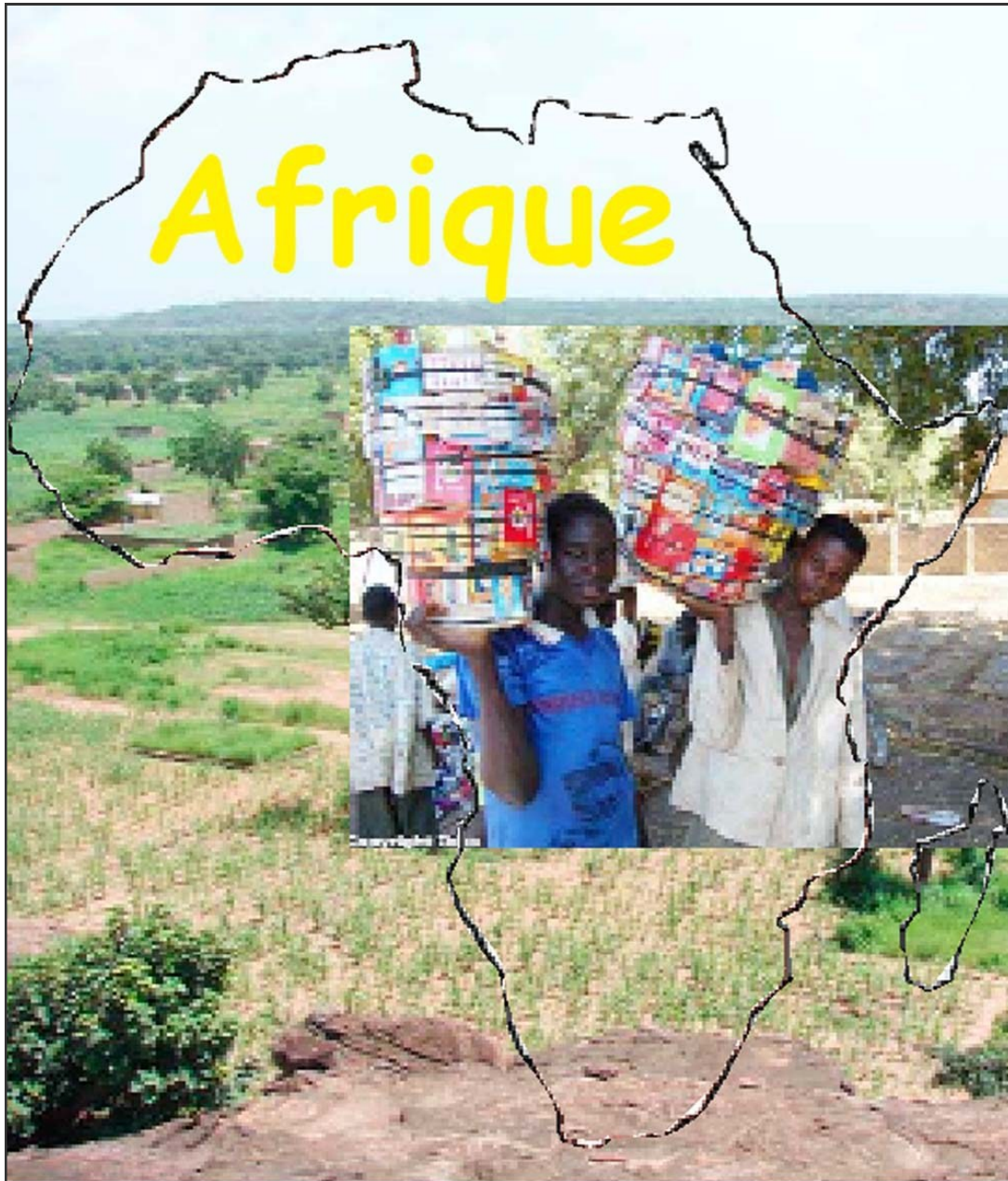


# WHICH TABLETS TO BUY ?



Thank you to all who agreed to help  
to produce this document.

