Risks and Benefits of Medicines and Medical Devices – Perceptions, Communication & Regulation

Report on Qualitative Research among the General Public

Research Study Conducted for The Medicines & Healthcare products Regulatory Agency

Ipsos MORI

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Introduction

Background & Objectives

Ipsos MORI was commissioned to undertake a qualitative and quantitative research programme to discern and quantify the perceptions of the general public and of healthcare professionals (HCPs) about the risks associated with medicines and medical devices, and of how well they are regulated and communicated in the UK.

This memorandum reports on the qualitative work that was undertaken with the general public. The core objectives of this part of the research programme were to explore:

1. Experiences of medicines and medical devices, and their perceptions of risk associated with them;

2. Perceptions of how medicines/devices are regulated and how they should be regulated;

and

3. Attitudes towards the communication of information about medicines/devices.

For the qualitative general public research, six focus groups were conducted, supplemented by six in-depth telephone interviews.

The focus groups were run by experienced Ipsos MORI moderators. Two groups were held in the north (in Manchester), two in the midlands (in Birmingham) and two in the south (in St Albans). Quotas were set for: age, gender, social grade, those who have visited their GP in the last year, those who have had surgery in the last year, those who have used any medicine in the last year and those who have used or experienced devices used in connection with their health. The groups each lasted one and a half hours. They were held between 25 - 31 Jan 2006, and digitally audio recorded, and video recorded (in St Albans only) with participants' permission. MHRA attended two of the focus groups as observers, sitting in another room and being connected via a video link. The depth interviews lasted 45 minutes, on average, were moderated by Ipsos MORI executives and also audio recorded. The topic guide, which was developed by Ipsos MORI in consultation with MHRA as an aide memoir for group moderators, asks about issues to do with medicines and medical devices. All six groups were asked to comment on both. A summary of the composition of each group is given in the table below. Three of the six focus groups were conducted among those aged 55+, to reflect the fact that a higher than average proportion of older people will have had experience of using medicines frequently, or of using devices:

	Age	Social Class	Gender	Quotas	Group Attendance
Group 1 St Albans 25/01/06	55+	C2DE	Good mixture	Some to have had surgery in last year, and some to have seen GP in last year	10
Group 2 St Albans 25/01/06	35-54	ABC1	Good mixture	Some to have seen GP in last year	6
Group 3 Birmingham 26/01/06	55+	C1C2	Good mixture	Some to have seen GP in last year	8
Group 4 Birmingham 26/01/06	35-54	C2DE	Good mixture	Some to have had surgery in last year, and some to have seen GP in last year	7
Group 5 Manchester 31/01/06	18-34	C1C2	Good mixture	Some to have obtained medicine or device from pharmacy in last year, and some to have seen GP in last year	10
Group 6 Manchester 31/01/06	55+	ABC1	Good mixture	Some to have obtained medicine or device from pharmacy in last year, and some to have seen GP in last year	10

The telephone depth interviews aimed to pick up 'hard to reach' people who: may find it difficult to come to focus groups e.g. people living in rural areas, carers or disabled people; or who may not be represented in a high enough proportion nationally to guarantee that they would be recruited for a focus group (i.e. people from BME (Black and Minority Ethnic) groups. In this memo findings from the depth interviews are blended in with the focus groups findings where applicable.

A summary of the quotas and depth interviews conducted are shown in the tables below:

Quotas Set:

Geographical distribution	6 interviews distributed across The North, South and Midlands (one interview to be in a rural location – see below)
Gender	Aim for a good mix
Age	2 with elderly people (aged over 60) – one of which needs to live in a rural area
Ethnicity	1 with a BME participant
Carers	2 with people who care for others (not in a professional capacity) e.g. for an elderly relative
Disability	1 with a disabled participant (respondent must have a disability which has a profound impact on their everyday life (for example, those who have partial or no sight, wheel chair user, etc). We are **not** looking to recruit people with learning difficulties or long term illness.
Medicines and Devices	All to have used medicines and/or medical devices in the last year. At least 1 of these to have used devices or experienced devices used by healthcare professionals in connection with their health

Depth Interviews Conducted

Respondent Details	Date/Time	Quota
Male Suffolk	Monday 30/01/06 10am	Elderly
Female Birmingham	Monday 30/01/06 11am	BME
Male Manchester	Monday 30/01/06 5pm	Carer
Male Birmingham	Tuesday 31/01/06 11am	Elderly (carer)
Female Manchester	Tuesday 31/01/06 5pm	Disabled
Female Hertfordshire	Wednesday 01/02/06 2pm	Rural (carer)

By its very nature, qualitative work provides insight into issues and a feel for the range of opinions held. However, the numbers of participants are small and results cannot be regarded as being representative of the general public as a whole. That representation will come from the forthcoming quantitative work.

Publication of Findings: Our standard Terms and Conditions apply to this, as to all studies we carry out. Compliance with the MRS Code of Conduct and our clearing is necessary of any copy or data for publication, web-siting or press releases which contain any findings derived from Ipsos MORI research. This is to protect our client's reputation and integrity as much as our own. We recognise that it is in no-one's best interests to have survey findings published which could be misinterpreted, or could appear to be inaccurately, or misleadingly, presented.

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Summary of Key Findings

Confidence in medicines and medical devices seems to stem from an overall confidence in doctors. This echoes sentiments from Ipsos MORI's long-standing work on trust in doctors, which reveals that doctors are the most trusted group by the public (to tell the truth) and that they have held top position or joint first position[1] since measurements began over two decades ago[2]. However, there was strong feeling and concern in some groups that over-worked doctors can give the wrong advice. Despite this concern, most say they do take or use what their doctor recommends. Some, however, are more wary, feeling that doctors are rushed and overworked and thus can make mistakes.

Most seem to trust doctors to weigh up the risks and benefits involved in taking medicines. Some group members say that reports in newspapers often negatively affect their confidence in taking a medicine. Others generally make a habit of consulting side effects listed about a medicine or device that is recommended to them by their doctor. This suggests that side effects listed in pack inserts have a dual role in that they can both increase or decrease confidence in a medicine, depending on the perceptions of the patient who reads them and what is stated in the insert.

Older participants (aged 55+) form opinions on medicines and medical devices based on personal experience, or experience of friends and family. They are generally positive towards medicines and see them as vital. Any negative perceptions only apply to medicines – those who have used devices (who tend to be fewer in number) are much more positive about these.

Some **younger Participants (aged 18-55)** talked about negative experiences with antidepressants which they had had. Others expressed concern about the side-effects of painkillers. Their general approach to taking medicines is cautious. They say they only take what is needed as they worry about getting accustomed to, or becoming dependent on them. Most read leaflets about medicines and their side effects. However, some say they take a particular medicine even though they know it has side effects They are not necessarily consciously weighing up the benefits against the risks, but rather focus on any immediate benefit. Younger participants across the groups feel they can place more trust in their doctor than older people. The general feeling is that they need to do so as the choice of, and possible interaction between, drugs is very confusing. Some say they gain confidence in taking a medicine from reading about the drugs, and often "Google" them, looking into things beforehand.

