“Forum for Microbiological Medicines”
Established tradition based on science – Therapy for today and tomorrow
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“Forum for Microbiological Medicines”

Established tradition based on science – therapy for today and tomorrow

For several years, therapy with microbiological medicines has been gaining importance. The “Forum for Microbiological Medicines” – an initiative of the German Pharmaceutical Industry Association (Bundesverband der Pharmazeutischen Industrie e.V., BPI) and BPI member companies producing microbiological pharmaceuticals and diagnostics – builds on this development. This initiative aims to further enhance the acceptance of the treatment method called “microbiological therapy”. Efforts are actively supported by the Hufeland-gesellschaft e.V. – the umbrella organization of medical societies for complementary and natural medicine.

1. Goals of the initiative

Traditionally, microbiological therapy ranks among “special” treatment methods, even though it is not explicitly identified as such in relevant pieces of legislation. The initiative is striving for a representative role of microbiological therapy in European and national drug laws and also in social laws.

The “Forum for Microbiological Medicine” wants to help increase the awareness of this treatment method with detailed information and to include microbiological medicine in the political and social health debate. The Forum wishes to represent the positions and concerns of physicians, of natural medicine therapists and, most importantly, of patients – for a better acceptance of microbiological therapy in the future. This brochure is addressed to circle of experts and policy makers in the public health sector.

2. Microbiological therapy – Over 100 years of research

The historic development of microbiological therapy started in the 19th century: on August 15th 1885, the paediatrician Theodor Escherich first described the bacterium coli commune, which was later renamed Escherichia coli (E. coli) in his honor. Trying to find an antagonistic therapeutic approach for intestinal infections, Alfred Nissle isolated the first probiotic E. coli strain in 1917. The bacterium E. coli “Strain Laves 1931” was scientifically described in the eponymous year. In 1954 Dres. Kolb and Rusch set up a microbiological laboratory. The Working Group for Microbiological Therapy (Arbeitskreis für Mikrobiologische Therapie e.V.) also started in 1954. It was founded by several physicians who wanted to treat and cure patients by using natural bacteria. The term “microbiological therapy” was coined during that period, and first commercial products with Escherichia coli and enterococci as well as other microbial
Homeopathy, a further discipline of natural medicine, also benefits from the curative effect of bacteria. This therapeutic approach goes back to Wilhelm Lux, a veterinarian in Leipzig. He obtained a homeopathic dilution from scabies pathogens in cattle and used this dilution to successfully treat other animals. Today, medicines are manufactured from different bacterial cultures while following the rules of the homeopathic pharmacopoeia. These medicines are called nosodes. They strengthen the resistance of patients and help them overcome infections. Nosodes from bacteria can therefore be considered as microbiological medicines in a broader sense.

Microbiological therapy – Proven by over 100 years of practice

With the breathtaking development of antibiotics and a change of attitude of the scientific society in the 70s of the last century, the therapeutic approach of “healing with bacteria” somewhat faded. Together with herbal remedies, microbiological medicines were frequently used by physicians and therapists with a natural medical orientation.

Over the past 90 years, however, microbiological therapy has proven its importance for medical practice. Major contributions to this development were made by medical associations such as the Alfred-Nissle-Gesellschaft and the Arbeitskreis für Mikrobiologische Therapie e. V.
being treated with bacteria – which are usually seen as pathogens – may take some time to gain acceptance.

From the scientific point of view, there are many good reasons for an increased application of microbiological medicines:

The intestinal microflora forms a protective shield. This shield consists of over 1,000 trillion bacteria, including immunoactive bacteria such as E. coli and enterococci which modulate the immune system. Excessive use of antibiotics may damage the protective intestinal microflora and increase the risk of chronic infection. This can be prevented by resorting to probiotics in a target-ed manner in order to control minor infections – especially in children (“probiotics” is a frequently used term for microbiological medicines). An increased application of microbiological medicines in general practice could effectively contribute to reducing the development and spread of antibiotic resistances.

**Antibiotic resistances may be reduced by applying microbiological medicines**

In November 2008, the German Antimicrobial Resistance Strategy (DART) of three Federal Ministries (of Health, Food and Consumer Protection, and Research) adopted a program with central fields of action which included a reduction in the use of antibiotics in general practice.
Microbiological medicines – An alternative to antibiotics in the treatment of minor infections

Modern microbiological therapy uses many bacterial species and different strains. They include, inter alia, over five different species of lactobacilli, three species of bifidobacteria, two species of enterococci, and several strains of Escherichia coli. Common features of these probiotic bacteria are their positive effects on the human immune system.