Your interest and advice, your professional skills,  
the many proof-readings and various other forms  
of support have helped bring  
this educational tool into being.



## **Africa Europe Faith and Justice Network – AEFJN**

### **A Bridge linking Africa and Europe**

AEFJN strives to promote equity and economic justice in the relationships between Europe and Africa.

**AEFJN'S MEMBERS** many of them former missionaries, have experience of the reality of life in Africa and maintain close links with the people there.

**OUR VALUES:** our Christian faith, respect for the dignity of each human being and the equitable sharing of the earth's resources.

**OUR OBJECTIVES:** to promote sustainable development in Africa, listen to the voice of Africa and echo it to the European Institutions.

AEFJN's **WORK** involves gathering, sharing information, campaigning and lobbying at national and European levels on the underlying causes of poverty, and on the impact of EU policies on Africa. We also respond to crisis situations and offer suggestions for action.

AEFJN's main themes are:

- ◇ Family farming with a focus on land grabbing.
- ◇ Trade and Corporate Justice
- ◇ Access to quality medicines
- ◇ Small arms Control.
- ◇ Climate Change

**“Which Tablets to Buy?”**  
**or “How to Guarantee the Quality of Medicines in my Health Centre”**  
**was produced by an international AEFJN team**

## **Introduction**

Our main concern is for our patients and their health. We welcome them, listen to what they have to say and make the diagnosis. We provide care and medication appropriate to their age and condition.

In 2006 AEFJN sent out a questionnaire to our missionaries in Africa and received 82 replies from 23 countries. These confirmed what we already thought: the quality of medicines arriving in Africa is not always guaranteed as it is in Europe.

Guaranteeing the quality of medicines is currently delegated to the authorities of the exporting countries.

The regulatory authorities of the Global South cannot, or do not wish to, accept the responsibility for guaranteeing quality, or consequently the health of the patients.

This is why each of us needs to take precautions to be sure that the medicines we are buying for our patients are safe and effective.

So that everyone can benefit from the right to good quality medicines – wherever they may live – a group of organisations working in the health field has written **The Charter for the Assurance of Quality Medicines, Vaccines, Diagnostic products and small Medical Equipment**. With it comes a list of technical checks that need to be made.

Altogether there are about seven or eight pages to read

In case the meaning of some words is not clear ....

At our health centres in Africa, how can we assure the quality of the medicines we are buying? What do we need to know? What precautions should we take?

***Let's think about our Charter in terms that are more familiar***



Benedict is a nurse at the health centre in Makanene, a village in West Africa.

On his table, three tablets are telling their stories about how they got there...

They look identical: all of them are round and similar in colour.

One of them is called **Monsieur Paracetamol**, another **Mr. Paracetamol** and the third **Papa Sitamal**.



- \* “Good morning, brothers. How about introducing ourselves to each other?”
- \* “Mmm, it’s a long story, a bit too long” replied Mr. Paracetamol, clearly embarrassed “but tell me where *you* come from.”
- \* “Well, I am told that in Europe there were people with aching joints and a temperature ... so some researchers found something that would bring them relief and they started making a drug from an active substance called Paracetamol.” explained Monsieur Paracetamol.
- \* “What is an **active substance**?” asked Papa Sitamal timidly.
- \* “It’s the part of the medicine that **does the healing**; in my case this substance, **paracetamol**, reduces pain and fever. Usually, it’s just a small part of the medicine; but take a look, it’s written on my box ... 500mg!” replied Monsieur Paracetamol.
- \* “So, do you contain other substances?” enquired Mr. Paracetamol
- \* “Of course,” replied Monsieur Paracetamol, “The manufacturer always adds an **excipient**, one or more neutral substances that they mix in with

me, the drug, to help the patient swallow me more easily. Look at what's written on the box: enough excipient to make the tablet dividable."

