Financial Exp ND 8.07.2014 p-2

IIM-Ahmadabad and Harvard tie up to train Indian taxmen

Fe Bureau

In a major branding exercise both for India's top B-school IIM Ahmedabad and babus of the much-feared Income Tax department, the former has roped in no less than the Harvard Business School (HBS) to train taxmen to become more citizen friendly and responsive. IIM-A's Executive Education wing has tied up with HBS Executive Education to offer a four-week course to senior officials of the Income Tax department to provide perspective, skills and insights. “One of our key priorities is to connect not only with the private sector but also with public sector institutions, and renowned B-schools,” said Professor Ashish Nanda, director, IIM-A. Thirty Central Board of Direct Taxes officials of the rank chief commissioner of income tax and above will spend two weeks at the IIM-A campus and two weeks at the HBS campus.

http://www.financialexpress.com/news/iima-and-harvard-tie-up-to-train-indian-taxmen/1267717

Times of India ND 8.07.2014 p-3

First FYUP batch in dark over course

NEW DELHI

: There is an entire batch of students that's carrying the baggage of the four-year-undergraduate programme (FYUP) and will do so for another two years. Classes for the new academic session are set to start in two weeks but the university administration seems in no hurry to come to its help. Its silence over convening of the academic council for initiating structural changes has once again forced the students and teachers to the path of agitation. The UGC has now convened a meeting of the standing committee on Tuesday to discuss the issue.

With the rollback of FYUP - and as directed by UGC - the first batch of students under that programme is to be migrated to the three-year structure and offered degrees on successful completion of three years. This process now requires statutory approvals - from AC, committee of courses and finally EC. After waiting for a week, 12 members of the AC have submitted a requisition for a meeting of the AC.

Vice-chancellor Dinesh Singh had announced the rollback of FYUP on June 27 and next day convened the AC and EC to ratify the same and to restore the three-year programme. However, 10 days later, the administration has not made any move towards changing the structure. The VC ought to have started the process of course restructuring at once through AC, EC, faculties and committees of courses of the departments in order to ensure that it is completed before commencement of the academic session on July 21.

Demanding immediate steps from the DU administration, Nandita Narain, president, DUTA, said: "The task should have been initiated on June 21 itself following the UGC's order stating that FYUP was at variance with the national policy." DUTA is now demanding assignment of teaching work to teachers, timely appointment of teachers and preparation of a time-table so that teaching can start on commencement of the academic session.

J Khuntia, chairman, Academics for Action and Development (AAD, Rathi) said: "The syllabi for the second year students under the erstwhile FYUP should have come by now as the students are eager to know the kind of adjustments that have been made to accommodate them inside the coming two academic sessions. They The university cannot remain silent on this most important issue involving the future of nearly 54,000 students who were illegally enrolled in FYUP last year. It is time that the university administration behaves responsibly. Otherwise, DUTA will be forced to agitate."

Even in the case of BTech and bachelor in management studies courses, where clear guidelines from the UGC were issued on June 29 and 30, respectively, DU has so far made no move to safeguard the careers of these students.

http://timesofindia.indiatimes.com/city/delhi/First-FYUP-batch-in-dark-over-course/articleshow/37983780.cms

Business Standard ND 8.07.2014 p-14

10 women directors a day to meet norms

900 listed firms yet to comply with new Sebi requirement, due in less than 90 days, for at least one woman on the board of directors

India Inc will have to add 10 women directors a day to their boards to comply with the market regulator's new requirement. The Securities and Exchange Board of India's (Sebi) requirement for all listed companies to have at least one woman director by October 1. As many as 904, or 62 per cent, of a total of 1,462 National Stock Exchange-listed companies are yet to appoint one, analysis done by indianboards.com shows.

The website maintains a database on board members of listed companies. It says only 91 women directors have so far been appointed to 97 directorship positions in 94 companies since Sebi announced this norm on February 13.

“Of these 94 companies, 16 already had a woman on the board before the Sebi guideline was announced (and appointed a second woman on their board), implying that only 78 companies have since complied with the requirement," says Pranav Haldea, managing director, PRIME Database.

