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To: Ekdahl, Andrew [DPYUS]; Kilburn, Randy [DPYUS]; Kurring, Paul [DPYGB]; Berman, Paul [DPYUS]
CC: Twomey, Richard [DPYGB]
Sent: 3/16/2009 7:00:42 PM
Subject: ASR / Australia

Dear all,

I have seen numerous emails on the issue of ASR in Australia, covering subjects such as ASR future, support for Australia and ASPAC, Silent launch, KOL involvement, etc ... At this stage, I would like to make the following recommendations :

- Strategic issues such as this should remain confined to internal discussions without involving external parties, notably KOLs
- Such issues should not be discussed directly with the markets unless we have specific recommendations to make. In this case, I expect Australia management to be confused as to our position, the support that will be offered, and where that support will come from.
- The team is fully appraised as to the situation with ASR & XL and is working on recommendations moving forward. Once those recommendations are fully defined, then each group (US and Int'l) should reach out to the markets and communicate those recommendations.
- The question around Silent should be separated from ASR. The launch plan for Silent is the most thorough, controlled and forward looking launch I have seen in DePuy and is very robust. I do not see the need to question its validity or intent at this stage.
- The general question as to the support to ASPAC is still wide open, but only in terms of physical presence. All other support activities are still very much on-going as normal.

Looking now at some specific issues around Australia, here is what needs to be noted :

- ASR was launched with a high level of sales and surgeon education. Most surgeons were fully trained. The UK and German surgeons were also fully trained – 100's of surgeons have been through the training school in Hamburg. The issue seen with ASR and XL today, over 5 years post-launch, are most likely linked to the inherent design of the product, and that is something we should recognise.
- Dr Oakeshott, the local KOL, has been out of action for a while with ill-health. His results to-date are good.
- Because of issues with the Registry, the local Australian organisation, together with Paul's team, our clinical group and RA groups, have done a tremendous job over the past 2 years at re-positioning ASR, increasing the amount of training, limiting the availability to high volume users, ...
- Launching products in Australia is an issue – because of the way the registry does measure effectiveness. This should not preclude us from launching there but on the contrary should push us to put in place much more robust clinical evaluation protocols, early user groups, ... Unfortunately, we are continuously discarding this need by reducing our clinical spend and still launching products with minimum clinical experience. The Australian approach will be adopted in many markets around the world so we need to learn from this.

So, looking forward to the next steps, my proposal is as follows :-

- 1) Paul K to arrange appropriate in-market support for Australia as a matter of urgency – discussion with local management
- 2) Paul K to write a status letter for the attention of Dr Schmalzried – *if this is deemed appropriate at this stage*
- 3) WW SLT to discuss future needs for Clinical Evaluation work in Australia
- 4) Paul K to distribute the Silent launch plan to all.

Hoping this will resolve this situation quickly.

Best regards

Raph