The above probiotics are used in the treatment of the following diseases:

- Minor infections (as an alternative to antibiotics),
- Acute and chronic infection in ENT (e.g. rhinitis, sinusitis, otitis, tonsillitis),
- Chronic infection of the respiratory tract,
- Chronic urogenital infection,
- Inflammatory bowel disease,
- Atopic eczema,
- Diseases of the allergic spectrum,
- Intestinal complaints (e.g. diarrhea, constipation, irritable bowel syndrome).

The scientific relevance of this therapeutic option is increasing among medical therapists. But the potential of microbiological medicines is far from being fully exploited.
Microbiological therapy – strengthening the immune system in a holistic manner

The most common diseases in medical practice include chronic infection of the respiratory tract, digestive problems, food allergies, and eczema. All of these diseases can be treated with microbiological medicines.

These diseases go along with changes in the immune system and a decrease of the body’s defensive system. With their various microorganisms (barrier function) and defense tissues – such as lymph nodes and Peyer’s patches – the intestines have a central role in defense. A length of almost seven meters and a surface of over 300 m² make the intestines our largest immune organ. Over 80% of acquired immunity originates in the intestines. The intestinal immune system can modify the entire immune activity of the body. In chronic disease, the use of microbiological medicines can re-establish the normal balance. Bacteria in microbiological medicines influence mucosal cells – i.e. our “internal interface” – which send important signals for numerous reactions of the immune system. Symptoms are not suppressed but underlying causes are treated.

Microbiological therapy – Immune regulation is the key to good health.

Studies have also proven the efficacy of microbiological medicines in complex clinical scenarios with a variety of causes, such as irritable bowel syndrome.

Disease patterns – e.g. in irritable bowel syndrome and eczema – clearly show that there is no simple cause-effect relationship. On the contrary, several triggers are involved and they can have different impacts.

The intake of microbiological medicines also results in an increased formation of protective antibodies of the mucosa (secretory IgA). With this self-activating protective shield, bacterial and viral infections – e.g. of the respiratory tract – are overcome faster and more easily, and relapses are prevented.
Different medicines with suitable bacteria are available to physicians for this purpose. Today, comprehensive training of physicians in microbiological therapy is offered by the Arbeitskreis für Mikrobiologische Therapie e.V.. The certificate awarded in the training course of microbiological therapy demonstrates to patients the competence of their attending physician in this field.

Natural healing has a long tradition in Germany. Here, some 15,000 physicians have an additional qualification in natural medicine. The training for this qualification has a holistic orientation and enables the full use of all options of microbiological therapy.

Training in natural medicine lasts several years and includes an overview of complementary medical methods. During this training physicians become familiar with the principles of microbiological therapy. As a result of well-founded scientific studies, microbiological therapy has also gained an important position in “mainstream” medicine.
A glance at other European countries – e.g. Austria, Benelux, Italy, and Switzerland – shows that microbiological therapy is firmly established in European medicine. Today, microbiological therapy is being applied in over 20 countries worldwide, resulting in a high level of awareness and wide range of users.

Irrespective of the good starting position for drug therapy with natural bacteria, regulatory and health-political framework conditions for natural therapeutic principles have worsened over the past 15 years.

Only a few years ago, microbiological medicines with their natural bacteria, i.e. bacteria naturally occurring in humans, had the status of “biological medicines”. In contrast, small and medium-sized manufacturers of these medicines must make intensive efforts today to clearly separate their drugs from the so-called “biologicals”. The latter are modern biotechnological products manufactured in part from genetically modified microorganisms.

A safe therapeutic principle which proven relevance in medicine for many decades is now constantly being confronted with the requirements for “biologicals” in regulatory procedures.
The demands for legislation are clear: adequate regulatory requirements are needed for microbiological medicines. Such rules need to pay due attention to the established good manufacturing practice and to drug safety and efficacy as proven by experience and clinical trials. This step is essential to secure the future of microbiological therapy!

*Manufacturing method: microbiological medicines are no biologicals.*

Already now, suitable instruments are available, e.g. including microbiological medicines in the authorisation rules for “traditional medicinal products”. According to a report by the EU Commission dated May 30th, 2007, on the application of provisions to traditional herbal medicinal products, an extension of relevant marketing authorisation requirements to microbiological medicines would be rational.

As this is about maintaining the diversity of therapies, the above demand is supported, inter alia, by major medical associations for naturopathic treatment and complementary medicine. From the beginning over 100 years ago to the present, microbiological medicines have been used successfully. They are the first biological medicines with a scientific background. Hardly any modern, evidence-based drug can look back on such a long tradition.

**Please contact any of the following organizations for further information:**

- Arbeitskreis für Mikrobiologische Therapie e. V.  
  www.amt-herborn.de
- Alfred-Nissle-Gesellschaft e. V.  
  www.a-nissle-ges.de
- Bundesverband der Pharmazeutischen Industrie e. V.  
  www.bpi.de
- Hufelandgesellschaft e. V.  
  www.hufelandgesellschaft.de

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