Standard drugs and drug standards

A comparative historical study of pharmaceuticals in the 20th century

Newsletter 2 – March 2009

Some words from the Chair

First off I would like to thank all members of the network for making the start of this program so successful. This goes especially for the Strasbourg team, who with the Opening Conference, made such a great contribution to the success of the program. Our network currently consists of 60 scholars from all over Europe, and the Strasbourg conference alone brought 10 new members on board.

In the coming year we will reap the fruits of our labors. With three workshops and two panels registered for the European Association of the History of Medicine and Health conference, we are off to a good start.

In this year there will also be two significant changes. After long deliberation the Steering Committee has resolved to make the Exchange Program somewhat more flexible. It will now be opened up for shorter applications and for a broader circle of scholars.

The second major change has to do with coordination. In March, Christophe Masutti will be switching to a Research Fellowship in one of the network's research projects. He has done a terrific job during his time here with us, and not just myself but all of us here thank him heartily and hope that he remains in close contact with the RNP. Our intention is to fill the vacated position again in April. Should the coordination in the coming weeks be somewhat less smooth than usual though, I beg you to bear with us!

Berlin, March 2009
Volker Hess, chair of DRUGS

After the very nice Opening Conference held in Strasbourg the 4th and 5th December 2008, DRUGS has reached its cruising speed. 3 workshops on main topics of the programme are planned for 2009, respectively in April, June and December. The contents of these workshops are detailed below.
In September, we will launch the second term of the Exchange Programme. Please note that the Steering Committee decided to change the formalities (applications can eventually be submitted for a two-years project, with evaluation of a mid-term report). Moreover, the Exchange Program is now open to postgraduate students, post-doctoral researchers, early career researchers and established researchers.
We would like to remind to all members that some short travels grants are available for 2009. These grants are supported by ESF for short visits of up to 15 days. The procedure is open to RNP members who wish to spend time in another local group. Applications can be adressed to the Steering Committee (via Volker Hess, Chair of the programme) at least three months before the visit. The total budget for 2009 cannot exceed 5000 EUR. This budget will be divided in order to balance it between local groups and to consider every application irrespective of the order of their arrival.

Schedule 2009

- *1st February 2009* : Call for application Exchange Programme (dead line: *1st May 2009*)
- *23-25th April 2009* : Workshop *Standardizing psychoactive drugs and drug uses in the twentieth century*, Utrecht.
- *16-18th June 2009* : Workshop *Circulation of Antibiotics: Journeys of Drug Standards, 1930-1970*, Madrid
- *1st September 2009* : Launch 2nd term Exchange Programme
- *October 2009* : Working group meeting Team 3 "Biological Drugs" at Paris
- *28-28th November 2009* : Workshop Team 2 "Cardiacs", Manchester.

Opening Conference
4^{th} – 5^{th} December 2008

Org.: Prof. Christian Bonah, Dr. Christophe Masutti, Dr. Anne Rasmussen

The Opening Conference of DRUGS took place at Strasbourg, France, with the support of the University of Strasbourg, The Maison Inter-universitaire des Sciences de l'Homme Alsace (MISHA), la Région Alsace and the Institut Universitaire de France (IUF). Initially planned to convey 30 participants, the opening conference gathered 59 participants and speakers and its organization has thus shown the effective networking process under way since the launching of the 'Drugs' networking program in spring 2008.

Using the theme of standardization, applied both to objects and practices, the Opening conference explored the present state of historical analysis of the development of twentieth-century medicine by looking at the production, distribution, prescription and consumption of medicines throughout the century. Contributions presented general overviews of standardization of therapeutic agents and used examples from major classes of therapeutic agents, such as sulfa-drugs, hormones, and psycho-active drugs to characterize the present state of research in the field. The aim of the conference consisted in evaluating the present state of research in order to contribute in the future to a better understanding of industrial, administrative and clinical standardization conceptualizing the 'therapeutic revolution' (1920-1990) in which a series of 'miracle' drugs has changed the face of Western medicine.

Rather than taking twentieth-century developments in the production and evaluation of drugs as 'natural' responses to a series of practical problems, presentations examined the evolution of industrial standards and drug trials, along with prescription and clinical practices, from a long-term historical perspective. Thus, for example, by looking at the role played by accidents or proposed, but rejected, alternatives to standard modern practice, speakers and participants aimed to reveal the multiple forces that have shaped our modern medical world.

This approach takes us beyond the usual protagonists in this history – research scientists and their clinical partners – allowing important groundwork in the contextualization of this field with respect to the intervention of the state, industry, and other actors. A richer view of the context for the scientific innovation that lies behind the modern pharmaceutical industry promises to open up new perspectives in the analysis of today's health systems.

Furthermore, as standardization is a theme common to a number of disciplines, the proposed approach showed possible lines of interdisciplinary discussion allowing fruitful exchange between researchers who otherwise might not meet. Thus, the conference reached its immediate aim to launch an international networking experience around a rich theme with a rich historical terrain, and significant contemporary interest that will be developed during the next years along the programme outline and through working teams established in Strasbourg at the Opening conference.

Scientific content and discussion

Standardization is the key concept around which the 'Drugs' ESF networking programme is constructed, mobilizing the concept both as an inter-disciplinary analytical tool, and as a transversal characteristic of modern technological systems. The Opening conference was thus organized along four sessions spreading over two days. A first session was devoted to the presentation of relevant research and critical reappraisals of 'standardization' as a category and analytical tool for drug history. A second session consisted of three roundtable discussions reflecting upon standardization as a history of practices and social settings throughout the twentieth century. A third session intended to prepare and organize further research along the proposed idea to pursue issues through studies of major drug classes such as psycho-active chemicals, antibiotics, medicines of biological origin (e.g. sera, vaccines, hormones, plants, etc.) and chronic disease treatment as in cardio-vascular and cancer therapy. The final and fourth session was dedicated to a wider perspective on 'evidence-based' medicine and the question of regulatory regimes for twentieth century drug development and production.

Over the last two decades, the questions of drug innovation and drug safety have become major public issues in Europe. On one hand, the promise of a new era of drug development associated with the mobilization of biological knowledge, biotechnology, and a new model of individualized therapies is high on the agenda. On the other hand, major concerns have emerged among health professionals, pharmaceutical firms and government bodies. These fears focus on the declining number of 'true' molecular innovations, on the multiplication of 'me-too' medicines, on the organization of mandatory clinical trials, as well as on the therapeutic risks generated by prescriptions, especially those that target the risk of future disease in currently asymptomatic populations, and, last, but not least, on issues of the cost of drugs and access to therapies.

