# Strategies to uplift the Ayurvedic and Herbal Supplements to International Standards

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**Abstract**

Though India has an abundance of herbal drug resources, we are a very insignificant player in the global market. The prevalence of common names for diverse herbs, poor knowledge of phytochemicals present, high adulteration including unethical extraction procedures are the main issues plaguing our herbal supplements. Establishment of a separate section or Ministry on Herbal medicines separate from Ayurveda, Unani and Siddha; preparation of Monographs of High quality (comparable to those published by European Economic Community) with the active principles, other compounds, antioxidants and available clinical researches and establishing Quality standards for all the plants on quality, quantity, and extraction methods of all available herbal remedies will elevate the levels of our supplements to global standards and thus help us to capture a great share in International market.

**Keywords**

Global market, Ayurveda, Herbal medicines, Monographs, Quality standards

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## 1. Introduction

The Global herbal supplements market, in terms of value, is projected to reach around USD 86.74 billion by 2022 at a CAGR of 6.8% from 2016 to 2022, is expected to reach US$ 550 billion by 2030 at a CAGR 18.9% through 2030 and reach a valuation of US$ 411.2 billion by the year 2026. At present, the total global herbal market size is approx. 62.0 billion dollars. In this, India's contribution is only one billion dollars, that is a mere 1.6%, while the European union has the biggest market share of 45%, ASEAN countries 19%, Japan 16%, North America 11%, and rest of European Union 4.1%. Countries like Japan and China have successfully marketed their traditional medicines abroad. Their alternative therapies are well-accepted in Europe and US. Product like Ginseng – the famed aphrodisiac from China is having the same property as of Ashwagandha- an ayurvedic medicine, yet it accounts for over US$ 800M of international market as compared to all our herbs put together (which is less than US$ 1M). When compared with the Chinese and the Japanese level of penetration in the global market, India is not at all figuring anywhere.

The potentials of India that it has 16 Agro-climatic zones, 10 vegetative zones, 15 biotic provinces, 426 biomes, 45000 different plant species and 15000 medicinal plants that include 7000 in Ayurveda, 700 in Unani medicine, 600 in Siddha medicine and 30 in modern medicine. This makes India one among 12 megabiodiverse countries of the world, which despite having only 2.5% total land area, accounting for over 8% of the recorded species of the world. The forecast is that the global market for herbal products is expected to be $5 trillion by 2050. Herbal remedies would become increasingly important especially in developing countries. India, with its biodiversity has a tremendous potential and advantage in this emerging area.

If we spend a few minutes scrutinising the "modus operandi" by which the developed nations promoted their herbals in the market, we may be able to follow the same or similar programmes to bring our herbal wealth in the international market. In 2012, 73 WHO member states had established National Research Institutes for traditional and herbal medicine, and 119 were regulating herbal medicines. Yet, 105 member states cited "lack of research data" as a top difficulty with respect to regulatory issues related to the practices of traditional medicine, and 68 cited a lack of financial support for research on traditional medicine as a challenge. Clearly, this represents an opportunity for the global community to bring together centuries of varied experience and research and regulatory experts to improve the quality of traditional medicine.

The European Economic Community (EEC), recognizing the need to standardize approval of herbal medicines, developed a series of guidelines- The Quality of Herbal Remedies. These guidelines outline standards for quality, quantity, and production of herbal remedies. According to these guidelines, a substance's historical use is a valid way to document safety and efficacy in the absence of scientific evidence to the contrary. A guiding principle should be that if the product has been traditionally used without demonstrated harm, no specific restrictive regulatory action should be undertaken unless new evidence demands a revised risk-benefit assessment. Prolonged and apparently uneventful use of a substance usually offers testimony of its safety. The WHO guidelines give further advice for basing approval on existing monographs: If a pharmacopoeia monograph exists it should be sufficient to make reference to this monograph. If no such monograph is available, a monograph must be supplied and should be set out in the same way as in an official pharmacopoeia. To further the standardization effort and to increase European scientific support, the phytotherapy societies of Belgium, France, Germany, Switzerland, and the United Kingdom founded the European Societies' Cooperative of Phytotherapy (ESCOP). ESCOP's approach to eliminating problems of differing quality and therapeutic use within EEC is to build on the German scientific monograph system (below) to create "European" monographs. In Europe, herbal remedies fall into three categories. The most rigorously controlled are prescription drugs, which include injectable forms of phytomedicines and those used to treat life-threatening diseases. The second category is OTC phytomedicines, similar to American OTC drugs. The third category is traditional herbal remedies, products that typically have not undergone extensive clinical testing but are judged safe on the basis of generations of use without serious incident (Ghosh 2019).

