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## Committee on Social Affairs, Health and Sustainable Development

### *Sub-Committee on Public Health and Sustainable Development*

## Minutes

### **Breast cancer awareness-raising event as part of the Pink October events, held in Strasbourg, on Monday, 10 October 2022**

The PACE Sub-Committee on Public Health and Sustainable Development organised a public hearing on raising awareness of breast cancer, in particular addressing the themes of discrimination against breast cancer patients and the “pink washing” phenomenon with the participation of:

- ✓ Mr K. M. Gopakumar, Legal Advisor and Senior Researcher, Third World Network (TWN) (*online participation*)
- ✓ Ms Nathalie Clastres, Head of Service – Promotion of Diagnoses, Prevention and Promotion of Diagnoses Service, National Anticancer League (*la Ligue nationale contre le cancer*), France

**Ms Olena Khomenko** (Ukraine, EC/DA), **Second Vice-Chairperson of the committee**, introduced the topics and speakers and then gave the floor to Mr Gopakumar for a presentation on the functioning of breast cancer detection services in developing countries and the barriers created by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in terms of access to breast cancer treatment.

**Mr Gopakumar** first congratulated the PACE sub-committee on having taken up this very important topic of discussion. He also thanked the sub-committee for providing him with the opportunity to share his views on the existing inequity in breast cancer treatment and hoped that this deliberation would lead to substantive measures to change the prevailing inequities in breast cancer treatment.

There was a shocking disparity in breast cancer survival rates among various countries. While the survival rate was 9 out of 10 (meaning patients lived more than 5 years after diagnosis and treatment) in high-income countries, only 6 out of 10 patients survived in India. The survival rate was 4 out of 10 patients in South Africa and even lower in sub-Saharan Africa.

Reasons for this prevailing inequity included late detection, health system limitations and poor socio-economic determinants. The most important – and least discussed - reason, however, was the inequity in the availability of affordable cancer treatments and medicines. While these medicines were available in developed countries, their high cost impeded access in developing countries. The exorbitant cost of these medicines prevented developing country governments from rolling out a national treatment programme with the most efficacious medicines for breast cancer. For example, the three CDK inhibitors used to treat HR+ breast cancer, which constituted nearly 2/3 of breast cancer cases, were inaccessible to the majority of patients in developing countries, including India. The monthly cost of Ribociclib, one of the CDK inhibitors, was 58 140 Indian rupees (INR) per month, while for Palbociclib the figure came to INR 95,000 and for Abemaciclib, INR 11 938 – 23 876.

India, as the hub of generic drug production, had the capability to manufacture these drugs at an affordable price. Similarly, many other developing countries with manufacturing capabilities had the ability to manufacture such drugs. The patents system, however, compromised the ability of developing countries to manufacture these life-saving drugs for breast cancer patients. In addition, the extended patent terms due to secondary patenting further hindered the availability of these drugs for the population which needed them the most. For example, in 2021, due to patenting, the drug Ribociclib had been available to fewer than 4 000 patients, whereas the cumulative number of patients requiring treatment had been over 100 000. This huge gap in

<sup>1</sup> The minutes were approved and declassified by the Sub-Committee on Public Health and Sustainable Development at its meeting on 26 January 2023.

access to treatment forced us to look at the pivotal question of how to make such medicines available to the burgeoning patient population. Restricting or removing patent protection or issuing compulsory licences could ensure the availability of an affordable generic version. The political pressure on developing countries against the issuance of compulsory licences prevented such measures from being adopted, however.

A similar situation could be observed with regard to the availability of monoclonal antibodies (mAbs) required for the treatment of HER2+ breast cancer and triple negative breast cancer. Access to these mAbs was heavily concentrated in developed countries. Although many mAbs were out of patent protection, their availability in developing countries was severely restricted due to high development costs. These high costs were due to the comparative trial requirement (which was a significant barrier in itself, even in the absence of other IP protection) as well as other IP protections, such as trade secrets. As a result, the originators continued to enjoy monopoly rights and pricing even after the patent expired.

