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**NOTE**

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Subject : EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS  
COUNCIL MEETING ON 8 AND 9 JUNE 2009

**Presidency's Conferences**

"eHealth for individuals, society, and economy" (Prague, 18 - 20 February 2009)

"The Microbial Threat to Patient Safety in Europe" (Prague, 15 - 16 April 2009)

"Financial sustainability of Health Systems" (Prague, 10 - 12 May 2009)

– *Information from the Presidency*  
(Other business item)

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Delegations will find annexed an information from the Presidency on the above-mentioned subject.

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***- Information from the Presidency-***

**I. CONFERENCE ON “EHEALTH FOR INDIVIDUALS, SOCIETY AND ECONOMY”**

A conference on “eHealth for Individuals, Society and Economy” (eHealth 2009) was held in Prague on 18 – 20 February 2009. The conference, which was co-financed by the European Commission (Information Society and Media Directorate-General and the Directorate General for Health and Consumer Protection), was an important, high-level political and expert event in the field of eHealth. Invitations were accepted by 520 participants from European Union countries, states from the European Free Trade Association, European Union candidate countries, Western Balkan states, the Republic of Moldova, the Former Yugoslav Republic of Macedonia and, last but not least, important representatives from the European Commission, the European Parliament, the World Health Organisation and other specialist from European associations and institutions.

The main areas discussed included topics such as telemedicine, interoperability, cross-border healthcare, motivation for healthcare staff and patients, support for the transformation of health systems, communicating the benefits of eHealth to citizens, and economic models or financing of eHealth. Health ministers had an opportunity to talk about these subjects in ministerial panel discussions.

At the conclusion of the conference, a **Prague Declaration was adopted** by the European Union Member States, Republic of Croatia, Republic of Turkey and the Former Yugoslav Republic of Macedonia. The Prague Declaration focuses on the benefits of eHealth for individuals, society and the economy, telemedicine and interoperability. Following a meeting of State secretaries held in Prague in February 2009, the Prague declaration focuses also on the high-level coordination in the field of eHealth.

The Prague Declaration<sup>1</sup> states that special attention needs to be devoted to the fulfilment of current strategic goals and to patient safety and the consolidation of patients' rights and the management and control structure for eHealth. Together with the European Commission, Member States are striving to simplify the construction of an eHealth sector, which allows all citizens to have access to healthcare. To this end, it is necessary to constantly develop efforts, particularly in terms of extending telemedicine services, interoperability and Europe-wide cooperation and exchanges of best practices.

**Member States were invited by the Prague Declaration to adopt national strategies for eHealth so that individuals (patients and health workers), society and the economy can exploit the positive impacts of eHealth.** They were also invited to take part in discussions on a Europe-wide structure for the management and control of eHealth, which is becoming another impulse for the introduction of new services and the removal of current obstacles.

For more information please visit the **following website**: [www.ehealth2009.cz](http://www.ehealth2009.cz).

## **II. CONFERENCE ON “THE MICROBIAL THREAT TO PATIENT SAFETY IN EUROPE”**

One general negative trend in many EU Member States is the loss of antibiotics' clinical effectiveness to an extent that was unforeseen even five years ago. Consequently, within the framework of coordinating the activities of the Presidencies of Slovenia, France, the Czech Republic and Sweden, the issue of preventing and controlling antimicrobial resistance and healthcare-associated infections in hospitals was included among the main priorities of the Czech Presidency of the EU Council in the field of public health protection. Naturally, this effort is closely connected with continually improving the quality of healthcare and patient safety.

In connection with the aforementioned priority, a **conference** called “The Microbial Threat to Patient Safety in Europe” was held in Prague on 15 – 16 April 2009, which was **devoted to the following three main topics**:

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<sup>1</sup> See Annex I to the Annex

## 1. Hospital antibiotic stewardship: standards and indicators for European hospitals

*At the same time as implementing effective measures in the prevention and control of infections, it is necessary to curb the overuse of antibiotics in European hospitals.*

*Consequently, the Czech Presidency presented “**Proposal of Concept Framework and Measurable Elements for Hospital Antibiotic Stewardship Programmes**”<sup>2</sup> as one of the main outcomes of the conference. Before applying these in healthcare facilities across Europe, however, it is necessary to continue the expert and political debate that has commenced on this subject and to achieve a consensus on this basis.*

## 2. How healthcare characteristics influence antimicrobial resistance and healthcare-associated infections

*Based on the extensive reforms of health systems that have occurred in many new EU Member States in the last 15-20 years, the conference drew attention to the **impact of systemic healthcare parameters on the occurrence of antimicrobial resistance and healthcare-associated infections**. In connection with the limited public resources invested in health systems, it is necessary (not just against the backdrop of an economic crisis) to focus on an analysis of the strengths and weaknesses of health systems and to seek internal reserves in the context of their funding.*

*A study conducted by the Czech Ministry of Health showed that in an accredited tertiary care hospital, for example, the group of patients affected by healthcare-associated infections comprised around **10% of all hospitalised patients** (after excluding short-term stays of up to 48 hours) **but that they used up around 40% of costs with a mortality rate that was 10 times higher**. These indicators are excessive in the case of patients hospitalised for longer than 50 days. These comprise 1% of patients but use up 20% of total hospital costs and nearly every fourth patient dies. The vast majority of them (almost 90%) are affected by healthcare-associated infections – very often caused by multidrug-resistant microorganisms – at least once during their stay in hospital.*

