

Sativex[®] in MS Spasticity EU Regulatory Update



18 March 2010

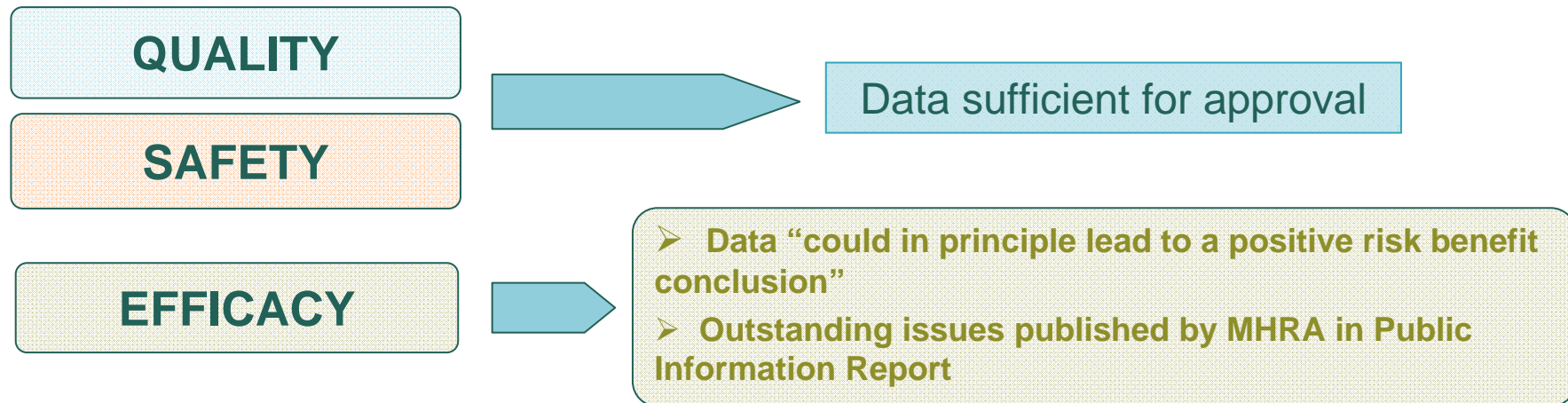


Notice

Past performance should not be seen as an indication of future performance. Actual results and developments may differ materially from those expressed or implied by this briefing depending on a variety of factors. The contents of this briefing are intended only for persons having professional experience in matters relating to investments. Persons who do not have professional experience in matters relating to investments should not rely on the contents of this briefing.

Current Regulatory Submission Background

- Previous 2007 “Decentralised” submission
 - UK, Spain, Netherlands, Denmark



- Additional Phase III study conducted 2007-9 to address outstanding issues
 - Formal scientific advice received from UK and Spain regulatory authorities
- Positive Phase III results reported in March 2009
- Resubmitted in May 2009 to UK and Spain under decentralised procedure

Sativex Decentralised Procedure (DCP)

- Application filed in UK & Spain under DCP
- UK acts as “Reference Member State”, Spain is “Concerned Member State”
- At each stage in the DCP process, initial assessment reports are produced by the UK regulator, MHRA, and sent to Spanish regulator for review and comment
- Assessment reports classify issues as “major” or “points for clarification”
- DCP requires UK & Spain to agree that there are no “major” issues to be resolved in order to deem the medicine “approvable”
- Once there are no “major” issues or clarification points, the DCP can conclude with a positive decision to approve Sativex

