## UN health agency to examine lower-cost 'biosimilar' drugs in effort to expand access to cancer treatment

4 May 2017 — As a step towards making some of the most expensive treatments for cancer more widely available in low- and middle-income countries, the World Health Organization ( $\underline{\text{WHO}}$ ) said today that it will launch a pilot project for prequalifying so-called "biosimilars," or lower cost drugs.

Biotherapeutic medicines, which are produced from biological sources, such as cells rather than synthesised chemicals, are important treatments for some cancers and other non-communicable diseases. Like generic medicines, biosimilars, which are usually manufactured by other companies once the product's original patent has expired, can be much less expensive versions of innovator biotherapeutics.

"Innovator biotherapeutic products are often too expensive for many countries, so biosimilars are a good opportunity to expand access and support countries to regulate and use these medicines," <a href="mailto:said">said</a> Dr. Marie-Paule Kieny, WHO Assistant Director General for Health Systems and Innovation, in a press statement.

In September, the UN health agency will invite manufacturers to submit applications for prequalification of biosimilar versions of two products in the WHO Essential Medicines List: rituximab (for non-Hodgkin's lymphoma and chronic lymphocytic leukemia), and trastuzumab (to treat breast cancer).

The decision comes after a two-day meeting in Geneva between WHO, national regulators, pharmaceutical industry groups, patient and civil society groups, payers and policymakers to discuss ways to increase access to biotherapeutic medicines. WHO also plans to explore options for prequalifying insulin.

"Biosimilars could be game-changers for access to medicines for certain complex conditions," said Dr. Suzanne Hill, WHO's Director of Essential Medicines and Health Products. "But they need to be regulated appropriately to ensure therapeutic value and patient safety."

According to WHO, if it finds that biosimilars submitted for prequalification are comparable in terms of quality, safety and efficacy to originator products, it will list the medications and become eligible for procurement by UN agencies. As many low- and middle-income countries rely on WHO prequalification before buying medicines, an additional benefit could be to increase competition and further reduce the price of medicines.

WHO will also review its 2009 Guidelines on the evaluation of similar biotherapeutic products to ensure that WHO's guidance to national regulatory authorities reflects recent evidence and experience.

Increased use of biosimilars will also require patients and their physicians to understand and trust that the benefits of this type of medicine substantially outweigh any risks. WHO will be looking to countries with positive experience of biosimilars and partners for support in educating prescribers and patients on their benefits and in advocating for greater awareness of biosimilars.

In addition, WHO will advocate for fairer prices for all biotherapeutics to ensure that these treatments can truly benefit public health. This will include support to countries to develop price-setting strategies that foster sustainable markets to deliver treatments to patients, savings to payers and incentives to producers to keep manufacturing the medicines needed.

# In Ethiopia, UN rights chief urges authorities for greater freedoms, especially space for critical voices

4 May 2017 — Speaking to the press during his mission to Ethiopia, the United Nations High Commissioner for Human Rights today highlighted the need for greater and freer civic space, with "broader latitude for the contributions of critical or dissenting views" to decision-making in the country.

"All governments need to be held to the mark by independent media and the vital action of civil society and human rights defenders," High Commissioner Zeid Ra'ad Al Hussein <u>said</u> at a press conference in the capital, Addis Ababa.

"I am convinced the Ethiopian Government will find its most important and productive investment will be in the rights of the people, which build strong and safe societies."

In his remarks, the UN rights chief hailed the contributions of the Horn of Africa country ranging from its contributions to UN peacekeeping efforts as well as its commitment to protect the human rights of its people as illustrated by its accession to a number of human rights treaties and their reflection in the Ethiopian constitution.

He also expressed that the work of the Ethiopian Human Rights Commission was heartening and called on the Government to continue further steps to grant the body more independence.

However, speaking on the unrest in the country in November 2015 and August 2016, and the response of the security forces, Mr. Zeid urged the authorities to allow access to UN human rights officials to visit the affected region and establish the facts.

"The extremely large number of arrests — over 26,000 — suggests it is unlikely rule of law guarantees have been observed in every case. I believe my staff ought to be given access to the affected areas, and I renew my request," he added, noting that he would continue to follow-up on the case.

The High Commissioner also spoke on the importance of economic, social and cultural rights and stressed that progress on these rights would translate into civil and political rights advances.

He also offered his support and that of his Office, <u>OHCHR</u>, to the Government and the people of Ethiopia in confronting the challenges posed by the drought plaguing large parts of the region.

SEE ALSO: As new drought hits Ethiopia, UN urges support for Government's 'remarkable' efforts

During his visit, High Commissioner Zeid met with a number of senior Ethiopian officials, including the Prime Minister, Hailemariam Desalegn, Ministers, legislators, and human rights officials and defenders.