According to indiaboards.com, as of May, 80 companies had appointed 85 women on their boards.

PRIME Database has also raised concerns over appointment of women directors from within the promoter group."...nearly one-fourth (directorship positions) have been filled by appointing women belonging to the promoter group. These women shall have the same voice as the promoter, defeating the very purpose of genuine (independent) gender diversity," says Haldea.

Of the 74 women appointed to 80 directorship positions within these companies, 19 are from the promoter group. Further, there are 59 women directors who are first-time appointees. Of which, 15 are from the promoter group and 18 are non-independent, leaving only 26 women directors who are "apparently independent", the study said.

On an overall basis, there are a total of 8,987 persons occupying a total of 11,527 directorships in NSE-listed companies. Of these, 546 women directors hold 673 positions, about 5.8 per cent of all the directorship positions. Only 33 companies have a woman as chairperson, of which only one is independent.

Among the women directors, Renu Sud Karnad has a presence in eight companies, the highest number of directorships. She is an independent director in five of these. Ireena Gopal Vittal is second with positions on six company boards, all independent. Ramni Nirula also has six positions on a board, of which four are independent. Among the companies, Apollo Hospital Enterprises, with four women on its board, has the highest number. However, none of these occupy an independent director's position.

http://www.business-standard.com/article/markets/10-women-directors-a-day-to-meet-norms-114070700359_1.html

Economic Times ND 8.07.2014 p-17

UGC Set for Revamp after FYUP Rollback

Urami

The government is all set to initiating a restructure of the higher education regulatory set up in the country. In a reply to a written question in the Rajya Sabha, human resource development minister Smriti Irani said the government is considering setting up a high level of committee of experts to suggest a comprehensive restructuring and revamping of the higher education regulator University Grants Commission (UGC).

HRD ministry sources said it will focus on “a cleanup” and “restructuring” of UGC in the wake of the controversy ahead of the roll back of the four year undergraduate programme in Delhi University.

They said the restructuring efforts would also include the All India Council for Technical Education and the National Council for Teacher Education.

During the recent face off with the Delhi University, UGC had forced the university scrap the four year undergraduate course as it was not in keeping with the “10+2+3 structure” provided in the National Policy on Education, 1986. However, the commission had cleared at least two other such four year programmes in Bangalore University and Bharathidasan University, Tiruchi--in 2011-12 and 2010-11, respectively.

Sastra University vice-chancellor R Sethuraman has drawn the ministry’s attention to this situation. In a letter to higher education secretary Ashok Thakur, he has stressed that the UGC has been allowed to create an “academic mess” and that “It is high time that the UGC was directed to set the house in order”.

Restructuring the higher education regulator is part of the BJP’s poll promise.

UGC, formally established by an Act of Parliament in 1956, is the statutory body for the coordination, determination and maintenance of standards of university education in the country. Over the years, despite the changes in higher education with entry of private players, its emphasis has continued to be on its grant disbursal functions.

Hence, there is a need to expand its regulatory functions, officials said.

“Over the past decade, the UGC has responded to changes in the sector be it private universities, deemed universities, collaboration with foreign institutions through executive orders. This approach has more often than not been reactive rather than proactive. As a result the regulatory oversight that exists over the different actors in the higher education sector has not been adequate,” said a ministry official.

Even before the FYUP mess, ministry officials were working on the amendments to the UGC Act.

Irani told Parliament that the focus of the restructuring would be to promote access, equity, quality and employability of the higher education sector.

Financial Exp ND 8.07.2014 p-4

MS Mehta appointed RInfra CEO

Reliance Infrastructure (RInfra), part of the Reliance Group, has appointed MS Mehta as chief executive officer of the company with effect from Monday, it said in a statement.

He will take over as CEO from Lalit Jalan, who held the portfolio for over seven years.

With the new CEO inducted, RInfra has elevated Lalit Jalan as director (corporate strategy and affairs), who will steer future growth initiatives and efforts of the group, the statement said.

Mehta, a mechanical engineer and an MBA from the Indian Institute of Management - Ahmedabad, held the post of Group CEO of Vedanta Resources for five years. In his tenure of 14 years in Vedanta, he was instrumental in steering the group into the ranks of the top five natural resources players in the world.

