

PREFACE

The nature of drugs that are approved for use in clinical practice has changed dramatically in past years. Currently, more than one third of new drugs introduced for use in hospitals are produced by biotechnological technology based on genetic engineering.

Crommelin has described this change as a *paradigm shift*: the traditional approach to evaluating a drug has fundamentally changed and completely different areas of knowledge have had to be developed to evaluate the real intrinsic values and adverse effects of this new type of drugs (Chapter 2).

In addition, the regulatory environment has changed. All biotechnology drugs approved in Europe are done so centrally by EMEA, with transparency and quality in the evaluation that are a great benefit. The public assessment reports, available from the EMEA website when a new drug is licensed, are a great asset and should be compulsory reading for every hospital pharmacist dealing with these products - in fact for dealing with any new drug, whether biotechnological or traditional.

Further complicating the landscape are the follow-on products that are coming onto the market as patents on the original products expire. Due to the complicated production systems, these follow-on products, apart from the simple ones like insulin and calcitonin, are not identical and are called biosimilars. They are supposed to behave similarly in a biological environment, e.g. in patients. But, paraphrasing George Orwell, some are more equal than others, and how can we tell which they are?

The *European Journal of Hospital Pharmacy* (EJHP) has taken the initiative to start a series of around 20 papers, highlighting all relevant aspects of the class of biopharmaceutical drugs, from chemistry to nomenclature via immunogenicity to risk management. We deemed it to be useful to collect these papers, published in *EJHP Practice* in the course of 2006-2007, into a single volume, to assist the hospital pharmacist in evaluating these products.

To further facilitate this process, a checklist has been compiled with all factors that should be taken into consideration when evaluating a biopharmaceutical drug (Chapter 5), whether it be an innovator product or a biosimilar. We hope that with this volume we support the hospital Pharmacy and Therapeutic Committees in their task of making difficult decisions and of making this process more transparent.

We wish to thank all the authors for their effort and inspiration in completing this volume. Without the relentless support of Ms Lasia Tang, EJHP Publisher, and her team, this volume would not have been possible and we are grateful for her enthusiastic and indispensable help.

We welcome suggestions for additional papers on this topic in the *European Journal of Hospital Pharmacy Practice*, a unique educational platform for all European hospital pharmacists.

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