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Stiftung Warentest and the Pharmaceutical Market

ABSTRACT. For a couple of years now, the Stiftung Warentest and its magazine *test* have informed the FRG consumer about groups of drugs primarily administered through self-medication (Over-The-Counter drugs = OTC). These reports are based on descriptions and assessments of drugs available on the market. *test*'s ongoing effort in this field is unique on the European consumer scene.

So far 500 — primarily OTC — drugs related to 24 fields of application were discussed in *test*. Only less than half of the drugs received the positive recommendation "suitable for therapy." The enclosed package leaflet was examined with respect to the comprehensiveness and intelligibility of the statements made. The results obtained were similar.

The reports are a permanent reminder of the regulatory deficit of the German Federal Health Office (Bundesgesundheitsamt = BGA) whose decisions frequently show no evidence of an active stance in favour of consumer interests. Another aim is to reduce the drug producers' information and marketing monopoly. Basically, the *test* reports constitute an attempt to introduce more rationality into the drug area and thereby to improve the consumer's drug safety.

Some years ago, Stiftung Warentest — a private government-sponsored foundation — started to dedicate four or five issues a year of its monthly consumer journal *test* to the discussion of groups of drugs primarily administered in self-medication (Over-The-Counter drugs = OTC). These reports are based on descriptions and assessments of drugs available on the market. *test*'s ongoing effort in this field is unique on the European consumer scene, especially since the initiative was not the idea of a team of journalists purely interested in its publicity effect. The following contribution will examine the detailed reasons *test* had and still has for attempting to tackle the pharmaceutical market and will dwell on how it goes about this task, how the effort has been received by its readers, and the results that have been achieved.

TESTING DONE BY STIFTUNG WARENTEST

Stiftung Warentest has a long tradition of informing and advising

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consumers. Although not terribly popular among producers these are compelled to accept it as a testing authority for technical products. The consumers more often than not use the test results as a guideline when they go about purchasing cameras or washing machines, radio-sets or electric razors. The tests conducted examine among other things technical standards, safety, and usefulness; the criteria applied refer to product-specific requirements and expectations which the consumer ought to take into consideration. The results of the comparative tests are expressed in value judgements ranging from "very good" to "good," "satisfactory," and even "poor." The importance attributed to each of the testing criteria in passing a final judgement is defined prior to the test.

Favourable assessments are in high demand among producers, since they constitute good advertising material and bring about market advantages vis-à-vis the competitor whose products rated less well. Hence *test*'s evaluations directly affect the position and acceptance of a product on the market. It is, therefore, highly likely that the approximately four to five million readers of the about 700,000 copies of *test* published every month will stick to these assessments if they intend to buy more or less intricate products whose quality they can't discern because of the vastness of the market, the hardly comprehensible technical details, and — last, but not least — the often impenetrable pricing system. Summing up, this means that the job of explaining products is not left to the producer alone, but is also assumed by a consumer-oriented body that helps consumers to take decisions by supplying advice and comprehensible information compiled on the basis of comparative tests. Such were the ideas that fostered the decision to tackle the pharmaceutical market. For there is no doubt that drugs range among those products that definitely do require additional explanation, particularly when the market supplying such products is as crammed and lacking transparency as is the case in the Federal Republic of Germany.

SOME SPECIFICITIES OF THE GERMAN DRUG MARKET

A comparison of the numbers of medicinal products available on several European markets makes this statement all the more understandable. Figure 1 proves this point (for further information, see Glaeske & Schefold, 1988).

XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX	XX XXX	XXX	XX	X
FRG 150,000	F 12,000	CH 5,200	DK 3,900	GB 2,050

X = around 2,500 products

Fig. 1. Numbers of medicinal products available in several countries.