"Under his leadership, Vedanta implemented several large projects and spread the Vedanta footprint across India and other geographies worldwide. His passion for excellence and focus on unlocking value helped Vedanta to maintain its global cost leadership position across segments, and to grow its revenues multifold to R90,000 crore ($15 billion) in FY 2014," the statement said.

http://www.financialexpress.com/news/ms-mehta-appointed-rinfra-ceo/1267722

Financial Exp ND 8.07.2014 p-17

Cipla to invest £100 m in UK arm to strengthen international business

Cipla will be investing 100 million pounds (around R1,028 crore) in its UK subsidiary over the next few years in a bid to further strengthen its international business, the company said in a statement on Monday.

“The company, in collaboration with the UK government, has expressed its intention to make investments of up to £100 million in its UK subsidiary over the next few years,” Cipla said in a filing with the bourses.

“The investments are expected to facilitate the launch of a range of products in the area of respiratory, oncology and antiretroviral medicines to further Cipla’s higher purpose of universal affordable access.”

Stating that the investment underscored the importance of the UK market in Cipla’s long-term strategy, it added that the pharmaceutical company planned to utilise a part of this investment towards research and development, clinical trials, and expand further internationally as well.

The announcement of its intention to invest further in the UK comes close on the heels of two international transactions closed by Cipla whereby it invested in pharmaceutical distribution companies.

In June, Cipla signed a definitive agreement to acquire a 51% stake in a pharmaceuticals manufacturing and distribution business in Yemen for an initial consideration of $21 million, with additional investment to be made over the next three years on the achievement of certain milestones. In the same month the company announced that it was acquiring a 60% stake in a Sri Lankan pharmaceutical distribution company for $14 million.

Cipla had also announced on June 17 that it will acquire a 60% stake for $14 million in its Sri Lanka-based distributor which will market Cipla's products in the island country.

The drugmaker currently generates 60% of its consolidated revenues of R10,100 crore from international markets, with Europe contributing 6% to overall sales in fiscal 2014.

In its quarterly conference call with investors held in May, Cipla said that it will focusing on respiratory drug launches in Europe with a new inhaler likely to be launched in "two or three bigger markets in Western European markets" in the second half of fiscal 2015.

http://www.financialexpress.com/news/cipla-to-invest-100-m-in-uk-arm-to-strengthen-international-business/1267669

Economic Times ND 8.07.2014 p-16

DCGI Wants Pharma Cos to Share Clinical Trial Benefits with India

Soma Das

Wants cos to ensure early launch of new therapies here if trials prove successful
This move is part of steps DCGI has taken last week to bring clarity in the clinical trials space and ensure patients are not exploited

Multinational pharmaceutical companies keen to conduct clinical trials for new drugs on Indians would have to ensure an early launch of those therapies in India if the trials result in commercial production, the drug regulator has said.

In an order issued last week, the Drug Controller General of India (DCGI) said innovator drug firms would have to seek approval for such new drugs (New Chemical Entities and New Biological Entities) in India soon after obtaining marketing clearance in their respective countries.

The DCGI has directed drug firms to furnish an undertaking along with their application for clinical trials, promising that once they manage a marketing clearance for the new therapy in their respective country or a developed market, they would file for an approval in India and ensure the therapies are “marketed in India speedily, preferably by production within the country“.

This is meant to expedite launch of cutting edge therapies in the country , particularly in cases where India has participated during the trials. Of the total 140 newly discovered drugs that were launched between 2006 and 2010 globally , only 39 (28%) are available in the Indian market. This gap between the number of new drugs launched globally and such therapies introduced in India is the sharpest in the segment of cancer treatment, although the gap in other ther apies such as cardiovas cular and neurology also remains significant, according to the database of IMS Institute for Healthcare Informatics, a global pharma market research firm.

