HOW TO IMPLEMENT THE NEW LEGISLATION ON HERBAL MEDICINAL PRODUCTS (HMPs) IN EUROPE?

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THE EUROPEAN MARKET OF HERBAL PRODUCTS IS HEAVILY SEGMENTED DUE TO MANY REASONS INCLUDING THE LACK, UNTIL RECENTLY, OF HARMONIZED COMMUNITY REGULATIONS.

IN THE PAST, SOME MEMBER STATES HAVE ADOPTED SIMPLIFIED NATIONAL PROCEDURES TO REGISTER MEDICINAL HERBAL PRODUCTS, WHEREAS IN OTHER MEMBER STATES HERBAL PRODUCTS HAVE CONTINUED TO BE MARKETED UNDER DIFFERENT COMMERCIAL CLASSIFICATIONS (E.G. FOOD SUPPLEMENTS, HERBAL REMEDIES OR OTHER PRODUCTS), GENERALLY IMPLYING A LESS STRICT REGULATORY CONTROL.

CONSIDERABLE UNCERTAINTIES HAVE ALSO BEEN REGISTERED, PARTICULARLY BEFORE THE ADOPTION OF THE REGULATION 258/1997/EC ON NOVEL FOODS, IN THE CLASSIFICATION OF PRODUCTS CONTAINING BIOLOGICALLY-OCCURRING SUBSTANCES EXTRACTED FROM HERBAL PRODUCTS AND ADMINISTERED AT MUCH HIGHER LEVELS AND OF OTHER HERBAL PRODUCTS DERIVED FROM POORLY KNOWN HERBS IN EUROPE.

IT IS NOT SURPRISING, THEREFORE, THAT DIFFICULTIES AND TENSIONS EXIST BECAUSE OF THE DIFFERENCES AMONG E.U. MEMBER STATES IN THEIR APPROACHES PARTICULARLY TO CLASSIFY SOME HERBAL PRODUCTS AS FOOD SUPPLEMENTS OR TRADITIONAL OR WELL ESTHABLISHED OR OTHER TYPES OF MEDICINAL PRODUCTS.

INDICATIVE IS THE RECENT COURT OF JUSTICE JUDGEMENT ON CONTROVERSIES CONCERNING SEVERAL PRODUCTS LEGALLY-MARKETED IN THE NL AS FOOD SUPPLEMENTS BUT CONSIDERED MEDICINAL PRODUCT IN DE BECAUSE THEY CONTAIN FAR TOO HIGH LEVELS OF VITAMINS (E.G. ABOUT 1000 MG OF VIT. C OR 268 MG VIT. E PER TABLET) OR PHARMACOLOGICALLY-ACTIVE NATURALLY OCCURRING SUBSTANCES (E.G. 50 MG OF BIOFLANOID EXTRACTS PER TABLET) OR BACTERIA (E.G. LACTOBACILLUS ACIDOPHILUS, BIFIDOBACTERIUM BIFIDUM, AND LACTOBACILLUS THERMOPHILUS) WIDELY USED IN GASTRO-ENTERIC MEDICINES.

HOWEVER, DURING THE YEARS 2002-2004, THE ADOPTION OF NEW COMMUNITY DIRECTIVES IN THE PHARMACEUTICAL AND FOOD SUPPLEMENTS SECTORS, HAVE MADE POSSIBLE TO MOVE FORWARD THE ACHIEVEMENT OF THE INTERNAL MARKET FOR HERBAL PRODUCTS (ALTHOUGH A TRANSITIONAL PERIOD OF SEVEN YEARS IS FORESEEN FOR PRODUCTS ALREADY ON THE MRKET ON 30 APRIL 2004).

WHEN THIS PROCESS WILL HAVE BEEN COMPLETED, IT WILL NOT BE ANY MORE POSSIBLE FOR A NUMBER OF IDENTICAL HERBAL PRODUCT OR FOR HERBAL PRODUCTS ONLY DIFFERRING FOR INSIGNIFICANT DETAILS (SO-CALLED BORDERLINE PRODUCTS) TO BE SOLD IN DIFFERENT MEMBER STATES (OR EVEN IN THE SAME MEMBER STATE) AS MEDICINAL PRODUCTS, HERBAL REMEDIES, FOOD SUPPLEMENTS OR OTHER PRODUCTS.

IN FACT, DIRECTIVE 2004/24/EC HAS INTRODUCED THE NEW CATEGORY OF TRADITIONAL HERBAL MEDICINAL PRODUCTS AND DIRECTIVE 2004/27/EC HAS MADE MORE CLEAR THE DEFINITION OF MEDICINAL PRODUCT BY PRESENTATION (AS APPLICABLE TO SUBSTANCES PRESENTED FOR TREATING OR PREVENTING DISEASES IN HUMAN BEINGS) AND OF MEDICINAL PRODUCT BY FUNCTION (AS APPLICABLE TO SUBSTANCES WHICH MAY BE ADMINISTERED TO HUMAN BEINGS TO RESTORING, CORRECTING OR MODIFYING PHYSIOLOGICAL FUNCTIONS BY EXERTING A PHARMACOLOGICAL, IMMUNOLOGICAL OR METABOLIC ACTION OR …….)" .