In the FRG 80 percent of the industry's sales of medicinal products — in 1987 they amounted to approximately 10.9 billion DM — can be traced back to prescriptions made by physicians. About 20 percent or not quite 2.7 billion DM (consumers pay about 4.7 billion DM) are spent on self-medication, i.e., on OTC-products that can be bought in pharmacies or supermarkets without prior consultation of a doctor. When referring to packet units the ratio between the prescription market and the OTC market presents a slightly different picture: Here about 35 percent of all packets of drugs sold are bought by self-medicating consumers, i.e., 440 million (360 in pharmacies and 80 in supermarkets) from among 1.25 billion packets (Selfmedication, 1989).

Negative Lists

Thus, each inhabitant of the FRG is supplied with an average of six packets of drugs a year that find their way to the consumer without a doctor's prescription. Such drug purchases are also brought about by the existence of a so-called *negative list* that came into force on April 1st, 1983. It contains all medicines no longer covered by the social health insurance systems, which in the FRG cover approximately 90 percent of the population. They include medicines for so-called petty diseases such as flu (flu and headache tablets), cough (cough syrups), sore throat (tablets to suck), travel sickness (medicines for nausea), and the like. The health insurance companies expected this negative list to reduce their costs. But for the insured consumers it was

tantamount to "prescribed self-medication," compelling them to take decisions on purchases that previously were taken by the family doctor. The main problem was that the pharmaceutical market had not been rendered amenable and transparent enough to suit the needs of the consumers. Hence they based their decisions on often outdated habits or else on advertising. But instead of supplying objective information, newspaper, radio, and television ads put forward only the advantages of the drug they wish to promote.

Too Much for the Consumer

The political decision makers responsible for compiling the negative list will have a hard time explaining which criteria a consumer should use for choosing among 200 pain-killers, 200 tranquillizers, 235 laxatives, 90 remedies for influenza, 175 remedies for sore throat, 290 remedies for coughs and colds, 250 remedies for stomach and intestinal troubles, 160 remedies for gall-bladder trouble, 260 tonics, etc.

These numbers are given in the IMS statistics compiled by the Institute of Medical Statistics for pharmaceutical producers. They contain data referring to turnovers and sold packet units of individual preparations. In the FRG they are not available to the general public. There are a lot more drugs on the market with a lower turnover or with only local importance, e.g., more than 600 additional pain-killers.

How much consumer-oriented information must be demanded if we consider that 0.9 billion DM are spent on OTC advertisements which exclusively reflect supplier interests and can hardly be regarded as a suitable source of consumer information?

True, the Federal Republic has an authority that is responsible for licensing drugs and monitoring the market, the Bundesgesundheitsamt (BGA). But an analysis of its activities reveals

— a low threshold of market access

— a hesitant and not overly courageous approach to market regulation, for instance if a product suspected of adverse effects should be withdrawn from the market expediently.

Such a philosophy does not further the type of active consumer protection that the crammed FRG market so urgently requires. The BGA seems rather to support the marketing interests of the producers. But the main objective of producers is to get many products onto the market as quickly as possible and to keep them there as

long as possible in order to make much money. Such marketing interests will, of course, invariably clash with the interests of consumer protection:

— Thus analgesic combinations containing phenacetin stayed on the market for far too long although the risk of nephropathy caused by the regular administration of high doses of this analgesic had long been discussed in standard pharmacological literature. Such combinations were withdrawn from the market as late as April 1st, 1986.

— Combinations of analgesics and barbiturate derivatives have also been on the market for far too long. These are high-risk drugs causing habituation and dependence, an effect that had been published some tens of years ago. The BGA announced the withdrawal of the drugs from the market one year ahead of time to allow the producer to get rid of their drugs in time. Thus consumers were exposed to potential risk one year longer than necessary.

— Still on the market are combinations with benzodiazepine derivatives that are administered in therapies requiring long-term treatment, for instance for coronary troubles or depressions (examples: Persumbran and Limbatril). The Federal Health Office is therefore partly responsible for the fact that today, such drugs are prescribed for no other purpose than for keeping alive a developing tranquilizer-dependence.

There are many other examples of the lack of control of the pharmaceutical market and hence of unnecessary risks for the consumer.