In the Member States of the European Union (EU), a harmonized legislation on medicinal products has been enforced, which specifically defines herbal medicinal products and traditional herbal medicinal products. The scope was to create a regulatory environment that takes into account the particular characteristics of herbal medicinal products. The harmonization of standards is intended to harmonize assessment and facilitate access to the market in different Member States. The standards defined by the EU herbal monographs of the Committee on Herbal Medicinal Products (HMPC) and the quality requirements laid down in the European Pharmacopoeia, represent an excellent model of multinational harmonization of the regulatory environment for herbal and traditional medicines. It has also been demonstrated that this framework

is at least partially applicable for herbal and traditional medicines from Traditional Chinese Medicine (TCM) to gain access to the EU market. Moreover, the HMPC provides specific guidance documents and pilot projects on monographs on the safety and efficacy of Chinese herbal drugs. In the European Pharmacopoeia, the number of quality monographs of herbal drugs with an origin in TCM is continuously growing. These developments indicate that globalization of traditional medicines is an ongoing process. Communication and cooperation between regulators, the scientific community and interested stakeholders will set the stage for the convergence of diverse regulatory environments. This will contribute to worldwide availability of traditional medicines based on appropriate standards.

EDQM (European Directorate for the Quality of Medicines and HealthCare) is a Directorate of the Council of Europe that traces its origins and statutes to the Convention on the Elaboration of a European Pharmacopoeia. It supports the implementation and monitoring of the application of quality standards on medicinal products. Harmonized standards are published in the European Pharmacopoeia after adoption by the European Pharmacopoeia Commission. Members of the European Pharmacopoeia Commission include other countries as well as the EU Member States, and a further group of countries contributes as observers. The quality requirements defined in the European Pharmacopoeia are binding standards within the EU. The EDQM also provides reference standards for assays and tests. For pharmaceutical substances, the EDQM grants certificates of suitability, which confirm compliance with the standards of the European Pharmacopoeia and which can be part of the dossiers within an authorization procedure. The EDQM coordinates a network of Official Medicines Control Laboratories in order to collaborate and pool expertise, and to effectively use limited resources with the aim of achieving effective public quality control of medicines.

With respect to herbal medicinal products in the EU, the European Pharmacopoeia provides general monographs and specific monographs on herbal drugs or herbal drug preparations. These monographs address all quality issues related to herbal drugs and herbal drug preparations, such as methods, tests, identification, assays, heavy metals, aflatoxins, pesticides, and microbial contamination. Specific expert groups (i.e., 13A, 13B, and TCM) have been established at the EDQM to elaborate monographs on herbal drugs and/or herbal preparations (Werner and Wiesner 2019).

While the whole world is preparing itself to market herbal products in a huge way, India is found sleeping. In India, we do not have a separate Ministry on Herbal

medicines and they are merged with other disciplines like Ayurveda, Siddha, Unani, Homeopathy etc. under Ayush, which is controlled by top notch Ayurvedic experts. For the great scholars in Ayurveda, botanical names and the chemical constituents are anathema. The global market may not understand the intricacies of Ayurveda. Therefore, we have to market our products in language which they can understand, i.e., scientific language. Way back in 2004, I had written an article in Currect Science entitled "The impediments preventing India from becoming a herbal giant" (Daniel 2004) which was highly appreciated.

In India, herbal medicines (and Ayurvedic medicines too) are plagued with a myriad of inherent problems. They are the following:

1. Selection of plants
2. Adulteration of raw materials
3. Extraction procedures
4. Lack of knowledge on active components, synergism, biocatalysers, antioxidants etc.

