Awareness regarding the importance of evaluating medicinal products before allowing them to be sold in the market was reached at different times in different countries. While the United States implemented appraisals in the 1930s under the Food and Drug Administration, most other countries including the majority of Europe awakened only after the thalidomide tragedy of the 1960s. The next few years witnessed a rapid progress in laws, regulations and guidelines for reporting and evaluating the data on the safety, quality and efficacy of new and existing medicinal products. The pharmaceutical industry at this time was reaching out to global markets but paradoxically the registration of medicines still remained the responsibility of individual countries. This led to duplication of time-consuming and expensive test procedures despite the fact that the fundamental obligations of each country to evaluate the quality, safety and efficacy of drugs were based on similar tenets. The European Community (now the European Union) was the first to realize the need to correct this disparity in order to lessen the delay in making safe and efficacious new treatments available to patients.

The EMEA (European Medicines Evaluation Agency) was established by the European Council of Ministers in July 1993. The agency is the centralized pharmaceutical regulatory body of the EU, responsible for “coordinating scientific resources existing in member states, with a view to evaluating and supervising medicinal products for both human and veterinary use.” The agency is primarily responsible for the scientific evaluation of applications for granting European marketing authorization to medicinal products. The website of the agency (www.emea.eu.int) does much more than impart information about the agency and its activities; it provides for an effective interface with health professionals, scientists and those with marketing interests.

The various links in the web page go on to inform that the EMEA comprises a management board; committees responsible for preparing opinions on medicinal products for human use—Committee for Proprietary Medicinal Products (CPMP), veterinary use (CVMP) and the designation of ‘orphan drugs’ status (COMP); and a secretariat responsible for coordinating pre and post-authorization evaluation of human and veterinary medicines. The work is coordinated by a network of more than 3000 European experts and associated scientific resources. The EMEA is also building and coordinating a new Europe-wide drug safety database, called EudraVigilance, which will enable the electronic exchange of individual case safety reports (ICSRs). Initiatives such as the Pan-European Regulatory Forum (PERF) have been set up to help individual countries prepare their regulatory submissions before their accession to the EU based on good manufacturing practices, pharmacovigilance and quality manage-
The Quality Review of Documents (QRD) templates are available for referencing various products based on these guidelines. A perusal of these provides an insight into the conventions that are followed in submitting pharmaceutical products for approval.

The links on human and veterinary medicines lead on to various sub-topics that explore diverse subjects such as bioterrorism, gene therapy, orphan products, pharmacovigilance, herbal products and many other technical and commercial topics. These summaries are linked to documents which provide the latest guidelines for use of important drugs. The user-friendliness of the web pages is further enhanced by the presence of “Fast Track to Favorites” and many other thoughtful links. The page on General Reporting gives information on press releases, notable news, documentation, publishing, standard operating procedures and administrative aspects of the agency. Given the diverse nature of the site a good place to begin would be the “Using our website” link or the hyperlinked “Site map”. Navigation throughout the site is easy but the search facility spews up a number of non-specific results.

The wealth of content on pharmaceutical issues and the ease of navigation makes this site a must-see for anyone interested in learning more about the numerous aspects of appraisal of medicines, the status of medicinal products derived from biotechnology, current pharmacovigilance issues, and for those interested in marketing their medicinal products in Europe.

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INDIAN PHARMACOLOGICAL SOCIETY

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