Combining in a most visible form therapeutic hopes and anxieties, pharmaceutical innovation and disaster during the second half of the twentieth century, Sophie Chauveau presented the industrial production and distribution of blood and blood products in France. Albeit not a classical pharmaceutical 'drug', blood products are at the

same time pharmaceuticals representing the complexity of recent drug development and distribution and rather untypical in the sense that their economic system of collection and distribution in France has been closely affiliated with a non monetary system of donation and 'gift economy'. From a quite different angle, Jeremy Greene proposed a contribution reflecting upon standardization issues related to brand-name and generic drugs during a long twentieth century commenting on the rise and fall of brand names as a means to produce, codify and distribute pharmaceuticals between state regulation and industry driven quality standards.

Subsequently, Jacob Tanner widened the analytical framework presenting the concept and practices of standardization in social and economic history of industry, technology and medicine throughout the twentieth century questioning how standards reduce complexity, how they structure society and participate in the creation of new knowledge. Viviane Quirke focalized the first session again on standardization in the domain of pharmaceutical research and development insisting particularly on the passage from industry case studies to broader studies of R&D in the pharmaceutical industry and the limits of investigation inherent to bottom-up approaches. Finally, John Abraham questioning the role of standards in understanding the modern drug regulatory period drew attention to the construction and change of standards over time and to their actual use in practice and application. Drawing on case studies ranging from Proctolol (1972) to carcinogenic risk assessment for NSAIDs the contribution analyzed differing standards in clinical trial efficacy and risk-benefit analysis and their evolution over time.

All the contributions indicated that from the historian's perspective, today's discussions are very much informed by the vision we have of the past, especially of the half century preceding the initial sense of crisis that emerged in the 1980s. This period, which is considered to have been the golden era of the 'therapeutic revolution', has become the standard against which present-day expectations, developments, and difficulties are measured. Thus, understanding the scientific, economic, social, and cultural patterns that determined the trajectory of drugs during the decades from 1920 to 1970 is not only important for the history of the medical sciences in the twentieth century, but is also a resource for reflecting upon choices that face Europe's healthcare systems today.

The second session of the conference was intended to pursue through three roundtables with short programmatic presentations incentives and orientations opening up horizons for new research and future workshops of the networking programme.

❧ **Roundtable 1** organized by Maria Jesus Santesmases and Toine Pieters focused attention on standardization between production and the clinic. Initial statements were presented by Patricia Barton on standardization and the patient especially related to the question of lowering the boundaries in the non-Western world. George Weisz proposed a methodological approach to compare diagnosing and treating premenstrual syndrome in five western nations and Ilana Lowy presented the case study of how "chemical contraceptives ż were regulated between 1920 and 1960 in the United States and the United Kingdom. Lead questions addressed during the discussion were focused first on how new drugs shape new ways of diagnosis and novel forms of therapy; and how these changes affect drug profiles, the profiles of the target populations and the boundaries between health and disease. Second, the discussion questioned how the gendering of pharmaceuticals and their relationship to women/men's bodies evolve. In some cases drugs arrived on the market in a gendered form; in other cases, drugs were used as if 'neutral', not gendered (antibiotics, ie.) despite the fact that sometimes clinical trials included mainly one type of patient (i.e. white middle class men). These concepts may contribute to treating patients/consumers as agents in the relevant histories. Third, further discussion concerned what differences and similarities are established as part of the process of the societal embedding of drugs on a national and international level. Fourth, participants and speakers endeavored what role the promise of specificity (between bench and bedside) played in this process or what agencies were involved in turning the pharmaceuticals under survey into agents with specific effects. Finally, discussions returned to the question what role regulation played in establishing safety and effectiveness standards.

❧ **Roundtable 2** organized by Volker Hess and Christian Bonah addressed the theme of standardizing and regulating drugs in national and international spaces. Bettina Wahrig opened the roundtable with a contribution on standardizing and categorizing drugs from the perspective of precarious substances highlighting the connections between drug's potential harmful effects and other substances considered as poisons or deleterious for human health from a pharmacy perspective. Iris Borowy elaborated on standardizing and categorizing drugs from a political perspective especially during the interwar period differentiating between biological drug standards evolving from scientific needs, commercial needs and the growing implication of the League of Nations leading to the creation of over 50 standards in the drug domain under the leadership of Thorvald Madsen. Christian Bonah addressed the argely neglected study of the birth of the European economic community and questions of drug exchange and standardization from the perspective of the French political agenda in a top down approach; whereas Volker Hess extended the presentation by the case study of the introduction of chlorpromazine in France and Germany in 1952/53 taking a complementary bottom-up approach. Both presentations confronted comparative approaches with a growing tendency to a europeanization of drug regulation and drug exchange immediately after WWII.

Lead questions in the following discussion included first the approval of medicines under the intervention of outside or over-reaching actors (state, nation, 'continent') as a normative intervention. One way to consider national and international spaces is a chronological devel-

opment approach implying that we move from professional/industrial to political/administrative and finally to post-state-nation/public ways of regulating. A second point is to consider a geo-political line of analysis from comparisons between national settings to international approaches of regulatory sciences and drug standards and approval. Secondly, the discussion highlighted that it seems useful to investigate in these spaces where collaborations and oppositions lie between administrations, professions, consumers and industries and to investigate top down versus bottom up practices of standardization leading eventually to the question what is standardized (and what is not) at the administration/state level.

❧ **Roundtable 3** organized by Christoph Gradmann and Michael Worboys turned to the relationship between standardizing, marketing and consuming. Michael Worboys investigating the 'Wright' way to standardizing therapeutic vaccines during the early twentieth century stressed the contradiction that led vaccine therapy under Wright to the marketing of standard vaccines for non-standard use. Flurin Condrau from a radically different perspective turned to the standardization of infection control from the angle of hospital history. Looking at antibiotics and hospital governance in the 1950s the contribution added the perspective of additional institutional settings and actors to the arena of drug standards. In additional statements Viviane Quirke portrayed the role of the medical doctor in the pharmaceutical industry between research and marketing, and Jeremy Greene further extended his comments on evidence based medicine and evidence based marketing as a possible avenue for a history of drug standards. Lead questions during the discussion included first, given that the statements in the roundtable encompassed a history of more than 100 years, that it seemed important to highlight changing constellations of marketing, standardization and uses of medicines in various historical contexts. Participants and speakers concluded that it matters to question to which degree and in which way the standardization of medicines can be discussed in relation to marketing at different points in time and space. Secondly, discussions focused on the question of the dynamics between marketing and standardization asking who is driving whom (at which time) and for which purpose.

