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Auf dem Weg zu massgeschneiderten Medikamenten?

Kurzfassung der TA-SWISS Studie «Pharmakogenetik und Pharmakogenomik»

Vers des médicaments individualisés?

Résumé de l'étude TA-SWISS «Pharmacogénétique et Pharmacogénomique»

Are tailor-made drugs just around the corner?

Abridged version of the TA-SWISS study «Pharmacogenetics and Pharmacogenomics»

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The Centre for Technology Assessment is attached to the Swiss Science and Technology Council, which advises the Federal Council on scientific and technological issues.

Are tailor-made drugs just around the corner?

Abridged version of the TA-SWISS Study «Pharmacogenetics and Pharmacogenomics»

Source: www.zuendstoff-antibiotika-resistenz.de

«For risks and side-effects, please read the leaflet inside the pack...»

Today there are effective drug treatments available for a number of diseases that only a few decades ago would have been fatal. But what can help many people may be harmful to a few. Not least because of genetic factors, their bodies react differently to certain therapeutic substances than do most other people's. Pharmacogenomics is developing drugs that will take the patient's individual genetic make-up into consideration.

The German medical journal «Deutsches Ärzteblatt» estimates that in Germany alone, the taking of therapeutic drugs causes serious side effects in 120 000 cases every year. Sixteen thousand people die as a result. Many of these instances of intolerance are due not least to individual characteristics in the genetic material of those affected. Pharmacogenetics aims to provide a remedy.

One per mille genetic variation

However dissimilar they may look outwardly, the genetic blueprint for all human beings is virtually identical: 99.9% of the genetic material of two unrelated persons is the same. The genetic make-up of a human being (his or her entire DNA sequence) is comprised of a sequence of over 3 billion base pairs, the four «characters» of the genetic material DNA. This means that with a variability of one per mille, two persons will still have about three million places in their genetic material where the base pairs are different. These variant base pairs are known technically as «single nucleotide polymorphisms», SNPs, or «Snips», for short. One SNP occurs roughly every thousand base pairs. Researchers regard these individual variations as one of the main reasons for superficial differences and susceptibility to diseases.

The challenge for pharmacogenetics consists in filtering out, from the multitude of SNPs, those that affect the uptake and processing of active medicinal constituents. This quest is made all the more difficult by the fact that several variations are often required on different genes to produce a specific clinical picture. But if it becomes possible to combine genetic characteristics with appropriate samples of the metabolism, one of the basic prerequisites for the development of more effective drugs is in place.

Genetically determined side-effects

The way a drug works is determined, firstly, by the way it is taken up, processed and then excreted by the body. Secondly, it depends on how medicines interact with target proteins in the cells.

The metabolism, and therefore also the breakdown of active therapeutic constituents are made possible by certain proteins, known as enzymes. Particularly detailed research is being done on what is known as the Cytochrome P450 enzymes (CYP450), which affect the modification and breakdown of a whole range of drugs. In between six and ten per cent of the white, and about one per cent of the Asian population, these enzymes have genetically-related functional defects. As a result, the people affected take much longer to break down and excrete certain drugs than individuals whose CYP450 enzyme functions are not restricted. For example, patients suffering from some forms of depression who are among the «slow metabolising» group run the risk of experiencing more serous side-effects with certain drugs than do the rest of the population. That is because many anti-depressants are broken down by a specific enzyme of the CYP450 group.

One example of the problems in the interaction between drugs and receptors (target proteins) is provided by the treatment of hypertension. The angiotensin converting enzyme (ACE) plays an important part in regulating blood pressure. It is known from medical practice that patients respond in very different ways to the so-called ACE inhibitors. Researchers have been able to show that certain variants of the gene that stimulates the production of ACE ultimately influence the therapeutic efficacy of the ACE inhibitor.

Change of emphasis for pharmaceutical research

The sequencing of the human genome has in principle opened the way for pharmaceutical researchers to access data that will enable the dosage and composition of drugs to be tailored to genetic sub-groups in the population.

As a result, there is now an increasing change of emphasis in drug research that began to emerge as many as 30 years ago: instead of manufacturing new substances and subsequently testing them for their biological effects, as had hitherto been the case, since the 1960s researchers have been increasingly looking for target structures (known technically as «targets»). As knowledge of the human genome has improved, the intention now is to increase the number of known targets from the present 500 or so to over 10 000, and thereby to create new approaches to the treatment of diseases.

