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THE BUSINESS WITH JOINTS

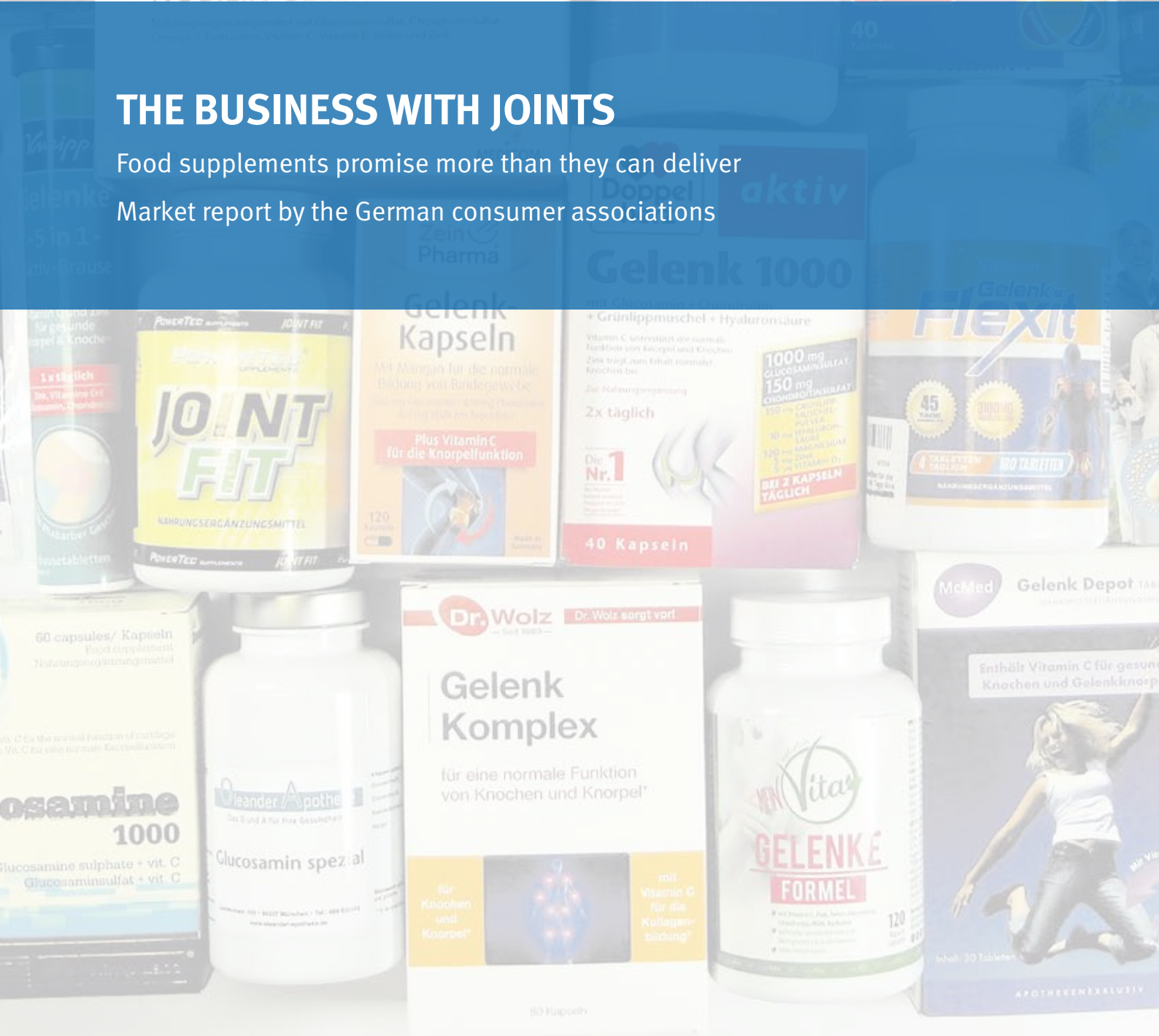
Food supplements promise more than they can deliver
Market report by the German consumer associations





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1. THE PROBLEM

Both glucosamine and chondroitin are natural elements found in connective tissue, cartilage and synovial fluid in the human body. They are also present in foods, but are not nutrients and have no nutritional value. After vitamins and minerals, food supplements containing glucosamine and chondroitin are amongst the frequently sold food supplements. According to information from health service provider IMS Health, consumers in 2012 spent over EUR 100 million on over-the-counter medicinal products and food supplements containing glucosamine, chondroitin, hyaluronic acid, green lipped mussel powder or gelatine [1]. The enquiries on the website of the consumer associations (CA) www.klar-text-nahrungsergaenzung.de demonstrate that consumers require verified information on food supplements for joints. At 40%, most illness-related enquiries relate to this product group.

It is questionable whether these substances protect against osteoarthritis or the loss of cartilage. Their incorporation into cartilage and the positive effect are also unclear. The ability for cartilage to regenerate itself is fundamentally regarded as extremely low to impossible.

According to current studies, the effects of glucosamine or chondroitin in both food supplements and medicinal products are contradictory [2-4]. While some studies show a slight improvement in symptoms, in many others there is no demonstrable difference compared to taking a placebo [5]. In a current Spanish study from 2017, the placebo actually had an even stronger effect in treating pain in the case of osteoarthritis of the knee than the combination of glucosamine and chondroitin sulphate [6]. In its guidelines, Osteoarthritis Research Society International records that products with glucosamine and chondroitin do not deliver any benefits in the treatment of osteoarthritis of the knee joint [7]. The new clinical practice guideline of the American Academy of Orthopaedic Surgeons (AAOS) also advises against the use of glucosamine sulphate in the treatment of patients with osteoarthritis of the hip. Reason for this: The available evidence demonstrates no benefit compared to placebo preparations with regard to an improvement in functionality, reduction of stiffness and easing of pain [8].

For years, glucosamine and chondroitin were promoted as "joint nutrients" with suggestions such as "to build cartilage" or "for mobility". Health-related promotion for glucosamine and chondroitin has been prohibited by law since 2013 (Commission Regulation (EU) 1066/2013), after the European Food Safety Authority (EFSA) classified as not scientifically proven the link between consumption of these substances and the proposed health claims attributed to them. Those claims included such statements as: "contributes to maintaining the normal function of joint cartilage" and "contributes to the protection of joint cartilage when there is excessive movement or load and to improved mobility of the joints". The EFSA added to this assessment that there was no scientific proof that glucosamine and/or chondroitin have a preventive effect in maintaining the structure or functioning of the joints or cartilage of healthy people.

Aside from their questionable benefits, taking products that contain glucosamine or chondroitin can even carry health risks [9-11].

- Food supplements containing glucosamine and chondroitin can be a health risk to patients who are taking anticoagulants (coumarin anticoagulants) because the two substances can increase the blood-thinning effect of the drugs and thus cause bleeding. When taking glucosamine, there is also the risk of hypercholesterolemia.
- More specifically, people who suffer from diabetes mellitus also have limited glucose tolerance and should monitor their blood glucose levels when taking glucosamine, as it can interact with the metabolism of glucose (e.g. the functionality of the insulin-producing pancreas cells can be inhibited).
- People who suffer from an allergy to crustaceans/shellfish should watch out for corresponding allergen labelling, because glucosamine is frequently made from these creatures. There is also a risk for people who are allergic to fish in the case of products containing chondroitin from fish tissue.