❧ **The third session** of the conference was dedicated to meetings of the working teams of the 'Drugs' network. Following the preceding discussions of general issues of drug standardization during the twentieth century, the working teams are conceived as 'object-oriented' collaborations during which the current research on a group of therapeutic substances (psycho-active chemicals, antibiotics, medicines of biological origin e.g. sera, vaccines, hormones, plants, etc. and chronic disease treatment as in cardio-vascular and cancer therapy) is discussed and prepared for further realization under the auspices of the network.

❧ **The fourth and final session** was intended to bring together major concerns linked to drug standardization in a synthetic manner. Harry Marks in a contribution on the history of twentieth century therapeutic reform addressed two final questions. First, how evidence is established, what counts at a given time and place as evidence for standardization and what happens when different modes of evidence collide? Second, the contribution inquired into the moral expectations of evidence. At the heart of his investigation lay the late but triumphant acceptation of randomized clinical trials as routine practice in the 1970s. Eventually Jean-Paul Gaudillière summarized from different perspectives and case studies the ambivalent relationships between standardization and regulatory regimes declined in four systemic ways as professional, administrative, industry and public/ consumer based. The contribution stressed the incentive to consider regulation beyond its definition as a legal intervention of the state rather as a series of formal and informal activities organizing the invention, the production, the commercialization and the uses of drugs pointing thus to further means and motives for the investigation of the history of drug standards throughout the twentieth century.

Results and impact on future direction of the field

The idea of the therapeutic revolution is rooted in the notion that the twentieth century witnessed a radical shift in medical practice, with major improvements in patient care originating in the development and widespread use of entire classes of new and effective drugs: antibiotics, neuroleptics, antidepressants, sex steroids, cortisone, etc. Whether taming microbes, exorcizing madness, or mobilizing the body's own hormonal mediators for therapeutic ends, these molecular innovations seemed to fulfil the promise of miracle cures.

The era of the therapeutic revolution is also considered as the period when medical practice was transformed by the rise of the statistical evaluation, the development of cooperative research, the homogenization of research protocols, and the centralization of clinical trials, as well as their administration by 'independent' agents. The advent of controlled clinical trials is often interpreted as a tendency rooted in the rationalization of medicine or, alternatively, in the development of statistical methods, without making any connection with the history of drugs. Thus, the explanation usually given is the rise of state regulation, and its outcome was the introduction of the controlled, randomized, clinical trial as the 'gold standard' for such assessment. In order to revaluate this dominant picture, the conference has underlined the role played by the medical profession in developing new methods for assessing efficacy that resulted in the introduction of controlled trials independently of any legislative pressure. Furthermore, while it is easy to see reforms as being triggered by new discoveries or by administrative difficulties encountered in the drug approval process, the initial impetus was often medical crises such as the thalido-

Figure 1: DRUGS Opening Conference. Photo by Oivind Larsen.

mide disaster in the early 1960s. And the adoption of specific modes of evidence as roots for subsequent standardization practices is often slower and more complex than hindsight might suggest. It seems reasonable to investigate in more detail and in a comparative manner the multiple relationships between drug disasters and reforms in drug authorization and the standards implemented or adopted by these regulatory changes just as well as the slow changes in modes of evidence production and standardizing practices. Finally, the conference outcome has stressed the contribution of industrial practices to changes in evaluation procedures.

Increased contact between clinical physicians and industry provided a feed-back system, where clinical information could be integrated into the internal processes of research and development. These multiple and multidirectional exchanges and systems of information require more sustained comparative analysis. To conclude it can be stressed that the conference highlighted that the concept of standardization should be understood as the collection of techniques that result in selection and homogenisation. The conference has shown that the concept thus offers a common heuristic framework for the diverse approaches to the objects of study within the different domains of economy, health policy, and medicine. Using this concept also provides the means for understanding the pharmaceuticals under consideration from the perspective of a generalized process that lies behind most complex systems in our modern societies and that still needs much further inquiry. In this second sense, standardization is an essential feature of industrial production and product quality control as well as administrative and bureaucratic procedures, and can also be identified, for example, in the moves to standardize clinical treatment by means of prescription guidelines and consensus conferences. It offers a view on the mechanism shaping local standards of experimental practices, national styles of regulation regimes as well as localised markets, regional demands, and habits of usage.

More generally, standardization has enabled communication, interaction, negotiation and – not the least important – trading between partners who are separated in space, or even time. The conference has amply shown that standardization can be conceived as a key technology of trust and serves as one of the founding principles of modern society. It is for these reasons that the 'Drugs-Network' will concentrate its immediate future initiatives on an interdisciplinary approach of the history of twentieth-century pharmacy from the perspective of standardization, taking into account the areas of research and development, production, local and international marketing, quality control, pre-clinical and clinical testing, and the practices of prescription and consumption of pharmaceutical products.

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Workshop Team 4 "Psychochemical"

Standardizing psychoactive drugs and drug uses in the twentieth century

23-25 April 2009 (Utrecht)

Org.: Stephen Snelders (s.snelders@vumc.nl)

The workshop is a collaborative project of the Working Group on Psychotropic Drugs of the European Science Foundation. The Working Group includes researchers from the universities of Zurich, Berlin (the Charité), Brussels and Amsterdam (VU-University Medical Center). At the first meeting of the Working Group in Zurich on 19 September 2008 the general ideas and set-up of the workshop were discussed and agreed upon. Execution of the ideas and organization of the workshop were delegated to Dr Stephen Snelders, Research Fellow, VU-University Medical Center, Amsterdam.

The Descartes Center for the History and Philosophy of the Sciences and the Humanities, University of Utrecht, agreed to host and co-finance the workshop. The Descartes Center is involved in the ESF network and program around drug standardization: Professor Toine Pieters is member of the steering group.