With the exception of one or two, for older Participants, 'risk' is something that they found hard to conceptualise. The consensus was often one of having few concerns, because they trust what their doctor is prescribing. Some members of the older groups say they are not really worried about safety. Their general feeling

[1] Once - with teachers in the late 1980s.

[2] For example, MORI/Sunday Times; MORI/Cancer Research Campaign, MORI/BMA/RCP work on 'trust in professions', and MORI/OST 1998/9 and 2004

is that if you can buy the medicine or device, you assume it is safe. Older participants do not really think of medical devices in terms of risks associated with them. Rather than a specific deliberate weighing up of risks versus benefits before they take something, older participants work on a trial and error basis and willingness to accept greater risk is dependent on how ill the person is.

Younger participants do not generally have strong concerns about the safety of medicines or devices. Most concerns and fears centre on dependence (e.g. painkillers and anti-depressants) and no real concerns are shown about devices. Some worry about long-term effects of medicines (e.g. from the contraceptive Pill), but this does not stop them from taking it. Causes for concern are generally other people's bad experiences but there is acceptance that one does not really know until you have tried it yourself. There is also recognition among younger groups that different people react to medicines in different ways, and that not everything is known about drugs when they are released.

The general assumption among older participants is that pharmaceutical companies test drugs, and that therefore must be 'someone independent' who checks them, but participants were not aware of who that person or organisation might be. Although it would depend on circumstances surrounding a problem with a drug, older participants generally see responsibility and blame for anything going wrong as lying with the pharmaceutical industry. Some say the doctor or surgeon has some responsibility too, in that they should not use medicines or devices unless they are sure they are *'ok'*. Much like their older counterparts, younger participants generally say they would like to think that medicines and devices are regulated and presume that they are, but they do not know specifically *how*.

Among older Participants, doctors are the most trusted source of information and *'drug companies'* the least trusted. Members of all older groups say they trust information provided in pack inserts. GPs are cited as the preferred communications channel for information on risks of medicines and medical devices. For more general information about risks and benefits of medicines and devices, a diverse range of sources is mentioned; such as: TV, newspapers and patient conferences. Participants are generally distrustful of information from pharmaceutical companies.

Younger participants like their older counterparts, tend to trust information from their GPs the most. However, they are more inclined to refer to the internet compared with older participants. Young people are less trusting of the media than older people. Distrust of information from pharmaceutical companies is also apparent among younger participants. They trust personal experience and express more desire to make up their own mind. There is a desire for transparency among all groups. This stems from a general concern that drug companies have too much influence over communications of risks and benefits of medicines and devices.

Awareness of MHRA among older participants was confined to 1-2 individuals. They feel MHRA should publicise itself more – through press releases, *Which?* Reports, broadsheets, and leaflets/posters in surgeries. The consensus is that

regulators are currently not strict enough and some express concerns about money in the medicines and devices industry having an undue influence on regulatory decisions. All agree there is a need for a very strong regulatory body with medical and non-medical people involved. They want this body to provide full details about new products, giving a balanced evaluation of both the risks and the benefits. Most younger participants have not heard of MHRA. All show a unanimous desire for MHRA to publicise itself more in surgeries, on T.V. and via pop-ups on the Internet. Younger people feel that regulation does happen, but they would not generally ask how things are regulated.

The general public qualitative research shows that there is a need for MHRA to communicate the stringency and thoroughness of its regulatory procedures. It is this reassurance that is required by the public who (from the evidence of these groups), for the most part, recognise that everything in life involves some risk.

General Public Qualitative Findings

Confidence in Medicines/ Medical Devices

Older Participants (aged 55+)

Older participants aged 55+ have taken a variety of medicines and used a range of devices. Responses to them depend much on personal experience, or experience of friends and family. For example, the general consensus among participants in St Albans (aged 55+, C2DE) is that they are happy with their experiences and even though some have experienced side effects, this seems to be accepted as an inevitable part of taking medication. On the other hand, most of the Birmingham group (aged 55+, C1C2) talked about their negative experiences, especially in terms of side effects. However, this negative perception only applies to medicines – those who have used devices e.g. a replacement knee or a leg support, are much more positive about these. In fact, few issues concerning confidence in devices arose from any of the elderly groups For this reason most of the participants were more inclined to talk about medicines throughout the focus group and telephone depth discussions[3].

Those aged 55+ are generally positive towards medicines and see them as vital. They credit them for the fact that they are alive. Most of those aged 55+ are on some sort of medication themselves (They have a range of conditions such as diabetes; heart conditions, kidney stones, arthritis etc).

An elderly respondent in the depth interviews states that he only takes medicines if they are absolutely necessary.

> *I won't take them unless it's absolutely really, really necessary. I'll put up with a headache rather than take Disprins and what have you. I very rarely take anything for a cold other than upping the vitamin C and that sort of thing. I'm more into, I'm more into natural health products really.*
>
> Male, Elderly, Rural area, In-depth telephone interview

A disabled telephone interview participant also holds this view:

> *I don't like medication to be quite honest. I prefer to get something from the health shop if it's possible to replace normal medication and I use Country Oil and it's good for arthritis.*

[3] It is difficult to know exactly why older people in Birmingham were more negative towards medicines than older people in St Albans (the social classes overlap, but maybe C1s have higher expectations). It could be the difference between an urban and more rural area, particularly as those in Birmingham commented that their GP was busy/ too busy to spend time with them. However, it needs to be noted that the numbers involved in this phase are small.

Female, Disabled, In-depth telephone interview

However, the elderly depth interview respondent goes on to say that medicines have been invaluable to his life. As a builder, creams helping his dermatitis allowed him to carry on working through the affliction and painkillers are now helping him to cope with his arthritis.

> *I've got arthritis, again through the building trade, and I've been on glucosamine sulphate tablets now for the past five years and I really do think they help. I'm almost 68 and I'm still going down the golf course and still enjoying life*
>
> Male, Elderly, Rural area, In-depth telephone interview

Confidence in medicines and devices seems to stem from an overall confidence in doctors[4]. Elderly participants in the St Albans group say they trust their doctors: if their doctor recommends or prescribes something, they will take it. Again, elderly people in Birmingham are more negative. There was strong agreement and concern in the group that over-worked doctors often give the wrong advice. Despite this concern, however, most say they do take or use what their doctor recommends and agree that this contact with doctors is far more preferable than buying medicines directly from the internet for example. Trial and error is the key to gaining confidence in a medicine or device among older people aged 55+: if a product works and they don't experience serious side effects, they keep using it. Confidence is also gained from looking at side effects listed in pack inserts with medicines.

As for influences on whether or not they actually take a certain medicine, again a doctor's recommendation is the strongest factor among those aged 55+. This does not mean that people take things without thinking about it though: members of the St Albans group say that reports in newspapers often negatively affect their confidence in taking a medicine, and members of the Birmingham group generally make a habit of consulting side effects listed about a medicine or device that is recommended to them by their doctor. This suggests that side effects listed in pack inserts have a dual role in that they can increase **or** decrease confidence in a medicine, depending on the perceptions of the patient who reads them and what is stated in the insert. St Albans and Manchester (ABC1) elderly participants seem to trust doctors to weigh up the risks and benefits involved in taking medicines, however, Birmingham participants are more wary - feeling that doctors are rushed and over-worked and thus can make mistakes. This perception was largely based on personal experience.