- According to the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung – BfR), it is not possible to evaluate the health risks of taking glucosamine or chondroitin for pregnant women and nursing mothers, nor for children and young people, due to a lack of data.

Many consumers believe that taking glucosamine or chondroitin products promotes health. The manufacturers enhance these beliefs through active promotion and the use of, in some cases, questionable statements or images. But food supplements are not intended to prevent, alleviate or cure illnesses. This is the function of medicinal products, which have been tested for effectiveness and safety and approved by the authorities prior to going on sale.

Health claims about the effect of nutrients or other substances are not permitted in the area of joints. According to a current ruling by the working group of food chemistry experts from the German federal states (ALS) and by the Federal Office of Consumer Protection and Food Safety (BVL), using the term "joint" in product names, advertising improved joint functionality and showing a moving joint are not permitted, as this assumes a cause-effect relationship which, according to expert opinion, is not the case [12]. An image of this kind would signify an unlawful extension of the approved health claims. This also applies to claims that are in fact permitted for vitamins and/or minerals with regard to connective tissue, cartilage or bones if they are used in relation to joints. Despite this, numerous joint products contain the addition of vitamin C or zinc, on which the advertising is then based.

2. AIM OF THE MARKET REPORT

The consumer associations' market report focused on the large market segment of food supplements containing glucosamine and chondroitin which are offered for joints. The experts evaluated the products available both from bricks-and-mortar retailers and via the internet and examined direct sales as an example. The aim was to check whether the products could pose a health concern due to their composition. The market report also focused on the labelling and promotional statements.

3. APPROACH

The market report was carried out in the period between March and April 2017. A total of 25 freely available products were included and examined more closely in respect of the criteria stated in the objectives. 14 products came from bricks-and-mortar retailers (pharmacies, chemist's shops, discount stores, fitness shops, health stores, supermarkets), while 11 products were obtained via the internet.

The BfR maximum dose recommendations for vitamins and minerals in food additives and the nutrient reference values (NRV) from the Food Labelling Regulation were used to evaluate the micro-nutrient content. The BfR's recommendations take into account the supply situation in Germany and the risk involved in consuming too much of individual substances. These BfR recommendations for the maximum daily dose of individual vitamins and minerals in food additives are not legally binding and the manufacturers are therefore not obliged to comply with them [13, 14]. However, they help consumers to buy products safely. The nutrient reference values that apply across the EU (relating to healthy adults) for the daily consumption of vitamins and minerals pursuant to the Food Information for Consumers Regulation (EU FIC) include consumption via daily food and drink as well as via food supplements [15]. Vitamins and minerals contained in food supplements must be stated on the packaging as a percentage of the NRV.

It is particularly worth noting the consumption of 1,250 mg of glucosamine per day, which is considered to be pharmacologically effective by the European Medicines Agency (EMA) [9] and which corresponds to a dose of 1,584 mg of glucosamine sulphate. According to this, food supplements with a daily dose of at least 1,250 mg of glucosamine should be judged to be medicinal products. Other scientists already consider around half this value to be pharmacologically effective [16]. Because current data leads us to conclude that daily consumption of 800 mg of chondroitin sulphate can be pharmacologically effective [17, 18], this reference value was used to evaluate the food supplements.

The consumer associations also tested the promotional techniques used for this product group. In doing so, particular focus was put on the wording and the legality of the health claims used. Complete and correct labelling of warning messages was also checked. In the case

of goods from bricks-and-mortar retailers, they analysed the promotional claims made on the packaging. Claims on the insert leaflet or the inner packaging were not included in this, as they are not visible to consumers when making a decision at point of purchase and thus not significant when making a purchase. To evaluate the health claims made by the online products, information both on the product (to the extent that images were visible) and claims from the online product description were used.

4. RESULTS

4.1 COMPOSITION AND DOSE

The market report made by the consumer associations presents the situation in the segment of food supplements containing glucosamine and chondroitin. In addition to glucosamine and chondroitin, the main other ingredients were vitamin C, vitamin E, zinc, copper and manganese. In the case of food additives bought online, methylsulfonylmethane (MSM), an organic sulphur compound, was also involved.

4.1.1 Doses frequently too high

As there are no legally stipulated maximum doses for glucosamine and chondroitin, the following doses were used as a basis in the evaluation:

- Glucosamine sulphate 1,584 mg (EMA measurement) [9]
- Chondroitin sulphate 800 mg (measurement according to current studies) [17, 18]

According to us products with a higher content and corresponding pharmacological effect should not be permitted to be food additives.

Glucosamine sulphate with a possible pharmacological dosage was found in the case of three products from online retailers. The highest recommended daily dose was 2,400 mg of glucosamine sulphate (Fig. 1). In the case of other products, 2,000 mg was stated as the recommendation. Consuming 2,000 mg of glucosamine sulphate per day is the equivalent of consuming 1,571 mg of glucosamine. In addition, three further food supplements obtained online and one product from a bricks-and-mortar retailer with a daily recommendation of 1,500 mg of glucosamine sulphate (equivalent

to 1,178 mg of glucosamine) were close to being in the stated pharmacological range (Annex 1 and 2).

Four online products and one food supplement from a bricks-and-mortar pharmacy had a daily recommended dose of 800 mg and 1,200 mg, respectively (Fig. 2). These high daily doses of chondroitin sulphate could mean that these five products were pharmacologically effective [17, 18].

MSM had been added, mainly for products obtained online – nine products contained this additive (Fig. 2), while this was only the case for one product from a bricks-and-mortar retailer. According to manufacturers' promotional claims, this substance is meant to help in the case of inflammation, osteoarthritis and skin diseases, and even protect against cancer. However, these effects have not been scientifically proven sufficiently for them to be used for promotional purposes and as recommendations. Due to a lack of approved health claims, manufacturers are not permitted to make promotional health claims about MSM. Therefore, health claims of this kind are mainly found not on the products themselves, but on various websites. The reason is still given as a (non-existent) lack of sulphur.

4.1.2 Doses of vitamins and minerals too high

Taking a closer look at the purchased products, our attention was drawn to combinations with other minerals, vitamins and additives. All 14 food supplements obtained from bricks-and-mortar retailers and four from online retailers were also enriched with vitamins and/or minerals. For example, the products from bricks-and-mortar retailers had a total of 78 additional individual substances. Eleven out of 14 products from bricks-and-mortar retailers and three out of eleven from online retailers exceeded BfR recommendations for vitamins and minerals. A comparison with the NRV shows that nine products from bricks-and-mortar retailers and two from online retailers exceeded the NRV for at least one vitamin or mineral (Tab. 1). Food additives from bricks-and-mortar retailers most frequently exceeded the BfR recommendations for zinc, copper, manganese, vitamin D and vitamin E. For products from online retailers, this was the case for zinc, selenium, vitamin E and manganese. The following distribution resulted when using the NRVs: Products from bricks-and-mortar retailers most frequently contained too high levels of vitamin E,

followed by too high levels of vitamin B6. In the case of products from online retailers, there was no difference compared to the BfR recommendations, with the exception of vitamin C in one product (**Annexes 1 and 2**).