A call for proposals (deadline fixed on 1st 2008) was issued within the ESF network and in the various media of drug and medical history research.

❧ **Publication**: An international peer-reviewed journal, Studies in History and Philosophy of Science, Part C: Studies in History and Philosophy of Biological and Biomedical Sciences, has agreed to publish an edited volume with the contributions to the workshop.

Presentation

Psychoactive drugs and drug treatments, within psychiatry, as well as those that have entered the public domain, have begun increasingly to attract the interest of historical researchers. An aspect of this research is the search for generalized concepts that can be used to understand the dynamics of the life-cycles of drugs. One such concept, and the focus of the new research program sponsored by the European Science Foundation, is that of 'standardization'. Standardization, understood as the assembly of techniques that result in selection and homogenization, seems to have been an important feature of the development, production, distribution, regulation and use of psychoactive drugs since at least the early 1900s. It also seems to be a characteristic feature of developments in local experimental and clinical practices, national styles of regulation, shaping of consumer demand, and national and local cultures of consumption.

This workshop will focus on present research into the histories of psychoactive drugs from this perspective of standardization, especially studies that connect practices at local, regional and (inter-)national levels. Starting with barbiturates in the early 1900s, and followed by amphetamines in the 1930s, standardized compounds were increasingly used in the treatment of mental problems within medicine, but also in the public sphere for purposes of self-medication, recreation or self-enhancement.

In the 1950s, new drugs, such as chlorpromazine and other antipsychotic drugs, as well as the benzodiazepines and the hallucinogens, created what has often been regarded as a therapeutic revolution in psychiatry, not to mention a 'drug revolution' in society. The concept of a therapeutic revolution, however, is a contested notion. Historical evidence, for example, points to ongoing problems in establishing the psychopharmacological effects of drugs in clinical practice. Additionally, there is evidence of continuity with earlier developments in psychiatry. Also, researchers continue to face many important, unanswered questions. How were these psychotropic drugs and their various uses subjected to a process of standardization? To what extent did attempts to standardize drugs and treatments also prompt the standardization of patient and other user groups (in terms of gender, age, or even ethnicity)? And what role can we ascribe to state administration and financing, as well as company marketing in the standardization process? Or, to what extent did drugs as 'precarious matters' possess aspects of instability, ambivalence, and risk that resisted attempts at standardization?

The workshop's key themes are the extent of standardization, its meaning for understanding the dynamics of the life-cycles of drugs and treatment and other practices of use, as well as the failures of and obstacles to the process of standardization.

❧ *Meanings of methadone*, by Caroline Jean Acker (Carnegie Mellon University, Pittsburgh, USA)

One factor powerfully influencing the trajectory of a psychoactive drug is its relationship to the boundaries separating licit from illicit drugs. Such boundaries attempt a form of drug standardization, but one which is less dichotomous than regulators might wish. Any drug having the potential to be both a legitimate medicine and a street drug poses complex challenges of standardization, whether of indications or of negative effects. Even consumers are hard to standardize, as distinctions between patients and street users may blur. From its development by German chemists in the 1930s to its present role as both analgesic and treatment for opioid dependence, methadone illustrates how opiate agonist properties can complicate the process of standardizing psychoactive drugs.

Methadone came to life in 1937 as a vindication of German pharmaceutical self-sufficiency: a drug comparable to morphine in its analgesic power which could be synthesized without imported starting materials. Captured by the Allied powers at the end of World War II, methadone, as an opioid agonist, was taken to the U.S. Public Health Service Addiction Research Center, an internationally recognized center for determining the addictive potential of opioid analgesics. The Center's determination that methadone was addicting in a manner similar to morphine doomed it as a marketable analgesic but suggested its utility in the detoxification of heroin and morphine addicts, the drug's second phase. Third, Vincent Dole and Marie Nyswander reconfigured opiate addiction as a metabolic disorder and reconstructed methadone as a maintenance drug, analogous to insulin in the treatment of diabetes. In doing so, they also reconfigured the addict as a person with a physiological rather than psychiatric abnormality. Yet the perceived criminality of the addict lived on to fuel methadone's fourth phase as a plank in Richard Nixon's platform to curb crime in American cities by offering methadone maintenance treatment for opiate addiction. Fifth, the harm reduction movement reconfigured methadone yet again as a protection against HIV infection as it helped opiate addicts cope with addiction without using syringes. Similarly, methadone's recent relegitimization as an analgesic in private practice adds to the ambiguities that prevent easy classification of this multi-faceted drug.

❧ *East Side Story: The standardization of psychotropic drugs at the Charite psychiatric clinic 1955-1975*, by Viola Balz & Matthias Hoheisel, Humboldt University, Berlin, Germany

The discovery of new psychotropic drugs around 1950 often serves as the starting point for the historical narrative of a 'revolution in psychiatry'. Another important frame to the history of drugs is the analytical category of standardization. In common use it shows the unification of therapeutical practices. These are closely related to shared instruments of assessment within the scientific community, allowing its members to communicate. At the same time, standardization might also be regarded as a process of systemizing medical observations at a local institution, thereby unifying doctors' treatments. In the latter sense, we aim to examine the possible impact of psychotropic drugs on observational routines as e.g. the attempt to validate psychiatric diagnosis,using the example of the Charité psychiatric clinic. The time period investigated ranges from 1955 to 1975, when therapeutical decisions in everyday practice were strongly grounded in the psychopathological tradition of Karl Leonhard. This clinical approach was opposed to the focus on 'target symptoms' in psychopharmaceutical research within and outside the GDR. To evaluate the influence of psychotropic drugs on the standardization of clinical practice, we examine two different groups of drugs in clinical records and scientific publications. In 1959, Imipramine was introduced at the clinic. Clinical research was closely bound to the clinical record as a system of documentation and is undertaken in a casuistic manner. The therapeutical usage is closely connected to the clinical diagnosis, as will be exemplified with clinical records. No efforts are being made to receive imports of Diazepam, which only became available in the clinic after national production in 1968. Why do benzodiazepines – even thereafter – gain no scientific attention at the local clinic, although being of profound interest to other psychopharmaceutical researchers in the GDR? Employing a quantitative sample of records, the usage of Benzodiazepines is demonstrated as a symptomatic therapy, crossing virtually all psychopathological imperatives. As older sedatives did before, they seem to silently complement main therapeutic strategies. Our paper tries to demonstrate how clinical processes of drug-standardization may draw upon the local traditions of knowledge, while resisting the psychiatric discourse of that time. Simultaneously, the example of the Charité reveals that this way of knowledge production became increasingly precarious around 1970. As symptomatological standardization became one of the key points of interest in the research on psychotropic drugs, the local way of systematization lost ground in the scientific discourse of the GDR.