Although not the consensus view, one participant in the Manchester elderly group feels very wary of all medicines. She views them as being toxins that are foreign to your body. Thus she is very careful of what she puts into her body across the board (food and drink, for example). Her negative views originate

[4] Which echoes Ipsos MORI's long-standing tracking work, revealing that the huge majority of the public trusts doctors to tell the truth (MORI/BMA 1998-2005; MORI/Cancer Research Campaign 1997; MORI/Sunday Times 1983-1996).

from bad reactions to medicines when she was seriously ill, and conflicting advice from doctors about what to take.

However, in certain cases respondents in the 55+ Manchester group made the decision that some medicines were not worth the risks of the side-effects, despite doctors' prescriptions (especially when they were suffering from other complaints that might be exacerbated). They found out about the risks through a range of means, including the leaflets provided with medicines, and websites. Despite the consensus among this group that they trust their doctors' judgement, they do not believe that doctors (especially GPs) are fully informed about what is available. In some cases they have themselves asked the doctors about certain treatments.

One respondent who suffered from arthritis had read about a painkilling patch which could be used instead of having to swallow tablets. She followed this up with her doctor and although it was unknown to her doctor at the time, she is now using it. Another respondent had unsuccessful surgery to put a stent in a blocked artery. He heard from a contact in the US that the artery could be cleared by using laser treatment and reported this to his doctor. This was investigated and he is now being referred to one of the few centres in the country which offer the treatment.

Confidence for one elderly telephone interview participant centred on the presence of a regulator to act against counterfeit medicines:

> *Well, if I had to go to the doctors I must admit after reading articles in the papers, I would be thinking 'Now is this tablet he's given me bona-fide'. It's quite disturbing, but the actual pharmacies and hospitals are being supplied them and I think it's something; a governing body should be jumping on like a ton of bricks. It's really, really important. But it's, but again, it's only a report I read in the newspaper.*
>
> Male, Elderly, Rural area, In-depth telephone interview

Another elderly telephone interview participant, who is also a carer, has the same concerns.

> *My wife's on thyroxin and when we get the tablets from Boots's the boxes are always the same colour. When she got the last lot they were different colours and she wanted to know why and what she was worried about was were they trying to give her tablets, inferior tablets from somewhere else, like not made in England.*
>
> Male, Elderly (carer), Manchester, In-depth telephone interview

Younger Participants (aged 18-34 in Manchester and St Albans) & (aged 35-54 in Birmingham)

A variety of medicines are used across the younger groups. Two respondents from the Birmingham (C2DE) group talked about negative experiences with antidepressants. There was strong agreement within this group that aspirin is *'a godsend'*, and they couldn't live without it – two did however express concern about its side effects. All but two respondents among the Manchester (C1C2) younger group are dependent on medicines or devices on a regular basis.

A BME telephone interview participant who takes blood pressure tablets and has had MRI scans also stressed the importance of medicines and devices in her life:

> *I have a lot of confidence in them. They are necessary, you need them, you've got to have them, you can't do without them, because how would you plan get well if you don't use these things? They are absolutely necessary.*
>
> Female, BME, Birmingham, In-depth telephone interview

The general attitude to taking medicines among the Manchester group is that of caution. They say they only take what is needed (one respondent spoke of her reluctance to let her two year old be put on asthma medication). However there is a feeling that if you have been brought up with a treatment (e.g. medication for asthma; certain painkillers etc), you start to think of them as 'normal' and cease to worry about them, or even to be cautious towards them. The same applies in the St Albans (ABC1) group: many try to avoid medicines unless they really need to take them, as they worry about getting accustomed to them and then finding that they do not work when they need them. They also often feel that if they feel ill, there might be a simple reason for it (e.g. dehydration).

St Albans participants say they read inserts and find out information about side effects. However, some members of this group say they take the medicine despite knowing it has side effects. (Although it is not the case for all participants, there seems to be a greater tolerance of risk - in the form of side effects and having less trust in doctors - among younger, compared to older participants. This is something which could be examined further in the quantitative phase).

Despite being slightly older, views among the Birmingham group do not differ much from those in Manchester and St Albans: they feel they 'must have' medication e.g. antibiotics if prescribed by the doctor, but many try to stay clear of medicines unless they really need to take them. The greatest concern seems to be worry about getting dependent or over-reliant on medicines. These slightly older participants (Birmingham group) also talk about reading leaflets about medicines and their side effects. However, some admit to taking the medicine even though it has side effects (though they seem to know that every medicine can have side effects). Others read side effects and decide not to take medicine if those side effects seem potentially worse than their illness. Consensus within this group forms around the perception that information given about medicines or

devices can sometimes be confusing, especially when the packaging, or name change. Some group members say side effects are only listed by companies to 'cover themselves' against lawsuits, rather than in the interests of patient safety.

Younger participants across the groups feel they can place more trust in their doctor than elderly people.

> *If you are not well, if you are ill and you go to the doctor and you are your asked to do these things, you just have to do them. You can't do without it, there's no other way out.*
>
> Female, BME, Birmingham, In-depth telephone interview

The general feeling is that they need to do so as the choice of and possible interaction between drugs is very confusing. As long as the doctor or pharmacist explains their symptoms properly, they are pretty confident they will give them the right medication. Members of the St Albans (ABC1) group gain confidence in taking a medicine from reading about the drugs and often "Google" them, looking into things beforehand.

Perceptions of Risks and Benefits

Older Participants (aged 55+)

Specific medicines that people are worried about include: Hormone Replacement Therapy; steroids; drugs containing blood fractions; blood transfusions; 'fear of needles', anti-malaria tablets; Prozac; beta blockers; painkillers (e.g. Aspirin, Paracetamol, co-codamol); antibiotics; new drugs on the market; blood pressure medications; devices for syringing ears and wheelchairs. These concerns are based on individual experiences, as well as media coverage highlighting concerns.

With the exception of one or two participants, 'risk' is something that members in the older groups aged 55+ found it harder to conceptualise. The consensus was often one of having few concerns, because they trust what their doctor is prescribing. Some members of the St Albans group say they are not really worried about safety – if you can buy the medicine or device, you assume it is safe. Other members of this group say that they **do** worry about possible interaction with other drugs, in which case they consult their doctor.

Elderly participants don't really think of devices in terms of risks associated with them. An elderly telephone interview participant said:

> *I suppose the time will come when you have to go with whatever will aid you, haven't you? Basically it's needs must, isn't it? So I don't think I'd think about it twice if I had to be in a wheelchair I'd have to be in a wheelchair and that would be it.*
>
> Male, Elderly, Rural area, In-depth telephone interview

Discussions about risk amongst the groups were often framed around trust in doctors. Participants in the Birmingham group are less trusting of their doctors' advice than those in St Albans. They say doctors are too busy to know right thing to prescribe and which drugs are safe. They write out prescriptions before they tell you what's wrong with you – they want to feel confident that their doctor has thought about it. Some participants in this group feel that risk comes from large pharmaceutical companies. For example, one participant expressed concern that profit-driven big industry ignores natural remedies such as diet and health education - in favour of chemical remedies. Another added that stricter safeguards are needed to prevent drugs being put on the market before they are tested.