Stimulated by such findings Consumer Organizations started to develop concepts of consumer information in the field of medicinal products in 1984. The health guide book *Bittere Pillen*, of which 1.3 million copies have been sold so far, was also influential. The great success of this book made it only too obvious that people were in need of comprehensible information on drugs and their benefits and risks.

THE WAY *test* WORKS

Drug Efficacy Studies as a Base

The testing method of evaluating a drug or a substance on the basis of published scientific literature goes back to a study conducted in the United States between 1966 and 1969 (Drug Efficacy Study,

1969). In the U.S., study commissions were set up with the task of assessing all pharmaceutical products available on the market. These commissions made comparative evaluations which they deduced from standard pharmaceutical literature, from medical records (secondary literature), as well as from original studies (primary literature). The results of this research were intended to supply the Food and Drug Administration (FDA) with information about drugs of doubtful consumer utility as well as about products requiring further clinical testing. One of the most important reference books that includes these assessments is the Physicians' Desk Reference (PDR), the most used drug compendium for medical doctors in the United States. This drug register is elaborated and published jointly by the Association of Pharmaceutical Producers and the Pharmaceutical Commission of American Physicians.

The categories of assessment are: "effective," "probably effective," and "possibly effective." "Possibly effective" implies that further studies are required in order to fully assess the usefulness of the specific drug.

Contrary to most of the other national drug lists for physicians, the PDR adds to its detailed product descriptions an assessment of every single drug. Sidney Wolfe's book *Pills that don't work*, published in the early eighties (Wolfe & Coley, 1981), is regarded as a sort of summary of all those drugs whose efficacy has not been proven beyond all doubt. Wolfe's implication was that all drugs mentioned in his book ought to be withdrawn from the market as soon as possible. (In the FRG the "Alarm-Telegramm" of the Berlin pharmaceutical information service similarly tries to indicate superfluous and potentially dangerous drugs available on the German pharmaceutical market; Möbius, Becker-Brüser, & Schönhöfer, 1989).

About ten years later the U.S. method of assessment was adapted for a German government project run by the Bremen Institute for Prevention Research and Social Medicine. The project's commissions comprised general practitioners, clinical doctors, and pharmacologists. The results were published in four volumes (Greiser, 1981—1984). Two more chapters have been completed since, but are not yet available in the book stores.

Both projects yielded rather similar results: Between 30 and 60 percent of the examined drugs scored badly. In the FRG the high

rate of negative judgements was primarily due to the great number of combination products with nonsensical compositions that add up to more than half of all drugs supplied on the market. Since all evaluations were accompanied by quotations from the literature it was easy for the reader to understand why a certain drug was classified "positive" or "negative." For the assessment of combination products the so-called Crout's criteria were applied to determine whether or not the composition of a drug was appropriate and plausible (Crout, 1974). The main criterion was whether each substance of the combination might contribute towards successful therapy in the claimed fields of application.

The results of both projects were criticized by the drug producers mainly on the grounds that the assessments were based not on empirical studies but "only" on the existing literature. This criticism, however, is highly doubtful, since it is the producers themselves who contribute to the literature: They themselves initiate and publish studies that are up to the highest therapeutic and medico-statistical standards and that hence are accepted as evidence for the therapeutical efficacy of drugs. If the evaluation of the published data gives rise to doubts concerning the therapeutic efficacy of certain drugs, then that is all the more reason for not recommending such a product for therapy.

The Federal Health Office — A Safeguard for Efficacy?

As mentioned above the BGA is responsible for licensing drugs and monitoring the market. Therefore, should it not also guarantee that marketed drugs are only those whose usefulness has been proven under the Medicines Act and which therefore ought to receive a positive judgement?

Certainly, the BGA was and is the authority responsible, but many experts criticize the quality of its work. The transparency commission, for instance, whose activity is based on an Act of Parliament, made a comparative examination of drugs comprising ten different groups of indications and came to the depressing result that the efficacy of 47 percent of all relevant preparations could not be sufficiently proven although they were all available on the market and were frequently administered by doctors.

The ten transparency lists compiled upto 1985 using the classi-

fications "efficacy proven" and "efficacy uncertain or doubtful" yield the results shown in Table I.