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<sup>2</sup> See Annex II to the Annex

*If a public health insurance system is set up so that complicated cases can provide a healthcare facility with the highest financial income, this can result in a conflict between economic priorities and efforts to ensure maximum patient safety. The cost effectiveness of preventive measures need not be immediately apparent under these circumstances.*

*In this context, the transformation experience of the Czech Republic has provided a noteworthy stimulus for an assessment of the risks ensuing from the organisational adjustment of a health system. The cost effectiveness of preventing and controlling antimicrobial resistance and healthcare-associated infections is based on convincing proof from relevant epidemiological studies. **Investments in the prevention and control of a single case are 2-5 times lower than dealing with a disease that has already occurred.***

### **3. Leadership and accountability: reducing risks for patients related to antimicrobial resistance and healthcare-associated infections**

*Within the framework of a workshop called “Leadership and Accountability” the specific experiences and well-established procedures of selected EU Member States were presented. **While mutual communication and cooperation between experts and politicians is essential for creating effective systems of prevention and control, exchanging experiences and cooperation between EU Member States is also an inherent part of this process.***

All materials as well as on-line broadcast of the second Conference day (April 16) are available on the following website: <http://czpres.mzcr.cz/Categories/82-Priority-of-Antimicrobial-Resistance.html>.

### **III. CONFERENCE ON THE “FINANCIAL SUSTAINABILITY OF HEALTH SYSTEMS”**

The financial sustainability of health systems is a very topical issue. In particular, the urgency of this subject is underscored by the current economic recession, an ageing European population, technological advances and innovations as well as rising patient expectations and demands.

**Consequently, it is necessary to look at the concept of financial sustainability not only from an accounting point of view, but primarily within the context of the entire economy.** In connection with this, it is necessary to be aware that a system without a shortfall is not unequivocal proof of effectiveness.

Under the Czech Presidency of the EU Council, a ministerial conference on the “Financial Sustainability of Health Systems” was held in Prague on 10 – 12 May 2009. The conference was the culmination of the Czech Presidency’s priority with the same name. The event was attended by around 250 people from EU Member States, Norway and Switzerland, the European Commission, the European Observatory on Health Systems and Policies, the Organisation for Economic Cooperation and Development, the World Bank, the World Health Organisation, and other organisations and European associations, including patients’ organisations. Conference participants included health ministers from the Czech Republic, Lithuania and Cyprus, the European Commissioner for Health Androulla Vassiliou, the Deputy Secretary-General of the OECD Aart de Geus, and the WHO’s Deputy Regional Director for Europe Nata Menabde.

Four studies were prepared within the scope of the “Financial Sustainability of Health Systems” priority, which contribute to a deeper understanding of the entire issue and to the sharing of experiences across European countries. The objective is to define the concept of sustainability in contemporary contexts, not just in economic terms, but also in terms of demographics and current medical advances. The purpose of this is to facilitate discussion between European Member States and to support the exchange of information.

**It is necessary to realise that financial sustainability is not a target, but an essential condition for the operation of health systems, not just in the short term, but primarily in the long term as well.** This can be achieved in three basic ways: Increasing the amount of resources utilised, reducing the provided benefits (demands) of the system, and improving effectiveness, i.e. by increasing the equivalent value that we receive for the money invested in health services. Health is one of the most important values in the life of a person. **Consequently, it should be our goal to strive for health and health systems that are functional in the long term, which can be only achieved by improving their efficiency.**

The studies as well as other materials are available on the **following website**:

<http://czpres.mzcr.cz/Categories/83-Priority-of-Financial-Sustainability-of-Health-Systems.html>.

The Prague Declaration

**20 February 2009: eHealth 2009 Conference Declaration**

**eHealth for Individuals, Society and the Economy**

The benefits of eHealth for a safer and more efficient health sector have long been recognized by expert stakeholders. Since 2003, a series of annual eHealth high level conferences have assessed the progress of the Member States on the way to effective and patient-friendly health services based on the application of latest information technologies. A number of recent eHealth initiatives from the Member States and the European Commission have been providing additional support to launching new projects for better and more effective health services. These initiatives stress the need to keep the momentum so that the potential advantages of gradual deployment of ICT in the health sector are not compromised by barriers of legal, technical, economic or any other nature.

We consider it crucial that the benefits of eHealth applications and services are further enhanced and properly distributed among all the relevant stakeholders:

- ***eHealth for Individuals*** (patients and healthcare professionals alike)

For individuals, eHealth brings new possibilities in terms of increasing quality and effectiveness of services. eHealth provides new tools to take care of patients with chronic diseases. Within the European context, it can facilitate implementation of cross-border healthcare and contribute to the continuity of care.

- ***eHealth for Society***

For society, eHealth represents a challenge for interoperability, e-literacy, and accessibility of new technologies. It also presents great opportunities for research and development. The Lead Market Initiative earmarked eHealth sector as one of the strategic areas with high growth and innovation potential.

- ***eHealth for Economy***

eHealth offers solutions that can bring enormous savings. If properly deployed, eHealth could contribute to the transformation of the health sector and change substantially business models of healthcare facilities. These issues are gaining in importance in current economic climate putting increased pressure for delivery and cost efficiency in all sectors of the economy, the health sector being no exception.

Although significant progress has been achieved since the last eHealth conference, today we have decided to move further and address those areas which are important for the full utilization of eHealth potential. Member States are therefore encouraged to take concerted action on telemedicine, interoperability and European cooperation including exchange of best practices.