This move is part of a series of measures that the central drug regulator has taken last week to bring clarity in the clinical trials space and ensure patients are not exploited. Among other steps, the DCGI has said that no investigator or physician can conduct more than three trials at a time. Until now, there were no limits to the number of trials a physician could undertake at a given time. The regulator has decided that while approving new drugs already approved elsewhere, clinical trials can be waived here for products “in cases of national emergency, extreme urgency, epidemic, orphan drugs for rare diseases and drugs indicated for conditions, diseases for which there is no therapy“, according to another order reviewed by ET. For biosimilars, which have been marketed for over four years in countries like the US and have been established as safe and efficacious, pharma companies can seek marketing approvals from the drug regulator with short and smaller trials without undergoing lengthy phases of clinical trial as is currently mandated. This is also meant to ensure faster availability of new therapies in India.

DCGI has further noted that while conducting placebo trials, under which a group of people is administered `fake drugs' or `sugar pills' not intended to have therapeutic effect, the patient should not be weaned off the drugs he is already taking.

These are select recommendations from the Ranjit Roy Chaudhury committee set up to clean the clinical trial sector.
The panel submitted its report last year.

The health ministry, which reviewed the report, has decided to act over some of the recommendations.

Hindustan Times ND 8.07.2014 p-12

The real test lies in proper testing

Krishna Sharma

Despite the stringent product patent regime since 2005, Indian pharma has stayed a leader in affordable medicine and vaccines, largely because of 'biosimilars'. These are biological medicines developed to be similar to existing medicines but are not the same as generics, which have simpler chemical structures and are considered identical to their reference products. The active substance of a biosimilar and its reference medicine are living organisms that are more complex [eg, monoclonal antibodies (mAbs)].

Since their complexity may result in a degree of variability in molecules of the same active substance and pose considerable risk to patient safety, biosimilars are tested against more stringent standards than conventional generics.

As regulatory pathways are becoming clearer in several jurisdictions, including the United States, the global market for biosimilars is expected to explode. With patents on a number of blockbuster products expiring, the global market of biosimilars approved in highly regulated markets is projected to be $15 billion by 2020. Several Indian and multinational companies are looking to enter this highly regulated space.

Though India's Guidelines on Similar Biologics were notified on September 15, 2012, to be at par with the World Health Organization's international guidelines on safety, efficacy, quality and immunogenicity, they are yet to be implemented. The surprising stand taken by the Drug Controller General of India (DCGI) is that compliance is not mandatory. This does not bode well for the industry. Compliance with regulation is an absolute must for India to be able to tap the export market.

The DCGI is well aware of the inadequacies in the current approval procedure. In August 2013, an expert committee to guide the DCGI on regulating biotech products was constituted, only to be nixed a few months later.

The European Union was the first to develop regulatory and scientific guidance to authorise biosimilars and approved the first biosimilar, Omnitrope (somatropin), in 2006. To date, it has approved 18 in four therapeutic areas.

There are two key drawbacks in India's system. One, there's a cloud over what analytical tests are conducted at the product characterisation stage to establish structural similarity and identify the differences; and two, very minimal Phase III study being required on a small sample size (100-150 patients).

India must move fast to stay in the reckoning. It was only in November 2013 that the EU approved the first biosimilar mAb, Remsima and Inflectra, which are biosimilars of J&J's Remicade. A total of 871 people were included in the clinical trials. Mylan has been conducting clinical trials for biosimilar of Trastuzumab in the EU with 600 patients, while in India it has conducted only Phase III trials on 132 patients.

Against this backdrop, the outcome of the Delhi High Court case brought by Roche against Biocon and Mylan in February gains significance. Roche has alleged that Biocon/Mylan has misrepresented its drugs as a biosimilar of its bestselling breast cancer drug, Trastuzumab (Herceptin), without having undergone the required tests.

At the heart of this imbroglio is the non-implementation of the Guidelines on Similar Biologics and compliance with India's Schedule Y of the Drugs and Cosmetics Rules, 1940. Whatever the positions of the parties involved are, the impression created is that India's regulatory system is lax.

The 59th report of the Parliamentary Standing Committee on Health has come down heavily on the drug regulatory environment that compromises patient safety. It also impacts India's export potential.

India cannot afford to give the impression that it has a slack and opaque system.