This table clearly shows that the transparency commission considered 47 percent of the drugs it examined of uncertain or doubtful efficacy.

An assessment of typical self-medication drugs would not have yielded a different result. On the contrary, here even more doubts prevail concerning the usefulness of many preparations (such as geriatric preparations, multivitamin preparations, and various remedies for flu). Hence it was the findings of the transparency commission itself that supported the demand for a more active consumer policy.

The choice of the products examined by Stiftung Warentest is made on the basis of sales statistics supplied by the drug producers. This is the only way of determining the 20 or 30 most important drugs and it enables a high rate of recognition among readers. But if there are extreme price differentials and the high turnovers obtained in spite of low sales are only due to high pricing the base of comparison may sometimes also be the packet units sold.

TABLE I
Efficacy According to Transparency Lists

Field of indication	Efficacy proven	Efficacy uncertain or doubtful
Angina pectoris	177	222
Arterial hypertension	502	156
Peripheral arterial circulatory disturbance	103	181
Diabetes mellitus	190	87
Disturbed fat metabolism	83	32
Gout	163	41
Myocardial insufficiency	163	220
Cardiac dysrhythmia	238	57
Circulatory disturbance	243	159
Peripheral venous circulatory disturbance	209	647
	2,071 (53%)	1,802 (47%)

Source: Dölle & Schwabe (1986).

REACTIONS AND RESULTS OF *test* REPORTS

Some Findings

The so-called "expert opinions" that the reports contain (this expression is intended to show that they are not typical tests) were received favourably or very favourably by the consumers, depending on the topic. The drug producers, on the other hand, kept trying to play down the relevance of the findings and maintained that they created feelings of insecurity in consumers. This statement is of course not surprising if we consider that the results published in *test* invite a debate on the quality of drugs and are clearly critical of a whole series of products. The verdicts "unsuitable combination" or "insufficient proof of efficacy" might in the long run cause a loss in sales. A negative product image will disturb its marketing outlets. So far, the most comprehensive series of assessments was published in December 1988 in a special drug issue that discussed nearly 500 different products. Of particular interest are the assessments of the various groups of drugs, since they offer an insight in the quality of the drug market in the Federal Republic of Germany (Table II).

As can be seen, on average half of the high selling products in each application group was found not to have proven its innocuity.

The Togal Case

So far the producers of medicinal products have contested only a single negative assessment. They called upon the Munich regional court of Bavaria to examine the appropriateness of the statements made in a *test* expert opinion on analgesics in February 1986.

The law suit centred round the drug *Togal*, with a sales of 4.2 million in 1987 and an industry turnover of approximately 15 million DM. *Togal* is a combination product containing the following substances: acetylsalicylic acid 250 mg; lithium citrate x 2 H_2O 42 mg; quinine dihydrochloride H_2O-free 1.5 mg.

The product was assessed as follows: "An inappropriate combination product, quinine and lithium in this analgesic are irrational and not innocuous substances."

The devaluation must have sounded particularly derogatory in the ears of the *Togal* producers, since a product of similar content differing merely in dosage had been licensed by the BGA only a

TABLE II
Suitability of drugs according to *test*

Groups of drugs	Number	Suitable or possibly suitable	Less or not suitable
Natural remedies	(20)	8	12
Teas	(20)	7	13
Vitamin preparations	(20)	10	10
Mineral preparations	(20)	11	9
Geriatric preparations	(20)	—	20
Analgesics*	(20)	7	13
Sleeping pills*	(20)	13	7
Tranquillizers*	(20)	5	15
Laxatives	(20)	8	12
Travel tablets*	(20)	11	9
Anorectics*	(20)	5	15
Iron tablets	(20)	10	10
Sports ointments* (suitable for rubbing in, efficacy not clearly proven)	(20)	20	—
Remedies for			
Flu	(20)	—	20
Cough*	(20)	10	10
Sore throat	(20)	6	14
Rheumatism*	(20)	11	9
High blood pressure*	(20)	17	3
Low blood pressure*	(20)	7	13
Disturbed circulation*	(20)	10	10
Stomach and intestinal troubles (e.g., antacids)*	(20)	11	9
Liver and gall troubles*	(20)	—	20
Pre-menstrual syndrome	(4)	—	4
Acne*	(20)	12	8
Total	464 (100%)	199 (43%)	265 (57%)