An elderly telephone interview participant stressed the importance of finding alternatives to what he called 'addictive' drugs such as anti-depressants:

> *Yes,, I think, doctors should look at alternative ways rather than putting people too quickly on to anti-depressants. Same way they're trying now to get people off all the steroids and things, I think it's something people should be aware, made aware of and be very careful and if there's an alternative route, take it, i.e. herbal. Or counselling perhaps in the case of depression.*
>
> Male, Elderly, Rural area, In-depth telephone interview

Older participants aged 55+ in the main do not weigh up risks against benefits; they feel they are taking a medicine to help their condition or illness, so they do not worry too much about it unless they have a particular reason to do so. Members of the Birmingham group say that things they see on TV and in the media make them look for and read things about a medicine, whereas in the past they used to just take whatever was given to them. For one participant, the Dr Shipman mass murders raised concerns and now makes them ask their doctors more questions.

> *If the doctor prescribed a certain drug I'd want to know the background of it, yeah, because I think you are what you put in your mouth*
>
> Male, Elderly, Rural area, In-depth telephone interview

The same elderly participant thinks the responsibility for risk/benefit decisions lies with the patient::

> *In a chemist there should be no risk, where people can buy over the counter there should be no risk whatsoever. But the doctor should say, look, I'm going to prescribe these, we think this will cure the problem but there will be side effects and you should be made aware of the side effects. Openness basically, and then the patient or whatever can make either his or her decision on whether they take it because it's their bodies after all, isn't it?*

Male, Elderly, Rural area, In-depth telephone interview

Rather than a specific deliberate weighing up of risks versus benefits before they take something, they work on a trial and error basis. As people wish to minimise or avoid side-effects completely (and benefits of medicines are sometimes seen within the context of having no side effects) they often make sure they are ***aware*** of the side effects. If they suffer them, they go back to their doctor and change their medication. A key consensus among the Birmingham group is that they know side effects can vary from individual to individual and thus one would never know what the risk would be until they took the medicine or used the device. Older participants aged 55+ mostly say they leave it up to their doctor to make such risk/benefit decisions for them. There is some demand for more information about possible alternatives to prescribed medicines and devices e.g. acupuncture or herbal remedies.

Willingness to accept greater risk is dependent on how ill the person is – if they know that something will cause negative side effects but may also help them overcome their illness, they will consider taking it. However, they did recognise the potential risks associated with taking certain medicines. They felt it was a question of balancing potential risks with immediate medical need. One respondent in the Manchester group had to make a choice as to whether or not to keep her husband on heart medication which was found to have serious effects on other organs.

A carer interviewed by telephone expressed concern over antidepressants and states that he sometimes acts on these concerns and prevents his wife (who has schizophrenia) from taking them:

> *Sometimes I do have to remind them (doctors) that if she's not well an antidepressant tablet isn't the answer to everything because I have to live with her and then she's, what's the word, zombified all day. It just makes my job harder, doesn't it?*

Male, Carer, Birmingham, In-depth telephone interview

He then goes on to say….

> *I do feel from the schizophrenic side that they try to have her to get more of these trial tablets. I'll say 'No, she's not having those', and they will respect my opinion.*

Male, Carer, Birmingham, In-depth telephone interview

This person's view is that the risk of the possible occurrence of side effects is favoured by doctors and the NHS over providing full care for a patient, as the cheaper of the two options. For example, he mentions that the alternative to antidepressant drugs is to pay for permanent care for his wife, which would be unaffordable.

He continued:

> *On the National Health it's the lesser of the two evils isn't it? If they don't dose them up to some degree then they've either got to have full care by somebody, or they've got to be looked after in hospital, which costs a lot of money. So it is sometimes easier to hand out the tablets and send them home.*
>
> Male, Carer, Birmingham, In-depth telephone interview

Younger Participants (aged 18-34 in Manchester and St Albans) & (aged 35-54 in Birmingham)

Members of the St Albans (ABC1) younger group do not have strong concerns over the safety of medicines or devices. They are generally quite trusting and say a minority are unsafe, but these are withdrawn quite quickly. Most concerns and fears centre on dependence (e.g. painkillers and anti-depressants) and no real concerns are shown about devices. Some worry about long-term effects of medicines (e.g. the contraceptive Pill), but this does not stop them from taking it.

It is apparent that younger people tend to think about the risks involved with medicines and medical devices more than older people do. Amongst younger groups, there is recognition that some medicines are risky, although there is less of a worry with medical devices. A few respondents in the Manchester group talked about examples where they feel (or have felt) that treatments are simply not worth the risk, namely:

- Cosmetic surgery generally (other than when there are strong medical reasons in favour of it - for example reconstruction following breast removal, or psychiatric problems associated with cosmetic issues);

- Where the severity of a condition doesn't justify taking a risk. (One respondent gave the example of passing on the opportunity of a hormonal implant which would help balance problems that she experienced at particular times of the month. She did this because of the experience of side-effects that women who had had the treatment were reporting, in chat-rooms).

Causes for concern are generally other people's bad experiences but there is acceptance that you do not really know until you try it yourself. There is some reliance on hearsay and stories in the news, among members of the St Albans group. Participants in this St Albans group are largely indifferent to pronouncements about medicines: the feeling is that every medicine is unsafe to someone, and everything seems to have risks and we only learn by our mistakes.

There is also recognition among younger groups that different people react to medicines in different ways, and that not everything is known about drugs when they are released (one respondent spoke of developing an addiction to a medicine which he has specifically been told was not addictive). Generally however, participants in the younger groups do not think about the risks associated with taking medication unless they experience side-effects. This is much like the views expressed among the older participants.

A good example is the following view expressed by a BME telephone interview participant:

> *It's like my blood pressure tablets, I've read the instructions about it and it tells you a lot about the side effects, but I can't allow the side effects to stop me from taking them, because I need to take them.*
>
> Female, BME, Birmingham, In-depth telephone interview

Younger people do think a little more in terms of risk/benefit analysis. Those who are unsure about taking a treatment say they do research themselves (for example on the internet), but they may also rely on word-of-mouth (One respondent in the Manchester group had not taken malaria tablets when he visited Kenya because a friend had had a very severe reaction). There is also some suspicion about the reliability of certain devices – for example commonly available blood pressure monitors that are not "BMA approved".

Much like older participants aged 55+, younger people tend to think of risk in terms of a trial and error process. They read pack inserts for knowledge about possible side effects but they accept that different individuals experience different effects, so you do not really know the risks until you take the medicine. Again, much like older participants aged 55+, they want to know more about other options and alternatives as well.

Middle-aged participants in the Birmingham group tend to worry when a product has been discontinued and they are unsure why. They show specific concern over the MMR jab, antibiotics, strong over-the-counter drugs and laser eye surgery. As with younger participants, Birmingham group members are concerned about developing dependence on medicine but have no real concerns about devices (all devices are seen in a positive light, and as being essential).

