

# europaean INDUSTRIAL PHARMACY



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Email:

info@euromedcommunications.com

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Cover photo: A model of a section of a genome (see Life Sciences Report 2014: Genome 2.0 on page 6)



## The shape of pharma to come

Welcome to the September issue of *European Industrial Pharmacy*. As I pen this editorial, the last days of summer are passing away, and I hope that you all had the opportunity to enjoy a well-deserved break. Certainly, the industry has shown no sign of any lull in activity. Indeed, as I look over the events of the last few months, I am

reminded of Professor Luigi Martini's prediction of pharma heading for the perfect storm years ago. How right he was – this year's events and the events that they herald, in my opinion, are nothing short of cataclysmic.

The defining activity for 2014 has to be the breathless pace of merger and acquisition activity – and the best (or the worst?) is yet to come. The year's two most hotly debated mergers still weigh in the balance, and are likely to evoke high emotions in the players involved, as well as in politicians and society as concerns and scrutiny abound. My concern, and that of my colleagues on the Bureau, is the inevitable consequence to industrial pharmacists and other colleagues caught in the cross-fire of the moment and its aftermath. I speak of the loss of employment that follows,



notwithstanding all previous assurances, as streamlining and expense curtailment are imposed on the new entities to ensure that rising expenses and demands for lower market prices do not sink the ship on its maiden voyage. The fact that such events are inevitable is of little consolation to the unsung heroes in the story of every medicinal product – indeed, perhaps it is all the more saddening that their potential

plight appears not to provoke the necessary prophylaxis until it is too late.

I cannot promise that EIPG can prevent all this. To those who experience the *douche glacée* of having to seek new employment having donated years of their every thought and effort to making a difference in the quality of life of patients, I can, however, promise that EIPG is concerned and does care – collectively and individually – and will continue to do its best to support industrial pharmacists as they seek their roles in tomorrow's pharma.

A handwritten signature in black ink, appearing to read 'Claude Farrugia'.

Professor Claude Farrugia  
Vice-President Communications, EIPG

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# SUPPLEMENTARY PROTECTION CERTIFICATES: OF CLARITY AND CONFUSION

by Ian Moss

**The law surrounding supplementary protection certificates is difficult and uncertain. Three December 2013 judgments from Europe's highest court clarify one issue but create several more.**

Ian Moss is an Associate in Hogan Lovells' London Intellectual Property team specialising in hard IP.

## Background

Since 1993, patentees in Europe have been able to extend the 20-year protection afforded by their patents for medicinal products by seeking the grant of a supplementary protection certificate (SPC). The grant of an SPC extends the protection provided by a patent by up to a maximum of 5 years. SPCs were deemed necessary to offset the delay in bringing medicinal products to market resulting from the need to obtain prior marketing approval and are fundamental to ensuring the financial viability of pharmaceutical research and development. The European Regulation establishing the SPC system stated that without SPCs "the period of effective protection under the patent [is] insufficient to cover the investment put into research". However, precisely what can be protected in this way is often uncertain due to the wording of the SPC Regulation, resulting in national courts making numerous references to the Court of Justice of the European Union (CJEU) for guidance.

This article deals with three judgments given by the CJEU at the end of 2013 and considers the state of the law in their aftermath.

## The 2013 judgments

The grant of an SPC requires that

the relevant "product" is protected "as such" by a patent; there is a valid marketing authorisation (MA) in relation to the product; the product has not already been the subject of an SPC; and the MA relied on is the first authorisation to place the product on the market as a medicinal product. On 12 December 2013, the CJEU gave its judgments in *Georgetown University v Octrooicentrum Nederland*<sup>1</sup>, *Actavis v Sanofi*<sup>2</sup> and *Eli Lilly v Human Genome Sciences*<sup>3</sup>. The judgments consider issues to do with the requirements that the relevant product be covered by a basic patent in force and that the product in question has not already been the subject of an SPC.

The referring Courts sought guidance from the CJEU in relation to a total of 10 questions which the CJEU reformulated such that it only considered two.

1. Can multiple SPCs be granted based on the same basic patent?

2. To qualify for SPC protection, does the product have to be identified in the patent claims by its structural formula or is it sufficient if it is covered by a functional formula in the claims?

In relation to *Georgetown* (in particular), the failure to consider the specific questions referred is disappointing. In *Georgetown*, the referring court had additionally



sought guidance regarding (i) the effect co-pending SPC applications have on one another; and (ii) the effect of surrender of an existing SPC including the applicable law, whether the effect is retrospective and whether it entitles a patentee to seek a new SPC which would otherwise have been blocked. While the questions were phrased such that answering them became unnecessary, they deal with important issues which are likely to generate additional references in due course.

## Question 1

The UK Intellectual Property Office (and other national offices) has historically been willing to grant multiple SPCs in relation to the same patent where that patent covers multiple products (for which MAs have been obtained). However, prior to *Georgetown* and *Actavis*, the CJEU's earlier cases (*Medeva*<sup>4</sup>, *Biogen*<sup>5</sup>) potentially indicated that only one SPC should be granted per patent.

In *Actavis*, Sanofi held a patent protecting a class of compounds including irbesartan, an anti-hypertensive. Also covered by the patent were combinations of irbesartan with other active ingredients, including an unspecified diuretic. On the basis of its patent and an MA granted for Aprovel (containing irbesartan alone), Sanofi was granted an SPC which expired in 2012. A further SPC was also granted on the basis of the same patent and a later MA granted for CoAprovel (containing irbesartan in combination with the diuretic hydrochlorothiazide). The effect of CoAprovel is equivalent to treatment with separate tablets containing each active ingredient (the CJEU stated that there is no new therapeutic effect). Actavis challenged the validity of the



second SPC, arguing that the combination was not protected as such by the patent.

In answering question 1, the CJEU noted the purpose of the SPC regime is "to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject of the basic patent", not "the marketing of that invention in all its possible forms" in combination with other actives "simply referred to in the wording of the claims of the patent in general terms", as to do so would be contrary to the requirement to balance the pharmaceutical industry's needs against those of public health and encouraging research. The CJEU's judgment concluded that a patentee in possession of an SPC based on an innovative active ingredient which is protected as such by the basic patent and an MA for that active ingredient alone is able to oppose the use of that active ingredient alone or in combination. Further SPCs based on a later MA for the same active ingredient in combination with another active should only be granted where the additional active(s) are also protected as such by the patent. Where this is not the case, a new basic patent which does protect as such the combination may be the basis of a new SPC.

In *Georgetown*, the university held a patent to a human papillomavirus (HPV) vaccine utilising proteins isolated from the HPV-6, HPV-11, HPV-16 and HPV-18 strains. In The Netherlands,

*Georgetown* applied for and was granted an SPC covering a combination of all four strain proteins (amongst other SPCs). However, an application for an SPC in relation to HPV-16 alone based on the same MA was refused on the basis that only one SPC should be granted per basic patent.

Considering the question, the CJEU noted that, in principle, a basic patent protecting multiple products may allow for multiple SPCs provided there are relevant MAs. The CJEU reiterated that the purpose of SPCs is "to encourage research in the pharmaceutical sector by granting one SPC per product", and that to find otherwise (i.e. that only one SPC may be granted per patent) would be to encourage multiple patents where one would suffice. The CJEU distinguished *Actavis* on the basis that both HPV combinations and HPV-16 alone were protected as such by the basic patent. In this situation, in which a basic patent protects as such both a combination of active ingredients and those active ingredients singly, and, where an MA in respect of the combination exists, a patentee may be granted SPCs for both the combination and the individual active ingredients.

The judgments are perhaps fact sensitive but, in both, the CJEU focused on what products were protected as such by the patent in determining whether that patent could be a basis for multiple SPCs.