MOREOVER, IN CASE OF DOUBT, WHERE, TAKING INTO ACCOUNT ALL ITS CHARACTERISTICS, A PRODUCT MAY FALL WITHIN THE DEFINITION OF "A MEDICINAL PRODUCT" AND WITHIN THE DEFINITION OF PRODUCT COVERED BY OTHER COMMUNITY LEGISLATION, THE PROVISIONS OF DIRECTIVE 2004/27/EC (MEDICINAL PRODUCTS) SHALL APPLY.

THE REGULATORY HARMONIZATION PROCESS CONCERNING FOOD SUPPLEMENTS (DIRECTIVE 2002/46/EC), HOWEVER, HAS ONLY BEEN FOCUSSED SO FAR ON MINERALS AND VITAMINS. THEREFORE, OTHER SUBSTANCES WITH A NUTRITIONAL OR PHYSIOLOGICAL EFFECTS BEING USED AS FOOD SUPPLEMENTS ARE STILL BEING MARKETED UNDER NATIONAL REGULATIONS.

SUCH A DEVELOPMENT WILL MAKE POSSIBLE FOR A LARGER NUMBER OF PRODUCTS TO BENEFIT OF:

- A PRE-MARKETING CHECK, CARRIED OUT PRODUCT BY PRODUCT OF QUALITY AND SAFETY BY THE COMPETENT HEALTH AUTHORITY;
- APPROPRIATE LABELLINGS AND INFORMATION LEAFLETS TO ENSURE MORE EFFECTIVE CONSUMER'S INFORMATION;
- POT-MARKETING SURVEILLANCE AND REPORTING OF ALL SUSPECTED ADVERSE EVENTS BY COMPANIES HOLDING REGISTRATIONS.

IN VIEW OF THE SIGNIFICANT MARKET RE-ORGANIZATION EXPECTED IN RELATION TO THE ABOVE-MENTIONED DEVELOPMENTS, BOTH NATIONAL AND COMMUNITY INITIATIVES WITH THE PARTICIPATION OF ALL STAKEHOLDERS WILL BE NECESSARY.

AS FAR AS NATIONAL INITIATIVE ARE CONCERNED, SO FAR ONLY INITIATIVES FROM BELGIUM AND THE UK HAVE BEEN REGISTERED.

THE BELGIAN APPROACH TO REGULATE BORDERLINE PRODUCTS CONSISTS IN ONLY ALLOWING AS FOOD PRODUCTS SPECIFIC PARTS OF THE PLANT OR IN ADOPTING FOR SPECIFIC HERBAL PARTS MAXIMUM LIMITS FOR ACTIVE OR MARKER SUBSTANCES.

THE UK APPROACH TO REGULATE BORDERLINE PRODUCTS WILL CONSIST IN AMENDING THE EXEMPTION FROM THE REQUIREMENT FOR A LICENCE UNDER SECTION 12(2) OF THE RELEVANT ACT AND IN SUBMITTING MOST, IF NOT ALL, HERBAL REMEDIES SOLD OVER THE COUNTER IN THE UK TO REGISTRATION.

VERY IMPORTANT ON-GOING COMMUNITY ACTIONS TO FACILITATE THE INTERNAL MARKET ACHIEVEMENT FOR HERBAL PRODUCTS ARE AS FOLLOWS:

- PRODUCTION BY HMPC/EMEA OF COMMUNITY HERBAL MONOGRAPHS (TRADITIONAL AND WELL-ESTABLISHED PRODUCTS);
- PRODUCTION BY HMPC/EMEA OF THE LIST OF HERBAL SUBSTANCES, PREPARATIONS AND COMBINATIONS;
- DEFINITION BY THE EUROPEAN COMMISSION OF MAXIMUN LEVELS OF MINERALS AND VITAMINS IN FOOD SUPPLEMENTS.

MOREOVER, THE FOLLOWING ADDITIONAL COMMUNITY INITIATIVES WOULD BE HIGLY DESIRABLE TO GUIDE THE PRESENT PHASE:

- ESTABLISHMENT OF EUROPEAN COMMITTEE WITH REPRESENTATIVES OF THE EUROPEAN COMMISSION AND MEMBER STATES TO HARMONIZE CRITERIA TO DEAL WITH AND TO DECIDE ON BORDERLINE PRODUCTS ON A CASE BY CASE APPROACH;
- ADOPTION OF ADDITIONAL SPECIFIC RULES FOR FOOD SUPPLEMENTS INCLUDING A POSITIVE LISTING OF ALL SUBSTANCES WITH NUTRITIONAL OR PHYSIOLOGICAL EFFECTS.