Finding those genetic variations, among the millions that exist, that are key to the efficacy and side-effects of a drug is, nevertheless, a costly undertaking. An added problem is that in many cases the effect of a treatment depends not only on the genetic make-up of the patients concerned, but also on their lifestyle.

Pharmacogenetics

Pharmacogenetics examines genetic factors that explain individual differences in reactions to drugs. The aim of pharmacogenetics is to optimise pharmacotherapy by drugs where the choice and dosage are tailored to the genetic conformation of the individual, so that the efficacy will be increased and the side-effects reduced.

Pharmacogenomics

Pharmacogenomics, unlike pharmacogenetics, is concerned in particular with the development of drugs. This also involves the use of pharmacogenetic methods. However, pharmacogenomics focuses primarily on the effects of drugs on gene expression and the identification of new target structures for drugs.

«The metaphor of the ‹personal pill› is misleading, as it generates false expectations and hopes.»

The quotations are taken from TA-SWISS Study 48/2004

Contentious issues

Classifying the many different factors that influence the effect of drugs requires wide-ranging studies and extensive sets of data from genetic material. One possible source for such genetic data are so-called biobanks. These have sparked off considerable controversy on the subject of pharmacogenetics: exactly how should the data stored in these banks be encoded in order to prevent them being misused and to guarantee the personal rights of the donor, without placing too severe limitations on research as a result? To whom do the blood and tissue samples that are collected in these banks actually belong? And how should information be handled that not only enables conclusions to be drawn about therapeutic susceptibilities, but also about a person's predisposition to genetic disorders?

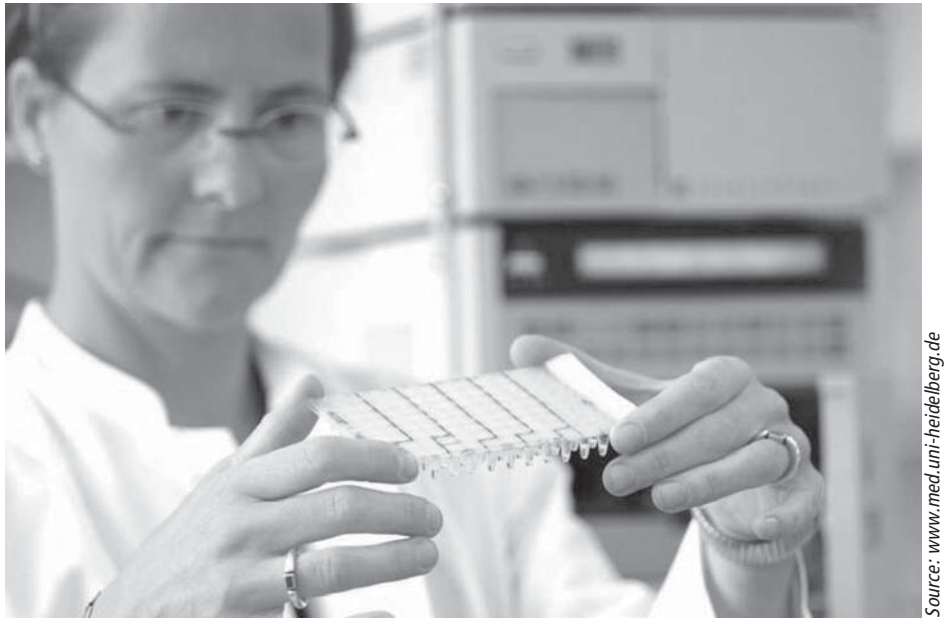
Pharmacogenetic drugs could also alter the relationship between the patients and the doctors treating them. Is there reason to fear that doctors will use pharmacogenetic testing to reduce their patients' personality to their genetic identity, and no longer take social or personal historical factors into consideration for their treatment? Is there a danger that sick people with an unfavourable genetic profile will be increasingly excluded from therapies? Do we have to consider the possibility that the drug market is being progressively split into those drugs that are tailored to special sub-groups in the population? What sort of consequences would that have for the pharmaceutical industry?

