

From Making Medicines to Optimising Outcomes:

The evolution of a profession 1912-2012

Fédération
Internationale
Pharmaceutique

International
Pharmaceutical
Federation



1912 · 2012
100 YEARS OF
ADVANCING
PHARMACY
WORLDWIDE





CONTENTS

Summary	04
Introduction	09
The origins of pharmacy	12
Nineteenth century achievements	
An increasingly regulated environment	
FIP and the world in 1912	
Pharmacy in the twentieth century	23
Demographic change and human development	
Health service development	
Regulating the pharmaceutical sector	
<i>Pharmacy controls</i>	
The influence of the pharmaceutical industry	
The changing face of community pharmacy	
<i>Changing the face of pharmacy in Russia and Central and eastern Europe</i>	
<i>US and Canadian experience of pharmacy change</i>	
<i>Change in France and Germany</i>	
<i>Pharmacy development in the Netherlands</i>	
<i>Community pharmacy reforms in the UK</i>	
<i>The changing face of pharmacy in Brazil</i>	
<i>Nigerian pharmacy development</i>	
<i>The face of community pharmacy in India and China</i>	
<i>Japan's experience of pharmacy adaptation</i>	
Hospital pharmacy: growth and challenges	
<i>Professional leadership</i>	
Opportunities for better health	56
Improving access to medicines	
Improving the professional use of medicines	
Improving medicines taking	
Pharmaceutical sector re-regulation?	
Supporting pharmaceutical innovation while reducing avoidable costs and waste	
Preventing counterfeiting	
Optimising medicines safety and use in hospitals	
Improving medicine, nursing and pharmacy in the community	
Enhancing self-care and protecting public health	
Conclusions	74
References	78
Appendix 1: Contributors and methods	80
Appendix 2: An illustrative timeline of pharmaceutical developments (1800-2012)	82

SUMMARY

- The hundred years since the establishment of the Fédération Internationale Pharmaceutique (FIP) in the Netherlands in 1912 have seen fundamental changes in world health. Globally, average life expectancy at birth has increased by over 25 years, from under 40 to about 65 years. Mortality declines have been most dramatic amongst infants and children. Birth rates have also fallen world-wide. Yet it will take another century for the growth in world population to end and the (health care) transition process to be completed.
- As communities develop their populations age and the prevalence of non-communicable disorders such as vascular diseases, type II diabetes and cancers (NCDs) rises. Modern pharmaceuticals have to date played an important yet limited part in world health improvement. But as people increasingly value and seek active ageing pharmaceutical care will become more important, along with healthy lifestyles.
- During the 20th century pharmacists lost their role as the developers and makers of medicines to the pharmaceutical industry. The volume of prescription medicine dispensing undertaken by pharmacists also increased greatly in many countries. Such trends changed the nature of pharmacists' relationships with doctors and the public.
- Pharmacy is continuing to evolve and to make important new contributions to health and to safe and effective medicines use. Its strategic aims as a global health profession relate to ensuring that all pharmaceutical products are used to optimal effect, and completing the world-wide processes of demographic, epidemiological and care transition.
- In poor nations pharmacy's current priorities centre on facilitating better access to good quality medicines and the cost effective provision of the support needed to use them well. World-wide, the profession has a role to play in enabling individuals and populations to enjoy improved levels of health and ability at every life stage.
- Delivering the promise of healthy, disease free, ageing will be important for the future of pharmacy. By 2100 the ratio of elderly people to children will, world-wide, have increased by a factor of about ten as compared with when FIP was first established. But this need not impose unaffordably increased health care costs. If pharmacy services are developed appropriately it could lead to ongoing gains in *per capita* productivity.

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- Specific tasks for 21st century pharmacists range from ensuring that antibiotics, anti-virals and anti-malarials are used rationally, through to wherever possible preventing conditions like cancers, diabetes and strokes.
 - There is evidence from the Netherlands and elsewhere that good pharmaceutical care avoids needless hospital admissions amongst people with non-communicable (and other) conditions. Pharmacy led research in areas such as HIV/AIDs has also shown that improved adherence in medicines taking contributes to better outcomes.
 - Managing medication programmes more effectively and helping people overcome medicines taking problems in ways that enhance self care also reduces waste and promotes health. There is evidence that using medicines to better effect might lead to annual cost reductions and welfare gains that, if fully realised, would be comparable in value to total medicines spending in the US or Europe (that is, up to SUS 500 billion).
 - Pharmacists are developing new relationships with doctors, nurses and the public. In countries such as the US, Canada, the UK, Sweden and France they are already positioned to contribute to clinical care directly and to enhance doctors' and the public's use of medicines. But in other parts of the world this is not as yet the case.
 - Even within Europe there are major historically determined differences in the roles and numbers of pharmacists working in hospitals and the community. For example, in Germany there are (relative to bed numbers) less than half the hospital pharmacists found in nations such as Finland. Likewise in countries such as Greece, Spain and Italy there are currently well over twice the number of community pharmacies (relative to population) found in Denmark, Sweden or the Netherlands.
 - FIP has raised global awareness of the benefits of developing hospital pharmacy, and of extending community pharmacy services. There are also opportunities for pharmacists to build new relationships with pharmaceutical companies, and to combine supplying mature medicines at a minimum sustainable cost with helping to ensure that new medicines development is considered in a cost-benefit model from a global public interest perspective.
 - Recent developments in countries ranging from Brazil to China, India and Turkey highlight the parts pharmacists can play in areas such as supporting the appropriate use of traditional



medicines (which remain commonly used by over half the world's population) and improving the supply of modern treatments to communities in need of them. In countries such as Nigeria pharmacy leadership has also helped to prevent medicines falsification and enhance drug quality.

- Future trends towards the automation of dispensing could, with other developments, free pharmacists to take on further extended health care roles. This might threaten the historical separation of pharmacy from medicine. But approached positively it may allow economically sustainable service provision in ways that meet evolving consumer preferences, and in practice strengthen pharmacists' abilities to validate and where possible to improve doctor and nurse led medicines use.
- FIP has through its partnerships with the WHO and other leading bodies raised the profile of pharmacy as an ethical, evidence and value led, profession committed to global health improvement. It has also made important contributions – through, for example, the Pharmacy Education Taskforce – to the development of pharmacy education and pharmacists' understanding of the social determinants of effective medicines use.
- The Federation's achievements between 1912 and 2012 provide a foundation for continuing to adapt pharmacy's relationships with the medical profession, other health care providers and medicines users. Its future work should help health policy makers understand the potential for pharmacy to continue evolving in ways that will improve the cost effectiveness of primary and secondary health care throughout the world.
- However, no profession or business can safely regard its long term survival as assured. FIP also needs to raise awareness of threats, including the danger that poorly planned attempts to generate short term financial savings could – if they were to stop pharmacists from being able to deliver anything more than a basic drug supply service – deprive communities across the world of significant long term benefits.
- History indicates that to continue being relevant to 21st century needs, pharmacists must offer timely and economic ways of solving contemporary health problems and go on attracting public and political support. Pharmacy's ongoing success will – as with all professional trades – ultimately depend on its members' abilities to recognise and publicly communicate that what matters most to them is preserving the lives and optimising the wellbeing of the people and populations they have the privilege to serve.



FROM MAKING MEDICINES TO OPTIMISING OUTCOMES: THE EVOLUTION OF A PROFESSION 1912-2012

A report on Pharmacy, Pharmaceuticals and Global Health, commissioned by FIP and prepared by the UCL School of Pharmacy on the occasion of the Federation's Centennial Congress, 3-8th October 2012

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INTRODUCTION

The last hundred years have seen dramatic improvements in world health, including the successful control of many forms of infectious disease and major declines in infant, child and maternal mortality. Global life expectancy at birth, taking survival in poorer and richer populations together, increased from under 40 years in the first decade of the twentieth century to some 65 years today. In the economically most advanced countries average life expectancy for men and women at birth is now about 80 years.

The population ageing associated with such developments has been accompanied by a rising overall prevalence of non-communicable conditions, such as the vascular diseases and type II diabetes. In emergent economies like, for example, India, Mexico and Turkey, the incidence of the latter is now rising as fast or faster than it is in the US and Europe. However, in age specific mortality terms nearly all communities are healthier than ever before. The main motors of this success have been improvements in food supply, sanitation and access to good quality water, coupled with – especially in the second half of the twentieth century – more effective pharmaceutical products and better surgical care. Local exceptions to this pattern are most likely to relate to problems such as alcohol and other forms of ‘social drug’ abuse, or the exceptional challenges associated with HIV infection in some communities.

Better medicines supply has depended in large part on community and hospital pharmacy services. Even so, it remains the case that the poorest third of the world’s people do not yet have adequate (or in some instances any) access to modern pharmaceuticals. The available data also suggest that in the order of 50 per cent of the world’s people are still predominately reliant on traditional herbal and allied treatments when they fall ill (Zhang, 1999; Heinrich, 2012). Traditional remedies help relieve distress and can offer a foundation upon which to build progressively more effective health services. Yet such figures highlight the world-wide scale of the future pharmaceutical care improvements still to be achieved.

Against this background, this report marks the Centennial year of the Fédération Internationale Pharmaceutique (FIP, or International Pharmaceutical Federation), the global body for three million members of the world-wide pharmacy profession. FIP was first established in The Hague in 1912. In the century since then pharmacy has – like world health – undergone fundamental changes. These have taken place in response



to evolving public needs and values, together with advances in medicinal and the other technologies underpinning health care delivery.


In the initial few decades of the twentieth century the role played by pharmacists moved from one centred on making what were – at least by today’s standards – limited volumes of relatively simple medicines to one more focused on dispensing much larger amounts of industrially produced, often more sophisticated, preparations. The loss over time of the medicines making function represented (as the contemporary records of FIP deliberations show) a significant challenge to pharmacists. Yet they successfully adapted to facilitate safer and progressively more efficient medicines prescribing, dispensing and use during the second half of the twentieth century.

More recently, pharmacists working in many countries have entered into another period of transition. As the number of pharmaceutical innovations for the treatment of common diseases outside hospitals has tended to decline there has been a progressive genericisation¹ of medicines use in the community setting. At the same time opportunities for computerising and/or mechanising aspects of medicines supply and information provision have grown, creating new pressures for pharmacy to adapt. The main direction of progress is towards that of supporting better medicines selection and use in order to optimise the benefits of spending on pharmaceutical technologies, and contributing directly to clinical care and public health improvement.

Differing local environments are – at least in the short to medium term – providing differing specific opportunities for ongoing pharmacy based service development. Some estimates indicate that even in regions with good access to pharmaceutical care at present around a half of all medicines supplied are not taken to optimum effect. This does not necessarily mean that a similar proportion of potential therapeutic gain is lost. But throughout the world improved medicines taking, coupled with measures that improve access to effective treatments, could significantly enhance the prevention and alleviation of both long term conditions and acute ill-health (WHO, 2003).

The aim of this UCL School of Pharmacy analysis is to describe and explain the global development of community and hospital pharmacy in the context of the demographic

¹ Technically, generic medicines are prescribed and supplied under their approved/non-proprietary names, and should be effectively identical between sources. But the term can also be used to refer to branded products supplied without intellectual property protection other than that conferred by trade names or marks. Pharmaceutical markets such as that of India may be described as largely generic, but encompass many thousands of competing branded products.




and allied developments of the last century and projected future trends. It also seeks to evaluate the challenges and opportunities facing pharmacy as both a regulated business and a health care profession at the start of the twenty first century, and to consider public interests in its ongoing evolution.

This study in part draws on a structured literature review and a survey of pharmacy development which received responses from nineteen contributing nations – see Appendix 1. The first section offers a brief overview of FIP’s starting situation in the period leading up to the European/World War of 1914-1918. It also considers aspects of the historical development of pharmacy with regard to heritages such as, for instance, Ayurvedia in India and traditional Chinese medicine, and the impacts that not only European science but also (exploitive, as well as on occasions beneficial) European colonialism and trade policies had on shaping pharmacy across the globe.

Subsequent sections evaluate the health, health care and professional developments of the twentieth century in further detail, and consider the current situation of pharmacy in its modern context. The ways in which pharmacy and pharmacists can continue to adapt and contribute to health improvement are discussed.

At one level historical and social analyses are primarily concerned with the specific actions of individuals at given times and the structures and objectives of groups and institutions in their national contexts. But the most important goal of this report is to promote an understanding of long term global trends, and the forces driving them. Humanity faces serious challenges in the twenty first century, in areas ranging from, for example, living with atmospheric and other forms of pollution through to coping with the consequences of ongoing population growth in the least advantaged parts of the world community and problems such as youth unemployment in richer, ageing, communities. In the latter the sustainability of current relatively costly and sometimes inadequately responsive systems of health care delivery is also coming under increasing challenge.

However, despite these broad realities and other uncertainties facing pharmacy, the conclusion offered here is that if the pharmaceutical sciences and pharmaceutical care continue to adapt and progress the profession ought in future to be able to play an increasingly important part in cost effective, patient and consumer need focused, service provision. If – despite the sacrifices that may prove necessary – adequate educational



and material investments are made and informed public health and health service policies promoted, pharmacy should continue to serve as a global asset capable of generating progressively increasing health and welfare returns.


Decision makers faced with immediate pressures to reduce spending while extending access to health services should be aware of the potential for pharmacy as a regulated business sector and health profession to help resolve health problems in new ways. At the same time pharmacists and pharmacy related interests must – to not only defend themselves but arguably more importantly to protect public interests – understand the continuing need to modernise and go on improving individual and community health outcomes in changing circumstances.

THE ORIGINS OF PHARMACY

There is evidence that people have been treating themselves with medicinal substances for as long as the species *Homo sapiens* has been in existence. Humans and in all probability their evolutionary predecessors have for all practical purposes always used plant, animal and mineral substances as not only foods or food complements but instrumentally to alleviate distress and cure illnesses.

Within recorded history the roots of pharmacy are said to have been first established in the world of the ancient Sumarians, who lived in the area that is modern day Iraq from about 4000 BC. The practitioners of the healing arts of this point in history typically combined the roles of priests, pharmacists/herbalists and physicians, as indeed do some shamans and other traditional medicine providers today. Although their approach was not necessarily scientific in modern terms, there is little doubt of its utility to their communities. The Sumarians were, for example, aware of the ability of opium to relieve pain.

Similar progress took place in other parts of Asia and Africa at and after that time. For instance, the early Aryans invaded northern India in around 1500 BC, overwhelming earlier civilisations such as that of the Indus valley. Ayurveda (literally, the science of life) initially stemmed from that period, although it was not until over a millennium later that Acharya Charak produced the Charak(a) Samhita. This early form of a pharmacopeia remains central to Ayurvedic medicine. It describes the medicinal qualities and uses of in the order of 100,000 plants and plant derivatives (Vaidya, 2012).



Traditional Chinese medicine (TCM) has a similarly important heritage, as have other African, South American and Australasian approaches based on ancient knowledge which do not have a written basis but which have been passed on by word of mouth. The oldest book of Chinese medical theory, the Huangdi Neijing or ‘Yellow Emperor’s Inner Canon’, dates from around 2000 years ago. This drew upon and consolidated orally transmitted knowledge and beliefs of much greater antiquity.

Early European thinking about the causes of health and ill-health was linked to that of ancient Egypt, where 5,000 years ago people appear to have believed that disease was caused by malignant demons. Such supernatural explanations of human suffering persisted through into Greek civilisation. But by the 6th century BC the treatises of the Hippocratic Corpus² marked the beginnings of a rational, evidence based, approach. This continued on into Roman medicine and to the work of the first century philosopher and physician Galen of Pergamon. The latter was at that time a Greek city located in what is today Turkey. Galen was the first observer clearly to define a drug as a substance that acts on or in the body to bring about a functional change.

It would be beyond the scope of this analysis to attempt to describe Galen’s model of medicine and the concepts that gradually superseded it in the period leading up to today. But from a pharmacy development perspective the following points are worth emphasis:

- After the fall of the Roman Empire the emergent Arabian powers, driven by the imperatives of the early Islamic period, played a significant role in preserving and further developing Galenical medicine and medicines. They were able to do so in part because of the skills Muslim chemists acquired in areas such as alcohol distillation from around the end of the seventh century. (The word al-cohol is of Arabic origin, and probably originally meant ‘the essence’ or spirit in the sense of an active ingredient.) Arguably, the first recognisable ‘apothecary’s store’³ of the post-Roman era was established in Baghdad in the eighth century (Anderson, 2001).

² There is uncertainty as to whether or not any of the seventy or so treatises in the Hippocratic Corpus were written by Hippocrates. He was, however, a real and influential historical figure.

³ The noun apothecary (as with apotheker in German, or apotecaire in old French) stems back to the Latin and ancient Greek terms for a storehouse. In much of Europe it was used before the emergence of modern pharmacy as a separate profession to refer to a medical practitioner who supplied medicines.


- At around the start of the second Christian millennium the use of relatively potent medicines, which demanded special skills for their safe preparation and application, began spreading back up into Italy from north Africa. This brought with it risks as well as benefits, and was in part responsible for the Constitution of Melfi (also known as the Salernitan edikt) of 1231. Issued by the then King of Sicily, the Holy Roman Emperor Frederick II, this differentiated between and defined in law the separate roles of physicians and pharmacists. Its goal was to protect the public from misdiagnoses on the one hand and from inappropriately made and supplied medicines on the other.

This legislation (which built on the long established position of the City and University of Salerno as a place of medical excellence) is often taken to be a seminal reason why European countries such as France, Germany, Italy and Spain developed at a relatively early stage a clearer division between apothecaries and doctors than that which evolved in, for instance, the English and British influenced settings. A key point to stress is that the existence of pharmacy as a discrete occupational and professional entity has always been linked to the regulation of medicines supply and use, and the maintenance of defined standards of practice. A core element of the contribution of modern pharmacists, like that of their medieval predecessors, relates to risk limitation.

The further development of European pharmacy's progenitors involved the work of monasteries as proto-hospitals and dispensaries alongside (from the twelfth century onwards in countries ranging from Spain to the Netherlands and what is today Poland) that of increasingly specialised drug and spice vendors. These last eventually became established as apothecaries. It was, for instance, at the end of the 16th century that the English apothecaries were recognised by King James 1 as a discrete profession, separate from the grocers with whom (like their French contemporaries) they were previously joined⁴.

Some countries, such as Germany and Hungary, already had relatively sophisticated regulations in place governing the role of the apothecary by around the 1500s. The basic principles included a clear separation between the tasks of physicians and pharmacists, defined prices and a licensing procedure based in part on the number of inhabitants to

⁴ The apothecary's role in England differed from that in most of mainland Europe in as much as – particularly after the Great Plague of London in the 1660s – many were more concerned with health care delivery than was generally so elsewhere, although they normally only charged for medicines making and dispensing. The 1815 the Apothecaries Act confirmed this situation and enabled apothecaries who were minded to do so to act as general medical practitioners. Those who were more focused on making and supplying medicines subsequently joined up with the chemists and druggists to form a unified pharmacy profession in the middle of the nineteenth century, while the more care oriented apothecaries joined with the physicians and surgeons to form a unified British medical profession.



be served. The predominant role of the apothecaries in countries such as France in the 1700s was to make medicines for individual patients according to physicians' prescriptions. In 1777 a Royal declaration definitively separated French apothecaries from grocers and spicers, transforming the former into '*pharmaciens*' and replacing the old medieval guild with a College of Pharmacy.

