The above decisions from TBA clearly took into consideration risk-related factors.

However, it seems that in G1/07 the position taken by EBA is more straightforward, and attaches more importance to the risks stemming from the application of the examined surgical method than ever before. Indeed, in this decision risk-related factors have been deliberately taken into account several times by the EBA, even in the final order. This did not happen in the previous TBA rulings.

Moreover, the risks which are relevant in G1/07 seem to be more objectively related to and stemming from the claimed method, and particularly its physical intervention on the body (without linking the risk factor with the involvement of practitioners). On the other hand, the previous cases heard by TBA linked the medical risk exclusively to the further issue of whether a medical or technical staff should be responsible for carrying out said processes: i.e., a subjective requirement. In other terms, by stressing that an invasive method involving a substantial health risk should be excluded from patentability without requiring the presence of medical staff, the EBA made such a risk requirement more “objective” (as opposed to the previous TBA decisions).

Such a change in EPO case law is probably also due to a previous opinion released by EBA itself in G1/04 (concerning *inter alia* the proper interpretation of the terms “diagnostic methods”). In this opinion it was held *inter alia* that whether or not a diagnostic method should be excluded from patentability may not depend on the participation of a medical or veterinary practitioner. This is because (i) it is difficult (if not impossible) to provide a definition of medical or veterinary practitioner in Europe within the framework of EPC and (ii) therefore for reasons of legal certainty the European patent grant procedure may not be rendered dependent on the involvement of such practitioners. This appears to be correct, as the exclusion at issue refers to the method, and not to the individual carrying out such method. Likewise, risk factors are related to medical methods as such, not to the further issue of whether medical or technical staff should participate and be responsible for carrying out these processes.

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7 Yet the EBA decision added that surgical methods such as the one described in the patent application is excluded from patentability if it also requires professional medical expertise to be carried out.

8 G1/04, OJ EPO 2006 (Reason No 6.1).
The main rationale for creating a specific regulatory framework for THMP was the need to overcome difficulties encountered by Member States in applying the pharmaceutical legislation to herbal medicinal products in the same way. That is why a specific registration procedure for THMP was introduced in the Directive 2001/83/EC\(^2\) by Directive 2004/24/EC\(^3\) (Articles 16a to 16i).

The above deadline was set by Article 2(2) of the Directive 2004/24/EC which specifies that national competent authorities shall apply its provisions within seven years after its entry into force. The legislative provision is applicable only to those THMP which were already on the market at the time of its entry into force.

It is also worth underlining that Directive 2004/24/EC allows non-medicinal herbal products that meet the criteria of food legislation to be regulated under food legislation in the European Union\(^4\). However, the supremacy of the regulatory regime for medicinal products (including THMP) over all the other regulatory regimes is a well-established principle. This brings as a consequence that unless a product clearly fulfils the definition of food, it will fall into the pharmaceutical legislation regime; this will also apply in “borderline” cases pursuant to Article 2(2) of the Directive 2001/83/EC. Indeed, this provision states that, in cases of doubt where a product may fall within the definition of either a “medicinal product” or a product like food, cosmetic, medical device that is covered by other EU legislation (related to food\(^5\), cosmetics\(^6\), medical devices\(^7\)), such a product will be subject to the provisions of the 2001 Directive.

It should be noted that THMP can be considered a species of the genus medicinal products whose definition is contained in the Directive 2004/24/EC.

THMP are defined as herbal medicinal products\(^8\) that fulfil the following conditions\(^9\):

- they have indications appropriate exclusively to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;
- they are exclusively for administration in accordance with a specified strength and posology;
- they are an oral, external and/or inhalation preparation;
- the period of traditional use\(^10\) has elapsed;
- the data on the traditional use of the medicinal product are sufficient; in particular the product must prove not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

It follows that other traditional products that do not fall under the scope of this definition are not subject to the provisions of the Directive either.

The simplified registration procedure is intended for herbal medicinal products with a long tradition but which do not fulfil the requirements for a marketing authorisation. In particular they do not meet those requirements whereby an applicant can demonstrate by detailed references to published scientific literature that the constituent (or, if applicable, the multiple constituents) of the medicinal product has a well-established medicinal use with recognised efficacy and acceptable level of safety. This simplified procedure allows the registration of herbal medicinal products without requiring particulars and documents on test and trials on safety.
and efficacy\textsuperscript{11}, provided that there is sufficient evidence of the medicinal use of the products throughout a period of at least 30 years, including at least 15 years in the EU.\textsuperscript{12} The above could be demonstrated in different ways, such as statements/testimonials made by physicians, pharmacists or other sources of knowledge.

The presence in the herbal medicinal product of vitamins or minerals on the safety of which there is well-documented evidence will not prevent the product from being eligible for THMP registration, provided that the action of the vitamins or minerals is ancillary to that of the herbal active ingredients regarding the specified claimed indication. However, in cases where the competent authorities judge that a traditional herbal medicinal product fulfils the criteria for authorisation in accordance with Article 6 of the Directive 2001/83/EC (full authorisation procedure) or registration pursuant to Article 14 of the Directive 2001/83/EC (simplified registration procedure for homeopathic medicinal products), the provisions related to the simplified THMP procedure shall not apply\textsuperscript{13}.

Classification of a certain product as THMP will determine whether the harmonisation deadline imposed by Article 2(2) of the Directive 2004/24/EC will apply.