A contribution to the public debate

Despite the fact that pharmacogenetics has raised numerous questions, it is a topic that has been largely ignored by the public debate. In the few media reports on the subject, most of them have welcomed the «personal pill»; it brings the promise of more effective drugs with fewer side-effects and cost savings in the development of new therapeutic products. But some critical voices have also been raised. These refer, among other things, to the risk of creating an increasingly apparent «two-class medicine».

Up to now, it is evident that the debate has been largely restricted to informed groups, and this offers an opportunity for a technology assessment study: it might provide clarification of some issues ahead of a general public debate, preparing the way for a broad, diverse and rational public debate on the benefits and risks of pharmacogenetics and pharmacogenomics.

For the TA-SWISS Study «Pharmacogenetics and Pharmacogenomics» an interdisciplinary team of experts from the fields of medicine, public health, economics, jurisprudence and ethics considered the different facets of the subject. They used a variety of methods for their investigations: in addition to detailed analyses of the literature, they carried out a survey of informants who come into contact with the new types of drugs, but from different viewpoints. The controversial assessments of pharmacogenetics that have been extrapolated from these qualitative surveys are considered and evaluated by the authors in the second part of the TA-SWISS Study. The study concludes with a number of recommendations.



Source: www.med.uni-heidelberg.de

«The main benefit of pharmacogenetics is greater drug safety.»

A new-generation cancer remedy

Breast cancer is the most common cause of death among women between the ages of 35 and 55, and in most EU States the number of new cases of breast cancer rises annually by about 1.5 per cent. The standard treatment comprises the surgical removal of the infected tissue followed by hormone treatment, chemotherapy or radiation treatment. But «breast cancer» is not always breast cancer, and the therapeutic approach therefore has to be varied. It has already been known for some years from clinical practice that in patients whose tumours show a high level of the protein HER2 the development of the disease often takes a less favourable course than in other patients. The drug Herceptin works in a «tailor-made» way for the 25–30% of women with breast cancer whose tumours reveal high levels of HER2. This therapeutic product drug has extended by 65% the life expectancy of patients who would previously have died on average after three years, rather than the seven years among HER2-negative patients. In 1999 sales of Herceptin in the USA totalled USD 188 million, and sales figures have continued to rise, to USD 276 million in 2000 and to USD 300 million in 2001. However, Herceptin does not necessarily require a pharmacogenetic test, as only the proteins present in the cancer tumours are analysed, not the patient's genetic profile. To that extent, Herceptin is not a «typical» genome-based drug, although it does indicate the direction which the development might take.

«The effect of a treatment often depends not only on the genetic make-up of the patients concerned, but also on their lifestyle.»

How experts assess the future for pharmaceuticals

According to the experts, the greatest benefit they expect from pharmacogenetics is an improvement in drug safety. Nevertheless, it is feared that new marginal groups might emerge, who because of their genome cannot be offered such drugs, even with their lower incidence of side-effects. The experts questioned have differing views on whether pharmacogenetics will result in a rise or a fall in the healthcare costs, and whether it will prove to be economically viable for the pharmaceutical industry.

How do experts assess the opportunities and risks of pharmacogenetics and pharmacogenomics? In order to clarify this, the authors of the TA-SWISS Study questioned a total of 16 persons who are experts in the medical, legal, economic or social fields. If we consider the responses, it is evident that some of the opinions are very widely divergent. Differences of opinion are particularly apparent with regard to the long-term assessment of pharmacogenetics and pharmacogenomics. All of them are agreed on just one point: the main benefit of pharmacogenetics lies in greater drug safety.

Fewer side-effects, greater confidence, greater difficulty in understanding

Those who took part in the survey are unanimous in their assessment that the most important benefit of pharmacogenetics is that drug safety will increase and that side-effects will consequently decrease. Improved drug safety could in turn boost patients' confidence and increase their motivation to follow their doctor's instructions. In this case, experts talk of better «compliance» – an essential prerequisite for successful treatment.

About half of those questioned think that pharmacogenetic testing in particular could mean changes in what is required of the medical profession. These tests can only provide probability data on what effect a particular therapy might have in specific cases. It is impossible to make an absolutely certain prediction. All those concerned find it difficult to handle uncertainty, and this could be detrimental to the understanding between doctor and patient. It is striking that this risk was referred to, not by the medical laity, but almost exclusively by people with medical training. Non-medical people, however, give prominence to other risks and dangers, such as the danger of pharmacogenetic data being misused by insurance companies.