❧ *Standardization of the licit opium market and the growth of trafficking in post independence India*, by Patricia Barton, University of Strathclyde, Glasgow, UK

The new state inherited a broad set of problems in the area of narcotics control from the British while being forced to pay at least lip service to the prohibitionist Gandhian rhetoric of its constitution. During the early years of independence, the new drug standardization authorities struggled to cope with the competing agendas of licit and illicit drugs. Drugs destined for the licit narcotics market continued to leach into the black market because the attempted standardization of their quality naturally

made them even more attractive to illicit traders and purchasers.

❧ *Children and psychoactive drugs*, by Brigitte Chamek, Université Paris Descartes

Until the 1990s, children and adolescents were excluded from clinical trials. In the mid-1990s the US Food and Drug Administration (FDA) took an explicit stance encouraging companies and government organizations to initiate studies on children and adolescents. A pivotal change occurred in 1997 with the FDA Modernization Act, which granted 6 months additional exclusive marketing rights to pharmaceutical companies which conducted FDA-approved paediatric studies. This financial incentive has led to a number of important industry-sponsored paediatric psychopharmacology studies.

The average annual growth rates for the prescription of psychoactive drugs to adolescents increased from 1994 to 2001, with a rapid acceleration after 1999. The number of drugs put on the market with new indications for the use on children's psychiatric disorders has grown enormously in the last decade in North America and more recently in Europe, Asia and South America too. The new European legislation in favour of paediatric medication, adopted in June 2006, grants 6 months additional exclusive marketing rights to the pharmaceutical companies which conduct EU-approved paediatric studies. This financial incentive will probably lead to the same increase in medication for children.

The case of Risperidone, an atypical psychotropic drug, will be analysed. Risperidone is prescribed to more than 10 million people worldwide and generates about 2 billion dollars in annual sales for Janssen. It is considered now as a useful medication for children with autism and other disorders exhibiting disruptive behaviours. The number of scientific publications praising the beneficial effects of Risperidone is impressive compared to those insisting on the Risperidone-associated diabetes mellitus risks and other metabolic problems. When the words Risperidone and autism are selected as key words, the Pub Med data base, used by scientists and physicians, starts by giving the references in favour of Risperidone. How do pharmaceutical companies succeed in promoting their drugs despite huge side effects? How do they succeed in preventing or discarding studies on these side effects? Why do new molecules always seem better than the previous ones? We explored some mechanisms whereby company marketing can both transform the perceptions of physicians and shape the experience of those seeking treatments.

❧ *Standardizing the evaluation of psychoactive drugs as medicines: The case of atomoxetine*, by David Cohen, Florida International University, Miami, USA

In parallel with the long-standing psychiatric portrayal of mental distress and misbehavior as conventional medical diseases, there has been a systematic attempt within psychopharmacology and on the part of drug regulatory agencies over the past half-century to 'conventionalize' the use of psychoactive substances as medicines. This has involved, notably, the standardization of the evaluation process of psychoactive substances destined for prescription. Despite notable differences between physical and mental afflictions and conventional and psychoactive medications, the latter are today expected to go through an identical pre-marketing evaluation process as that expected of conventional medical drugs. The salient feature of this standardization has been the incorporation of psychotropic drug clinical trials into the randomized controlled trial (RCT) format borrowed from conventional medicine. Nearly fifty years ago, some pioneer psychopharmacologists wondered whether the RCT was appropriate to ascertain the diffuse and complex effects of psychoactive drugs. This issue is revisited in a contemporary case study: the clinical and regulatory evaluation process of the psychotropic drug atomoxetine, leading to its market approval in 2002 by the U.S. Food and Drug Administration (FDA) as the first 'non-stimulant' drug for the treatment of Attention Deficit-Hyperactivity Disorder in children and adults. The data is drawn from the eleven published clinical trials that existed prior to atomoxetine's approval, and on a series of internal FDA review documents of these trials. The analysis focuses on the interplay between the drug-company submitted clinical findings and the FDA regulatory expectations, to discuss the extent to which atomoxetine's psychoactive effects were actually revealed, how its desired and undesired effects were charted, and how its marketable identity as a 'non-stimulant' was established. The analysis also considers the impact-on the standardization of the pre-marketing evaluation of psychoactive drugs-of the pharmaceutical industry's ubiquitous involvement in financing and conducting clinical trials.

❧ *Merging trials and publicity: Historical changes in the standards of research, authorship, and articles*, by Trudy Dehue, University of Groningen, The Netherlands

In the early 20th century, the unwanted effects of psychotropic drugs induced government interference with the drug-market. The condition was established of experimental proof of efficacy and safety, and, eventually, the double blind randomized clinical trial (RCT) became the gold standard of clinical research. Discussion of the historical development of this instrument helps to demonstrate that it is not as neutral as it seems but standardizes the possible means to deal with misery and disease. In addition, immense interests have become involved in RCT's as the pharmaceutical stock market presently soars or plunges on the basis of even interim trial results. As a consequence, pharmaceutical companies increasingly turn to commercial research organizations (CRO's) that, for their very existence, are fully dependent upon their clients. Slogans such as 'Your partner from bench to market' express the mission of CRO's to serve their costumers' interests. I will discuss methodological handbooks from the commercial clinical research branch that demonstrate how the privatization of drug testing changed the origi-

nal RCT-standards of what it means to do research, to be an author, and to write/read an article. Due to these changes the boundaries have also vanished between attempts to get new drugs through the licensing process and into the bodies of as many people as possible.