The detailed events leading to the creation of the profession of pharmacy as it is currently constituted across the world differed from nation to nation and region to region. For example, in Russia modernising action taken by Tsar Peter the Great (1672-1725) created an eighteenth century model of pharmacy which drew from western European scientific experience and served mainly city and aristocratic and military populations. It was arguably more distanced from the herbal and related forms of medicine that continued to serve the mass of people living in rural Russia than was so in much of the rest of Europe. In Germany and Austria, for example, pharmacy has through to the present retained a relatively strong traditional (non-prescription) medicines supply role.

The Russian 'elite centralist' approach also led on to a division between pharmacists' entitlements to make medicines and the rights of drogueries/non-pharmacist drug sellers to purchase and provide pharmaceuticals directly to the public. This influenced the subsequent history of the Russian pharmaceutical sector in a number of ways up until, and in some respects after, the 1917 revolution.

In the American frontier society of the 1700s, by contrast, physicians typically compounded the medicines they prescribed. But towards the end of the 18th century this role began to be taken over by individuals who were originally doctors' 'drug clerk' employees. The latter over time began to call themselves druggists, apothecaries or pharmacists, and to dispense medicines and diagnose patients' conditions in a manner similar to that of English apothecaries. This led to tensions with physicians, who saw them as unqualified competitors and in the decades before and following the American revolution expressed growing concerns about the quality of treatments offered by 'quacks'.

Other illustrations of differing pharmacy development paths can be drawn from South America and the African and Asian countries subject to European colonisation in the eighteenth and nineteenth centuries. For example, in Brazil in the 1740s legislation was introduced requiring medicines suppliers to obtain and display official approvals. This intervention eventually led on to the initial introduction there of pharmacy degrees in the 1830s (about a decade after the nation's independence from Portugal) and the

establishment of the first autonomous pharmacy school in Ouro Preto at the end of that decade.

Compared with this progress, the rate of pharmacy development in countries such as, say, India and Nigeria, which did not become independent from Britain until the second half of the twentieth century, was substantially slower. But notwithstanding such variances, the general direction of travel towards a professional group separate from medicine and concerned with the manufacture and safe supply of effective medicines either directly to the public or in response to medical prescription had been established across much of globe by the end of the 1700s.


Nineteenth century achievements

The century to follow saw several strands of progress relevant to the ongoing evolution of medicines, pharmacy and pharmacy practice. In addition to advances in what may broadly be termed the pharmaceutical sciences (which include inorganic and organic – carbon compound based – chemistry, alongside pharmacognosy, pharmaceuticals and pharmacology⁵) and areas such as the germ theory of disease, they included:

- the further introduction of laws and regulations relevant to medicines supply and drug quality, and protecting public interests in controlling access to potential poisons;
- the establishment of new professional bodies, and as a part of this the development of specialised educational institutions and more comprehensive disciplinary and allied mechanisms within pharmacy; and
- the emergence between the mid-1800s and start of the 1900s of the early modern pharmaceutical industry, as factory based production methods began to be capable of generating well packaged medicines of consistently high quality.

In the nineteenth century German pharmaceutical scientists played a leading role in the discovery of a number of chemical elements, and the identification of plant alkaloids. Morphine, the main active ingredient of opium, was for instance first isolated in 1804 by a pharmacist and multiple pharmacy owner called Friedrich Sertürner, who also contributed to fields such as the scientific understanding of infectious disease transmission before his relatively early death. Diamorphine (heroin) was synthesised and brought into clinical use by British and German chemists towards the end of the 1800s, shortly

⁵ These areas of study relate to deriving medicines from plants and other natural sources, developing active chemicals into medicinal presentations, and understanding how drugs act. The Greek word pharmakon originally referred to a poison or remedy, and is the origin of the word pharmacology.



before other novel pharmaceutical products such as barbiturate based medicines and aspirin (acetylsalicylic acid) were introduced into the then still largely unregulated market (see Appendix 2).

These and related achievements, along with the advances pioneered by biological scientists such as Louis Pasteur (one of whose most important contributions was the introduction of the first rabies vaccine in the 1880s) helped to establish an environment in which pharmacists were seen as having a centrally important role to play in discovering new ways of combating disease. Growing awareness of the power of scientifically developed medicines to influence health outcomes helped pharmacy to gain an increased social standing. In environments like Germany (where Otto von Bismarck also introduced a form of health insurance and the first old age pensions in the 1880s) the societal status of pharmacists was at that time more equivalent to that of the medical profession than is as yet so in much of the world today.

Scientific developments also opened the way to the establishment of economically successful pharmaceutical companies like Bayer AG (which was originally founded by Friedrich Bayer and Johann Weskott in 1863) and E. Merck in Germany, Hoffman-La Roche and Sandoz and Co in Switzerland and Beechams and Allen and Hanburys (both of which are now part of GSK) in the UK. These built on foundations originally created by the dyestuffs industry and wholesaling apothecaries. Similar American enterprises included Eli Lilly, Burroughs Wellcome and Co and Pfizer. Although over time such companies took the role of making medicines away from individual pharmacists, they in the twentieth century provided an expanding range of pharmaceuticals for the profession to supply and help people employ to optimum effect.

An increasingly regulated environment

As societies advance the ways they produce goods and services and consequently become wealthier, healthier and more complex, they develop new structures and institutions to enhance the governance of activities such as health care. Progress towards safer environments typically takes place sequentially at three linked but distinct levels, namely:

- **professionalisation** and the formation of representative bodies, codes of practice and educational facilities dedicated to enhancing practitioner integrity and competency, particularly in relation to the services offered to individuals. The drivers behind this are


often taken to be altruism and ethical goals. Yet at the heart of professionalism there is an economic exchange involving the granting of provider monopolies (market protection) in return for supplier side guarantees of product and service quality (consumer protection);

- **managerialism** and the continuous evolution of institutional excellence and service and product quality, driven by (regulated) market competition. The effectiveness of this approach rests primarily on individual customers seeking good medicines and sound advice, and being able to choose in an informed way which pharmacies, practices or hospitals to go to in order to obtain desired health outcomes; and
- **political leadership** and the creation of not only relevant laws and effective regulatory structures but also, as societies become able to bear the costs, nationally administered systems of care and public health improvement. The fundamental force underlying this form of progress is electoral preference, and the implementation of collectively agreed policies through bureaucratically managed mechanisms (Foster et al, 1994; Freidson, 2001).

Different communities have, for historically and geographically influenced reasons, had varying preferences as to the extent to which they have relied on codified, relatively rigid, rules as opposed to more flexible general behavioural principles to underpin their approaches. This in Europe may be illustrated by comparisons between, say, France and Germany as opposed to Great Britain. There have also been differences between communities in the reliance placed on market choices as opposed to centrally determined policy directions. This last can be illustrated by comparing US and Russian values and policies.

Levels and durations of economic prosperity also affect what options are at any given time politically viable and socially acceptable. But from a pharmacy development perspective surprisingly consistent changes have at all three levels taken place globally since the start of the 1800s.

In England and the other countries of the United Kingdom, for example, access to drugs was at the latter time still effectively unregulated. No sales records were kept, however toxic the items supplied. But by the middle of the nineteenth century concern about the misuse of poisons, particularly arsenic, had grown to a degree that demanded political action. The then newly formed Pharmaceutical Society (which was established in 1841/42, along with what is today the UCL School of Pharmacy, in advance of the then apothecaries dividing into general medical practitioners and pharmacists *per se*) and the precursor body to the British Medical Association made a proposal to government for the control of arsenic sales.




The resulting Arsenic Act of 1851 was the one of the first steps in the introduction of a series of drug safety laws and regulations across the globe. This has led today in all more economically advantaged nations to the majority of medicines being available only by medical prescription, and a relatively strong counter-balancing pharmacy monopoly over their dispensing.

The United States provides other illustrations of early regulatory development. Despite the fact that a School of Pharmacy was established in Philadelphia as early as 1821, the majority of US ‘apothecaries’ continued to learn on-the-job via apprenticeships. This led to widely varying levels of expertise, which were in turn associated with persistent fears about inferior quality, adulterated or otherwise hazardous medicines (some of which were in fact ‘dumped’ into the US market by British and other traders) and unscrupulous business practices. Some medicines were, for example, advertised as innovative cure-alls, but often contained no more than unlabeled opium derivatives, laxatives and/or ethyl alcohol.

In 1906 the Pure Food and Drugs Act was introduced in a system level attempt to improve the safety and quality of US food and drugs. It outlawed the selling of misbranded and contaminated food, beverages and medicines; required labelling for a selected list of ingredients in patent medicines (such as alcohol, cocaine and morphine); and prohibited false advertising. In reality, this legislation contained multiple loopholes and was poorly enforced. Yet it paved the way for the further development of the US Food and Drugs Administration (FDA), and the arrangements which much more effectively regulate all aspects of pharmaceutical sector activity in the US today.

The creation of the FDA was in some ways paralleled by that of the Chinese State Food and Drug Administration (SFDA) almost a century later, albeit that as later sections of this study note the position of pharmacy in China remains very different from that found in north America, most of Europe and parts of Latin America. Other examples of progress that took place across the world in the middle and late 1800s and that paved the way for the creation of FIP in 1912 range from the introduction in many countries of rules around the ownership of pharmacies through to the establishment of new academic institutions.

In, for instance, Argentina, the Protomedicate – a national body derived from the traditions of the Spanish Royal Court – determined in the mid 1800s that pharmacists had to




reside in their pharmacies, could not own more than one ‘shop’, and should not practice simultaneously as a doctor or any other type of health professional. An illustration of the development of pharmacy’s academic infrastructure was provided by the establishment in Tokyo in 1873 of a pharmacy department in the Imperial University of Japan. The objective of the latter was to provide professional training to help the nation use to good effect growing imports of unfamiliar western medicines.

The Japanese Pharmaceutical Association (JPA) was formed in 1893 in part to support this end, and to support an associated policy favouring (along lines similar to those pursued in parallel circumstances in Southern Europe close to 1,000 years earlier) the separation of prescribing and dispensing. However, this last goal conflicted with Japanese physicians’ perceived rights and interests. As a result the separation of medicines supply and medical practice in the Japanese community did not move forward significantly for another 80 years, until concerns linked to the promotion of medicines and the behaviour of doctors during the pharmaceutical revolution that followed World War II helped force change⁶.

During that interim period pharmacy in Japan, as was subsequently so in countries such as India, became increasingly focused on disciplines such as pharmaceutical chemistry and pharmaceuticals, and on drug discovery and production. This was arguably at the expense of therapeutics and influencing the use of medicines in an integrated, socially informed as well as pharmacologically appropriate, manner in order to optimise health outcomes. It is only relatively recently that pharmacy in Japan, as in most other parts of the world, has entered this next phase of professional development.

Before moving on to consider the establishment of FIP and pharmacy’s achievements and opportunities in the twenty and twenty first centuries a final exemplary issue to consider here relates to medical and pharmaceutical education in America, following the initial establishment of the FDA. In 1910 the Flexner Report (Flexner, 1910) argued for substantial reform of US medical education and improvements in clinical and other teaching. Subsequent changes included a significant rationalisation of US medical schools. But from a pharmacy perspective the most important impact of Dr Flexner’s work was (even though he viewed pharmacy as very much secondary to medicine) to open the way to a clearer separation between dispensing and prescribing.

⁶ Legislation passed in 1956 was intended to implement the policy of separating prescribing and dispensing. But this relied on voluntary action by the medical profession. In 1974 the Japanese government changed the way that doctors were remunerated. This proved a more effective way of rebalancing professional and public interests.



After the Flexner Report's publication American doctors began to move away from providing dispensing services towards a greater focus on disease identification and management. The then lack of mandatory pharmacy degrees limited the capacity of the apothecaries/pharmacists of the day to add value to scientific medicine. Yet they responded by restricting the scope of their diagnostic and allied activities. Over time, this pragmatic settlement permitted more collaborative working between pharmacists and members of the US medical profession.

The further development of positive, constructive, relationships across the full spectrum of pharmaceutical, nursing and medical activity remains to this day a vital area for service improvement in the US and elsewhere. The analysis presented here suggests that continuous adaptation will be required as dispensing processes become more computerised, and population needs shift further away from acute illness treatment towards support for disease prevention and active ageing.

FIP and the world in 1912

In countries leading the trend towards industrialisation, many of the steps leading to the emergence of the modern pharmacy profession were in place by the first decade of the twentieth century. Yet forging contacts between pharmacists from different nations was still only possible via at best *ad hoc* pharmaceutical congresses. Against this background it was proposed (in September 1910) at a meeting of the Netherlands' Society of Pharmacy that an international pharmacy federation should be established. Its initially stated objective was to '*protect pharmacy by international means both as a profession and as an applied exact science*' (International Systems and Communications Limited and International Pharmaceutical Federation, 2000).

The formal constitution of the Fédération Internationale Pharmaceutique/International Pharmacy Federation (FIP) was established under Dutch law on the 25th September 1912. The Federation's founding membership included twenty national pharmaceutical associations, most of which had originated in the richer countries of Eurasia⁷. Their shared objectives encompassed:

- unifying pharmaceutical education and teaching organisations;
- organising regular and occasional international pharmaceutical meetings;

⁷ Including Austria, Belgium, Denmark, Finland, France, Germany, Hungary, The Netherlands, Romania, Russia (encompassing Poland), Sweden, Switzerland and the United Kingdom.




- collecting documents dealing with the practice of pharmacy in every country and communicating to its members records of progress in scientific and practical fields alike; and
- facilitating international agreements relating to issues like patent and trademarks legislation.

The next section describes some of the advances made in relation to these and related pharmacy agenda items during the remainder of the 1900s. But before that it is relevant to reflect on what the world was like in 1912, and how far humankind as a whole travelled in the last century. At the start of this last, for example, the global population was still only 1.7 billion, as compared with 7 billion today. About a quarter of this total (some 400 million individuals) were Europeans, while over a half of the remainder lived in Asia.

Average ‘real’ income per person in countries like the UK, the USA and Germany was approaching 20 times that enjoyed in the world as a whole. In 1912 approaching one in every four of the world’s citizens lived in the British Empire, which did not reach its maximum size until the 1920s. One in every eight lived in France’s Empire. The Russian and Turkish Empires were smaller, but together contained in the order of 10 per cent of the world’s population. (Today, 1 person in every 50 is a Russian Federation citizen: towards the end of Tsar Nicholas II’s rule 1 person in every 15 lived in the Russian Empire.)

In the era in which FIP first came into being professional concerns typically related to the need to develop more consistent medicinal definitions and production standards (and hence to produce more comprehensive pharmacopeias) and to issues such as the regulation of pharmacy ownership. But the realities of Imperialism help to explain why many of those involved in pharmacy policy at that time also seemed more worried about questions like whether or not professional qualifications obtained in ‘possessions’ outside Europe should be recognised within the borders of the ‘great powers’ than they were with improving world health (Anderson, 2012).

From a modern perspective it is revealing to note, for instance, that when in 1899/1900 a famine caused by monsoon failure in India killed a million people in British administered areas alone the UK government of the day adopted a *laissez-faire* attitude. It was argued that dependence on external aid should be discouraged. Likewise, although efforts were made at around that time to learn from Indian and other forms of traditional medicine, relatively little systematic effort was made by any of the colonial nations to bring the benefits of western medicine to subject populations. Much the same can be said, for instance, of Vietnamese experience of French colonialism.



Key events that took place in 1912 included the sinking of the Titanic; the establishment of the Republic of China; the holding of the games of the fifth Olympiad of the modern era in Stockholm; the introduction of a relatively safe form of Salvarsan (arsphenamine), a synthetic drug developed by Paul Ehrlich and Sahachiro Hata for the treatment of syphilis (Proto, 2010); and the signing in The Hague of the International Opium Convention. The latter, which took place in large part because of US pressure, required participant States to curb the production, distribution and consumption of opium, morphine, heroin and cocaine, and to restrict their use to 'legitimate medical purposes'. Its near universal acceptance by 1919 stood in stark contrast to the policies of half a century or so earlier, when Britain had used military force to in effect promote opium use in China.

PHARMACY IN THE TWENTIETH CENTURY


FIP was able to hold its first scientific Congress in The Hague in 1913. But in 1914 the trauma of the First World War interrupted the Federation's early work and prevented further international meetings until 1922. By that time the established, apparently secure, world order in which FIP had been created was effectively at an end. Its demise led in time to fundamental changes in the communities served by pharmacists everywhere.

The phenomena this section seeks briefly to describe and analyse from a world-wide pharmacy development viewpoint are:

- global demographic and epidemiological transition and its social impacts, including the introduction of universally accessible health care systems;
- the emergence of the modern pharmaceutical industry, and with it increasing numbers of new 'post-Galenical' medicines for both common and rarer diseases; and
- the evolution of community and hospital pharmacy in the period between the linked wars of the first half of the 1900s and the beginning of the current century, with its fresh challenges to the sustainability of health care in general and – arguably – the pharmaceutical sector in particular.

Demographic change and human development

The term demographic transition refers to the reductions in death and birth rates and the age structure changes characteristic of populations moving from subsistence agriculture towards becoming relatively wealthy industrial (or 'post industrial') communities. Central trends include falling infant mortality and infectious disease incidence




and prevalence rates followed, after a period of rapid population increase, by commensurate fertility declines. The latter, rather than greater longevity alone, cause 'population ageing'.

People living in post-transitional societies have extended average life expectancies and hence a raised probability of living long enough to experience conditions such as heart disease, cancer or Alzheimer's Disease, as opposed to dying earlier from parasitic, bacterial or viral disorders. The term 'epidemiological transition' reflects this shift in mortality and morbidity patterns.

In 1912 nations such as, for instance, Germany, France, the UK and the US had average life expectancies at birth of no more than 50 years. Japan at that time had a life expectancy of just 39 years, while in most of the rest of the world the equivalent figure was nearer 30 years. Even in the most advanced communities of the day, such as Sweden, child mortality (the rate of death up to the age of 5 years) was still in excess of 100 per 1000. This compares with an equivalent figure there of 26 in 1950 and a present one of under 5 per 1000.

In Afghanistan and many sub-Saharan Africa countries today, and in poor areas within nations like India, Pakistan or (notwithstanding relatively rapid South American progress in recent decades) Bolivia, child mortality is still higher than it was in Scandinavia at the time of FIP's formation a hundred years ago. Nevertheless, major progress towards demographic transition has been made in all the world's regions. (See, for instance, Rosling et al, 2005). This is in part evidenced by the rapid declines in birth and maternal mortality rates seen in nations like Turkey and, to varying degrees, the north African and Middle Eastern States during the last few decades.

Such advances are normally associated with factors such as women gaining better access to education, contraception and opportunities for work outside the home. But in countries where access to medicines and pharmaceutical and other forms of health care is less advanced fertility and population growth rates remain high, together with key indicators such as maternal mortality. Nigeria, for example, had a population of about 20 million when FIP was first formed. By 1950 it was still only 30 million, compared with 170 million (one in six of all Africans) now and a projected total of approaching 400 million in 2050. Alongside such figures, one in every seven of the deaths that are globally associated with child bearing currently takes place in Nigeria.