- ***Moving forward on telemedicine deployment***

The Commission's Communication on telemedicine<sup>3</sup> from November 2008 outlines the areas for improvement and presents an action plan aimed at full exploitation of the opportunities offered by telemedicine. Building the confidence of patients as well as that of health professionals in telemedicine services, bringing legal clarity and solving technical issues, as well as facilitating market development are identified as the main challenges. A clear commitment within Member States to handle above-mentioned items will secure that the market of telemedicine applications is less fragmented and not limited to one-off and small-scale projects.

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<sup>3</sup> COM(2008) 689: Telemedicine for the benefit of patients, healthcare systems and society



- ***Interoperability and development of common standards***

The rapid acceptance and take-off of eHealth depends to a large extent on a common set of standards for electronic health records, patient summaries, emergency data and other services. The lack of interoperability has been identified as one of the main areas to address, as already laid out in the existing EU action plan on eHealth. While several initiatives fostering the adoption of standards are making progress<sup>4</sup>, an agreement on a consistent set of EU-level harmonized standards is lacking. The main objective of these initiatives is to facilitate access to health care to all EU citizens wherever they happen to work or travel.<sup>5</sup> Key elements to achieve interoperability are associated with ontological and semantic standards as well as technological standards. The implementation of the eHealth Interoperability Standards Mandate M403 is an initiative that should be widely supported for enabling interoperability of eHealth systems and services in Europe.

- ***European cooperation and exchange of best practices***

The annual eHealth high-level conferences bring a unique opportunity to exchange best eHealth practices between EU Member States. A benchmarking study on ICT use among European general practitioners<sup>6</sup>, released last year, revealed a large gap between Member States and between readiness and actual use of eHealth. While most health professionals are now routinely using ICT, there is substantial scope for improvement in what concerns the interconnection of the electronic networks of different health actors. The electronic exchange of patient data and the ICT-supported interactions between health professionals and with patients also require additional developments before becoming established, working routines.

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<sup>4</sup> For example the recent Commission's communication on cross-border interoperability of electronic health record systems: COM (2008) 3282 or epSOS (Smart Open Service for European Patients) project.

<sup>5</sup> Work is also under way as regards the Directive on application of patients' rights in cross-border healthcare.

<sup>6</sup> Benchmarking ICT use among General Practitioners in Europe, final report, April 2008 (by empirica in association with Ipsos).

## **What next? Special attention to be paid to three areas**

While many initiatives are ongoing, we have for the immediate future identified three areas to which special attention should be paid in order to facilitate the development, implementation and usage of new eHealth services and solutions.

- ***Fulfilling existing strategic goals and setting new ones***

EU Member States declare their intent to fulfil the goals set out in the i2010 initiative, eHealth action plan and specific national strategies to promote eHealth in the European Union. In relation to the drafting of new initiatives we consider it necessary that eHealth issues are given relevant space. The above-mentioned Commission communication on telemedicine urged Member States to assess their needs and priorities in telemedicine by the end of this year. Any new national eHealth strategies which result may be presented at next year's conference.

- ***Patient safety and empowerment***

The introduction of new ICT in the health sector has a positive effect on patient safety and quality of care. Member States are encouraged to strengthen the involvement of patients via communicating targeted patient safety policies and solving legal and ethical issues. The data protection and privacy issues also require special attention since they have a significant impact on eHealth uptake. It is therefore important to seek a common approach to optimize existing directives on data protection and privacy.

- ***Governance structure for eHealth***

The eHealth sector has now reached a level of maturity that requires consideration to be given to the most appropriate arrangements for Europe-wide governance. All Member and partner European states are invited to take part in discussions on the options for new arrangements. These discussions are determined by the need to achieve interoperability and speed-up deployment so that patient safety and continuity of care can be ensured within the Member States as well as at the cross-border level.

**Proposal of Concept Framework and Measurable Elements for Hospital Antibiotic  
Stewardship Programmes**

**Hospital Antibiotic Stewardship Programme (H-ABS-Programme)**

***Introduction***

Systematic prevention and control of antimicrobial resistance is necessary to maintain long-lasting effectiveness of antimicrobial agents for treatment and prophylaxis of infections. Loss of their clinical effectiveness represents a significant threat for patients affected by serious, life threatening infections in the hospital setting.

Effective prevention and control of antimicrobial resistance in hospitals is based on complementarily implemented activities focused on decrease in selective pressure of antimicrobials associated with their inappropriate use as well as reduction of spread and transmission of resistant micro-organisms.

These principles are generally declared in the Council Recommendation on Prudent Use of Antimicrobial Agents in Human Medicine, as well as in the recently proposed Council Recommendation on Patient Safety incl. Prevention and Control of Healthcare Associated Infections.

Whereas standards and measurable elements focusing on prevention and control of infections in healthcare institutions already exist (e.g. JCI accreditation standards, IPSE standards and indicators), similar standards are not yet available for implementation of hospital antibiotic stewardship.

Recent EU projects (e.g. ABS International), have defined principles of hospital antibiotic stewardship which can form the basis of discussions on appropriate standards and measurable elements to improve practices in healthcare institutions across Europe. These standards could be included as accountability criteria for hospital accreditation.

