

Health Technology Assessment - A Comparison between Germany, Russia and Great Britain

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In recent years there has been a clear tendency to a more rigorous analysis of clinical efficacy and safety (so-called “additional benefit”) of a new drug by health authorities, because these factors affect the decision on drug cost reimbursement reasonability [3].

There are several approaches to the additional benefit evaluation which are described in different documents, such as the German law about the marketing of new pharmaceuticals (AMNOG; Arzneimittelmarkt-Neuordnungsgesetz), British Health and Social Care Act 2012, and Russian Government Decree № 871 28.08.2014.

The German methodology concentrates on risk ratios of mortality, morbidity, HRQoL (health-related quality of life). Based upon these criteria there are six levels of additional benefit:

- 1) major additional benefit;
- 2) significant additional benefit;
- 3) marginal additional benefit;
- 4) not quantifiable additional benefit;
- 5) no additional benefit;
- 6) less additional benefit [4, 7].

In the United Kingdom National Institute for Health and Care Excellence (NICE) is responsible for additional benefit assessment. The major indicator for cost-benefit analysis is Quality-adjusted life year (QALY), which concentrates on patient’s perception of illness. There are several levels of QALY cost, based upon which the decision on reimbursement is made [1, 2, 5, 6, 8].

Russian methodology uses integral scales with points which are summed up to the resulting number, in accordance with which the decision is made. Apart from clinical efficacy and safety, many other criteria are taken into consideration (e.g. generic drug availability in Russia).

Finding: the three value assessment methodologies vary greatly from one another. The German system does not value the personal perceptions of patient’s health (as does QALY), but emphasizes on statistical reasoning. The British system values the personal feelings more due to the implication of QALYs system. The Russian methodology gives less attention to clinical indicators in comparison with other two systems, however it does consider indirect economic factors.

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Иллюстрации

Additional benefit	Mortality	Morbidity	HRQoL	Adverse effects
Major	Significant increase in life expectancy <i>RR=0.85</i>	Long-term relief of all symptoms <i>RR=0.75</i>	Significant increase of HRQoL <i>RR=0.75</i>	Significant decrease of adverse effects <i>Not applicable</i>
Significant	Moderate increase in life expectancy <i>RR=0.95</i>	Relief of severe symptoms, long-term relief of moderate symptoms <i>RR=0.90</i>	Considerable increase of HRQoL <i>RR=0.90</i>	Considerable decrease of adverse effects <i>RR=0.80</i>
Marginal	Any measurable increase in life expectancy <i>RR=1.00</i>	Any relief of symptoms <i>RR=1.00</i>	Increase of HRQoL <i>RR=1.00</i>	Any decrease of severe adverse effects, measurable decrease of other adverse effects. <i>RR=0.90</i>

Рис. 1. Detailed prospect of risk ratios and levels of additional benefit