Increases in survival in later life have, compared with those seen at the time of birth, been by comparison modest. Life expectancy at age 65 was throughout the world around 10 years until well into the second half of the twentieth century, in poorer and more affluent settings alike. Currently it is close to 20 years in the more advantaged nations (OECD 2012). Yet such data are also consistent with an overall picture of sustained progress, and radically changing health care requirements.

From a pharmacy standpoint their most important world-wide implication is that while there is a continuing need to improve access to good quality vaccines and established and innovative medicines to treat conditions like HIV, TB, leprosy, malaria and helminthic (parasitic worm) infections in the poorest communities, it is no less of an urgent priority to enhance the preventive, maintenance and (if and when possible) curative care available for people at risk from NCDs such as coronary heart disease and type II diabetes. The latter is rapidly becoming more prevalent in emergent economies such as, for example, India, Turkey and the UAE than it is in regions like Europe and even the US.

The ways in which community and hospital pharmacists, together with those working in industry based and management roles, can most effectively contribute to health improvement are discussed later. It is relevant to highlight here the fact that while in the twentieth century threats to the lives and health-related wellbeing of people living in most societies have declined, the amounts of money that they have been willing (and for the moment at least able) to spend on health services have risen.

This has not been because health care has been the main driver of better public health during most of the twentieth century, or (as, for instance, Japan's record relative to that of the US implies) due to rapidly rising health service cost increases being an inevitable facet of population ageing. It is more probably because of changing individual and community values, increased public funding of health services, and a reduced public and political willingness to tolerate health and safety threats and hazards of any sort. Such factors are central to the concept of 'care transition' described in Box 1.

It is salient to the 21st century development of pharmacy to note that health expectations will very probably continue to rise. Finding affordable ways of providing more effective life-long care is therefore an important challenge for health care funders and providers alike, including professionals such as pharmacists and businesses like pharmacies.



Health service development

In the two decades after World War I industrialised countries like the US, France, the UK and Canada typically spent in the order of 3 per cent of their annual GDPs on health care. Today the equivalent figure for ‘developed’ nations across the world is about 10 per cent, although in the case of the US approaching 17 per cent of that country’s relatively high national income is presently accounted for by health sector outlays. Public spending on health care in America has for some decades been – at about 8 per cent of GDP – comparable as a proportion of national wealth with that recorded in, say, the UK, Sweden, Australia or Japan. It is the additional spending made via private insurance schemes and direct out-of-pocket payments which is atypically high in the US.

Within these totals 1-2 per cent of GDP (that is, in the order of 15 per cent of all health spending) is currently devoted to medicines, vaccines and allied product costs and pharmaceutical service provision. In regions such as Europe there have been historically stable contrasts between the relatively high overall pharmaceutical sector costs seen in ‘Mediterranean’ model countries like Greece and Spain (which have had low prices for patent protected medicines, balanced by relatively expensive generic/off patented branded products) and the lower overall (despite higher unit prices for newer medicines) spending observed in North Western Europe.

These differences may now be reducing, in part because of the impacts of the ‘Euro crisis’ and the impacts of global economic restructuring. Yet the fact that they endured for approaching half a century serves as a reminder that efficiency in the pharmaceutical sector and health care generally is a function of far more than securing low average drug prices and labour costs. It is still the case across the world that combinations of low prices for innovative medicines coupled with relatively high (if still comparatively affordable) off-patent medicine costs and lower wages for groups such as nurses compared to higher rewards for successful doctors and pharmacy business owners can be indicative of health system failings.

Health spending in regions like western Europe and north America began to accelerate after World War II, when many more advanced nations consolidated their health insurance and allied schemes to in effect provide universal coverage. The principles upon which systems such as the UK NHS (which was functionally established in 1948) are founded differ from, for instance, those characteristic of the Bismarckian thinking underlying German health care funding or the national and private insurance based models

characteristic of Canada and the US. The specifics of pharmacy funding also vary⁸. But for practical purposes there has been considerable convergence in areas such as access to medicines and most if not all other forms of effective treatment and care.

Box 1: Care transition and pharmacy development

Demographic and epidemiological transition are well described concepts, and despite some variations between cultural contexts fairly consistent in their nature. The social, economic and psychological changes observed during and after populations pass through fundamental changes in mortality and fertility are by contrast more complex, and variable between nations and regions.

Over simplified, deterministic, interpretations of the ways in which people's values and behaviours alter as they come to enjoy the greater levels of physical and psychological security associated with long average life expectancies and small family sizes should be avoided. But as societies move from traditional agricultural life styles characterised by 'young' age structures and high death and birth rates towards being industrialised communities with low 'vital' rates and greater relative numbers of people aged 60 and over, the developments that occur include:

- trends towards greater equality between men and women, as the latter spend lower amounts of time in pregnancy and on child care activities and enjoy increased educational and career opportunities;
- improved levels of health at all ages, and associated changes in reasoning styles and mental capacity. For instance, the 'Flynn effect' relates to the highly significant (15 point plus) rises in average intelligence test scores seen as communities move through transition (Flynn, 2009);
- reduced prejudice linked to racial differences and factors such as disabilities, illnesses or sexual orientations;
- improved access to contraception and better standards of child care and protection; and
- increased levels of public (or mandatory private) investment in health and social care systems.

The early and middle stages of transition are typically associated with rises in the relative status and authority of health professionals such as medical doctors and pharmacists. However, as overall levels of education rise and patterns of employment change, people typically begin to seek more control over their own health and the management of long term and other conditions. The relationships between health care providers and users tend to 're-normalise', and become more like those in other parts of the economy. To some pharmacists such social shifts may seem challenging. Yet what is referred to here as 'care transition' should open up new opportunities for productive pharmaceutical care partnerships, and fresh ways of further enhancing welfare through the pharmacologically and socially informed use of medicines alongside other forms of personal and public health care.

⁸ FIP supported analyses have found that across the world about one pharmacy visit in seven does not result in a payment of any sort. Advice is given free. Nevertheless, in less advanced societies community pharmacy is typically exclusively funded from sales revenues. More expensive items are normally more profitable to supply than less costly ones. Similar realities apply in the context of medical care, especially when doctors dispense the medicines they prescribe. But as health care systems develop pharmacists' incomes tend to become more reliant on structured fees and incentives designed to promote cost effective medicines use and the provision of pharmaceutical care that demonstrably improves health outcomes.




This cannot as yet be said for much of Asia, Africa and Latin America. Health care development has often been slowest in the areas with the highest objective levels of need. It is of note, for instance, that in India total health related spending even today accounts for little more than 4 per cent of GDP, of which only just over 1 per cent (that is, 25 per cent of all health sector resources) is met from the public purse. Most pharmaceutical costs there have to date been paid out-of-pocket, in a context where access to professional care of all types is highly inequitable.

Some commentators fear that as the populations of the ‘mature’ industrial societies age and at the same time face increased competition from ‘BRIC’ and allied nations like Brazil, the Russian Federation, India, Indonesia, China and Turkey, they will not be able to continue the public funding of universal health services. Were such a trend to develop it would have considerable implications for pharmacy as a global profession, and for pharmacies as professionally and publicly regulated businesses. But there is in fact evidence as ‘the BRICs’ become wealthier that they are taking the provision of population-wide health protection and care to be an increasingly important priority. This suggests that predictions of good quality health care becoming unaffordable in established economies should not be given undue credence, albeit that threats to the future sustainability of services everywhere demand careful attention.

In Brazil, for instance, the 1988 Federal Constitution mandated the formation of the nation’s Unified Health System (SUS) to provide health care to the whole population. Notwithstanding continuing problems with aspects of publicly funded care quality, the SUS can now claim to be the biggest healthcare system in the world. As described below, Brazil has recently pioneered developments in the roles of community pharmacists and pharmacy based services, in part to extend access to medicines in less advantaged localities. Likewise China has recently extended health care funding provisions in rural areas, while in India in 2011 a High Level Expert Group advocated a form of pan-Indian universal coverage (Redy et al, 2011). Such observations imply that it will continue to be important for pharmacy and pharmacists to understand the public and political imperatives underlying health care reform, and to continue to adapt in ways that help both governments and pharmacy service users achieve their highest priority objectives.

Regulating the pharmaceutical sector

The increasingly complex and costly regulation of medicines safety and quality catalysed at the start of the 1960s by the Thalidomide tragedy was associated with the trends




outlined above, as has been the extension and amendment of controls on pharmacy practice. Following the FDA's initial establishment in 1906, the US has played a leading role in the world-wide regulatory development. This was partly because in America in 1937 the early (German and French science pioneered) antibiotic sulphanilamide was sold as an elixir containing diethylene glycol, a toxic solvent more appropriately used in anti-freeze products. It killed over 100 people, many of them children. This led in 1938 to the Food Drug and Cosmetic (FDC) Act, which demanded pre-market testing by pharmaceutical manufacturers to establish drug safety.

It also required more medicines to be supplied by doctor's prescription. However, despite these precautions three years later nearly 300 deaths resulted from the use of another US manufactured early antibiotic, sulfathiazole, taken in pills that accidentally contained the sedative phenobarbital. This fatal error led the FDA to introduce new medicines manufacturing and quality controls, which eventually led to the development of modern Good Manufacturing Practice (GMP) standards.

The establishment and development of the FDA was the result of events not unlike those which have in the last few decades occurred in China, Nigeria and the Indian sub-continent. They to a degree reflected the fact that America, although developing rapidly, still in some ways lagged behind Europe during the 1930s. Nevertheless, because of the controls introduced from that time onwards Dr Frances Kelsey, a medically qualified pharmacologist serving as an FDA drug reviewer, was in 1960 able to prevent the US approval of Thalidomide as a sedative pain killer and anti-emetic for use in pregnancy. This was because she had concerns about a lack of data on the drug's ability to cross the placenta, and an absence of clinical trial results⁹. Following the discovery of the teratogenicity of Thalidomide, the Kefauver-Harris Drug Amendment made more adequate drug testing mandatory.

On the other side of the Atlantic the experiences of World War I also generated pressures for the introduction of a prescription only medicines category. In Britain, for instance, concerns about cocaine use by soldiers led in 1916 to action to prevent the supply of cocaine and a number of other drugs to members of the Armed Forces, unless ordered by

⁹ Frances Kelsey had when a young graduate taken part in reviews of the elixir of the sulphanilamide case. Some pharmaceutical and medical scientists in Europe reportedly shared concerns about Thalidomide that were related to hers in the late 1950s. But the lack of a rigorous approach to medicines licensing at that time meant that it was nevertheless marketed in countries such as the UK and Australia, as well as in Germany where its originator, Chemie Grünenthal, had been established in 1946.




a doctor on a written prescription which had been dated, signed and marked '*not to be repeated*'. This legislation was quickly extended to civilians, and shortly afterwards the Dangerous Drugs Act of 1920 (following on from the 1912 Hague Convention) regulated the import and sale of drugs with addictive properties, including derivatives of opium, cocaine and cannabis.

From a social science perspective, changing expectations of work-force and military discipline and performance, coupled with public health concerns and the problems and opportunities linked to the introduction of new medicines such as, for instance, heroin (first marketed by Bayer in 1895 as a 'non-addictive morphine substitute') resulted in curtailments in the free pharmacy supply of potential intoxicants and addictive formulations. By 1933 in the UK the Pharmacy and Poisons Act was brought in to cover additional medicines which it was felt by the legislators of the day required a medical prescription. This extended the medical profession's control over public access to substances that decision makers judged might harm individuals, families and/or national economic wellbeing, and with it the balance of the power and dependency relationships between doctors and pharmacists.

After the second World War the introduction of penicillin provided a stimulus for additional regulation. It was observed at the time that antibiotics were also '*capable of causing danger to the health of the community if used without proper safeguards*'. Legal reforms followed throughout the industrialised nations. For example, in America the 1951 Durham-Humphrey amendment additionally restricted pharmacists' freedom to supply medicines without a medical prescription. The impact of such measures, coupled with the fact that as access to drugs improved the pharmacists responsible for their supply spent an increasing amount of time dispensing rather than in face-to-face contact with the public, helped to reduce the perceived standing of the profession as the second half of the twentieth century progressed. Although pharmacy owners' incomes remained on the whole robust, the generally understood authority of pharmacists declined. With regard to other aspects of medicines regulation it was not until the shock of the Thalidomide event that a radical discontinuity occurred, and all developed countries moved to follow the US example of obligatory clinical trial based drug approval.

An important European illustration of this trend, which was to impact on the ongoing development of the pharmaceutical sector as a whole, was the introduction of Council Directive 65/65/EC on new medicines authorisation. This last was an exemplar for and




precursor to further legal and regulatory changes in not only the European Community Member States at that time (including, for instance, Germany, the Netherlands and France¹⁰) but also in countries ranging from Britain to, at the opposite end of the earth, Australia and New Zealand.

In the British context, for instance, the 1968 Medicines Act introduced the concept of pharmacy (P) medicines, as distinct from prescription only medicines (POMs) and general sales list (GSL) products, which can legally be sold anywhere. In much of the rest of the world the GSL and/or P categories remain either unknown or more limited in their application than in the UK model. In the US the P category has not as yet been introduced, for example, although as a concept it has recently gained attention increasing support. By contrast in many EU Members States there are fewer GSL medicines available than is so in the US and the UK.

In the less industrialised world regulatory progress in the first half of the twentieth century was more focused on more basic aspects fostering basic pharmaceutical supply integrity. For example, Tunisia's first drug-specific laws were introduced in 1942. They controlled aspects of medical and pharmaceutical promotion, as well as medicines provision. All finished pharmaceutical products imported or manufactured in Tunisia were required to undergo a Technical Committee review and to obtain a certificate of approval from the Ministry of Health before being put onto the market.

South of the Sahara, the existence of Nigerian pharmacies supplying allopathic medicines in cities such as Lagos to European colonists and limited numbers of African customers dated back to the 1890s. There the Poisons and Pharmacy Ordinance of 1923 preceded the setting up of the country's first School of Pharmacy that same decade, although as previously noted the great majority of people remained dependent on West African traditional medicine. In east Asia, Singapore in 1931 similarly adopted a Poisons Ordinance that categorised drugs according to how toxic they were and limited access accordingly.

¹⁰ In the Netherlands a new legal basis for the licensing of pharmaceutical manufacturing and distribution was first established in 1956. Following that the Medicines Act of 1958 required the Medicines Evaluation Board (MEB) to regulate the admission of medicines to the Dutch market. But the MEB only started work in earnest in 1963 in the wake of the Thalidomide disaster. West Germany brought in new regulations on drug safety in 1961. The law there was subsequently revised again to include strengthened requirements for proof of the quality, efficacy and safety of new drugs.



In India (following World War I) a penal code intended to regulate the import, possession and sale of poisons was introduced in 1919, along with additional controls on the quality of imported drugs. However, enforcement was inadequate. Some British and other traders and manufacturers were alleged to have taken advantage of the situation by supplying inferior, and on occasions adulterated and dangerous, medicines into the Indian marketplace. These were often sold to the public by staff with little or no relevant pharmaceutical knowledge.

Most people in India remained primarily dependent on traditional medicines, which at that time were probably no less (and perhaps in some instances more) effective than allopathic treatments for most everyday purposes. It was arguably in the field of surgery that western medicine was more significantly advanced as compared to both Chinese and Indian practices. But in 1926 a large scale quinine fraud led to significant public concern about falsified/counterfeit and adulterated imports, and pharmacy standards. It was recommended that the Indian government should introduce food and drug and pharmacy and poisons legislation similar to that which by then had been adopted in the UK. Yet substantive progress was very slow until after the country's independence at the end of the 1940s, when the 1948 Pharmacy Act was first published.

Pharmacy controls

Alongside the other health sector developments illustrated in Appendix 2, many countries introduced or enhanced controls on the number and location of pharmacies during the twentieth century. They also limited activities such as pharmacy service and medicinal product advertising. In France, for example, the Ordre National des Pharmaciens was established in 1945, in part to govern the distribution of community pharmacists on the basis of the population to be served in each locality. Previous French controls had dated back to 1803, and legislation introduced shortly after Napoleon had taken control of the First Republic.

By 1980 French regulation had further advanced to include, for instance, limits on the numbers of pharmacy students in training, based again on demographic criteria. In West Germany, by contrast, where community pharmacies had been for the most part taken over by the State during the brief period of Nazi administration, the Constitutional Court decided in 1958 that legal restrictions on their numbers violated the human rights and professional freedoms guaranteed in the post-war constitution. However, Germany – like many other nations – retained restrictions on pharmacy ownership, preventing the




formation of the corporate pharmacy chains permitted in America and (since the 1880s) in Britain.

Many examples of similar controls on how pharmacies can be owned and run, the strength of their monopoly over the supply of prescription and over-the-counter medicines, their freedom to compete, and the extent to which they are involved in activities such as, say, giving vaccinations, taking blood samples and blood pressures or substituting generic drugs for more costly products prescribed by doctors, could be taken from all over the world. However, the most significant observation to make here is that by the time the twentieth century came to a close a number of observers and institutions had started to question the degree which such regulations were continuing to protect public interests. Issues relating to such concerns, and similar doubts about the utility of some modern forms of drug regulation in the radically changed world of the twenty first century, are considered later.

The influence of the pharmaceutical industry

The evolution of pharmacy as a profession has taken place separately from, but been closely inter-linked with, that of the pharmaceutical industry. During the first half of the 1900s this was principally illustrated by the progressive transfer of medicines making to factory production. In addition to those already mentioned, some significant new pharmaceuticals – perhaps most importantly insulin formulations – were also introduced in the inter-war period. But it was not until the middle to late 1940s and the mass supply of penicillin, followed by the marketing of products such as the tetracycline antibiotics in the 1950s, that the international pharmaceutical industry in a form similar to its current configuration came into being.

The therapeutic revolution of the second half of the twentieth century provided pharmacies and pharmacists with a wider range and increasing volumes of medicines to supply, albeit that as dispensing came to dominate their work an increased income from this source was typically gained at the cost of reduced professional contact with medicine users. The growing complexity of the treatments offered by the pharmaceutical industry extended opportunities for community and hospital pharmacists to contribute to the safe and effective use of medicines. They have in the main achieved this via ensuring their appropriate supply, alongside contributions such as countering inappropriate promotional messages and fostering good therapeutic practices (van Mil, 1999).




Nevertheless, pharmacy has often tended to progress in ways which are not easily visible to observers outside the profession. Pharmacists have sometimes seemed to be withdrawing into their dispensaries, rather than engaging more effectively in clinical care delivery and public health enhancement. The current expansion of interest (on the part of pharmaceutical companies as well as health care funders) in areas such as promoting high quality prescribing and greater adherence in medicine taking as a means of improving health outcomes may in future help to reverse any such past trends. But this is likely to depend critically on pharmacists being able to demonstrate and communicate their capacity effectively to change medicines usage and other health related behaviours, and to promote wider acceptance of the legitimacy of their roles in this field amongst the public and (medical) doctors.

Another set of challenges faced by pharmacists in the more affluent nations has since around the start of the 1990s related to the slowing of pharmaceutical innovation in the previously key arena of developing new drugs for the prevention and treatment of commonly occurring conditions in the community setting. The consequent 'genericisation' of the community pharmacy market has helped to reduce the costs of medicines for patients and health service funders. Yet it has also created financial difficulties for both pharmacies and research based pharmaceutical companies.