## *Objectives*

- Ensuring effective, safe and cost effective antibiotic treatment and prophylaxis of infections as an integral part of care for patients in the hospital setting.
- Prevention and control of antimicrobial resistance by means of prudent use of antibiotics in order to maintain their long-term effectiveness for treatment and prophylaxis.
- Reduction of occurrence of difficult-to-treat infections caused by multi-drug resistant micro-organisms, threatening quality of care and the safety of hospitalised patients.

## *Principles*

- Establishing an interdisciplinary hospital antibiotic stewardship programme focused on the optimisation of quality of antibiotic usage and control of antimicrobial resistance at the hospital level.
- Creating an organizational structure to lead hospital antibiotic stewardship programme, specification of its scope, functions, activities, competencies, leadership and accountability, incl. indispensable support of hospital management.
- Ensuring sufficient capacity of the hospital antibiotic stewardship programme in terms of human, material and technical resources.
- Creating and implementing basic tools for hospital antibiotic stewardship (e.g. an antibiotic list with specification of restricted drugs, control of antibiotic consumption, local surveillance of antimicrobial resistance, local guides for diagnostics of infections incl. clinical microbiology, local guides for initial and pathogen specific therapy, for surgical prophylaxis, consulting and supervising of antibiotic usage, etc.).
- Performing epidemiological surveillance of antimicrobial resistance as required for optimisation of antibiotic treatment and prophylaxis at the local level (e.g. local rates and trends of antimicrobial resistance, outputs of local surveillance of healthcare associated infections, regional and national epidemiological patterns of community acquired infections incl. levels of antimicrobial resistance of key pathogens).

- Systematic evaluation of quality of antibiotic usage in the hospital setting, based on relevant scientific knowledge, focused on identification of inappropriate practice. Continuous improvement of quality of antibiotic usage using relevant, validated, feasible and cost effective quality indicators and quality management procedures.
- Effective co-ordination of the hospital Antibiotic stewardship programme with the Programme on prevention and control of infections focused on the control of spreading of resistant pathogens.
- Continuous quality improvement of the hospital antibiotic stewardship programme, regarding capacity building, structure, organization, functions and effectiveness, based on implementation of action plans reflecting evaluation of adequate structure indicators and level of implementation of specific standards.

### **Proposal of Concept Framework and Measurable Elements for Hospital Antibiotic Stewardship Programme (H-ABS-Programme)**

#### **1. *Establishment and objectives***

A healthcare institution establishes a specific, interdisciplinary programme, focused on high quality of antibiotic usage, aiming at long-lasting sustainability of effectiveness of antimicrobial agents for treatment and prophylaxis, at reduction of risk of antimicrobial resistance as well as difficult-to-treat infections due to multi-drug resistant pathogens threatening patient safety.

#### **2. *Scope and priorities***

The scope of H-ABS-Programme takes into account the clinical spectrum and epidemiological characteristics of community-acquired and healthcare associated infections, which occur in patients, to whom the healthcare institution provides care. Priorities of H-ABS-programme are appropriate in relation to the structure, scope and characteristics of provided healthcare (such as a spectrum of clinical disciplines, characteristics of patient populations, proportion of ICU beds, etc.).

### **3. *Conditions for effective operation***

- 3.1. Management of the healthcare institution is responsible for ensuring sufficient resources (in particular human, financial and technical) and support of H-ABS-Programme.
- 3.2. The healthcare institution supports the personal development of professionals in the interdisciplinary antibiotic management team.
- 3.3. The healthcare institution disposes of sufficient capacity regarding diagnostics and clinical management of infections, appropriate to the scope and characteristics of provided healthcare.
- 3.4. The healthcare institution has sufficient capacity of clinical microbiology services with an optimal spectrum of examinations allowing pathogen-specific therapy and providing necessary and interpretable data for optimizing initial antimicrobial therapy, prophylaxis, and also effective prevention and control of antimicrobial resistance.
- 3.5. The healthcare institution has access to the required data on the antimicrobial resistance for optimisation of antibiotic use and effective prevention and control of antimicrobial resistance.
- 3.6. Inappropriate influence of marketing and promotion of pharmaceutical industry on operation and activities of H-ABS-Programme must be avoided. Relationships between H-ABS-Programme and the pharmaceutical industry must be regulated by national legislation, ethical rules of professional societies and bodies, and local rules established by the healthcare institution.

### **4. *Structure, organization, personnel and management***

- 4.1. H-ABS-Programme is co-ordinated by an interdisciplinary antibiotic management team (AMT), whose composition, roles, responsibilities and leadership are defined, recognized and supported by the hospital management.
- 4.2. AMT is composed of experienced specialists with relevant education, training and authority, representing appropriate disciplines related to the scope of hospital antibiotic stewardship and prevention and control of antimicrobial resistance (e.g. clinical microbiology, infectious diseases, intensive care, surgery, hospital pharmacy, infection control, other clinical disciplines as appropriate, etc.).

- 4.3. AMT is responsible for ensuring, co-ordinating and managing of all functions and activities of H-ABS-Programme (reference to 5).
- 4.4. Sufficient numbers of clinical consultants with appropriate education and training are available to provide their services for clinical wards regarding support of prudent use of antimicrobial agents for individual patients (reference to 5.4).
- 4.5. H-ABS linked physicians effectively co-operating with AMT are established on clinical wards, to ensure all appropriate functions and activities of H-ABS-Programme at this level.
- 4.6. Supporting staff is available for optimal operation and ensuring functions of H-ABS-Programme as appropriate and necessary (e.g. data documentation assistants, IT specialists, epidemiologists and biostatisticians, possibly also project managers, communication and public relations specialists, etc.).