* These groups also contain ethical drugs.

couple of months earlier. *Togal* has been marketed with this very combination of substances since 1914. Considering that lithium (undesired side effect: possible renal disturbances) and quinine (undesired side effect: allergy) are of hardly any use in reducing pain the BGA might have been expected to reassess the drug when the producers applied for a renewal of the marketing authorization. In

spite of the fact that this knowledge is time-worn the BGA missed its chance of banning this outdated irrationality from the market, on October 24, 1985: It accepted the combination under the current Medicines Act. In the eyes of the producers, Stiftung Warentest should not have turned down the officially accepted conception of an analgesic.

The evaluation of *Togal* in *test* was based on an analysis of the literature that mainly discussed whether combinations of analgesics could in any case be appropriate; and if so, which of the substances can be combined on the basis of a reasonable benefit-risk assessment.

The court accepted the entire verdict that was derived from a survey of the literature. The evidence submitted by the suing company in justification of the combination was not only rejected, but disqualified as "promotion." The company's action was dismissed. The court's opinion reads:

> *Togal* analgetic tablets are easily accessible to the consumer, since they do not require a doctor's prescription even though they must be sold in pharmacies. It appears commendable in the interest of good consumer information that all usually arising side-effects be mentioned.

One legal observer writes about this judgement:

> The problem of this case derives from the fact that there are different levels of drug safety, that these are being contested in medical science and pharmacology, and that the BGA and *test* had different ideas about drug safety. The question arises: Is a journal specializing in consumer information bound to the criteria of safety applied by the BGA or may it apply stricter criteria? (. . .) In the case of *Togal* it will suffice to state that consumer information derived from applying stricter criteria is legally admissible and desirable from a health policy point of view. The producer's interest in selling his products must be rated lower than the consumer's interest in receiving comprehensive information on possible risks of medical therapy. The case makes clear that considerable economic interests are at stake in pharmaceutical production and that health and the need for information may clash with marketing concerns. In such cases the conflict between the two must be settled by legal action (Hart, 1987).

Such events plus the comments they entailed not only reaffirmed the activity of Stiftung Warentest, but also derided the BGA. How was it possible for this body to have admitted such a product, how was it possible for their assessment to have yielded any kind of positive result — considering that the BGA based its judgement on the same information as Stiftung Warentest?

There is no ultimate and conclusive explanation, but assumptions can be made. The licensing philosophy of the BGA is not so much based on the criteria of innocuity and appropriateness of a combination, but rather on accepting a much broader margin of risk: If a drug has no clear-cut effectiveness or appropriate combination, but is classified as low-risk, it may be licensed; if it is assessed in the same way, but obviously is less innocuous, it will not be licensed. Hence the license is not granted on account of a comparison with drugs already licensed in the same field of application, but rather represents an isolated decision. Assessments such as those made by Stiftung Warentest always contain a comparison with other available products and take into consideration the most recent opinions of experts that are subject to dynamic changes. Hence licenses granted may very well clash with consumer protection. Comparative assessments, on the other hand, supply consumer information and aim at elaborating recommendations that will enable the consumer to make a reasonable choice among the drugs admitted to and supplied by the market.

The drug *Togal* under discussion should not have been licensed in the first place. The positive decision was possibly taken because the risks of lithium and quinine were not taken seriously enough and because the application of the Crout standard to license only those combination products with appropriate substances was not given sufficient attention. The *Togal* story attracted a lot of attention among experts and Stiftung Warentest gained an important victory in the conflict of interests between suppliers of medicinal products on the one side and consumers on the other.

CONCLUSIONS

So far 500 — primarily OTC — drugs relating to 24 fields of application have been discussed in *test.* Only less than half of the drugs mentioned received the positive recommendation "suitable for therapy." Together with the products, the information enclosed in the package was examined with respect to comprehensiveness and comprehensibility of the statements made. The results obtained were similar.

