Gesellschaft Schweizerischer Industrieapotheker
Swiss Society of Industrial Pharmacists

GSIA Continuing Education Program

Market Access

1st April, 2020

Actelion Pharmaceuticals Ltd

Gewerbestrasse 16, 4123 Allschwil

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www.gsia.ch

Dear Colleagues

Continuing our successful program of biannual education meetings, I am pleased to provide you with some information on our first meeting in 2020.

We will convene at Actelion Pharmaceuticals Ltd, Gewerbestrasse 16, 4123 Allschwil from 09.00 to 17.00 on the 1st April

The meeting theme will be 'Market Access'. As we see the development of and introduction of new 'break-through' innovative treatments the funding and patient access to these therapies is dependent on how 'payers' consider these therapies and how, as an industry, we develop and provide the necessary data to secure access.

The 'Market Access Synopsis' provides a good summary of the current Market Access situation. The topics identified represent key themes that we further detail in our meeting, please compare enclosed agenda.

We have brought together a speaker panel of Market Access experts who have many years of experience in the industry, consultancy or academia. As such I am sure that our meeting will be very stimulating and allow for a lot of discussion.

I look forward to seeing you all in April

With best regards,

Kathrin

Kathrin

Market Access – a Synopsis

Market access remains one of the key challenges today in securing patients have funded or reimbursed access for a new technology. It is the process to ensure that all appropriate patients who would benefit from a new medicine or therapy are able to get rapid and sustained access at the right price.

Payors represent the 'gate-keepers' to market access and are a broad group of people or organizations. These include Health Technology Assessment HTA bodies (e.g. UK NICE), funding organizations (e.g. insurance funds – Swica / Helvana) and may exist at national, regional (e.g. in Italy and Spain) and at a local level (e.g. hospital formulary committees and commissioning bodies). Given constrained or finite budgets payers need to have budget certainty, and be assured that any new medicine fulfils a significant unmet need, is clinically effective in the longer term and represents value for money.

To secure market access companies need to generate strong clinical, patient and health care system relevant data. This requires the right design of phase II / III trials, in particular the inclusion of appropriate end-points (surrogate vs hard endpoints), patient reported outcomes / QoL instruments and the potential pre-specification / stratification of sub-groups. Patients are playing an increasing role in the definition of trial end-points, particularly in rare disease, and these are important in payer decision making, albeit may be less accepted by regulatory organizations (EMA / FDA). Payers are also increasingly demanding evidence of the longer-term effectiveness of a product and as such real-world evidence / observational / registry data planning should be integrated into any clinical development plan. Given these challenges companies need to take an integrated multi-stakeholder approach, including R&D, medical affairs, HEOR, regulatory affairs and commercial functions in their market access planning.

In the last few years there has been an increased focus on medicines in the treatment of rare diseases, particularly in oncology. With this we have seen the development of break-through innovations, including the development of cell and gene-therapies, including the recent approval of CAR-T therapies (Kymriah & Yescarta) and other gene-therapies (Luxturna and Zolgensma). An estimate by MIT anticipates that there will be a further 36 new FDA approved gene therapies by 2022 and that the top 10 most expensive therapies in the US by 2022 will be cell and gene-therapy products. These therapies are likely to bring major patient benefits in terms of disease burden and quality of life, but most importantly target one-time therapies claiming cure. However, with the introduction of such cutting-edge technologies traditional pricing and reimbursement mechanisms may not be appropriate for the funding of these therapies, i.e. the shift from regular payments for treatment to a one off (high-cost) payment. As a consequent of this we are seeing the development of more 'innovative' payment mechanisms such as payment for outcomes, mortgage / annuity style arrangements and other risk-sharing mechanisms. In addition to 'price' payers are also concerned about the durability of response for these therapies.

Market Access - A Primer

Morning

Time	Topic (Prelim. Title)	Speaker
9:00	Welcome, Organization	GSIA
9:05	Introduction to Market Access and role across the lifecycle of a product	Jan Posthumus, Basilea Pharmaceuticals
9:50	Market Access in Switzerland	Balz Ryf, Vifor Pharma Schweiz
10:30	Coffee break	
11:00	Market access challenges for new disruptive therapies - demonstrating payer value and sustainability	Carina Schey
11:30	Case study session 1 - Pricing and reimbursement - new technologies require new payment and reimbursement models	Josephina Haberl, Dolon Ltd
12:00	Panel discussion	Chair – Carina Schey
12:30	Lunch	

Afternoon

Time	Topic (Prelim. Title)	Speaker
13:30	Cell and gene-therapies – Payment Mechanisms	tbd
14:15	Case study session 2 - Pricing and reimbursement - new technologies require new payment and reimbursement models (continued)	Josephina Haberl, Dolon Ltd
14:45	Coffee break	
15.15	The growing role of the patient in Market Access	Jean-Bernard Gruenberger, Novartis
15:45	Panel discussion	Chair – Carina Schey
16:30	End of the day and departure	

Agenda is subject to change without notice