The consumer associations were particularly critical of the high doses of vitamins and minerals, particularly in the case of food supplements from bricks-and-mortar retailers (**Fig. 3**).

- Two food supplements from bricks-and-mortar retailers and one product from an online retailer contained too high daily doses of vitamin E. For example, in the case of one product from a pharmacy, the daily dose of 40 mg (**Fig. 3**) was 267 percent higher than the BfR recommendation for food supplements of 15 mg per day. Some scientific studies indicate that taking antioxidants – also including vitamin E – in the form of food supplements could, in certain circumstances, also have negative, converse effects (e.g. possible negative impact on lifetime and on muscular stamina and strength) [19-24].
- Too high doses of vitamin D of 20 µg per day were found in two products from bricks-and-mortar retailers (**Fig. 4**). Based on the BfR's assessment, this presents a health risk, as too high levels of vitamin D could lead to headaches, nausea and loss of appetite, and in the worst case, even to kidney calcification and the formation of kidney stones.
- Of particular note in the product range from bricks-and-mortar retailers was Glucosamin-Spezialkapseln (daily dose of 20 mg) with a dose of manganese 20 times higher than that recommended by the BfR for food supplements (**Fig. 5**). Too much manganese may have a negative effect on the uptake of iron. Vegetarians or people with iron deficiency need to pay particular attention to this. Unspecific complaints, such as increased perspiration, tiredness and dizziness are potential side effects of a daily intake of 20 mg or more of manganese [25].
- Of note was a product from an online retailer with a high dose of both zinc and selenium (**Fig. 6**). Long-term consumption of too high a quantity of zinc (≥ 25 mg/day) can, for example, lead to disturbance in

the balance of copper and iron, and in the immune function and fat metabolism [26].

Other additives:

In isolated cases, the tested food supplements contained other additives, such as hyaluronic acid, collagen and green lipped mussel extract ("contains glycosaminoglycans"). Hyaluronic acid, collagen and glycosaminoglycans are naturally occurring substances in cartilage, but there is no safe evidence that they can find their way to the cartilage when taken as a food supplement and then rebuild it [27]. Fish oil and spices such as turmeric and ginger were also found in two products. They can actually act as positive additions to a normal diet, but there is no safe scientific proof that they have a positive effect on joints when taken as a food supplement.

Extensive information on individual substances that are touted to help joints, connective tissue and bones, such as omega-3 fatty acids, frankincense extract or turmeric can be found online at www.klartext-nahrungserganzung.de.

Duty of disclosure:

From a legal perspective, food additives are foods and are not subject to an approval process. Before being launched onto the market, they must be disclosed to the Federal Office of Consumer Protection and Food Safety (BVL). It is sufficient to state the name of the product and of the responsible person (manufacturer, retailer or importer) and to include a sample of the label.

Some manufacturers do not comply with this duty of disclosure. A request to the BVL showed that nine of the total of 25 products could not be found in the BVL's database. This involved two products from bricks-and-mortar retailers and seven products from online retailers (Annexes 1 and 2).



Figure 1: Composition of a food supplement from an online retailer with a high recommended daily dose of glucosamine sulphate, where 2,400 mg of glucosamine sulphate equates to around 1,885 mg of glucosamine (Gelenk Mix Aktiv)



Figure 2: Composition of a food supplement from an online retailer with a high recommended dose of glucosamine sulphate, chondroitin sulphate and methylsulfonylmethane (Nutriza Select Glucosamine Chondroitin MSM)

Type of business	Number of products enriched with vitamins and minerals	Number of products exceeding the BfR's recommended maximum daily dose in food additives [13, 14].	Number of products that exceed the NRV reference value for daily vitamin and mineral consumption [15].
Bricks-and-mortar retailers	14	11	9
Online	4	3	2

Table 1: Product fortified with vitamins and minerals – subdivided by exceeding BfR and NRV



NOBILIN GELENK AKTIV

Verzehrempfehlung: 2 Soft-Gel-Kapseln pro Tag

Zusammensetzung	Tagesdosis (2 Soft-Gel- Kapseln) enthält:	% der empf. Tagesdosis*
Fischöl	1.000 mg	-
davon Ø enthalten		
- Omega-3-Fettsäuren	300 mg	-
davon EPA	160 mg	-
davon DHA	100 mg	-
Glucosaminsulfat	500 mg	-
Chondroitinsulfat	200 mg	-
Vitamin C	200 mg	250
Vitamin E	40 mg α-TE	333
Zink	8 mg	80
Selen	30 µg	55

* nach EU-Lebensmittelinformationsverordnung

- Vitamin C trägt zu einer normalen Kollagenbildung für eine normale Knochen- und Knorpelfunktion bei.

Mindestens haltbar bis Ende: siehe Seitenlasche.
Kühl, trocken und vor Licht geschützt lagern. Nicht über 25 °C lagern.



NOBILIN GELENK AKTIV, Zutaten:
Fischöl (28,2 %), Glucosaminsulfatdikaliumchlorid [Krebstiere] (18,8 %), Gelatine, Sojabohnenfett [teilweise gehärtet], L-Ascorbinsäure, Chondroitinsulfat (6,3 %), Feuchthaltemittel: Glycerin, Sorbit; D-alpha-Tocopherol, Zinksulfat, Natriumselenat, Stabilisator: Bienenwachs, Emulgator: Sojalecithine, Farbstoffe: Titandioxid, Eisenoxide und Eisenhydroxide

Bruttogewicht pro Kapsel: 1.770 mg

Nicht für Schwangere, Stillende, Kinder und Jugendliche unter 18 Jahren geeignet. Bei Verwendung von Cumarin-Antikoagulanzen bitte Rücksprache mit dem Arzt halten. Diabetiker und Personen mit eingeschränkter Glucosetoleranz wird eine Überwachung des Blutzuckerspiegels und des Insulinbedarfs empfohlen.



Nahrungsergänzungsmittel

120 Kapseln = 212 g

Figure 3: Composition of a food supplement from a bricks-and-mortar retailer with a high recommended daily dose of vitamin C, vitamin E and zinc (Nobilin Gelenk Aktiv)

tetesept Gelenk 1200 intens plus – Mit hoch dosiertem Vitamin D₃ und C für gesunde Knochen und Knorpel.

- Unterstützen Knorpelaufbau und Kollagenbildung
- Tragen zur normalen Bindegewebsbildung bei
- Wichtig für gesunde Knochen

Inhaltsstoff	Tagesdosis (1 Tablette)	% NRV*
Glucosaminsulfat	1200 mg	**
Vitamin C	80 mg	100 %
Vitamin D	20 µg	400 %
Vitamin E	1,8 mg	15 %
Kupfer	150 µg	15 %
Zink	1,5 mg	15 %

* Anteil der Referenzwerte für die tägliche Zufuhr gemäß Europäischer Lebensmittelinformationsverordnung (LMIV), NRV = Nutrient Reference Value / ** keine Empfehlung nach LMIV vorhanden

Figure 4: Composition of a food supplement from a bricks-and-mortar retailer with a high recommended daily dose of vitamin D (tetesept Gelenk 1200 intens plus). The product also contains copper, which, according to BfR recommendations, should not be included at all in food supplements.