## 2. Selection of Plants

In India, a curious phenomenon exists and that is "Problem of plenty". For every disease, a large number of curative plants exist in literature. In a recent book, Subramanian (2016) opines that there are 1085 plants subjected to at least one scientific study on their hypoglycaemic effects. He lists 585 plants traditionally used in controlling diabetes of which 115 plants are used as nutraceuticals. Similarly, hundreds of plants are used for rheumatism, cardiac problems, kidney stones, digestive problems, fever, cough, prostate problems, etc. Another overwhelming problem is that, for a Sanskrit name of a herbal drug, different plants are used at various parts of India. These different plants may belong to varying families or orders and have very different chemical constitutions. There should be a monograph in each one of these plants. Some of such drugs are the following:

A. **Shankhapushpi:** 4 plants such as *Convolvulus pluricaulis, Evolvulus alsinoides* (Convolvulaceae)*, Clitoria ternatea* (Fabaceae) and *Canscora decussata* (Gentianaceae).
B. **Ananthamool:** 4 plants like *Hemidesmus indicus, Decalepis hamiltonii, Ichnocarpus frutescens* and *Cryptolepis bucchanani* (Asclepiadaceae).
C. **Pashanbhed:** 6 plants like *Bergenia ligulata* (Saxifragaceae)*, Aerua lanata, Celosia argentea* (Amaranthaceae), *Ammania baccifera* (Lythraceae), *Coleus*

*ambonicus* (Lamiaceae), *Glossocardia linearifolia* (Asteraceae) and *Scoparia dulcis* (Scrophulariaceae).

**D. Gokhru:** 5 plants such as *Tribulus terrestris* (Zygophyllaceae), *Pedalium murex* (Pedaliaceae), *Acanthospermum hispidum, Xanthium strumarium* (Asteraceae) and *Martynia diandra* (Martyniaceae).

**E. Parpataka:** *Fumaria parviflora* Lam. (Fumariaceae).
Substitutes:

*i.* *Justicia procumbens* L. (Acanthaceae). Part used: Whole plant.
*ii.* *Oldenlandia corymbosa* L. (Rubiaceae). Part used: Whole plant.
*iii.* *Peristrophe bicalyculata* Nees. (Acanthaceae). Part used: Whole plant.
*iv.* *Polycarpea corymbosa* (L.) Lam. (Caryophyllaceae). Part used: Whole plant.
*v.* *Rungia repens* (L.) Nees. (Acanthaceae). Part used: Whole plant.

**F. Liquorice/Jeshtimadh/Mullethi:** *Glycyrrhiza glabra* L. (Fabaceae)
Substitutes:

*i.* *Abrus precatorius* L. (Fabaceae). Part used: Root.
*ii.* *Alysicarpus longifolius* (Spreng.) W. & A. (Fabaceae). Part used: Root.
*iii.* *Taverniera cuneifolia* (Roth) Ali. (Fabaceae). Part used: Root.
*iv.* *Maerua arenaria* (DC.) Hook. f. & Thoms. (Capparaceae). Part used: Root.

**G. Snakeroot/Senega:** *Polygala senega* L. (Polygalaceae) Root.
Substitutes:

*i.* *Acalypha indica* L. (Euphorbiaceae). Part used: Root.
*ii.* *Adhatoda vasica* Nees. (Acanthaceae). Part used: Root.
*iii.* *Polygala chinensis* L. (Polygalaceae). Part used: Root.
*iv.* *Catunaregam spinosa* (Thunb.) Tirveng. (Rubiaceae). Part used: Root.

**H. Ashoka:** *Saraca indica* L. (Roxb.) deWilld. (Caesalpiniaceae)
Substitutes:

*i.* *Bauhinia variegata* Linn. (Caesalpiniaceae). Part used: Stem bark.
*ii.* *Bombax ceiba* L. (Bombacaceae). Part used: Stem bark.
*iii.* *Polyalthia longifolia* (Sonia.) (Annonaceae). Part used: Stem bark.
*iv.* *Shorea robusta* Gaertn. (Dipterocarpaceae). Part used: Stem bark.
*v.* *Trema orientalis* (L) Bl. (Ulmaceae). Part used: Stem bark.

