Feedback from the break-out groups and large group discussion

1. What information would inform decisions in this context

Epidemiology and emergence of resistance

- Timing and pattern of emergence of resistance relative to antimicrobial use; changes in the percentage development of resistance; trends in resistance patterns
- Levels of use of antibiotics
- Percentage of the population showing resistance to a particular antibiotic
- Use of antibiotics in agriculture: types and level of use of antibiotics for this purpose
- Relative importance of different stressors in relation to the emergence of antibiotic resistance to a specific antibiotic
- The level of control of decision makers over the stressors
- Possibility of prediction of level of resistance in the future e.g. in the next five years
- Sources of infection (e.g. community acquired or hospital acquired) and associated resistance
- The impact of different antibiotics on the resistance patterns of each other
- Cross resistance (if a person is resistant to one antibiotic he may be resistant to other antibiotics)

Feasibility of researching for new antibiotics

- Information relevant to patents of antibiotics: buying of patents, cost of patents, chances of exclusivity of a patent being safeguarded in practice
- Potential payoffs
- The real options
- The risks involved in the development process
- The level of innovation that can be developed
- The probability of the success in developing a new antibiotic
- Factors that will affect the possible income from the antibiotic (e.g. this will be subject to the success of the technology)
- The willingness of payers to reimburse the innovation, even if this is not optimal
- Issues relevant to adherence to antibiotics
- Side-effects from antibiotics
- The proprietary nature of knowledge: even if a drug development process fails, the information should be made available so that other developers benefit from it (possibly not to repeat the same things which do not work)
- The willingness of society to pay and support innovations in cases of public health need
- If there is a new antibiotic ideally its use would be restricted to cases where there is no alternative, however the industry would like to increase the use of a new drug as much as possible

- Regulation should reduce the burden for the industry to motivate new antibiotics – special considerations for an area of unmet medical needs
- Models of how experts predict the effects of introducing new antibiotics

Impact of antimicrobial resistance

- The damage which antibiotic resistance causes to society
- Antimicrobial resistance is an area of unmet medical needs
- The health risk from antimicrobial resistance; public health impact/risk
- If there are new antibiotics, will the consumption of old antibiotics change
- Potential legal and liability consequences for hospitals if there are nosocomial acquired infections from the hospitals

Measures to deal with resistance

- The availability of a rapid test to decide quickly whether a patient is resistant to an antibiotic
- The possibility of reducing antibiotic use to reduce resistance
- Whether hospitals have set-ups to do surveillance
- Restriction on how antibiotics will be used in the different countries – there should be agreements on antibiotic use which are abided with by all countries
- There should be monitoring of antimicrobial resistance even due to off-label use of antibiotics

2. How best to structure and communicate the scientific uncertainties to inform regulatory and reimbursement decisions

- Keeping an update about antibiotic resistance patterns and their development
- There can be a stigma involved with communication on levels of antibiotic resistance because resistance can be associated with bad prescribing or hygiene practices in hospitals
- Stress on the perspective that antibiotic resistance leads to a significant public health need
- Consideration of the possible outcomes of not treating an infection
- The legal and liability consequences to a hospital or a service if there is a hospital-acquired infection, or if it has to suspend some of its activities (e.g. elective surgery) because of risk of transmission of infection with MRSA
- Financial implications: of treating and of not treating the infections

3. What are the key issues in the particular countries in the network

- Resistance and resistance patterns vary significantly from one country to another; there is a significant difference between the countries in the north and those of the south
- The ability of specific hospitals to keep up to date and change their recommendations on antibiotic use
- Sources of infection and relevant patterns of resistance: hospital acquired and community acquired

- Ability to affect changes in prescribing patterns in order to reduce resistance: e.g. control of use of antibiotics, combination use
- Behavioral differences between countries
- There are different reimbursement systems, responsibilities as to who pays for health care and public expectations in different countries
- Which entity does the decision of which antibiotic to be used – the HTA agency or the individual hospitals
- Difference in the level of accountability and enforcement on prescribers in different countries e.g. in holding physicians accountable to abide with prescription guidelines
- Differences in prescribing in different countries
- Differences in the level of agricultural use
- Delinking
- The possibility of mutual agreement by experts in different member states to achieve a coordinated effort
- Level of blame for the cause of antimicrobial resistance