Figure 5: Composition of a food supplement from a bricks-and-mortar pharmacy with a very high recommended daily dose of manganese (Glucosamin spezial Kapseln). According to the BfR, manganese should not be used in food supplements.



Figure 6: Composition of a food supplement obtained online with a high recommended daily dose of zinc and selenium (Mein Vita Gelenke Formel)

4.2 CRITICAL EXAMINATION OF THE PROMOTIONAL CLAIMS

The market report also checked and compared the promotional claims on products from bricks-and-mortar and online retailers for their accuracy/lawfulness. It also recorded what additional promotional claims were used in the case of products ordered online.

4.2.1 Target groups for promotion

Half of the products (seven of the 14 products) from bricks-and-mortar retailers used words, graphics or images to address one or more target groups. Athletes were most frequently named or depicted (on six products), followed by claims or images relating to elderly people (five products). Stress on the joints due to overweight was referenced on four products. Out of the seven products that did not name or depict a target group, five products carried the image of a joint.

In the case of products from online retailers, three of the eleven products addressed a specific target group. These established a reference to athletes. In comparison to bricks-and-mortar retailers, online products were more frequently advertised in general terms. In particular, it was suggested that people who suffer from pain would experience relief by taking the product. Out of eight products that did not address a specific target group, a joint or painful arm was depicted on six products (Fig. 8).



Figure 8: Examples of joint images on the packaging (ZeinPharma Gelenk-Kapseln and Biomenta Gelenk-komplex forte)

4.2.2 Promotions using health promises

The Health Claims Regulation (HCVO) together with the positive list regulates which health claims are permitted on foods and the conditions under which they may be used to promote products [28, 29].

Only two products from bricks-and-mortar retailers make do with absolutely no health claims. A total of 114 health claims were found on the other 12 products (on average 9.5 claims per product).

Out of 11 health supplements from online retailers, all used health claims to promote the product. A total of 60 health claims were found: on average 5.5 claims per product. Some claims were only found in the descriptions of the products obtained online.

Most health claims were found on the back of the relevant product, or in the description in the case of the online products.

In the case of the food supplements obtained from bricks-and-mortar retailers, the health claims mainly related to vitamins or minerals – most frequently vitamin C and zinc. As health claims relating to glucosamine or chondroitin are not permitted, some providers have moved to using permitted claims for vitamins and minerals (provided they contain 13 per cent of the NRV), for example:

- Vitamin C and/or zinc "contributes to normal collagen formation for the normal function of cartilage" or
- Vitamin C and/or zinc "contributes to the maintenance of normal bones"

However, a direct reference to joints is not permitted [12].

Things are different for the promotion of online products. Here, the health claims predominantly relate to the entire product and/or to glucosamine or chondroitin compounds. These claims are not permitted under the HCVO.

Checking all the claims against the specifications in the HCVO showed that 73 per cent, i.e. 44 out of 60 health claims on products from online retailers, were not approved under the HCVO (Fig. 9). For products from bricks-and-mortar retailers this was only two per cent.

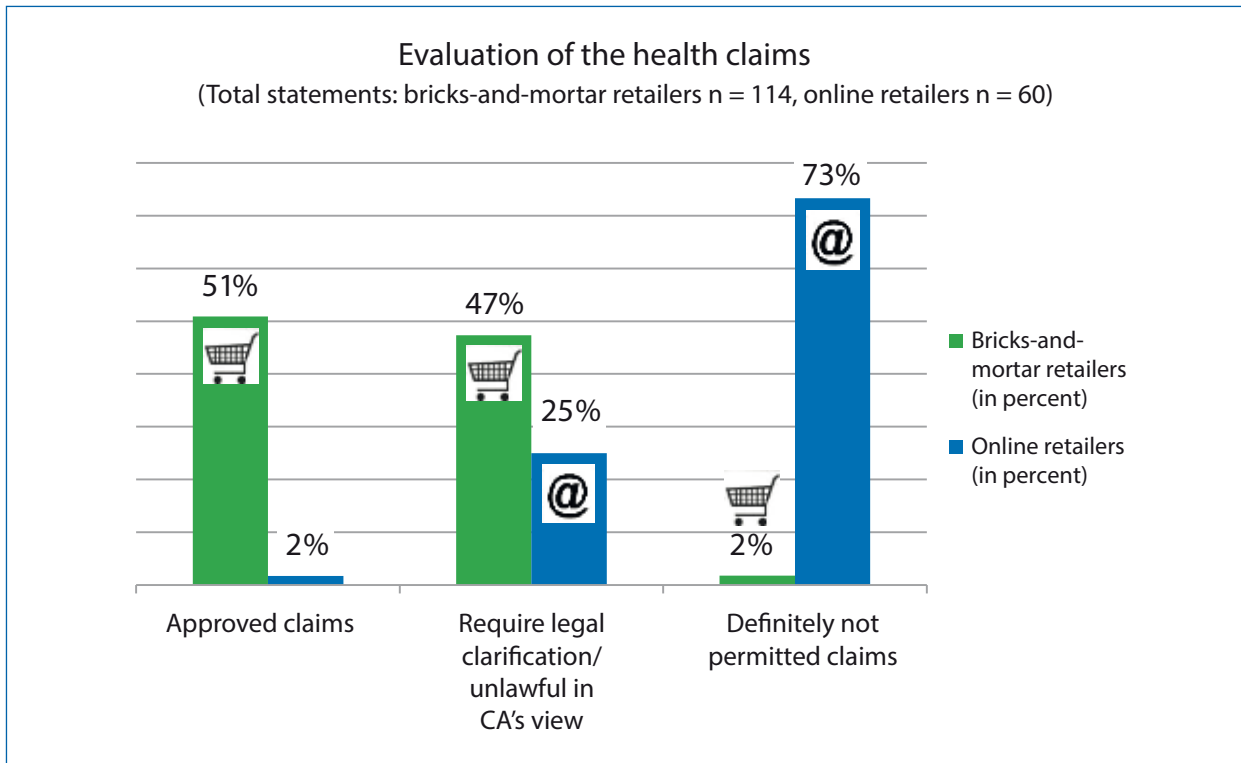


Figure 9: Evaluation of the health claims on food supplements containing glucosamine and chondroitin.

* In the opinion of the consumer associations, these health claims are unlawful as they do not comply with the requirements of the Health Claims Regulation. The legitimacy of these formulation variations has not yet been legally clarified.

Especially in the case of online products, the breaches are clear and frequent. And so, for example, the following was promoted:

- "For joint complaints..." (Fig. 10),
- "Combats osteoarthritis and joint pain",
- "Glucosamine can bring relief in the case of slight to moderate osteoarthritis (joint deterioration), such as in the case of joint swelling or joint stiffness." or
- "Chondroitin helps in the formation of sinovial fluid and also inhibits inflammation."



Figure 10: Examples of unlawful health claims (eubiopur Arthro Plus and Vital Flex Pro)

Further examples of unlawful health claims with the corresponding product reference are listed in Annexes 3 and 4.

Products from bricks-and-mortar retailers were also promoted using unlawful health claims. In the case of two products, these claims related to several substances although they are not permitted for all of them (Fig. 11).