**Question 2**

Prior to *Lilly*, CJEU case law had made clear that to be protected as such by a basic patent the product must be "specified"<sup>6</sup> or "identified"<sup>7</sup> in the claims. In *Lilly*, Human Genome Sciences held a patent for the protein Neutrokin-α and antibodies which bind specifically to it. Lilly wished to market a pharmaceutical containing such an antibody, referred to as tabalumab, and sought a declaration that any SPC granted to Human Genome Sciences on the basis of an MA obtained by Lilly for

tabalumab would be invalid because it was not protected by the basic patent. The parties' interpretations of "specified"/"identified" differed markedly, with Lilly arguing that, to be protected as such, the formulation of tabalumab should have been structurally defined in the claims.

The CJEU held that a functional definition of the product in the patent claims is sufficient for the patent to be protected as such, if that definition, in combination with the patent specification as a whole, relates "implicitly but necessarily and specifically" to the product in question. Determination of whether this is so was held to be a question for national courts because the scope of a patent must (in Europe) be determined in accordance with European Patent Convention provisions over which the CJEU has no jurisdiction. As with "specified"/"identified", this language lacks clarity and unfortunately compounds the issue by creating two areas for interpretation where previously there was one.

**Comment**

Following the CJEU's judgments in *Georgetown*, *Actavis* and *Lilly*, it is clear that a patentee can obtain more than one SPC per basic patent where that patent protects as such more than one product. Unfortunately, what is protected as such is still unclear, indeed it may actually be less clear than it was before. This was recently illustrated by the UK High Court, which gave its post-reference judgment in *Lilly*. Giving judgment required interpretation and application of "implicitly but necessarily and specifically" which proved challenging, the Judge noting that "one thing the Judgment does not give is the clear guidance which the reference was designed to obtain". As the Judge granted permission to appeal, the UK Court of Appeal will soon have opportunity to

Continued on page 9

**UK SPC figures, 1 January 2010 to 31 June 2014**

SPC applications	Number
Applications lodged	299
Granted	172
Entered into force	184
Expired	173
Lapsed	9
Invalid	7
Rejected	16
Data taken from www.ipo.gov.uk.	



# LIFE SCIENCES REPORT 2014: GENOME 2.0

by Richard Gibbs

**I**n June 2014, leading international intellectual property firm Marks & Clerk published its Life Sciences Report 2014: Genome 2.0. The report looks at intellectual property trends in the genome market and is based on patent analytics conducted in three selected areas: sequencing technology, personalised medicine and synthetic biology. The data shows that public research organisations are driving advances into the study of genome-related technologies, with the private sector lagging behind. Further, the report highlights that despite over €1 billion of public funding coming from the EU for research into personalised medicine between 2007 and 2012, it is the US public institutions that are leading the way in personalised medicine and synthetic biology. In the field of sequencing technology, the data shows that Californian giants Life Technologies and Illumina are dominating patent filings, but disruptive technologies are emerging to challenge the status quo.

Dr Richard Gibbs BSc, PhD is a Chartered and European Patent Attorney based at the Glasgow office of the international firm of intellectual property advisers, Marks & Clerk. Dr Gibbs advises clients in patenting and other IP matters in the field of biotechnology and has particular expertise in technologies relating to antibodies, vaccines, biologics, virology, bacteriology and molecular biology. He has worked with all of Scotland's major universities and is a regular speaker at IP conferences and events. Dr Gibbs joined the patent profession after a period as both a research scientist and a university lecturer having obtained an honours degree in medical microbiology and a doctorate in immunology and microbiology from the University of Edinburgh.

## Introduction

In the last year, there has been plenty of activity in the life science sector with the *Myriad* and *Prometheus* rulings complicating the legal framework, government investments bringing energy to the sector and companies, large and small, making investments and industry acquisitions.

Since the end of the first era of genome sequencing, the challenge has been to apply our understanding to practical applications. It is not enough to simply identify a particular gene as associated with a disease, or to

identify genes coding for a particular cellular pathway. Rather, we now have the ability to pinpoint a specific genetic variation in a specific patient, which can predict disease progression and drug efficacy. We are now personalising medicine.

Meanwhile, synthetic biology is growing. The first commercial applications of this are in the industrial and fuel space, but bespoke designed drugs and entirely novel synthetic products are not far behind.

Linked to the surge in interest in both personalised medicine and



synthetic biology are rapid developments in the field of sequencing. With the US\$1000 genome now almost a reality, there are increasing expectations that new methods of sequencing will further lower the cost and reduce the time taken to elucidate the information essential to both these disciplines.

Marks & Clerk's 2014 Life Sciences Report reviews patent filing data and geographical trends to determine where the industry has been and where it is going.

## Methodology

The 2014 Life Sciences Report is based on data provided by CPA Global. Patent landscaping was carried out for patent applications published around the world between 1 January 2003 and 31 December 2013 relating to three separate areas of technology: sequencing technology, personalised medicine and synthetic biology.

## Personalised medicine

The development of personalised medicine has, in part, been fuelled by the need to supplement those drugs that are only effective in treating small proportions of the population. Personalised medicine allows doctors to screen patients to determine if they are likely to respond favourably to a particular treatment and/or to tailor drug therapies to patients.

Of the top applicants in personalised medicine, over half are



**Table 1: Top filers in personalised medicine between 2003 and 2013**

Organisation	Patents*
1 NIH	304
2 Roche	127
3 University of California	85
4 INSERM	80
5 Johns Hopkins University	81
6 Novartis	72
7 US Department of Health	68
8 Oncotherapy Science	61
9 University of Southern California	46
10 Bayer	45
=11 Mayo Foundation	44
=11 Siemens Healthcare	44
13 Amgen	40
14 University of Texas	39
15 Epigenomics	37
16 Merck	36
17 Dana Farber Cancer Institute	35
=18 CNRS	31
=18 Janssen Diagnostics	31
=18 Stanford University	31
=21 Ohio State University	30
=21 GlaxoSmithKline	30

\* Patent applications since 2003, one entry per patent family. Data for 2012 and 2013 incomplete due to an 18-month delay in publication after filing.

public bodies and most are US research agencies, hospitals or universities (see **Table 1**).

The National Institutes of Health (NIH) lead the way in the field, applying for more than twice as many patent families as the second largest applicant, Roche, since 2003. While the number of patents applied for by the NIH has fallen over recent years, others (notably the French organisations INSERM (Institut National de la Santé et de la Recherche Médicale) and CNRS (Centre National de la Recherche Scientifique)) have become more active in the field.

Of the major pharmaceutical companies, only Roche, Novartis and Bayer are among the top 10

applicants. Blockbuster drugs – often considered the “Holy Grail” of the pharmaceutical industry – are a concept contrary to personalised medicine, so this is not wholly surprising. Indeed, annual application numbers from private businesses among the top 22 filers dropped 43% between 2006 and 2011.

In terms of geographical filing trends, more individual patent applications were made in the US (8382) than in any other jurisdiction, followed by Europe (4383), Japan (2606), Canada (2359) and Australia (2335). Newer markets, such as China and South Korea, show low numbers of filings and, of those applications filed in China, the vast majority are from domestic companies. Foreign organisations are clearly yet to consider China a key geography for personalised medicine.

At this point, it is perhaps worth making a note on legal developments within the area of patent eligibility. In recent years, patents claiming gene sequences have led to significant debate and the development of new legal doctrine. Most notably, the US has considered this at some length, causing great concern for the industry. Following the widely-reported *Myriad* case, the United States Patent and Trademark Office (USPTO) issued new guidelines<sup>1,2</sup> for determining the patentability of claims which involve laws of nature, natural phenomena or natural

products. Product claims are only allowable if there is a “marked difference” in structure between the claimed product and a product occurring in nature. Most crucially, the guidelines extend the Court’s ruling in *Myriad* to all natural products. As such, medicinal formulations containing naturally occurring agents, such as antibiotics, antibodies or peptides, all of which have traditionally been patentable, may become more difficult to protect. Unsurprisingly, concerns have been raised over the apparent change in the law, but it remains to be seen whether the courts themselves will adopt a similar position to the USPTO. In the meantime, the increased burden in obtaining and defending patent rights may have a negative impact on patent filings in the US, particularly from public entities.