- \* "So can the **maker** do what he wants?" was Papa Sitamal's sinister question.
- \* "No way!! First I have to be "**prequalified**", replied Monsieur Paracetamol pompously.
- \* "Pre-what?" asked Papa Sitamal taken aback.
- \* "Yes, **pre-qua-li-fied!** To be sure that I'm a good quality product, I (and you too) have to conform to the **norms and standards set by WHO** (the World Health Organisation) and to the **internationally known pharmacopeia** (the official descriptive list of all drugs). The norms are the rules that specify the technical prescriptions, the instructions to follow in the making of a product. '**Standard**' here means '**norms of production**'. So, to be sure that I conform to all these norms, I have been tested and I've been declared '**prequalified!**'" explained Monsieur Paracetamol at length.
- \* "But I have heard that most countries do not have the technical capacity and resources to set up a system that can assure the quality of products." retorted Mr. Paracetamol.
- \* "WHO produces a list of certain prequalified products made by such and such a manufacturer at such and such a factory. For products not on the list, you have to find a good manufacturer yourself and a supplier that pays attention to quality. It's not easy, but the purchasing and distributing agencies of our countries theoretically get their stock from manufacturers and distributors who can best guarantee the quality of the drugs. That is why Benedict gets what he needs exclusively from the national distribution centre", continued Monsieur Paracetamol. "**The quality, effectiveness** (the desired effect is achieved) and **the safety**

(absence of bad side effects) of these products have been evaluated and checked in accordance with *international standards*. What's more, *the manufacturer could prove that his factory site had been passed by the*



*inspectors of WHO's Prequalification Programme and of the national pharmacy Inspectorate that is responsible for pharmaceutical safety.* All these precautions make it possible to have access to medicines whose quality has been checked.

\* "It's all Chinese to me", whispered Papa Sitamal.

\* "I'm beginning to understand" said Mr. Paracetamol

who then added "but tell me *your* story."

\* "You're very inquisitive, brother, but I'll tell it to you on one condition: that you tell me yours afterwards." replied Monsieur Paracetamol.

\* "Well, OK, but you first," conceded Mr Paracetamol.

Papa Sitamal remained silent pretending to move away.

\* "After my birth – sorry - my production" Monsieur Paracetamol continued, I was put in a brand new and perfectly sterile metal box with other tablets just like me. Just imagine, there were hundreds of us and yet there was room for everyone. This box – perfectly dry – was hermetically sealed and stored in a cool place. We were then given a strange description that has stayed with us all this time: an *essential generic medicine!*"

\* "*Essential generic?* What does that mean?" enquired Mr. Paracetamol.

\* "How come I have to tell you everything? Aren't you a medicine like me? You wouldn't be a sub-standard medicine, or worse still, a fake, would you?" Monsieur Paracetamol retorted, somewhat irritated.



Mr. Paracetamol blushed while Papa Sitamal turned his head and looked uneasily all around him.

Monsieur Paracetamol began again:

- \* “**Essential**” means that WHO has judged that the active substance, **Paracetamol** (whose name I proudly bear) does indeed relieve pain and reduce fever and that the price- quality ratio is good.



**Generic**” shows that I contain the same active substance as **the brands** that you find in pharmacy shops with names such as **Efferalgan**; but in fact I was made legally by another manufacturer, not the one who made the original product, nor the one who first marketed it, nor the one who patented it. And

the quantity of **active substance**, the **paracetamol**, acts as quickly as **Efferalgan**, so its effectiveness is exactly the same – that’s what they call **‘therapeutic equivalence’**. But my main advantage over **Efferalgan** is that I am sold at a lower price! You see?”

- \* “Yes, I see.” replied Mr. Paracetamol, but I want to pick up on a comment you made a little while ago. You said ‘sub-standard medicine, or worse still, a fake’. Excuse me, but what do you mean by that?”