❧ *General overview of the history of standardization in the making and taking of psychotropic drugs*, by David Healy, Cardiff University, UK

While there was an increasing standardisation of medical training and practice from the late 19th century, until the 1950s/1960s, Medicine remained essentially a cottage industry, with marked variations from practitioner to practitioner and region to region. Since then 3 factors have contributed to a growing standardisation of clinical practice. First the pharmaceutical industry has standardised its drug development processes and these have fed through into clinical practice in the form of measurement technologies and disease mongering. Second, an unexpected increase in healthcare costs from the 1960s has forced managers to review the delivery of services in an effort to provide quality care efficiently. Third, the uncertainties implicit in health care have led to a turn to standardisation in an effort to resolve disputes in an apparently value neutral way.

In contrast to the earlier standardisation that was linked to professionalism, more recent standardisation has been industrial in nature and has all but made the concept of a professional irrelevant. This paper will outline how pharmaceutical companies have re-engineered the drug development process putting a premium on measurement technologies and how this has interacted with managerial interests and social uncertainties to change the character of Medicine.

Standardisation does not have to yield a necessary outcome. It happens within a framework in which the prescription only status of drugs, the patent laws, and the ability of pharmaceutical companies to sequester trial data all play a part. The final part of this paper will attempt to show alternative domains, which remain unstandardised, in which an effort to standardise medical processes would yield an entirely different outcome.

❧ *The transformation of normal into pathological states of mind: A sociological account*, by Allan Horwitz, Rutgers, The State University of New Jersey, USA

For centuries, people have used a variety of medications such as alcohol, opium, and cocaine to alleviate problems stemming from the stresses and strains of everyday life. During the 1950s the minor tranquillizers and in the 1960s the benzodiazepines became wildly popular ways to deal with tension, malaise, and anxiousness. By the 1970s, however, psychiatry faced a crisis of legitimacy centering on its inability to name and treat the many diffuse problems that it dealt with. The DSM-III transformed these amorphous problems of living into a large variety of discrete mental disorders, especially the mood and anxiety disorders, which became the targets for the SSRIs that emerged in the late 1980s. The standardization of psychotropic drugs for non-psychotic conditions was largely a product of psychiatry's successful creation of standardized categories of diseases.

❧ *Psychotropic drugs, psychiatric organizations and standardization in Denmark*, by Jesper Vaczy Kragh, University of Copenhagen

In recent year, the history of psychopharmacology has received increasing attention from scholars. Especially the advent of chlorpromazine and antidepressants has attracted the interest of historians, and the introduction of the drugs in the 1950s has been studied from different perspectives. Medical historians have thus stressed the important role of the pharmaceutical industry, regulatory agencies, and prominent psychiatrists in the development, use, and regulation of the drugs. However, relatively little has been written about the role of local psychiatric societies. Focusing on the history of psychiatry in Denmark, this paper argues that the largest of these organizations, The Danish Psychiatric Society (DPS), made a vital contribution to a process of standardization within psychiatry. DPS was, for instance, a key player in the development of common standards regarding clinical trials and diagnostic classification systems. These innovations, however, were not initiated in the 1950s. As pointed out in other studies, older drugs such as chloral hydrate, morphine, and amphetamine had previously transformed psychiatric practices in the late nineteenth and early twentieth century. Yet the process of standardization of Danish psychiatry was particularly prompted by the introduction of Cardiazol shock therapy and insulin coma therapy in the late 1930s. Shortly after the advent of Cardiazol and insulin therapy, the members of DPS were deeply engaged in discussions about testing methods and co-operative trials. The introduction of Cardiazol and insulin therapy also made DPS recommend a uniform diagnostic classification system. Yet standardization of psychiatry in Denmark was not just a national matter; and the Danish plans of regulations were influenced by Swiss, German, and Austrian psychiatrists. In general, Danish psychiatrists were eager to adopt international standards regarding diagnostic classification and clinical trials, and they discussed these issues with colleagues from other European countries. Drawing on archival sources from the DPS and Danish state mental hospitals, this paper outlines this exchange of information across borders, the process of standardization in Danish psychiatry and the history of psychotropic drugs from 1900 to the 1960s.'

❧ *Psychotropic drugs, psychiatric concepts and standardization in Belgium and the Netherlands (1950-1970)*, by Benoit Majerus & Toine Pieters, University of Brussels – University of Utrecht

Historians generally agree that the introduction of chlorpromazine, marketed either as Thorazine® or Largactil®, marked the start of a new era of drug treatment in psychiatry. The concept of a therapeutic revolution, how-

ever, is a contested notion. Historical evidence points to continuity with earlier therapeutic developments in psychiatry. In our paper we will argue that in following the introduction and use of chlorpromazine in the Belgium and the Netherlands we see an intriguing tango between old and new treatment features. Marketed as a new and innovative remedy chlorpromazine made its way into Belgian and Dutch psychiatry in an ad-hoc and pragmatic way as a helpful neighbour of existing psychotropic therapies and other bodily cures. We do see, however, early efforts by pharmaceutical companies, in particular Rhone Poulenc and its international marketing & sales subsidiary Barberot Specia, and academic researchers and psychiatrists to standardize pharmacotherapeutic concepts and practices on an international level. We will show how these efforts were counterbalanced by the idiosyncrasies of national and local styles and cultures of healing the mind.

❧ *Failed standardization of THC (Cannabis)*, by James Mills, University of Strathclyde, Glasgow, UK

THCeluded pharmacologists until 1964 and as such the substance proved impossible to standardise. This goes some way to explaining why it dropped out of medical usage in the Victorian period and was commonly treated as an intoxicant for most of the twentieth-century; it was difficult to fit into 'scientific' medical practices.

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Workshop Team 1 "Antibiotics"

Circulation of Antibiotics:
Journeys of Drug Standards, 1930-1970
June 16-18, 2009 (Madrid)

Centro de Ciencias Humanas y Sociales, Consejo Superior de Investigaciones Científicas, Madrid, Spain

Org.:
Ana Romero (ana.romero@cchs.csic.es)
María Jesús Santesmases (mariaj.santesmases@cchs.csic.es)

Antibiotics have been celebrated everywhere since they were widely distributed at the end of WWII and onwards. The production in different national settings of the first drug available in this group, penicillin, successful clinical trials with it in the treatment of infections and the popular reception it met with, became public and medical knowledge. As agents of a medical revolution which shifted borders between health and disease and created new spaces for therapy, the life-saving capacity of antibiotics was one of the most popular "scientific" successes in 20th century history.

