Abstract

This study aims to the similarities and differences in the registration policy and the compensation policy between extramurale regular medicins and extramurale orphan drugs. This will lead to an answer on the following presentation of the question: What are the differences between the extramurale pharmaceutical- and the orphan drugs compensation- and the registration policy on the level of judgement and decision process in The Netherlands and what could be the consequences for a patient with a rare disorder?

Either extramurale orphan drugs and extramurale regular medicines should be handled equally is a ethic dilemma. In England this discussion already took place. McCabe and the NICE say that the functional demands for both medicins should be equal and expensive orphan medicines should not be compensated on a regular base (McCabe e.a. 2005). Moberly however states that everything should be done to nurse a patient with a rare disease. According to Moberly extramurale orphan drugs should be threated as a exception (Moberly 2005). In The Netherlands this discussion did not took place and the differences in the compensation policy between extramurale orphan drugs and extramurale regular drugs is not clear. To find out if there is a difference between the compensation policy between extramurale orphan drugs and extramurale regular medicines and the way parties concerned look at this, there's been held a qualitative resource. A wide view on the compensation policy is obtained by interviewing different concerned parties.

With help of the framework of Hutton the judgement and decision making phase of the compensation policy of extramurale regular medicines and extramurale orphan drugs are compared (Hutton 2006). This report stated that the judgement between extramurale regular medicines and extramurale orphan drugs is equal. A request for insertion in the Medicine Compensation System (MCS) for both medicines at the Ministry of national Health, Welness and Sport was send to the college of health insurance (CHI). The CHI had a special commission, The Commission for Pharmateutical Help (CPH). Either for extramurale regular medicines and for extramurale orphan medicines the CPH judges whether the medicin is replaceable or not. The commission also judges on the therapeutical surplus value and the suitability. If the CPH states a positive advice to the CHI and the CHI passes the advice to the Ministry, the ministry determines according to this advice whether the extramurale regular medicin or the extramurale orphan drug joins the MCS or not.

Just at the stage of decision-making a difference between the compensation policy for extramurale orphan medicines and extramurale regular medicines is made. This is shown in

the fact that the CHI is more kind in it's advice for extramurale orphan drugs. Because the suitability and the therapeutical surplus value of orphan drugs are hard to determine, the CPH judges less hard on extramurale orphan drugs on the pharma-economic file. Sometimes even exemption is given for handing in this file (Van Weely 2008, personal communication). For extramurale orphan drugs that have no proven suitability and therapeutical surplus value there is a special subsidy scheme, so they can be compensated. Therefore the medicin can still be provided and there is a subsidy for further research.

So there is a difference in decision making between the compensation policy for extramurale orphan drugs and extramurale regular medicins.The CPH and the CHI judge less hard on extramurale orphan drugs as on extramurale regular medicines. Also there is a subsidy scheme for extramurale orphan drugs that can be declined if there are not enough data available about suitability and the therapeutical surplus value of the medicin. Therefore an orphan drug is hardly always compensated. So there are no negative consequences in the compensation and registration policy for a patient with a rare disorder.