The USPTO’s stance on the patentability of natural products is not followed in other jurisdictions, although territories, such as Europe, impose other restrictions on the patentability of, for example, stem cells<sup>3</sup> and methods of treatment and diagnosis.

### Synthetic biology

Synthetic biology refers to the engineering and manipulation of existing biological systems and the creation of new systems for various purposes. Currently, the main commercial application of synthetic

#### *Myriad versus Association for Molecular Pathology*

In June 2013, the US Supreme Court handed down its ruling in this high-profile case, which sought to establish if *Myriad*’s patents on the BRCA1 and BRCA2 genes, which increase susceptibility to breast cancer, were valid. The Court ruled that inventions deriving from isolated human DNA cannot be patented and that *Myriad*’s patents were, therefore, invalid. This ruling, together with the 2012 *Mayo versus Prometheus* ruling, was later applied by USPTO in its ‘Guidance For Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products’.

#### *Mayo versus Prometheus*

In March 2012, the US Supreme Court handed down its much-anticipated decision, relating to the patentability in the fields of diagnostic testing, personalised medicine and biotechnology. The judgment held that that the claims in *Prometheus*’ patents, which were directed to methods for optimising the efficacy of a drug, were directed to laws of nature and, consequently, not patentable.



**Table 2: Top filers in synthetic biology between 2003 and 2013**

Organisation	Patents*
1 Russian Government	49
2 NIH	33
3 Russian Department of Science	28
4 University of California	27
5 Bristol-Myers Squibb	25
6 Russian Department of Higher Education and Research	24
7 Nanjing University	23
8 Zhejiang University	21
=9 Riken	20
=9 University of Jiangnan	20
11 Tsinghua University	17
12 CNRS	15
=13 Japanese Science and Technology Agency	13
=13 Kyoto University	13
=15 Chongqing University	11
=15 Corning	11
=15 US Department of Defense	11
=15 US Department of Energy	11
=19 Beijing University of Science and Technology	10
=19 Merck	10
=19 National Science Foundation	10

biology is in the biofuels space, but other uses in pharmaceuticals, materials science and biosensing technology are perhaps not far off.

At first glance, the figures for patent applications in this area appear dramatically different from the other sectors analysed in the report, with the Russian Government topping the list of applicants and the Russian Department of Science and the Russian Department of Higher Education and Research following closely behind (see **Table 2**). Similarly, Chinese universities and institutions are heavily represented in the rankings. However, these entities do not tend to file widely outside their home country. This strongly suggests reasons for filing other than to simply protect the

technology. The only European organisation among the top filers is CNRS (12th place).

The main split in the data seems to be the distinction between private corporations and public bodies. By far the majority of applications are made in the name of public bodies. Private organisations file relatively few applications, representing only three of the top 21 filers and only two patents have been filed by pharmaceutical companies Bristol-Myers Squibb and Merck since 2007. This may indicate that the technology is still at a relatively early stage, coming primarily from research institutes and universities.

Even with the Russian and Chinese data included, the US is the major target for patentees, with a total of 3360 applications filed there since 2003. A key difference to other technologies, however, is that China comes second with 1545 applications. This may be inflated by the number of applications filed in China only, but it may also represent Chinese investment in the field.

### Sequencing technology

Since discovering the double helix, scientists have been driven by an insatiable desire to decode and understand the complex chemical signatures of the genome. As part of this, the technology used to sequence nucleic acids has seen rapid development in recent years and now finds application not only as a standard research tool but in personalised medicine, forensic science and agriculture.

Unlike the other areas of technology we analysed, private companies represent the leading patent applicants (see **Table 3**). The two largest players in the field of sequencing technology are Illumina and Life Technologies (now Thermo Fisher Scientific). Although public research institutes and universities do not figure heavily among the top applicants, the NIH and Harvard University are the largest of this type of filer.

One interesting observation is the emergence of smaller companies

**Table 3: Top filers in sequencing technology between 2003 and 2013**

Organisation	Patents*
1 Illumina	80
2 Life Technologies	70
3 Pacific Biosciences	35
4 Roche	24
5 NIH	23
=6 Harvard University	20
=6 Intel	20
=6 BGI Shenzhen	20
9 Abbott	17
=10 University of California	15
=10 Columbia University	15
=12 Hitachi	13
=12 Stanford University	13
=14 Agilent Technologies	12
=14 Oxford Nanopore Technologies	12
=16 Helicos BioSciences	10
=16 Keygene	10
=16 Sequenom	10

with disruptive technologies. For example, Oxford Nanopore Technologies' innovative nanopore-based sequencing methods are the subject of a number of patent applications, the earliest of which were filed in 2009/10.

The data also highlights the emergence of Chinese company BGI Shenzhen (BGI) as a major force in the sequencing field since 2007/8. BGI technology is spread over a wide area covering methods and consumables for use in sequencing.

In terms of the key territories for total patent applications filed, the US is a long way in front with a total of 2871 publications since 2003. However, Europe and Japan feature strongly too with 739 and 520 publications, respectively. China is yet to match these territories, but since BGI have only recently risen to prominence, this is perhaps not surprising.

### Discussion

As the medical applications of genome research become clearer



and we enter an age of personalised medicine, the protection of intellectual property becomes increasingly important. While big pharma companies have not shown the same enthusiasm as public bodies for personalised medicine, we may well start to see an increase in filings coming from these types of company; but they will have to catch up and may have to rely on licensing models for many years before entering the market on their own terms.

However, we must not forget the new USPTO guidelines issued in the wake of the *Myriad/Prometheus* decisions. Unless these are revised, they could have a disastrous effect on patent applications in the personalised medicine area, leaving companies unable or unwilling to commercialise their research.

The sequencing technology market appears to have matured and companies with disruptive technologies are appearing among the top filers. We are also seeing interest from emerging markets like China – where life sciences companies have, for many years, lagged behind their electronics counterparts in terms of patent filings around the world.

Synthetic biology is the least established of the technologies we have analysed, with patent filing figures easily skewed by local considerations. Private companies are clearly yet to make up their minds on the benefits of research into this area with vacillating interest from both pharmaceutical and industrial companies in the area.

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### SUPPLEMENTARY PROTECTION CERTIFICATES: OF CLARITY AND CONFUSION

*Continued from page 5*

consider the CJEU's new test and provide further guidance. References seeking further clarity remain likely.

In *Lilly*, the CJEU also made comments considering whether the patentee's level of involvement in the development of a product granted an MA on the basis of a functional specification was relevant to the grant of an SPC. The UK Judge noted the comments and considered them to relate to an argument as to the party entitled to any SPC granted; an argument no longer being pursued in this case. That issue is for another day.

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- <sup>5</sup> C-181/95 ECLI:EU:C:1997:32.
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# PHARMACOPOEIAL HARMONISATION: AN HISTORICAL PERSPECTIVE

by Tony Cartwright

**M**ichael Anisfeld's article in the March issue arguing the case for a single worldwide pharmacopoeia ignores the very considerable progress already made in international harmonisation of standards. Pharmacopoeial harmonisation has been a continuous process since 1864 when the British Pharmacopoeia superseded the national pharmacopoeias of London, Edinburgh and Dublin. Achievements include harmonisation of the strengths of materia medica by International Agreements in 1902 and 1930, establishment of international biological standards in 1924, and a system of International Nonproprietary Names in the 1950s. The standards of the European Pharmacopoeia are now official in 38 countries. Although the pace of harmonisation through the Pharmacopoeial Discussion Group is slow, real progress has been achieved. The future lies in enhanced cooperation and work-sharing between the national and regional pharmacopoeias rather than a new Global Pharmacopoeia.