Competition and diversification of manufacturing capabilities could have a huge impact on the price and availability of treatments. For example, the HPV vaccine which had been available at a cost of US\$35 to 40 recently, would soon be available at a price of less than US\$1 in India. This would result in a marked reduction in the number of cervical cancer patients.

The existing inequity had been created by design and violated peoples' right to enjoy the benefits of science and its applications under ICESCR (International Covenant on Economic, Social and Cultural Rights).

Mr Gopakumar believed that breast cancer treatment should be declared a global public good and countries encouraged to take the following measures:

- Facilitate competition in small molecules categories that were patented and currently used to treat breast cancer, e.g., CDK inhibitors like Ribociclib. That could be achieved by encouraging developing countries to use the available TRIPS flexibilities such as compulsory licences and government use licences. Or to temporarily suspend the enforcement of patents on these molecules.
- Encourage competition in the case of biologics, especially monoclonal antibodies which constituted one of the most expensive parts of the breast cancer treatment regimen. The cost could be significantly lowered by removing the clinical trial requirements to produce non-originator mAbs. The removal of clinical trial requirements for monoclonal antibodies found its basis in the recently modified WHO biosimilar guidelines, the evaluation of which was conducted based on thorough scientific evaluations. In addition, cell line sharing could help to scale up production through diversification. In this regard, all assistance should be provided to developing countries to implement the WHO Guidelines with required modifications.
- Prevent pharmaceutical companies or their associations from exerting undue influence against countries using TRIPS flexibilities.
- Encourage the local production of breast cancer medicines in developing countries. That could be achieved by providing public funding for the development of new products for the treatment of breast cancer, providing assistance to fill the technology gaps and developing processes for cheaper production.
- Provide more funding for the WHO, the development of treatment protocols and their implementation in developing countries so that they could roll out a free national treatment plan for breast cancer.
- Provide assistance to train health care professionals to scale up the treatment.

**Mr van Pareren** thanked Mr. Gopakumar for an enlightening and insightful presentation. He asked about access to reliable diagnosis upstream in the developing countries mentioned.

**Mr Gopakumar** confirmed that the same inequity could be observed in terms of access to diagnosis, although his presentation had focused on access to treatment. The challenge was to develop a comprehensive screening pathway in these countries, using technologies already available to perform these initial screenings and diagnoses more widely. More advanced technologies such as imaging, mammography and biopsy were then used as confirmatory tests. The key issue was to promote widespread initial screening and diagnosis, which did not necessarily require advanced or expensive technologies.

**Ms Khomenko** asked Mr Gopakumar about the flexibilities and opportunities afforded by the international legal framework in this area, in particular international trade law and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In terms of providing more equitable access to breast cancer treatments.

**Mr Gopakumar** said that in theory, TRIPS allowed governments to make accommodations to ensure the availability of drugs and treatments. For example, where a patent-protected drug was not available at an affordable price, governments could decide to introduce compulsory licences or government use licences. In practice, however, this was never done, mainly because of the political pressure from pharmaceutical companies and other governments on countries considering introducing compulsory licenses of this kind. Furthermore, most of the time, pharmaceutical companies held multiple patents for the use of the same

molecule. This wide protection effectively extended their monopoly beyond the original patent. All this explained the reluctance of states to take advantage of the flexibilities afforded by TRIPS. Ideally, reference should be made to the Sustainable Development Goals (SDGs) and a decision taken to suspend patents for the duration of the crisis in access to breast cancer treatments due to their excessive price.

**The Chairperson** then gave the floor to Ms Nathalie Clastres, Head of Service, Prevention and Promotion of Diagnoses, National Anticancer League (*La Ligue nationale contre le cancer*) France, to talk about the League's campaigns in France to promote better national strategies for breast cancer prevention and screening, and their efforts to combat "pinkwashing" in relation to breast cancer.