- \* “Medicine is **‘falsified’** when the information given on the label doesn’t tally exactly with what it contains. It could be that the actual ingredients, or the proportions, don’t match with what’s on the label – even though the



ingredients could be standard; or it could be a **‘counterfeit’** that contains false ingredients or an insufficient quantity of the ingredients... That’s criminal.”



\* “So what can be done to be sure of the quality? Is that even possible?” asked Mr. Paracetamol.

\* “Yes, but let me finish telling you my story before I come to that.” answered Monsieur Paracetamol. “First of all we had to leave Europe and be accepted in other countries, in Africa, Latin America and Asia. In theory, it’s up to the importing country to agree to the registration of a drug, based on a technical report from the exporter and a pharmacological study. We had been travelling by boat for days and days before we reached the country’s harbour; as it was cool and dry in the ship’s hold, our quality did not suffer from the ‘cruise’! We then went through the customs formalities - fortunately the paperwork was all in order. Next, we were taken to the central purchasing depot where we were sorted and put away according to our category and age. We were still kept in a cool, dry place.”

\* “You were lucky” interrupted Mr. Paracetamol. “I wasn’t protected like that; the carriers left me in the sun – and the rain – and some people got hold of me and I ended up in the street. I’ve no idea how I’m still alive and yet next to me there were some drugs in an even worse state.”

Monsieur Paracetamol continued:



\* “One day someone came to fetch us from our shelves and we learned that his name was Benedict. He had a list that corresponded, so he said, to the medication needs of the patients at his health centre. He looked at us closely and asked the seller at the central purchasing depot some questions and requested some documents with the authorisation number and the lot registration number.

Once the boss of the depot had given him all this authentication, Benedict turned his attention to the name of the manufacturer and the prequalification of the medicines he was buying. As it was the first time he was buying from

this depot, he asked for a copy of the GMP (Good Manufacturing Practice) certificate which is part of a quality assurance system that covers the production and testing of pharmaceutical ingredients as well as the testing of diagnostic products.

That's when I realised that, to protect his patients' health, Benedict had to ensure that the technical norms had been respected at every stage.

- \* I was produced, checked and recognised as stable, in other words my active substance – paracetamol – and all the other ingredients weren't going off. To ensure I remain stable long enough, a few more formalities had to be followed: I was wrapped in a little pocket made of perfectly sterile plastic; that's what they call primary packaging. And the metal box I am kept in, the secondary packaging, is sterile, waterproof and airtight. All this means that I keep fresh right up to the end of my life as declared by my manufacturer, in other words my expiry date.



Mr. Paracetamol replied:

- \* “Wow, what a story!”
- \* “Take a good look at the box I've come out of. There were 1000 of us tablets in there. What can you see on the box? There's a label with the following obligatory information:

My **generic name**: Paracetamol

My **composition**: 500 gm Paracetamol plus the excipients sorbitol and sodium.

My **pharmaceutical format**: I am a dividable tablet because I have a little furrow across my middle so that I can be split into two almost equal parts.

The **name of my manufacturer**: CIPLA. It's a well-known Indian company.

My **lot number**: 15348

My **expiry date**: the date I must be used by. Mine is 112011, before November 2011. Often the manufacturers even add the **date of production**.

**How I should be administered**: as I am meant to be swallowed, it says 'orally'.

**PARACETAMOL**

Composition: paracetamol 500mg, excipient sorbitol, sodium (sufficient for purpose). in tablet form

Pharmaceutical format: dividable tablet

CIPLA

I 5348

Expiry date: use by 11 2011

How to administer: orally

Authorised drug: No. 325 SU 700 1

**PARACETAMOL 500 mg**

**COMPOSITION** Paracetamol 500mg. Excipient sufficient for purpose. An effervescent, dividable tablet;

**PHARMACEUTICAL FORMAT**: effervescent, dividable tablet . Box of 16 tablets.

**LIST OF EXCIPIENTS WITH KNOWN EFFECTS**: sorbitol, sodium.

**THERAPEUTIC INDICATIONS**: this medicine contains paracetamol and is to be given in cases of pain and/or temperature such as headache, flu symptoms, toothache, stiffness, painful periods. This should be used only for adults and children weighing more than 13kg (or from the age of 2)

**METHOD OF ADMINISTRATION** oral. To be drunk after being dissolved in a glass of water.

Drug authorisation number: 325 SU 700 1.