In parts of regions such as Europe economic factors are presently serving to exacerbate the latter by exerting additional downward pressure on medicine prices and pharmacy earnings. An optimistic interpretation of this situation is that it will in time force increases in productivity that will serve to ensure the ongoing relevance and affordability of pharmacy based services. But policy makers and other stakeholders in health improvement should be aware that it might instead undermine established pharmacy networks so that their potential to provide anything but a minimal cost supply service becomes seriously impaired. Should this be permitted it could block the further evolution of pharmacy services and cut off opportunities for introducing primary care and wider health system improvements that could significantly benefit populations everywhere.

Before turning to look in more detail at the ways in which pharmacy might continue to adapt its role in the 2100s, a final point to consider with regard to the interface between the global pharmaceutical industry and pharmacy relates to traditional medicine. As previously noted the provision of herbal and allied medicines remains important to a substantial proportion of the world population. From 1978 onwards the WHO has




recognised the special potential of traditional health practices to provide benefit (Zhang, 1999), particularly when employed alongside their modern allopathic counterparts.

The most celebrated example of where successful efforts have been made to achieve such ends is that of the Chinese People's Republic. In the 1950s the then government authorised an attempt to create a formal system of TCM (traditional Chinese medicine) which would eliminate 'superstitious' elements and standardise effective practices. Almost half a century later in 1999 a much changed Chinese administration implemented professional licensing regulations for TCM practitioners aimed at bringing their qualification and registration procedures into line with those for 'mainstream' doctors and pharmacists.

Although there is some limited evidence that the relative standing of TCM with sections of the Chinese public may be declining compared with that of research based allopathic medicine (Xu and Yang, 2009), it remains widely respected and trusted. China also has other important lessons to offer the world with regard to pharmacy development. For instance, in many parts of the country expanding hospital dispensary drug supply is reportedly a preferred way of enabling communities to gain better access to publicly funded treatment (Wong, 2012). The long term cost effectiveness of such strategies could prove questionable. But current concerns about the viability of using better disseminated community based pharmacy networks for this purpose underline the importance of reputational standing and demonstrable professional integrity for pharmacists everywhere.

The changing face of community pharmacy

At the start of the 20th century European pharmacies were still recognisably modelled on the practices of their historic predecessors, the apothecaries. The main focus of pharmacists was still on the production of elegant 'bespoke' medicines (the term *secundum artem* was – and still is – used to refer to the art of making a product with skill), despite the fact that outside the use of opiates the efficacy of many treatments was still very limited by today's standards. The procurement, storage and compounding of specific medicines by pharmacists was valuable to both physicians and patients. Their unique knowledge and skills were in the main recognised by the societies in which they lived and worked, positioning pharmacists as members of 'the professional class' (Giam et al., 2011).



Elsewhere in the world European pharmacy traditions had to varying degrees been imposed upon, and/or adopted by, other cultures. Beyond this, a deeply rooted and well recognised role for medicines makers existed in virtually every human community. As with all other crafts, however, mass production technologies became, as the century progressed, sufficiently reliable to replace hand and small batch medicine manufacturing. In the case of ‘pharmacy’s industry’ (the Latin word *industria* was originally used to describe any form of diligent activity directed to a defined purpose) this fundamental change coincided with an international flowering of medicines research and innovation. After 1945/46 the products of this revolution became a world-wide driver of population level health improvement.

In the face of this shift, community pharmacy adapted to concentrate more on medicines supply and information provision, coupled in some settings with retailing in health linked areas such as beauty products and chemistry related fields like photography services (Anderson, 2001). The move towards an increased volume of, and financial reliance on, dispensing as opposed to activities like compounding extended the pharmaceutical wholesaler’s role. Within a few decades such developments led community pharmacy largely to lose three (active pharmaceutical ingredient procurement, drug storage and medicine compounding) of the four pillars that had been the mainstay of its work for a millennium. But pharmacy as a business prospered and continued to play a valued role throughout the world.

In fields such as education (see Box 2) and continuing professional development the profession also remained successful, and expanded its activities as the century progressed. The recent work of the WHO UNESCO FIP Pharmacy Education Taskforce offers a clear example of this. Under FIP’s auspices an initial global consultation on pharmacy education was held in 2006 in Salvador Bahia, Brazil. This was followed by a second global consultation in Beijing in 2007, where the Taskforce partnership was consolidated with WHO and UNESCO. This led on to the development of an action plan launched in March 2008 at the Global Health Workforce Alliance (GHWA) forum on human resources for health held in Kampala, Uganda.

Progress in hospital pharmacy (see below), which to date has been most notable in countries such as the US, Australia, Canada, Sweden and the UK, has also provided an important channel for strengthening the profession’s health contributions. In future closer linkages between clinical pharmacists working in both hospital and community settings

Box 2: Pharmacy Education


Traditional pharmacy education normally took the form of apprenticeships and learning by ‘on the job’ experience. But in the nineteenth century the first ‘modern era’ pharmacy schools began to be established (see main text) and some universities in north America and Europe started to offer degree and similar level courses. Developments in the ‘pharmaceutical sciences’ (including experimental pharmacology and bacteriology) led to a widening of pharmacy syllabi in the early 1900s. A trend towards formal education in academic as opposed to active health care settings continued on throughout the remainder of the century.

The decline of medicines manufacturing in pharmacies and the associated development of new supply and advisory roles for pharmacists led to additional educational reforms in the last 50 or so years. Subjects such as anatomy, physiology and clinical pharmacology were incorporated into pharmacy courses, which also increased in length. This reflected the growing body of relevant knowledge and the perceived need to increase the capacity of pharmacists to act as ‘pharmaco-therapeutic’ advisors to both medical and other health professionals and members of the public.

The development of clinical pharmacy from the 1960s and 70s onwards stimulated the development of pharmacy degree courses incorporating substantial practical training and experiential learning. Those now offered include Doctorates of Pharmacy (Pharm.Ds) as well as Masters and Bachelors courses which include periods of pre-registration or integrated experience in clinical care facilities. The typical duration of pharmacy education at undergraduate and allied levels is now five or six years. Pharmacists may now receive teaching in social science disciplines such as health psychology, economics and ‘public health’. However, developments in these contexts have to date been variable and on occasions disappointing.

The education of most healthcare workers is now based on a “know how” rather than a “know all” approach. Students should be prepared for lifelong learning since their initial education cannot provide them with all that they will in future need to comprehend. The FIP adopted a Continuing Professional Development (CPD) model in 2002 which recognises that each individual pharmacist is personally responsible for *‘the maintenance, development and broadening of knowledge, skills and attitudes, to ensure competence as a professional, throughout their career’*.

Alongside progress such as this the FIP Pharmacy Education Taskforce (which was formally initiated in November 2007 – see main text) is responsible for delivering the Pharmacy Education Action Plan. This work, supported by UCL School of Pharmacy involvement, embodies a comprehensive approach to maintaining and improving the profession’s education world-wide, and advocates a needs-based approach to helping pharmacists enhance their competencies. FIP also works (along with partners such as WHO and UNESCO) in close collaboration with the International Pharmacy Students Association (IPSF) to support and enrich the education and personal development of pharmacy students, and to contribute to better public health across the globe.



and the education and training of pharmacy undergraduates and postgraduates might provide a path towards a further consolidation of pharmacy's place in well co-ordinated health (and social) care delivery.

However, the main point to stress here is that towards the end of the 20th century continuing technical and social change (including the development of computer based stock control and dispensing systems and electronic individual health records, coupled with growing consumer demands for personally focused care) created further pressure for adaptation. Community pharmacy is responding by moving more in the direction of person centred health service delivery, while maintaining and where possible improving the efficiency and effectiveness of medicines supply.

Examples of the pharmacy service developments being explored across the world relate to the identification and management of circulatory disease risks and, as alluded to earlier, support for adherence and appropriateness in medicines taking. This is especially important in long term condition related contexts such as asthma, COPD, diabetes and Parkinson's disease case management. Such innovations could help assure affordable future public health improvement, although as the next main section of this analysis indicates their successful introduction into commonly accepted practice faces many barriers. They range from legal and regulatory inflexibilities to present (socially defined, and hence modifiable) public preferences for medically led care. The historical record also identifies professional resistance to adopting new practices as an additional hurdle to be overcome in most if not all settings.

The latter may even exist in a proportion of those responsible for pharmacy education. However, there can be no doubt that during the twentieth century pharmacy has been able to achieve change. Positive progress has taken place, albeit on occasions at a cost to not only those professionals least able to accommodate new ways of working but to members of the public reluctant to accept new service relationships. It would be too great a task to attempt to report comprehensively on a hundred years of global community pharmacy adaptation to new needs and opportunities. But the selected examples below offer an overview of the processes involved, and their impacts upon societies and people in them.

Changing the face of pharmacy in Russia and Central and eastern Europe

In the two decades leading up to 1917 pharmacists were in a challenged position in Russia. This was because of growing competition from foreign pharmaceutical manufac-

urers, and the fact that non-pharmacy drogueriers (which at the time of FIP's formation outnumbered pharmacies 2:1) were able to sell medicines at prices pharmacies found difficult to match¹¹. But in the period following the revolution the situation changed radically. Pharmacies, like all other health care resources (including early pharmaceutical company investments) were nationalised and after the civil war of 1918-20 incorporated into the Semashko¹² health care system. This (in some ways reflecting earlier Tsarist values) was characterised by total State control.

Initially the number of pharmacies declined. But it rose again to some 10,000 by 1940. Their focus on providing public health related support to local populations was strengthened¹³. However, the results of the Soviet reforms (which initially coincided with an ideologically driven reduction in the social status and authority of doctors) were in practice relatively disappointing. As in other parts of the world the burden of communicable disease fell, and access to care was for many people improved. But in the period after World War II the Soviet system found it difficult to counter the growing prevalence of NCDs and of life-style related problems, including those linked to tobacco and alcohol use.

Russian community pharmacy remained active in areas such as providing care for people with minor injuries and infections. Yet there were significant problems with medicines supply – timely access to innovative medicines was for the majority of people at best limited by international standards – and many pharmacists were reportedly dissatisfied with their incomes and social standing. Doctors remained dominant within the clinical arena.


In 1992 the then newly established Russian Federation abolished the State monopoly on the manufacture and distribution of pharmaceuticals. This created fresh opportunities for the formation of private pharmacy chains as well as individually owned pharmacies. Yet with this there also came new forms of stress and distress amongst sections of the community.

Presently there are a little over 60,000 'pharmacy type institutions' in Russia, of which about half are classified as pharmacies and the remainder are smaller resources carrying

¹¹ There were approaching 4,000 pharmacies in Russia in 1912, as opposed to over 7,000 'drugstores'.

¹² Nikolae Semashko was the Soviet Republic's first Health Commissar, as well as a Professor of 'Public Hygiene'

¹³ This approach is reflected (in theory at least) today in the policies of countries such as the UK, and also by some modern calls to remove business and profit seeking imperatives from the professional practice of pharmacy.




either limited numbers of prescription medicines or OTC products only. These, together with the almost 3,000 hospital pharmacies in the country, are run by about 190,000 senior and less senior pharmacists, providing for a total population of 140 million. Measures have been taken to redevelop Russian capabilities in the pharmaceutical industry and drug development context through legislation enacted in 1998 and 2010. But there are concerns that pharmacy development itself remains relatively neglected (Pyatigorskaya and Maksimkina, 2012). It is of note, for example, that there is presently no national pharmaceutical association representing the Russian profession in the FIP.

Similar patterns of pharmacy development took place in nations such as Poland after 1945. In that case, pharmacy had in the nineteenth century developed in response to German and Austro-Hungarian influences, as well as those of Imperial Russia. During the nation's brief period of independence after the First World War pharmacy appears to have been perceived as a relatively attractive calling. But in the 'cold war' period that followed World War II Polish health care was reshaped to fit the Semashko model.

Notwithstanding factors such as marked differences in Poland between urban primary care practice centred on polyclinics and rural pharmacies, the results were broadly similar to those in Russia. Access to care for some sections of the community was enhanced, but pharmacy lost social and financial status. Further, as both the pharmaceutically driven therapeutic revolution and demographic changes progressed, the supply of newer medicines remained limited. In the wider health care system problems such as patients feeling obliged to make 'informal' payments for care to poorly paid doctors emerged.

Since the collapse of the Soviet system in 1989, new arrangements for the public funding of health care have been introduced. Pharmacists and their representative bodies in Poland have sought to modernise and improve services in hospitals as well as the community. But as yet only partial progress towards enhanced patient centred pharmaceutical care appears to have been made. Despite the fact that conditions in the country have significantly improved in the last two decades, absolute Polish spending on medicines remains low in EU terms.

Similar remarks apply to many other parts of Eastern Europe. But in Hungary pharmacy has relatively robust roots dating back well into the middle ages (Meszaros, 2012). There community pharmacies were designated as public health institutions requiring public



control in the 1870s. Over 800 were in place by the start of the 20th century, when the pharmacist Gedeon Richter first started manufacturing medicines commercially. Today there are three times as many Hungarian community pharmacies (that is, some 2,500) serving about 10 million people. Since 1988 a five year degree curriculum has been in place, and in 2009 legislation enabling all pharmacists to enjoy the title of Doctor of Pharmacy was introduced. The extent to which this will help to rebalance public expectations of pharmacy and medicine, and interactions between the two professions, remains to be seen.


Simplistic judgements about Russian and eastern European health care achievements during the Soviet era should be avoided. At the same time awareness of the good intentions of policy makers such as Professor Semashko and the practical limitations of Soviet health care highlight the importance of individual motivation in sustainable public health improvement, and the potential contributions of both professionalism and competitive enterprise to achieving health system excellence.

For pharmacists, the experience of communism in Russia might also be taken to demonstrate the possible hazards of adopting an inadequately financed public health improvement role without being in a position to optimise publicly or privately funded medicines use. To the extent to which this implies that it would be a high risk strategy for pharmacists globally to in future seek to deliver objectives such as changing health behaviours without being able to rely on an adequate income from the provision of the medicines central to their expertise this issue will be returned to later in this analysis.

US and Canadian experience of pharmacy change

Following Abraham Flexner's 1910 recommendations on medical education and the separation of prescribing and pharmacist dispensing in America, there was a relatively rapid improvement in medicines supply to the US public in the three decades leading up to World War II. The role of pharmacies became better established. However, this was not always for conventional reasons. For example, after the advent of prohibition in 1919 'drug stores' tended to become popular places to gather because alcohol containing formulations could be legally dispensed by pharmacists 'for medicinal purposes'.

From the 1940s onwards the expansion of the pharmaceutical armamentarium led to rapidly increasing pharmaceutical sales in the US. This industry led success helped to assure pharmacy incomes. The flexibility and diversity of the American system



also permitted innovation in hospital and community practice alike, and over time the establishment of a number of differing corporate pharmacy, internet pharmacy and ‘pharmacy benefit management’ models. It may also be argued that the plurality and lack of consistently defined primary medical care in the US system has created opportunities for pharmacies and pharmacists to play relatively strong care co-ordinating roles. In the absence for many people of a ‘medical home’, the part of pharmacists in areas such as medication management became a natural focal point.

US clinical pharmacy developed on a number of fronts in the 1970s and 1980s. But by far the most widely acknowledged step forward was Hepler and Strand’s (1990) concept of pharmaceutical care. This can be defined as ‘*the responsible provision of drug therapy (by pharmacists) for the purpose of achieving definite outcomes that improve a patient’s quality of life*’. Within this Strand and Hepler included all aspects of disease and symptom prevention and treatment, together with identifying and either preventing or resolving potential and actual drug-related problems. Their analysis had a rapid impact on FIP. For example, in 1993 the Federation recognised pharmaceutical care provision as good pharmacy practice (GPP).

Other more recent examples of important US developments range from the establishment of the Pharmacy Technician Certification Board (PCTB) in 1995 to the introduction of the so called Part D medication benefits for older Medicare users in 2000. This last considerably expanded funded and affordable access to pharmaceutical treatments for older people in America. The scale of the American system is reflected in the fact that the PCTB has now certified over 400,000 technicians, and that there some 60,000 chain drugstores alone¹⁴.

Similar developments in the direction of a more pro-active approach to supplying medicines and positively influencing their use have taken place in Canada, where one year pharmacy diplomas and two year Pharmacy degrees were first granted in 1914. Pharmacy services there have been provided within a relatively comprehensive State national insurance and Provincial care delivery framework. During the past decade policy related initiatives such as the Romanow report on the future of health care in Canada and work undertaken by the Canadian Pharmacists Association (including a 2004 report on *Pharmacists in Primary Health Care* and a 2008 publication entitled *Blueprint for Pharmacy*) have sought assertively to extend the clinical role of community pharmacists.

¹⁴ The US population is presently 314 million. All pharmacists in the US now take a PharmD qualification, which requires a total of up to eight years University education. Currently there are in total about 300,000 working pharmacists in the United States

Change in France and Germany


In comparison with the experiences of their contemporaries in Russia and other eastern European countries and those in north America, community pharmacists in Germany and France have – despite their being at the epicentre of repeated military conflicts – in a number of respects enjoyed what might be regarded as enviable stability during much of the 20th century. For instance, physician dispensing has not (in contrast to its prevalence in parts of nearby Switzerland) been a significant issue during this period. Similarly, pharmacy ownership has, notwithstanding calls from parts of the European Commission for ‘deregulation’ and greater competition between professional service providers, effectively remained the prerogative of individual pharmacists and small pharmacy partnerships in both countries.

Throughout the therapeutic revolution from the late 1940s onwards the French and German populations have in addition enjoyed well funded and good quality health care systems. These to date have not required community pharmacies to change their ways of working to the extent demanded in nearby nations such as The Netherlands and the UK (see below). However, this should not be taken to suggest that there has been an absence of pharmacy development.

In Germany, where University education for pharmacists was first made mandatory in 1875, insurance companies and governmental interests have fostered regulated internet medicines supply in pursuit of pharmaceutical cost savings. There have also been shifts towards tendering for medicines supplies designed to ensure savings for care funders. At the same time some health care funders have, together with ABDA (the Federal Union of German Associations of Pharmacists) and the KBV (representing statutory health insurance physicians), sought to incentivise closer working between primary care doctors and community pharmacists. One objective has been to allow the latter to play a more active part in providing medicines management services for people with long term conditions.

In France there have recently been similar politically and professionally led initiatives. Most notably, health care reforms introduced in 2009 were designed to broaden the role of community pharmacists. Over and above previously established rights in fields such as generic substitution, French pharmacists now have responsibilities relating to health coordination, screening and case finding, and chronic disease monitoring and therapy improvement¹⁵. The extent to which such interventions have as yet led to significant

¹⁵ A form of generic substitution by pharmacists was instituted in France in 1998, primarily to help contain expenditures. Medically approved generic substitution was introduced into German community pharmacy practice in 2004. In the UK over



shifts in either pharmacy or medical practice should not be over-stated. But they are indicative of a direction of pharmacy development similar to that discernable in many other countries across the globe.