**Ms Clastres** thanked the sub-committee for inviting her to contribute to this discussion in the context of Pink October and the fight against breast cancer. 58 500 women were affected by breast cancer each year in France, and approximately 12 100 still died from it. It was estimated that one woman in eight would be diagnosed with breast cancer in her lifetime. It was the leading cause of cancer death, accounting for one fifth of deaths, all cancers combined. The incidence of breast cancer had followed a relatively steady curve in metropolitan France between 1990 and 2018. Mortality was declining thanks to early diagnosis and treatments that were accessible in France. The democratisation of access to treatment was a significant but recent phenomenon, particularly for so-called triple-negative cancer. It was hoped that this democratised access to treatment for triple-negative cancer, which accounted for 15% of breast cancer cases, would improve the lives of patients and increase the survival rate.

The most effective weapon against breast cancer in France was early detection. Screening had been in place in France since 2004 and was available to all women between 50 and 74 years of age who had no risk factors other than their age. The programme had been initiated by the Ministry of Health under the aegis of the National Cancer Institute (INCA). The National Anticancer League was also involved in the programme under which women were offered a free mammogram every two years, with the results read twice by different radiologists. The second reading detected approximately 6% of breast cancer cases that had not been detected the first time round. In France, there was still room for improving the quality of these readings, in particular through the use of digital images. Communication and awareness raising among women about the importance of getting a mammogram every two years was also key, since mammograms could detect subcentimetre lesions or tumours (just a few millimetres in size). Screening mammography was very much the benchmark test for early detection of breast cancer, therefore.

For women at "high" or "very high" risk, a different approach was required, depending on the individual's personal or family history of breast and/or uterine or ovarian cancer. The age at onset, including in other family members, should likewise be considered. It would also depend on whether or not the person had been exposed to high levels of chest radiation, particularly before the age of 30, for example while being treated for Hodgkin's disease. Women with genetic predispositions, including BRCA1 and BRCA2 genetic mutations, should likewise receive special follow-up.

It was also recommended that women who did not yet have access to regular screening and free mammograms (because it was not recommended for their age group) see a doctor, gynaecologist, or midwife for a professional palpation at least once a year from the age of 25 onwards. With "medical deserts" springing up in many parts of the country and a shortage of health professionals, France risked joining the ranks of the developing countries in this respect. Not only were there fewer and fewer gynaecologists but also women themselves were going to the gynaecologist less and less, and not seeing a midwife either.

Between examinations (mammogram and/or palpation by a health professional), it was advisable to monitor for signs of breast cancer throughout one's life. Among the various awareness-raising activities conducted by the League was educating women about the signs to watch out for and the best practices to follow (for example, through the buses operated by the League during Pink October). The screening rate for the whole of France (around 46% in 2020-2021) was well below the European recommendation (70%). Covid-19, together with the steady decline in the number of radiologists in France, had also resulted in major delays in patient care in 2020-2021, prompting many women to skip their screenings. It was important to raise awareness in this area, as otherwise France was liable to see an increase in the number of cases of larger lesions and tumours that were more difficult to cure (and required more complex treatment).

Mindful of that fact and in an effort to tackle the serious public health challenges thrown up by breast cancer, the Estée Lauder Foundation had created the "Pink Ribbon" in 1992 to draw public attention to the issue and to encourage as much investment as possible in breast cancer research. In France, the Pink Ribbon association had been set up in 1994, as an offshoot of the American Breast Cancer Research Foundation (BCRF). Its objectives were to promote early detection (or organised screening) and to support research through a communication and fundraising campaign, known as Pink October. The Pink Ribbon had now become an international symbol and the Pink October awareness campaign a key fixture in the French and indeed the global events calendar. Numerous activities in support of Pink October were held every year. Amid the euphoria, however, the "pink ribbon" initiative had also suffered its fair share of abuses.