**The code**: this is a series of figures and letters giving the authorisation number of the manufacturing or importing company and the product's registration number.

What's more, in the box you will find instructions that give important information about me in simple English.

The information on the label appears again, but there are also the therapeutic indications and the mode of administering it. This information makes it easier for Benedict and even the patients to use me."

\* "On these instructions, where's the **International Common Denomination (ICD)?**" asked Mr. Paracetamol.

\* "In my case, it's **Paracetamol**. For others it's ascorbic acid or amodiaquine ... it's vital that this **active substance** that has been recognised is shown."



"I see that Benedict has a very important role to play", concluded Mr

Paracetamol. “He must always read the label on the box carefully, check that all the indications are mentioned there as well as on the instructions, pay attention to the date after which the patient mustn’t take the medicine anymore and have the courage to throw out medicines that are out of date – and tell everyone he works with to do the same. By being very careful, Benedict and his colleagues will be able to avoid the fake and the counterfeit medicines.”



\* “Yes” added Monsieur Paracetamol, “But let me continue to tell you my story. When Benedict had finished going round the central purchasing depot he had found all the drugs that he’d written on his list. He put some of us in strong, securely closed cardboard boxes while he put the more fragile ones in cool boxes.

He loaded us into the vehicle and, although we were jostled about on the road, we were well protected.

When we reached our destination, Benedict and his co-workers took us out of our boxes and put us on the shelves, all of us except the products in the ice boxes that they put straight in the fridge. Each drug was put out according to its expiry date and its date of arrival; the room where we were staying was cool, dark and locked, just like at the central depot.”

\* Mr Paracetamol interjected: “Sir, I see that you are a medicine whose quality has been assured, but that I’m not!”

\* “Why do say that?” asked Monsieur Paracetamol.

\* “I’m here because Benedict confiscated me from an itinerant salesman; he has been treating me as a sub-standard medicine! I have to admit that I do not conform to all the quality assurance criteria; for example, I’m not sure how much active substance I contain nor if I’m equivalent to Efferalgan. As my Indian manufacturer knew that I was destined for export to Africa, I was made on another, less sophisticated, production line than the paracetamol that was destined for Europe. However, the box I was in was more attractive than yours and I was even better wrapped than you. You know, my travelling

conditions were terrible and the heat was unbearable ; when the boat leaves for Europe, though, everything is spotless. I wasn't 'prequalified' by a trusted agent and they didn't carry out the necessary controls when we entered the country. So if a sick person swallows me, I may well not have the desired effect. I could even do him harm!"

- \* "Incredible!" deplored Monsieur Paracetamol. "How could a manufacturer think of making second class drugs for Africa? And how come our government agrees to putting medicines like you on the official list? Could it be that they are willing to risk endangering patients' lives for the sake of earning more money? That's sickening."



Next Monsieur Paracetamol turned to Papa Sitamal who had gone silent.

- \* "You're not saying anything. It must be your turn to tell your story."

Then with sadness Papa Sitamal said:

- \* "I too was caught by Benedict; I was on a market stall with the sun beating down on me and I was pestered for hours on end by the flies. Although I am so like you that you might not tell the difference, I am in fact a fake medicine, a counterfeit, an illusion."
- \* "What?!" exclaimed the two other tablets simultaneously.
- \* "Yes" Papa Sitamal explained, "I do not contain the product that is shown on the box even though it looks so good. What's more, the information on the label is completely false."
- \* "Tell us the whole story" requested the other two.
- \* "The truth is I'm a tablet made of corn flour compacted with a nice-tasting glue – what you apparently call an excipient! I was made in a secret

laboratory near the capital city. Between ourselves, there are masses of fake medicines like me and many people are taken in by them – even doctors and nurses! Ha ha, ha!” guffawed Papa Sitamal.

