The Development and Future of BRICS Countries in the Pharmaceutical Sector

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Abstract:
BRICS is the acronym for an association of five major emerging national economies: Brazil, Russia, India, China, and South Africa. It is a union of like-minded governance. The acronym “BRICS” was initially founded in 2001 by economist Jim O’Neill, of Goldman Sachs, in a report on growth prospects for the countries of Brazil, Russia, India, and China – which together represented a significant share of the world’s production and population. In 2006, the four countries initiated a regular informal diplomatic coordination, with annual meetings of Foreign Ministers at the margins of the General Debate of the UN General Assembly (UNGA). The interaction was successful and led to the decision that the dialogue was to be carried out at the level of Heads of State and Government In annual Summits The first Summit was held in Yekaterinburg in 2009, which became BRICS in 2011 with the inclusion of South Africa. Moreover, BRICS became a new and promising political-diplomatic entity, far beyond the original concept tailored for the financial markets. After the Yekaterinburg Summit, five annual Summits were held (Brasilia, 2010; Sanya, 2011; New Delhi, 2012; Durban, 2013; and Fortaleza, 2014). The leaders of the member countries have been holding at least one annual meeting. In Durban last year, the first cycle of Summits was completed, each member country having hosted a meeting of leaders. Regarding the first pillar, the efforts towards reforming the structure of global governance, especially in the economic and financial fields- Financial G-20, International Monetary Fund, World Bank – receive a special emphasis, as well the reform of political institutions, such as the United Nations. Intra-BRICS cooperation has also been gaining density: a broad agenda that has been developed, comprising areas such as finance, agriculture, economy and trade, combating transnational crime, science and technology, health, education, corporate and academic dialogue and security, among others. The objective of this study is to compare the Pharmaceutical Regulations Followed by the BRICS Countries, to study the Growth of the BRICS Countries in the Pharmaceutical sector and to study the impact of BRICS and the pharmaceutical industry.

Keywords: BRICS Summit, Generic drug Registration, Emerging Markets, Make in India, BRICS Trade.

INTRODUCTION:
BRICS is the acronym for an association of five major emerging national economies: Brazil, Russia, India, China , South Africa. It is a union of like-minded governance. The acronym “BRICs” was initially founded in 2001 by economist Jim O’Neill, of Goldman Sachs, in a report on growth prospects for the countries of Brazil, Russia, India, and China – which together represented a significant share of the world's production and population. The BRICS group also acts as a bridge between developed and developing countries. For example, in the WTO, the BRICS countries are trying to promote a fair order regarding agricultural policies. They are attempting to promote the liberalization of the international economic order to diminish agricultural subsidies in the United States and the European Union, which would make developing countries’ agricultural products more competitive.

4. The BRICS group will also play an increasingly important role in assisting developing countries in gaining an advantage in trade and climate change negotiations, as well as on issues related to the export of manufacturing products.

5. Developing countries on the periphery of the group will be able to leverage the NDB and the CRA to increase their bargaining power.

6. The group established the BRICS Business Council, made up of 25 prominent entrepreneurs from the five countries and representing many industries and economic sectors.

7. The BRICS also formed an information-sharing and exchange platform that expands beyond economic cooperation to also involve educational, cultural, and environmental engagement.

8. They have a shared interest in challenging the current governance of Western financial institutions like the International Monetary Fund and the World Bank for that they have announced the establishment of the bank.

9. They will advocate for the interests of middle powers on global forum.

THE ROLE OF BRICS IN THE DEVELOPING WORLD
The role of BRICS Brazil, Russia, India, China and South Africa as emerging protagonists in international development cooperation is significantly and rapidly changing. Over the last decade, BRICS have increased their financial as well as technical assistance and established distinct ways and means of economic cooperation, especially through the southsouth - cooperation with Low Income Countries (LIC).

BRICS are striving to develop political influence, thereby changing the traditional western donors such as the EU. BRICS impact on LICs through trade, foreign direct investment and development financing are significant and these south- south effort need to be reflected in EU development strategies. The high level conferences in Paris, Accra and Monterrey have not appreciated BRICS’ role as emerging donors, but the Busan Global Partnership strategy has considered obvious changes in global development architecture more openly. Size, key areas and institutional settings of foreign assistance are differing among BRICS.
REGISTRATION OF DRUGS IN BRAZIL

**ANVISA** (National Health Surveillance Agency) or (Agencia Nation De Vigilencia Sanitaria) is the regulatory agency that controls the management, import, storage, distribution and sale of health related products and services in the country.

