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Commentary

The Pharmaceutical Sciences in 2020: Report of a Conference Organized by the Board of Pharmaceutical Sciences of the International Pharmaceutical Federation (FIP)

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Abstract. The Board of Pharmaceutical Sciences (BPS) of the International Pharmaceutical Federation (FIP) has developed a view on the future of pharmaceutical sciences in 2020. This followed an international conference with invited participants from various fields (academicians, scientists, regulators, industrialists, venture capitalists) who shared their views on the forces that might determine how the pharmaceutical sciences will look in 2020. The commentary here provides a summary of major research activities that will drive drug discovery and development, enabling technologies for pharmaceutical sciences, paradigm shifts in drug discovery, development and regulations, and changes in education to meet the demands of academia, industry and regulatory institutions for pharmaceutical sciences in 2020.

KEY WORDS: Pharmaceutical Sciences in 2020.

INTRODUCTION

In 2007, the Board of Pharmaceutical Sciences (BPS) of the International Pharmaceutical Federation (FIP) launched a process to develop a view on *The Pharmaceutical Sciences in* 2020. In projecting forward, the Board posed four questions:

- What major research activities will drive drug discovery and development?
- What will the enabling technologies be?
- What paradigm shifts will there be in drug discovery, development, regulation and usage?
- How will changes in education meet the demands of academia, industry and regulatory institutions?

These issues were discussed at an international conference convened in Amsterdam in 2008 (1) with participants from a broad spectrum of backgrounds (scientists, venture capitalists, industrialists, regulators—see Electronic supplementary material, list of conference participants). A series of plenary lectures provided a basis for further discussion within small groups, each chaired by an experienced pharmaceutical scientist. While considerations of what is practical and affordable were acknowledged, the participants were encouraged to be wide-ranging and bold in their projections. The results of the deliberations of the groups were presented by the chairs in open forum on the final day of the conference and are summarised here.

MAJOR RESEARCH ACTIVITIES THAT WILL DRIVE DRUG DISCOVERY AND DEVELOPMENT

Consistent with its breadth, pharmaceutical science will continue to feed off research and innovation in many adjacent fields, especially in relation to target identification, systems biology, *in vitro*/*in silico* prediction of pharmacokinetics, pharmacodynamics and toxicology, bioengineering/materials science/nanotechnology, personalized medicine, information technology/bioinformatics and research at interfaces.

Approaches to identifying new targets based on the use of disease models, genomic information and RNA-DNA-based approaches will mature. More attention will be given to polypharmacology, the principle of targeting multiple sites of action at the same time, active immunotherapy and targets for neglected and emerging diseases.

The trend towards moving away from a reductionist to a more holistic approach in understanding pharmacology is likely to continue with the belated realisation that "omics" as such are not the solution to everything but should be incorporated into a fuller mechanistic and quantitative appreciation of biological systems. This will fuel a re-emphasis on understanding function, extending into the renaissance of clinical pharmacology within translational research.

Significant advances that have been made in the mechanistic prediction of pharmacokinetic behaviour based on the use of human *in vitro* systems and computer modelling will be extended into pharmacodynamics and, particularly, toxicology (driven by the pressure to reduce animal experimentation).

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The interface between formulation science and engineering will continue to be at the frontier of new product development, with applications extending ever further into targeted delivery and monitoring—although the cost-benefit of such developments is difficult to anticipate.

While the promise of personalised medicine has been elusive, it is anticipated that with an increasing recognition that environmental, behavioural and social influences as well as genetics are important components of drug response, there will be a more realistic, evidence-based application of pharmacogenetics in the future, supported by economic analysis of its value.

Alongside developments in computer technology, there will be an increasing need to make better use of latent and forgotten information and literature. This will facilitate not only basic research in linking up pieces of information, but will also provide the broad information base required to deliver personalised healthcare to patients.

In as much as innovation flourishes where research cultures meet, the boundaries between the three Ds (diagnostics, drugs and devices) will blur.

ENABLING TECHNOLOGIES FOR PHARMACEUTICAL SCIENCES IN 2020

In order to deliver the research outlined above, it is envisaged that significant developments will occur in key technologies.