Consensus among the Birmingham middle-aged group does not differ greatly from the middle-aged group in St Albans and the younger group in Manchester. These Birmingham participants mostly say they have to be 'very sick' to take medicines as they worry about their effects and ingredients. This precautionary principle applies somewhat less to those with children, who tend to give their children what a doctor prescribes without questioning it as much as they would do if it were for themselves. Parents do express worry about side effects but it seems that the risks of *not* giving their child the prescribed medicine are more salient.

As with older and young participants, discussion of risk centres on trial and error. Most trust their doctor in the first instance and seek an alternative if the prescribed medicine is wrong for them. The perception is that the amount of information on side effects is confusing, so they do not particularly like having to make the decision themselves – they like to be guided by their doctor

The consensus is that participants do not really make risk/benefit decisions; they use trial and error because different medicines and devices produce different effects, so you do not really know the risks until you take the medicine or device. As with the elderly Birmingham group, concerns are expressed over doctors' workload, meaning that doctors do not always have time to consider whether what they are prescribing is the right thing for that individual patient.

Regulation

Older Participants (aged 55+)

The general assumption is that pharmaceutical companies test drugs, and that there must be someone independent who checks them, but participants were not aware of who that organisation might be.

> *I would hope they're monitored on a regular basis by the governing body of the, I can't remember what they're called now and I hope they're doing their job and checking on everything on behalf of the taxpayer. I would rather it be independent but that needs checking on a regular basis so there's no chance of anybody getting kick backs from pushing different drugs. I think that needs a very close scrutiny.*
>
> Male, Elderly, Rural area, In-depth telephone interview

Some members of the St Albans elderly group (C2DE) spontaneously mentioned NICE and BMA as regulators. Two members of the Birmingham (C1C2) group mentioned 'a regulatory body that controls the drug companies', one of whom expressed doubt that this body has enough funds to do their job properly - and speculated that it may be influenced by drug companies. In fact, most of the Birmingham group expressed concern that drug companies are not adequately regulated in terms of drugs being released onto the market without adequate testing.

There is an acceptance that we do not always know about the long-term effects of a drug and we have to trust the regulators to act when a problem arises. The withdrawal of Vioxx was used (spontaneously) as an example of this by one member of the St Albans group. However, an example of a drug being withdrawn (Seroxat - which was spontaneously mentioned) also led the Manchester (ABC1) group to feel that the controls were not tight enough.

Perception of the regulation process is not clear for any of the groups. This is a finding which is entirely consistent with Ipsos MORI's previous work on regulation (of anything) among the general public. Among the St Albans group, the consensus was that if a product is found to have risks through patient complaints, GPs' feed back these complaints to drug companies or some NHS body. Concern is expressed that pharmaceutical companies have too much influence.

An elderly telephone interview participant shows strong concern about the regulatory process due to a programme he had seen on TV

There was a TV report[5], I think it was MacDonald on TV about the drugs. They set up an office and these guys were importing drugs from America. They weren't the proper drugs, yet they were selling them to pharmacies, hospitals and everything and there's a massive building, a regulatory body that's supposed to be checking into this. They even interviewed them, still give them a licence and the check was negligible. I think the guy spoke about football halfway through the interview. That was very worrying, very worrying. When it's considered, well they showed you the size of the building, the amount of the work, people that work in this building at tax payers' expense. If they're not doing their job then quite frankly somebody needs to sort it out. That is one of the most disturbing reports I've seen for a long while.

Male, Elderly, Rural area, In-depth telephone interview

However, a carer interviewed by telephone was more positive about the regulatory process:

Well I think obviously they need to test them thoroughly which we presume that that would be the case. They've got to be tested thoroughly because one human being can react so different to one drug compared to another. It's like another man's meat can be another man's poison. I would presume that they would have a committee wouldn't they of some sort, they must have something, the Government, that must discuss and analyse all these medicines etc before they go on to the market. But when you hear of a new drug come out it's normally announced that the drug is going to be fine and do this and that and it's been thoroughly tested and approved. Sometimes if it isn't, certainly health officials will mention that they think it should have a longer period of quarantine before they put it on the market.

Male, Carer, Birmingham, In-depth telephone interview

Another carer interviewed over the phone feels very strongly about the need for regulation of medicines:

I think it is, it is important cos otherwise surely you'll get companies that are just producing tablets saying this is a miracle drug and it's purely financial and it doesn't do what it says and it's just rogue and it's horrible. They've got to be monitored haven't they, cos it could be dangerous.

Female, Carer, Hertfordshire, In-depth telephone interview

[5] This programme was broadcast on 9 January - not long before the Ipsos MORI/MHRA qualitative work.

Although it would depend on circumstances surrounding a problem with a drug, older participants aged 55+ generally see responsibility and blame for anything going wrong as lying with the pharmaceutical industry. Some say the doctor or surgeon has some responsibility too, in that they should not use medicines or devices unless they are sure they are *'ok'*.

> *They should be tested, tested to destruction basically for as long as possible. It should be, well I should imagine on orally taken drugs then it should be a time factor where these things are tested and tested thoroughly. But you can't take the risk factor out of everything in life, can you?*
>
> Male, Elderly, Rural area, In-depth telephone interview

All elderly participants generally feel that standards of regulation should be identical - no matter whether the product is designed for children or for adults.

Younger Participants (aged 18-34 in Manchester and St Albans) & (aged 35-54 in Birmingham)

Much like their older counterparts, younger participants are generally of the view that they would like to think medicines and devices are regulated and presume that they are, but they don't know specifically *how*. Examples of ways in which medicines or devices might be regulated (mentioned in the St Albans ABC1 group) are: adverse effects are reported; or the effects of a drug are monitored on people before it goes onto the market. The consensus among Birmingham younger participants (of how regulation might take place) was that patients would report the effects of a medicine or device to their GP, then the product would be recalled, and then it would be investigated.

One member of this group speculated that medicines might be tested on animals before they go on to the market, and he went on to say that this alone is not an adequate way to test a product.

Members of the St Albans group and the Birmingham groups spontaneously mentioned 'the BMA' (incorrectly) as being a regulator. Members of the Birmingham group, along with a carer in a Birmingham depth and the elderly person in the rural depth, seemed to place an emphasis on the role of the media in the regulation process (rather than just in the communication process). This is because some mentioned surprise at hearing about adverse effects in the news, rather than official sources such as a regulator.

Younger Manchester (C1C2) participants seemed to be more knowledgeable. Their feeling is that drug companies monitor their own products but that there is also an independent body involved. There is awareness of the FDA in the US but no mention of the MHRA.

Trust in a regulator would come from them being perceived as having the right qualifications and being independent of the pharmaceutical companies (i.e. in being a non-profit organisation). The kinds of things which younger participants feel should be taken into consideration when a drug is approved are: long-term side-effects; possible interactions with other drugs and short-term side effects such as allergies etc.

