



Celgene and European Thalidomide Group Meeting 17th October 2008 - Radisson SAS Hotel, Zurich

Attendees

European Thalidomide Group Representatives

Belgium	Judith Horvath	Dysmelia A.S.B.L.
Ireland	Carmel Daly McDonnell	Irish Thalidomide Survivors
Italy	Nadia Malavasi	Thalidomidici Italiani Onlus
Italy	Vincenzo Tomasso	Thalidomidici Italiani Onlus
Japan	Tsugumichi Sato	Ishizue Foundation
Netherlands	Joop Konings	Dutch Thalidomiders
Norway	Rune S. Kristiansen	Norwegian Thalidomide Association
Spain	Jose Riquelme	AVITE
Spain	Rafael Basterrechea	AVITE
UK	Freddie Astbury	Thalidomide UK
UK	Glenn Harrison	Thalidomide UK
UK	Vivien Kerr	The Thalidomide Society

Celgene

Sol Barer	CEO & Chairman of the Board
Janine Collins	Head of EU Risk Management
Gillian Ivers-Read	Sr Vice President, Project Leadership
Siv Lindqvist	Medical Liaison, Finland
Kevin Loth	Director, External Relations, Europe
Pablo del Pino	General Manager, Spain
Stefano Portolano	General Manager, Italy
Andrew Robertson	General Manager, UK and Ireland
Nakisa Serry	Director, Legal Counsel Europe
Paul Sheehan	Senior Director, Head of Global Risk Management
Clare O'Neill	Meeting Co-ordinator

Key objectives:

1. Introduction to Celgene and overview of Celgene's commitment to patient safety
2. Update on implementation of EU Thalidomide Pregnancy Prevention Programme
3. Create an open forum to discuss issues relating to safe use of thalidomide in EU

Overview of Group Discussion

J. Konings: *Drew attention to the fact that the takeover of Pharmion was a surprise and questions whether more could have been done to inform the thalidomide groups*

Celgene: Due to legal constraints neither Celgene nor Pharmion could discuss the acquisition in advance of its closing.

T. Sato: *Can Celgene confirm that studies on monkeys have shown Revlimid to be teratogenic?*

Celgene: Yes, interim studies have indicated that Revlimid is teratogenic. The risk management programme for Revlimid was developed on the assumption that Revlimid is teratogenic. Although this result is a great disappointment, it does not have practical implications for patient safety.

F. Astbury: *Is multiple myeloma just an old person's disease?*

Celgene: The majority of patients are in their sixties or older but there are some younger patients.

J. Riquelme: *Drew attention to the fact that the thalidomide groups in Spain are still fighting for compensation. At the University of Madrid it was found that thalidomide was still being advertised ten years after its supposed withdrawal from the market. A poster campaign has been initiated to stimulate doctors to recognize thalidomide victims. Will Celgene help to fund this awareness campaign?*

Celgene: Celgene has empathy with the struggles that the thalidomide groups face, particularly in Spain, but we will not become involved in these political situations that do not concern us.

N. Malavasi: *Drew attention to the new Austrian Association and requested that they become involved in future meetings.*

J. Riquelme *All stressed the importance of regular meetings and asked Celgene to commit to this.*

N. Malavasi

G. Harrison

J. Konings

& V. Kerr:

Celgene: Celgene are committed to continue regular dialogue with the thalidomide groups; including meetings as and when required.

C. McDonnell: *Drew attention to the past history of thalidomide in Europe and the amount of hurt it has caused. Thalidomide groups are still very nervous of the future and it is difficult to trust that there will be no further cover-ups.*

R. Kristiansen: *Could thalidomide be used to treat a disease that affects younger people?*

Celgene: Thalidomide may legally be used 'off-label' to treat other diseases, the majority of off-label usage has been related to other forms of cancer. In any case, the Pregnancy Prevention Programme must always be used irrespective of the disease being treated.

G. Harrison: *Drew attention to the fact that so much non Celgene thalidomide was being used without a risk management program – and it was this that motivated the thalidomide groups to support regulation. What is Celgene doing now to ensure that only their thalidomide and the associated risk management program is being used in Europe?*

- Celgene:** Celgene is vigilant in trying to enforce its 'market exclusivity' rights for Thalidomide Pharmion. In addition, Celgene is diligent in ensuring that the PPP is properly implemented when the Thalidomide Pharmion is prescribed. Finally, letters have been sent to various importers/wholesalers, health authorities and customs authorities in the EU to inform them of the requirement that all Thalidomide Pharmion prescriptions be accompanied by the PPP as is required by the marketing authorization, and to explain to them the critical patient safety concerns related to any thalidomide that is distributed without a PPP.
- G. Harrison:** *Thalidomide associations have decided that they will send letters and lobby to ensure there is safe use of unlicensed thalidomide. The associations will keep Celgene informed of any resulting actions.*
- Celgene:** Celgene agrees that no thalidomide should be used without a proper safety system in place.
- G. Harrison:** *What would happen if a baby was born with a disability from thalidomide and what responsibilities would Celgene have?*
- Celgene:** Celgene take the same position Pharmion did. We promise to live up to our responsibility.
- R. Kristiansen:** *Does Celgene now control thalidomide globally?*
- Celgene:** Celgene now supplies thalidomide in the US, Canada, the European Union and other countries such as Australia and Asia pacific.
- G. Harrison:** *Have patient and victim organizations been involved in materials used in the risk management programme?*
- Celgene:** Materials, used in all markets have been developed in consultation with patient and thalidomide groups.
- G. Harrison:** *Thalidomide groups would all be willing to help in the education process of, for instance, young doctors who have never seen a thalidomide victim before.*
- G. Harrison:** *What happens to drugs when no longer needed? Does Celgene now have exclusivity for 20 years?*
- Celgene:** Celgene has EU market exclusivity for 10 years. After this time period, if Celgene is still selling thalidomide, nothing would change in terms of our commitment to risk management. Because of thalidomide's importance to patients we do not foresee the situation where thalidomide will no longer be needed. After Celgene's market exclusivity expires, it will be possible for other manufacturers to obtain a licence. However, Celgene hopes that in the future any supplier of thalidomide would have to implement a comprehensive safety programme.
- G. Harrison:** *How can we ensure that blind people have access to PPP materials?*
- Celgene:** This issue is on our agenda. We will bring together all the people responsible for PPP to find a solution that will work in all countries.
- G. Harrison:** *Can Celgene send clarification to the thalidomide groups on the new industry guidance on sponsorship? We need to develop an acceptable compromise to ensure that Celgene is compliant but does not jeopardise the standing of thalidomide groups.*
- Celgene:** Celgene will send clear guidance to the groups so that they are aware of the new guidance.

G. Harrison: *Can we have clarification on the situation with thalidomide in Japan?*

Celgene: In Japan, thalidomide will be supplied by Fujimoto Pharmaceuticals, not Celgene.