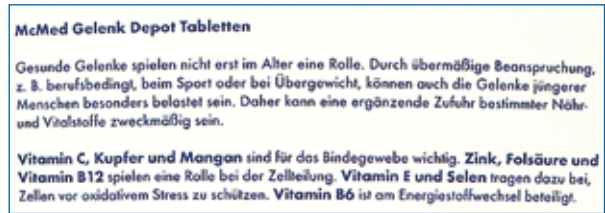


Figure 11: "Connective tissue" health claim only permitted for copper and manganese, but not for vitamin C (McMed Gelenk Depot Tabletten)

In the opinion of the consumer associations, a further 69 health claims should be subject to legal scrutiny. These are classified in Figure 9 as "require legal clarification/unlawful in CA's view".

Key examples that led to this conclusion were:

- **Elements of permitted claims missing:** The word "normal" as part of the permitted claim was missing particularly often, e.g. in "contributes to maintaining normal connective tissue". The health claims "Vitamin C contributes to normal collagen formation for the normal function of cartilage" and "Vitamin C contributes to normal collagen formation for the normal function of bones and cartilage" were often shortened to "Vitamin C supports the normal function of bones and cartilage" or similar sounding claims (Fig. 12).



Figure 12: Shortened health claims (tetesept Gelenk 1200 intens plus)

The following claims are permitted under the HCVO:

Vitamin C contributes to normal collagen formation for the normal function of cartilage.

Vitamin C contributes to normal collagen formation for the normal function of bones.

- **Generalised claims that do not name a specific substance:** In the case of products from online retailers, general or unspecific claims were frequently made, such as "important for cartilage" or "for highly stressed joints". The consumer associations consider it insufficient if the substance that is intended to achieve the stated effect is not named directly next to this information. Asterisked claims on the front of the product relating to information given, for example, on the reverse, does not compensate for this (Fig. 13).



Figure 13: Insufficient asterisked information relating to health claims from the consumer associations' standpoint (Gelenk Komplex Dr. Wolz)

- **Highlighting a particular site of action:** Extending a claim to a specific site of action is also unlawful. For example, instead of referring generally to cartilage, the reference was made to joint cartilage (Fig. 14):



Figure 14: Promotional statement on the front of a food supplement containing glucosamine, where a specific site of action (joint cartilage) is highlighted (McMed Gelenk Depot Tabletten)

Under the HCVO, only the following claim is permitted:

Vitamin C contributes to normal collagen formation for the normal function of cartilage.

Only the health claims on the products were used to validate "highlighting a specific site of action (joint)".

The ALS also evaluated the use of approved health claims for vitamins and minerals in combination with the product names. In Opinion No 2016/42, the food chemistry experts came to the view that using an actual approved claim (e.g. "Vitamin C contributes to normal collagen formation for the normal function of cartilage") in connection with a product name that contains the term "joints" (e.g. "Gelenkkapseln" (joint capsules), "Gelenk-depot" (joint store) or "Gelenkkomplex" (joint complex)), or depicting a moving joint, was unlawful [12].

Gelenk Komplex Dr. Wolz

Gelenke, die gut versorgt sind und normalen Belastungen unterliegen, sind programmiert, ein Leben lang zu funktionieren. Eine Nährstoffversorgung wird umso wichtiger, je höher die Belastungen, z.B. durch Sport, körperliche Arbeit und erhöhtes Körpergewicht, sind.

Die Omega-3-Fettsäuren in Gelenk Komplex Dr. Wolz sind reich an EPA (Eicosapentaensäure) und DHA (Docosahexaensäure).

- * Vitamin C trägt zu einer normalen Kollagenbildung für eine normale Funktion der Knochen und einer normalen Kollagenbildung für eine normale Knorpelfunktion bei
- ** Vitamin C trägt zu einer normalen Funktion des Nervensystems bei
- *** Vitamin E und C tragen dazu bei, die Zellen vor oxidativem Stress zu schützen

4.2.3 "Free from" promotion

At least one "free from" promotion which was marketed as being of additional health value was found on ten out of 14 products from bricks-and-mortar retailers and on five out of eleven from online retailers. In the case of the products from bricks-and-mortar retailers, the most frequent offers were "gluten free" and "lactose free" (or wording with the same meaning). Products from online retailers mainly indicated that they were free from genetically modified organisms.

4.3 MANDATORY AND RECOMMENDED INFORMATION

The market report also aimed to check whether the information stipulated by law and recommended by the BfR was present and correctly labelled on the food supplements from bricks-and-mortar and online retailers containing glucosamine and chondroitin.

4.3.1 Warning and usage information

According to paragraph 4 of the Health Claims Regulation (NemV), food additives must be labelled with the following information [30]:

- Food additives should not be used as a substitute for a balanced and varied diet and a healthy lifestyle.
- Do not exceed the stated recommended dose.
- Keep out of the reach of small children.

The information was found to be correct and legible on all preparations from bricks-and-mortar retailers.

In the case of products from online retailers, attention was paid to those details that were obvious when making the purchase decision, i.e. on the product photo or in the product description. All the required information was found on ten food supplements. One product was missing the information on dose and the information on a balanced diet.

4.3.2 Information for specific consumer groups

Food supplements containing glucosamine or chondroitin can be problematic for people with diabetes mellitus or limited glucose tolerance, people who are allergic to crustaceans, and for patients who are taking anticoagulants (coumarin or warfarin). Due to a lack of data, it is not possible to assess the health value of an intake of glucosamine or chondroitin for pregnant women or nursing mothers [9-11]. Therefore, for precautionary reasons, the BfR considers it a requirement to put corresponding information on food supplement labels, and manufacturers should include these in order to increase safe usage. Unfortunately, with the exception of allergen labelling and the provisions relating to specific substances listed in Annex 3 of the EU FIC, this information is not required by law. But the EU FIC provides the framework for such information via Article 4, para. 1b(i) and manufacturers should use this. However, such information was not present on all checked products. **Table 2** provides an overview.

There was no significant difference between the food supplements from bricks-and-mortar retailers and online retailers. We noted one product from a bricks-and-mortar retailer (pharmacy) which did not carry any of the information (**Fig. 5**).

Information for...	products from bricks-and-mortar retailers n=14	products from online retailers n=11
Diabetics/people with limited glucose tolerance	11	8
People who are taking anticoagulant drugs	11	8
People allergic to crustaceans or fish	13*	11
Pregnant women and nursing mothers	8	9

* This missing information suggests that no ingredients from crustaceans or fish were used.

Table 2: Information for specific consumer groups

4.3.3 Other usage information

The following claim was found on the website for one food supplement (Vital Flex Pro): "In addition, glucosamine sulphate has no side effects – even when used long-term. It can therefore be used with confidence for preventive purposes. Glucosamine sulphate can be administered for an unlimited time. In contrast to pain-killers, it is free from any side effects."

This information is false and also supports consumers' notions that food supplements are completely harmless and, in contrast to medicinal products, cannot have any side effects. For example, if food supplements and drugs are taken at the same time, there can be reciprocal effects. The effect of drugs can also be inhibited or intensified.