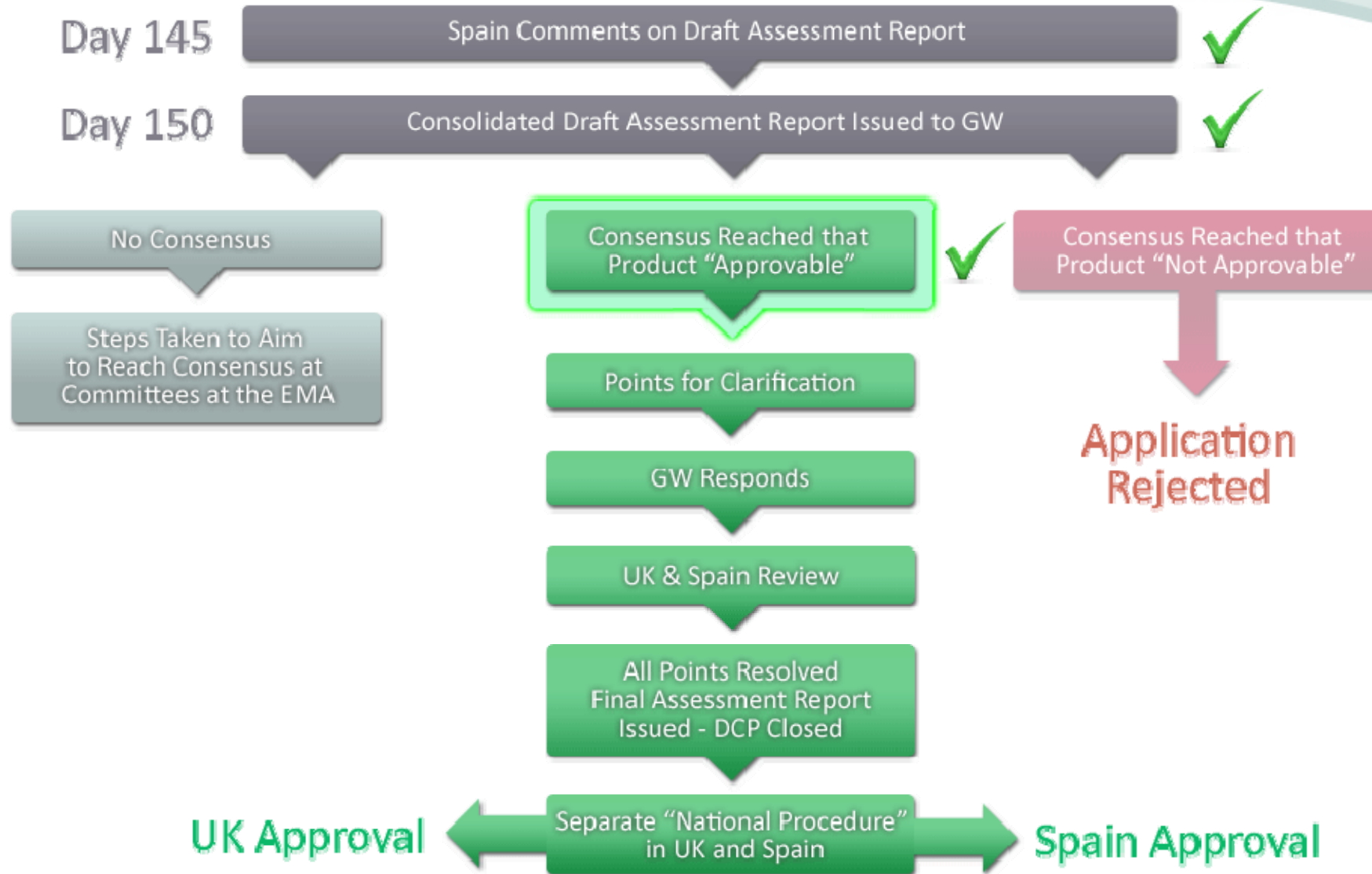
DCP Process – “Assessment Step 1”

Application Filed



Step Two

DCP Process “Assessment Step 2” plus National Procedure



Sativex DCP Current Status

- Day 150 assessment report now received and confirms that the UK & Spain have reached consensus that there are no “major” quality, safety or efficacy issues to be resolved
- “Points for clarification” are outstanding which relate to finalisation of wording on the patient information insert
- GW has already updated the patient insert and is now awaiting review and agreement from the regulators
- Once this wording is finalised, the DCP can be closed with a positive decision to approve Sativex

Post DCP Next Steps

- After DCP is successfully closed, the final step is the “national phase” which is separately handled in the UK and Spain
- The purpose of the “national phase” is to finalise local wording on product packaging and related documents
- UK national phase expected to be approx 30 days, following which UK approval is granted
- UK launch can occur immediately post UK approval, expected Q2 2010
- Spain national phase may be slightly longer than the UK, following which Spain approval is granted
- Spain launch can only occur after subsequent pricing approval, expected H2 2010

European Mutual Recognition Procedure (MRP)

- Following UK approval, GW will seek approval in selected other European countries via the MRP
 - List of additional countries is currently being considered with Almirall
- The UK will act as Reference Member State for the MRP
- After GW submits MRP application, MHRA will update its Final Assessment Report and send it to other European authorities
- MRP process is similar to the DCP in seeking views from other authorities and for GW to then provide responses via the UK for subsequent resolution