Minutes Affordable Drugs Congress Cinderella and Inspire2Live, April 15th 2016 - The workshops

The Quality adjusted Life Year (QALY).

- How does the QALY threshold negatively affect the price of a drug?
- QALY: mystery→how are you going to price the drug?
- One could ask: 'What will happen if we lower the QUALY to €20.000?' Will the price be lower?
- Does QALY represent the reality?
- QALYs are based on wrong data. A new method has to be developed to determine how patients perceive the quality of a treatment. Consider a real world data to measure the real effect of a therapy.
- Urge to be transparent to the public and explanation by data; prizing has to be in harmony with the value of surviving; intransparancy is old-fashioned!
- The discussion on the monetised value of 1 (extra) year of life in good health should not be conducted by the public. (What is the price based on clear components and what is the value of a medicine?) The value allocation per QALY is not to give. This point should be included in the negotiations with the PI.

Pricing.

- Prices of drugs should be transparent.
- There should be a discount for medicines for metastatic disease.
- A Third party is needed who is monitoring the differential pricing system in Europe (this will be transparent). This is probably the best way to reach fair pricing.
- Only develop new drugs when prices are maximized (not all participants endorse this action). Indication specific pricing is an alternative option.
- Monitor the use, how many are sold and afterwards we can make a deal.
- Turn from drug pricing to a health plan.
- Drug prices are the problem (or should be) of an accountant and not for the physician and the patient.
- The industry will benefit more from value based pricing.
- Health Technology Assessment (HTA) could be used to strengthen our negotiation position with pharmaceutical industry. Based on HTA we know how prices are set or can be set.
- EMA should be concerned with pricing policies, even when not mentioned in their guidelines. Brussels should impose this. Doctors often cannot act independently due to budgeting by hospitals.

Negotiate!

- If The Netherlands tries to push the market and sets the prices lower than the rest of the EU, pharma wouldn't have the problem to say ''no''. This will put The Netherlands in an untenable political position. It would be different if EU would collectively change the price for a QALY into €20.000.
- A threshold (QALY) is a start of the negotiation.
- Successful negotiation: what are you prepared to do (what concessions can you make)?
- If we, as a society, refuse to buy the expensive drugs (like in the UK), these would be still available by placing the drug in the cancer fund (like in the UK).
- We should set up a central authority to negotiate and coordinate the negotiations with the pharmaceutical industry.
- We need a negotiation tool. Also consider budget impact.
- We should start with price negotiation on national level. This will not make NL very strong.
- Use the power of social media.
- Same prize for all countries (Min. Schippers) and international collaboration in negotiations.

Generics.

- In general, it has been observed that many patients do not accept generic drugs. Is this because the physicians do not explain the generics in a proper way because they have an interest?
- In US PI trains doctors and they tell them that biosimilars and generics are not the same.
- It is frightening that many doctors do not know what bio-similars are.
- We need to increase the awareness and knowledge of both professionals and patients on bio-similars.
- We need to determine the pros and cons of cheaper alternatives.
- Trust between patient and physician is very important.

Patents.

- The Patent should be held by the government (public domain).
- Patents are obtained based on therapeutic indications.
- We should prevent that small biotech companies sell their drug to big pharma.
- Changing patent legislation and/or buying drugs from India will upset the big pharma.
- A disruptive idea: import generic drug from India and test it in the laboratory for its efficacy and let the pharmacist perform the formulation and sell it on prescription.
- Patents impose enorm costs.
- We need alternative mechanism for research & development of drugs.
- Founding a central bank for healthcare on European scale and introduce rules, health technology assessment (FDA is not involved in prizing, only in health). The government is playing a role in innovations, research and is shareholder. The patents are possessed and controlled by the government.
- Pharma acts like: 'Paying fire fighters when they show up at the fire. How much are you willing to pay?'
- Wasteful marketing, legal cases, lobbying.
- Patents are directing research towards patentable products.

Public funded trials.

- Clinical research should only be done by independent institutions.
- If clinical trials are publically funded, it is expected that the prices of bio-similars would be much lower.
- Promotion of the drugs should be maintained and there will be paid attention.
- We could consider recommending to include publically funded programs in the next horizon 2020 call (Subsidy program by the European Commission).
- It would be time-consuming (it takes two years between idea generation to printing the protocols for a clinical trial) to start a publically funded clinical trial due to many regulatory hurdles.
- It should be possible to carry out clinical trials much cheaper but when publically funded the reimbursement of the hospital for a trial should be equal industry because otherwise the hospital puts the patients in the industry trial.

Role of the patient.

- Patients should unite and show themselves. Conflict of interest of patients should be avoided. Independencies of the patients should be supported.
- Patient advocates could pick up transparency requirements of the "black box". The total costs of a medicine are admittedly difficult to calculate, but the price of a product is indeed to establish.
- Patients unite, be independent and show yourself. AIDS was successful. Politicians can help.

Outcomes of the discussion (we work out these ideas in the next weeks).

- The drug prices could be lowered if clinical trials were <u>funded publically</u>. These clinical trials can still be coordinated by the pharmaceutical industry.
- Buy generics or the ingredients (*e.g.* pertuzumab, is currently in the lock) from abroad (India or China). Work out this idea and discuss it with the minister.
- We will take steps for a maximum price set by EMA as a precondition for registration in Europa.
- Both the EMA and physicians and patient advocates should be involved in the steps to be taken.
- The public should be involved in the movement for affordable drugs to increase the pressure on the PI. This requires a good definition of the issue in the media (women's magazines). With 'Brandpunt' (a Dutch TV program) already made contact. At one point should also be approached Members of Parliament. Doctors, patient advocates and researchers can have a significant role in this. It has been suggested to form of a pharma-coalition and start an online petition.