4.4 WIDE RANGE OF PRICES

When calculating the costs of food supplements containing glucosamine, we noticed some marked differences. In bricks-and-mortar retailers, the prices of the acquired products ranged from EUR 0.16 to EUR 1.00 for the manufacturer's recommended daily dose. On average, consumers can expect to pay between EUR 0.39 and around EUR 142 per year for these products. In online retailers, the average spend per daily dose of EUR 0.58 and annual spend of around EUR 211 were significantly higher. Here the daily costs ranged between EUR 0.33 and EUR 1.10 (Figs. 15 and 16). The prices varied enormously, even when the ingredients were almost identical. Consequently, the differences did not permit any conclusions to be drawn on the quality of the products.

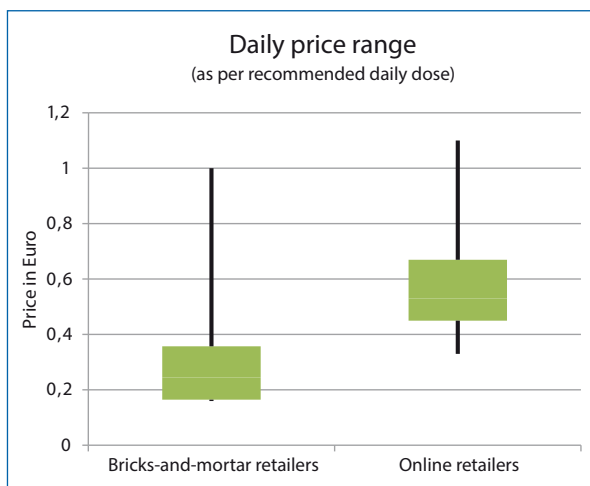


Figure 15: Daily price range of the documented food supplements

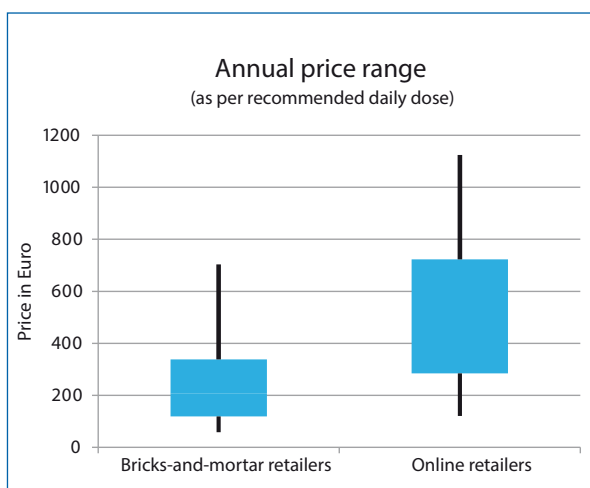


Figure 16: Annual price range of the acquired food supplements

4.5 MULTI-LEVEL MARKETING

Multi-level marketing (MLM) is a special form of direct distribution that is established on multiple levels. Some manufacturers of food supplements also use this form of distribution. In contrast to traditional direct sales, it is made attractive to customers by allowing them to act as independent sales partners and generate their own customer base. The company's aim is to sell products through a continually expanding network of co-workers. Generally these people are not experts and receive sales training from the manufacturers. These "advisers" then receive a share of the profits via a pyramid-like earnings system. The more customers and salespeople are enlisted, the greater the earnings should be. And so, each potential new customer is also a potential new co-worker. Special events and lucrative prizes for corresponding performance increase the pressure to succeed – thus advisers are mainly motivated by profit. Most already have to have bought a minimum amount of products at their own cost. Profit sharing and bonus calculations only take place after these products have been successfully sold on. The consumer associations consider direct sales to groups of friends, acquaintances, relatives or colleagues to be particularly problematic, as it makes rational purchasing decisions difficult.

Food supplements are not intended to cure or alleviate illnesses. Claims of this kind are not permitted to be used for promotional purposes on product packaging or online descriptions, and breaches can be penalised accordingly. In contrast, it is practically impossible for the responsible supervisory authorities to control oral claims that are circulated via sales events or through word-of-mouth propaganda. Only the participants at the sales event can confirm whether the company's mainly independent sales partners ("advisers") comply with the legal requirements or get carried away and use unlawful claims about cures for promotional purposes. As a result, the manufacturers avoid responsibility, by alleging that they do not know what their agents are saying. They would, however, be in a position to examine their partners' online promotional activity. In February 2008, the Cologne Higher Regional Court (File No: 6 U 149/07) decided that MLM companies are liable for false and exaggerated promotion on their sales partners' websites.

Three direct providers were included as examples in the product research:

- Amway GmbH: Amway Glucosamin NUTRILITE (825 mg glucosamine hydrochloride per day)
- Lifeplus International: Lifeplus Joint Formula (1,200 mg glucosamine sulphate per day)
- PM-International AG: FitLine Gelenk-Fit (500 mg glucosamine sulphate per day)

The allergen labelling for shellfish and crustaceans was present in all three product descriptions. There was only insufficient important advice for the purchaser: Amway and PM-International provided no information for pregnant women and nursing mothers, for diabetics and for patients who are taking anticoagulants.

Lifeplus Joint Formula was missing the warning information that the stated dose should not be exceeded, that the product is not a substitute for a healthy diet and that it should be kept out of the reach of children.

Food supplements sold via MLM cost twice as much as many other products sold, for example, in chemist's shops, supermarkets or pharmacies. The average cost of the former products was EUR 0.80 per daily dose. However, the higher price gives no indication as to whether the product is of a superior quality or whether its ingredients have better bioavailability.

In its terms of business, Lifeplus International refers to a US jurisdiction, in that legal disputes are to be conducted in the USA (Arkansas).

Before ordering from direct providers, the customer must first register and then usually has to set up a customer account. Amway und Lifeplus International then establish the connection to the sales partner, PM-International calls up the person giving the recommendation.

5. CONCLUSION AND DEMANDS

Osteoarthritis is the most frequent joint ailment worldwide. Deterioration of the joint cartilage mainly affects older people and people who place undue or improper stress on their joints. The level of suffering is great, whether it is due to overexertion from work or sport, or from overweight. Many patients find the limited options offered by pharmacotherapy to be unsatisfactory and want to "do something" more to help themselves. Affected consumers have a strong need for information, which some manufacturers exploit to spread their promotional messages. The fact that enquiries relating to illness dominate the website www.klartext-nahrungsergänzung.de also seems to confirm this.

Effectiveness not proven

Glucosamine and chondroitin are offered both as medicinal products and as food supplements. It is questionable whether taking these substances can protect against osteoarthritis or the loss of cartilage. Their incorporation into cartilage and the hoped-for prevention and/or healing of cartilage damage resulting from this are also unclear. Results of studies on the efficacy of glucosamine and chondroitin in combating joint wear and tear continue to show that they generally are no more effective than placebos.

! The same applies to the joint remedy product group: Testing/approval by the authorities of all food supplements advertised in Germany (pursuant to section 5 of the Food Supplement Regulation – NemV) in respect of safety and accuracy of the promotional statements is required urgently before they are first brought onto the market instead of the notification procedures used to date.