Tony Cartwright is a retired pharmaceutical regulatory consultant. He worked with the British Pharmacopoeia Commission and the UK Medicines Control Agency in a variety of roles before joining a Contract Research Organisation. He was the first Chairman of the Quality Working Party for the European Committee for Proprietary Medicinal Products, and chaired some of the early International Conference on Harmonization topic discussions on quality topics. He is now an occasional consultant and writer. He has just written a book entitled *The British Pharmacopoeia, 1864 to 2014: Medicines, International Standards and the State*.

Readers will have enjoyed Michael Anisfeld's humorous polemic entitled 'Unstandard Standards' in the March 2014 issue of *Industrial Pharmacy*. This argued the case for a single worldwide pharmacopoeia. There is a cogent case to be made for increasing the speed and extent of pharmacopoeial harmonisation. Sadly, however, Mr. Anisfeld's article gave a rather selective and flawed analysis of the history and progress of pharmacopoeial harmonisation. This article is written to provide readers with a more complete review.

The earliest attempts to systematise knowledge about drugs and their preparations were the formularies, such as those produced by Dioscorides (c.40–90 AD) 'De materia medica' and by Galen (129–c.210 AD) 'On the Power of Simple Drugs'. The first official pharmacopoeias were produced by individual physicians or groups of physicians for use in their own cities or city-states. The official guide for the apothecaries of Florence was the 'Nuovo receptario...' published in 1498. Other cities such as Barcelona, Saragossa and



Nuremberg followed. The first use of the word 'pharmacopoeia' was in 1548 with the publication by the French physician Jacques du Bois of his 'Pharmacopoea, libri tres'.

The first truly national pharmacopoeia was the London Pharmacopoeia published by the Royal College of Physicians in 1618 and official in England. In 1754, the College of Physicians in Dublin adopted the text as official in Ireland. Ten editions were published, the last in 1851. The first edition of the Edinburgh Pharmacopoeia was in 1699 and the last in 1841. The first edition of the Dublin Pharmacopoeia was in 1806 and the last in 1850. The Edinburgh Pharmacopoeia was the basis of the Pharmacopoeia of the Massachusetts Medical Society in Boston in 1809. Since more than 90% of the articles in the 1820 first edition of the United States Pharmacopoeia (USP) derived from the Massachusetts Pharmacopoeia, the Edinburgh Pharmacopoeia provided much of the content of the first USP.

The first edition of the British Pharmacopoeia (BP) was published in 1864 and this was the first internationally harmonised pharmacopoeia. It superseded the three national Pharmacopoeias of London, Edinburgh and Dublin. The Preface to this edition stated that it reconciled 'the varying usages, in pharmacy and prescriptions, of the people of three countries hitherto in these respects separate and independent...' Indeed, 2014 is being celebrated as the



sesquicentenary (150th birthday) of the first publication of the BP. The early editions were official in the British Empire and all of the British Dominions in North America, Africa, Asia, the West Indies, India and Australasia. The BP is still widely used in over 100 countries.

Many of *materia medica* in the early national pharmacopoeias were herbal preparations which could vary in strength. Nineteenth century travellers were exposed to the hazard of what purported to be the same material having different strengths in different countries. In 1902, an International Conference was held in Brussels for Unification of the Formulae for Potent Drugs and Preparations in several of the national pharmacopoeias. This led to the adoption of a series of recommendations in the form of an International Agreement. In 1930, a further International Agreement became operative and this was applied in the 1932 BP. For example, Tincture of Digitalis was standardised at 10 per cent by weight and Opium Powder at 10 per cent of anhydrous morphine.

In 1924, the Health Committee of the League of Nations set up after World War I established a Permanent Commission on Biological Standardisation and their standards were used in carrying out the biological assays in the 1932 BP, such as the test for potency of Digitalis. The Permanent Commission held sessions in 1926, 1928, 1930, 1931 and 1934. An inter-governmental conference was held in Geneva in 1935 recommending that a Permanent Commission on Biological Standardisation would adopt international standards to be used in all countries. These were distributed by the Danish State Serum Institute and the National Institute of Medical Research in London. In the 1970s, the responsibility for provision of biological standards in the UK was transferred to the National Institute for Biological Standards and Control (NIBSC), which is now part of the Medicines and Healthcare Products Regulatory Agency. NIBSC

is the main custodian of biological reference materials for World Health Organization (WHO) together with other custodian laboratories in the Anti-Viral Research Branch of the National Institute of Allergy and Infectious Diseases (NIAID) and the Centers for Disease Control and Prevention in the USA, at the European Directorate for the Quality of Medicines and Healthcare (EDQM), the Paul Ehrlich Institute in Germany and the University of Washington in Seattle, USA. These biological standards are used in pharmacopoeial tests specified in the major pharmacopoeias.

In 1937, the Health Organization of the League of Nations set up a Technical Committee of Pharmacopoeial Experts to start work on the International Pharmacopoeia. The first meeting was held in May 1938 and the second in Geneva in 1939. The work was interrupted by World War II. In 1947, the WHO decided to set up an Expert Committee on Unification of Pharmacopoeias. The first edition of the International Pharmacopoeia was published in two volumes in 1951 and 1955. In 1975, it was decided that the main purpose of the International Pharmacopoeia would be to serve the needs of the developing world and, in particular, to provide monographs for drugs on the Essential Drugs List and those important to the WHO programmes. Thus, the latest edition includes monographs on antimalarial drugs, antiretroviral drugs and combination products for treatment of tuberculosis.

When the modern synthetic chemical drugs were marketed in the 20th century, their manufacturers sold the products under a trade name. The pharmacopoeias then sought to devise a simple non-proprietary name which could be used as the title of the drug substance monograph instead of the complicated systematic chemical name – the generic name. Many countries adopted their own national lists of non-proprietary

names – such as the British Approved Names and the United States Approved Names (USANs). During World War II, the BP Commission issued new approved names for drugs that were now manufactured in Britain but had previously been imported from Germany. In 1953, the WHO instituted a formal system for establishment of International Nonproprietary Names (INNs). This procedure has now been updated a number of times. The use of INNs is mandatory in the European Union under Directive 2001/83/EC; however, some older national names may still be used elsewhere. Thus, Paracetamol is the INN and Acetaminophen used in the US is a USAN.

The European Pharmacopoeia (Ph. Eur.) is an example of pharmacopoeial harmonisation which already encompasses many countries. It was established in 1964 with eight countries originally participating, and now has 38 signatories to the Pharmacopoeia Convention and 18 other countries (including the USA and the Russian Federation) participating as observers at the meetings of the European Pharmacopoeia Commission. The first volume of the Ph. Eur. was published in 1969. The latest edition is the eighth which was published in July 2013. The Ph. Eur. includes general monographs for drug products, drug substances and excipients and these are official in all of the 38 signatory countries, which include all of the European Union countries. National Pharmacopoeias can translate and reprint the text and monographs. Thus, for example, the text of the BP includes all of the general methods and monographs from the Ph. Eur. However, the BP also includes monographs for all of the major pharmaceutical medicinal products prescribed in the UK, so is much more than a 'clone of the Ph. Eur.' that Mr. Anisfeld mentions.

As Mr. Anisfeld described, the tripartite Pharmacopoeial Discussion Group (PDG) consisting of representatives from the USP, the



Ph. Eur. and the Japanese Pharmacopoeia was established in 1989. It meets to consider proposals made by national associations of manufacturers of pharmaceutical products and excipients for the work programme. Its programme of harmonisation includes general test methods, General Chapters, methods for biotechnology products and excipient monographs. Currently, 29 of the 35 General Chapters and 46 of the 62 excipient monographs in its programme have been harmonised. Although the harmonised excipient monographs comprise only a small proportion of those used, they are amongst the most frequently used by manufacturers in their products. The PDG is looking at ways to improve the speed and extent of harmonisation and this is to be welcomed.