**Types of Product Registration:**
For registration purposes, ANVISA classifies products in the following categories (Law 9.782/99):
1. Medicine Products (Drugs): for human use, their active substances and other inputs;
2. Pharmaceutical Raw Materials: drugs or raw materials to be used in medicines.
3. Health Product: Medical-hospital, Odontological and Hemo/therapeutic equipment and materials and those intended for laboratory and image diagnosis.

**Registration:**
- The process to request the registration of the national and imported drug products shall consist of the documentation below. Applications with incomplete documentation will not be analyzed. A maximum of three manufacturers shall be accepted per active ingredient.
- Proof of payment of Sanitary Surveillance Inspection Fee or proof of exemption (original);
- Up-to-date copy of the company’s Operation License (Sanitary Permit);
- Copy of the company’s Functioning Permit or of the Special Functioning Permit when fitting, published in the DOU.
- Copy of the (GMP) Good Manufacturing practice emitted by ANVISA for the production line in which the drug product will be manufactured.

**For imported drug products:**
- Submit the Medicine Registration Certificate including the manufacturing site that shall be the same manufacturing site of the drug product being object of registration in Brazil.
- Specify the stage of the imported drug product as raw material, in bulk or finished product;
- Copy of the Good Manufacturing and Control Practices certificate (GMP) emitted by ANVISA for the production line in which the drug product of registration will be manufactured.
- Copy of Good Manufacturing Certificate emitted by ANVISA for the packaging line facilities of the company requesting registration when dealing with raw materials or bulk products;
- Copy of the Good Manufacturing and Control Practices certificate (GMP) of at least one production line emitted by ANVISA for the facilities of the company requesting registration in cases of imported raw materials or in bulk products in which the registration petitioner has a permit to manufacture drug products or needs to outsource its distribution, storage and/or packaging.
- Submit the quality control specifications and methodology used by the importer. These shall be the same ones submitted for the approval of the registration.
- Submission of the copy of the Pilot Batch Production Notification with the ANVISA protocol number, if existent.
- The Up-to-date copy of the technical responsibility certificate emitted by the Regional Pharmacy Council of the federated unit in which the pharmacist acts professionally.
- The compliance certificate with the conditions established in the legislation in force for the control of (TSE).
- FP1 and FP2 petition forms
- Models of the package insert, label and cartridge. The information in the package insert can be no less than that contained in the package insert of the Reference Drug.
- Production report
- Standard formula; production process; equipment used in the drug product’s manufacture with details of the maximum individual capacity and definition of the size of the industrial batch;
- Complete description of the master formula with designation of the components, respecting the denominations of the DCB, INN or the name listed in the chemical abstract substance (CAS), in the order of priority
- Description of the amount of each substance expressed in the metric system or Standard unit, with indication of its function in the formula and the respective quality specification reference described in the Brazilian Pharmacopoeia or, in its absence, in another official code authorized by the legislation in force;
- A Copy of the complete production and quality control reports including the order of production, detailed production process and ongoing controls is required referring to three manufactured pilot batches or to three industrial batches produced in the last three years. In case of drug products with three or more different concentrations and proportional formulas, submit the reports of the smallest and highest concentration.
- Production and quality control report of a batch of the drug product produced with the active ingredient that corresponds to each manufacturer presented;
- Results and evaluation of the accelerated stability study of a batch of the drug product produced with the active ingredient that corresponds to each manufacturer presented, in compliance with the criteria contained in the Guide For Stability Studies.

**PROCEDURE FOR DRUG REGISTRATION IN RUSSIA:**

**Drug regulatory bodies:**
- Federal Service on Supervision in Sphere of Public Health Services and Social Development (Roszdravnadzor)
- Nat
- National Centre of Pharmaceutical Products Expertise (FGU).