Ultrafast computing will be facilitated by a move from silicon-based to other forms of microprocessor technology (biological and photon-based systems). Future software will rapidly make it possible to visualise increasingly complex, data-rich, dynamic systems, allowing realistic, real-time predictions at molecular, cell, organ, whole body and societal levels, as well as the creation of increasingly sophisticated virtual realities. Furthermore, cheap, ultrafast access to and transmission of huge amounts of information and databases will be possible. These and other developments will continue to transform personal interactions and education.

Stem cells and other techniques in regenerative medicine have the potential to radically alter the treatment of major diseases, such as cancer and neurodegenerative disorders. If they deliver within the next decade, they could lead both to a significant decrease in the use of some classes of drugs as well as the opening of new avenues for the use of pharmaceuticals. Developments in this area are likely to have a major impact on disease modelling and drug screening.

Increases in the ability to follow levels of drugs and biomarkers by non-invasive imaging in all parts of the body and even within single cells will add huge value to the application of pharmacokinetic and pharmacodynamic modelling, toxicological assessment and translational medicine.

Engineering technologies that allow miniaturisation will emerge increasingly from the realms of science fiction into reality with the exciting potential for the application of nanotechnology (nanobots/chips/smart membranes/nanoshells) in drug delivery and the pervasive, real-time monitoring of compliance/adherence to treatment (pharmionics), diagnosis and drug safety/efficacy.

Economic considerations will continue to drive the development of increasingly sophisticated robotic systems, particularly in the areas of iterative organic synthesis, compound screening procedures and oversight of manufacturing processes.

Enhanced and pervasive information technology for sharing knowledge will enable much more efficient transfer and sharing of pre-competitive data and information. It is likely that a growing "non-silo R & D mentality" will emerge, resulting in large, multidisciplinary, web-based research information networks aiming to minimise duplication and, thereby, facilitate drug design and development (*e.g.* caBIG—cancer Biomedical Informatics Grid; https://cabig.nci.nih.gov). The semantic web will extend the process of automated information gathering to intelligent sorting and interpretation.

PARADIGM SHIFTS IN DRUG DISCOVERY, DEVELOPMENT AND REGULATION IN PHARMACEUTICAL SCIENCES BY 2020

The blockbuster business model for drug discovery and development is unlikely to be sustainable as increased R & D costs are coupled with a disproportionately lower financial yield from new pharmaceutical products. In the future, the arsenal of new drugs is expected to comprise a larger number of high value, niche agents tailored more closely to individual patient needs and each associated with smaller sales.

While Big Pharma will continue to hold a dominant position in clinical drug development and marketing, academia and SMEs (Small-to-Medium Enterprises) are likely to have more prominent roles in discovery and, along with CROs (Contract Research Organisations), in pre-clinical development and the establishment of generic technology platforms. Public-private partnerships will be an established model bridging the gap between industrial and academic research. Pharma will realign from a product to a healthcare management focus with greater integration of diagnostics, drugs and devices and more emphasis on preventative and lifestyle medicine. The diagnostics-drug-device paradigm is illustrated by the combination of cholesterol monitoring—use of statins and insertion of drug-eluting stents.

As a result of healthcare cost containment policies and other related trends, R & D plans will incorporate third-party willingness to pay, and, thereby, pharmacoeconomic assessment will be further incorporated into medicine regulation. This may lead to the wider implementation of new models, such as the "no cure—no pay" or "payment for outcomes" approaches, providing that agreement can be reached on appropriate end-points. It is not yet clear what impact this type of model will have on incremental innovation

Incentives for developing treatments for neglected diseases will be increased by the establishment of public-private-development partnerships involving collaboration between companies, governments, academia and charitable and non-profit organisations

Economic constraints on the development of medicines will tend to drive a more holistic and socially oriented view of R & D. Not only will this be reflected in the development of new remedies, but there will be increasing recognition of the need to provide better education of prescribers and patients in the safe and effective use of existing drugs in an attempt to reduce the significant burden on health services associated with inappropriate drug and dosage selection.

Successful development and registration of biologicals has begun to outpace that of small molecules, especially in the area of oncology. However, considerable investment in the discovery of products based on small molecules will continue, especially in areas such as CNS pharmacology. Biosimilars will become increasingly important with respect to pharmaceutical development and usage.