Collaboration and cooperation between the pharmacopoeias has been practised for many years. Thus, the BP and USP have collaborated almost from the beginning exchanging information, copies of new editions and with visits by senior staff. In 2004, the International Conference of Drug Regulatory Authorities discussed the idea of a worldwide approach to setting pharmacopoeial specifications. This led WHO to organise a series of International Meetings of World Pharmacopoeias. A guideline on Good Pharmacopoeial Practice is being developed. Work-sharing and mutual acceptance of monographs

was also discussed.

Mr. Anisfeld quotes two examples of possible difficulties in achieving harmonised standards. The first example is that of Paracetamol Tablets in the US and UK having different dosages, implying a lack of harmonised drug standards. However, his article confuses the usual strength of the commercial tablet preparations available in the two markets (325mg in the US and 500mg in the UK) with the recommended dosage of the drug. He asks 'surely British headaches are not more severe than American headaches requiring higher dosages of the same drug...'. In fact, the recommended adult doses of paracetamol for treatments of pain and fever in the two countries are nearly identical.

The second example relates to the difficulty in identifying safe drugs to include in a pharmacopoeia, and Mr. Anisfeld suggests aspirin as such an example. He asserts that aspirin was known for hundreds of years as a folk-medicine. The active constituent in willow bark is salicylic acid not aspirin, and it was more than just a folk-medicine as it was the subject of one of the first reported clinical trials by the Reverend Edward Stone in 1763. The first synthesis of aspirin was by Charles Gerhardt in 1853. In 1897, Felix Hoffman improved the synthesis and made it into a commercial process which Bayer could then use to market the drug. Mr. Anisfeld suggests that safety

issues now known about aspirin would have prevented its approval by today's regulatory agencies. However, the agencies do not just look at safety per se. They now review the risk/benefit and the undoubted benefits of aspirin for a variety of indications would mean it would be approved. Aspirin was the second most commonly prescribed drug in the community in England in 2013.

Mr. Anisfeld also argues that his single worldwide pharmacopoeia would produce considerable savings in cost and manpower as there would be no need to have the staff of national and regional pharmacopoeias. His analysis allocates all of the costs of the USP Convention and the EDQM to the USP and Ph. Eur. However, the USP produces a number of other compendia and the EDQM also has many other responsibilities.

Mr. Anisfeld does not tell us what would be included in his single worldwide pharmacopoeia – whether it would include tropical medicines, herbal medicines, Ayurvedic medicines and homeopathic medicines. The national and regional pharmacopoeias can respond to local needs and the practices of medicine and pharmacy, and can include indigenous medicines as well as modern synthetic chemical and biological drugs. The future surely lies in enhanced cooperation and work-sharing, rather than inventing a new Global Pharmacopoeia.

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# A unique and comprehensive guide to ensure regulatory compliance and success in pharmaceutical regulatory inspections

Edited by Madhu Raju Saghee  
*Quality Assurance, Micro Labs,  
and Director of PHSS, India*

Foreword by Peter D. Smith  
*Vice President, Strategic Compliance,  
PAREXEL Consulting, USA*

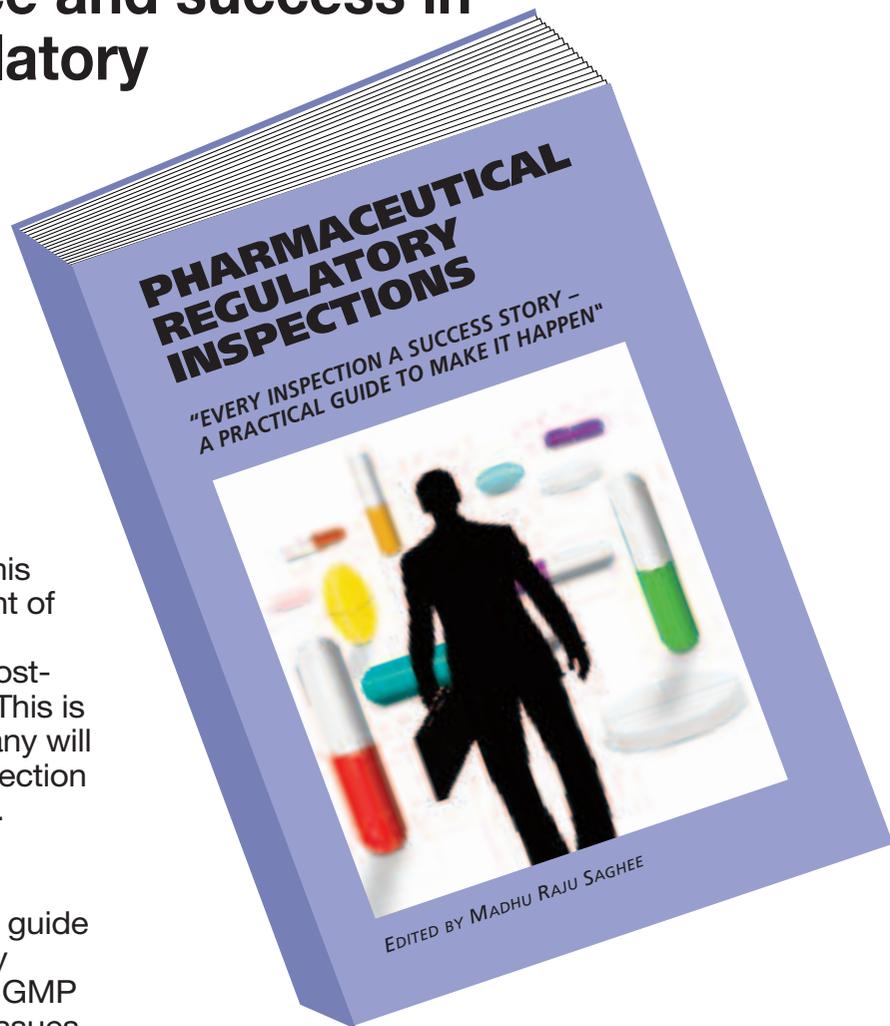
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### Foreword

– Peter D. Smith

### Preface

– Madhu Raju Saghee

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The second report on the 2009 recommendation on Patient Safety and Quality of Care (Citizen's Charter) report 2009/151/01, published last month, has, in the last year, resulted in major changes to many EMA regulations.

All professionals working in the supply of medicines should familiarise themselves with the content of these amended regulations since they bring with them additional legal responsibilities and accountabilities which form an essential part of all continued professional development programmes.

A wide range of e-Learning modules explaining the changes are available online from PharmaConsult Global Ltd and are offered to the industrial pharmacist members of professional associations affiliated to EIPG. Prospective registrants can review details of the course by clicking on "Details" (next to "Buy now") and "View Detailed Description" where the course description and short demo of the e-Learning module is available.

PharmaConsult Global e-Learning modules comprise of a presentation, reading material, a delegate assessment questionnaire, and completion. Each month, we will feature two of the e-Learning courses and will also provide a webinar which will allow the delegate to discuss the impact of the new regulation with international subject experts and peers to get a detailed understanding of the course.

### **The PROPOSED programme of e-Learning and subject expert discussion groups available from September 2014**

#### **September 2014: Biotechnology and Biosimilars**

This course provides an introduction to the international GMP standards required to support manufacturing and inspection activities of biotech manufacturing facilities and drug

products, and the *EMA Guideline on Similar Biological Medicinal Products Containing Biotechnology-derived Proteins as Active Substance*.