**I. Dasamoola** (Aparna et al. 2012)

i. **Bilva**, *Aegle marmelos* Corr. (Rutaceae) Bilva

ii. **Syonaka**, *Oroxylum indicum* Vent. (Bignoniaceae) as Syonaka
Substitute: *Ailanthus excelsa*
iii. **Gambhari**, *Gmelina arborea* Linn. (Verbenaceae)
Substitutes: *Gmelina asiatica* Linn, *Trewia nudiflora* Linn and *Premna flavescens* Ham
iv. **Agnimantha**, *Clerodendrum phlomidis* Linn.f. or *Premna integrifolia*
Substitutes: *Premna mucronata* Roxb., *Premna corymbosa* Rottl., *Clerodendrom inerme* Gaertn. and *C.multiflorun* Kuntze
v. **Patala**, *Stereospermum suaveolens* (L.f.) DC.
Substitutes: *Radermachera xylocarpa* Roxb., *Stereospermum colais* Mabb., *S. chelonoides* DC., *S. tetragonum* DC. and *S. personatum* Chatt.
vi. **Brhati**, *Solanum indicum* Linn. (syn. *Solanum anguivi* Lam.)
Substitutes: *Solanum melongena* Linn.
vii. **Kantakari**, *Solanum xanthocarpum* Schard and Wendle
viii. **Salaparni**, *Desmodium gangeticum* (L.) DC/ *D. laxiflorum* DC./ *Pseudrathria viscida* W & A.
Substitutes: *Desmodium polycarpum* DC., *Uraria lagopodiodes* DC., *U. hamosa* Wall., *Flemingia paniculata* Wall. and *F. stricta* Roxb.
ix. **Prsniparni** *Uraria picta* Desv., *U. lagopodioides* DC., *Desmodium triquetrum* DC.
Substitutes: *Uraria hamosa* Wall.
x. **Goksura**, *Tribulus terrestris* Linn.
Substitutes: *Pedalium murex* Linn., *Tribulus alatus* Del., *Acanthospermum hispidum* DC, *Xanthium strumarium* L. and *Martynia diandra* Glox.

Of the ten plants of Dasamoola, the herbaceous plants are used as a whole because of the difficulties in collecting tons and tons of dry roots. This is a dangerous practice as the roots have a different chemistry than that of other plant parts as evidenced in *Solanum americanum* (personal data). A systematic study on the various parts of these plants is lacking. Similar is the case with the tree species of Dasamoola. As the collection of roots necessitates uprooting the whole trees, many manufacturers use the stem also along with roots. Therefore, these practices practised in India are absolutely unethical.

### 3. Adulterants - The Major Factor

Apart from the type of substitution of original plants, it is observed that 80% of raw materials in India are adulterants (Chopra et al. 1956). This is the most serious and

dangerous problem existing in India. Most of the raw materials are collected by unskilled laborer's and hardly a botanist knowing Taxonomy is available with the suppliers. Many a times unrelated plants get mixed with the genuine plants. As there is no quality control with most of the suppliers, it is the buyer who have to guarantee the genuineness of drug. A plant material can be identified with the help of morphological, micromorphological, anatomical or phytochemical character and a trained botanist can do all these. In how many pharmaceuticals are there trained Botanists?

I had the misfortune to visit the storehouse of a major supplier of herbals. The whole area was in shambles. Bags were arranged in shelves, but there were rats and lizards, their excreta, dust and dirt everywhere. When I checked the materials in one of the gunny bags, the plant material was infected by saprophytic fungi like *Mucor, Aspergillus* etc. In addition, the material had leaves torn and/or infected with pathogenic fungi of the plants. Thus, aflatoxins are a major concern in Indian materials. These toxins cause major outbreak of hepatitis, multiple aflatoxicosis etc. leading to acute illness and deaths.

## 4. Extraction Procedures

### 4.1. Selection of medicinal plants in a formulation

A number of herbal pharmaceuticals are copy cats. They make a list in a formulation by copying the names of plants from a successful formulation of a well-known company, change the sequence and percentage and make a new formulation which is partly successful.

### 4.2. Polyherbal or monoherbal formulations!!

Some manufacturers have the notion that the more plants you add in a formulation, the more potent it is. This is a wrong notion, because if your formulation has 40 component plants, the content of each plant will be a mere 2.5%. If there is an active principle in that plant, it will be in micrograms. So, the product will have active principles of all 40 plants, but each in miniscule amounts, unable to cause any pharmacological activity. The lesser the number of component plants, each will be properly represented in the drug. I have a product with a single plant, two products with 2 plants and 3 products with three plants each. All are giving good results.