Finally, some of those questioned point out that habits that are disease-inducing could be disregarded if medicine focuses the treatment too much on the patients' genetic disposition. Also, holistic treatment methods that rely not only on medication, but also on behavioural changes by the patient, could be pushed into the background.

New therapies – rising healthcare costs?

From a health economics point of view, it is disputed whether a new therapeutic approach will help people in good health to live to an increasingly old age, or whether the extra years will be paid for by chronic ailments (and correspondingly rising outlay on drugs). Seven of those questioned expect that the application of pharmacogenetics and the carefully targeted therapies that go with it will lead to a reduction in healthcare costs with precise dosages and fewer undesired effects.

One in five of those questioned who expect an increase in costs as a result of pharmacogenetic drugs justify this by suggesting, among other things, that there will be more – and more expensive – drugs, that drug development will become more expensive, and that preventive treatments could increase. Where the information generated by pharmacogenetic or pharmacogenomic tests indicates susceptibility to disease, there is then a greater incentive to treat those affected, even where no symptoms have yet become apparent. Accordingly, it is feared that there will be a further expansion of volume without any calculation of the long-term cost/benefit ratio.

A profitable business?

Those questioned disagree about whether pharmacogenomics will develop into a profitable business for drug manufacturers. While some think that drug development costs will fall, because the licensing tests can be carried out more selectively, others expect that the licensing procedure will become increasingly complex.

Some of those questioned regard it as an economic opportunity, as although fewer patients can be treated because of the targeted treatment, higher prices can be charged for the drugs. There is, however, also the fear that in a fragmented market there is a considerable risk that drugs that are costly to develop may not be successful.

Pharmacogenetic minorities, data protection, surplus information

The pharmaceutical industry could succumb to the temptation in future to manufacture primarily drugs for «worthwhile» patient groups whose genetic profile is widespread among the population. Half of those questioned consider there to be a real risk that individuals with a rare genotype might be excluded from successful therapies. Some experts also raise the possibility of active discrimination by medical insurance funds, which could refuse to pay for treatments where the success of the treatment might be jeopardised by the genetic make-up of the patient.

Source: www.med.uni-heidelberg.de

Over a third of those questioned raised concerns about data protection. Their fear is that genetic data could be improperly used, for instance by health insurers or employers. Finally, one issue regarded as particularly awkward is the fact that pharmacogenetic tests can be used not only to determine how a person reacts to a particular drug, but also whether that person is susceptible to genetic disorders. Six of those questioned regard such «surplus information» as being psychologically, socially and ethically questionable, especially if patients are confronted with that information without being prepared for it.

«The accusation that genetic minorities would be discriminated does not go far enough.»

Less individual than claimed, not as discriminating as feared

There is no doubt that pharmacogenetics does have a considerable inherent medical potential, even though metaphors like «personal pill» or «designer drug» are misleading. However, its impact on other areas – for example on healthcare costs and on the continued development of the therapeutic products market – are more difficult to assess. From an ethical viewpoint, the potential for discrimination in the field of pharmacogenetics and pharmacogenomics is smaller than is often feared. With regard to the biobanks that are important for research, from an ethical and also from a legal point of view the crucial factor is that data protection and the protection of personal rights are guaranteed.

«There is disagreement about whether pharmacogenomics will develop into a profitable business for drug manufacturers.»

At the current time it has not yet been conclusively established exactly which positive and negative potentials of pharmacogenetics are likely to be realised. From a variety of specialist perspectives, the authors of the TA-SWISS Study have examined selected postulated consequences of the new technology, analysed their development possibilities, and carried out an evaluation based on medical, public health, economic, ethical and legal perspectives.

Therapeutic precision and efficacy

Whether a specific drug will be effective in an individual case is something that can normally be determined only when it has been tested. Pharmacogenetics raises the prospect of more precise instruments, its aim being to use genetic tests to establish the degree of probability of a drug being effective on a person with a specific genetic profile, and how great is the probability of side-effects.

In spite of its positive potential, pharmacogenetics is not without risks. One of these is based on the «probability» nature of genetic tests, as even when the probability of therapeutic success determined by the test is small, it cannot be ruled out that in individual cases the treatment will still work. There is the danger of patients being excluded from therapy because of their genotype, even thought the treatment might still help in individual cases.