"Pinkwashing", as it was known, had first been observed in the 2010s in the United States and had caught on in France between 2014 and 2018. The term essentially referred to the pink ribbon marketing frenzy where it was unclear who the real beneficiaries of the campaigns were or even what the message was. For example, Pink October perfume packs carried claims that 1% of profits went to charity, but without specifying what portion of the sale price would be donated and to whom. At the same time, the growth of "Pink October" products had thrown up questions about the profits that brands made on these products and how much money was actually passed on and ploughed into fighting breast cancer, as well as prompting concerns about the control and supervision of the funds and their use. Health magazines, such as *Rose* magazine, which specialised in breast cancer, carried ads for alcohol even though alcohol was responsible for 15% of breast cancers. All this raised questions about the message that marketing and advertising operations of this kind conveyed. Something else advertising agencies liked to do to mark Pink October was organising races. Yet only a small portion of the proceeds of these races actually reached breast cancer organisations or research projects directly dedicated to the cause. Once again, this raised questions about the share of profits that advertising agencies retained from sports events staged in support of Pink October. Non-profits with no links to the fight against breast cancer were sometimes also present at Pink October events, raising funds for their own cause (e.g. guide dogs association).

To combat such practices, France's National Anticancer League had introduced a best practice charter (2017). It was strongly recommended to refer to this when organising events and activities in support of Pink October. The League's *départemental* committees and partners were required to comply with it. In particular, when organising a Pink October event, it was important to explain the purpose of the event (fight against breast cancer as part of the month-long drive to promote breast cancer screening, known as Pink October) and not to simply feature the pink ribbon without any context or explanation. Such clearly-worded messages were essential to preserve the meaning of the Pink October movement and combat abuses. The partners must also undertake not to use the funds raised for any purpose other than the fight against cancer.

It was essential to have these kinds of conversations and to educate people about Pink October so that it did not lose its meaning. The term "Pink October" had become a rather fuzzy label in recent years, applied to all manner of events and products with no connection to the fight against breast cancer. A whole "Pink October" industry had sprung up. The issue needed addressing in order to put a halt to the self-serving PR stunts around Pink October. Public institutions could get it wrong, too, as the many buildings lit up in pink during the month of October and the huge number of "Pink October" events testified. Close attention must be paid to ensure that funds were intelligently channelled into research and the fight against breast cancer.

**Ms Arpadarai** emphasised the importance of awareness raising in the fight against breast cancer. An event had recently been held in Azerbaijan at which doctors had explained that breast cancer was a one hundred percent curable disease if discovered in time. This was the message that should be communicated to all women regarding breast cancer and breast cancer screening. Awareness and education were essential therefore, especially given women's reluctance to go for screening and check-ups. In Azerbaijan, there was still a lot of progress to be made on these fronts.

Turning now to the question of the age at which screening should commence, it was recommended to start check-ups from the age of 25. Because, however, of the existence of the medical deserts mentioned earlier, there was, it seemed, an issue with screening capacity, and hence a discrepancy between the recommendation to provide check-ups and screening from age 25 and the reality on the ground.

**Ms Clastres** clarified that it was not mammography screening that was recommended from age 25. The breasts were too dense at that age to be able to see lesions clearly on a mammogram. 80% of breast cancers occurred after the age of 50. From age 25, it was more a question of educating women to go for check-ups and see a health professional once a year for a palpation, rather than risk missing a change and possible cancer that might develop before the age of 50. This was particularly important because breast cancers that occurred before age 25 were much more aggressive cancers that needed to be detected and treated as early as possible. One unfortunate consequence of Covid was the tendency among women to be more lax about going for check-ups (both palpation and mammograms). Women needed to be educated to pay attention to their bodies and take charge of their health. In more than nine cases out of ten, breast cancer was in fact now curable. Provided it was not an aggressive or triple-negative cancer, the survival rate could be as high as 100%. If it was caught late, however, the consequences and impact on the daily lives of the women concerned were far more serious. Pink October was a great opportunity to raise awareness about breast cancer and to get women going for check-ups. A bottleneck tended to occur in October, however, due to this awareness campaign, with large numbers of women trying to make appointments at the same time. This led to longer waiting times, prompting some women not to bother. In such cases, it was better to wait a few months for an appointment than to put off going for a check-up until the following year and so risk missing possible nascent lesions and tumours. Attention needed to be maintained throughout the year.