Members of the St Albans group say they would expect higher standards of regulation for prescribed drugs than for drugs available over-the-counter as the former are stronger. Over-the-counter drugs are perceived as being less risky because anyone can buy them. Birmingham participants do not hold this view – they would expect high standards of regulation across all types of medicines and devices. Some examples of particular concern given are: MMR and 'drugs that can be abused' e.g. methadone, valium or paracetamol.

Should something go wrong, most differentiate between a doctor's error (for example, not factoring in other, co-existing medical problems that a patient may have in addition to the one being treated) which would be the doctor's fault, and a specific problem with a medicine or device for which the company producing the product would be to blame. All agree that a large scale and thorough investigation should occur. There are some participants among the groups who do say however, that if medicines are labelled clearly then risk/benefit decisions can be made by patients and they should take some of the blame. Most, however, say that risk/benefit decisions should be made before a drug goes onto the market.

Communication of Risk of Medicines/Medical Devices

Older Participants (aged 55+)

In accordance with the findings above with perceptions of risk of medicines and medical devices, doctors are the most trusted source of information on medicines and *'drug companies'* the least trusted. There was little awareness of manufacturers of medical devices. Again, Birmingham group members are a little more concerned about advice from doctors than participants from other groups. Members of all older groups aged 55+ say they trust information provided in pack inserts (Most read these very carefully to ensure they are aware of any side effects which they may suffer). Some trust newspapers (*'If it is a good paper with a good scientific report'*), and some also trust TV. One participant in the St Albans group says adverts can be trusted because '*they can not say things that aren't true*'. One participant in the Birmingham group does not trust the Internet as a source of information as he perceives that it is *'heavily influenced by drug companies'.*

As for how risks **should** be communicated, this depends on what one's level of interest is. If you are taking the medicine or using the device, the most common preference is through GPs. However, for general information about risks and benefits of medicines and devices, a diverse range of sources is mentioned; such as: TV, newspapers and patient conferences. Participants are generally distrustful

of information from pharmaceutical companies – which is consistent with much of Ipsos MORI's previous work in this area[6].

In the event of a risky medicine or device being withdrawn, elderly respondents generally would want to know why it has been withdrawn, what the consequences of taking/using it are to them, and what the alternatives are. There was a feeling among the Birmingham participants that the medical profession keeps a lot to itself – participants want to see a lot more information on medicines and devices e.g. leaflets in GP surgeries. All older participants aged 55+ say they would report a problem with a medicine or device, and all would go to their doctor in the first instance.

Younger Participants (aged 18-34 in Manchester and St Albans) & (aged 35-54 in Birmingham)

As is the case with older participants aged 55+, young people tend to trust information from their GPs the most. However, as would be expected, they are more inclined to refer to the internet ('NetDoctor' was specifically mentioned in the St Albans group). Some also say they trust pharmacists. Young people are less trusting of the media than older people, as they feel that the media sensationalises stories about risky medicines and devices. In line with the findings from older participants, distrust of information from pharmaceutical companies is apparent among younger participants. Some younger participants in St Albans (ABC1s) say they actively investigate a medicine or device before using it and do not blindly trust the prescription from their doctor.

Younger people's attitudes to communication of risk are slightly different from those among older people. Although they trust what doctors say about medicines (and associated risks), they equally would not "*take it as gospel*".

> *Well, patients have the right. Every patient has got the right to decide what they want to take or what they don't want to take. So if they feel that the risk is too high, compared to benefits, then they have got the right to not take it, but even if they put it on the market, they can't make them take it, can they?*
>
> Female, BME, Birmingham, In-depth telephone interview

They trust personal experience and express more desire to make up their own mind. They trust friends to tell them the truth about experiences that they may have had, although they would not necessarily assume that that they would have the same reactions. They want communication on risks to come from an independent body, unconnected with Government.

The middle-aged group from Birmingham are similar to their older counterparts in that they express the desire for more communication between doctor and patient and want clearer explanations of both short- and long-term side effects. One group member said they want to know about the evidence behind a

[6] Please see http://www.ipsos-mori.com/polls/2004/ost.shtml

medication i.e. how many years have been studied, how many studies, who has conducted them and what is the cost of producing the product.

Examples of sources of information on medicines and devices that younger groups would like to use are: TV documentaries; a monthly magazine detailing risks and benefits of commonly used and prescribed medicines and devices; and a blanket leaflet to households alerting people to risks.

If a product is to be withdrawn, younger participants want to know why this is the case and what alternatives are available. If they personally were taking it, they would ideally want to be told by their doctor. Also some want to see that the medicine or device is being monitored in the longer-term, to make sure they have not been negatively affected. What emerged from all groups is a need for transparency – there is a general worry that drug companies have too much influence over communications of risks and benefits of medicines and devices.

Awareness of MHRA & Key Messages

Older Participants (aged 55+)

No-one in the St Albans older group aged 55+ had heard of MHRA. The feeling among this group is that they should publicise themselves more – through press releases, *Which?* Reports, broadsheets, and leaflets/posters in surgeries. There was no awareness that there are currently MHRA posters in (some) GPs' surgeries.

Birmingham group participants agree that there must be a regulatory body - but none know who it is. The consensus is that they are currently not strict enough and some participants express worries about the amount of money in the medicines and devices industry which may have an undue influence on regulatory decisions. All agree there is a need for a very strong regulatory body with non-medical people involved. They want this body to provide full details about new products, giving a balanced evaluation of both the risks and the benefits.

One Birmingham participant aged 55+ had heard of MHRA because his doctor reported his adverse reaction to an anti-malaria drug. All participants think MHRA should publicise themselves more. Some popular suggestions are: through leaflets/posters in surgeries, TV adverts, popular soaps e.g. Eastenders.

A carer interviewed by telephone wants to see more visible action taken by the MHRA to combat counterfeit medicines:

> *Well I don't want to be prejudiced but after seeing that programme on the television a couple of weeks ago it really did open my eyes at just how easy it is today for bogus companies to start up on making tablets etc and filtering them into hospitals and on to the National Health Service. It does need vetting a lot more and I think the Government ought to really step up their procedures if they haven't*

already done so on making sure that the companies that make all this medication are actually qualified people to be able to do this job.

Male, Carer, Birmingham, In-depth telephone interview

Younger Participants (aged 18-34 in Manchester and St Albans) & (aged 35-54 in Birmingham)

Much the same perceptions emerge from the groups with younger participants. Most have not heard of the MHRA. One member of the St Albans group had heard of MHRA because they had been advised by their GP to seek MHRA's help over a health and safety claim. All show a unanimous desire for MHRA to publicise themselves more in surgeries, on T.V. and pop-ups on the Internet. Younger people feel that regulation does happen, but they would not generally ask how things are regulated. They are happy to know that there is a place they can go to for information on risks and benefits of medicines and devices.

In the Manchester group, once the role of the MHRA was discussed, participants put forward the idea of putting the MHRA's phone number on posters displayed in surgeries so that people can contact them if they have any concerns (unaware that this is the case on MHRA posters in some GPs' surgeries at present). They also give the idea of colour-coding boxes of medicines according to the level of risk associated with taking them, but some dismiss this idea as having the potential to put off people who actually need the medicine from taking it.