Considering the lack of information and the obvious obstacles a consumer has to overcome, the vendor of the drugs, the pharmacist,

might very well be expected to bridge the gap between producer and customer. But unfortunately pharmacists do not play the desirable role of active filters between the exaggerated promises and the realistic usefulness of OTC preparations. Their income is based on the sales of medicines: The higher the sales, the higher their earnings. Under such circumstances, how could pharmacists be expected to advise their customers properly? They would then have to discourage the customers from buying half of the products they sell. Most of the time the scales between ethics and "monethics" are unfortunately tipped to the advantage of the latter.

Hence the expert opinions of Stiftung Warentest could be interpreted as an "emergency measure" intended to reduce the information monopoly of the drug producers. But they are also a permanent reminder of a regulatory deficit of the BGA whose decisions frequently show no evidence of an active stance in favour of consumer interests. Basically, the *test* reports constitute an attempt to introduce a little more rationality into the pharmaceutical market-place and thus to improve the consumer's drug safety — for the saying that the Federal Republic of Germany is the "pharmacy of the world" has long since lost its positive connotation.

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ZUSAMMENFASSUNG

Die Stiftung Warentest und der Arzneimittelmarkt. Seit einigen Jahren stellt die Stiftung Warentest in ihrem monatlich erscheinenden Verbrauchermagazin *test* Arzneimittelgruppen vornehmlich aus dem Bereich der Selbstmedikation vor. In diesen sogenannten Warenkunden zu bestimmten Arzneimittelgruppen finden sich bewertende Beschreibungen der einzelnen Mittel. Mit der kontinuierlichen Bearbeitung des Themenkomplexes steht die Zeitschrift *test* in der europäischen Verbraucherszene einzigartig dar.

80% des Industrieumsatzes auf dem bundesdeutschen Arzneimittelmarkt — 1987 ca. 10.9 Mrd. DM — gehen auf "arztliche Verordnung zurück, ca. 20% oder knapp 2.7 Mrd. DM entfallen auf den Bereich der Selbstmedikation (OTC-Markt). Bezogen auf die Packungseinheiten sieht die Relation Verschreibungsmarkt/OTC-Markt noch etwas anders aus: Hier werden nämlich ca. 35% aller verkauften Arzneimittelpackungen innerhalb der Selbstmedikation verbraucht, von 1.25 Mrd. Packungen also etwa 440 Mio. (360.9 Mio. in Apotheken und 80 Mio. in Supermärkten). Die Testmethodik basiert auf der Auswertung von veröffentlichter wissenschaftlicher Literatur für ein Arzneimittel bzw. für einen Wirkstoff. Herangezogen werden hierfür Standardlehrbücher der Pharmakologie und der angewandten Medizin (Sekundärliteratur) ebenso wie Originalarbeiten (Primärliteratur).

Bislang sind rund 500 Arzneimittel aus 24 Indikationsbereichen, vornehmlich aus dem OTC-Bereich, in der Zeitschrift *test* vorgestellt worden, weniger als die Hälfte aller genannten Mittel konnten dem Verbraucher als "geeignet für die Therapie" empfohlen werden. Mit den Produkten wurden auch jeweils die Beipackzettel auf Verständlichkeit und Vollstaïdigkeit der Angaben untersucht. Diese Untersuchungen ergaben ein ähnliches Resultat.

Die Ergebnisse zeigen vor allem Regulationsdefizite des Bundesgesundheitsamtes, dessen Entscheidungen oft eine aktive Wahrnehmung von Verbraucherinteressen vermissen lassen. Die *test*-Veröffentlichungen stellen auch den Versuch dar, ein Stück des Informations- und Vermarktungsmonopols der pharmazeutischen Hersteller zu verringern. Und sie können letzlich als Weg zu mehr Rationalität auf dem Arzneimittelmarkt und damit zu größerer Arzneimittelsicherheit gewertet werden.

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