**National Centre of Pharmaceutical Products Expertise (FGU):**
- Section of trade name experti131313se
- Institute of Preclinical and Clinical Expertise
- Institute of Products Quality Control
- Section of coordination and data-base handling
- Specialized Commissions (bioequivalence, clinical, preclinical)
- Quality Control Laboratory

**General Requirements:**
- GMP Certificate
- Valid Manufacturing License.
- Complete Dossier of a Drug In Russian language.
- Fees towards Registration
- Power of Attorney (if any)

**Procedure of dossier submission:**
- It should be in Russian language
- Electronic and Paper form in 2 copies
- A standard Template should be created.
- Submit dossier directly to FGU
- Complete Review of dossier by FGU (approx. 18 months)
- Issue of certificate/ Rejection by Roszdravnadzor.

**REGISTRATION OF DRUGS IN INDIA**

**Regulatory Agency:**
Central Drug Standards Control Organization (CDSCO). Control by Drug Controller General of India under Ministry of Health and Family Welfare
Types of drug registration:
Pharmaco-chemical drugs, medical bio-products, vaccines, serum containing antibody, bio-products for diagnosis in vitro, traditional drugs, drugs originated from pharmaceutical materials, medicinal raw materials shall be registered in the following types:
1. New drug registration
2. Generic registration;
3. Registration renewal

1. New drug registration dossier of a new pharmaco-chemical drug, vaccines, serum containing antibody, medical bio-product should include:

Introduction
A brief description of the drug and the therapeutic class.

Chemical and pharmaceutical information
- Chemical name, code name or number, if any; non-proprietary or generic name, if any; structure; physic-chemical properties.
- Dosage form and its composition
- Test specifications
- Active ingredients
- Inactive ingredients
- Tests for identification of the active ingredients and method of its assay
- Outline of the method of manufacture of active ingredients.
- Stability Studies

Marketing information
- Proposed package insert/promotional literature
- Draft specimen of the label and carton

Special studies conducted with the approval of Licensing Authority
- Bioavailability/ Bioequivalence and comparative dissolution studies for oral dosage forms
- Sub-acute animal toxicity studies for intravenous infusions and injectables.

2. First-time registration dossier of generic drugs (only apply for pharmaco chemical drugs), should include:
   a) Administrative dossier and product information;
   b) Quality dossier.

3. Registration renewal dossier, including:
   a) Administrative dossier and product information;
   b) Quality dossier;
   c) Post-marketing report

Country Specific requirements for India:
- A copy of plant registration/approval certificate issued by the Ministry of Health/National Regulatory Authority of the country of origin.
- A copy of approval, if any, showing the drug is permitted for manufacturing and/or marketing in the country of origin.
- A copy of Pharmaceutical Product Certificate
- Certificate of Good Manufacturing Practices
- Batch release certificate issued by NRA- National Regulatory Agency for imported products.
- Undertaking to declare
- A copy of Site Master file
- Certificate of Analysis from Central Drug Laboratory (India) of three consecutive Batches
- Product Permission Document (PPD)
- General information on drug product
- Raw material Specification
- Product Labeling (should conform to the specifications under the Drugsand Cosmetics Rules 1945)
- Primary, secondary package label and package insert in English
- Summary of the packaging procedures for Indian shipments (including box sizes, packing volumes)
- Environmental risk assessment

REGISTRATION OF GENERICS IN SOUTH AFRICA:
Regulatory Authority: MCC (medicines control council)

Types of Applications:
- Multisource/generic applications and innovator product line extension applications that include clinical information in support of efficacy and safety of the formulation/dosage form, or indication/s or dosage regimen.
- Multisource/generic applications and innovator line extension applications that include comparative bio-availability/bioequivalence studies as proof of efficacy.
- Multisource/generic applications and innovator line extension applications that include comparative dissolution studies as proof of efficacy.
- Multisource/generic applications and innovator line extension applications that include any other comparative studies as proof of efficacy.