Possible side effects

Appropriate information for special groups of people is not always available. Food supplements containing glucosamine or chondroitin can be problematic for people with diabetes mellitus or limited glucose tolerance, as well as for patients who are taking anticoagulants (coumarin or warfarin). Due to a lack of data on the health risks, pregnant women and nursing mothers, and children and young people should also avoid products containing glucosamine and/or chondroitin.

! Establishing a central reporting system for the collection of unexpected (side) effects of food supplements which can be accessed by consumers would be desirable. Information on the risks and undesired effects ought to be stipulated by law.

Unlawful health claims

Health claims must be expressly approved by the European Commission. To date, there is no such approval for the purpose of "joints". However, this does not prevent the providers of food supplements from putting on their packaging claims that vitamins and minerals support joint function. In the view of the consumer associations, this approach must be questioned. As well as economic loss suffered by consumers as a result of having been deceived about the effect/effectiveness, unlawful claims also harbour real risks, e.g. if medical care is dispensed with due to medicinal claims.

! In this case, the supervisory authorities are required to take stronger measures and penalise the health claims that are not permitted under the Health Claims Regulation.

Products obtained online

Products obtained online, in particular, frequently promise more than can be scientifically proven and is permitted. In the case of the daily dose for glucosamine and chondroitin, these products are frequently only marginally below or within the potentially pharmacological range. While the provider is marketing such products as food supplements, they are circumventing the testing and verification requirements that are stipulated for medicinal products.

It demonstrates that a harmonisation of the legal framework at a European level is just as necessary as a coordinated way of working between the authorities in the EU member states.



The legislator should stipulate a positive list for additives with associated maximum doses in food supplements and the competent supervisory authorities should be required to apply sanctions.

Consumer clarification

It should be explained to those consumers who place their hopes in food supplements for joints that food supplements are not medicinal products and therefore the authorities have not tested them either for safety or efficacy, nor approved them. Furthermore, a declaration should be made about the risks and effective alternatives, such as avoiding becoming overweight and engaging in regular physical activity. Only then will consumers be in a position to make a conscious decision and accept any possible risks.



In the case of painful joints, useful treatment methods should be discussed with the treating doctor.

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7. ANNEX

Annex 1

Complete overview of the glucosamine-containing food supplements from bricks-and-mortar retailers that were checked

Annex 2

Complete overview of the glucosamine-containing food supplements from online retailers that were checked

Annex 3

Examples of unlawful health claims for online products

Annex 4

Unlawful health claims for products from bricks-and-mortar retailers



The product overview reflects the position at the time of the market survey. Since this date, the product presentation, labelling and/or composition could have changed. We request that providers and consumers let us know when amended products can be found in shops or online.

Annex 1:

Complete overview of the glucosamine-containing food supplements from bricks-and-mortar retailers that were checked

No	Product name	Company/ manufacturer	Type of business	Manufacturer's recommended daily dose of glucosamine sulphate	Manufacturer's recommended daily dose of chondroitin sulphate	Exceeds recommended daily maximum dose for vitamins and minerals in food supplements (BfR) ¹ :		Exceeds reference dose for daily vitamin and mineral consumption (NRV) ²		Number of health-related statements on the product		
						Yes	No	Yes	No	Permitted	Unlawful in CA's opinion	Definitely not permitted
1	altapharma Gelenk-Vital	Dirk Rossmann GmbH	Chemist's shop	1,000 mg	100 mg	Copper, manganese, zinc	Vitamin C, Vitamin E, Vitamin B6, Vitamin B12, folic acid, selenium		Vitamin C, Vitamin E, Vitamin B6, Vitamin B12, folic acid, selenium, copper, manganese, zinc	5	1	0
2	DAS gesunde PLUS Gelenk Depot-Tabletten	din-drogerie markt GmbH + Co. KG	Chemist's shop	1,000 mg	100 mg	Copper, manganese, zinc	Vitamin C, Vitamin E, Vitamin B6, Vitamin B12, folic acid, selenium	Vitamin E, Vitamin B6	Vitamin C, Vitamin B12, folic acid, selenium, copper, manganese, zinc	6	12	0
3	Doppelherz aktiv Gelenk 1000	Queisser Pharma GmbH & Co. KG	Chemist's shop	1,000 mg	150 mg	Copper, manganese, zinc	Vitamin C, Vitamin D, Vitamin E, magnesium, selenium		Vitamin C, Vitamin D, Vitamin E, magnesium, selenium, copper, manganese, zinc	13	2	0
4	Gelenk Komplex Dr. Wolz	Dr. Wolz Zell GmbH	Health food shop	1,000 mg	500 mg	Vitamin E	Vitamin C, folic acid	Vitamin E	Vitamin C, folic acid	5	5	0
5	Glucosamin spezial Kapseln ³	microprevent GbR	Pharmacy	1,500 mg	800 mg	Manganese		Manganese		0	0	0
6	Kneipp Gelenke 5 in 1 Aktiv-Brause	Kneipp GmbH	Supermarket	800 mg	40 mg	Zinc	Vitamin C, Vitamin E		Vitamin C, Vitamin E, zinc	2	3	1
7	McMed Gelenk Depot Tabletten	roha apotheken-dienste GmbH	Pharmacy	1,000 mg	100 mg	Copper, manganese, zinc	Vitamin C, Vitamin E, Vitamin B6, Vitamin B12, folic acid, selenium	Vitamin E, Vitamin B6	Vitamin C, Vitamin B12, folic acid, selenium, copper, manganese, zinc	6	4	1
8	MULTINORM Gelenk-Tabletten 1000 mit Vitamin C	SANKT PIRMIN Naturprodukte GmbH	Discount store	1,000 mg	100 mg	Vitamin E, selenium	Vitamin C, Vitamin E, Vitamin B6, selenium	Vitamin C, Vitamin E	Vitamin B6, selenium	4	2	0
9	Nobilin Gelenk-Aktiv	MEDICOM Pharma GmbH	Pharmacy	500 mg	200 mg	Vitamin E, zinc	Selenium, Vitamin C	Vitamin C, Vitamin E	Selenium, zinc	2	0	0
10	Olimp Gold Glucosamine 1000	Olimp Laboratories Sp.z.o.o., PL	Fitness shop	950 mg	-		Vitamin C		Vitamin C	2	1	0
11	PowerTec Joint Fit Gelenk-Kapseln ³	Sporternahrung Mitteregger GmbH	Fitness shop	684 mg	684 mg		Vitamin C, Vitamin E, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, niacin, pantothenic acid, biotin, folic acid		Vitamin C, Vitamin E, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, niacin, pantothenic acid, biotin, folic acid	0	0	0
12	taxofit Gelenke 1200 complete	MCM Klosterfrau Vertriebsgesellschaft mbH	Chemist's shop	1,200 mg (glucosamine hydrochloride)	-	Vitamin D, copper, zinc	Vitamin C	Vitamin D	Vitamin C, copper, zinc	3	15	0
13	tetesept Gelenk 1200 intens plus	tetesept Pharma GmbH	Chemist's shop	1,200 mg	-	Vitamin D, copper	Vitamin C, Vitamin E, zinc	Vitamin D	Vitamin C, Vitamin E, zinc, copper	0	9	0
14	VitaFit Gelenk Tabletten	Principle Healthcare Europe GmbH	Discount store	1,000 mg	100 mg	Copper, manganese, zinc	Vitamin C, Vitamin E, Vitamin B6, Vitamin B12, folic acid	Vitamin E, Vitamin B6	Vitamin C, Vitamin B12, folic acid, copper, manganese, zinc	10	0	0

1) **Bundesinstitut für Risikobewertung (BfR)**: BfR's recommended maximum daily dose for vitamins and minerals in food supplements (not legally binding). Alongside the supply situation in Germany, also principally includes the risk that there is too high a consumption of individual substances [13, 14].