### 4.3. Best ways to prepare a formulation

Creating an effective supplement is an arduous job. One has to read quite a lot of literature on properties of medicinal plants. The tips to create a good formulation is as follows:

1. If there are many plants showing anti-diabetic property, select the plants on which a large number of clinical researches had been carried out. Since the clinical researches prove the efficacy of a herb, your medicine also will give results. If one of the plants is found better keep it as the major component.
2. Insist on the correct botanical identity of the drug. You should have a trained Botanist or Pharmacist who should conduct a random checking on the raw materials.
3. A practical advice: Do not bargain on the cost of raw materials!! You may get a reduction of 5 to 10% in costs, but the supplier will add more than 5-10% spurious materials.
4. Your formulation should contain locally or easily available plants. If it is to be transported from faraway places, the cost of transport also will be on you.
5. It is better to get raw materials and extract them at your premises. If somehow plants are not available and you have to get extracts, see that you have a good laboratory and scientists to analyze extracts for the active and characteristic components and their concentration.
6. Extract plant materials using deionised water. This will prevent lead and other metal contaminants from your medicine.
7. Extract plant material consecutively three times, at least 2 hours each time with 10 times fresh water. As there are many compounds having different solubilities in plants, the first extract would contain about 50% of the soluble materials. The easily soluble glycosides will be extracted easily and first. This will saturate the extracts and no more compounds come into solution even if you boil for days. Now filter the extract through filter clothes, take the residue and extract with same amount of water. This will bring 20-25% of compounds remaining in plants unextracted in first extraction and contains compounds which are moderately soluble in water. Filter this also and the residue is extracted with a third aliquot of water for 2 hours. This extract will give you 10-15% of compounds which have very less solubility. The rest of compounds will not come in water. Combine all the three extracts and concentrate it to dryness. In practice, the yield will be double when compared with that of a single extraction and thus very profitable.

**4.4. Water soluble and insoluble compounds**

About 40% of the plant compounds are insoluble in water. Only the polar molecules get dissolved in water. All the lipids such as oil (both fixed and volatile oils) resins, steroids, carotenoids etc remain within the plant even after extraction with water.

The Table 1 shows the number of water soluble and lipid soluble compounds in two plants, Ashwagandha and Safed Musali. The plants containing lipids were customarily kept in oil to dissolve out these compounds. Such oil extracts would contain a limited amount of lipids. But concentrating oil to get an extract rich in biomolecules is a great problem. Therefore, an ideal extraction involves a first extraction using an organic solvent like isopropyl alcohol and a second extraction of the residue with water. To give an example garlic and ginger contain sulphides and gingerols which are insoluble in water. Even curcuminoids need to be extracted with alcohol.

**Table 1: Showing the compounds soluble in water and alcohol**

| Plant | Hydrophilic compounds | Lipophilic compounds |
|---|---|---|
| ***Chlorophytum borivlianum* S. & F/** | Chlorophytoside I, Borivilianosides of the F, G, and H series; polysaccharide, and Vitamin C at 0.67% of dry weight | **Lipids:** Neotigogenin, Neohecogenin, and Tokorogenin· Fatty Acids (linoleic acid, 11 and 14-Eicosadienoic acid, hexadecane), Stigmasterol and other phytosterols consisting of 0.9% total weight |
| ***Withania somnifera* Dun.** | Glycosides such as withanoside-IV, -VI, sitoindoside-IX, -X, coagulin Q, and viscosalactone | Abrine, trigonelline, abruslactone A, hemiphloin, montanyl alcohol, abrol, abrasine, precasine and precol, abraline, abricin, abrusgenic-acid, abrusgenic-acid-methyl-ester, abruslactone, abrussic-acid, campesterol, cycloartenol, delphinidin, gallic-acid N, N dimethyl-tryptophan, N, Ndimethyl-tryptophan-metho-cation-methyl-ester, abruquinones A, B, C, D, E, F, O, G, abruslactone, and oleanolic acid |

### 4.5. Other snippets

There are number of instances where a good knowledge of phytochemical methods becomes handy. Some of them are the following:

1. When alkaloid containing plants are extracted with water, adding 0.5% conc. HCl or acetic acid will enhance more amount of alkaloids getting extracted.
2. Extracting phytochemicals from mucilage containing plants with water will bring out all polysaccharides in water to make it a very viscous solution. In such cases,

extracting the dry plant powder with alcohol (IPA) will bring out pure chemicals. For example, quinones of *Aloe*, and *Cassia* seeds etc.