A BME telephone interview participant says that the MHRA has an important role to play in helping the public take more control of their healthcare.

The MHRA should explain to people the risks and the benefits more. There is no medicine that is completely free of risks. So people need to be explained to more and be told what they are going into beforehand. So if they freely go into it, they carry some of the responsibility as well, not just the medical profession who are taking all the responsibilities.

Female, BME, Birmingham, In-depth telephone interview

Appendices

Topic Guide

Core objectives

1. Explore general public's experience of medicines and medical devices, and their perceptions of risk associated with them
2. Perceptions of how medicines/devices are regulated and how they should be regulated
3. Examine attitudes towards communication of information about medicines/devices

(Note to moderators: This research does not cover the cost of medicines or devices or the extent to which the NHS provides them. Please bear in mind MHRA is not concerned with cost. That is the job of NICE (National Institute for Clinical Excellence). MHRA weighs up benefits against risks. NICE weighs up benefits against costs. MHRA says whether products work and are acceptably safe. NICE says whether they work well enough for the NHS to pay for them.

Please note that the topic guide covers both medicines and medical devices. While we want comments on both sets of products, it is not necessary to insist on covering both for every question.

Outline of the research programme

6 X 1 ½ hour focus groups with members of the general public
Groups to be held in weeks commencing 23 Jan & 30 Jan 2006
10 respondents recruited, for 6-8 to participate

	Age	Social Class	Gender	Quotas
Group 1 Home Counties 25/01/06	55+	C2DE	Good mixture	Some to have had surgery in last year, and some to have seen GP in last year
Group 2 Home Counties 25/01/06	35-54	ABC1	Good mixture	Some to have seen GP in last year
Group 3 Birmingham 26/01/06	55+	C1C2	Good mixture	Some to have seen GP in last year
Group 4 Birmingham 26/01/06	35-54	C2DE	Good mixture	Some to have had surgery in last year, and some to have seen GP in last year
Group 5 Manchester 31/01/06	18-34	C1C2	Good mixture	Some to have obtained medicine or device from pharmacy in last year, and some to have seen GP in last year
Group 6 Manchester 31/01/06	55+	ABC1	Good mixture	Some to have obtained medicine or device from pharmacy in last year, and some to have seen GP in last year

For all groups:

Half or more to have used medicines or medical devices in the last year. At least 2 of these to have used devices or experienced devices used by healthcare professionals in connection with their health. Do not include any healthcare professionals or people working in e.g. hospitals, GP surgeries, dental surgeries, pharmacies or care homes.	**Notes**	**Approx timing**
1. Introduction	Sets the scene and asks about experience of medicines and medical devices	15 mins
2. Perceptions of risks and Benefits	Aims to examine the public's overall perceptions of risk and benefits in relation to medicines and medical devices	25 mins
3. Regulation	Spontaneous awareness of regulation. Looks at what general public's expectations of and attitudes towards regulation are.	25 mins
4. Communication of risk	How people currently, and prefer to, find out about risks associated with medicines and medical devices	20 mins
5. Conclusion and Key Messages	Summary and key messages	5 mins

Key Questions	Notes/approx timing
1. Introduction	15 minutes
1.1 Scene-setting: Thank interviewees for taking part Introduce self, Ipsos MORI and explain the aim of the discussion Role of Ipsos MORI – research organisation, gather all opinions: all opinions valid, disagreements OK Confidentiality: reassure all responses anonymous and that information about individuals will not be passed on to any third party. Get permission to tape record – transcribe for quotes, no detailed attribution. First name Where you live? Who with? (household details)	**Welcome**: orientates interviewee, gets them prepared to take part in the discussion. Outlines the 'rules' of the discussion (including those we are required to tell them about under MRS and Data Protection Act guidelines). No detail about specifics (e.g. the regulation or MHRA) at this stage. This ensures that spontaneity is retained for initial discussions and that the participants are not overwhelmed with information.
1.2 Introduction: **Just to start with, could you tell us a bit about your experiences with medicines and medical devices in general? For the purposes of this discussion, we've got some examples of medical devices on this card. You might call some of these things "medical equipment".** HAND OUT SHOWCARD LISTING MEDICAL DEVICES When thinking about medicines we mean any medicines you get from a doctor or over-the-counter, including vaccinations. *How do you personally regard medicines/medical devices? PROBE: Are they important or unimportant in your life? Do you regard them as essential? Why do you say that? What do you expect from them? What value do we get from them? Why do you say that? Probe for examples.* When did you personally last take a **medicine** or use a **medical device** (Please include all kinds, including over-the-counter and prescription)? Which **medicines/medical devices?** IF APPLICABLE: How about your children and other people you look after? For what conditions? Have they generally been	**Introduction**: provides contextual background information about the participants relevant to the subject being investigated (which can then be used in the analysis). MHRA defines medical devices as: all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap. Please note that herbal and homoeopathic medicines are included but vitamins and dietary supplements are excluded.

good/bad? Why is that? How do you feel about taking medicines/using medical devices? *Explore:* *What level of confidence do you have in medicines/medical devices to help you? Why do you say that?* *What gives you that confidence?* ***What influences your decision to personally take a medicine/use a medical device**?* o *how much pain I'm in* o *whether I've used it before* o *whether I've tried other things and failed* o *recommendations? – if so, by whom e.g. Doctor/ friend/ relative/ colleague* o *promotion/communication or an advert. What sort?* *How about your children/people you look after?* *Do you ever 'hold out' on taking a medicine/using a medical device, even if you are in pain? Why?*	

2. Perception of Risks and Benefits	25 minutes
What are your thoughts on the safety of medicines and medical devices? **Is there any medicine or device you are particularly concerned about? Why do you say that?** HAND OUT PAPER/PEN TO EACH IN TURN. ASK GROUP MEMBERS TO DISCUSS THEIR CHOICE FURTHER IF THEY WANT TO **What concerns/worries/fears about the safety of medicines/ Devices, if any, do you have?** What sorts of risks and downsides do you feel medicines/ devices raise? *Why do you say that?* **What is it, if anything, that encourages you to take a medicine/use a device?** *PROBE FOR REASONS* **When you are thinking of taking a medicine/using a device, do you ever think in terms of the benefits and risks that are involved? Do you weigh them up against one another? What do you take into account?** IF NECESSARY: **Do you ever think the risks might be too great when you compare them with the benefits/improvements you might get?** PROBE: What is important to you when making this decision? Any personal experience? What difference does it make if a medicine/ device is prescribed or available over-the- counter? **What do you feel are the things that cause you to be concerned about some medicines/ devices and not others?** REFER TO EXAMPLES MENTIONED. *PROBE: What kinds of medicines/ devices, if any, do you regard as just too risky? What risks are you prepared/not prepared to accept?* *E.g.* *- Would not give certain medicines/ devices to children;* *- Would not take a new medicine/use a new device on the market* *- Would not take a medicine/use a device if knew/read/heard there had been some 'problems' with it. What kinds of problems?* *- Other (Specify)* And thinking now about particular medicines and pronouncements about them (e.g. that certain drugs are unsafe), does that news ever influence you in your medicine taking habits? In what way?	**Moderator: this is a KEY SECTION** This section establishes perceptions of medicines/ devices, particularly exploring issues of their uses, trust in them and perceptions of their risks and benefits. **Please address medicines and devices together but if people consistently differentiate, explore perceptions of each and why they are different.** Also, once people have grasped the concept of 'medical devices' you can refer to 'devices'.