The webinar will consider the original data required to register a biosimilar product and any other topic introduced into the interactive discussion.

#### **October 2014: Product Development**

This module is an introduction to international regulatory requirements for training staff working in product development, manufacturing and distribution with the basis of the knowledge essential for obtaining a marketing authorisation for a new product.

The webinar will consider case studies for the development of different dosage forms, and the regulatory priorities considered essential in different regions.

#### **October 2014: Pharmaceutical Quality Management Systems**

This course will examine the application of the ICH standards Q9 Quality Risk Management, Q10 Pharmaceutical Quality Systems, and Q11 Development and Manufacture of API, for the standard pharmaceutical processes required by regulatory authorities in the US and Europe, and the additional legal responsibilities of key management.

The webinar will review the requirements for pharmaceutical quality management systems in product development, clinical trials, API manufacture, product manufacture and product distribution.

#### **November 2014: Medical Devices**

This module will provide an overview of the current medical device requirements and data





expected by the FDA and EMA to achieve a marketing authorisation.

The webinar will consider the impact on registration by adding an active ingredient in combination with the medical device.

### **November 2014: GMP Manufacturing**

This course will introduce the historical background to the GMPs to provide the necessary understanding regarding the regulatory authorities' concerns with respect to product protection. It will discuss the movement towards harmonising the GMPs in the world's regulatory markets by discussing the GMPs from the US and Europe. ICH Q7 will be discussed as a general set of agreed requirements and, finally, findings from recent FDA inspections will be presented as we understand the reasons for GMPs in such a way as to provide a necessary understanding of why we do what we do.

The webinar will discuss the impact of the changes made to *Volume 4 Good Manufacturing Practice (GMP) Guidelines* in the last 12 months

### **December 2014: Pharmacovigilance**

The course will review good pharmacovigilance practices and the set of measures in the *Guidelines on Pharmacovigilance* (Volume 9B October 2011) and *Good Vigilance Practice* (published February 2014) drawn up to facilitate the performance of pharmacovigilance in the EU.

The webinar will consider the requirements for becoming a qualified person responsible for pharmacovigilance.

### **January 2015: GMP Manufacturing**

This course will discuss the reasons for GMP, evaluate the background and drivers for GMP both in the US and Europe, and evaluate inspection findings from manufacturing sites from around the world.

The webinar will consider the impact of introducing changes to *Volume 4 Good Manufacturing Practice (GMP) Guidelines*.

### **January 2015: Regulatory Affairs**

This module provides an introduction to international regulatory requirements in product development, manufacturing and distribution for all staff working in health care and the pharmaceutical industry.

The webinar will review the issues arising from discontinuing use of NeeS to present data for product registration in the different member states of Europe.

### **February 2015: Clinical Research**

This is a practice course designed for sponsors and investigators, as well as their research staff members, and includes the most common rules to avoid non-compliance, known as "The 12 rules".

The webinar will discuss introduction of the requirements of the EU regulation 536/2014 in to clinical trials practice and the differences in requirements from the Directive 2002.

### **March 2015: Good Distribution Practice**

This course will review the NEW *Good Distribution Practice of Medical Products Guidelines* 2013 343-10 and the *Falsified Medicines Directive* 2011/62 which came into effect in many European states from January 2013.

The webinar will discuss the benefit that introduction of pack serialisation will have on the distribution of pharmaceutical products

***The topics for discussion in all of the webinars may be changed if there are different issues identified by delegates for discussion.***



# regulatory review

**Worryingly, during the period covered, it should be noted that, again, there were incidents of lack of sterility assurance on products from two different compounding pharmacies in the USA. Also an outbreak of blood poisoning (septicaemia) occurred in England from *Bacillus cereus* infection. The source was probably contamination of a single day's production of intravenous liquid products (total parental nutrition). There was also a multi-batch product recall in the UK following the potential for chemical contamination of product which was discovered during an Medicines and Healthcare Products Regulatory Agency (MHRA) inspection.**

## USA

The Food and Drug Administration (FDA) has issued the following Guidances/draft Guidances for Industry.

### **Immunogenicity Assessment for Therapeutic Protein Products**

This outlines and recommends adoption of a risk-based approach to evaluating and mitigating immune responses or adverse immunologically related responses associated with therapeutic protein products.

### **Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the Public Health Service Act**

This assists developers, sponsors of biologics license applications, and other interested parties in providing information that will help FDA determine the date of first licensure for a reference product.

### **Neglected Tropical Diseases (NTD) of the Developing World**

This will assist sponsors with little experience in working with the FDA. It addresses FDA's current thinking regarding the overall drug development program for the treatment or prevention of NTDs,

including clinical trial designs and internal review standards to support approval of drugs.

### **Compounding Outsourcing Facilities Under Section 503B of the Food, Drug & Cosmetic (FD&C) Act**

This interim guidance reflects FDA's intent to recognise the differences between compounding outsourcing facilities and conventional drug manufacturers, and tailors current good manufacturing practice (CGMP) requirements to the nature of the specific compounding operations conducted by outsourcing facilities while maintaining the minimum standards necessary to protect patients from the risks of contaminated or substandard compounded drug products. FDA will focus its inspectional and enforcement efforts on those aspects and such operations that pose the highest risk to patient safety, in particular, sterility assurance, safety, subpotency, superpotency, and labelling or drug product mix-ups.

### **Pharmacy Compounding of Human Drug Products Under Section 503A of the FD&C Act**

This announces FDA's intention to regulate/use enforcement on such establishments now that section 503A has been amended by Congress to remove the advertising and solicitation provisions that were held unconstitutional by the US Supreme Court in 2002.

### **Drug Supply Chain Security Act: Identification of Suspect Product and Notification**

This is intended to aid trading partners in identifying a suspect product and terminating notifications regarding illegitimate product.

### **Expedited Programs for Serious Conditions - Drugs and Biologics**

This provides a single resource for information on expedited programs for serious conditions e.g.: fast track

designation/breakthrough therapy designation/accelerated approval, and priority review designation.

## Europe

### **Strategy for elemental impurities and upcoming International Conference on Harmonisation (ICH) Q3D guideline**

A strategy for the revision of European Pharmacopoeia (Ph.Eur.) texts concerned has been drawn up to ensure a consistent approach between licensing authorities and the Ph.Eur.

### **Ph.Eur. first draft finished product monograph with chemically defined active substance**

The Ph.Eur. Commission has started working with these monographs. The first such draft monograph has now been published for comments. This expands the scope of the Ph. Eur. The monographs will follow the same general principles as for other monographs.

### **Use of a Certificate of Suitability (CEP) for a starting material in an application for a CEP**

A document is now available from the European Directorate of the Quality of Medicines to provide clarification on this issue.

### **Qualified person (QP) declaration re GMP compliance of active substance manufacture**

The European Medicines Agency has released the final version of the QP Template and the related Guidance document.

## MHRA

### **MHRA position on freight consolidation depots (freight forwarders)**

Since the application of the Falsified Medicines Directive (FMD), both export and holding of human medicines for export requires authorisation. Some companies/sites not previously regulated now



require a wholesale distribution authorisation (WDA(H)). Good distribution practice (GDP) inspectorate has also issued guidance on short-term storage of ambient and refrigerated medicinal products, confirming situations requiring a WDA.

#### **MHRA updated Guidance Notes 5 and 6**

These updates outline the key obligations for maintaining the licence/registration and will help applicants and those who hold a manufacturer's licence, wholesale dealer's licence or broker registration.

#### **Consultation (MLX387) safety feature: 'black' and 'white' lists**

The FMD has introduced obligatory 'safety features' to verify the authenticity of medicinal products.

- All prescription medicines will bear the safety features unless listed by the European Commission.
- All non-prescription medicines will not bear the safety features unless listed.

MHRA seeks views on products that should be listed.