Also, while in Ethiopia, the UN top human rights official signed a Memorandum of Intent with the Government to strengthen OHCHR Regional Office in Addis Ababa programmes on capacity building for stakeholders across the region, including Ethiopia.

During his mission, Mr. Zeid also met with Chairperson of the African Union Commission, Moussa Faki Mahamat, and other senior African Union (AU) officials, with whom he discussed human rights priorities with the AU, as the regional bloc's new leadership develops its vision and frameworks for impact across the continent.

### <u>Displaced civilians in South Sudan's</u> <u>Upper Nile at risk of further</u> <u>violence, UN rights chief warns</u>

4 May 2017 — The United Nations human rights chief today urged the Government of South Sudan to halt any further military offensives towards Aburoc in the Upper Nile region.

"Civilians in Aburoc are at serious and imminent risk of gross human rights violations, inter-ethnic violence and re-displacement," <u>said</u> UN High Commissioner for Human Rights Zeid Ra'ad Al Hussein.

He said these people fleeing from towns like Tonga and Kodok were forced to walk through the bush for up to 150 kilometres in searing temperatures. Many

reportedly died along the way, but the rest ended up in Aburoc where they face grave violence and shortages of food, water and healthcare.

"These are women, children and men at the mercy of military commanders, on both sides of the political divide, who have consistently shown little or no regard for the protection of civilians," he added.

RELATED: <u>UN calls for protection of civilians sheltering in South Sudan's Upper Nile area</u>

Despite the August 2015 peace agreement, South Sudan slipped back into conflict due to renewed clashes between rival forces — the Sudan People's Liberation Army (SPLA) loyal to President Salva Kiir and the SPLA in Opposition backing former First Vice-President Riek Machar.

Aburoc, a town on the west bank of the River Nile, holds between 35,000 and 50,000 people, most of whom arrived in recent weeks after SPLA attacks on areas to the south.

Civilians in Aburoc now find themselves in areas controlled by the opposition armed group, facing a military offensive by the Government forces.

The High Commissioner urged the Government to adhere to the pledges made by President Kiir on 25 March, when he committed to declare a unilateral ceasefire, and to work towards political engagement to bring the conflict to an end.

Mr. Zeid called on all parties to the conflict to comply with international humanitarian law, including taking all feasible precautions to prevent civilian casualties.

He also called on the Government to grant the UN Mission in South Sudan (<u>UNMISS</u>) access to Aburoc and Kodok, and to ensure that humanitarian agencies are able to deliver crucial aid to the internally displaced population.

# Myanmar: Displaced Rohingya at risk of 're-victimization' warns UN refugee agency

4 May 2017 — The tens of thousands of members of Myanmar's Rohingya community who fled inter-communal violence in north of the country and sought refuge in Bangladesh remain highly vulnerable and risk being "re-victimized even in exile" unless urgent action is taken, a senior United Nations refugee protection official has warned.

According to Office of the UN High Commissioner for Refugees (<u>UNHCR</u>) estimates, as of February, some 74,000 Rohingya members were living in camps and makeshift sites in Bangladesh, many in need of adequate shelter before the rainy season starts.

"Without proper support, they also face risks such as child labour, gender-based violence and trafficking," said Shinji Kubo, UNHCR Representative in Bangladesh, in a <u>news release</u> issued by the Office.

While Rohingya displacement has persisted for decades, it made headlines last October when attacks on border posts in Myanmar's northern Rakhine province triggered a security clearance operation that drove an estimated 43,000 civilians into neighbouring Bangladesh by the year's end.

In a <u>report (issued in February) into the violence</u>, the UN human rights wing (<u>OHCHR</u>) had documented mass gang-rape, killings, including that of babies and young children, brutal beatings, disappearances and other serious human rights violations by Myanmar's security forces.

Many witnesses and victims interviewed by OHCHR had also described being taunted while they were being beaten, raped or rounded up, such as being told "you are Bangladeshis and you should go back" or "What can your Allah do for you? See what we can do?"



A boat off the coast of Myanmar's Rakhine province. (file) Photo: OCHA

#### Inter-communal violence, economic hardship driving desperation

The latest findings released by UNHCR in its new report on mixed movements in south-east Asia indicate that more than 168,000 Rohingya members could have fled Myanmar in the last five years. The total number of Rohingya refugees in the region and those internally displaced is estimated at 420,000 and 120,000 respectively.

Prior to the recent violence, Malaysia was the preferred destination for many Rohingya.