At this, Monsieur Paracetamol got really angry.

- \* “You’re a fake, a counterfeit. You deliberately and fraudulently pretend you are something else, so your manufacturer rakes in the money while the sick don’t get the treatment they need and risk being poisoned or even dying! That’s despicable!”



Monsieur Paracetamol was about to attack Papa Sitamal but Benedict intervened:

- \* “Papa Paracetamol, I understand your anger. Like me, you can see the danger that the sick are in if they take sub-standard or fake medicines. I could earn a lot of money with these so-called drugs but if I did could I still be called a nurse? Leave it to me. These two tablets are going to have their just deserts: I’m going to destroy them.”



Some women carrying their children had observed the whole scene and applauded Benedict, ululating.

## Conclusion

Choosing and giving out quality medicines that are good for the patients’ health is the most important task of **caregivers**.

They need to learn about which drugs to prescribe: know their names, the names of the trustworthy/well-known pharmaceutical companies that produce them, their quality, their possible side effects and their expiry date, etc.

WHO has drawn up a list of essential drugs it is regularly updated. It is good to refer to it constantly.

No need to remind the carer to look carefully at the dosage that varies according to the age of the patient. Some products are presented in different colours, dosage and different times of taking them according to whether it is for a young child, an adolescent or an adult. If the wrong dosage is given it will not work or else could be harmful.

Great vigilance is needed to ensure medicines don't go off or out of date. Some products have a very short lifespan and need to be stored carefully.

Benedict and his co-workers take care to have the medicines they have prepared near at hand in the consulting room. If they take them out of the box they can give them to the patient more easily. They take time to explain clearly to the patient how to take the medicine.

The Mekanene dispensary is in a village, but a few miles away there are other health centres and Benedict and his co-workers meet up regularly.

They discuss together their work and what medicines they need. By coming together to buy what they need from the central purchasing store, they find they can check on the quality of the drugs together and even demand higher standards from the supplier.

The **patients** also need to take responsibility for the care they receive and the drugs they are given or buy.

They must learn about the need to treat themselves with good quality drugs.

The caregivers, facilitators and educators must help them understand that it is dangerous to buy medicines on the open market. They must be told of the importance of taking the right dose.

It is also necessary to help people understand that good health is an important resource and it is important to be ready to spend money on it when necessary: quality has a price.

Above all, they must not take remedies if they are unsure of their origins and effectiveness or how well they have been stored.

# **CHARTER FOR QUALITY ASSURANCE OF MEDICINES, VACCINES, DIAGNOSTIC PRODUCTS AND SMALL MEDICAL EQUIPMENT**

## **Preamble**

By means of consultation, coordination and the organisation of shared activities, this initiative hopes to build a bridge between the academic world and those working with the patients. Be-cause Health is working with WHO and other competent agencies in a special way on the theme of medicines.

The quality of medicines administered to patients is one of the major concerns expressed recently by numerous national and international protagonists. As health organisations working cooperatively, we naturally use medicines, vaccines, small medical equipment and diagnostic products with the patients in our care. In order to deliver good quality curative and preventive care, it is important to be able to assure the quality of all these items.

For this reason, our organisations are undertaking to contribute to the implementation or strengthening of quality assurance by agreeing, via a quality assurance charter, to take special care when buying these products. Hopefully, this action will gradually result in better regulation of the market and a culture and ethic of quality and responsibility among all who are involved in this vital field.