An aging population will lead to an increased demand for health care along with more complex treatment and the use of polypharmacy. Markets for pharmaceuticals will expand with the projected emergence of middle classes in countries such as India and China. In addition, the growth of drug discovery and development is likely to increase in these areas as multinational companies seek to increase the globalisation of their operations and opportunities.

Universal access to medicines will be a crucial issue in the context of the existing system of protection of intellectual property rights. The WHO global strategy and plan of action on public health, innovation and intellectual property may have a dramatic impact on the global availability of medicines and drivers of innovation.

The increasing regulatory burden has contributed to prolonged drug development times and a decline in the marketing of innovative new drugs. This will require more creative thinking on the part of industry and regulatory authorities to reward innovation while maintaining safety standards for therapies as demanded by society.

Barriers between the different traditional phases of drug discovery and development will blur (e.g. post-marketing surveillance will be integrated with Phase III studies), and there will be a need for more advanced pharmacovigilance systems that interrogate efficacy as well as safety.

Regulatory bodies will be asked to increase the transparency of the decision-making process. They may develop and implement ideas for shorter pre-market and longer post-market periods of new drug evaluation in selected therapeutic areas. To this end, new ways of managing uncertainty and better methods to detect potential risk earlier will be developed. These trends are illustrated by initiatives such as the "Critical Path" in the US (2) and the follow-up of the "EMEA Roadmap to 2010" in Europe (3), although their impact is as yet hard to predict.

There will be increased pressure to combine (some of) the regulatory requirements on a global basis. Trends to harmonise national and international standards, as well as marketing approval procedures, will continue and have increasing impact. Globally accepted quality standards may be developed in the future. However, this will not necessarily imply a universal quality standard. Quality should be considered in terms of a modular system, where features and standards can be added at a national level to a generic framework.

CHANGES IN EDUCATION TO MEET THE DEMANDS OF ACADEMIA, INDUSTRY AND REGULATORY INSTITUTIONS

In order to accommodate projected changes in the pharmaceutical sciences, the training of the workforce will be of paramount importance, with significant implications for both undergraduate and graduate teaching and the development of interdisciplinary education, transnational and life-long learning programmes. The best educational programmes will be very different from today, reflecting the rapid changes in and application of new knowledge from advances in (molecular) biology, materials sciences and informatics and new ways of teaching and learning based on advanced information and computer technology. There will also be a need for strong, socially aware components. Many academic institutions need to increase their recognition (at high levels) of the role that drug development plays in their national economies, and to focus on courses that service this function. The most successful academic groups will have critical mass, proven quality (through track record and open, high quality peer review) and will conduct their communication in English.

It is questionable whether many Schools of Pharmacy will adapt their curricula or be able to recruit and retain staff to meet the diversity of the educational needs in the pharmaceutical sciences. At the undergraduate level, there is a concern that the pull towards more clinically based programmes may be at the expense of underpinning science. At the graduate level, the primary backgrounds of students will be more diverse, reflecting the need for interdisciplinary research manifesting as increasing interaction with engineering, materials science and bioinformatics.

The pedagogic format will continue to move away from large class lectures and laboratory classes to focus on small group teaching, problem solving tutorials and computer-assisted learning. Distance learning, transnational programmes, peripatetic teaching and virtual universities should increasingly facilitate the training and continuing professional development.

There are likely to be specific shortages in the labour market. For example, currently, it is difficult to recruit high level PK-PD modellers. Ways to address this include the attraction of individuals with engineering backgrounds and the establishment of distance learning courses that cater both to deficiencies in mathematical skills in many biological scientists and deficiencies in understanding of biology and the drug development process in those coming from engineering and statistics backgrounds.

CONCLUSIONS

Significant shifts in pharmaceutical research, in pharmaceutical business models, and in regulatory approaches are envisioned by the year 2020.

- Globally operating companies increasingly will buy in technologies/concepts for new drugs from small private enterprises and the academic world. Product development will be coordinated by these global players. Major activities will be outsourced to specialized companies and institutions. Quality of the work and speed will be decisive factors for success.
- Regulatory authorities will be more transparent in their decision-making process, and global harmonization will grow.
- Future therapeutic interventions will use new tools provided by new enabling technologies. The paradigm of individualized medicine will be accepted as

standard in many therapeutic fields, and the borderlines between diagnostics, drugs and medical devices will blur.

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