2) **NRV (Nutrient Reference Value)**: Reference dose for daily consumption pursuant to Food Labelling Regulation (EU) No 1169/2011 [15].

3) Food supplement was **NOT stored in the database of the Federal Office of Consumer Protection and Food Safety (BVL)** (promotional requirement pursuant to section 5 of the Food Supplement Regulation).

Annex 2:
Complete overview of the glucosamine-containing food supplements from online retailers that were checked

No	Product name	Company/manu- facturer	Type of business	Manufac- turer's rec- ommended daily dose of glucosamine sulphate	Manufac- turer's rec- ommended daily dose of chondroitin sulphate	Exceeds recommended daily maximum dose for vitamins and minerals in food supplements (BFR) ¹⁾		Exceeds reference dose for daily vitamin and mineral consumption (NRV) ²⁾		Number of health-related statements on the product		
						Yes	No	Yes	No	Permitted	Unlawful in CA's opinion	Definitely not permitted
1	Arthrosense ³⁾	Glucosana, NL	Online	1,000 mg (glucosamine hydrochloride)	800 mg		Vitamin C		Vitamin C	0	0	2
2	Biomenta Gelenkkomplex forte	Biomenta GmbH	Online	1,000 mg	400 mg	Zinc	Selenium		Zinc, selenium	0	0	3
3	eubiopur Arthro Plus	eubios GmbH	Online	1,400 mg	430 mg					0	1	6
4	Gelenk Mix Aktiv ³⁾	German Elite Nutrition Inc., US	Online	2,400 mg	520 mg					0	0	1
5	Gym Flex die Gelenk Alternative ³⁾	Natur Total B.V., NL	Online	2,000 mg	400 mg					0	0	6
6	MeinVita Gelenke Formula ³⁾	Body World Group GmbH	Online	1,200 mg	600 mg	Seleni- um, zinc	Vitamin C	Vitamin C, selenium, zinc		0	3	2
7	Nutriza Select Glucosamine Chondroitin MSM ³⁾	Nutriza Select, US	Online	1,500 mg	1,200 mg					0	0	8
8	Ultimate Nutrition Glucosamine Chondroi- tin MSM ³⁾	Ultimate Nutrition Inc., US	Online	1,500 mg	1,200 mg					0	1	1
9	Vital Flex Pro ³⁾	Natur Total B.V., NL	Online	2,000 mg	400 mg					0	0	13
10	Vit4ever Gelenk Flexit	Vit4ever (Europe), UK	Online	1,400 mg	800 mg					0	3	1
11	ZeinPharma Gelenk-Kapseln	ZeinPharma Germa- ny GmbH	Online	1,500 mg	600 mg	Vitamin E, manga- nese, zinc	Vitamin C	Vitamin E, manga- nese, zinc	Vitamin C, zinc	1	7	1

1) **Bundesinstitut für Risikobewertung (BfR)**: BfR's recommended maximum daily dose for vitamins and minerals in food supplements (not legally binding). Alongside the supply situation in Germany, also principally includes the risk that there is too high a consumption of individual substances [13, 14].

2) **NRV (Nutrient Reference Value)**: Reference dose for daily consumption pursuant to Food Labelling Regulation (EU) No 1169/2011 [15].

3) Food supplement was **NOT stored in the database of the Federal Office of Consumer Protection and Food Safety (BVL)** (promotional requirement pursuant to section 5 of the Food Supplement Regulation).

Annex 3: Examples of unlawful health claims for online products

No	Product name	Claim used	Rationale for not being permitted pursuant to Health Claims Regulation [28]
1	Arthrosense	Combats osteoarthritis and joint pain Glucosamine can bring relief in the case of slight to moderate osteoarthritis (joint deterioration), such as in the case of joint swelling or joint stiffness.	<p>Promotional statements declaring that taking food supplements containing glucosamine and chondroitin has a protective effect on the joints of healthy people are not permitted.</p> <p>Permitted claims for the function of joints, connective tissue and cartilage are:</p> <ul style="list-style-type: none"> • Vitamin C contributes to normal collagen formation for the normal function of cartilage. • Vitamin C contributes to normal collagen formation for the normal function of bones. • Manganese contributes to the normal formation of connective tissue. • Copper contributes to maintenance of normal connective tissue.
2	Biomenta Gelenkcomplex forte	Chondroitin sulphate can also achieve relief in the case of degenerative joint disease (osteoarthritis), e.g. in the hips, knee or fingers. Hyaluronic acid is important for joint suppleness and mobility. For highly stressed joints	
3	eubiopur Arthro Plus	For joint pain after sitting for long periods For joint stiffness in the morning To prevent joint stress at work or playing sport To help with osteoarthritis	
4	Gelenk Mix Aktiv	Contains all important nutrients for healthy, functioning joints	
5	Gym Flex die Gelenk Alternative	Recommended for painful joints Promotes healing and also preventive	
6	MeinVita Gelenke Formel	To nourish joints with zinc, vitamin C Supports connective tissue	
7	Select Glucosamine Chondroitin MSM3	Key building block of cartilage Helps lubricate and protect joints Reduces joint pain and stiffness	
8	Nutrition Glucosamine Chondroitin MSM3	Supports joint flexibility and mobility	
9	Vital Flex Pro	Recommended for painful joints Promotes healing and also preventive Glucosamine supports the formation of hyaluronic acid, which is important for synovial fluid. Glucosamine strengthens joint cartilage. Improves cartilage regeneration and joint function. Glucosamine is vital in renewing already damaged joints. Glucosamine supports cell development in joints. Glucosamine and chondroitin strengthen cartilage. Chondroitin helps in the formation of synovial fluid and also inhibits inflammation. Optimal protection for your joints With manganese for cartilage function	
10	Vit4ever Gelenk Flexit		
11	ZeinPharma Gelenk-Kapseln		

Annex 4: Unlawful health claims for products from bricks-and-mortar retailers

No	Product name	Claim used	Rationale for not being permitted pursuant to Health Claims Regulation [28]
6	Kneipp Gelenke 5 in 1 Aktiv-Brause	Vitamin C and zinc for healthy cartilage and bones	No permitted claim for zinc and cartilage function
7	McMed Gelenk Depot Tabletten	Vitamin C, copper and manganese are important for connective tissue.	No permitted claim for vitamin C and connective tissue.

DESIGN.

Verbraucherzentrale Bayern e.V.
Verbraucherzentrale Hessen e.V. (lead institution)
Verbraucherzentrale Nordrhein-Westfalen e.V.
Verbraucherzentrale Sachsen e.V. (lead institution)
Verbraucherzentrale Sachsen-Anhalt e.V. (lead institution)

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