3. Regulation of M/MD	25 minutes
Do you think medicines and devices are monitored in any way to check what risks or benefits they have? - **By whom?** - **Who would you trust to do so?** - For what reasons? - Have you heard of any problems? - Any current issues come to mind? How much control is there on the types of medicines/ devices that are produced? Why do you say that? How important would you say this issue of regulation of medicines/devices is, compared to other issues in your life? Why do you say that? Would you describe the assessment and monitoring of medicines/ devices as something that is: - important, but best left up to the experts; - important, and something that the public needs to be involved in. In what way? - unimportant - Other (Specify) **What do you think happens in cases of risky medicines/ devices?** THIS QUESTION IS NOT ESSENTIAL Who would bear responsibility if something went wrong and a patient was to suffer? Why? **If a medicine harms somebody, who would you blame** PROBE for: Government, drug companies, doctors, regulators, yourself etc **3.1 Expectations of Regulation** What factors should be assessed and monitored before medicines/devices become available? And after they have become available? What else? Why do you say that? **Do you expect higher standards of regulation for certain products? E.g. for use with children; over the counter vs. prescribed? Why/why not?**	This section explores awareness of regulatory bodies and their role. Additionally, it looks at what assurances respondents feel they need. It allows the group to discuss regulatory requirements without having to have prior knowledge of processes and procedures. FOR INFORMATION *Pharma companies conduct clinical trials. MHRA inspects the conduct of some trials and examine all results critically. If MHRA is satisfied that drugs are beneficial and sufficiently safe, it licences them. It requires companies to continue to satisfy it about safety through Periodic Safety Update Reports.* *For devices there are few clinical trials but where there are MHRA has to approve them. Otherwise, the higher risk devices are approved, on the basis of companies dossiers, by licensed "Notified Bodies" that MHRA audits, and the lower risk devices are simply registered with them.* *For both medicines and devices, MHRA receive reports of problems and investigate. It may then withdraw them, limit their use or issue warnings.*

Do you think those who regulate medicines and devices should only licence those products where the benefits outweigh the risks hugely, or should patients have the opportunity to weigh up the risks and benefits themselves? Does it depend on the severity of the problem/risk to patient safety? How much confidence do you have in the way medicines/ devices are regulated at the moment? Why do you say that?	

4. Communication	20 minutes
Which sources of information about risks of medicines / devices do you most trust? Why do you say that? **And which sources of information about risks of medicine/ devices do you least trust?** Why do you say that? What communication about risks of medicines/ devices do you recall, from any source? **How do you think risks of medicines/ devices should be communicated to the public?** e.g. *PROBE: company that makes them, doctors, pharmacists, practice nurses, other health professionals, patient groups, leaflets that come with medicines, NHS direct, Internet, media, magazines/newspapers, friends/ family/ colleagues, medical encyclopaedia?* **Do you actively look for information on medicines/medical devices?** Why/why not? PROBE FOR EXAMPLES. What information do you look for? Where do you look? *PROBE: company that makes them, doctors, pharmacists, practice nurses, other health professionals, patient groups, leaflets that come with medicines, NHS direct, Internet, media, magazines/newspapers, friends/ family/ colleagues, medical encyclopaedia?* How much information do you get/use from sources such as those above? Is this enough? Why/why not? **If a medicine or device you were using had to be withdrawn, how would you want to find out? What information would you want to know?** There was an announcement last year that a fairly common painkiller is being withdrawn in the UK because of concerns about it. Have you heard about it? IF YES: What have you heard and where from? Do you know which drug it is and why is it being withdrawn? The drug is co-proxamol and it is being withdrawn as there are concerns about the high risk of accidental death from slight overdose and its frequent use in suicides **If you thought there was a problem with a medicine or device that you were using, would you tell anybody or report it? Who would you tell?**	

5. Conclusion and Key Messages	5 minutes
Finally, just to conclude, can you summarise for me what you think about the regulation of M/MD at the moment? *Prompt where necessary:* Is there anything else you'd like to say? What would be the number one thing that you'd like to see? Ipsos MORI is undertaking this work for MHRA -the Medicines and Healthcare products Regulatory Agency - which is interested in people's views on regulation of all types of M/MD. Has anyone heard of MHRA? *If not, explain role:* *MHRA is the Medicines and Healthcare products Regulatory Agency. It's part of government. There used to be two different Agencies: MCA for medicines and MDA for devices.* *MHRA know that no product is entirely free of risks, so they weigh up the evidence to ensure that the benefits to patients justify the risks.* *And they keep watch over medicines and devices. They take action to protect the public if there is a problem.* *It wants to make as much information as possible publicly available* Is there any key message you would like us to feed back to MHRA? Thank respondents, explain the next steps: "MHRA will use the findings in a major review it is doing at present, to help it improve regulation and communicate better with patients and the public" and close.	Formally ends the discussion and provides reassurance that the findings will be both appreciated by and useful to MHRA Also gauges how many people have heard of MHRA, and how many have a reasonable idea of what it does.

Showcards

Some of the More Common Medicines	
Type or Action	**Examples**
Antibiotics (Infections)	Penicillin, Erythromycin, Amoxicillin, Tetracycline
Anticonvulsants (Epilepsy)	Benzodiazepine, Convulex
Antidepressants	Prozac, Fluoxetine, Tricyclics
Asthma Drugs	Corticosteroid, Theophylline, Salbutamol
Cholesterol Lowering Drugs	Zocor, Cholestyramine, Gemfibrozil
Heart Medications	Alpha/Beta Blockers, Diuretics, Lisinopril
Heartburn and Ulcers	Antacids, Gaviscon, Zantac, Cimetidine
Hormone Preparations	Oral Contraceptives, Microgynon, Femodette, Thyroid Drugs
Laxatives	Lactulose, Senokot
Painkillers	Aspirin, Paracetamol, Nurofen, Codeine, Non-Steroidal Anti-Inflammatory Drugs
Skin Treatments	Anti-Fungals, Antibacterials. Acne Treatments, Epaderm, Eumovate
Sleeping Pills, Tranquilizers	Diazepam, Nytol
Vaccines	for Measles, Mumps, Influenza

Examples of More Common Medical Devices and Equipment

Operating tables Anaesthetic equipment Surgical instruments Latex gloves Incubators for babies Drug pumps Hospital beds X-Ray equipment CT and MRI scanners Ultrasound scanners Medical and ophthalmic lasers Dental equipment and materials Wheelchairs Walking sticks and frames	Replacement hips and knees Pacemakers Breast implants Thermometers Plasters and dressings Condoms Contact lenses & care products Hearing aids Syringes and insulin pens Blood pressure monitors Blood glucose strips and meters Pregnancy test kits Cholesterol test kits Urine test strips