## **5. *Functions and activities***

### **5.1. Local surveillance of antimicrobial resistance**

Competent professionals regularly process, evaluate, compare and interpret local data regarding clinically and epidemiologically important patterns of antimicrobial resistance, to be adequately useful for updating local guides for initial antimicrobial therapy, for effective control of spread of resistant micro-organisms, as well as restriction of particular groups of antimicrobials with potential risk for selection of resistance. Intelligible and easy to implement outputs of this activity are routinely disseminated to all concerned personnel as appropriate.

### **5.2. Local surveillance of antibiotic consumption**

Competent professionals regularly process, evaluate, compare and interpret local data regarding consumption of antimicrobials to detect its important quantitative and qualitative changes as soon as possible, when a detailed analysis of reasons of observed trends is needed for early implementation of appropriate control measures. Intelligible and easy to implement outputs of this activity are routinely disseminated to all concerned personnel as appropriate.

### **5.3. Categorisation of antimicrobial agents and creating antibiotic lists**

The healthcare institution through AMT defines and regularly updates a generic list of essential antimicrobial agents according to the scope and characteristics of provided care, as well as spectrum and epidemiological characteristics of occurred infections. Categorisation of restricted drugs under supervision of AMT incl. description of specific rules for its use and prescribing is integrated. Appropriate additional information can be included, such as pricing, dosage, etc. This list (antibiotic list) is widely available for all prescribing physicians, the hospital pharmacy and other relevant healthcare workers.

### **5.4. Development and regular updating of local guides for diagnostics, treatment and prophylaxis of infections**

Interdisciplinary AMT develops and regularly updates local guides for diagnostics, treatment and prophylaxis of infections in co-operation with clinical and diagnostic hospital departments. These guides have to correspond to the scientific knowledge, relevant international and national guidelines, have to take into account adequate national, regional and local epidemiological characteristics and have to be well understandable and available.

### **5.5. Clinical consulting and services focusing on support of prudent use of antimicrobial agents**

Services on clinical consulting of individual patients for differential diagnosis, treatment and prophylaxis of infections are an integral part of H-ABS Programme. These activities also cover supervision of usage of restricted drugs and interpretation and active reporting of critical results of microbiology examinations aimed at early conversion from initial to pathogen specific therapy, where possible. Consultations must be widely available and routinely documented at patient records to ensure continuity of care.



## 5.6. **Systematic measuring, evaluation and improving quality of antibiotic usage**

H-ABS-Programme implements activities focused on systematic improvement of quality of antibiotic usage in the interest of optimisation of treatment and prophylaxis of infections. Adequate procedures and measures are used, which are of scientific relevance, validated, feasible, cost effective, and ideally resulting from measurement of relevant quality indicators.

## 5.7. **Education and training**

The healthcare institution ensures through AMT regular training of prescribing physicians and other relevant healthcare workers in diagnostics, treatment and prophylaxis of infections, focusing on appropriate use of antimicrobial agents as well as prevention and control of antimicrobial resistance. Training activities cover information on recent problems of antimicrobial resistance, inappropriate use of antimicrobials and adequate control measures for improvement. AMT members and clinical consultants take part in systematic continuing education and training in all areas needed for their professional skills.

## 6. **Tools**

Specific tools are developed and available at all appropriate levels to ensure optimal operation of H-ABS programme. These tools are complementary to its functions (reference to 5) and cover particularly:

- Antibiotic lists
- Local guides for diagnostics of infections including microbiology laboratory
- Local guides for initial antimicrobial therapy
- Local guides for pathogen-specific antimicrobial therapy
- Local guides for surgical prophylaxis
- Tools for controlling of antibiotic consumption

- Tools for controlling of antimicrobial resistance

## **7. *Integration of H-ABS-Programme to the hospital programme on quality and safety, links and relationships***

- 7.1. Continuous quality improvement of the hospital antibiotic stewardship programme is regularly evaluated using appropriate methods (measuring structure indicators, auditing implementation of H-ABS standards). Outputs of this evaluation are used for further development through realization of H-ABS action plans with appropriate timing.
- 7.2. H-ABS-Programme is linked to the programme on prevention and control of infections of the healthcare institution and their effective co-operation is running on daily basis. Representatives of both programmes are reciprocally involved in their organizational structures.
- 7.3. H-ABS-Programme activities are linked and integrated to the hospital drug policy, especially in terms of rational and cost effective use of medicines, reduction of medication errors, undesirable adverse reactions and drug interactions. Representative of H-ABS-Programme is a member of organizational structures responsible for agenda of hospital drug policy (such as hospital drug and therapeutic committee).
- 7.4. Relationships of H-ABS-Programme with co-operating healthcare facilities and subjects (e.g. general practitioners, ambulatory specialists, hospitals) are covered and co-ordinated.
- 7.5. H-ABS-Programme of healthcare institution is linked to the national inter-sectoral co-ordination mechanism as appropriate, including involvement to the international co-operation in the field of antibiotic usage and antimicrobial resistance (e.g. ECDC agenda).