The Organisations signing up to this Charter,

*Believing* that all patients, wherever they live, have the right to be cared for with medicines, vaccines, diagnostic materials and equipment whose quality is guaranteed,

*Considering* that the products available to our health teams and partners in the South should conform to the same quality norms as those used in the North,

*Recognising* that the current situation is a matter of great concern,

Adopt the following quality assurance system for the products mentioned above:

To assure the quality of the products available to the projects of our organisations in the South, the drugs, vaccines, medical material and the in vitro diagnostic medical devices that we judge to be essential must conform:

- ◇ to the norms and standard defined by WHO (see technical reports1) and to internationally renowned pharmacopeia;
- ◇ to the norms and standards defined by the ISBT [International Society for Blood Transfusion] (see technical reports), or to the norms and standards set out by the European Union uniquely for products found in Appendix IIA and B of Directive 98/79/EC of the EU (see technical reports).

We consider the following products to qualify for our organisations:

- ◇ Any pharmaceutical product prequalified under the WHO prequalification project.
- ◇ Any pharmaceutical product registered in a well regulated country (EU, US, Japan) and that is listed among our essential drugs.
- ◇ Any vaccine prequalified by WHO
- ◇ Any vaccine registered in a well regulated country and that is listed among our essential products.
- ◇ Any medical material and the in vitro diagnostic medical devices prequalified or qualified by WHO and/or by the International Society for Blood Transfusion
- ◇ Any in vitro diagnostic medical devices authorised in Europe and found in Appendix II A&B of Directive 98/79/EC of the EU that features in our list of essential products.
- ◇ Any medical material and the in vitro diagnostic medical devices authorised

in a well regulated country (US) and that features in our list of essential products.

If products do not conform to these criteria, we reserve the right to check their conformity with the appropriate standards (See user's guidelines at [www.aefjn.org/index.php/358/articles/charter-for-the-quality-of-medicines.html](http://www.aefjn.org/index.php/358/articles/charter-for-the-quality-of-medicines.html)) This evaluation may be delegated to individuals or organisations that we believe to be suitably equipped to do the checking.

The members of Be-cause Health who sign this Charter undertake to work with professional auditors who are responsible for the monitoring of the approved factory sites. The audits are carried out according to WHO's Good Manufacturing Processes.

At any time samples of products that have been delivered can be sent away for analysis in an official laboratory.

## **Declaration of Honour**

The distributor or manufacturer gives his word of honour:

- ◇ that he agrees to collaborate, if necessary, with the auditors appointed by our organizations
- ◇ that the information provided is accurate and correct
- ◇ that any changes in the manufacturing process or the source of a product will be promptly communicated.

Any error or omission, whether intentional or not, can lead to the immediate disqualification of the product (s) and / or invalidation of producer.

It can also lead to the cancellation of all commercial contracts concluded on this basis.

## Personal notes

## **SIGNING OF THE 'CHARTER FOR QUALITY ASSURANCE OF MEDICINES, VACCINES, DIAGNOSTIC PRODUCTS AND SMALL MEDICAL EQUIPMENT**

Name of Organisation:

Postal Address and Country of Organisation:

E-mail Address of Organisation:

Name of the undersigned:

Role of the undersigned:

E-mail address of the undersigned

I/We, the undersigned, undertake

- ◇ To be very attentive to the quality of drugs and other medical products used by our organisation;
- ◇ To use this Charter for commercial dealings with our suppliers and producers of medicines and other medical material;
- ◇ To alert other members of Be-cause Health if there are any problems or incidents where we work;
- ◇ To take part, if necessary and possible, in collective initiatives relating to the audit;
- ◇ To do everything possible, as a partnership, to improve the medium term situation if in our work we are faced with national systems or private networks that do not guarantee a quality checking.

Date

Signed and sealed:

**Please** complete these details and send this form to: **AEFJN, 174 rue Joseph II, 1000 Brussels, Belgium**

E-mail address: **aefjn@aefjn.org**



## **Africa Europe Faith and Justice Network – AEFJN**

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