day for the Treatment of Moderately Active Ulcerative Colitis	Procter & Gamble Pharmaceuticals	Divested to Warner Chilcott 2009. Current European license holder is Abbvie. P&G no longer have these study reports.
2005-003033-41	2005040	A Non-invasive Evaluation of Bone Microarchitecture Modification in Osteopenic Postmenopausal Women by 3D Peripheral Quantitative Computed Tomography: A 12 Month, Multicenter, Double-blind, Randomized, Parallel Group Study Comparing Weekly Oral Risedronate 35 mg and Placebo	Procter & Gamble Technical Centres Ltd., Uk	Divested to Warner Chilcott 2009. Current license holder is Abbvie. P&G no longer have these study reports.
2006-001179-39	2005108	A Randomised, Double-Blind, Placebo-Controlled, Parallel-group, Multicentre, 24 week Study to Evaluate the Efficacy and Safety of Transdermal Testosterone (300 mcg/day) in Naturally Menopausal Women with Hypoactive Sexual Desire Disorder Receiving Systemic Transdermal Estrogen, Oral Non-Conjugated Equine Estrogen, or No Estrogen Therapy	Procter & Gamble Technical Centres Limited	Divested to Warner Chilcott 2009. Warner Chilcott was subsequently granted a marketing authorisation by EMA for Intrinsa. P&G no longer have these study reports.

EudraCT number	Sponsor code	Title	Sponsor at trial initiation	Current license holder/data owner
2006-001310-32	2006444	A double-blind, randomized, 6-week, parallel-group clinical trial to assess the safety and efficacy of Asacol 4.8 g/day (800 mg mesalamine tablet) versus Asacol 2.4 g/day (400 mg mesalamine tablet) for the treatment of moderately active ulcerative colitis (ASCEND III)	Procter & Gamble Pharmaceuticals	Divested to Warner Chilcott 2009. Current European license holder is Abbvie. P&G no longer have these study reports.
2007-005008-41	2007033	A Phase II, Randomized, Adaptive Design, Multicenter, Parallel Group, Placebo-controlled, 58-day, Dose-ranging Study of ATI-7505 in Patients with Postprandial Distress Syndrome	Procter & Gamble Pharmaceuticals	Trial data for naronapride currently owned by Rennixion.
2011-002443-10	2011035	A Randomized, Open-Label, Single-Dose, Parallel Group Study to Evaluate the Utility of Magnetic Resonance Imaging (MRI) in Demonstrating the Nasal Decongestant Efficacy of an Active Control (Vicks® Sinex® Micromist®) Relative to a Sham Control at 8- and 12-Hours Post-Dosing	Procter & Gamble	This study was conducted on an authorised medicine, per label, to evaluate the effectiveness of a diagnostic tool in demonstrating nasal decongestant efficacy of Vicks Sinex Micromist. We believe this has been submitted in error to EudraCT. Please let us know if this is in scope of the reporting requirements
2005-005207-42	2005079	A study to assess the efficacy of a combination of natural plant extracts in natural colds.	Procter & Gamble	POSTED