This workshop will focus on current research into the histories of antibiotics from the perspective of the circulation of standards, in particular, studies that connected practices in different social and cultural domains, and how those standards spread. Clinicians, researchers, patients and health authorities shaped antibiotics cultures. Even if the concept of "revolution" is currently under debate, these new drugs and their effects moved social and professional knowledge, norms and standards. From one place to another, networks of users and consumers rearranged their practices.

The aim in suggesting the notion of circulation is to draw attention to the issue of the journeys those standards made. We would like to explore how antibiotics' standards travelled and how national norms, clinical protocols, research and professional practices, as well as public knowledge, influenced each other and eventually shaped public health and epidemiology. This means that there were trajectories, physical trajectories. Batches of antibiotics travelled; protocols and instructions of use and production were distributed and received in particular local settings, promoted by national authorities. Bacterial resistance to antibiotics contributed to shape research and medical practice and played a part in increasing knowledge about the mechanisms of the action of antibiotics at cellular level and as well forming the basis upon which further search for new antibiotics developed. Penicillin was the first of a long series of antibiotic drugs: streptomycin's successful effect in the treatment of tuberculosis followed, as did chloramphenicol and tetracyclines. Figures of treatment results, of cure and resistances, travelled as well.

This workshop is a collaborative project of the Working Group on Antibiotics of the European Network DRUGS, funded by the European Science Foundation. This group includes researchers from the universities of Manchester, Oslo, and Amsterdam, CERMES (Paris) and the Centro de Ciencias Humanas y Sociales (Madrid).

Proposals for papers should be sent to Dr Ana Romero (ana.romero@cchs.csic.es) or Dr María Jesús Santesmases (mariaj.santesmases@cchs.csic.es) by 1 March 2009. Abstracts should not exceed **350 words**.

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Workshop Team 2 "Cardiacs and cancer therapy"

Drugs, Standards, and Chronic Illness

27-28th November 2009 (Manchester)

Org.:
Carsten Timmerman, University of Manchester (carsten.timmermann@manchester.ac.uk)
Viviane Quirke, Oxford Brookes University (vquirke@brookes.ac.uk

The call for papers will be launch the 26th February, with a deadline fixed the 8th May

Workshop to be held at the
Centre for the History of Science, Technology and Medicine
University of Manchester
27-28 November 2009

Non-communicable illnesses such as cancer or heart disease have long been feared. Having previously been conceived of as 'diseases of civilization' or 'degenerative diseases', in the twentieth century, when the threats posed especially by tuberculosis declined in the industrialised world, these illnesses turned into major issues for policy makers and public health experts, pharmaceutical companies and an anxious public. Cancer and cardiovascular disease and the role that the development and marketing of treatments for chronic illness have played in the broader history of standardization in medicine will be the central theme of this workshop.

The histories of cancer, cardiovascular disease and other non-communicable illnesses have much in common, but there are important differences between them that are worth exploring. Many of the blockbuster drugs of the last 50 years have been developed for the treatment of cardiovascular disorders. In the course of this development, some illnesses have been transformed from acute to chronic (e.g. malignant hypertension) and it has become acceptable to treat physiological parameters that do not cause symptoms but are statistically associated with illness later in life (e.g. mild hypertension or hypercholesterolaemia). In contrast, and with few exceptions, cancer drugs have often been used to treat what might otherwise be considered as orphan diseases and have rarely been as commercially profitable as cardiovascular drugs. Nevertheless, cancer has been central to the development of many of the practices, such as testing, clinical research, and standardization, which are increasingly applied to other fields of medicine, above all the multi-centre randomised clinical trial.

We are especially interested in contributions that are in themselves comparative or invite comparisons, between different illnesses (for example heart disease and cancer) or across different national contexts.

Papers may discuss issues surrounding notions of the chronic and the acute or the relationship between risk and disease. Or they may look at spaces of drug administration: from inpatient to outpatient departments. Institutional developments will also have to be discussed. Another issue worth exploring is the concept of 'chemotherapy'. What did it mean in different contexts? Regulatory institutions, policies and practices also lend themselves to international comparisons. Such practices were closely related to the clinical specialties dealing with the different diseases, inviting comparisons between them. Further points for discussion will be issues related to the consumption of medicines, the role of patients and patient organizations, and questions of gender. All these can be viewed as leading to the establishment of standards that were different between countries and diseases, in a process that can be studied historically and geographically.

We plan to organise the workshop around the following main analytical points:

- The management of risk and efficacy
- The structure of biomedical research: laboratories, clinics, protocols
- Market conceptualisation, market realities, sales and uses
- Regulatory frameworks and regulatory practices

Please send abstracts (no more than **500 words**) to
Dr Carsten Timmermann: carsten.timmermann@manchester.ac.uk and
Dr Viviane Quirke: vquirke@brookes.ac.uk
Deadline for abstracts: 3 April 2009

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Exchange Programme: Call for Applications

Standard Drugs and Drug Standards:
A comparative historical study of pharmaceuticals in the 20th century (DRUGS)
DRUGS is a European Science Foundation (ESF) Research Networking Program (http://drughistory.eu)

Call for Applications for Exchange Grants for visits of 4 to 24 weeks to Network member institutions

Open to: postgraduate students, post-doctoral researchers, early career researchers, established researchers.

Dead Line: 1 May 2009

Information: volker.hess@charite.de

About the DRUGS programme

Using the theme of standardization, applied both to objects and practices, the Network is exploring the development of twentieth-century medicine by looking at the production, distribution, prescription and consumption of major classes of therapeutic agents, such as sulfa-drugs, hormones, and psycho-active drugs. The aim is to evaluate the contribution of industrial, administrative and clinical standardization to the 'therapeutic revolution' (1920-1990) in which a series of 'miracle' drugs changed the face of Western medicine.

The Network aims to examine the evolution of industrial standards and drug trials, along with prescription and clinical practices, from a comparative perspective. For example, by looking at the role played by accidents or proposed, but rejected, alternatives to standard modern practice, we aim to reveal the multiple forces that have shaped our modern medical world. This approach takes us beyond the usual protagonists in this history – research scientists and their clinical partners – allowing the important groundwork to be done on the contextualization of this field, with respect to the intervention of the state, industry, and other actors. A richer view of the context for the scientific innovation that lies behind the modern pharmaceutical industry, promises to open up new perspectives in the analysis of today's health systems. To develop the program further, we are pleased to announce the second round of training and research exchange opportunities. These are core elements of the Program and one of its most innovative elements. The Exchange Program enables postgraduate students, post-doctoral researchers, early career researchers, and established researchers to spend a period of between 4 and 24 weeks at groups within the Network to work on specific topics. The exchange can be split into a number of visits of shorter duration, for example, a 6-week visit may be taken in periods of 2 and 4 weeks. In addition, an applicant may apply to divide their exchange between more than one host. Please note, the minimum period for any single visit at a host institution is two weeks.