Yet it is still possible that differences will continue to exist between Member States in the classification of products as medicinal products or foodstuffs. Some Member States may consider a product is a medicinal product, while the others may take a view that according to current scientific knowledge, this classification has not been proved\textsuperscript{14}.

A product which constitutes medicinal product within the meaning of Directive 2001/83 may be imported into another Member State only upon acquisition of a marketing authorisation, even where it is lawfully marketed as a foodstuff in another Member State.\textsuperscript{15} This consideration makes the borderline issues between medicinal products and food extremely relevant for the application of the appropriate regulatory framework. The borderline between medicinal products and foodstuffs is to some extent controlled by the limitations on the sort of health claims that can be made for them, and by the fact that Article 2(d) of Regulation (EC) 178/2002\textsuperscript{16} expressly excludes medicinal products from the definition of food.

In applying the definition of ‘medicinal product’, Member States must take account of the results of international scientific research and, in particular, the work of specialised Community committees which advise the Commission on such matters.\textsuperscript{17} However, it should be emphasised that the opinions of such committees do not have any binding force, so they cannot abrogate the responsibility of national authorities for the protection of health in the absence of binding rules and effective supervisory measures at the community level\textsuperscript{18}. Furthermore, no legislation requires Member States to consult such committees before taking a decision concerning a particular product.\textsuperscript{19}

Bearing in mind the differences in classification across Member States, it is not possible to assume a priori that all traditional products will be classified as THMP. With awareness of substantial differences across Member States as far as classification of different goods as medicinal products is concerned, the correct transposition of Directive 2004/24/EC into national legislative systems and the policing of the application of its provisions are critical factors. The vast majority of products affected by the end of the transitional period will be products currently existing on the market outside the scope of the pharmaceutical regime, and there is no obvious interest on the part of producers to re-classify them as THMP. Products for which a big effort has been made to obtain authorisations as herbal medicinal products or “well-established use” medicinal products (before the provisions of Directive 2004/24/EC entered into force) will most probably retain their current au-

\begin{parnotes}
\textsuperscript{11} Standard requirements are described in Article 8 of the Directive 2001/83/EC, while Article 16c describes specific documental requirements for THMP registration.
\textsuperscript{12} Please see Article 16c(1)(c) of the Directive 2001/83/EC.
\textsuperscript{13} Please see Article 16a(2) and (3) of the Directive 2001/83/EC.
\textsuperscript{14} HLH Warenvertrieb and Orthica, para. 56; Commission v. Germany, “Garlic preparation”, para. 37; Hecht-Pharma, “Red Rice”, para. 28; Delattre, paras. 27–29; Commission v. Austria, paras. 59–60; Commission v. Germany, C-387/99, paras. 52–53; Laboratories Sargent of 12 March 1998, C-270/96, para. 23; Monteil and Samanni, para. 28.
\textsuperscript{15} HLH Warenvertrieb and Orthica, para. 60.
\textsuperscript{17} Motte of 10 December 1985, Case 247/84, paras. 20, 24; Delattre, paras. 31–32.
\textsuperscript{18} Motte, para. 20.
\textsuperscript{19} Delattre, paras. 31–32.
\end{parnotes}
thorisation status, as the latter requires higher criteria than those envisaged for THMP. However the remaining question is to what extent other products currently outside pharmaceutical regime yet at the same time fulfilling criteria for THMP definition will be voluntarily switched to the THMP category. Therefore policing the proper application of Article 2(2) of Directive 2004/24/EC by national pharmaceutical inspection authorities and/or by the European Commission may become an issue that determines the achievement of the intended harmonisation.

Given all the above, the Management Board of the European Medicines Agency has endorsed a number of actions aimed at improving the availability of herbal medicines in Europe, and emphasised the importance of coordinated actions within the European medicines regulatory network. This is in view of the April 2011 deadline, which marks the end of the transition period for Member States to apply provisions of Directive 2004/24/EC to traditional herbal medicinal products on the national markets.

However, it has to be underlined that the obligation set out in Article 2(2) of the Directive 2004/24/EC is addressed to Member States, therefore the European Medicines Agency and its Committee on Herbal Medicinal Products (HMPC) could only serve as platform for discussion and exchange of views and experiences associated with this exercise.

### Risk Communication

This section discusses issues related to risk communication across a range of publicly perceived high-risk industries (such as pharmaceuticals, nuclear, oil, etc.). It reports critically and provides analysis on risk communication as an outcome of risk research within these industries. Contributions are intended to include methods working towards the advancement of risk perception research and describe any lessons learned for successfully communicating to the public about risk.

### Regulatory Transparency:

Forthcoming Lessons from the FDA

Sweta Chakraborty and Ragnar E. Lofstedt*

Over the past ten years or so there has been a move from consensual style regulation to a new more participatory-transparent model in many parts of Europe and North America. This move may be primarily attributed to an erosion of public trust brought forth mainly through the sheer number of regulatory scandals ranging from MMR in the UK and Cox-2s in the US, the risks of which have been further amplified by the media. This has led to a new model of regulation that is more deliberative and transparent than its predecessor.

Arguably, the key component to this model is ensuring that the policy-making process is as transparent as possible. This includes: placing policy deliberations on the internet; making public correspondence between policy makers, the public, and lobbyists; having industry share information on pollution, clinical trials and other safety related data on the internet; and encouraging scientists to debate scientific uncertainties in public. It is difficult to disagree with this. Many of the past regulatory scandals came to fruition primarily because the regulatory policy-making process was non-transparent, with decisions made behind closed doors, and

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