Pharmacy development in the Netherlands

The Netherlands has long played a leadership role in pharmacy more significant than its small geographical and population size might suggest. One of the reported stimulæ for changes in pharmacy practice there in the 1950s was public and professional realisation of the fact that the pharmaceutical industry had started advertising drugs to prescribers in a relatively aggressive manner. In 1958 the Royal Dutch Medical Association (KNMG) and the Royal Dutch Pharmaceutical Society (KNMP) instigated – in advance of the Thalidomide tragedy – an initiative to establish community pharmacists as therapeutic advisors to Dutch primary care physicians, many of whom were working (and continue to work) as single handed practitioners or in small groups.

There was a consensus view that for pharmacists to achieve the necessary credibility in this role their knowledge of both physiology and anatomy needed to improve. To facilitate this all four Dutch schools of pharmacy had started to teach physiology, anatomy and pharmacology by 1962. ‘Social pharmacy’ also began to be incorporated into the curriculum at around that time. However, such studies were largely confined to understanding *‘the relationship between drugs and society’* as opposed to substantive topics such as the social determinants of individual and population health.

Foreshadowing the work of Hepler and Strand, Dutch pharmaceutical and medical policy debate began placing an increased emphasis on the importance of serving patient defined interests. This led the KNMP to call for pharmacists to play a more pro-active role in providing information to the people to whom they were responsible for supplying medicines.

Despite the Dutch ‘polder politics’ tradition of compromise and agreement this created some tensions with the medical profession. However, from the mid 1970s onwards medicines use evaluation instruments began to be employed in pharmacy practice in the Netherlands. Patient information began to be kept in pharmacies, initially via the use of

80 per cent of doctors’ prescriptions are now written generically, leaving very little opportunity in practice for additional substitution by pharmacists to generate economies. There are currently almost 50,000 community pharmacists in Germany and just over that number of community pharmacists in France.




card based systems. In 1985 a KNMP report entitled “*Apotheker 2000: the future of pharmacy*” presented a vision of pharmacy development similar to that contained in the seminal Nuffield report on pharmacy published in Britain the following year. With this, and continuing computer technology improvement, patient medication records began to be stored electronically. During the 1980s and 1990s community pharmacists further extended their role in supporting patients with regard to medicines taking problems and benefits (van Mil, 1999).

It is of note that pharmacy in the Netherlands had for much of the twentieth century been unusual, not just in Europe but globally, in that until 1995 patients were required to register with a single pharmacy. This is still often the *de facto* case. In addition, much dispensing was (and still is) undertaken by Scandinavian style ‘prescriptionists’ working without immediate pharmacist supervision in pharmacy systems for which pharmacists are ultimately accountable¹⁶.

Recent reforms in the Dutch health care system, which in some instances facilitated the introduction of tendering based medicine purchasing arrangements run by competing health insurers, have – in ways and to a degree perhaps not fully anticipated by legislators – reduced the revenues of many community pharmacies. A few closures have been announced. Concerns relating to the continuity of the supply of medicines obtained at the lowest possible cost have in addition been raised. But at the same time professional commentators have pointed to continuing progress in integrating the specialist skills and drug related knowledge of pharmacists in the delivery of service user oriented health care (van Mil and Schulz, 2006).

The KNMP published a ‘white paper’ on pharmacy in the Netherlands in the Spring of 2011 (Bouvy et al, 2011). This presented research evidence that further contributions from clinically oriented pharmacists working in the community setting could lead to significant additional cost savings through reductions in unwanted side effects and potentially avoidable hospital admissions. This important conclusion has reportedly been accepted by Dutch government sources.

¹⁶ Medication surveillance by community pharmacists also began in the Netherlands in the 1980s. Almost all Dutch pharmacies now have computer systems that hold patient medication data and perform relevant analyses. Records are virtually complete (except in the case of OTC medicines purchased from ‘drug stores’) as about 95 per cent of patients continue to use a single pharmacy. The system established since the start of the 1960s has meant that pharmacists and GPs often discuss pharmacotherapy at regular monthly meetings.



Community pharmacy reforms in the UK

The creation of the NHS swiftly transformed community pharmacy in Great Britain and Northern Ireland. Before 1948 dispensing and allied activities had accounted for no more than 10 per cent of the income of most pharmacies. But soon after the establishment of the health service prescription numbers rose from 70 million per year to 250 million. Dispensing fees became a major part of pharmacy earnings while other income streams declined. (See Figure 1 - today income from dispensing and allied payments accounts for over 80 per cent of the average NHS community pharmacy's revenue.)

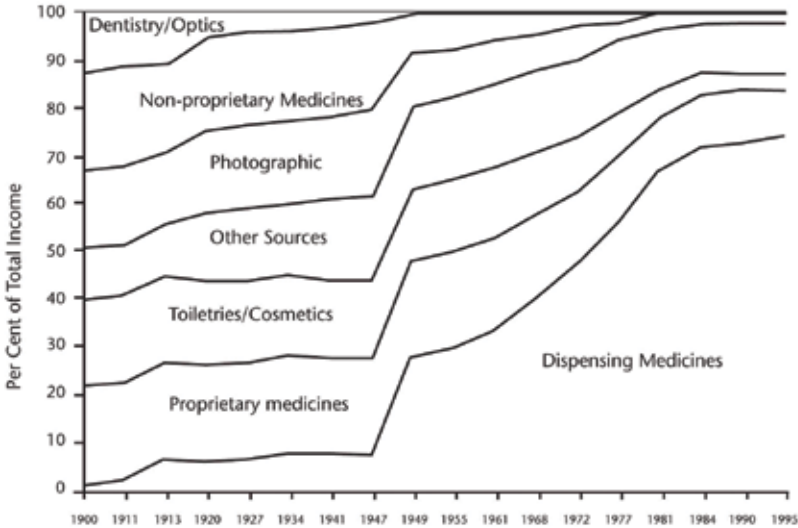
This trend arose because many people who had previously chosen to consult pharmacists about illnesses decided instead, for financial as well as other reasons, to visit their doctors to access free healthcare. Meanwhile pharmacists, due to their additional dispensing workloads, tended to move away from direct contact with the public to their dispensaries at the 'back of the shop' (Anderson, 2001; 2012). As with the extension of 'medical prescription only' supply rules, this influenced the public's perceptions of pharmacy.

Since the 1950s the annual number of NHS items dispensed by community pharmacies has risen to well over a billion a year in the UK as a whole. This has been in part because of factors such as population increases and ageing, reduced age specific levels of institutional care, and in recent decades reductions in prescription durations (Davies et al, 2012). The effect of such trends has been to ensure that –despite the fact that from the 1986 publication of the Nuffield report onwards Ministers and others have often referred to pharmacy as an '*under-used professional resource*' – community pharmacists have been kept increasingly busy. This reality, together with an on occasions seemingly defensive resistance to the delegation of dispensing responsibilities to qualified technical staff except on a closely supervised basis, has created barriers to pharmacy practice development strategies parallel to those pursued in the Netherlands.

In some UK government quarters apparent rigidities may have led to further questioning of the utility of community pharmacy, as evaluated from a public interest perspective. Yet despite this, following campaigns led by the Royal Pharmaceutical Society and the UK Health Departments' policy initiatives, there have been extensions in the parts played by NHS community pharmacists in 'public health' areas like smoking cessation and identifying cardiovascular disease risks. British policy makers have in addition sought to increase the range of P medicines available, to expand the numbers



Figure 1: Sources of income of community pharmacists in the UK from 1900 to 1995.




Source: Anderson, 2005.

of pharmacist and other non-medical prescribers, and to enhance pharmacists' contributions to the care of people with NCDs.

This last goal has been pursued through, for instance, incentivising medicine use reviews and (in order to improve adherence in medicine taking) funding support for people newly placed on long term medical treatments. (The English NHS' New Medicines Service parallels a similar initiative in the Netherlands.) Nevertheless, all but 2-3 per cent of the average NHS contracted community pharmacy's NHS income still presently comes from dispensing and allied medicines supply activities, as distinct from cognitive and 'public health' services.

The changing face of pharmacy in Brazil

Looking beyond the mature industrialised countries, Brazil has – with nations like Mexico, Turkey, China and India – enjoyed high levels of economic growth in the last 10-20 years. This has enabled it to fund the Unified Health System (SUS) and to provide better levels of care to its still expanding population. It is also relevant to observe that the development of a successful bio-pharmaceutical industry sector is, as with many



other emergent nations, a significant strategic policy objective for Brazil, alongside that of limiting the costs of new and established medicines. To this last end Brazil has played a notable role in fields such as extending access to HIV medicines.

There are presently in the order of 160,000 Brazilian pharmacists working across all sectors. Some institutions have supported the creation of multidisciplinary teams involving pharmacists alongside other health professionals in order to support better integrated care delivery. There have also been efforts to involve community pharmacists more effectively in delivering better care in poor localities.

For example, two types of Farmácia Popular have been established in the last decade, with the robust backing of former President Lula. These are either government owned (of which there were some 600 participating 'stores' in 2010) or privately owned community pharmacies which supply low cost – and tax free – medicines in economically less advantaged communities. There were over 6,000 privately owned 'aqui tem Farmácia Popular' participating by 2010, indicating a total capacity to improve medicines access for in the order of 10-15 million people.

However, despite this important example of how pharmacies and pharmacists might further evolve to make enhanced contributions to individual and public health pharmacy is across much of the SUS still largely seen as simply fulfilling a supply function (Joao, 2012). Many government owned pharmacies are also reported to be in need of physical improvement.

Nigerian pharmacy development

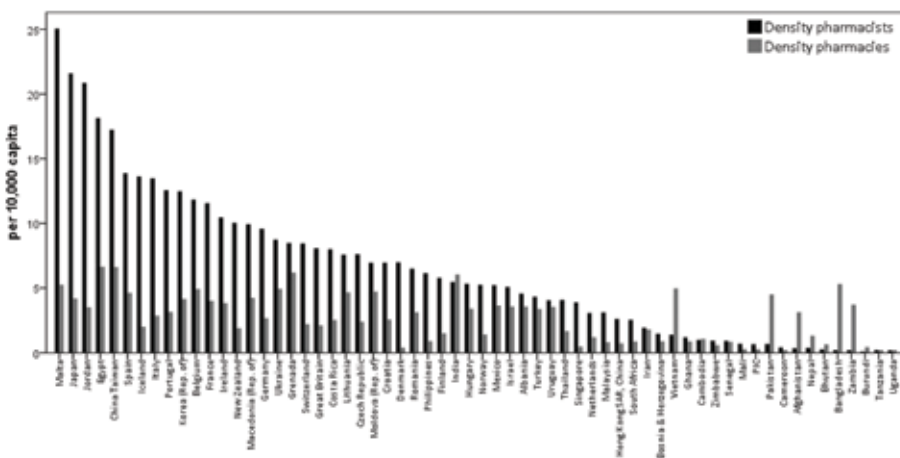
An Association of Dispensers was first set up in Nigeria in 1927. It became the Pharmaceutical Society of Nigeria in 1939, although even in as late as 1962 – half a century after FIP had been established – there were still only 487 registered pharmacists working in the country, 60 of whom were expatriates. Since then there has been considerable improvement in the pharmaceutical supply available to Nigeria's rapidly expanding population. There are now about 16,000 registered pharmacists and 1,700 community pharmacies. This is equivalent to about 1:100,000 population, which is very low by world standards (see Figure 2) especially when it is remembered that privately owned pharmacies are - as in the rest of Africa and other poorer regions – concentrated in urban areas.

Average life expectancy at birth in Nigeria remains under 55 years, and about one child in every five dies before the age of five. There are particular problems in poorer

areas such as the north of the country. However, increased effort is now being made to improve rural and peri-urban health care provision and to address problems such as high maternal mortality¹⁷. Examples of significant statutory and allied pharmacy related developments in recent decades include:


- The Counterfeit and Fake Drugs Decree, 1989;
- The Essential Drugs List Decree, 1989;
- The National Drug Law Enforcement Agency (NDLEA) Decree, 1989; and
- The NAFDAC Decree, 1993 (amended in 1999).

This last established the National Agency for Food and Drug Administration and Control. Thanks to robust local Nigerian leadership supported internationally by the work of organisations such as WHO and FIP and individuals like the late Ton Hoek (the Federation’s widely respected CEO between 1999 and 2012) NAFDAC has in the last ten to twenty years enjoyed considerable success in combating drug counterfeiting and assuring the quality of both locally made and imported medicines.



Source: FIP Global Pharmacy Workforce Survey Data 2012

¹⁷ As is also the case in other African countries, via – for example, Village Health Workers in Uganda, Health Extension Workers in Ethiopia and Community Health Workers in South Africa. Initiatives such as the establishment of ‘Millennium Villages’ also provide illustrations of how the linked problems of poverty, inequity and high levels of ill-health, disability and premature mortality from both infectious and non-communicable conditions can be addressed in settings such as sub-Saharan Africa (Wuliji, 2012)



Pharmacists in Nigeria have welcomed such progress. In parallel with developments in countries such as the US and elsewhere, Nigerian Schools of Pharmacy now provide a standard five year pharmacy qualification, while from 2002 the University of Benin began offering a six year Doctor of Pharmacy degree. Such progress is necessary in order to equip pharmacists with the knowledge and skills needed to provide modern pharmaceutical care, and to enhance pharmacists' efforts to ensure more rational drug use by doctors and the population as a whole.


But from a public health protection perspective there remain obvious challenges to be overcome in extending access to good quality and affordable (which for the very poor must in effect mean free) medicines and medicine use support (Onwuka, 2012). Significant elements of the drug distribution process are still chaotic, and an appreciable proportion of the population remains entirely reliant on traditional medicine because of a lack of even basic access to modern treatments.

Creating sustainable improvement in such circumstances cannot – experience throughout the world testifies – be achieved easily, or via supply models that have evolved primarily to meet the needs of people living in much more affluent circumstances. The success and continued relevance of 21st century pharmacy in countries such as Nigeria will in part depend on the profession's collective ability to optimise the benefits of medicines throughout communities, rather than only amongst relatively advantaged minorities.

The face of community pharmacy in India and China

Similar points apply to the development of community pharmacy in India, where the origins of the Pharmaceutical Society of India and the provision of degree level education for pharmacists also date back to the interwar period. There are today about 550,000 community pharmacies across the country, serving in the order of 1.2 billion people. (As with the People's Republic of China, about one person in every six in the world is a citizen of the Republic of India.) This widely disseminated network is a potentially important resource for the further development of universally available health care in a country where access to both preventive services and curative medicine remains poor for many people, despite rising average life expectancies at birth (Viadya, 2012).

However, critics of pharmacy in India may point out that most community pharmacies are owned by non-pharmacists and often employ people with limited qualifications.




It is also the case that in the Indian health sector the status of pharmacists (like that of all other non-medical health care professionals) has often been low as compared with that of members of the medical profession. A proportion of the latter still do their own dispensing, and may even in the hospital setting be unwilling to accept informed pharmacists' advice.

Modern Schools of Pharmacy in India are today working to equip more pharmacy graduates with the social as well as the more conventionally defined pharmaceutical competencies needed to raise medicines use standards. Yet many able individuals with full pharmacy degrees are still drawn to work in industry, in not only research roles but also the marketing of branded generic as well as patented products to doctors. Such observations underline the fact that it remains a significant challenge (in not only India, but in many other parts of Asia, Africa and the Americas) for even very highly motivated pharmacists to contribute effectively to medicines use optimisation, notwithstanding well recognised shortages of qualified health sector personnel.

Alongside a plethora of branded products, India has amongst the lowest medicine prices in the world. However, as experience in countries like Greece may also be taken to demonstrate, this is not a guarantee of good quality pharmaceutical care. It may in some contexts – including that of funding high risk innovative research, and encouraging the restrained and prudent use of drugs like antibiotics – threaten public interests. To the extent that the country can move successfully towards the universal provision of more adequate publicly funded primary and secondary health care, important new opportunities should arise for the profession. But local concerns about inappropriate and corrupt practices will need to be resolved, regardless of whether or not more centrally or State level tax or insurance raised funding can be channelled towards service provision.

Affordable health care improvement is also likely to require new patterns of health staff training. Such progress may although desirable from a public policy perspective (the Indian government has recently, for instance, proposed an intermediate level medical qualification) be seen as a threat to historically defined professional structures and expectations.

Turning to China, the communist system instituted in 1949 led to a strengthened recognition of the need to improve public health. In the period from then until the mid 1960s large numbers of doctors were trained and new hospitals and health centres were built



(Neumeyer and Guan, 1982). Subsequently, the so-called ‘barefoot doctors’ were introduced. These former farmers/agricultural workers were typically given six months to a year’s health related training before going to practice in their communities. This system provided in rural areas a model of service delivery which some commentators regard to this day as an important example of effective health development. However, after the Cultural Revolution period the progressive privatisation of the Chinese economy led to the break-up of the barefoot doctor experiment.


For sections of the Chinese community such events for a period made access to health care more difficult than was previously the case. Yet average life expectancy at birth in the People’s Republic of China is now 75 years. For Chinese women, whose social situation and standing relative to men has improved greatly compared to that experienced by many in the feudal state still in existence when FIP was first muted, it is currently approaching 78 years.

This success has in part been achieved by the combined use of traditionally based and modern medicine(s), albeit that the health care role of community and other pharmacists in China has yet to be fully established. Historically, a strong functional division between diagnostic, prescribing and dispensing activities of the type that evolved in Europe over the last 1,000 years has not existed in the Chinese health culture.

This is not to suggest that the more integrated traditional approach was or is necessarily undesirable in the Chinese setting. But it is of note that even in modern hospitals’ pharmacy departments can be directed by medically qualified heads. Outside atypical areas like Hong Kong, community pharmacies often supply virtually any drug without prescription, and may be staffed by people lacking adequate pharmaceutical knowledge. As in India, much of the twentieth century focus of leading individuals with pharmacy backgrounds has been on the industrial and commercial application of the physical pharmaceutical sciences, rather than on pharmaceutical care and ensuring the most productive use of medicinal and allied products. There may therefore be important opportunities for further strengthening the role of community pharmacists and pharmacies as the country continues to become wealthier, older, and more concerned with cost effective health and welfare promotion.

Japan’s experience of pharmacy adaptation

The final national level example of pharmacy development discussed here is that of



Japan. Following the 1868 Meiji restoration¹⁸, Japan had a unique experience of ‘western medicine’ being introduced into a previously isolated community with strong internal traditions, in which doctors (*Kusushi*) were responsible for both diagnosing and treating disease and making and supplying treatments (Arakawa, 2012). The initial introduction of pharmacy was required to accommodate the importation and supply of foreign medicines. This history may to a degree explain why pharmacy as a profession is still sometimes regarded as junior in status to nursing and medicine.


As described earlier, it took over a century for the roles of dispensing and prescribing successfully to be separated. This eventually took place after the introduction at the end of the 1950s of universal (public) health insurance, and a subsequent combination of changes in pharmacy education and medical payments (Akiba et al, 2012).

Today there are about 200,000 Japanese pharmacists, three quarters of whom work in the community. Some 50,000 community pharmacies serve a total population of just under 130 million people. Unlike the situation in virtually all other richer countries there are no recognised pharmacy technicians in Japan, although some types of non-prescription medicine can be supplied by non-pharmacists with Prefectural qualifications. Pharmacy ownership is not restricted to the profession’s members, although pharmacists must be in place to manage the dispensing of both traditional herbal and allied preparations (which as in German speaking Europe are still relatively widely used) as well as most allopathic medicines.