There are additional dangers in the interpretation of the results of pharmacogenetic tests by the treating doctor. Firstly, there are other, external factors (e.g. other drugs being taken at the same time) that affect the efficacy of medicines, apart from genetics. Secondly, it is not always possible to conclude from an existing genetic defect precisely which protein function is involved, because to a certain extent these can change – according to age, for example. So, if doctors base their selection of therapeutic product and its dosage solely on the genetic profile of the patient, they are not immune from errors. One of the future challenges for doctors lies in how they deal with these uncertainties – and in their ability to help patients to understand them.

It does, however, seem unlikely that pharmacogenetics could fundamentally alter the relationship between doctor and patient, in view of previous medical experience. It poses no real threat to the core competence of doctors to perceive patients as complete persons and to communicate with them. Moreover, it is hardly likely that doctors will confuse genetic characteristics with the personal individuality of their patients.

How individual is the «personal pill»?

In describing the goals pursued by pharmacogenetics and pharmacogenomics, people often use individualised metaphors such as «personal pill» or «designer drugs». These metaphors are misleading, as they generate false expectations and hopes. Specifically, they suggest that it is a question of choosing or developing drugs that are tailored to the genetic identity of each individual patient. Although there is an element of individualisation in pharmacogenetics to the extent that the type and dosage of the drug is determined on the basis of a patient's genetic profile, this does not take into account important individual elements such as age, weight or diet. It must be emphasised that as far as pharmacogenomics is concerned, with regard to the development of new drugs individualisation is not of paramount importance for industry. That would be tantamount to limiting their own sales opportunities, because the market will be fragmented and its potential reduced as a result. For these reasons it would be absolutely desirable to refrain from using metaphors of individualisation: there is no need to use misleading images to advertise something good.

The market is unpredictable

The pharmaceutical industry is very important for the Swiss economy. It employs almost 30 000 people in this country (some 90 per cent of them in the Basel region) and since 1995 has recorded growth levels in excess of 20 per cent. In addition, at CHF 210 per working hour it achieves the highest productivity of all Swiss jobs.

Pharmaceutical industry specialists are divided on the question of whether the drug market will fragment and whether this heralds an end to the «blockbusters» (drugs realising sales of over USD 1 billion). The fact that genome-based drugs can be used for different diseases, and will therefore remain appropriate for many patients, counters any idea of fragmentation. However, should therapeutic products in future be matched to genetically characterised sub-groups, this could encourage the breaking up of the market. What is in any event certain is that even in the future the pharmaceutical industry

Source: www.zuendstoff-antibiotika-resistenz.de

will concentrate on manufacturing drugs for diseases that frequently occur in developed countries.

There is at present no conclusive assessment of the long-term significance of pharmacogenetics for the Swiss economy. It is expected that the pharmaceutical industry will be investing in new approaches, purely on competitive grounds. Switzerland is not, however, one of the leading nations in the operation of databases and the production of chips that are essential for the evaluation of genetic tests. And it is precisely those areas that could particularly benefit from pharmacogenetics.

Long-term effect on healthcare costs

It can be assumed that pharmacogenetics and pharmacogenomics, albeit not in the short term, (i.e. within the next three years), but quite possibly in the long term will become crucial in terms of healthcare expenditure. It is nevertheless difficult to assess whether costs will actually rise or fall. One potential cost-reducing factor is that side-effects will occur less frequently and less severely, there will no longer be any unnecessary therapies and hospitalisations, and more targeted treatments will be possible. The increasing need for genetic tests could push costs up, and the high price of the new drugs will offset any efficiency-related savings. At the present time it is not possible in overall terms to balance the effects of pharmacogenetics and pharmacogenomics against the costs.

Concerns about discrimination

With regard to pharmacogenetics, the widespread concern about possible discrimination – in the sense of arbitrary inequality of treatments – is formalised in two particular fears: firstly that insurance companies could charge higher premiums for those people whose genetic profile holds out little hope of successful therapy, or may even no longer wish to insure them at all. Secondly, people who belong to a genotypic minority could in future be excluded from effective therapies simply because it is not viable for drug manufacturers to produce drugs that will only be used by a small number of patients.

