Prof. Dr. Dominique Sprumont

Institut de droit de la santé Université de Neuchâtel 26, Avenue du 1^{er}-Mars 2000 Neuchâtel dominique.sprumont @unine.ch

404940-103165 01.03.2004-31.03.2006

PD Dr. Stephan Harbarth Service Prévention et Contrôle de l'Infection, Hôpitaux Universitaires de Genève (HUG) stephan.harbarth@hcuge.ch

Legal implications of antibiotic resistance: Analysis of Swiss legislation and comparative law (D, F, UK)

Objectives One of the major goals of the project is to give a practical answer to the juridical problems posed by the problem of antibiotic resistance, given the legal requirement, i.e. respect of the fundamental rights of patients and health care professionals, and the medical and scientific constraints.

Conclusions Swiss legislation relating to the fight against epidemics in general and antibiotic resistance in particular was analysed in detail. Moreover, a comparative law analysis of nearby countries was conducted. This was completed by a questionnaire survey of Swiss and European specialists on the appropriate measures to be taken for antibiotic resistance surveillance and control.

One of the major findings of the study is that the Swiss legislation is generally well adapted to the public health needs in this field. However, even with the available resources, the lack of the necessary data for developing an appropriate strategy at the national level is of concern. Therefore, it is important to guarantee that Switzerland collects more data on the prevalence of antibiotic resistance to determine its public health impact in order to be able to apply appropriate strategies and countermeasures. In particular, the collection of more focused clinical data should be organized on a long-term basis with support of the public health authorities (not as a research project). Furthermore, certain antibiotic resistance problems could be included in a mandatory or voluntary declaration surveillance scheme. To conclude, the legal framework to facilitate continuing action of surveillance and antibiotic resistance control could be outlined. The findings strongly support the need for further policy action and concerted measures on a national scale to reinforce and standardize locally implemented strategies.

Main results and findings

Analysis of the actual Swiss legislation The way of spread of an infection – human to human (Federal Epidemics Law 1970), animal to human (Federal Law on Animal Epidemics), food to human (Federal Law on Foodstuffs) – is fundamental in determining how to handle it by means of constraint (legislation). Analysis of the Federal Law of 18 December 1970 on Protection against Contagious Diseases in Humans (Epidemics Law) [Bundesgesetz vom 18. Dezember 1970 über die Bekämpfung übertragbarer Krankheiten des Menschen (Epidemiengesetz)] revealed that:

- with Art. 2, with the broad notion of "pathological agents", the current law is flexible enough to include current and new forms of bacterial resistance.
- the law does not explicitly mention the possibility of imposing treatment against infectious diseases. However:
 - with Art. 17 (obligation to get medical analysis) and Art. 16 (obligation to be hospitalised), the law contains a legal basis sufficient to entail a minor limitation of individual freedom.
 - Art. 10 allows the Federal State, in case of grave crisis situations, to intervene and impose treatment for certain categories of the population. Forced treatment must remain the option of last resort and in extreme circumstances only.

Currently, the revision due for 2008 of the Federal Law of 18 December 1970 on Protection against Contagious Diseases in Humans (Epidemics Law) is planned to act at five well-established levels to fight against contagious diseases and epidemics: prophylaxis, early warning, analysis of cases, surveillance and measures to fight the diseases.

Analysis of comparative legislations (F, D, UK) French and German laws have been recently revised in order to take into account the hazard posed by nosocomial infections in hospitals and ambulatories. Reporting of nosocomial infections is now mandatory. Although no specific legislation on the problem of antibiotic resistance could be found, centres for the surveillance and analysis of antibiotic resistance were instituted. These centres have to propose practical measures for handling the problem of antibiotic resistance. In France, for care facilities centres, health surveillance has been made a licensing requirement. That is, in order to remain a licensed facility, each care facility centre is required to take all health surveillance measures to guarantee quality of nosocomial hygiene. Periodical controls are established.

Legal implications of antibiotic resistance: Analysis of Swiss legislation and comparative law (D, F, UK) Research field: Society, law and economics

Summary of the results of a survey conducted among Swiss and European experts A large majority of experts think that MRSA (methicillin-resistant *Staphylococcus aureus*) will increase in clinical and public health importance throughout Europe and Switzerland within the next 10 years. A majority of Swiss experts are in favour of mandatory declaration of MRSA bacteremia. Forced treatment and isolation of MRSA carriers is considered ethically acceptable by a majority of experts. These forced measures are not part of routine infection control practice but have been observed already by one-third of the experts.

Publications of the NRP 49 project

Haenni C, Harbarth S, Sprumont S. La résistance aux antibiotiques: quells enjeux juridiques? Rapport IDS No 9, Georg éditeur, 2006, 164 pages, ISBN : 2-8257-0926-3

Harbarth S, Sprumont S. Surveillance of MRSA – does Switzerland need a mandatory declaration? Swiss-Noso. Under review 2006.

Vincent JL, Brun-Buisson C, Niederman M, Haenni C, Harbarth S, Sprumont D, Valencia M, Torres A. **Ethics roundtable debate: a patient dies from an ICU-acquired infection related to methicillin resistant** *Staphylococcus aureus* – how do you defend your case and your team? *Crit Care.* 2005 Feb;9(1):5-9. Epub 2004 Dec 15.