REGISTRATION OF GENERICS IN CHINA:
Regulatory Authority: China- State Food and Drug Administration (SFDA)

Classification of Drugs:
In China, drugs are classified as three types: Chemical Drugs, Biological Drugs, or Traditional Chinese Medicine/ Natural Drugs.
- a) For chemical drug registration, there are 6 different classes
- b) For therapeutic biological product registration, there are 15 different classes
- c) Biological product registration (vaccines) also contains15 different classes

Registration Procedures:
According to the current information there are two different registration procedures available in China. On the one hand there is the standard review procedure which is applicable for most of the NDAs. The review time for an NDA for an NCE takes approx. 13.5 months whereas the NDA for an NBE takes approx. 24 months. During the standard review procedure it is not possible to have any consultation of CDE in order to discuss topics of the NDA procedure. Also rolling submission of the NDA dossier is not possible for the standard review procedure. The second registration procedure which is established by SFDA as of January 1st, 2009 is the special review procedure. This new procedure is applicable for NCEs or NBEs which are not yet approved in any market, for new medicinal products which are used for treatment of AIDS, malignant tumour and/or rare disease and have obvious clinical therapeutically advantages and for new medicinal products which treat diseases for which there is no effective therapy. The review time for an NDA under this special review procedure takes approx. 12 months. Another advantage of the special review procedure is that a rolling submission is permitted (e.g. safety, stability, CMC development, etc.) and also pre- and in process consultation at CDE during the NDA review process is allowed. The advantage of special review procedure will be lost once the drug is approved in any country worldwide.

REGISTRATION OF GENERICS IN SOUTH AFRICA:
Regulatory body: MCC (medicines control council)

Types of Applications:
- Medicine applications for registration for humans are divided into the following types for the determination of fees and allocation to reviewers for evaluation:
- Multisource/generic applications and innovator product line extension applications that include clinical information in support of efficacy and safety of the formulation/dosage form, or indication/s or dosage regimen.
- Multisource/generic applications and innovator line extension applications that include comparative bio-availability/bioequivalence studies as proof of efficacy.
- Multisource/generic applications and innovator line extension applications that include comparative dissolution studies as proof of efficacy.
- Multisource/generic applications and innovator line extension applications that include any other comparative studies as proof of efficacy.

Publication References
• others, not mentioned above e.g. liquids/solutions.

Requirements of An Application:
From 1 July 2009 submissions in ZA CTD (Common Technical Document for South Africa) format will be accepted.

Part 1 Administrative Information:
The details as per the application form should be completed.

a) Applicant/prospective holder of the certificate of registration
b) “Business address” in relation to a business that is carried on in the Republic of South Africa, means the full physical address of the premises where such business is conducted.

c) Person authorized to communicate with Council.

d) “Proprietary name” means the name that is unique to a particular medicine and by which it is generally identified and which, in the case of a registered medicine, is the name approved in terms of Section 24 (8) of the Act in respect of such medicine.

Medicines which are not identical in composition or strength are not regarded as the same medicine and should be submitted separately. However, different strengths of the same dosage form may be submitted individually in one dossier.

e) Pharmacological classification.

f) Dosage form: Select the most appropriate dosage form from this list, when completing the administrative data. This dosage form will also be reflected on the medicine registration certificate.

g) ‘Approved name’ in relation to a medicine means the internationally recognised name of such medicine, or such other name as the Council may determine, not being a brand name or trade name registered in terms of the Trade Marks Act, 1963.

h) The API and strength per dosage unit applies only in the case of a dosage form with a single API.

i) The descriptive name of biological medicine, e.g. viral vaccine, viral antiserum, bacterial vaccine, bacterial antiserum, allergen, immunoglobulin or blood product, as given in a recognized pharmacopoeia or where such name does not exist, a name determined by the Council.

j) The country of origin, i.e. the country where the original development was done. If development took place in more than one country all the countries should be specified.

k) The name and complete physical address including the country, of all the manufacturing and packer facilities/sites for the medicine should be given. The site performing each stage of manufacturing and packaging where these do not all occur at the same site, should be clearly indicated.

l) The name and complete physical address including the country, of the final product testing laboratory(ies) (FPRC) and final product release responsibility (FPRR) should be given. If applicable the details of both the pre- and post-importation FPRC and FPRR should be given.

The following are required for all the manufacturing, packaging, FPRC and FPRR sites:

i) Site (Plant) Master File (SMF)

ii) Confirmation of a Technical agreement between the parties, and a schedule of the limits of responsibilities accepted by each of the parties as specified in a Technical agreement or addendum to the contract should be included.

iii) From the country of manufacture, if not South Africa:

• A copy of manufacturing licence or a statement by the competent medicine regulatory authority that the manufacturing facility complies with GMP.