#### **Generic Medicine Quality Forum**

MHRA co-hosted the first meeting of a new forum focused on ensuring the manufacturing quality of generic medicines in the UK.

### **International**

#### **ICH**

#### **Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk (M7)**

This guideline emphasises both safety and quality risk management in establishing levels of mutagenic impurities that are expected to pose negligible carcinogenic risk. It outlines recommendations for assessment and control of mutagenic impurities that reside or are reasonably expected to reside in final drug substance or product, taking into consideration the intended conditions of human use. Implementation of M7 is

encouraged after publication; however, because of the complexity of the guideline, application of M7 is not expected (with certain exceptions) prior to 18 months after ICH publication.

#### **India**

#### **Track and trace requirements delayed for primary packaging of exported product**

India has deferred the requirement of affixing barcodes on primary level packaging until a new date is notified. However, the requirement to affix bar codes on tertiary and secondary level packaging, which have already been implemented, continue to be in force.

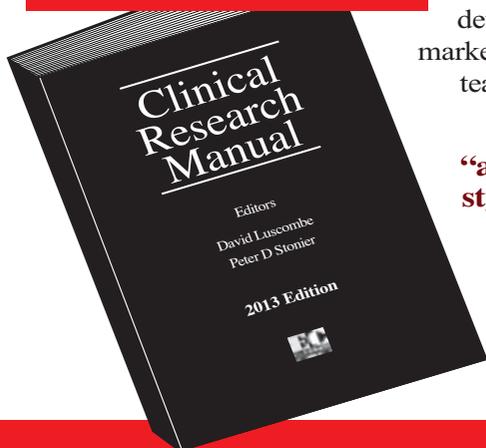
*For further information on these and other topics we suggest you refer to the websites of relevant regulatory bodies and to current and past editions of "GMP Review News" published by Euromed Communications. To subscribe to this monthly news service contact [info@euromedcommunication.com](mailto:info@euromedcommunication.com)*

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## bottled brown

### Mother lode

NHS data held by hospitals and GP practices are not combined. Combining, according to Professor Sir John Savill, Head of the Medical Research Council, "could turn the UK into the best clinical lab in the world and the benefit would be felt first in the UK". Once all this is explained properly, Sir John thinks the public will accept this as a "no brainer". Governmental decision may be about now. The long-established, large British NHS holds gargantuan information: a mother lode. Patient data types are green: anonymous; amber: "pseudonymised" by removing identifiers, such as name and postcode; and red: identifies patient.

### What we could achieve

Combined NHS retrospective data, including patients' genetic backgrounds, diagnoses, drugs, and outcomes, could permit mining for patterns. For example, the most effective drugs for patients with specific genetic natures might emerge.

One illustration is that, for breast cancer, the "FEC" (fluorouracil, epirubicin and cyclophosphamide) regime may "achieve" excellent results in one patient but be less efficacious in another. This may be associated with the varying genetic nature of those two patients. This would supplement *in vitro* research into cancer cell lines of varying genetics that recently resulted in a chemotherapy/cancer "encyclopaedia". The buzz phrase is "personalised medicine"; buzz

word: "tailored".

Such medicine output could rocket; a revolution aided by the NHS working in concert with the pharmaceutical industry. It is keen to play its part in finding the best drugs for specific jobs: tomorrow's "magic bullets", contributing its expertise in toxicology, pharmacology, statistics and so on.

Modern statistics, probing investigational design, computer programs, collaborative yet canny industrial eyes and the gargantuan data from a properly joined-up NHS could mine that precious mother lode.

### Concerns about confidentiality

But it may be aborted because of concerns about patient confidentiality from "consent fetishists" (to quote Sir John). They are concerned that "amber data" may result in identification of individuals. That risk does exist. Amber data could tie, with a reasonable degree of certainty, a small minority of patients' genetics to the outcome of their treatment with a specific drug.

The patient-identifying unambiguous "red data" appears not on offer to the pharmaceutical industry. I wonder why. I speculate that, generally, the public only hear about the pharmaceutical industry when something goes wrong; think Devonport incident, Thalidomide, TGN1412. Bad press includes carelessness, only interested in profit; one sideline is bribery.

I would not wish to include sharing of red data with insurance companies. But I do ask, "Why not

share red data with the pharmaceutical industry?"

Individual companies already possess it for their specific clinical trials. Pharmaceutical industry staff include professionals, such as chartered scientists, medical practitioners and pharmacists (bound by their ethical codes and liable to be struck off), and others who have signed confidentiality agreements. Comparatively "junior" "lay" administrative staff, who have signed confidentiality agreements, in British GP surgeries and hospitals, routinely access patients' red health data and respect their confidentiality. Certainly, risks exist. Broaches occur; individuals and systems have suboptimalities. Government organisations are less-than-perfect. One illustration is the loss of millions of records of personal data from the UK Department of Work and Pensions in 2008. By the way, your kindly superstore, helped by their loyalty card scheme, from changes in the pattern of your purchasing, may well know before your GP when you anticipate an addition to your family.

### Stance

Industry having patient data is a risk worth taking – given the immense potential benefits. Industry would benefit – and societies, globally. This outline is simplistic; industrial leaders must be mindful of *Realpolitik* but, maybe, the pharmaceutical industry, indisputable health benefactor, should be more bullish.

Malcolm E. Brown



# news from the EIPG

## EIPG Pharma Weekly Roundup

Claude Farrugia, Vice-President Communications, has organised a new addition to our publication line-up. The "Pharma Weekly Roundup" is an electronic Sunday weekly issued by EIPG presenting a summary of new items related to the pharmaceutical industry from the preceding week. You can access the latest and preceding issues and subscribe to email notifications of future issues, at <http://paper.li/EIPGeu/1403883135>. We should be pleased to receive your comments on this publication.

## PHAR-IN Competencies in Biotechnology – we need your response

The PHAR-IN Consortium is aiming to produce cutting edge continuing education courses for staff working in the biotechnology industry. Following our pilot, we need to obtain 500+ responses from individuals working in the pharmaceutical industry.

The PHAR-IN survey is available at [www.surveymonkey.com/s/pharin4](http://www.surveymonkey.com/s/pharin4)

Individual responses can be from a number of staff members of the same company, in any area, from research and development to production and quality assurance as well as sales and marketing, company agencies, medical information, training and regulatory affairs. To be statistically appropriate, we need a number of individual responses from each of our Member Association countries. Replies should be sent in by 30 September.

Based on your responses, we expect to produce courses for continuing professional development, a taught distance learning Masters and units of course study for undergraduates. *Please complete the questionnaire irrespective of whether you currently work in the biotech industry.*

## Online training for industrial pharmacy practice from PharmaConsult

PharmaConsult has announced their first series of short courses and webinars specifically prepared to help in the implementation of new regulations and guidelines. As regulatory issues arise, fresh e-Learning courses and accompanying webinars will be introduced. Initially, the courses will be in

the English language but Spanish translation is planned for the near future.

Any member of their National Association interested in taking one of the PharmaConsult courses can purchase at a discounted rate, if they go to the Members Area of the EIPG website at <http://eipg.eu/> and scroll down to the Members Area and add the password which is available from your national representative or from Jane Nicholson ([jane@nicholj.plus.com](mailto:jane@nicholj.plus.com))

In the Members Area, the PharmaConsult on-line training catalogue of e-Learning courses can be found. These include an Introduction to GMP, GMP for Biotechnology Products, Quality Management Systems, Basics of

ICH-GCP, an Introduction to Medical Devices in the UK and the USA. A short video about each course is available and can be run before deciding whether to buy.

## Technical Workshop on CPD and LLL for Health Professionals

Anni Svala, Vice-President Education and Training attended a workshop on continuous professional development (CPD) and lifelong-learning (LLL) for healthcare professionals. Her report is shown below.