**Ms Khomenko** asked Ms Clastres about the League's links with other national and international organisations, particularly where screening was concerned.

**Ms Clastres** explained that the *Ligue contre le cancer* had been behind the introduction of organised screening in France. Such screening had initially been trialled by the League in several parts of the country before being rolled out nationwide under the direction of the health authorities (*Direction générale de la santé*, DGS). Today, the League acted as a user association and spokesperson for patients within the National Cancer Institute and the DGS. It also carried out advocacy work with the authorities in order to highlight the shortcomings of the French system and bring about improvements.

**Ms Leyte** explained that the breast cancer screening programme in Spain had started in the 1990s and currently had full coverage. In Spain, screening was done every two years between the ages of 50 and 69. It was important that women not be afraid to go to the doctor if they suspected there was a problem. Perhaps schools could also be a place to raise awareness among young girls so that they would not be afraid later in life to go to a health professional if they noticed something that looked abnormal. Perhaps breast self-palpation should also be more widespread and standardised.

**Ms Clastres** said that, with regard to awareness raising and self-palpation, the League felt that schools were not the appropriate place to address these issues. Schoolgirls were far too young and not immediately concerned by the issue. Addressing it in school would only worry them unnecessarily. Awareness raising only began when they started using contraceptives and reached adulthood. Also, the League formally advised against using the term “self-palpation” because it was ambiguous. Palpation was something that really needed to be carried out by a health professional. A more appropriate term, therefore, was self-monitoring or self-examination in order to spot visual changes (puckering, dimpling, redness). It was a well-known fact, moreover, that self-examination had its limitations. In general, women were capable of palpating a lesion larger than one centimetre in size by themselves, if it was superficial. Lesions smaller than 1 cm or deeper lesions would only be detected through palpation by a health professional trained in the procedure, who could palpate much more deeply. It was important, therefore, that women do not turn away from going to see a professional once a year to have their breasts palpated.

**Ms Leyte** clarified her statement and said that she had in fact been thinking of women aged 18 years and older. Regarding self-palpation, she agreed it was important that this should not have any unintended adverse effects. Coming from a rural area of Galicia and having practised family medicine for years, Ms Leyte had been deeply saddened to see several women come to her surgery with large cancerous tumours that they had not reported earlier because they were afraid. Much more needed to be done on the education front to combat this fear of going to the doctor.

**The Chairperson** thanked all the participants and declared hearing closed.

Committee on Social Affairs, Health and Sustainable Development  
*Commission des questions sociales, de la santé et du développement durable*

**Sub-Committee on Public Health and Sustainable Development**  
***Sous-commission de la santé publique et du développement durable***

**List of presence / Liste de présence**

(27 seats / 27 sièges)