Our Exchange Program has three aims. First, visitors and hosts will learn about the approaches, methodologies and research cultures of different European research groups. Second, this circulation will deepen our collective understanding of the local specificities of research organization, local production and state surveillance, in particular the important national differences regarding the conservation of archives, the institutional arrangement of research facilities, the administration of medicine and health care. Third, the number and variety of exchanges should promote comparative research, for which the understanding of national styles is indispensable for any serious transnational analysis.

The applications will be evaluated with respect to:

1. the scientific quality of the research project;
2. career development aims appropriate to the level of the applicant;
3. the overall objectives the DRUGS Research Network Program; and
4. the expected benefit to the host member(s) of Network (see details of groups at http://www.drughistory.eu/?Organization:Research_network)

Formalities

The Exchange Program is an element of the ESF RNP DRUGS. The exchanges are aimed to generate improved collaboration between the European working groups in the field. Applicants must be affiliated to an academic institution in ESF member organizations. Exchange visit grants provide a living allowance of EUR 400 per week or EUR 57 per day, plus actual travel expenses up to a maximum of EUR 500. The exchange visit(s) should take place between the 15 July 2009 and 1 April 2010. Applications are made first to the Network, and successful applicants then join the ESF grant management system. This provides the facility for advance payment towards living costs,

normally 80 percent of the total for items other than travel. The remaining 20 percent, along with travel expenses, will be paid upon receipt of the scientific report for the Exchange. This report has to include a signed statement by the host on the exchange and all original travel tickets. In the case of cancellation or unreasonable delay (six months or more), all advances have to be returned to the ESF. If the length of the stay is shorter than the foreseen period, the grantee should reimburse the ESF the appropriate amount of unspent funds.

Extending the term of each exchange may be possible, but will only be allowed after the submission of a mid-term report.

The Evaluation Committee may suggest to the applicants some modifications of the working plan regarding appropriate hosting institutions, duration of time spent with groups, times and the phasing of visits. The terms of the second round of exchanges has been modified to allow participants more flexibility over the length and timing of exchange periods. It will be possible, following the evaluation of reports from this round, for the same applicant to submit another exchange proposal in the third round in 2010.

Schedule and process

- Deadline for applications: 1 May 2009
- Meeting of Evaluation Committee: 16-18 June 2009
- Notification of result: End of June 2009

The application is a two-step procedure. First, the applicants should send their application to the Exchange Program Evaluation Committee, see details below. The Committee will rank the applications and may propose modifications to the working plans. Following the evaluation stage, which is intended to be supportive and improve applications, selected applicants must complete the web-based procedure to join the ESF grant system at http://www.esf.org Please do not worry about the detail of this second stage, applicants that go through to that stage will be given advice.
For the initial stage, the following are required from each applicant:

- A short description of the proposed research project (maximum of 1000 words)
- The aims and rationale for each visit to a hosting institution(s).
- Curriculum vitae of two A4 pages.
- List of five most recent publications.
- A letter of recommendation from someone familiar with the applicant's work.
- A letter of acceptance from the host(s) at the receiving institution(s).
- Full address details of the prospective host(s).
- Proposed starting date.
- Number of weeks to be spent on each visit at the host institution(s).
- Estimated travel costs.

(Applicants should submit all of the documents detailed above in one PDF file.*)

Application must be submitted to:
Prof. Volker Hess, Chair of the RNP DRUGS
Institut fuer Geschichte der Medizin
Charite - Universitaetsmedizin Berlin
Ziegelstr. 5-9 10117 Berlin, Deutschland

* Use PDF Creator (http://www.pdfforge.org/) or OpenOffice.org to create your own PDF documents.

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Announcements

EAHMH

The European Association for the History of Medicine and Health (EAHMH) is organizing its bi-annual meeting, to be held in Heidelberg (Germany), 3-6 September 2009, with the following general theme to be discussed: "Global Developments and Local Specificities in the History of Medicine and Health". See http://www.eahmh.net/.

The participation of RNP members will be noticeable with two proposed panel sessions:

1. Session proposed by Volker Hess: "The Introduction of Modern Psychotropics: a global 'revolution' from local perspectives", with papers presented by Toine Pieters, Viola Balz, Matthias Hoheisel, Benoît Majerus, Nicolas Henkes
2. Session proposed by Christoph Gradmann and Flurin Condrau: "Antibiotics and the Golden Age of Medicine in Europe, 1940-1970", with papers presented by Marlene Burns, Flurin Condrau, Anne Lie Kveim, Maria Jesus Santesmases

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GEPHAMA : From Advertisement to Marketing. Pharmaceutical Enterprises, Patients, Physicians and the Construction of Medical Markets

The GEPHAMA project is supported by the french National Agency for Research (ANR) and the German Research Foundation (DFG). It started on January 2009 and it will ended in December 2011. It include three post-doctoral positions. The main applicants are Volker Hess and Jan-Paul Gaudillière.

The project will analyze the marketing of modern drugs as an heuristic approach for understanding the modern medical market. The industrial mass production, the use of communications media in marketing, the specialization of and the differentiation within the medical market (inpatient or outpatient treatment), the increasing internationalization of the market and last but not least the blessings and promises of the post World War II "therapeutic revolution": All these trends have allowed for the evolution of an ever more complex network of actors, institutions, interests, and power structures. With the focus on a short 20th century (1914-1990) the project is conceived of as a comparative study between France and West Germany, as an "histoire croisée" (entangled history) which examines comparable and internationally overlapping events (new drugs) or developments (scientific marketing) in their own specific national effects. This will especially be the case for the challenge posed by the US-American success in combining research with marketing. Which answers were found in each country-specific research, business, law, and social systems? What kind of French and German cultures of marketing developed out of the confrontation with American marketing methods?

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