Between 2012 and 2015, an estimated 112,500 of them risked their lives on smuggler's boats in the Bay of Bengal and Andaman Sea in the hope of reaching Malaysia, with hopes of finding work in the informal sector.

Those who made this difficult sea journey ranged from individuals fleeing the 2012 inter-communal violence in Rakhine to those who grew increasingly desperate amid restrictions back home on their freedom of movement and access to services and livelihoods.

However, after regional Governments increased action against maritime smuggling networks in 2015, the route has been disrupted, with no confirmed boat arrivals in Malaysia last year. Furthermore, among those who tried to reach Malaysia overland in 2016, more than 100 — about half of them Rohingya

- were reportedly arrested in Myanmar and Thailand.

The UNHCR report also explores other routes taken by the Rohingya, including to India via Bangladesh. It notes a steady but slowing stream of arrivals since 2012 numbering at least 13,000 people.

"Looking at the declining arrival numbers in India, it is safe to assume that this overland route has not replaced the maritime one," said Keane Shum of UNHCR's Regional Mixed Movements Monitoring Unit.

"Compared to those who went to Malaysia by sea, the Rohingya in India travelled in larger family units and chose the route as it was cheaper and safer."

**VIDEO**: Learning to Hope — Virtual reality film in Myanmar (Click and drag within the video to navigate). Credit: OCHA

#### Young women, girls at particular risk

In addition to analyzing displacement patterns, the report also looked at the situation of Rohingya women and girls in Malaysia, India and Indonesia, using a snapshot of some 85 women and girls. The findings revealed that majority among them were married young (at 16 or 17) and gave birth at an average age of 18. Almost a third of them reported facing domestic violence and many said that while they would like to earn their own income, only a few were doing so despite having skills.

Those in India appeared to be more literate and educated, and were more likely to have chosen their own husbands. In contrast, those in Malaysia were more likely to have married someone chosen by their families or by brokers or agents.

On its part, the UN agency has been working with host countries on temporary stay and protection of Rohingya refugees, including supporting them to access basic services and legal work to help them become more self-reliant until longer-term solutions are found as well as advocating with the Myanmar authorities for the full resumption of humanitarian access to vulnerable people in northern Rakhine state.

"We stand ready to support Government efforts to promote co-existence and address issues related to citizenship," said UNHCR.

### Europe: 24,600 refugee children 'in

### limbo' at risk of mental distress, UNICEF warns

4 May 2017 — Nearly 75,000 <u>refugees and migrants</u>, including an estimated 24,600 children, currently stranded in Greece, Bulgaria, Hungary and the Western Balkans are at risk of psychosocial distress caused by living in a protracted state of limbo, the United Nations Children's Fund (<u>UNICEF</u>) warned today.

&#8220We are seeing single mothers and children stranded in Greece, Serbia and Bulgaria who have not seen their husbands and fathers for months or even years, &#8221 <a href="mailto:said">said</a> Afshan Khan, UNICEF Regional Director and Special Coordinator for the Refugee and Migrant Crisis in Europe.

&#8220The family reunification process is slow, and its outcome uncertain and it is this uncertainty which can cause significant emotional distress and anxiety for children and families, setting them back for years to come, &#8221 she added.

In many cases, adult males are the first family members to make the trip to Europe, with the rest of the family following later.

Most stranded asylum seekers do not know whether or when they will be permitted to move forward. The situation is particularly acute for single mothers and children stuck in Greece or the Balkans waiting for reunification with family members in other EU countries.

But with the 2016 border closures and implementation of the EU-Turkey statement, other family members are being held up in transit countries from where they must apply for family reunification with their loved ones &#8211 a process that typically takes between 10 months and two years.

UNICEF and its partners in Greece are monitoring mental health and general depression among single mothers and children waiting for family reunification and providing psychosocial support.

&#8220Keeping families together is the best way to ensure that children are protected, which is why the family reunification process for refugee and migrant children is so important, &#8221 said Ms. Khan. &#8220With the number of those stranded continuing to rise, it is incumbent on member states to alleviate procedural bottlenecks so that families can get back together as quickly as possible. &#8221

Most of the family reunification requests originate from children and separated family members stranded in Greece, but because of the caseload and involvement of destination countries, the process can be painstakingly slow.

In 2016, nearly 5,000 family reunification requests, out of which 700 from unaccompanied and separated children, were made from Greece, with only 1,107 successful applicants having reached their destination country by the end of

the year.

Meanwhile, the number of refugees and migrants stranded in Greece, Hungary and the Western Balkans continues to grow &#8211 increasing by around 60 per cent over the past year from 47,000 in March 2016 to nearly 80,000 at the end of April.