Since 2006 the pharmacy degree course in Japan has required 6 years University education, of which six months is spent in hospital and community placements. These changes were in part instituted to open the way to closer pharmacist involvement in medicines selection and use, although progress has in this context reportedly been slow. To date hospital pharmacy practice in Japan has tended in relation to clinical care to lag behind community service development¹⁹. This contrasts sharply with the experience of

¹⁸ The Meiji restoration instituted direct Imperial rule in place of the previous feudal Shogunate. This opened the way to the modernisation of the economy, despite continuing social rigidities. Five students who from 1863 had studied in University College London under the chemist Professor Alexander Williamson played an important part in this process.

¹⁹ Japanese pharmacists were advised by the Pharmaceutical Association of the USA to establish a forum for hospital pharmacists in order to share opinions and enhance collaboration during the period of occupation at the end of the Second World War. The Japanese Society for Hospital Pharmacists was established in 1955. Some commentators have suggested that physician-controlled computerised prescribing and dispensing systems in use in Japan reduce the amount of time pharmacists need to spend on medicines dispensing leaving them free to concentrate on clinical roles (Kishi, 2000). However, this is questioned by others, who point to their limited authority to improve medical practices and the considerable amount of hospital pharmacist time still spent on activities such as manufacturing.



countries such as, for instance, the US and the UK, but to a degree reflects the Germanic pharmacy model.

Hospital pharmacy: growth and challenges

As examples such as that of Japan illustrate, hospital and community pharmacy have – although clearly related to each other – developed along differing paths. The role and standing of hospital pharmacy varies widely between national settings. At its best, American hospital pharmacy is amongst the most advanced in the world, with pharmacists solely concerned with clinical care and health outcome improvement being present on every ward of a significant proportion of hospitals. But in other countries, including many EU Member States, with equally sophisticated health care systems hospital pharmacy is much less developed.

The history of hospital pharmacy is closely related to that of hospitals themselves, and the purchasing and making of medicinal supplies. At the start of the 20th century the majority of pharmacists employed in hospitals globally were in charge of the production of Galenical medicines, often in basement-sited manufacturing areas. Some, because of economic pressures, produced additional products for use within their hospitals, such as soap solutions and baking powder.

However, in France at around that time hospital pharmacists also began to play an increased role in analytical chemistry. This is still reflected in aspects of French pathology and allied service provision today. In countries such as the UK the potential for hospital pharmacy to support and improve medical practice in ways beyond assuring consistent drug supplies also gained increased importance during the period from the 1930s to the 1950s. In that period the introduction of antibiotics and other innovative treatments (the first antipsychotic was developed by French scientists at the start of the 1950s) and the expansion of industrial manufacturing began creating new types of pharmacy service requirement. In 1955 the influential Linstead report listed ten (NHS) hospital pharmacy tasks. In addition to storing and supplying drugs and allied items of assured quality, these included:

- devising formulae for ‘special needs’;
- investigating ‘pharmaceutical problems’;
- assisting with the development of new treatments;
- promoting the economic use of medical supplies;


- facilitating efficient drug selection through advice to prescribers;
- instructing (sic) users of medicines; and
- training pharmacy students.

But it was not until the Thalidomide controversy that ward-based pharmacy emerged in the United Kingdom, with the work of individuals such as Graham Calder and John Baker²⁰ (Calvert, 1999). US clinical pharmacy also began to develop at around the start of the 1960s. By that time the therapeutic revolution had generated a range of new drugs that added to the perceived and actual risks of medication related errors and/or adverse events. This raised pharmaceutical information needs amongst doctors, nurses and patients (Smith, 2007). Along with the increased expectations of better educated patients and pharmacists themselves, such trends created a change motor in environments like those of north America, north western Europe and Australia.

Yet even today hospital pharmacy has not as yet developed as strongly in other settings. In Germany, for example, the first formal hospital-based clinical pharmacy services were not initiated until 1977, and the number of hospital pharmacists remains relatively low. Of Germany's 59,000 currently active pharmacists 83 per cent work in the community, as opposed to only 3 per cent in hospitals. This is equivalent to just 0.3 pharmacists per 100 beds (Helmstatder and Schulz, 2012). The UK and France have three times as many hospital pharmacists, serving smaller populations.

The first postgraduate courses in clinical pharmacy in India were also launched at the end of the 1970s, by which time some central and State government decision makers had become aware of its potential benefits (Singh, 2011). About a decade before the State of Karnataka had, for instance, required that hospitals should have a pharmacy controlled by a pharmacy graduate. Hospitals with more than 500 beds were also obliged to have a pharmaceutical manufacturing unit. In 1975 a national committee made related recommendations. But overall progress towards pharmacists being able to check and guide medically directed medicines use in order to protect patient and public interests was,

²⁰ Baker's and Calder's contributions in England and Scotland illustrate how individuals can influence the course of events additionally to the working of macro social and economic forces. Graham Calder was subsequently involved in the implementation of the Noel Hall report on NHS hospital pharmacy in the 1970s and the establishment of the Nuffield inquiry into pharmacy in the 1980s. The latter took place after remarks made by a Health Minister (Dr Gerard Vaughan) while Calder was working in London at the Department of Health, to the effect that 'One knew there was a future for hospital pharmacists, one knew there was a future for industrial pharmacists, but one was not sure that one knew the future for the community pharmacist'. Calder subsequently went on to, with other colleagues interested in the 'post supply era' development of clinical pharmacy such as Dr Bill Scott, further influence pharmacy policy in Scotland.



and remains, disappointingly slow in many presently industrialising countries. It appears that the more vulnerable communities are the more difficult it is for medical practices to be questioned by anyone but doctors themselves, in both hospital and community settings.


Professional leadership

In the Netherlands hospital pharmacists formed a separate Association in as early as 1928. A wide range of similar organisations now exists in countries ranging from Australia and New Zealand to, for example, Estonia, South Africa and Peru. However, some commentators have observed hospital pharmacy did not throughout the twentieth century have an adequate international basis (LeBlanc and Dasta, 2004).

FIP responded to this challenge by organising a global conference on the future of pharmacy in Basel, Switzerland. This was held in 2008 in association with the Federation's 68th Annual Congress, and led to the publication of a number of consensus statements. They in essence emphasise the Federation's commitment to the continuous improvement of medicines management and pharmaceutical care delivery in hospitals, and are presently serving to support the profession's efforts to facilitate further progress in every region. An important future challenge for hospital and community pharmacy leaders across the world will be to improve the co-ordination of pharmacy services across primary and secondary settings, both to improve health outcomes and facilitate care cost savings.

OPPORTUNITIES FOR BETTER HEALTH

Large sections of the world community are healthier and wealthier than ever before, thanks in part to modern medicines and vaccines. But because many people are living longer and expect to be able to do so in better health and with less disability than previous generations experienced in their 60s, 70s, 80s and even 90s, demand for both protective interventions and effective treatments is also higher than ever before. At the same time the poorest third or so of the global population – in the order of 2 billion individuals – still has inadequate access to medicinal and other therapies that, by the standards of the majority today, are basic essentials. They remain in relative terms highly vulnerable to infections, accidents and the consequences of violence. If they survive beyond younger adulthood they also face increased risks from the non-communicable conditions of middle and later life, like coronary heart disease, strokes and the cancers.




It is additionally apparent that as the populations of less advanced countries continue to grow, while those of richer ones consume progressively more natural resources, the global environment will come under increasing pressure²¹. Seen from the perspective of this ‘rich-world-poor-world paradox’, the most important strategic task presently facing pharmacy as a world-wide profession committed to improving health is that of helping speed the completion of the demographic and socio-economic transition processes outlined earlier. There is also a need for more efficient and affordable forms of preventive and ‘maintenance’ health care provision in post-transitional societies (Gottret and Schieber, 2006).

By building on the past and moving on from it, individuals with modern pharmaceutical qualifications can make important contributions to resolving such challenges and, via fostering bio-scientific developments that could in future not only further extend healthy life spans, enabling humanity to respond to threats to common global resources. To survive and prosper, the profession and its members must also adapt to changes such as the advances in computer technology that are allowing the increasing automation of ‘cognitive work’ such as dispensing and providing medicines and health information, and offering new ways of keeping and sharing clinical records and identifying needs.

Against this background, the final part of this report seeks to explore questions and opportunities relating to the future of pharmacy in the 21st century. It does not offer specific policy recommendations. Rather, it seeks to identify areas where effective policies are most needed, and to present observations relevant to the decisions policy makers will need to take. However, before examining the key themes identified during the preparation of this analysis an important introductory point to stress relates to pharmacies as both businesses and professional practice settings.

In the eyes of some critics, pharmacists are more compromised than, say, doctors or nurses by conflicting interests in financial profit as against the pursuit of altruistic ends. But this view is not accepted here. All medical and other forms of health care aimed at achieving health gain are normally provided for financial gain as well as moral purposes,

²¹ Current projections suggest that global demographic transition as conventionally defined will be completed by 2100. Assuming this to be the case and that (perhaps optimistically) catastrophic events are avoided the world population will by then – at 9-10 billion – be ten times higher than it was in 1800 and a little over 5 times the level it was at when FIP was established in 1912. By 2100 the average life span from birth is likely to have tripled since demographic transition first began in the eighteenth century in the UK, the Netherlands and France. The ratio of elderly people to children will by then have increased by a factor of ten, although this should not in itself be seen as imposing unaffordably increased health care costs. If pharmacy and other services are developed appropriately it may rather lead to gains in *per capita* productivity.




and hence need to be delivered within social and legal structures which counter perverse incentives and protect consumer and public interests. As discussed earlier in the case of pharmacy, at the historical heart of all professionalism there is a trade between granting service providers privileges that help to sustain their businesses and requiring them in return not to exploit their customers. In combination with externally imposed regulation, such arrangements serve to complement market forces and maximise collective security and prosperity.

All professions can therefore be regarded as trades marked out by an unusual degree of knowledge asymmetry between practitioners and the consumers of their products and services, and that consequently need special types of control to curb abuses of power. What is perhaps special about community pharmacy is the visibility of the interface between ‘selling and caring’.

In the past pharmacy has not had a generally recognised, high profile, international equivalent to the Hippocratic Oath. Yet as a modern profession it is legally regulated and subject to internal ethical codes. This is exemplified by the 2011 publication of joint FIP/WHO guidelines on good pharmaceutical practice (GPP). These stress the importance of not only ‘*doing no harm*’, but of positively pursuing economic efficiency and optimal levels of individual and public health gain resulting from medicines use. They follow on from FIP led policies relating to issues such as the global importance of better collaborative working between health professionals of all types.

Over and above such formal developments, pharmacists are by the nature of their roles, education and culture more concerned with reducing the possible dangers of medicines taking than with accepting high levels of clinical hazard in the hope of securing low probability therapeutic (and/or personal reward linked) benefit. Pharmacy in this context evolved to check medical authority and assure medicines use safety, even though doctors of medicine are normally seen as the main gatekeepers to accessing the drugs at the centre of pharmacists’ expertise.

Suggestions that the community (or any other) pharmacy model is inherently unsuited to the delivery of high quality health services in a manner that will benefit service users should be regarded as potentially prejudiced, and perhaps motivated by sectional as opposed to public interests. No profession or trade is entirely free from poor behaviour



and there are many important opportunities to improve further community, hospital and industrial pharmacy. But on occasions pharmacists may be criticised because of their role in improving drug use and health care delivery, rather than any failings.


As the world continues to change and new patterns of need and opportunity arise, the consumer choice and self care driven, professionally moderated and guided, service model widely provided by community pharmacists may prove better adapted to meeting future public needs than the less customer oriented, more paternalistic or authoritarian, approaches sometimes found elsewhere in primary and secondary care.

Improving access to medicines

The proportion of the population lacking adequate access to effective medicines is still over 50 per cent in many poorer countries. Such inequities reflect ongoing weaknesses in health systems and national and international medicines supply policies. Notwithstanding recent progress (led in part by bodies such as the Gates Foundation, rather than health professions themselves or governmental or allied agencies) all 21st century health sector stakeholders arguably share responsibilities for improving this situation. Pharmacy as a global profession also has an opportunity to facilitate better treatment and care for less advantaged groups living in relatively affluent communities, including those stigmatised because of difficulties like, for instance, learning difficulties or – despite the social progress of the last century – visible disfigurements.

A high profile illustration of an area where prejudice or ignorance has, along with poverty and a lack of global solidarity, impaired access to medicines is that of HIV/AIDS therapy. The most recently available data indicate that little more than a half of the ten million people living in Africa who could benefit from ARV treatment are in receipt of it (WHO, UNAIDS et al, 2011). Even in nations capable of affording more adequate service standards, universal access to anti-HIV treatment remains in many instances far from assured.

Similar and in some respects even greater problems exist in many widely debated health care fields ranging from the alleviation of avoidable suffering from parasitic and other still common infections to the prevention and treatment of diabetes, heart diseases and cancers. As the populations living in emergent economies like China, India, Turkey and Brazil age, treating the latter in ways that satisfy rising public expectations will inevitably become a more pressing challenge.



Pharmacy and pharmacists cannot alone resolve challenges that relate to fundamental deficiencies in material and socio-economic infrastructures and that (as with insufficient numbers of qualified health workers) prevent medicines and/or other health technologies being supplied and used to best effect. But in collaboration with other professions and the communities they serve across the globe pharmacy can play an important part in identifying and pursuing solutions to such problems. Over and above ensuring the efficient and effective working of given pharmacies and the provision of individual patient care, opportunities include:

- *Ensuring that Essential Medicines Lists are kept updated, and improving central supply systems.* Even the least developed countries today normally have Essential Medicines Lists (EMLs). Yet for these to bring benefit they need to be regularly updated, and national or regional level arrangements made for the affordable manufacture or purchase of included products. World-wide, pharmacists have a key part to play in executing such tasks, and meeting requirements such as the establishment of secure and reliable storage and distribution systems. Such measures can deliver important gains. For example, in Nigeria a central medical stores system was established during the 1990s, along with measures like the Bamako initiative (also known as the Revolving Drug Fund). Although many challenges are yet to be overcome, such interventions have improved affordable access to medicines via primary health care facilities. Ethically robust leadership by pharmacists such as that given by Professor Dora Akunyili while she headed NAFDAC (see above) can also serve to curb corruption and enhance the efficiency of drug supply processes.
- *Working with traditional medical practitioners and other alternative health workers to enhance local access to effective treatments.* As already evidenced, traditional medicine meets the needs of many hundreds of millions of people who have partial or no access to modern treatments. It typically remains widely trusted, even when on occasions questioned by scientific evaluations. Given this, pharmacy can and arguably should help to promote traditional medical practices wherever they are beneficial as evidenced through scientific investigation, and seek to improve them in circumstances where significantly better outcomes are achievable. When economic and other factors prohibit access to allopathic medicines via established forms of professional supply, it is also possible (as the Chinese barefoot doctor experiment and more recent community health worker initiatives in countries such as Brazil and Tanzania have illustrated) to institute alternative lower cost, more culturally appropriate, arrangements. In the past conventionally minded professional organisations have sometimes opposed such developments. But there is both a logical and an ethical case for their support.


- *Advocating health system reforms designed to benefit people with unsatisfactory access to pharmaceutical care.* As recent US experience relating to the passage and implementation of The Patient Protection and Affordable Care Act (2010) has demonstrated, health care reform is often controversial. This is particularly so when it involves people being required to make tax or insurance payments they judge not to be in their immediate best interests (Morgan and Kennedy, 2010). Professional organisations and their members may naturally wish to avoid partisan involvement in such debates. But if improving health is taken as central to the concept of professionalism, pharmacy and pharmacists have a responsibility to act as advocates for individuals and groups in special need of better pharmaceutical care, nationally and internationally.

A final point in this context is that although in the past professionalism was vital in societies seeking to assure service standards, twenty first century technical capabilities have extended the capacity of general management led and external regulatory systems to monitor, maintain and improve health care quality. This does not mean that professionalism is redundant. But it may reasonably be taken to indicate that to remain relevant to meeting societies' and their members' requirements professional bodies should in future seek to broaden their responsibilities. In pharmacy this can be seen as an aspect of progressing from a primary focus on making good quality medicines and defending the immediate viability of pharmacies to one of ensuring that pharmaceutical technologies are employed to optimal effect throughout the world.

Improving the professional use of medicines

Even when universally available, drug and allied products only generate benefit when they are used appropriately. Given in the wrong amounts and/or in the wrong circumstances they may either fail to have effect, or do more harm than good. Pharmacy today exists in part to ensure that poor prescribing in the community and sub-optimal professional use of medicines in hospitals and nursing homes does not offset the gains that universal access to treatment otherwise generates. Despite the financial challenges to which pharmacies and pharmacists in the Netherlands may recently have been exposed, their national example provides a notable illustration of this point.

The value of modern pharmacy has also been demonstrated by research conducted in many other nations. For instance, a recently published study covering nine years of collaborative working by physician-pharmacist quality circles in the Swiss canton of




Fribourg showed not only annual drug cost savings of some 40 per cent as compared with control practices, but also safety and potential therapeutic gains (Niquille et al, 2010). Pharmacy practice research conducted in the same area in the period 2002-05 also found drug cost savings of some 16 per cent as a result of enhanced pharmaceutical care in the nursing home setting, together with care quality and potential health outcome improvements (Locca et al, 2009).

Looking more widely, the moderation and appropriate targeting of antibiotic use is a topic of considerable global significance. A recent analysis by the IMS Institute for Healthcare Informatics suggested that in the order of \$US 60 billion a year could be saved by the more responsible use of such medicines, albeit that offsetting increases in their supply might also be justified in poorly served communities.

In a number of nations, including – for instance – Sweden, Australia and France, interventions such as the establishment of antibiotic use surveillance systems, linked to changes in prescribing and dispensing incentives and controls, have already been introduced in order to help ensure more optimal drug use. Pharmacists play vital parts in such efforts. For example, in Brazil the National Agency for Health Surveillance (ANVISA) identified pharmacists as the healthcare workers primarily responsible for the control of antibiotic misuse and overuse (IMS Institute for Healthcare Informatics, 2012).

However, in other parts of the world the inadequately regulated supply of antibiotics through pharmacies and on occasions other sources (including licit and illicit internet ordering and postal delivery systems) is part of the identified problem. Despite the health care advances of recent decades there are still, for example, reported government and other stakeholder concerns about antibiotic use in Turkey. There is also a significant level of controversy about excessive and/or otherwise irrational antibiotic use in settings such as India, where universal access to affordable health care is much less well assured. The types of harm resulting from inappropriate antibiotic use include not only financial waste but avoidable deaths and the emergence of bacterial resistance. It is hence an important example of an issue in which pharmacy as a world-wide profession can support protective change.

Nevertheless, naive interpretations of what could and should be achieved ought to be avoided. Reduced volumes of antibiotic use may not, for example, lead to *pro-rata* drug cost savings if countries or companies wish for strategic reasons to retain disseminated production capabilities and/or to encourage new investment in developing effective




antibacterial agents. In some cases compensatory price rises could occur if consumption volumes fall. Similarly, if community based or other pharmacists are in future to play a more pro-active role in providing antibiotic treatments where needed and preventing inappropriate supply when desirable, new funding may be required. From a policy perspective it is important to communicate that minimal cost public or private dispensing processes are often unlikely to be able to deliver optimal medicines use.

