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New Approach to Standardisation in the Internal Market

When talking about the Single Market, it should be mentioned that the New Approach and European standardisation have contributed significantly to its development. The facilitation of free movement of goods (healthcare included) between Member States comes as a consequence of the success achieving by the European standardisation system in removing technical barriers to trade.

With the removal of tariffs, the European Commission had to accept that non-tariff barriers to trade presented even more challenging obstacles for the Common Market. It was at this moment that the connection between economic and social policies became visible. Therefore, the elimination of non-tariff barriers to trade is not possible without having to intervene within the spectrum of social policies.

The evolution of the New Approach standardisation goes back to the 1969 Programme when trial to overcome different technical standards and regulations through vertical harmonisation proved to be a total failure; therefore, in 1985, the decisive New Approach to technical standards and regulations, was based on four horizontal principles:

Ó legislation was restricted to laying down mandatory requirements instead of detailed technical specification;

Ó the mandatory requirements were to be concretised by technical standards elaborated by European standardisation institutions;

Ó these technical standards were of a non-binding nature;

Ó compliance with the voluntary standards guaranteed free access to the internal market. Requirements for cooperation between the Commission and CEN/CENELEC were laid down in the 1984 Memorandum of Agreement while in 1989, the Council Resolution on the Global Approach to certification and testing made the following assessments :

ÓA consistent approach is developed in Community legislation by devising modules for the various phases of conformity assessment procedures, and by laying down criteria for the use of these procedures, for the designation of bodies operating these procedures, and for the use of the CE marking;

ÓThe use of European standards relating to quality assurance (EN ISO 9000 series), and to the requirements to be fulfilled by conformity assessment bodies operating quality assurance (EN 45000 series) is generalised;

Ó Setting up of accreditation systems and the use of inter-comparison techniques are promoted in Member States and at Community level;

Ó Mutual recognition agreements concerning testing and certification in the non-regulatory sphere are promoted;

ÓThe differences of existing quality infrastructures (such as calibration and metrology systems, testing laboratories, certification and inspection bodies, and accreditation bodies) between Member States and between industrial sectors are minimised by programmes;

Ó International trade between the Community and third countries is promoted by means of mutual recognition agreements, cooperation and technical assistance programmes.

Furthermore, the Commission and the Council started from the idea that a European product safety policy, based on strict product liability and voluntary technical standards elaborated under the New Approach, would suffice to balance out free trade and product safety. The adoption of the Product Safety Directive in 1992 can be understood as a partial failure of the original concept. It would then have been necessary to analyse the Product Safety Directive's impact on and inter-relationship with the New Approach. The Global Concept on Conformity Assessment must be understood as the counterpart to the New Approach. It guarantees access to the internal market and any conformity assessment involves a value judgment on product safety.

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