There is some controversy surrounding the question of whether insurers should be permitted to demand to see details of any genetic test results on insurance applicants before concluding a contract. The authors of the TA-SWISS Study argue that a distinction should be made between mandatory and voluntary insurance. Insurance such as mandatory health insurance, company pensions or disability insurance, which cover basic needs, should set their premiums independently of the risk profile of the individual policyholder, on grounds of fairness and solidarity. The situation is different with voluntary supplementary insurance. In this case, fairness requires that both parties – the insured and the insurer – should have access to the same risk-relevant information.

Otherwise there would be a danger of people who were aware of the efficacy and safety of certain drugs because of pharmacogenetic tests and who withheld this information from insurers being able to take out policies on

illicitly favourable terms, and therefore being covered at the expense of the other policy-holders.

The accusation that it would be discriminating against genetic minorities if no drugs were developed for them does not go far enough. The fact that there are rare genotypes and that no effective drugs exist for them against certain diseases, by contrast with most patients, does not justify talk of arbitrary inequality of treatment because there is no moral right to a functional therapy. There is, however, a moral duty to encourage the development of medicines that are beneficial to genetic minorities. The best way to do this is through government measures designed to encourage drug manufacturers to commit themselves to an enterprise that is less profitable for them.

Biobanks and patents as ethical challenges

In order to research complex disease mechanisms and on this basis to be able to develop new drugs, it is necessary to collect large quantities of genetic and lifestyle data and store them in biobanks. In Switzerland, there are currently three biobanks under construction, two of them in cancer research. From both an ethical and a legal point of view, these banks must be organised in such a way that on the one hand the stored data are protected as far as possible against misuse and that on the other hand the rights of the donors are guaranteed. Here, the right to be able to withdraw their samples at any time, and the right to be informed about findings that are relevant to their health are of paramount importance. At the same time, consideration should as far as possible also be given to the exchange of data in the interests of research. The taking of samples is ethically and legally justifiable only where it is based on informed consent. In particular, the donors should know the purpose of the research for which their samples are required and what rights they have against the biobank. «Benefit sharing», however, cannot be justified ethically: donors have no right to participate in the economic income from products resulting from research.

Finally, the patenting of genes, or rather of SNPs and their functions, is ethically disputed, even though it is legally permissible. From an ethical point of view, there are two arguments against such patents: firstly, they are incompatible with the normative concerns that are linked to the concept of the «common heritage of mankind», for instance concerns that genes and SNPs should be used for the good of all and in a fair way. And secondly, the determination of SNPs and their functions is a discovery, not an invention. Under current Swiss and European patent law, however, only inventions may be patented – a restriction that is also certainly justified in normative terms. Accordingly, from an ethical point of view SNPs cannot be patented, even if they occur in isolation and their functions are known. Patent law should therefore be modified or structured accordingly.

The «genetic special case»

In public discussions, genetic information usually takes on the aura of a «special case», in order to ensure that these data are handled in a particularly circumspect way. From an ethical point of view, however, it is not right to give them a special status simply *because* they are genetic and to imply from that that all genetic tests should have to satisfy special requirements in respect of data protection. Data are sensitive when they are important for one person; and that may be also the case for non-genetic data. It makes little sense for genetic data that merely provide information about the efficacy of a certain therapeutic substance to be classified as particularly sensitive personal information. But handling any «surplus information» is a tricky area. Such information can in principle also be obtained from samples that are taken «only» for pharmacogenetic tests. Surplus genetic information not only enables conclusions to be drawn about the susceptibility to disease of the person actually tested, but also about the genetic facilities of his or her blood relations.

It is important to remember that this assessment of the status of genetic data and information is not shared by the law. In the case of genetic data, for reasons of legal certainty the law does not differentiate, so there are no more or less sensitive genetic data. Genetic data are health data and as such, from a data protection law point of view, are data that require special protection. From a constitutional point of view, the high level of protection required under the constitution for genetic data must be given full consideration, and that is why there can be no exceptional provisions applicable to the area of pharmacogenetics and pharmacogenomics.

Source: www.med.uni-heidelberg.de

«Adequate funds must be invested for research into social factors and for disease prevention.»

Action required at several levels

There is a need for a public debate on pharmacogenomics, just as there is for some regulation of its legally relevant aspects. There is a need for action, too, with the construction of biobanks, the training of doctors and in other areas, so that the positive potential of genome-based drugs can be fully exploited and their risks reduced.