• A copy of the Certificate of GMP compliance in terms of the WHO Certification Scheme.

• Confirmation that the manufacturing site is inspected at regular intervals and a copy of the latest written inspection report (not older than 3 years), from a Medicine Regulatory Authority of the country of origin is available for inspection.

• A copy of the registration or marketing authorisation certificate.

• A Certificate of a Pharmaceutical Product in terms of the WHO certification scheme (Free Sales Certificate)

• FPRR should be vested in a person who has appropriate knowledge of the relevant aspects of the medicine and who is either the holder of the certificate of registration or in the employment of the holder of such a certificate.

• For subsequent amendments to the dossier PART 1Ac Amendment history, of the MRF1 should be completed in accordance with the Amendments guideline. Deletion of “post registration” as PART 1Ac history must be completed for all dossier amendments, pre- and post-registration.

All subsequent responses to Committees’ recommendations and Council resolutions must include a valid declaration that the response and information submitted is true, correct and relevant, i.e. PART 1A must be duly completed, dated and signed for each response.

DISCUSSION:
1) Building BRICS- pharma’s key emerging markets are becoming giants.[10]

The BRICS nations are developing pharmaceutical markets that are comparable in size to many of their more mature western counterparts. But in terms of the size of the opportunities for future growth, traditional markets are seemingly being dwarfed by the burgeoning behemoths of Brazil, Russia, India, China and South Africa. In fact, such has been the rate of progress that their collective tag as ‘emerging’ nations is undoubtedly out of date.

2) The journey towards becoming giants.[8]

The grouping of four diverse nations under one general banner-BRICS- has served a useful purpose for analysts, economists and corporate strategists for many years, but it has also masked the idiosyncrasies and challenges faced by each nation as their evolution has played out. Their individual journeys from emerging markets to major players on the global stage have not followed a template, but have underpinned by local variations on common challenges.

3) The future of the pharmaceutical industry is in emerging markets. When the growth at home slows, smart companies expand abroad.[5]

Stagnation suffocates a company’s growth, so when profits start to level out after years of growth, smart companies immediately begin to scour the globe for new sources of revenue to move their organizations back into a more profitable position. For the pharmaceutical industry, expanding into emerging markets is inevitable and will prove to be a critical step in the industry’s evolution, despite initial growing pains. A pharmaceutical company establishes a fully integrated system including the research and development processes all the way to the finished goods facilities owned by the same company. The up-front investment is large, but controlling all assets in the process has traditionally served as a reliable model in the long run.

The Pharmaceutical companies began looking to the promise of growth abroad in the BRICS. These countries comprise the top tier of emerging markets in the world because they are projected to be the most economically stable and with the likelihood of becoming similar to the US market, in time. As their economies matured, the most prevalent health conditions in the BRICS began to mirror those in the developed countries, such as the US. Issues such as chronic disease, diabetes, and obesity are becoming more prevalent as the middle class grows and life expectancies increase. This change in need is opening a whole new host of consumers for pharmaceutical treatments that were traditionally marketed to the western patients.

4) Proceed With Caution[4]

There are growing pains which should be expected. Instead of the enticing financial incentives in these countries, many top pharmaceutical companies have lost revenue from seeking to operate in these emerging markets without proper risk assessments.
and planning prior to implementation. This could be due to the fact that the supply chain operations, manufacturing processes, and regulatory requirements are vastly different from that of the Western world. With a primarily out-of-pocket payment system for healthcare services due to the underdeveloped nature of emerging market health infrastructure, pharmaceutical companies stand to both improve the standard of living of patients in the BRICs while also expanding their company’s global reach and customer base. Providing the expanding middle class with high-margin generics from Western brands is the hallmark of this sort of expansion. While it seems to be a simple solution, the key to success involves significant strategy rather than a “one size fits all” approach.

5) **Transforming the business potential of BRICS**

The BRICS nations have evolved significantly over the years. Today, BRICS countries are playing a far more important role in the global economy. They have spoken with one voice about the most important global economic and financial challenges like co-ordination of monetary and fiscal policies, macro prudent regulations, economic development, and so on. Formation of the New Development Bank and establishment of the Contingent Reserve Arrangement has only strengthened BRICS as a grouping. BRICS is being increasingly recognized as a reckoning global force economically as well as on the socio-developmental front.