Improving medicines taking

Even when medicines are universally accessible and appropriately prescribed, spending on them cannot produce better health if they are not taken, or are consumed in ways that negate their therapeutic value. Adherence in medicines taking, defined as the extent to which the individuals for whom treatments have been provided use them in ways agreed with informed professional advisors, has by many sources been estimated to be at or below 50 per cent in the chronic disease context. (See, for example, Trueman et al., 2010.) This results in both the physical wastage of medicines, which because of their potential toxicity should be appropriately disposed of in case of harm to other people or the environment, and waste due to lost potential health gain. The IMS study referred to above estimated that about half the projected total of US \$500 billion that might be generated by better medicines use could be derived from reduced rates of non-adherence.

There is good evidence in areas ranging from HIV/AIDS treatment to cancer care and the use of pharmaceuticals such as, say, imatinib that many people do not take drugs as recommended, even when their lives are at risk and regardless of whether or not they have paid for their medicines or received them free. The underlying reasons for non-adherence in medicines taking range from everyday life factors which may cause doses to be forgotten (or seen as unaffordable) through to inadequate professional support, fears of unwanted side effects and a lack of belief in the value of medicinal drugs (Horne et al., 2005). Sometimes conflicts between traditional medicine and ‘natural’ health concepts and the science underlying modern pharmaceutical care exacerbate such problems.

Effective approaches to improving adherence are likely to require multiple interventions at the ‘public health’ (community wide) and individual and family support levels. These ideally involve collaboration across professional boundaries. But while recognising the need for joint action, pharmacy and pharmacists can play important individual parts in improving medicines taking through activities such as medication monitoring and review.




There is already strong research evidence confirming this in many countries, including Australia (Rigby, 2010), the UK (Latif et al., 2011), the US (Centres for Medicare and Medicaid Services, 2012) and the Netherlands (Bouvy et al., 2011). Illustrations of successful pharmacist involvement in projects aimed at achieving better outcomes exist in areas such as asthma care in Germany and COPD patient care in Denmark. Likewise in the UK the recently instituted New Medicines Service (NMS) has been designed (against a background of research studies led by the UCL School of Pharmacy) to help people with conditions like asthma, COPD and type II diabetes take newly prescribed medicines to optimum effect. It also supports people who can benefit from taking anti-hypertensive, anti-platelet and anticoagulation therapies correctly.

As world-wide demographic and epidemiological transition proceeds there will be a growing need for such services, aimed at supporting medicines taking for both preventive and disease management purposes. There is a clear opportunity for pharmacists globally to promote better medicines taking alongside other aspects of pharmaceutical care and medicine management improvement. Yet adherence promotion is another area in which naive interpretations ought to be avoided.

In addition to the difficulties inherent in seeking to achieve demonstrable population level behavioural changes of any sort it is important to note that although large costs can be attached to the problem of non-adherence in medicines taking, the economic calculations on which such conclusions are based can in some respects be controversial. Their main elements typically relate to the projected subjective value of quality adjusted life years foregone because medicines have not been used to best effect, and the long term savings in health care costs that should result when disabling conditions are prevented. Yet the short term cash savings available to policy makers from investing in improved medicines taking are normally much more modest. To the extent that the latter will involve more prescriptions being dispensed, and hence more medicines being paid for, they may in some circumstances prove negative.

This is not to deny the social and economic value of increased adherence in medicines taking, or the desirability of pharmacists finding cost effective ways of contributing to its achievement. But in regions such as Europe it suggests a need for caution with regard to topics such as changing radically existing remuneration systems for dispensing medicines as opposed to providing ‘cognitive services’.




The most important public policy point to stress is that if disseminated community pharmacy based supply networks can be preserved (or, where they do not yet exist, created) this should in time lead to valuable opportunities for achieving highly cost effective (in essence, low marginal cost) public health gains. However, if the pursuit of short term savings (that may or may not materialise in ways that naive observers might anticipate) were to undermine pharmacy networks and reduce pharmacists' abilities to offer anything more than a basic medicines supply, then chances for substantively increased productivity levels might well be irrecoverably lost. By the same token, if pharmacy services do not continue to evolve in ways that add additional value by meeting health needs in more cost effective ways, then the case for minimising dispensing costs down to 'commodity' level would over time be strengthened.

Pharmaceutical sector re-regulation?

The history outlined in this analysis involves two main strands of regulatory development. The first relates to the practice of pharmacy as a professional activity distinct from medicine, and sheltered from full open market competition by controls on who can dispense medicines from what premises. The second relates to the testing and licensing of medicines. The former network of regulations emerged over a period of at least 1,000 years. The latter has developed more rapidly during the last century or so of human existence.

Few people would deny the importance of seeking to ensure that pharmaceutical products are well made, appropriately supplied and safely used. But in the recent past concerns have been raised as to whether or not the regulation of medicines research and marketing has become excessively costly and time consuming relative to the benefits generated. Some responsible for competition policy in the EU have also questioned the degree to which controls over the 'liberal professions' in areas such as the numbers, opening and ownership of pharmacies remain in the public's interest.

This second debate was in part stimulated by the so-called 'deregulation' of pharmacy ownership in Nordic countries like Iceland, Norway and Sweden. In the latter (unique) instance the previously State owned Apoteket pharmacies have been exposed to fresh competition, in part – policy makers reportedly hoped – to enhance the supply of self purchased OTC medicines to the Swedish public.




It would be beyond the scope of this overview of pharmacy's historical development to explore either of these fields in detail. Yet, in relation to medicines regulation the available evidence indicates that it is in both the public's and the profession's interest to ensure that the flow of new medicines to the world market-place is not needlessly impaired, and that novel uses for older medicines as pharmacy (or if desirable prescription only or general sale) medicines are permitted in as timely and economic a manner as possible. At present this is not necessarily the case anywhere in the world.

In stark contrast to the situation when FIP was being established in 1912, there is today a case for believing that pharmaceutical development is in danger of being over-regulated to an extent that harms rather than protects the public's health. Examples of the sorts of correction that pharmacy as a profession might wish to support include the introduction of more conditional licensing for innovative medical entities, and facilitating provisions for the marketing of more 'pharmacy only' medicines in the US and other regions where this category is presently absent or unduly restricted. Such measures might, for example, have a particularly important future role to play in cardiovascular disease prevention (Wald and Misselbrook, 2011). Conditional licensing could be of special value in contexts like cancer treatment²².

With regard to controls on community pharmacy ownership and related matters, different national administrations have throughout FIP's existence taken varying positions as to what should or should not be permitted (Vogler et al., 2012). Conflicts of opinion and interest have perhaps been most obvious with regard to the formation of 'commercially managed' chain or corporate pharmacies, as opposed to individually owned 'professional pharmacies'. At the same time some reformers appear to believe that in today's environment it would be in the public's interests to allow unlimited numbers of pharmacies to open in order to achieve 'market saturation' and so (in theory at least) lower professional charges.

Others, who may be more concerned with restricting medicine sales to optimal levels rather than maximum demanded volumes and/or for whom pharmacies are public health resources to be made as evenly and economically available as possible, are more

²² The 2001 European Clinical Trials Directive is frequently cited as a well-intended measure that has in practice disproportionately increased the costs of medicines innovation relative to the benefits accrued. New regulations governing clinical trials in the EU will come in to force in 2016. Their proponents hope they will allow faster assessments, simplified reporting procedures and an increase in transparency. Yet it is presently uncertain whether or not these and other measures proposed elsewhere in the world will protect public interests in the long term sustainability and productivity of pharmaceutical/bio-medical research.



likely to favour ‘rational allocation’. There is a case for both approaches, albeit that the logic of limiting and directing the numbers of publicly funded service providers of any sort is relatively strong.


Arguably, pharmacists should seek arrangements consistent with the delivery of good quality, sustainable cost, services for both individuals and their overall communities. Hence in settings where corporately owned chain pharmacies exist, special effort should be made to promote the continuity of personal care and, as desirable, sustained individual relationships between pharmacists and not only patients but also with their doctors²³. In areas where, as in France, the ‘mainland European’ model of professionally owned pharmacies is ascendant, joint investments in service developments that permit commonly established or contracted agencies to achieve savings to scale and pool learning experiences could prove increasingly valuable.

Supporting pharmaceutical innovation while reducing avoidable costs and waste

In the last two decades the rate of development of new pharmacological agents, particularly for frequently occurring conditions, has tended to slow. Although recent figures suggest a possible reversal of this trend, there have been fundamental shifts in medicines innovation. As described earlier, the great majority of the middle and late 20th century innovations that improved the treatment of common conditions in the community are now available as low cost generics. Newer medicines are more likely to be for rarer conditions being treated by specialists. Such developments have saved money for primary health care funders. But they have negatively affected the finances of some community pharmacies and research based pharmaceutical manufacturers.

The history of the 20th century helps to explain why there may be ongoing tensions between pharmacy and the pharmaceutical industry, despite their common origins. In the early 1900s a proportion of pharmacists blamed ‘industry’ for taking their role in making medicines. Subsequently, others objected to aspects of pharmaceutical marketing, or have been dismayed by supply chain changes that they felt unfairly reduced their incomes.

²³ There is sociological research evidence that in at least some if not all cultural environments pharmacists need to be personally known in order to be trusted by not only members of the public seeking clinical services but also by their physicians. (See, for example, Gidman et al., 2012.)




Conversely, some people working in pharmaceutical firms may have seen pharmacists as excessively critical and sometimes unduly resistant to the introduction of new treatments, while privately being heavily focused on maximising discounts and profit margins. From an industry viewpoint, pharmacy may also have seemed intent on taking income out of cutting medicine costs rather than improving patient care.

Pharmacists are legitimately concerned with reducing not only clinical risks but also needless expenses and avoidable medicines wastage, albeit that the actual (marginal production and purchase) cost of generically available pharmaceutical products can be very low compared with that of the professional labour that may on occasions be employed in attempts to secure savings. Such observations suggest that there will always be constructive tensions between pharmacists working in health care roles and those employed by companies or other institutions centrally concerned with developing and marketing medicines. But this does not mean to say that pharmacy as a global profession should not value therapeutic innovation, or have a realistically informed understanding of the economic arrangements needed to justify both public and private investment in high risk biomedical research.

This is once again an area which cannot be explored in detail here. But relevant policy issues relate to granting intellectual property protection, and the legitimate pricing of innovative as opposed to generic products. Off-patent and otherwise unprotected medicines should arguably be obtained at the lowest possible costs consistent with good production quality and sustainable, secure, supply. However, this is not the case with products that still enjoy IP rights, which exist primarily to protect national and world-wide public interests in maintaining adequate financial incentives for ongoing investment in new medicines. The challenge of supplying effective treatments to less prosperous populations ought not, it may be argued, be resolved by actions which will harm the future supply of better remedies to the world population as a whole.

Some aspects of disputes in this area can be traced back to the days of European colonialism described earlier in this report. The balanced exploration of this field can also be complicated by factors ranging from abusive or uncaring practices by research based or generic pharmaceutical companies to the possible desire of some nations to develop local industrial capacity regardless of the intellectual property claims of innovators. Nevertheless, opportunities exist to address the balance between drug development and supply related concerns more effectively than in the past, and in so doing to help (re)



build strong partnerships between pharmacists working in health care and medicines discoverers and makers. Pursuing such ends would be consistent with the original objectives of FIP, and its early interests in medicines related intellectual property.

Preventing counterfeiting


The quality and authenticity of medicines has been a cause for public concern throughout history. Even when people were wholly reliant on herbal and other ‘natural’ treatments there were dangers that medicinal plants would be misidentified by well-intended individuals, or deliberately misrepresented by those intent on fraud. In the 17th and early 18th centuries, for instance, widespread adulteration undermined European public confidence in the efficacy of Cinchona bark (the natural source of quinine, which was often in short supply) as a treatment for malaria, which was then prevalent in countries ranging from Greece to England²⁴.

Some economic estimates of the present scale of medicines counterfeiting may be exaggerated. Yet there is no doubt that falsification related hazards to the public’s health exist even in well protected regions such as North America and Europe. In poorer parts of the world, like sub-Saharan Africa and areas of southern and eastern Asia, the risks associated with medicines falsification are much greater. There is robust evidence that 15-50 per cent of the anti-malaria medicines supplied to vulnerable African and Asian communities have in the recent past been falsified, and that such problems have led not only to avoidable deaths but risked increased rates of drug resistance (Bate and Attaran, 2010; Newton et al., 2011).

Such problems will increase in low and middle income national settings if public expectations and demands for treatment rise faster than governments’ abilities and/or willingness to provide affordable universal access to care. The further sophistication of technologies like those needed to produce fake pharmaceutical packaging well and to deliver medicines via the internet will also serve to exacerbate the world-wide risks of medicines falsification.

Developments relevant to pharmacy and the work of FIP include recent international debate about the role of WHO in the prevention of counterfeiting, and plans to introduce medicines serialisation. The latter involves the unique numbering of pharmaceutical packs and/or bulk containers, to allow ‘tracking and tracing’ of medicines from their

²⁴ *Cinchona* bark was first described the 1677 London Pharmacopoeia as Peruvian bark (*cortex Peruvianus*)



place of manufacture through to the point of patient supply. By 2016/17 all Europe's 130,000 community pharmacies should have the equipment needed to verify the medicines supplied to them. Turkey already has a similar system (introduced in part to limit fraudulent claims for public payments) and relatively comprehensive proposals have recently been developed by China's drug regulatory body, the SFDA. Experiments with the use of such technologies are also taking place in sub-Saharan African countries such as Nigeria (Onwuka, 2012) and India.


Some governments have recently raised concerns about the work of IMPACT (the International Medical Products Anti-Counterfeiting Taskforce), a WHO associated initiative to which FIP in the past made a number of important contributions. Questions about its activities were related to fears that the protection of the global public against falsified medicines supply might in some way be linked to actions that would reduce access to generic products, and/or make intellectual property violations subject to criminal sanctions.

The question of whether or not such anxieties were or are justified is not considered here. But it is important to record that pharmacy and pharmacists have responsibilities and opportunities relating to maintaining all aspects of medicines quality, including preventing their falsification and the sale of sub-standard products. Better access to medicinal drugs will not achieve its public health goals if it is achieved at the expense of their safety or effectiveness.

Optimising medicines safety and use in hospitals

As secondary and tertiary care have become more specialised and medicinal therapies and surgical interventions more complex and (in some cases) hazardous, hospital pharmacists have pioneered more systematic approaches to assuring the safety and effectiveness of medicines use. There is little doubt that as drug based treatments for conditions such as the cancers continue to develop there will be a continuing demand for enhanced pharmaceutical care in hospital settings.

Hospital pharmacists have also played leading roles in areas such as AIDS treatment, and the mitigation of risks such as those of VTEs (venous thrombo-embolisms). However, as already observed there are still significant variations in the provision of hospital pharmacy services within and between countries. In the UK, for example, the available data shows that in some places hospital pharmacists spend less than 30 per cent of



their pooled time on clinical activities, while in others they devote more than 70 per cent. Across the European Union the average number of practising hospital pharmacists per 1,000 inhabitants is 0.047. Yet within this mean the level varies from 0.02 per 1,000 in Germany to 0.09 in Finland.


One suggested explanation for this is that in Germany nurses have a greater role in drug administration than elsewhere (Surugue and Vullo, 2006). But this is not necessarily desirable, or accurate. Some critics question, for instance, the extent of nurse education and training in Germany in relation to clinical care of all types (including, for instance, giving injections to patients) and relative to the *de facto* responsibilities delegated ‘down’ to them by doctors (Taxis and Barber, 2004).

In many less affluent countries hospital pharmacists still often spend most of their time on distributive and manufacturing activities. From an FIP perspective a key international opportunity relates to further developing the evidence base underpinning good practice, and communicating to audiences in settings where hospital pharmacy remains under-developed the costs of such weaknesses. In addition to reducing financial outlays on medicines that might be unnecessary, harmful or obtainable at lower cost, the positive advantages of clinical pharmacy in the hospital setting ultimately relate to delivering better health outcomes. Inadequate investments in hospital pharmacy may lead to significant losses of life.

Improving medicine, nursing and pharmacy in the community

The evidence presented in this report highlights the likely future importance of issues such as prioritising the prevention of disease and disability wherever possible, in order to improve further age specific levels of fitness and wellbeing. The historical development trends identified also emphasise the need to move away from infantilising relationships towards more equal partnerships between health care users and providers, and the value of helping more individuals to take greater control over their health care. Primary care and wider health systems must also to satisfy emerging world-wide demands become better coordinated to meet the needs of people who, either for limited periods or at the end of their lives, require more intensive forms of support.

The ongoing adaptation of community pharmacy and pharmacists’ working relationships with other health professionals should be central to achieving such goals. Robust, well co-ordinated and mutually supportive but not wastefully duplicative, partnerships




between primary care doctors and community pharmacists could be particularly important, although the interfaces between pharmacy and home and other nursing services also demand attention. In addition to permitting advances such as improved medicines management and a wider use of what are presently classified as ‘hospital only’ medicines in non-institutional settings²⁵, such developments could help facilitate the wider re-engineering of community and health (and when relevant social) care as a whole.

In more affluent nations the experiences of recent decades (as exemplified in localities ranging from Alberta in Canada to Switzerland in central Europe – see Mah et al., 2009 and Guignard and Bugnon, 2006) suggest that extended community pharmacy services – which as US innovations have illustrated can also involve individuals with nursing or medical qualifications – could in time provide relatively comprehensive preventive and ‘routine’ disease management services. This would leave medically led primary care centres with greater capacity to, where cost effective and in line with customer preferences, relieve hospital workloads and address complex needs more satisfactorily in the community.

Similar progress in middle and lower income countries could also help to extend the provision of affordable health care in urban and other relatively prosperous communities. But more radical options will be necessary to improve the care available to very poor populations. With extended education of pharmacists in many countries, pharmacists may need to take more aggressive actions to contribute to delivery of primary care services and enhancing medicines distribution and medication use systems.

Some observers have argued that evolution in this direction and in areas such as pharmacist prescribing could negate the role of pharmacists as guardians of prescribing quality, by undermining the core distinction between dispensing and treatment validation on the one hand and diagnosing and therapy selection on the other. But an alternative interpretation is that such progress should be seen as little more than an extension of the historically established category of ‘minor illnesses not needing medical treatment’. This traditionally includes acutely symptomatic, probably self limiting, conditions. Yet in post transitional environments there is a growing case for extending it to encompass treating common chronic illnesses and reducing uncomplicated asymptomatic health risks, such as raised lipid levels in later life.

²⁵ Organisations such as the Groupement Pharmaceutique de l’Union Européenne (PGEU) have highlighted many other opportunities relating to better medicines management and health care delivery by community pharmacists, in contexts ranging from emergency medicines supply to enhancing immunisation and case finding programmes.




Even though properly regarded as serious threats to long term wellbeing, the latter are in 21st century terms arguably ‘minor’ in the sense of not routinely requiring high cost medical management. The advent of computer based information, diagnostic and case management systems is also likely to be increasingly seen as not only capable of supporting more self-management on the part of members of the general public, but of facilitating new elective relationships between service users and health professionals.