**5. Lack of Knowledge on Active Components, Synergism, Antioxidants etc.**

Ayurvedic practitioners do not believe in active principles; since they believe that the plant act as whole. This concept is not acceptable to the western world which attribute the medicinal properties of any substance to a single or a group of compounds. But there are a great number of researches on the constituents of Indian medicinal plants, done in India and abroad. But mention is to be made on thousands of research articles where the plant is tested for groups of compounds like alkaloids, saponins, phenolics etc. Most of these papers use "Flimsy tests" to ascertain the presence of a group. For example, saponins are tested by shaking an aqueous solution vigorously for 30 seconds when saponins give a persistent froth. But the plants containing mucilage will also give froths. Such articles are to be shunned. Now the awareness is very high among consumers on what they eat or use. Unless we tell our customers what the supplement contains in terms of scientific language, our products will not be supported.

Synergism is another phenomenon playing a very big role in the activity of herbal medicine. A single Metabolome, the sum total of primary and secondary metabolites, contains about 4,000 compounds (it may even go up to 10,000). Some of the very common compounds especially phenolics have pharmacological activities which we never thought of earlier. Duke (1997) describes ferulic acid, gentisic acid, kaempferol glycosides and salicylic acid as pain relievers. Ascorbic acid, cinnamic acid, coumarin, myricetin, quercetin and resveratrol are explained anti-inflammatory. Sometimes a plant would contain more than one compound having the same activity. For example, both coriander and liquorice contain 20 chemicals with antibacterial action; Oregano and rosemary has 19; Ginger 17; Nutmeg 15; Cinnamon and cumin 11; Black pepper 14; Bay 10 and Garlic 13. Even the amount present in plants varies. For example, Liquorice contains up to 33% bactericidal compounds (dry weight basis); Thyme 21%; Oregano 8.8%; Rosemary 4.8%, Coriander 2.2% and Fennel 1.5%. Therefore, all these factors influence the activity of a herbal supplement.

The antioxidant content of a medicine also is an attribute helping the acceptance of a herbal medicine. The oxidative stress, in which the free radicals outweigh antioxidants in number, is suggested to be the cause of aging and other diseases like atherosclerosis, stroke, diabetes, cancer and neuro-degenerative diseases such as

Alzheimer's disease and Parkinsonism. Studies conducted worldwide have provided enough evidence stating that providing the body systems with sizable amount of antioxidants may correct the vitiated homeostasis (Tiwari 2001). Products of sea-buckthorn (*Hippophae rhamnoides*- Elaeagnaceae) are sold only because of its antioxidant content.

## 6. Conclusion

From the above discussion it is evident that Indian Herbal Industry needs an overhauling on its policies and practice. A few steps in this direction are the following:

1. Establishment of a section or Ministry on Herbal medicines separate from Ayurveda, Unani and Siddha.
2. Preparation of Monographs of High quality (comparable to those published by European Economic Community) with the active principles, other compounds, antioxidants and available clinical researches.
3. Establish Quality standards for all the plants on quality, quantity, and production of herbal remedies. This involves quality standards for the plant including its morphological, anatomical, micromorphological, phytochemical, aflatoxins and mineral and pesticidal contamination.
4. Establishing proper extraction standards for each plant drug so as to extract its active principles, antioxidants and synergistic compounds.

If all these issues are taken care of, our products, which are very wide, will get enough exposure and market.

## 7. Summary

Though we have an abundance of herbal drug resources, we are a very insignificant player in the global market of Herbal medicines. The prevalence of common names for diverse herbs, poor knowledge of phytochemicals present, high adulteration including unethical extraction procedures are the main issues plaguing our herbal supplements. Establishment of a section or Ministry on Herbal medicines separate from Ayurveda, Unani and Siddha; preparation of Monographs of High quality (comparable to those published by European Economic Community) with the active principles, other compounds, antioxidants and available clinical researches and establishing Quality standards for all the plants on quality, quantity, and extraction methods of all available plants herbal remedies will elevate the levels of our supplements to global standards and thus help us to capture a great share in Global market.

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