## Proposal of Concept Framework and Measurable Elements

STANDARDS	MEASURABLE ELEMENTS
<b>1. Establishment and objectives</b>	
1.0 A healthcare institution establishes a specific, interdisciplinary programme, focused on high quality of antibiotic usage, aiming at long-lasting sustainability of effectiveness of antimicrobial agents for treatment and prophylaxis, at reduction of risk of antimicrobial resistance as well as difficult-to-treat infections due to multi-drug resistant pathogens threatening patient safety.	<ul style="list-style-type: none"> <li>• Specific H-ABS-Programme reflecting defined objectives is established.</li> <li>• The H-ABS-programme has interdisciplinary character.</li> </ul>
<b>2. Scope and priorities</b>	
2.0 The scope of H-ABS-Programme takes into account the clinical spectrum and epidemiological characteristics of community-acquired and healthcare associated infections, which occur in patients, to whom the healthcare institution provides care. Priorities of H-ABS-programme are appropriate in relation to the structure, scope and characteristics of provided healthcare (such as a spectrum of clinical disciplines, characteristics of patient populations, proportion of ICU beds, etc.).	<ul style="list-style-type: none"> <li>• Scope of the H-ABS-Programme corresponds with the clinical spectrum and epidemiological characteristics of infections occurring in patients, to whom the healthcare institution provides care.</li> <li>• Priorities of the H-ABS-programme are defined and correspond with the structure, scope and characteristics of provided healthcare.</li> </ul>
<b>3. Conditions for effective operation</b>	
3.1 Management of the healthcare institution is responsible for ensuring sufficient resources (in particular human, financial and technical) and support of H-ABS-Programme.	<ul style="list-style-type: none"> <li>• Management of healthcare institution ensures sufficient human, financial and technical resources for optimal operation of H-ABS-Programme.</li> <li>• Management of healthcare institution provides continuous support for the H-ABS-Programme.</li> </ul>
3.2 The healthcare institution supports the personal development of professionals in the interdisciplinary antibiotic management team.	<ul style="list-style-type: none"> <li>• Personal development of professionals of interdisciplinary antibiotic management team (AMT) is supported.</li> </ul>
3.3 The healthcare institution disposes of sufficient capacity regarding diagnostics and clinical management of infections, appropriate to the scope and characteristics of provided healthcare.	<ul style="list-style-type: none"> <li>• Sufficient capacity for diagnostics and clinical management of infections occurring in patients, to whom the healthcare institution provides care, is available.</li> </ul>
3.4 The healthcare institution has sufficient capacity of clinical microbiology services with an optimal spectrum of examinations allowing pathogen-specific therapy and	<ul style="list-style-type: none"> <li>• Sufficient capacity of clinical microbiology services is available for optimal clinical management of infections.</li> </ul>

providing necessary and interpretable data for optimizing initial antimicrobial therapy, prophylaxis, and also effective prevention and control of antimicrobial resistance.	<ul style="list-style-type: none"> <li>Sufficient capacity of clinical microbiology services is available for effective prevention and control of antimicrobial resistance.</li> </ul>
3.5 The healthcare institution has access to the required data on the antimicrobial resistance for optimisation of antibiotic use and effective prevention and control of antimicrobial resistance.	<ul style="list-style-type: none"> <li>The healthcare institution has an access to the required data on the antimicrobial resistance.</li> </ul>
3.6 Inappropriate influence of marketing and promotion of pharmaceutical industry on operation and activities of H-ABS-Programme must be avoided. Relationships between H-ABS-Programme and the pharmaceutical industry must be regulated by national legislation, ethical rules of professional societies and bodies, and local rules established by the healthcare institution.	<ul style="list-style-type: none"> <li>Rules determining relationships with pharmaceutical industry are recognized and followed.</li> <li>Inappropriate influence of marketing and promotion of pharmaceutical industry on H-ABS-Programme is avoided.</li> </ul>
<b>4. Structure, organization, personnel and management</b>	
4.1 H-ABS-Programme is co-ordinated by an interdisciplinary antibiotic management team (AMT), whose composition, roles, responsibilities and leadership are defined, recognized and supported by the hospital management.	<ul style="list-style-type: none"> <li>Interdisciplinary antibiotic management team is established.</li> <li>Composition, roles, responsibilities and leadership of the AMT are defined, recognized and supported by the hospital management.</li> </ul>
4.2 AMT is composed of experienced specialists with relevant education, training and authority, representing appropriate disciplines related to the scope of hospital antibiotic stewardship and prevention and control of antimicrobial resistance (e.g. clinical microbiology, infectious diseases, intensive care, surgery, hospital pharmacy, infection control, other clinical disciplines as appropriate, etc.).	<ul style="list-style-type: none"> <li>Composition of AMT covers professionals of all disciplines related to the scope of hospital antibiotic stewardship and prevention and control of antimicrobial resistance.</li> <li>Members of the AMT are experienced specialists with relevant education and training</li> </ul>
4.3 AMT is responsible for ensuring, co-ordinating and managing of all functions and activities of H-ABS-Programme (reference to 5).	<ul style="list-style-type: none"> <li>The AMT ensures, co-ordinates and manages all functions and activities of the H-ABS-Programme</li> </ul>
4.4 Sufficient numbers of clinical consultants with appropriate education and training are available to provide their services for clinical wards regarding support of prudent use of antimicrobial agents for individual patients (reference to 5.4)	<ul style="list-style-type: none"> <li>Sufficient number of clinical consultants with defined competencies and responsibilities are available to provide their services for clinical wards.</li> <li>Clinical consultants have an adequate education and training.</li> </ul>
4.5 H-ABS linked physicians effectively co-	<ul style="list-style-type: none"> <li>H-ABS linked physicians are established</li> </ul>

