Antimicrobial Susceptibility Testing, A New Item in the Field of European Standardisation.

(Directive 98/79/EC on In vitro diagnostic medical devices)

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INTRODUCTION

Within the scope of its standardisation mission, the French Health Products Safety Agency (Afssaps) collaborating with the French Standard Association (AFNOR), has suggested a new item in the field of European standardisation: Antimicrobial Susceptibility Testing. This new work item was proposed in April 2002 to the CEN technical committee 140 (TC 140) which is responsible for the introduction of European standards for in vitro medical devices.

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 OCTOBER 1998 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES *OFFICIAL JOURNAL L 331, 07/12/1998 P. 0001 – 0037*

Since December 7, 2003, the 98/79/EC directive has been the sole regulation in the European Union being applied to the in vitro diagnostic medical devices and their accessories.
This **new approach** directive makes the manufacturer responsible for the design, manufacture, and performance which must conform to the essential requirements of the directive. This compliance allows CE marking and free circulation of the in vitro medical devices within the European Union. As a general rule, the European standardization, in combination with the new approach directive, promotes some **harmonized standards** to the manufacturers in their field of activity.

If a manufacturer attests that a product conforms to a **harmonized standard** whose reference is published in the OJEC, the national authorities accept that the products fulfils the "essential requirements" of the directive concerned.

Directive 98/79/EC

Article 5 - Reference to standards
1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards transposing the harmonised standards the reference numbers of which have been published in the Official Journal of the European Communities; Member States shall publish the reference numbers of such national standards.

Article 3 - Essential requirements
Devices must meet the essential requirements set out in annex I which apply to them, taking account of the intended purpose of the devices concerned.

EUROPEAN COMMITTEE FOR STANDARDIZATION (CEN) AND INTERNATIONAL STANDARD ORGANIZATION (ISO)

CEN
The CEN TC 140 is the technical committee in charge of in vitro diagnostic medical devices. The secretariat is Held by the DIN (Deutsches Institüt fur Normung) in Berlin. It has 28 national members.

CEN/TC 140 - Structure: Different Working Group (WG)

- **WG 1** Labelling and performance evaluation *
- **WG 2** GMP for IVD MDs*
- **WG 3** Quality management in the medical laboratory
- **WG 4** Reference systems
- **WG 5** Specimen containers
- **WG 6** Staining in biology*
- **WG 7** Culture media*
- **WG 8** IVDs for self testing
- **WG 9** Use of external quality assesment schemes
- **WG 10**

** no more in activity in 2004*

ISO
The ISO TC 212 is the technical committee in charge of Clinical Laboratory Testing and in Vitro Diagnostic Test Systems.
The secretariat is held by NCCLS (National Committee of Clinical Laboratory Standards). It has 33 participating members.

ISO/TC 212 - Structure: Different Working Group (WG)

- **WG 1** Quality management in the medical laboratory
- **WG 2** Reference systems
- **WG 3** in vitro diagnostic products
- **WG 4**

A NEW WORK ITEM IN THE FIELD OF EUROPEAN STANDARDIZATION

In the field of antimicrobial susceptibility testing, European and even international harmonization has been needed for a long time. The scientific committees from different countries (CASFM, BSAC, DIN, etc.) have worked in this way by founding the EUCAST committee (European Committee for Antimicrobial Susceptibility Testing).
To be in accordance with the new regulations (New approach directive) for which standardization is an essential foundation, the French Health Products Safety Agency has proposed two new work items to the European committee of standardization:

1: **WI 00140051 "Reference method(s) for testing the in vitro activity of antimicrobial agents against bacteria involved in infectious disease"**
2: **WI 00140052 "Evaluation of performance of antimicrobial susceptibility devices "**

The purpose of these standards is to obtain, after agreement of the experts from the participating countries, a standardization between all the European countries concerning the evaluation of performance of antimicrobial susceptibility devices to ensure reliable and reproducible tests for determining in vitro susceptibility testing of infectious bacteria. To achieve this, some experts have proposed to define one reference method which must be carried out during the performance evaluation done by the manufacturer.

These two items were proposed to the CEN TC 140 in Berlin on April,17, 2002 (document N518: French contribution to discussion on a possible new work item on Antimicrobial Susceptibility Testing). In January 2003, the European countries involved, voted for this new work item and decided to set up a new working group within CEN/TC 140:

WG10: Antimicrobial Susceptibility Testing

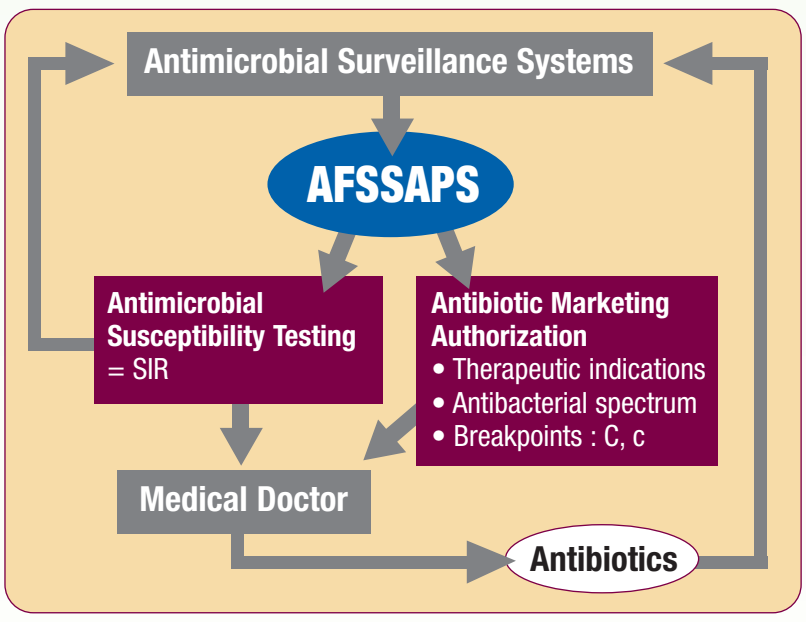
At the same time a new chairman was elected: Pr Arne RODLOFF (Germany) - The first meeting was in June 2003 in Berlin.

NEXT STEP FOLLOWING EUROPEAN STANDARD - A NEW WORK ITEM FOR ISO STANDARDIZATION

The **Vienna Agreement** is an agreement on technical cooperation between ISO and CEN. It allows ISO TC 212 and CEN TC 140 to work together on a common topic. In April 2003, during the meeting of ISO TC 212 in Sydney, it was decided to organize a vote of the countries to include these new items to the ISO TC 212 Program. In august 2003, the 33 countries adopted these new work items and decided to set up a new working group within ISO/TC212:

WG 4: antimicrobial Susceptibility testing

Pr James H. Jorgensen has been appointed Convener (USA).
Australia, Canada, Japan, Korea, Turkey and the United States have nominated some experts.
The new codification of the standards are **Pr EN ISO 20776-1** for the WI 1 and **Pr EN ISO 20776-2** for the WI 2
The first joint meeting was in October 2003 in France.



CONCLUSION

We feel that certain parameters concerning the Antimicrobial Susceptibility Testing would greatly benefit from standardization into European standard, easing the work of in vitro medical device manufacturers, pharmaceutical manufacturers, the National Competent Authority and biologists. If we consider the diagram above which shows the inter-connexion between the tasks of the regulatory competent authority (Afssaps), the medical practice and the antimicrobial surveillance systems (epidemiology), **the role of antimicrobial susceptibility devices** (which ensure reliable and reproducible results) **is obvious and vital.** Elaborate standards are used as a tool to improve these types of in vitro diagnostic medical devices.