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The views expressed by the author are personal.
http://www.hindustantimes.com/comment/analysis/the-real-test-lies-in-proper-testing/article1-1237882.aspx

Business Standard ND 8.07.2014 p-20

New poverty measures: Rangarajan used nutrition, spending and consumption behaviour

Says poverty estimates are reasonable

The latest official estimate of India's poor, from a committee chaired by C Rangarajan, head of the former Prime Minister's Economic Advisory Council, is based on certain normative standards of food and non-food consumption, as well asbehavioural aspects of classes concerned for consumption of some other items.

It not only takes normative levels for adequate nourishment, clothing, house rent, conveyance and education, but also considers behaviourally-determined levels of other non-food expenses.

The committee has estimated that almost 30 per cent of us were poor in 2011-12.It uses separate data sets for rural and urban parts.

The panel computed the average requirements of calories, proteins and fats on the norms set by the Indian Council for Medical Research in 2010. These are differentiated by age, gender and activity for all-India rural and urban regions. The report was recently given to the government.

Accordingly, the energy requirement as calculated by Rangarajan is 2,155 kcal per person per day in rural areas and 2,090 kcal per person per day in urban areas. This is significantly lower than the 2,400 kcal in rural areas and slightly less than 2,100 kcal in urban areas used by the earlier Lakdawala panel. The reason given is that the age profile and working conditions have changed with time.

The protein and fat requirements have been estimated on the same lines. These are 48g and 28g per capita per day, respectively, in rural India and 50g and 26g per capita per day in urban areas.

A food basket which simultaneously meets all the normative requirements of the three nutrients defines the food component of the poverty line basket proposed by the panel. These nutrient norms are met for persons located in the sixth fractile (25-30 per cent) in rural areas and for those in the fourth fractile (15-20 per cent) in urban areas, given in the National Sample Survey Office (NSSO) report on consumption expenditure for 2011-12.

Levels

The average monthly per capita consumption expenditure on food in these fractile classes is Rs 554 in rural areas and Rs 656 in urban areas, according to the NSSO report.

The non-food component of the poverty line basket has both a normative component and one given by the observed consumption pattern of households in the fractile group in which the food component is located.

The normative component relates to private consumption expenditure on education, clothing, shelter (rent) and mobility (conveyance). Since it is difficult to set minimum norms for these essential non-food items, the panel recommended that observed expenditures on these items by households located in the median fractile (45-50 percentile) be treated as the normative minimum private consumption expenditure on these items.

This works out to be Rs 141 per capita per month in rural areas and Rs 407 in urban areas, according to the NSSO report referred to.

For all other non-food goods and services, the observed expenditure of that fractile class which meets the nutrient norms (the 25-30 percentile in rural India and 15-20 percentile in urban India) is taken to define the poverty line in respect of these items. This works out to Rs 277 per capita per month in rural areas and Rs 344 in urban areas, on the basis of the NSSO survey of 2011-12.

The new poverty line, thus, translates to a monthly per capita consumption expenditure of Rs 972 in rural areas and Rs 1,407 in urban areas in 2011-12. Or, Rs 32 in rural areas and Rs 47 in urban areas on a per capita daily basis. However, Rangarajan says the best way is to take it on a monthly household consumption basis. Taking a household as five members, this would mean Rs 4,860 in rural India and Rs 7,035 in urban parts.

States

Similarly, the panel calculated states' poverty lines. Based on these, Chhattisgarh had the highest incidence of poverty, with almost 47.9 per cent of the population below the poverty line in 2011-12. Andaman and Nicobar had the least incidence, with only six per cent poor.

The states having the highest incidence of poverty, according to the Rangarajan formula, are Assam, Jharkhand, Manipur and Odisha, apart from Chhattisgarh. Those with the least number of poor as percentage of their population are Andhra Pradesh, Goa, Kerala, Punjab, Puducherry, and Lakshadweep. The percentage of people under the Rangarajan poverty line has been based on the national population of March 1, 2010.

http://www.business-standard.com/article/economy-policy/new-poverty-measures-rangarajan-used-nutrition-spending-and-consumption-behaviour-114070700956_1.html