<p>operating with AMT are established on clinical wards, to ensure all appropriate functions and activities of H-ABS-Programme at this level.</p>	<p>within clinical wards.</p> <ul style="list-style-type: none"> <li>• Roles and activities of H-ABS linked physicians are defined and followed.</li> </ul>
<p>4.6 Supporting staff is available for optimal operation and ensuring functions of H-ABS-Programme as appropriate and necessary (e.g. data documentation assistants, IT specialists, epidemiologists and biostatisticians, possibly also project managers, communication and public relations specialists, etc.)</p>	<ul style="list-style-type: none"> <li>• Supporting staff for operation of the H-ABS-Programme is available as appropriate and necessary.</li> </ul>
<p><b>5. Functions and activities</b></p>	
<p>5.1 <b>Local surveillance of antimicrobial resistance</b> Competent professionals regularly process, evaluate, compare and interpret local data regarding clinically and epidemiologically important patterns of antimicrobial resistance, to be adequately useful for updating local guides for initial antimicrobial therapy, for effective control of spread of resistant micro-organisms, as well as restriction of particular groups of antimicrobials with potential risk for selection of resistance. Intelligible and easy to implement outputs of this activity are routinely disseminated to all concerned personnel as appropriate.</p>	<ul style="list-style-type: none"> <li>• Data on local antimicrobial resistance are regularly processed, evaluated, compared and interpreted to identify remarkable trends and its reasons.</li> <li>• Outputs of these analyses are routinely disseminated to all concerned personnel.</li> <li>• Outputs of these analyses are used for updating local guides and antibiotic list.</li> <li>• Outputs of these analyses are used for effective control of spreading of multi-drug resistant micro-organisms in early warning mode.</li> </ul>
<p>5.2 <b>Local surveillance of antibiotic consumption</b> Competent professionals regularly process, evaluate, compare and interpret local data regarding consumption of antimicrobials to detect its important quantitative and qualitative changes as soon as possible, when a detailed analysis of reasons of observed trends is needed for early implementation of appropriate control measures. Intelligible and easy to implement outputs of this activity are routinely disseminated to all concerned personnel as appropriate.</p>	<ul style="list-style-type: none"> <li>• Data on local antibiotic consumption are regularly processed, evaluated, compared and interpreted to identify remarkable trends and its reasons.</li> <li>• Outputs of these analyses are routinely disseminated to all concerned personnel.</li> <li>• Outputs of these analyses are used for implementing appropriate control measures if needed.</li> </ul>
<p>5.3 <b>Categorisation of antimicrobial agents and creating antibiotic lists</b> The healthcare institution through AMT defines and regularly updates a generic list of essential antimicrobial agents according to the scope and characteristics of provided care, as well as spectrum and epidemiological characteristics of occurred infections.</p>	<ul style="list-style-type: none"> <li>• Generic list of essential antimicrobial agents (antibiotic list) is defined and regularly updated.</li> <li>• Antibiotic list is prepared by the AMT in co-operation with clinical departments.</li> <li>• Antibiotic list covers categorization of</li> </ul>

<p>Categorisation of restricted drugs under supervision of AMT incl. description of specific rules for its use and prescribing is integrated. Appropriate additional information can be included, such as pricing, dosage, etc. This list (antibiotic list) is widely available for all prescribing physicians, the hospital pharmacy and other relevant healthcare workers.</p>	<p>restricted drugs incl. description of specific rules of its use and prescribing.</p> <ul style="list-style-type: none"> <li>• Antibiotic list is widely available for prescribing physicians and other relevant healthcare workers.</li> </ul>
<p><b>5.4 Development and regular updating of local guides for diagnostics, treatment and prophylaxis of infections</b>  Interdisciplinary AMT develops and regularly updates local guides for diagnostics, treatment and prophylaxis of infections in co-operation with clinical and diagnostic hospital departments. These guides have to correspond to the scientific knowledge, relevant international and national guidelines, have to take into account adequate national, regional and local epidemiological characteristics and have to be well understandable and available.</p>	<ul style="list-style-type: none"> <li>• Local guides for diagnostics, treatment and prophylaxis of infections are developed and widely available for prescribing physicians.</li> <li>• Local guides for diagnostics, treatment and prophylaxis of infections are regularly updated.</li> <li>• Development and updating of guides for diagnostics, treatment and prophylaxis of infections is co-ordinated by the AMT.</li> <li>• Local guides correspond with the scientific knowledge, relevant international and national guidelines and take into account adequate national, regional and local epidemiological characteristics</li> </ul>
<p><b>5.5 Clinical consulting and services focusing on support of prudent use of antimicrobial agents</b>  Services on clinical consulting of individual patients for differential diagnosis, treatment and prophylaxis of infections are an integral part of H-ABS Programme. These activities also cover supervision of usage of restricted drugs and interpretation and active reporting of critical results of microbiology examinations aimed at early conversion from initial to pathogen specific therapy, where possible. Consultations must be widely available and routinely documented at patient records to ensure continuity of care.</p>	<ul style="list-style-type: none"> <li>• Services on clinical consulting of individual patients for differential diagnosis, treatment and prophylaxis of infections are routinely available.</li> <li>• Clinical consulting covers supervising of usage of restricted drugs.</li> <li>• Clinical consulting covers active reporting of critical results of microbiology examinations to convert initial to pathogen-specific therapy.</li> <li>• Consultations are routinely documented in patient records.</li> </ul>
<p><b>5.6 Systematic measuring, evaluation and improving quality of antibiotic usage</b>  H-ABS-Programme implements activities focused on systematic improvement of quality of antibiotic usage in the interest of optimisation of treatment and prophylaxis of infections. Adequate procedures and measures are used, which are of scientific relevance, validated, feasible, cost effective,</p>	<ul style="list-style-type: none"> <li>• Appropriateness of antibiotic usage is regularly measured and evaluated using adequate methods and quality indicators.</li> <li>• Relevant procedures for systematic improvement of quality of antibiotic usage are routinely used to optimize treatment and prophylaxis of infections.</li> </ul>