6) **Since India is presiding over BRICS this year, one cannot skip the questions about India’s remarkable growth.** The numbers are stunning, although some experts are quite critical of those figures. This is how India is tackling the main challenges of India’s economy.

India has consistently been a bright spot on the macroeconomic front and we believe it would continue to do so in the foreseeable future. While growth has moderated in the first quarter of the year, growth momentum would pick up in the second half of the year. FICCI’s Economic Outlook Survey estimates growth to be 7.8% in 2016-17, which is actually higher than the projection made in our previous survey indicating greater optimism with regard to our overall growth prospects.

Consumer demand which has been weak is expected to pick up with good monsoons and as benefits of the pay commission award percolate. Reform initiatives undertaken by the government and mega initiatives such as ‘Make in India’, ‘Digital India’ and ‘Skill India’ would usher in a period of high and sustained growth.

7) **This is how BRICS countries participate in such initiatives like “Make in India”, “Digital India” Examples of cooperation between India and its BRICS peers on this front.”**

India has sought participation of BRICS countries in its flagship initiatives such as ‘Make in India’, ‘Smart Cities’, ‘Skill India,’ and ‘Digital India.’ There have been regular dialogues and exchanges with our BRICS partners on these areas. Russia was the first country to invest under the ‘Make in India’ initiative in the defence sector. HAL has entered into a Joint Venture with Rostec of Russia to manufacture Kamov choppers in India, while Uralvagonzavod and the Kalyani Group have agreed on joint production of self-propelled artillery within the framework of the ‘Make in India’ program. Our government is moving to address some outstanding issues and a lot of measures have been taken, including steps to improve ease of doing business by simplifying procedures, bureaucratic overhaul, easing investment norms for a number of sectors and introduction of an investor friendly tax regime amongst others.

8) **The New Development Bank (NDB) has completed its first year of operations. The main achievements so far.”**

The establishment of New Development Bank has been a key milestone for not just BRICS economies but for all emerging economies and developing countries. It is a testament of coming of age of these countries in the world of development finance. In its one year since inception, the NDB has put in place all the major operational policies and procedures of the Bank. The NDB board has approved the first set of projects with a total commitment of US $811 million. Through its first set of loans, the Bank has established its credentials as an institution that supports green and sustainable infrastructure.

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<th>Drug Regulatory Authority (DRA)</th>
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<td><strong>BRAZIL</strong></td>
<td><a href="http://www.anvisa.gov.br">www.anvisa.gov.br</a></td>
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<td>Law on Circulation of Medicines, 2010</td>
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<td>Application for state registration of medicinal product [Form 1]</td>
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<td><strong>SOUTH AFRICA</strong></td>
<td><a href="http://www.mccza.com">www.mccza.com</a></td>
<td>The medicines and related Substances control Act [Act 101 of 1965]</td>
<td>Chairperson</td>
<td>English</td>
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SUMMARY:

• The pharmaceutical companies of BRICS countries are accelerating efforts through R&D investment, licensing deals, acquisitions and other partnerships. India is recognized for the generic drug industry, offering manufacturing expertise for outsourcing.
• BRICS has to also deal with a lot of challenges at present, since they are all emerging countries and differ in size and region.
• The BRICS are facing demographic disease trends, changing market designs and evolving regulatory requirements. Indeed, the entire global economy is at a difficult juncture at present.
• The growth of BRICS is compared to the US markets because of the market size and its promising potential. The changes in India's population and economy which changes the country's epidemiological profile.
• What has been broken can certainly be fixed, and BRICS, along with the rest of the global economy, through better co-ordination and collaboration will emerge stronger.

CONCLUSION:
BRICS has made laudable efforts to enhance co-ordination in the global arena and this is well established in various multilateral and pluri-lateral initiatives. BRICS nations have worked together in promoting stability and reliability of the global financial system through the BRICS Contingent Reserve Arrangement (CRA), through which countries have agreed to provide short-term liquidity support to members through currency swaps to help mitigate any external contingency. The New Development Bank is another notable achievement. BRICS is also discussing a framework for BRICS e-commerce cooperation to promote cross-border e-commerce. Intra-BRICS cooperation is now expanding to encompass new areas.

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