**Chairperson / Présidente :** Ms Nigar Arpadarai

**Vice-Chairperson / Vice-Président :** Mr Geraint Davies

**Members / Membres**

**Alternates / Remplaçant(e)s**

1.	<b>Mr</b>	<b>Armen Gevorgyan</b>	Armenia / <i>Arménie</i>		Zz...
2.	<b>Ms</b>	<b>Nigar Arpadarai</b>	Azerbaijan / <i>Azerbaïdjan</i>	Ms	Konul Nurullayeva
3.	M.	Simon Moutquin	Belgium / <i>Belgique</i>	Ms	Els Van Hoof
4.	<b>Ms</b>	<b>Zdravka Bušić</b>	Croatia / <i>Croatie</i>		Zz...
5.	<b>Ms</b>	<b>Minna Reijonen</b>	Finland / <i>Finlande</i>		Zz...
6.	M.	Alain Milon	France		Zz...
7.	Mr	Levan Ioseliani	Georgia / <i>Géorgie</i>		Zz...
8.	Mr	Andrej Hunko	Germany / <i>Allemagne</i>	Ms	Martina Stamm-Fibich
9.	Mr	Sokratis Famellos	Greece / <i>Grèce</i>	Ms	Foteini Pipili
10.	Mr	Joseph O'Reilly	Ireland / <i>Irlande</i>		Zz...
11.	Mr	Fabio Di Micco	Italy / <i>Italie</i>		Zz...
12.	Mr	Max Hengel	Luxembourg		Zz...
13.	Mr	Miloš Konatar	Montenegro / <i>Monténégro</i>		Zz...
14.	Mr	Andrzej Szejna	Poland / <i>Pologne</i>		Zz...
15.	Mr	Bolesław Piecha	Poland / <i>Pologne</i>	<b>Mr</b>	<b>Tomasz Latos</b>
16.	Mr	Pedro Cegonho	Portugal	Ms	Jamila Madeira
17.	Mr	Andi-Lucian Cristea	Romania / <i>Roumanie</i>	Mr	Ion Prioteasa
18.	<b>Ms</b>	<b>Carmen Leyte</b>	Spain / <i>Espagne</i>		Zz...
19.	Mr	Ola Möller	Sweden / <i>Suède</i>		Zz...
20.	Ms	Sibel Arslan	Switzerland / <i>Suisse</i>	Mme	Ada Marra
21.	<b>Mr</b>	<b>Halil Özşavli</b>	Türkiye		Zz...
22.	<b>Ms</b>	<b>Olena Khomenko</b>	Ukraine	<b>Ms</b>	<b>Larysa Bilozir</b>
23.	Mr	Geraint Davies	United Kingdom / <i>Royaume-Uni</i>		Zz...
24.					
25.					
26.					
27.					

*ex officio* : Ms Selin Sayek Böke (Chairperson / *Présidente*, Türkiye)

**OTHER PARLIAMENTARIANS PRESENT / AUTRES PARLEMENTAIRES PRESENTS**

Ms / *Mme* Sevinj Fataliyeva ..... Azerbaijan / *Azerbaïdjan*  
 Ms / *Mme* Parvin Karimzada ..... Azerbaijan / *Azerbaïdjan*  
 Ms / *Mme* Isabelle Santiago ..... France  
 Ms / *Mme* Nathalie Serre ..... France  
 Mr / *M.* Frédéric Valletoux ..... France  
 Ms / *Mme* Heike Engelhardt ..... Germany / *Allemagne*  
 Mr / *M.* Bob van Pareren ..... Netherlands / *Pays-Bas*  
 Ms / *Mme* Mirosława Nykiel ..... Poland / *Pologne*

**EXPERT / EXPERT-E-S**

Mr / M. K.M. Gopakumar, Legal Advisor and Senior Researcher / *Conseiller juridique et chercheur principal*,  
Third World Network (TWN)

Ms / Mme Nathalie Clastres, National Anticancer League / *Ligue nationale contre le cancer*, France

**SECRETARIAT OF THE PARLIAMENTARY ASSEMBLY /**  
**SECRETARIAT DE L'ASSEMBLÉE PARLEMENTAIRE**

Ms / Mme Greta Faggiani, Office of the Secretary General / *Bureau de la Secrétaire générale*

Ms / Mme Giada Corsoni, Trainee / *Stagiaire*

**Committee on Social Affairs, Health and Sustainable Development**  
***Commission des questions sociales, de la santé et du développement durable***

Ms / Mme Aiste Ramanauskaite ..... Secretary to the Committee / *Secrétaire de la commission*

Ms / Mme Yulia Pererva ..... Secretary to the Committee / *Secrétaire de la commission*

Mr / M. Guillaume Parent..... Co-Secretary / *Co-secrétaire*

Ms / Mme Anita Gholami ..... Co-Secretary / *Co-secrétaire*

Ms / Mme Prisca Barthel..... Responsable du Prix de l'Europe / *Responsible for the Europe Prize*

M Ms / Mme Françoise Schir ..... Assistant / *Assistante*

Ms / Mme Claire Fabre ..... Trainee / *Stagiaire*