It is a characteristic feature of Swiss policy on science, education, health, social affairs and the economy that there are no clearly defined targets, not only, but also in the field of pharmacogenomics and pharmacogenetics, that can be achieved by governmental action. If these targets are not defined, it has to be expected that various different uncoordinated activities at various different levels will create a need for unnecessary financial, personal and other resources. However, the targets aspired to can only be achieved if the general public is convinced that they are right.

Public debate

What is required is a wide-ranging public debate on the possibilities and limits of pharmacogenomics. Their clinical use depends on whether pharmacogenetic and pharmacogenomic strategies and test procedures are accepted by the public and patients. Public dialogue and clarification are therefore an important means of establishing a broad basis for the clinical implementation of pharmacogenetics and pharmacogenomics. The essential point is that discourse should not be used as a means to educate members of the public on clinical practice. Members of the public have the right to express their views about central issues of health policy.

Need for statutory regulations

The Swiss Federal law on research involving human beings, or possibly the Swiss Federal law on therapeutic products must incorporate regulations on pseudonymisation methods, the consent of the persons concerned and the right of access, with particular regard to *biobanks*. A review should be carried out on the establishment of principles for encoding procedures in the law or any implementing provisions.

There should not be any exceptional rules for pharmacogenetic and pharmacogenomic investigations. The special desirability of protection, and uncertainty in respect of the informational content of genetic data does not allow for any simplified preconditions with regard to genetic counselling and consent of the person concerned.

Because of the potential for misuse and the sensitivity of surplus information, however, there is most certainly a need for rules on handling data of this kind, taking into account the principles of data economy; and this should also be reviewed for the Swiss Federal law on research involving human beings.

Even people with a rare genotype should be able to benefit from effective therapies. The industry should therefore be given incentives to encourage them to develop drugs – known as «orphan drugs» – for these patient groups. Elements of an «orphan drug law» should be featured more strongly than before in the

legislation. In the USA and in the European Union the appropriate regulations are already in place.

Research policy

Duplication of private research sponsorship by public research sponsorship should be avoided. In view of the risk of overestimating genetic factors, the investigation of non-genetic factors should also be taken into account where public funds are invested in biomedicine. Adequate funds must be invested for research into social factors and for disease prevention.

There must also be a debate on the allocation of funding between basic and applied research, and in particular on the extent to which increased numbers of start-ups might help to achieve a successful breakthrough with more active economic support. This might give the Swiss national economy new impetus.

Biobanks

Every encouragement must be given to the construction of biobanks, in order to optimise the benefits of genome-based drugs for the health of the Swiss population. In this respect, every effort should be made in particular to achieve better cooperation between the public sector and industry. In addition, there must be funding for parallel research on the ethical, legal and social aspects of biobanks.

An appraisal of research interests, data protection and the personal rights of donors – above all the right to withdraw samples at any time – leads to the conclusion that the samples stored in the biobanks should have single or double coding. In the case of double coding in particular, care should be taken to ensure that relations between the key holders are regulated in such a way that the donors' right to withdraw, to be informed and to obtain information relevant to their health can be put into effect.

No non-specific use of genome-based drugs

With regard to the registration of medicines, care should be taken to ensure that appropriate indication rules are formulated to prevent pharmacogenomically produced drugs being used non-specifically. This would mean that greater consideration could also be given to the statutory requirements in respect of efficacy, effectiveness and profitability.

Doctors

Pharmacogenetic tests and genome-based drugs are not the sole preserve of a few specialists, but may in principle be used by any doctor. It is therefore all the more important to provide the medical profession with the appropriate training and further training. In the first instance, extensive knowledge is required on the evaluation and assessment of probability forecasts. Secondly, doctors will also have to be trained in the accurate interpretation of pharmacogenetic test results, drawing the correct therapeutic conclusions and giving the patient the appropriate advice and support.

Special incentives

Economic incentives should be created to promote a certain type of pharmacogenetic and pharmacogenomic investigations, namely investigations that aim to contribute in some way to improving the success and safety in therapy of drugs that have already been launched onto the market. It should in particular be a question of leaving drugs that have a good cost-benefit ratio on the market, and not replacing them by developing products that are much more expensive, but that offer little in the way of additional benefits.

«Members of the public have the right to express their views about central issues of health policy.»

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