<p>and ideally resulting from measurement of relevant quality indicators.</p>	
<p><b>5.7 Education and training</b> The healthcare institution ensures through AMT regular training of prescribing physicians and other relevant healthcare workers in diagnostics, treatment and prophylaxis of infections, focusing on appropriate use of antimicrobial agents as well as prevention and control of antimicrobial resistance. Training activities cover information on recent problems of antimicrobial resistance, inappropriate use of antimicrobials and adequate control measures for improvement. AMT members and clinical consultants take part in systematic continuing education and training in all areas needed for their professional skills.</p>	<ul style="list-style-type: none"> <li>• The AMT organizes regular training activities focused on prudent use of antimicrobial agents and prevention and control of antimicrobial resistance.</li> <li>• Prescribing physicians and other relevant healthcare workers participate in regular training activities focused on diagnostics, treatment and prophylaxis of infections, including prevention and control of antimicrobial resistance.</li> <li>• The AMT members take part in continuing education and training in all areas needed for their professional skills.</li> <li>• Clinical consultants take part in continuing education and training in all areas needed for their professional skills.</li> </ul>
<p><b>6. Tools</b></p>	
<p><b>6.0</b> Specific tools are developed and available at all appropriate levels to ensure optimal operation of H-ABS programme. These tools are complementary to its functions (reference to 5) and cover particularly:</p> <ul style="list-style-type: none"> <li>- Antibiotic lists</li> <li>- Local guides for diagnostics of infections including microbiology laboratory</li> <li>- Local guides for initial antimicrobial therapy</li> <li>- Local guides for pathogen-specific antimicrobial therapy</li> <li>- Local guides for surgical prophylaxis</li> <li>- Tools for controlling of antibiotic consumption</li> <li>- Tools for controlling of antimicrobial resistance</li> </ul>	<ul style="list-style-type: none"> <li>• Specific tools complementary to functions of the H-ABS-Programme are available to ensure its performance.</li> </ul>
<p><b>7 Integration of H-ABS-Programme to the hospital programme on quality and safety, links and relationships</b></p>	
<p><b>7.1</b> Continuous quality improvement of the hospital antibiotic stewardship programme is regularly evaluated using appropriate methods (measuring structure indicators, auditing implementation of H-ABS standards). Outputs of this evaluation are used for further development through realization of H-ABS action plans with</p>	<ul style="list-style-type: none"> <li>• Appropriate methods are regularly used to measure quality improvement of the H-ABS-Programme performance.</li> <li>• Further development of the H-ABS-Programme is realized through action plan with appropriate timing.</li> </ul>

appropriate timing.	
7.2 H-ABS-Programme is linked to the programme on prevention and control of infections of the healthcare institution and their effective co-operation is running on daily basis. Representatives of both programmes are reciprocally involved in their organizational structures.	<ul style="list-style-type: none"> <li>• Effective link and co-operation between the H-ABS-Programme and hospital programme on prevention and control of infections is ensured.</li> <li>• Representatives of the H-ABS-Programme and hospital programme on prevention and control of infections are reciprocally involved in their organizational structures.</li> </ul>
7.3 H-ABS-Programme activities are linked and integrated to the hospital drug policy, especially in terms of rational and cost effective use of medicines, reduction of medication errors, undesirable adverse reactions and drug interactions. Representative of H-ABS-Programme is a member of organizational structures responsible for agenda of hospital drug policy (such as hospital drug and therapeutic committee).	<ul style="list-style-type: none"> <li>• An effective link and integration of the H-ABS-Programme activities to the hospital drug policy is ensured.</li> <li>• Representative of the H-ABS-Programme is a regular member of organizational structures responsible for hospital drug policy.</li> </ul>
7.4 Relationships of H-ABS-Programme with co-operating healthcare facilities and subjects (e.g. general practitioners, ambulatory specialists, hospitals) are covered and co-ordinated.	<ul style="list-style-type: none"> <li>• Relationships of healthcare institution with other co-operating healthcare facilities and subjects are covered and co-ordinated by the H-ABS-Programme.</li> </ul>
7.5 H-ABS-Programme of healthcare institution is linked to the national inter-sectoral co-ordination mechanism on prevention and control of antimicrobial resistance as appropriate, including involvement to the international co-operation in the field of antibiotic usage and antimicrobial resistance (e.g. ECDC agenda).	<ul style="list-style-type: none"> <li>• The H-ABS-Programme is linked to the national inter-sectoral co-ordination mechanism on prevention and control of antimicrobial resistance as appropriate.</li> <li>• The H-ABS-Programme is linked to the international co-operation in the field of antibiotic usage and antimicrobial resistance as appropriate.</li> </ul>