Yet even if the logic of increasing consumer choice in health care is accepted this may not prevent some interests being threatened by the prospect of more flexible service provision paradigms, coupled with the simultaneous pursuit of better health outcomes and lower service costs. This may be especially so where, like in Spain and Italy, there are relatively high numbers of modestly paid, locally qualified, medical practitioners. Pharmacy and pharmacists should arguably seek to position in ways that minimise tensions with other stakeholders in health improvement. Yet all forms of competitively driven improvement and incremental adaptation will on occasions involve disputes as well as collaborative efforts. If direct conflict is always avoided progress towards better joint working may never become a sufficient mutual priority for effective action to be taken.

Enhancing self-care and protecting public health

‘Pharmaceutical public health’ and the support of self care are sometimes presented as novel service developments, additional to and separate from both the emergence of clinical pharmacy and traditional pharmacy roles. However, this is often more a matter of semantics rather than material substance. Pharmacists have always been involved in the provision of health related information and support to people who are normally well aware they are ultimately responsible for their own health. It is also highly questionable as to whether or not helping a pharmacy user to, for example, quit smoking with the use of medicines complemented by behaviour change support techniques is at heart very different from making clinical interventions aimed at, say, treating asthma effectively or helping people to cope with arthritic pain.

All modern health professionals are likely to benefit from having a population level overview of the direction of epidemiological trends and of processes like those of demographic and care transition, because such knowledge should enable them to align their efforts with changing population needs. But this does not mean that there is a legitimate place for a distinct ‘pharmaceutical public health’ sub-specialty. At worst this could result



in an undue separation of social scientific expertise from mainstream practice which would impair pharmacy's internal capacity to adapt, while also being alien to the multi-disciplinary nature of public health work.

In considering 21st century pharmacy's development opportunities, it is apparent that in circumstances in which much avoidable illness is related to life style choices associated with varying degrees of plenty rather than poverty, being able effectively to support behavioural adaptation will often be integral to facilitating the optimally productive use of medicines. Its value will not be confined to areas such as reducing non-adherence in medicines taking alone. The psychologically and socially linked communication skills involved in facilitating the latter are also likely to be of use in helping people avoid or live with conditions such as obesity and/or diabetes, to working productively with other professionals, and being able to monitor with sensitivity phenomena like adverse drug reactions and patterns of illicit drug use in patients or populations.

It is also apparent from the lessons offered by the experiences like those of pharmacy in the Soviet Union that there would be dangers for the profession anywhere in the world if it were to move too far away from its medicines use related competencies, and/or seek ill-advisably to take responsibility for promoting social changes that no one group could succeed in delivering. Placing too much reliance on 'public health' service provision separated from the broadly defined supply of pharmaceutical treatment could prove a hazardous error. Yet in looking forward it is reasonable to conclude that in future decades many more pharmacists are likely to come to regard social sciences such as health psychology, medical sociology/anthropology and health economics as being, with therapeutics, as central to their work as the more traditional domains of pharmaceutical chemistry, pharmacognosy, pharmaceutics and pharmacology.

CONCLUSIONS

The dangers of living in the past are like those of spending too long imagining the future. Both can draw attention away from the challenges of the present, and the need to address immediate threats and opportunities. Critics of 'academic' approaches to understanding pharmacy and how best it can serve the public are right to warn that, as businesses, pharmacies across the world must be concerned with keeping the income streams required to maintain their viability. Similarly, as professionals, pharmacists need to be constantly assured of the appropriateness of the medicines they are supplying, the




accuracy of their dispensing and their responsiveness to the needs and preferences of those they are serving.

However, for those seeking to safeguard the ongoing development of pharmacy in an evolving world it would also be wrong to deny the value of rational forethought about local and global trends, and the ways in which demand for medicines and the determinants of their effective use will alter as the twenty first century unfolds. Without open minded, critical, inquiry it will be impossible to determine what established aspects of the profession are most worth defending, and what new capabilities relating to pharmaceutical care provision are most worth pursuing.

In the 100 years since the formation of FIP, pharmacy as a profession has progressed from being fundamentally concerned with medicines compounding to being increasingly focused on facilitating optimal outcomes for individuals and populations from the clinically effective, economically efficient and socially appropriate use of modern pharmaceuticals. As the range of drug and biologically based treatments available has expanded there have also been fundamental developments in pharmacy education and in fields such as assuring the safety of medicines use and improving how people take them as part of the overall way in which they live and protect (and risk) their health.

There is much to be celebrated in what has already been achieved. However, pharmacists' success in adapting to a situation in which they are no longer the primary source of medicines – while at the same time having less direct authority to provide access to treatments than was typically the case at the start of the 20th century – has been only partial. In many countries pharmacists still have only limited, if any, ability to regulate and enhance medically controlled prescribing. In addition, even in areas where community pharmacists remain relatively free to provide treatments to the public as they judge appropriate, access to medicines is often determined more by their potential users' ability to pay than it is by their health needs.

The most vulnerable of the world's communities are often poorly served by health professionals of any type. In the least advantaged parts of the globe the supply and use of medicines such as antibiotics and anti-malarials tends to be chaotic and inadequately supported. Even in 'developed' nations like, say, Australia, Argentina, Germany, the US or the UK there is reason to believe that the contributions of medicines for preventing and treating conditions ranging from CVD, strokes, diabetes and kidney disorders to




mental health problems and the cancers could be significantly improved via enhanced pharmacy services in hospitals and the community. For example, in a therapeutic field as basic as the reduction of blood pressure recent WHO data show that across the world only about a third of individuals who could benefit from effective antihypertensive therapy are receiving adequate medication.

As the populations of post-transitional communities continue to age, and increasingly seek to do so as actively and enjoyably as possible, demand for more effective combinations of pharmacological intervention and behavioural change support (and/or nursing and social care for those in need of help with daily living) is set to increase. To the extent that new – convenient, affordable and sustainable – care models are required, pharmacists will like all other health professionals enjoy new opportunities to serve their communities.

Yet the future, unlike the retrospectively observed past, is by definition uncertain. Current experiences in Europe, where pharmacy is by world standards well established, illustrate the fact that – especially in times of economic contraction – there may be unexpected risks alongside prospects of planned progress. No group's survival should be taken for granted. Policies intended to promote financial savings might, accidentally or otherwise, undermine the capacity of pharmacies and/or pharmacists to go on adapting to meet future health needs. If and where this proves to be the case it will not only damage the profession's interests. It is also likely over time to generate added costs by blocking desirable lines of evolution.

The history presented here suggests that in addition to communicating effectively with national and international policy makers, pharmacy's ability constructively to shape its relationships with both the pharmaceutical industry and the medical profession will also prove vital for the future. One possibility that, for reasons already outlined, may not serve future public interests as well as might sometimes be hoped is that pharmacy will at some point in the 21st century be (re)joined with medicine. In such a scenario activities like drug storage and dispensing system management could become little more than residual technical and logistical (as opposed to health protection and improvement) functions. In regions that have not as yet had the opportunity to develop more pro-active pharmacy led approaches to improving medicines use and health care more broadly this may already be close to the actual situation.



Nevertheless, the view taken here is that it is more likely that pharmacy as a discrete health care profession will continue to adapt, and over time strengthen its global contributions to health. The scope of pharmacists' activities will vary between settings. But at their heart there will almost certainly continue to be a combination of assuring the availability of good quality (and good value) medicines and working with doctors, nurses and the public to apply knowledge about how to provide and use them to best effect. The trends of the last 100 years point to pharmacists across the globe becoming direct care providers for a widening range of common acute and long term conditions.

If humanity survives the environmental and other hazards ahead and eventually sees the completion of global demographic transition, there is good reason to hope that FIP will also still continue to exist and represent pharmacy on the international stage. Yet this is not a foregone conclusion. If pharmacists are to prosper in 2112 they and their leaders will need to have had the luck, skill, unity and commitment to have found timely, cost effective and competitively successful ways of meeting future service needs, and to have won robust consumer and political support. Pharmacy's survival will ultimately depend on its practitioners' abilities to recognise and demonstrate to other stakeholders in health that in the final analysis what matters most to them is not their own profession, or even the medicines at its centre. It is rather preserving the lives and optimising the wellbeing of the people and populations that professional status grants them the privilege to serve.

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Appendix 1: Contributors and methods

This paper draws from research conducted by the authors in a number of contexts, including work undertaken by James Davies during the preparation of his PhD thesis and an analysis of the impacts of population ageing on pharmaceutical and other forms of health care demand recently published by Dr Jennifer Gill and David Taylor. Over and above the structured literature review undertaken by Sarah Thum-Bonanno and a review of pharmacy in eastern Europe by Michal Wlodarski, the authors used qualitative insights generated by interviews with a range of stakeholders in pharmacy and broader health care development. Thematic analyses based on the latter were undertaken.

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Appendix 2: An illustrative timeline of pharmaceutical developments (1800-2012)

1800 Edward Jenner's work on vaccinating against smallpox, then still a major threat to global health, was published in all major European languages. (Smallpox was eventually eradicated at the end of the 1970s)

1804 Morphine was successfully isolated by Friedrich Sertürner in Germany

1846 Drs John Warren and William Morton performed the first public demonstration of pain free surgery using diethyl ether as a general anaesthetic

1853 Acetylsalicylic acid first made by Charles Frédéric Gerhardt, who buffered salicylic acid in an attempt to make it better tolerated. Despite his success 'aspirin' was not marketed by the German company Bayer until 67 years later

1856 Whilst attempting to synthesise the antimalarial quinine English chemist William Henry Perkins (an assistant to August von Hofmann, whom the Prince Consort had encouraged to come to London from Germany to establish the Royal College of Chemistry) inadvertently produced the first aniline dye. This led to the development of the synthetic dyestuffs industry in Germany and later the UK.

1864 Barbituric acid was first synthesised by Adolf von Baeyer: its clinical significance was not recognised until the early 20th century

1879 Louis Pasteur developed the first vaccine against cholera

1885 Louis Pasteur successfully vaccinated Joseph Meister against Rabies in France

1910 Paul Ehrlich and Sahachiro Hata developed the first 'chemotherapeutic' agent (Salvarsan for the treatment of syphilis) in Germany

1920s Frederick Banting and his colleagues isolated the hormone insulin in Canada, opening the way to the effective treatment of people with type 1 diabetes


1921 The Bacillus Calmette-Guérin (BCG) vaccine against TB was first used in humans following its development in France

1928 Alexander Fleming identified penicillin, although it had long been used as a topical treatment for infections in English and other folk medicine. Interest in penicillin remained minimal until the start of the 1940s and the work of Florey, Chain and Heatley.

1932 German scientist Gerhard Johannes Paul Domagk develops Prontosil, which became the first commercially available antibiotic

1943 Streptomycin, the first antibiotic effective against gram negative bacteria, is discovered by Albert Schatz in America. This became the first effective antibiotic for the treatment of TB, although it failed to save the life of George Orwell (who wrote *Animal Farm*) who died of Tuberculosis in 1948

1950 Paracetamol was first marketed in America as an analgesic, having been synthesised over 70 years



earlier but abandoned in favour of alternative drugs. In France chlorpromazine, the first antipsychotic was synthesised by Paul Charpentier

1952 Isoniazid (which had initially been synthesised before WW I) was marketed by the Swiss firm Roche together with other companies for the treatment of TB, with dramatic impact on public health

1955 The first benzodiazepine (chlor diazepam/Librium) medicine was synthesised by Leo Sternbach in Switzerland, who was seeking to developing new dyestuffs

1959 Nowell and Hungerford announced their discovery of the Philadelphia chromosome in people with Chronic Myeloid Leukaemia, a vital precursor to the development of Imatinib (see below, 2001)

1960 The first oral contraceptive pill was approved for use in America and the UK, closely followed by Germany, Australia and France. Yet 'the pill' was not approved for use in Japan for another 40 years

1961 Ibuprofen, the first NSAID, was patented by Andrew Dunlop and colleagues working at Boots in the UK. Its mode of action relates to that of Aspirin, which irreversibly inactivates the COX 1 enzyme

1964 Scottish pharmacologist James Black developed propranolol, the first beta-adrenergic receptor blocker, for the treatment of hypertension and indications such as myocardial infarction

1970 Following pioneering research by the Swedish scientist Arvid Carlsson, levodopa was introduced for the treatment of Parkinson's disease

1973 Japanese scientist Akira Endo identified the first statin. Lipid lowering medicines based on such moieties were first approved for use in humans in 1987. Tamoxifen was first marketed for late stage breast cancer in 1973, although its full value was not demonstrated until the 1990s

1975 Captopril, the first ACE (angiotensin-converting-enzyme) inhibitor for the treatment of hypertension, was developed by three US scientists

1983 Japanese scientists begin research on donepezil, which was marketed as a treatment for Alzheimer's disease in the 1990s

1987 Zidovudine (AZT) was marketed by Burroughs-Wellcome for the treatment of HIV infection

1996 Losartin, the first ACE II inhibitor, was launched

2001 Half a century after Nowell and Hungerford announced the discovery of the Philadelphia chromosome in CML, Imatinib, arguably the first 'molecularly targeted therapy', was approved by the FDA. It heralds the introduction of other small molecule and monoclonal antibody targeted therapies for cancers

2003 Completion of the Human Genome Project

2006 The FDA approved the first HPV vaccine, which can prevent cervical and other cancers

2012 Lorcaserin is licensed for the treatment of obesity, now one of the most significant health hazards facing 'developed' communities



Appendix 3: Milestones in the global development of pharmacy and healthcare

1777 In France a Royal Declaration separated pharmacists from grocers and spicers. Apothecaries were named ‘masters of pharmacy’ and it was declared that only they were allowed to prepare or sell medicines

1800 Napoleon banned cannabis use amongst his troops in Egypt, the first widely recorded drug prohibition of the modern era

1809 The State of Massachusetts instituted mandatory vaccinations for smallpox

1821 The foundation of the Philadelphia College of Pharmacy

1841/42 The Pharmaceutical society of Great Britain was formed, leading to the establishment of a School of Pharmacy in 1842 and the beginning of organised pharmacy education in the UK. The Royal Dutch Pharmaceutical Society (KNMP) was also founded in 1842

1851 The Arsenic Act provided the first statutory restriction on the sale and supply of a harmful substance in the UK

1852 The American Pharmaceutical Association was first formed

1874 Legislation is introduced to prohibit Japanese doctors from dispensing allopathic medicines, although it has limited impact

1875 University education for pharmacists was made mandatory in Germany

1880 “Multiple” pharmacies permitted in the UK

1883 Building on Prussian innovations, Otto von Bismarck introduces health insurance for some sections of the united German population.

1889 Old age pensions were introduced in Germany

1893 The Japanese Pharmaceutical Association (JPA) was established

1898 The Russian government allowed pharmaceutical factories to be established independent of pharmacies. But imports increased, and pharmacies faced strong competition from ‘drogueries’

1906 The Pure Food and Drugs Act in America outlawed interstate sales of misbranded and contaminated drugs, foods and drinks and led to the initial establishment of the FDA

1910 In America the Flexner Report led to reforms in medical education and greater separation of the prescribing and dispensing roles of physicians and pharmacists

1912 FIP was established with twenty national pharmaceutical associations. It now represents more than two million pharmacists internationally. Fifty years after the end of the second Opium War the International Opium Convention was signed in The Hague



1914 Pharmacy degrees first granted in Canada

1916 The Brazilian Association of Pharmacists was founded. It prioritised the development of a School of Pharmacy

1918 Nikolai Aleksandrovich Semashko becomes the Commissar of Health in Russia. In the aftermath of World War 1 the 'Spanish flu' epidemic killed about 100 million people globally

1928 The Netherlands Hospital Pharmacists Association was formed

1932 IG Farben filed a German patent for what was to become the first commercially produced antibiotic, Prontosil. By 1935 French scientists had identified sulfanilamide as the active metabolite

1942/43 The American Society of Hospital Pharmacists was established, and the mass production of penicillin commenced by the US War Production Board. By 1944 the American pharmaceutical industry was able to supply over 2 million doses to support the Normandy landings

1945 The Ordre National des Pharmaciens was formed in France in 1945.

1946 Following the end of WW II the United Nations was created

1948 The WHO and the UK NHS were established. In south Asia the Pharmacy Council of India was formed.

1955 The Japanese Society of Hospital Pharmacists was set up


1956 Building on observations made in Germany in the 1930s, the British Doctors Study provided evidence that smoking tobacco increased risk of lung cancer. During the twentieth century the world-wide harm to health caused by tobacco consumption was similar in magnitude to the benefits brought by pharmaceutical innovation

1958 It was judged in West Germany that controls on the numbers of community pharmacies were unconstitutional. But legal restrictions on pharmacy ownership were retained

1961 Thalidomide was withdrawn. Shortly afterwards the Kefauver-Harris Drug Amendment required drug manufacturers to provide evidence of drug safety and effectiveness before the granting of a license by the FDA

1965 Medicare, a national social insurance program for Americans aged 65 and older and younger people with disabilities and end stage renal disease, is established, but requires significant payments for medicines. Council Directive 65/65/EC requires fundamental reforms of drug safety regulation, while in China one million 'barefoot doctors' and three million rural health aides were trained.

1975 European Council Directives strengthened analytical, pharmacotoxicological and clinical standards and protocols with respect to testing proprietary medicinal products



1977 A WHO panel recommended 182 “essential” and 32 “complementary” drugs to be included in the then new WHO list of essential drugs. The Pharmaceutical Society of Australia is set up to provide a more unified nation structure for pharmacy there

1981 The first cases of HIV/AIDS were reported in the US

1984 The World Health Assembly urged Member States to supply ‘needed drugs’ and improve drug policies

1985/86 The KNMP releases *Apotheker 2000: the future of pharmacy* in the Netherlands: it is followed shortly afterwards by the publication of the Nuffield report *Pharmacy* in the UK

1990 Hepler and Strand’s concept of pharmaceutical care was endorsed by FIP as Good Pharmacy Practice (GPP). An International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use is held In Brussels.

1993 NAFDAC (The National Agency for Food and Drug Administration and Control) is established in Nigeria

1995 The European Medicines Agency (EMA) is formed in London.

1999 In the Netherlands pharmacy ownership regulations were changed and “multiples” were allowed for the first time. In the UK the National Institute for Clinical Excellence (NICE) was created, while in Brazil ANVISA, the National Health Surveillance Agency, assumed responsibility for drug licensing and allied activities

2002 The Swedish Pharmaceutical Benefits Board was formed, further emphasising the role of cost effectiveness analysis in the context of pharmaceutical care

2004 The Institute for Quality and Efficiency in Health Care was established in Cologne

2006 Independent Pharmacist prescribing was introduced in the UK

2010 The Royal Dutch Pharmacists Association (KNMP) released its White Paper paper on the competencies, economic contributions and future roles of pharmacists in the Netherlands.

2011 FIP published an updated report on GPP regulations. In the Netherlands a follow-up to the 2006 Hospital Admissions Related to Medicines (HARM) study (which showed that almost 40,000 patients were admitted to hospital each year due to problems with medication use) recommended that each person receiving complex pharmacotherapy should have a single ‘pharmaceutical care manager’.

2012 In France a reformed National Agency for the Safety of Medicines and Health Products was formed, following concerns about the quality of breast implants. The Patient Protection and Affordable Care Act (PPACA) was upheld by the Supreme Court of the United States.