Jane Nicholson, Executive Director EIPG, [jane@nicholj.plus.com](mailto:jane@nicholj.plus.com)

### Report on a Technical Workshop from Anni Svala

A technical workshop on continuous professional development (CPD) and lifelong-learning (LLL) for healthcare professionals in Europe was organised on the 20 June in Brussels. Over 70 healthcare professionals gathered together to discuss the differences and needs of CPD among European countries. EIPG was invited to represent the views and ideas of industrial pharmacists and Mrs. Anni Svala participated in the event on behalf of EIPG.

Significant differences in CPD in healthcare exist in European Union (EU), European Free Trade Association (EFTA) and European Economic Area (EEA) countries and there is a lack of comprehensive studies that allow comparison and meaningful dialogue across countries and professions<sup>1</sup>. In this context, the consortium consisting of the Council of European Dentists (CED), the European Federation of Nurses Associations (EFN), the European Midwives Association (EMA), the European Public Health Alliance (EPHA), and the Pharmaceutical Group of the European Union (PGEU), led by the Standing Committee of European Doctors (CPME) were contracted by the Consumers, Health and Food Executive Agency (CHAFAEA) and funded by the Health Programme to carry out a 12-month study concerning the review and mapping of CPD and LLL for five health professions (doctors, nurses, dentists, midwives and pharmacists) in EU, EFTA and EEA countries.

The technical workshop brought together experts and stakeholders in the area of CPD for the five sectors of health professions, including representatives of professional and regulatory bodies, CPD providers, academics, accreditation bodies, relevant EU projects and initiatives, and the European Commission<sup>1</sup>. The participants commented and evaluated the initial findings of the study and provided information to fill any gaps in the data collected.

The structure of the workshop allowed for active involvement of the participants, particularly through four parallel breakout sessions which were designed around horizontal issues. The total number of participants of the individual breakout sessions was limited to stimulate dialogue and discussion. Results of the workshop will be processed, together with the findings of the literature reviews and the survey, into a final report for the study in October 2014, which will include policy recommendations. Finally, some personal comments on the workshop. The event was well-organised and the agenda for the day was very comprehensive and nicely structured. It was interesting to see how continuous professional education and self-development is a part of professional identity among all healthcare professionals in Europe and the issues and concerns we are struggling with can be shared. By gathering together, we are able to discuss and raise the important questions to be solved. By sharing thoughts and ideas, we can learn from each other and are able to further improve our tools for CPD and LLL. Most importantly, we will come closer and collaborate!

#### Reference:

<sup>1</sup> European Commission. EAHC/2013/Health/07 Study concerning the review and mapping of continuous professional development and lifelong learning for health professionals in the EU: D.2 Discussion Paper, 3 June 2014. Luxembourg: Executive Agency for Health and Consumers, EC.

# events

## SEPTEMBER

22-24 September 2014 – Vienna, Austria

**Quality by Design - New Concepts for Chemical and Biotech Product Development and Optimisation**  
[www.diahome.org](http://www.diahome.org)

25-26 September 2014 – Valencia, Spain

**3rd International Summit on GMP, GCP & Quality Control**  
[www.pharmaceuticalconferences.com](http://www.pharmaceuticalconferences.com)

29 September 2014 – London, UK  
**5th Annual Biosimilars & Biobetters**  
[www.smi-online.co.uk](http://www.smi-online.co.uk)

29 September-3 October 2014 – Boston, MA, USA  
**12th Annual Cold Chain GDP & Temperature Management Logistics Global Forum**  
[www.coldchainpharma.com](http://www.coldchainpharma.com)

## OCTOBER

1-2 October 2014 – Heidelberg, Germany  
**GMP for Medical Devices**  
[www.gmp-compliance.org](http://www.gmp-compliance.org)

1-2 October 2014 – Barcelona, Spain  
**Quality by Design in Pharmaceutical Analysis**  
[www.gmp-compliance.org](http://www.gmp-compliance.org)

6-8 October 2014 – Huntington Beach, CA, USA  
**2014 PDA Universe of Prefilled Syringes and Injection Devices – Improving Patient Outcomes through Innovation**  
[www.pda.org](http://www.pda.org)

7-8 October 2014 – Dessau-Ro lau (nr Leipzig), Germany  
**Vaccines and Biologics – 10th BioProduction Forum**  
[www.gmp-compliance.org](http://www.gmp-compliance.org)

7-9 October 2014 – Paris, France  
**CPhI Worldwide**  
[www.cphi.com](http://www.cphi.com)

8-9 October 2014 – London, UK  
**Pharma Compliance 2014**  
[www.healthnetworkcommunications.com](http://www.healthnetworkcommunications.com)

8-9 October 2014 – Barcelona, Spain  
**11th Annual BioProduction 2014**  
[www.informa-ls.com](http://www.informa-ls.com)

8-9 October 2014 – Barcelona, Spain  
**Flexible Facilities & Manufacturing of the Future**  
[www.informa-ls.com](http://www.informa-ls.com)

12-15 October 2014 – Las Vegas, USA  
**2014 ISPE Annual Meeting**  
[www.ispe.org](http://www.ispe.org)

14-15 October 2014 – Berlin, Germany  
**Pharmaceutical Cold & Supply Chain Logistics**  
[www.pda.org](http://www.pda.org)

## NOVEMBER

2-5 November 2014 – Chicago, MI, USA  
**Pharma EXPO**  
[www.ispe.org](http://www.ispe.org)

4-5 November 2014 – Munich, Germany  
**Parenterals**  
[www.pda.org](http://www.pda.org)

4-6 November 2014 – Geneva, Switzerland  
**5th Annual Pharmaceutical Serialisation and Traceability Summit**  
[www.pharmaserialisation.com](http://www.pharmaserialisation.com)

5-7 November 2014 – Vienna, Austria  
**17th APIC/CEFIC European Conference on Active Pharmaceutical Ingredients**  
[www.gmp-compliance.org](http://www.gmp-compliance.org)

11-12 November 2014 – Geneva, Switzerland  
**World Biosimilar Congress 2014**  
[www.terrapinn.com](http://www.terrapinn.com)

12-14 November 2014 – Brussels, Belgium  
**World Orphan Drug Congress**  
[www.terrapinn.com](http://www.terrapinn.com)

12-13 November 2014 – Prague, Czech Republic  
**Setting Specifications and Acceptance Criteria**  
[www.gmp-compliance.org](http://www.gmp-compliance.org)

13-14 November 2014 – Prague, Czech Republic  
**Stability Testing for Drug Substances and Drug Products**  
[www.gmp-compliance.org](http://www.gmp-compliance.org)

19 November 2014 – Düsseldorf, Germany  
**PharmaLab Congress**  
[www.pharmalab-congress.de/ple\\_home.html](http://www.pharmalab-congress.de/ple_home.html)

19-20 November 2014 – Berlin, Germany  
**Annex 15 Conference**  
[www.gmp-compliance.org](http://www.gmp-compliance.org)

27-28 November 2014 – Vienna, Austria  
**9th Qualified Person Forum**  
[www.qp-forum.org](http://www.qp-forum.org)

## DECEMBER

2-3 December 2014 – Berlin, Germany  
**Outsourcing/Contract Manufacturing**  
[www.pda.org](http://www.pda.org)

9-12 December 2014 – London, UK  
**Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) Symposium 2014**  
[www.mhra.gov.uk](http://www.mhra.gov.uk)

10-11 December 2014 – Heidelberg, Germany  
**Rapid Microbiological Methods Conference**  
[www.rmm-conference.org](http://www.rmm-conference.org)

11 December 2014 – London, UK  
**Stability Challenges Part II: Assuring the Stability of Medicines from Manufacture to Clinical Use**  
[www.jpag.org](http://www.jpag.org)

